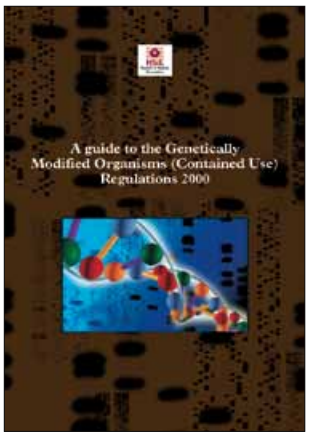
A guide to the Genetically Modified Organisms (Contained Use) Regulations 2000



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This book provides easy-to-understand guidance on the legislation on genetically modified organisms (GMOs). It will provide dutyholders with information regarding their responsibilities in respect to ensuring the criteria of a risk assessment are met and kept up to date, ensuring that a local genetic modification safety committee is established, the standards of occupational and environmental safety levels of containment which are appropriate and how accidents, if they do occur, should be recorded and who should be notified.

This publication will be useful to any person who manages the use of GMOs, as well as anyone involved in the manufacturing or indeed has responsibility for GMOs.

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Contents

Introduction

1 This booklet contains practical guidance on legislation covering the contained use of genetically modified organisms (GMOs). It replaces the previous guidance document, *A guide to the Genetically Modified Organisms (Contained Use) Regulations 1992*, as amended in 1996.[1]

2 The previous booklet gave guidance on:

- the Genetically Modified Organisms (Contained Use) Regulations 1992;[2] and,
- the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1996.[3]

These Regulations, and some further amending Regulations,[4] have now been replaced by the Genetically Modified Organisms (Contained Use) Regulations 2000.[5] These new Regulations are needed to implement European Directive 98/81/EC[6] which amends the Directive on contained use of genetically modified micro-organisms (GMMs).[7]

3 The Contained Use Regulations 2000 are made under the powers of the Health and Safety at Work etc. Act 1974[8] (the HSW Act) and the European Communities Act 1972,[9] and are concerned with protection of human health and safety and the environment from contained use activities involving GMMs (including animal and plant cell cultures). They also provide for protection of humans from contained use of genetically modified organisms which are not micro-organisms, that is 'genetically modified animals and plants'. (Note: this guide uses the phrase 'genetically modified animals and plants as being synonymous with genetically modified organisms which are not micro-organisms' where it aids understanding.)

4 Protection of the environment from contained use activities involving genetically modified animals and plants are enacted through relevant sections of the Environmental Protection Act 1990[10] (EPA) and associated regulations, the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996,[11] as amended by the Genetically Modified Organisms (Deliberate Release and Risk Assessment - Amendment) Regulations 1997.[12] The Department of the Environment, Transport and the Regions (DETR) is responsible for this legislation. (See Appendix 6 for contact details.)

5 Taken together the Contained Use Regulations 2000 and the GMO (Risk Assessment) (Records and Exemptions) Regulations 1996 (as amended) and EPA require, with certain exceptions, that anyone carrying out any activity involving genetic modification does so in conditions of contained use which satisfy the Regulations. Among other things this means carrying out a risk assessment for both human health and environmental protection, and in certain circumstances submitting a notification to the Competent Authority via the Health and Safety Executive,[13] and in some cases receiving the Competent Authority's formal consent.

1 HSE Books, ISBN 0 1776 1186 8
2 S.I. 1992/3217
3 S.I. 1996/967
4 The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1998, S.I. 1998/1548
5 S.I. 2000/2831 'Contained Use Regulations 2000'
6 OJ reference L330/13 of 5 December 1998
7 90/219/EEC, OJ L117/1 of 8 May 1990
8 1974 c.37
9 1972 c.68
10 1990 c.43
11 S.I. 1996/1106
12 S.I. 1997/1900
13 HSE acts as the post-box on behalf of the Competent Authority which comprises HSE, the Secretary of State and the MAFF Minister in England and Wales. In Scotland, the Competent Authority comprises HSE and the Scottish Ministers.

Other relevant legislation[14]

6 Note that this guidance does not cover all legislation which may have a bearing on work with GMOs. Other legislation includes, for example, controls on:

- human and veterinary medicines, under the Medicines Acts 1968[15] and 1971[16] and European Council Regulation No. (EEC) 2309/93;[17]
- pesticides, under the Food and Environment Protection Act 1985;[18]
- novel food or novel food ingredients, under European Council and European Parliament Regulation No. (EC) 258/97;[19]
- animal feed additives, under the Feeding Stuffs Regulations 1995,[20] the Feeding Stuffs (Establishments and Intermediaries) Regulations 1998[21] and the Feeding Stuffs (Zootechnical Products) Regulations 1998;[22]
- genetically modified plant pests or pathogens, any plant material modified so that it contains material derived from a plant pest or pathogen and any imported plant material, plant pest or pathogen, irrespective of the genetic modification process under the Plant Health (Great Britain) Order 1993[23] and the Plant Health (Forestry) (Great Britain) Order 1993;[24]
- transgenic animals, under the Animals (Scientific Procedures) Act 1986;[25] and
- the introduction of non-indigenous species under the Wildlife and Countryside Act 1981;[26]
- disposal of wastes[27] including:
  - liquid discharges under:
    - Part I of the EPA 1990, regulated by the Environment Agency (EA) in England and Wales and the Scottish Environmental Protection Agency (SEPA), for discharges from integrated pollution control sites;
    - Part III of the Water Resources Act 1991, regulated by the EA in England and Wales, and Part II of the Control of Pollution Act, regulated by the SEPA in Scotland, for discharges to controlled waters; and
    - the Water Industry Act 1991, regulated by the water companies in England and Wales (similar for Scotland), for discharges to sewers;
  - solid wastes under:
    - Part II of the EPA 1990, regulated by the EA in England and Wales and the SEPA in Scotland, for waste management licensing;
    - the Special Waste Regulations 1996 (as amended) and Environmental Protection (Duty of Care) Regulations 1991, for special waste (similar for Scotland) which may include clinical wastes and controlled waste;
    - there are additional controls on waste carriers and brokers;

14 For departmental contact points for further information, see list at Appendix 6.
15 1968 c.67
16 1971 c.69
17 OJ reference L214, 1-21 of 24 August 1993
18 1985 c.48
19 OJ reference L43 of 14 February 1997
20 S.I. 1995/1412
21 S.I. 1998/1049
22 S.I.1998/1047
23 S.I. 1993/1320
24 S.I. 1993/1283
25 1986 c.14
26 1981 c.69
27 Note that over the next seven years the Pollution Prevention and Control Act 1999 will replace and repeal the system under Part I of the EPA 1990 and regulate some waste activity currently controlled under Part II of the EPA 1990 and amend water legislation. It will also regulate, for the first time in an integrated manner, a number of additional activities such as intensive farming and food production.

- emissions to air under:
    - Part I of the EPA, regulated by the EA in England and Wales and the SEPA in Scotland for Part A processes and by Local Authorities for Part B processes;
    - Part III of the EPA, regulated by Local Authorities, for statutory nuisance provision (similar for Scotland); and
    - the Clean Air Act 1993, regulated by Local Authorities.

7 All of this legislation remains in force and is not affected by the Contained Use Regulations which deal specifically with genetic modification. In addition, all work activities, including those concerned with genetic modification, are covered by the HSW Act and relevant regulations made under that Act. These include, where appropriate, the Control of Substances Hazardous to Health (COSHH) Regulations 1999,[28] and the Management of Health and Safety at Work Regulations 1992[29] (MHSWR - as amended). In particular COSHH and MHSWR both have requirements for health surveillance. Under MHSWR, health surveillance must be provided as appropriate, having regard to the risks identified by the risk assessment. Under COSHH, health surveillance must be provided where:

- an identifiable disease or adverse health effect may be related to the exposure; and
- there is a reasonable likelihood that the disease or effect may occur under the particular conditions of work; and
- there are valid techniques for detecting indications of the disease or effect.

8 It is also important to note that in respect of matters affecting human health and safety you must also comply with the Safety Representatives and Safety Committees Regulations 1977[30] and the Health and Safety (Consultation with Employees) Regulations 1996.[31]

Legislation on the deliberate release of genetically modified organisms

9 A second EC Directive, 90/220/EEC,[32] deals with the deliberate release into the environment of genetically modified organisms. Regulations - the Genetically Modified Organisms (Deliberate Release) Regulations 1992,[33] as amended by the Genetically Modified Organisms (Deliberate Release) Regulations 1995[34] and the Genetically Modified Organisms (Deliberate Release and Risk Assessment - Amendment) Regulations 1997 - have been introduced under the Environmental Protection Act 1990 (the EPA) and the European Communities Act 1972. These Regulations, together with substantive provisions from the EPA itself, implement the deliberate release Directive. Separate guidance on the EPA and Regulations has been produced by the DETR. DETR/ACRE Guidance Note 2 deals with the EPA and the 1992 Regulations. DETR/ACRE Guidance Note 7 with the 1995 Regulations. Further details can be obtained from the DETR Biotechnology Unit, Ashdown House, 123 Victoria Street, London, SW1E 6DE Tel: 0207 890 5275, Fax: 0207 890 5259.

28 S.I. 1999/437 which includes provisions relating to biological agents
29 S.I. 1992/2051
30 S.I. 1977/500
31 S.I. 1996/1513
32 OJ reference L117 of 8 May 1990
33 S.I. 1992/3280
34 S.I. 1995/304

Devolution

10 The Contained Use Regulations 2000 cover the whole of Great Britain, ie England, Wales and Scotland. It should, however, be noted that, although Scottish Ministers have agreed to these for the time being, the Scottish Parliament is empowered to make its own regulations on the environmental and public health provisions (not covered by the HSW Act) of the European Directive on contained use. It may wish to do so in the future. Similarly, if the National Assembly for Wales seeks and is granted similar powers to those already devolved to Scotland, it too may wish to make separate regulations in due course.

Enquiries on the Contained Use Regulations 2000

11 For further advice on any aspects of the regulations or guidance in this booklet, please contact the Health and Safety Executive at either of the following addresses:

Health Directorate Division B
Rose Court
2 Southwark Bridge
London
SE1 9HS
Tel: 0207 717 6234 6297/6348
Fax: 0207 717 6199

(For advice on general policy and interpretation)

Technology Division 6
Magdalen House
Stanley Precinct
Bootle
Merseyside
L20 3QZ
Tel: 0151 951 4772
Fax: 0151 951 3474

(For advice relating to notifications and technical enquiries)

Organisation of this guidance booklet

12 This booklet is divided into two main parts:

- The guide to the Genetically Modified Organisms (Contained Use) Regulations 2000, including the reproduced legislative text.
- Appendices and Index.

Summary

13 The main requirements of the Contained Use Regulations 2000 and the sections of the EPA 1990 relevant to contained use and associated 1996 Regulations (amended in 1997) provide for:

- risk assessment in respect of human health and safety, and environmental protection of all activities involving GMOs. *(Regulations 6 and 7 of the Contained Use Regulations 2000; and Section 108 of EPA and associated Regulations)*;
- records of risk assessments. *(Regulation 8 of the Contained Use Regulations 2000; and EPA and associated Regulations)*;
- establishment of a local genetic modification safety committee (GMSC) to advise on risk assessments for human health and safety and environmental protection relating to activities involving GMMs, and human health aspects of activities involving genetically modified animals and plants. *(Regulation 16 of the Contained Use Regulations 2000)*;
- classification of all activities with GMMs into one of four classes which are related to the containment levels appropriate to control the degree of risk. *(Regulation 6 and Schedule 3 of the Contained Use Regulations 2000)*;
- classification of all activities involving genetically modified animals and plants into one of two classes (notifiable or non-notifiable) based on whether or not they are potentially more harmful to human health than the non-modified parental organism. *(Regulation 12 of the Contained Use Regulations 2000)*;
- advance notification to the Competent Authority (the Health and Safety Executive - HSE - acting as the post box) of an intention to use premises for genetic modification for the first time. *(Regulation 9 of the Contained Use Regulations 2000)*;
- notification to the Competent Authority (via HSE) of individual activities of classes 2, 3 and 4 involving GMMs. For all class 3 and 4 activities consents are required from the Competent Authority before users can proceed. *(Regulations 10 and 11 of the Contained Use Regulations 2000)*;
- notification to the Competent Authority (via HSE) of all individual activities involving genetically modified animals and plants which are potentially more harmful to human health than their non-modified parental organism(s). *(Regulation 12 of the Contained Use Regulations 2000)*;
- standards of occupational and environmental safety and levels of containment appropriate to the level of risk. *(Regulations 17, 18 and 19 of the Contained Use Regulations 2000)*;
- notification of accidents and, where appropriate, the drawing up of emergency plans. *(Regulations 20 and 21 of the Contained Use Regulations 2000)*;
- disclosure of information and public registers, with provision for confidentiality of commercially sensitive information and personal data. *(Regulations 22 and 23 of the Contained Use Regulations 2000)*;
- fees for notifications. *(Regulation 26 of the Contained Use Regulations 2000)*;
- an appeals mechanism for people aggrieved by a decision of the competent authority. *(Regulation 29 of the Contained Use Regulations 2000)*.

14 The activities covered by the Contained Use Regulations 2000 and those sections of the EPA related to contained use and associated regulations include: laboratory operations, housing and/or breeding of modified animals in animal houses or farm animals restrained by fencing (provided the fenced animals are not shedding genetically modified micro-organisms without sufficient biological or chemical barriers,)[35] the use of growth rooms, glasshouses or other plant growth

35 This would probably constitute a deliberate release to the environment.

facility of appropriate specification, and the large scale industrial use of fermenters. All such activities are prohibited unless they are carried out in conditions of containment which comply with the Regulations.[36]

15 'Contained use' is defined as any activity in which organisms are genetically modified or in which GMOs are cultured, stored, used, transported, destroyed or disposed of and where barriers are used to limit contact of the GMOs with humans and with the environment. This limitation in contact can be achieved through control measures involving physical, biological or chemical barriers, or any combination of these. Note that physical barriers need not always be present, but in such cases it must be clear that the biological/chemical barriers are sufficient for the level of risk. The degree of limitation of contact and choice of appropriate containment measures must always be determined by the risk assessment. A high level of safety for people and the environment must be provided.

16 Although genetic modification of humans is specifically not covered, some gene therapy activities may be, where the therapy is delivered using a GMM (for instance a genetically modified virus). In such cases the administration of the therapeutic substance[37] may constitute a contained use where it is possible to fulfil the requirements for limitation of contact of the GMM with humans and the environment. Obviously the patient themselves will be exposed. However, the degree of exposure will be related to the risk and limited to such an extent that harm is not caused. This can, therefore, be accommodated within the term 'limit contact'. The degree to which contact with other humans and the environment has to be limited is likely to be much greater. In particular this will include consideration of shedding of the GMM from the patient. If limitation of spread is not possible the gene therapy is likely to constitute a deliberate release and would be subject to provisions of the deliberate release legislation. Similarly clinical trials with live genetically modified vaccines may be controlled under the contained use legislation, unless there is uncontrolled shedding of a GMM such that limitation of contact with the wider population and environment is not possible. It should be noted that control may be effected by physical, biological or chemical means.

17 The contained use legislation covers the breeding on of a genetically modified plant or animal. Even when a genetically modified plant or animal is crossed with a non-genetically modified plant/animal the progeny will be considered to be GMOs. The one exception to this generality is when tests show beyond reasonable doubt that no modified genetic material has been passed to the progeny. The contained use legislation also covers activities involving modified organisms supplied by others. They do not cover the deliberate release of GMOs to the environment for experimental purposes or the marketing of products for deliberate release consisting of, or containing, GMOs. These activities are covered by the EPA and the Deliberate Release Regulations or relevant product legislation.

18 So long as a product and its use are as specified by a consent under the Deliberate Release Regulations, (or relevant product legislation), in the conditions for marketing, it will not be covered by the contained use legislation. Breeding on from such 'approved products' may be allowed under the conditions for marketing and in such cases would not be further regulated under the deliberate release or the contained use legislation. However, this will not always be the case and if in doubt you are advised to seek clarification.

36 If the activity constitutes a deliberate release to the environment, the Genetically Modified Organisms (Deliberate Release) Regulations will apply instead.
37 Note that if the therapeutic substance had a marketing approval under Council Regulation No. 2309/93, the contained use legislation would not apply.

Administrative arrangements

19 The Contained Use Regulations 2000 are overseen by a joint competent authority. For England and Wales, this comprises HSE, the Secretary of State and the MAFF Minister. For Scotland, the competent authority comprises HSE and Scottish Ministers. Similarly, the relevant sections of the EPA and related Regulations are jointly overseen in England and Wales by the Secretary of State and the MAFF Minister. For Scotland, the EPA and related Regulations are matters for Scottish Ministers. However, for administrative purposes duty holders have a single point of contact in HSE. All notifications under the Contained Use Regulations 2000 should be made via HSE. HSE will acknowledge the receipt of the notification and then copy the notification to the relevant Government Departments and devolved bodies (Environment, Transport and the Regions, Scottish Executive, Welsh Executive - as appropriate - and MAFF) for their consideration. HSE will request from users additional information if any Departments or devolved bodies seek any, or where HSE requires further information. Interdepartmental arrangements have been set up to ensure that HSE will co-operate with all the other parties in putting the Regulations into effect. Approval by each part of the competent authority will be necessary before consents can be issued. For notifications not requiring a consent, HSE, on behalf and with the agreement of the competent authority, will respond to the notifier following the completion of the scrutiny process.

20 Notifications containing the stipulated information should be made to the Health and Safety Executive:

The Notification Officer
Technology Division 6
Magdalen House
Stanley Precinct
Bootle
Merseyside
L20 3QZ
Tel: 0151 951 4772
Fax: 0151 951 3474

21 Notification forms may be obtained in paper form from the aforementioned address. They are also available on the Internet at the HSE web site (http://www.hse.gov.uk) and are reproduced in Appendix 5. The forms are designed to help users notify. However, **their use is not obligatory** and users may choose to supply the information stipulated in the legislation by other means. Typescript, or manuscript paper notifications are acceptable. However, for notifications in manuscript care should be taken over legibility. This is especially important in that it may be difficult to transcribe for the public register and could lead to mistakes. Unfortunately electronic notifications cannot be accepted at present, although we would hope to move to this in the future.

Enforcement

22 Enforcement of the Contained Use Regulations 2000 is the responsibility of the HSE. HSE inspectors have extensive powers under the HSW Act, including powers to enter premises and to require the provision of information relevant to their purposes and the production of documents. They may also take samples for independent analysis.

23 HSE also enforces the sections of the EPA relevant to contained use and associated regulations under the terms of an Agency Agreement with DETR.

Guidance from the Advisory Committee on Genetic Modification

24 HSE, with advice from the Advisory Committee on Genetic Modification (ACGM), has prepared a compendium of guidance on subjects related to the contained use of GMOs. It is referred to, where appropriate, in the guidance that follows and a list of current contents is in Appendix 2. The guidance is updated from time to time and copies may be obtained from HSE at either of the addresses given in paragraph 11. The text is also available on the Internet at the HSE web site.

Regulation 1 Part I Interpretation and general

Citation and commencement

Regulation 1

These Regulations may be cited as the Genetically Modified Organisms (Contained Use) Regulations 2000 and shall come into force on 15 November 2000.

Regulation 2 Interpretation

Regulation

(1) In these Regulations, unless the context otherwise requires -

" the 1974 Act" means the Health and Safety at Work etc. Act 1974;

"accident" means an incident involving a significant and unintended release of genetically modified organisms in the course of an activity involving genetic modification which presents an immediate or delayed hazard to human health or to the environment;

"activity involving genetic modification" means a contained use;

"class", in relation to an activity involving genetic modification of micro-organisms, means one of the four classes described in Schedule 1;

"competent authority" means

(a) as regards England and Wales, the Secretary of State, the Minister of Agriculture, Fisheries and Food and the Executive, acting jointly; and
(b) as regards Scotland, the Scottish Ministers and the Executive acting jointly,

and the expressions "competent authority as regards England and Wales" and "competent authority as regards Scotland" shall be construed accordingly;

"contained use" means 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;

"EEA State" means a State, other than the United Kingdom, which is a Contracting Party to the Agreement on the European Economic Area signed at Oporto on 2nd May 1992, as adjusted by the Protocol signed at Brussels on 17th March 1993[(a)] and adopted as respects the United Kingdom by the European Economic Area Act 1993[(b)];

"emergency plan" means a plan required by virtue of regulation 20;

"emergency services" means the police, fire and ambulance services;

"the Executive" means the Health and Safety Executive;

2(1)-(4)

(a) Cm 2073 and 2183
(b) 1993 c.51

Regulation

"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 within the terms of this definition -

(a) genetic modification occurs at least through the use of the techniques listed in Part I of Schedule 2; and
(b) the techniques listed in Part II of Schedule 2 are not considered to result in genetic modification,

and "genetically modified" shall be construed accordingly;

"joint competent authority" means the competent authority as regards England and Wales and the competent authority as regards Scotland, acting jointly;

"micro-organism" means 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;

"notifier" means a person who has submitted a notification to the competent authority pursuant to regulation 9(1), 10(1), 11(1) or 12(1);

"organism" means a biological entity capable of replication or of transferring genetic material and includes a micro-organism, but does not include a human or a human embryo; and

"working day" means any day other than a Saturday, a Sunday, Christmas Day or Good Friday, or a bank holiday within the meaning given by the Banking and Financial Dealings Act 1971(a).

(2) In these Regulations, -

(a) in relation to an activity involving genetic modification, any reference to an appropriate containment level is a reference to the containment level assigned to that activity in accordance with paragraphs 3(h) and 4 of Part II of Schedule 3;
(b) any reference to an activity involving genetic modification in a numbered class is a reference to an activity involving genetic modification of micro-organisms which has been classified as belonging to the class of that number in accordance with paragraph 3(i) and (j) of Part II of Schedule 3; and
(c) in relation to a notification submitted in accordance with regulation 13(1), any reference to the competent authority shall be construed as a reference to the joint competent authority.

(3) The provisions in -

(a) Part II of Schedule 8 shall be applied in accordance with Part I of that Schedule; and
(b) Tables 1a, 1b and 1c in Part II of Schedule 8 shall be applied in accordance with the notes set out at the end of the Table in question.

2(1)-(4)

(a) 1971 c.80

Regulation

2(1)-(4)

(4) In these Regulations, unless the context otherwise requires -

(a) a reference to a numbered regulation or Schedule is a reference to the regulation or Schedule in these Regulations so numbered; and
(b) a reference to a numbered paragraph is a reference to the paragraph so numbered in the regulation or Schedule in which that reference occurs.

Guidance

25 All activities involving genetically modified micro-organisms (GMMs) must be **classified** into one of four classes, which are referred to as class 1, class 2, class 3 and class 4. Those classes are defined in regulation 2(1) and Schedule 1. They are determined for individual activities as part of the risk assessment procedure detailed in Schedule 3.

26 **'Contained use'** covers any activity involving genetically modified organisms (GMOs - which include GMMs) under the conditions of containment laid down by the Regulations. Note that destruction and disposal of GMMs are covered by the definition of contained use. Where the disposal of non-inactivated waste is undertaken by contractors they would have to comply with the Regulations. (This applies to contractors who dispose of the GMMs from containment, not to people - eg sewage companies - who might incidentally handle GMMs in waste that has already been disposed of from containment.) Activities covered also include the actual process of genetic modification as well as using GMOs once constructed. Barriers are required to be in place to limit contact of the GMOs with humans and the environment. These barriers can be provided by physical, biological or chemical means, or a combination of any of these. They must provide a high level of safety for humans and the environment.

27 It should be noted that activities covered include the breeding on from any genetically modified plant or animal, and fusions of GMMs. The progeny of such crosses will be considered to be GMOs even if one of the parents was not itself a GMO and the cross was by natural means. Only if it can be shown beyond reasonable doubt that no modified material is present in the progeny could consideration be given to the progeny being non-genetically modified.

28 The definition of **'genetic modification'** includes any alteration of the genetic material (DNA or RNA, referred to in the Regulations as 'heritable material') of an organism using a method that does not occur naturally by mating and/or recombination. Essentially this means that for genetic modification to be said to have occurred there must have been a change to an organism's genetic material (not necessarily of the chromosomal/nuclear material) and the method used to achieve that change was not based on natural mating or recombination. For instance, pollination by artificial transfer of pollen from one flower to another would not constitute genetic modification as the genetic change was as a result of natural fertilisation (even though there was a degree of human interference). Similarly, hybrid viruses created by natural recombination following co-infection of a cell by two viruses would not be considered to be genetic modification. Note that it is not the techniques which are controlled but activities involving the GMOs which are created using the techniques. Such activities include the creation of the GMO.

29 Some examples of techniques included in the definition are listed in Schedule 2 Part I, however:

- the list is not exhaustive. Any technique which alters the genetic material of an organism by a way (ie using a method) that would not occur by natural mating or recombination can result in a GMO;
- gene deletions or the insertion of multiple copies of a gene count as genetic modification if they are brought about using any listed technique or other

2(1)-(4)

Guidance

artificial method (except those listed in Schedule 2, Part III, eg mutagenesis);

- techniques involving the direct introduction of heritable genetic material include methods such as particle bombardment of plant tissues, direct injection of naked DNA into an animal and the use of other gene delivery systems such as liposomes are considered to be genetic modification where the introduced genetic material is intended to be incorporated into the organisms genetic material in a reasonably stable fashion. This would not include the kinds of transient 'incorporation' which takes place during DNA vaccination. (In relation to human gene therapy see paragraph 32 which covers the definition of 'organism');
- cell fusion is a technique of genetic modification if it is achieved in a way that does not occur naturally. There are some exceptions to this (see guidance to regulation 3, paragraph 33).

30 Schedule 2 Part II lists techniques which are not considered to fall within the definition of genetic modification provided that they do not involve the use of recombinant DNA or RNA or organisms that are themselves GMOs. The one exception to the prohibition on using GMOs is that it is allowed to use GMOs created using the technique(s) listed in Schedule 2 Part III. (See guidance on regulation 3.)

31 **'Micro-organism'** covers all micro-organisms. The term includes bacteria, fungi, viruses, viroids, cell cultures and tissue cultures, including those from plants, animals and humans. It does not cover, for example, naked nucleic acid, plasmids or liposome gene delivery systems. The one exception to this is that full length copies of the genomes of viruses, that are known to be infectious in their own right, are considered to be micro-organisms even when they are not encapsulated or enveloped. Plant pollen and animal ova and sperm are not considered to be micro-organisms. However, where they are from GM plants or animals they are subject to the relevant controls governing GM animals and plants. Their dissemination must therefore be controlled appropriately.

32 **'Organism'** covers, in addition to all micro-organisms, all multicellular organisms not defined as micro-organisms, including plants and animals, but not including humans or human embryos.

2(1)-(4)

Regulation 3 Application

Regulation

(1) These Regulations shall have effect with a view to -

(a) protecting persons against risks to their health, whether immediate or delayed, arising from activities involving genetic modification of organisms; and

(b) protecting the environment against harm from activities involving genetic modification of micro-organisms.

(2) These Regulations (except regulation 17) shall not apply to the genetic modification of organisms solely by any of the techniques referred to in Part III of Schedule 2 nor to any organisms so modified.

(3) These Regulations shall not apply to any activity in which -

(a) genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used, where such organisms are or are contained in -

(i) a product marketed in pursuance of either -

3(1)-(7)

Regulation

*(aa) a consent granted by the Secretary of State, or, as regards Scotland, by the Scottish Ministers, under section 111(1) of the Environmental Protection Act 1990**(a)**; or*

*(bb) a written consent given by the competent authority of an EEA State in accordance with Article 13(4) of Council Directive 90/220/EEC**(b)** on the deliberate release into the environment of genetically modified organisms,*

and, in either case, that activity is conducted in accordance with any conditions or limitations attached to that consent;

*(ii) a medicinal product for human or veterinary use marketed in accordance with Council Regulation (EEC) No. 2309/93**(c)**; or*

*(iii) a novel food or novel food ingredient marketed in accordance with the provisions of Regulation (EC) No. 258/97 of the European Parliament and of the Council**(d)**; or*

(b) genetically modified organisms are released or marketed in cases or circumstances in which the consent of the Secretary of State or, as regards Scotland, the Scottish Ministers, is required under section 111(1) of the Environmental Protection Act 1990.

(4) Regulations 8 to 15, 17(2) and (3), 18 and 19 shall not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.

(5) Regulation 6 shall apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air, except that, in making the assessment required by regulation 6(1), the person undertaking that assessment shall not be required to include the steps set out in paragraph 3(h) to (j) of Part II of Schedule 3.

(6) These Regulations shall not extend to Northern Ireland.

(7) In this regulation, "product" means a product consisting of or containing a genetically modified organism or a combination of genetically modified organisms.

(a) 1990 c.43.
(b) OJ. No. L117, 8.5.90, p.15, as amended by Commission Directive 99/15/EC (OJ No. L103, 22.4.94, p.20) and Commission Directive 97/35/EC (OJ No. L169, 27.6.97, p.72).
(c) OJ No. L124, 24.8.93, p.1, as amended by Commission Regulation (EC) 649/98 (OJ No. L88, 24.3.98, p.7).
(d) OJ No. L43, 14.2.97, p.1 (to be read with Corrigenda published in OJ L173, 1.7.97, p.12 and OJ L187, 20.7.99, p.74).

3(1)-(7)

Guidance

33 The Regulations apply to all activities involving the contained use of GMOs with the following exceptions:

- the Regulations do not apply to GMOs produced solely through use of one or more of the techniques of genetic modification listed in Part III of Schedule 2. These techniques are excluded so long as the parental or recipient organism is not itself a genetically modified organism and, apart from the case of self-cloning, recombinant DNA or RNA is not used. The techniques listed are:

  mutagenesis (including that induced by chemicals and ionising radiation, but not including site directed mutagenesis where recombinant nucleic acid

3(1)-(7)

Guidance

molecules are employed. This latter technique would fall within the scope of the techniques listed in Part I of Schedule 2);

cell or protoplast fusion where the cells are derived from prokaryotic species which are known to naturally inherit each others genomic DNA through homologous recombination and integration;

cell or protoplast fusion of cells from any eukaryotic species including the production of somatic animal (including human) hybridomas and the fusion of plant cells;

self-cloning[38] - self-cloned micro-organisms are exempt from the Regulations only if the resulting GMM is unlikely to cause disease (or other harm) to humans, animals or plants. For GM animals and plants self-cloned organisms are exempt if they are unlikely to cause disease (or other harm) to humans. Disease is interpreted widely and includes allergenicity and toxicity as well as infection. Consideration of likelihood of causing disease should include whether the inserted gene which does not give rise to a harmful phenotype in the GMM could do so if passed to another organism by a natural process. (That is, whether the inserted gene might lead to an indirect harmful effect.) The term self-cloning covers the removal of DNA or RNA from an organism and the reinsertion of part or all of it into the same or phylogenetically closely related species which is known to exchange genetic material naturally by homologous recombination with the originator of the nucleic acid. The nucleic acid may have been altered by enzymic or mechanical processes and inserted into recombinant vectors before reinsertion. For the self-cloned organism to be exempt any recombinant vector must have an extended history of safe use in the recipient organism concerned. However, unlike previously, the vector need not be composed entirely of DNA/RNA from the same or closely related species.

It is permissible for all or any or none of the vector to remain in the final GMO and still constitute self-cloning. However, it is important to note that the flexibility for the vector to contain DNA/RNA which is not from the same or closely related species does not extend to the insert. Some common understanding of what is meant by the 'vector' is therefore needed. For the purposes of the 'self-cloning' definition a 'vector' may include things such as origins of replication, genes for the maintenance of vectors within the hosts, sites designed for cloning and marker genes[39] for identifying and/or selecting for transformants. The inserted, modified gene(s) or other sequences are not considered to be part of the vector. It should also be noted that vectors consisting of full length copies of the genomes of viruses would not be considered suitable vectors for self-cloning as they are micro-organisms in their own right (see paragraph 31). Similarly transforming vectors, such as those containing SV40 large T, would not be acceptable vectors as these would not be considered to be without hazard;

- the GMOs involved are, or are in, a product cleared for marketing under the Environmental Protection Act 1990, or under certain other product marketing legislation or European Community procedures, and the work does not involve further genetic modification, unless specifically allowed by the marketing

38 Note that self-cloned GMOs are not exempt from legislation on deliberate release to the environment. Therefore, even when they are exempt from control under the Contained Use Regulations, they must still be used under controlled conditions (unless a consent to release is held).
39 Note that for GM plants destined for deliberate release or marketing - especially as food/feed - there is an emphasis on moving away from using antibiotic resistance marker genes.

3(1)-(7)

Guidance

consent conditions. It should also be noted that the consent conditions normally apply to the product itself and not its manufacture, which may constitute a contained use activity. Some products containing or consisting of GMMs may be sold without a consent from the Secretary of State on condition that they are sold for use under contained use conditions, and in such cases the Contained Use Regulations apply in full. GM animals sold for research will be subject to the Contained Use Regulations unless they have a marketing consent (none do at present). Do not assume that just because a GMO is on the open market it does not have to be subject to control under the Contained Use Regulations;

- the activity is a deliberate release to the environment or marketing of a GMO subject to section 111(1) of the Environmental Protection Act 1990 (in which case the consent of the Secretary of State must be obtained);
- the transport of genetically modified organisms is subject only to: the requirements for risk assessment, including that the advice of the GMSC be sought, (but not classification) under regulation 6 or 7 (as appropriate) and 16; the requirement in regulation 17 for exposure of humans and the environment to GMMs to be kept to the lowest reasonably practicable level; and (for GM animals and plants) that the possibility of harm to humans is kept to the lowest reasonably practical level. The provisions of regulations 20 onwards also apply (as appropriate). This includes the need for emergency plans (where applicable) and notification of accidents. Notification and related requirements of regulations 9 to 15 do not apply. Nor do the requirements in regulation 8 for review and recording of risk assessments. The risk assessment must follow the required steps and considerations set out in Schedule 3 for GMMs and Schedule 4 for GM animals and plants. However, it will need to take particular account of risks associated with transport itself. Key aspects will be appropriate packaging and labelling, the supply of information where appropriate to the person transporting the GMOs, and consideration of possible accidents and where appropriate emergency measures to be taken.

  Note that the transport of GMOs may be subject to the provisions of the Carriage of Dangerous Goods by Road and Rail (Classification, Packaging and Labelling) Regulations 1994.

34 For activities involving GMMs the Regulations apply both to risks to human health and the wider environment. For activities involving GMOs which are not micro-organisms (eg genetically modified plants and animals) the Regulations apply to risks to human health only. (Environmental risks from genetically modified non-micro-organisms are controlled under the EPA and the associated Regulations.)

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35 These Regulations do not apply in Northern Ireland, which has separate but matching Regulations.

Regulation 4 Meaning of 'work' and 'at work'

Regulation 4

For the purpose of these Regulations and Part I of the 1974 Act, the meaning of "work" shall be extended to include any activity involving genetic modification and the meaning of "at work" shall be extended accordingly.

Guidance

36 The purpose of this regulation is to ensure that all contained use activities, irrespective of who they are undertaken by, are controlled. To achieve this the regulation extends the meaning of 'work' and 'at work' in the HSW Act so as to include all activities involving the contained use of genetically modified organisms, whether the person concerned is an employer, an employee, a self-employed person, or someone involved in genetic modification activities who does not fall into

4

Guidance 4

one of these categories, such as a student. All such activities are covered both by the general duties in Part I of the HSW Act and by the Contained Use Regulations.

Regulation 5 Modification of the Health and Safety at Work etc. Act 1974

Regulation

5(1)-(3)

(1) Sections 2(1), (2) and (3) and 7 of the 1974 Act shall be modified in relation to an activity involving genetic modification so as to have effect as if the reference to an employer therein includes a reference to an educational establishment providing a course of study, and the reference to an employee therein includes a reference to a student of that educational establishment and that student shall be treated as the employee of that educational establishment, to the extent that the activity involving genetic modification is under the control of that educational establishment.

(2) Section 3(2) of the 1974 Act shall be modified in relation to an activity involving genetic modification so as to have effect as if the reference in that section to a self-employed person is a reference to any person (except a student) who is not an employer or an employee and the reference in that section to his undertaking includes a reference to such an activity.

(3) In this regulation -

(a) "educational establishment" means a university, polytechnic, college, school or similar educational or technical institute; and
(b) "student" means any person studying at an educational establishment.

Guidance

5(1)-(3)

37 This regulation has two functions. First it modifies sections 2(1), (2) and (3) and 7 of the HSW Act so that students (including visiting students) are treated as if they were employees of the educational establishment where they are studying. The effect is to place the responsibility for the safe conduct of genetic modification activities on the 'employer' (ie the educational establishment). Educational establishment has a very broad interpretation and includes companies which offer technical training courses, eg on the operation of instruments. By including Section 7 of the HSW Act the regulation also requires students to take reasonable care for their health and safety and of any other person who may be affected by their actions (or inactions). The second function of this regulation is to modify section 3(2) of the HSW Act. Section 3(2) requires self-employed people to conduct their undertakings in such a way as to ensure, so far as is reasonably practicable, that people other than employees are not exposed to risks to their health and safety. Regulation 5(2) extends the meaning of 'self-employed person', in relation to an activity involving genetic modification, to anyone who is not an employer or an employee.

Part II Risk assessment and notification of activities involving genetic modification

Regulation 6 Risk assessment of activities involving genetically modified micro-organisms

Regulation

6(1)-(2)

(1) No person shall undertake any activity involving genetic modification of micro-organisms unless, before commencing that activity, he has ensured that a suitable and sufficient assessment of the risks created thereby to human health and the environment has been carried out.

(2) The person carrying out an assessment required by paragraph (1) shall take into account the matters set out in Part I of, and include the steps set out in Part II of, Schedule 3.

Guidance

38 This regulation requires that the risk of all activities involving GMMs must be assessed before the activity can be undertaken. The risk assessment must consider both human health and environmental safety. The risk assessment must take into account the matters in Part I of Schedule 3. These include: identification of any potentially harmful effects; characteristics of the proposed activity; the severity of any potentially harmful effects; and the likelihood of them occurring. Part II of Schedule 3 sets out the steps which must be followed in making the risk assessment. This includes the selection of the appropriate containment and control measures for the particular activity. Note that the risk assessment must take full account of the ultimate disposal options, including disposal to landfill licensed under waste management legislation and controlled waste.

39 Rather than requiring the person undertaking the activities to actually carry out the risk assessment, regulation 6(1) requires that person to ensure that a suitable and sufficient risk assessment has been made. This does not remove responsibility from the person undertaking the activity to ensure that the risk assessment is adequate, but does allow the risk assessment to be undertaken by a third party. This might be where one company is undertaking an ancillary activity under contract to another. Care must be taken that any risk assessment takes on board the local situation. This means that you should not simply accept a generic risk assessment (eg one supplied with a test kit). Similarly, if a project is being transferred from other premises, or even from a different part of the same notified premises, the risk assessment should be reviewed and advised on by the relevant local GMSC. (See regulation 16.)

40 Risk assessments will vary in the amount of detail necessary to draw conclusions about the hazards (potential for harm) of the activity, the likelihood that they will give rise to harm, and the control measures that are needed. Simple activities involving low hazard, well known and well understood micro-organisms may normally need less detailed consideration than complex activities involving hazardous and less familiar micro-organisms. For example, it would be permissible to undertake a generic risk assessment, following the procedure in Schedule 3, covering specified activities, at a specific premises that involved a series of named *Escherichia coli* K-12 strains, whose disablement was well characterised, a series of named non-mobilisable vectors and a broadly defined type of insert. Any future activities that fell within the boundaries set out for this generic assessment would then be covered and would not require individual assessment unless there was a particular reason for doing so.

6(1)-(2)

41 Alternatively, the risk assessment of work involving more hazardous GMMs

Guidance

would require much more detail on the exact vectors and inserts being used. For instance, work on pathogenic viruses that involves the cloning of genes from other viruses with a view to substituting for the function of particular genes would require close scrutiny. For example, the risk assessment of an activity that involved the cloning of viral polymerase genes in place of the polymerase gene of a pathogenic virus would require (for each construct) at least consideration of: (a) the properties of the parental virus, including the extent to which the infectivity or tissue tropism of the virus may be limited at the level of expression of the virus polymerase, (b) the known properties of each of the polymerase genes being cloned, (c) the likelihood that each gene would substitute for the function of the wild-type polymerase, (d) details of the precise way in which each gene would be cloned and the consequences that this might have for the expression of the gene as compared to the wild-type polymerase, and (e) likelihood that the modified virus may have an altered tropism or infectivity.

42 HSE/ACGM guidance on risk assessment and identification of appropriate containment and control measures can be found in the ACGM Compendium of Guidance (see paragraph 24 for details of where to obtain this guidance; the contents of the Compendium are listed in Appendix 2). Furthermore, users should be aware of the explanatory guidance on interpretation of the risk assessment procedure in Schedule 3 which has been produced by the European Commission in consultation with Member States. (See Appendix 1.) The ACGM guidance is fully compatible with this European guidance and cross refers to it where necessary.

43 In addition to requiring the selection of appropriate control measures, the risk assessment procedure also requires all activities involving GMMs to be classified into one of four classes: class 1, class 2, class 3 and class 4. The assignment to a class must be made on the basis of the outcome of the risk assessment process. Key factors will be the initial classification that was made on the basis of the hazard identification step and any additional containment measures that have been assigned over and above the minimum requirements appropriate to the initial risk class. To decide on the correct classification for an activity, users must compare the selected measures necessary to control the risk with the appropriate table in Schedule 8. Recognising that containment measures form a continuum rather than four discrete levels, many activities will require control measures which fall somewhere between two levels. For instance, the risk assessment may show that an activity requires laboratory level 2 containment with the addition of HEPA filtration of extract air and so falls between levels 2 and 3. In such cases the classification is to the higher level (in this example level 3, so class 3 is appropriate). The table on page 19 illustrates the range of possible containment levels and the corresponding activity classification.

44 It should be noted that the containment tables in Schedule 8 contain the phrase ‘required where and to extent the risk assessment shows it is required’. This indicates that the particular item may or may not be required and that this must be determined by the risk assessment. However, for the purposes of deciding the classification of the activity ‘required where and to extent the risk assessment shows it is required’ effectively means ‘yes or no’. Therefore, if an activity required level 1 laboratory containment but included the need for vector control (which is ‘required where and to extent the risk assessment shows it is required’ at level 1) this would not push the activity into class 2 (which has a requirement for vector control). Similarly, it should be emphasised that the classification is based on the level of containment required to control the risk, not necessarily the level of containment at which you propose to carry out the activity. For instance, the activity may be classified as class 1 based on the containment required to control the risk, but all of your laboratories meet level 2 containment requirements. This does not mean that the activity becomes a class 2 activity. (Note that in general it is not good practice to undertake activities at higher levels of containment than are warranted by the risk. However, in some cases it is unavoidable - especially between levels 1 and 2.)

6(1)-(2)

Guidance

Containment necessary to control the risk	Activity classification
Level 1 (or less)	Class 1[40]
Level 1 plus additional measures from Level 2 or Level 2 (without additional measures)	Class 2
Level 2 plus additional measures from Level 3 or Level 3 (without additional measures)	Class 3
Level 3 plus additional measures from Level 4 or Level 4 (with or without additional measures)	Class 4

6(1)-(2)

Regulation 7 Risk assessment of activities involving organisms other than micro-organisms

Regulation

(1) No person shall undertake any activity involving genetic modification of organisms other than micro-organisms unless, before commencing that activity he has ensured that a suitable and sufficient assessment of the risks created thereby to human health has been carried out.

(2) The person carrying out an assessment required by paragraph (1) shall take into account the matters set out in Part I of , and include the steps set out in Part II of, Schedule 4.

7(1)-(2)

Guidance

45 This regulation requires that a risk assessment be made for all activities involving genetically modified organisms other than micro-organisms (eg genetically modified animals and plants) before the activity can be undertaken. The risk assessment must consider human health. (The equivalent consideration of environmental risks must be undertaken under the relevant section of the EPA and associated Regulations.) The risk assessment must take into account the matters in Part I of Schedule 4. These include: identification of any potentially harmful effects to humans; characteristics of the proposed activity; the severity of any potentially harmful effects [to humans]; and the likelihood of them occurring. Part II of Schedule 4 sets out the steps to be followed in making the risk assessment. This includes the selection of the appropriate containment and control measures for the particular activity.

46 Rather than requiring the person undertaking the activities to actually carry out the risk assessment, regulation 7(1) requires that that person ensures that a suitable and sufficient risk assessment has been made. This has the effect of allowing the risk assessment to be undertaken by a third party. (But see paragraph 39 for further advice.)

47 As explained in paragraphs 40 and 41, risk assessments will vary in the amount of detail necessary to draw conclusions about the hazards (potential for harm) of the activity, the likelihood that they will give rise to harm, and the control measures that are needed.

7(1)-(2)

40 Note that because Class 1 is defined as 'of no or negligible risk', it is not acceptable to classify pathogens in Class 1, even if containment level 1 is appropriate. This might be the case for some plant or animal pathogens.

Guidance

48 HSE/ACGM guidance on risk assessment and identification of appropriate containment and control measures can be found in the ACGM Compendium of Guidance (see paragraph 24 for details of where to obtain this guidance; a list of contents is in Appendix 2.)

49 While not a requirement of regulation 7, to comply with regulation 12(2) a determination of whether the activity is notifiable must be made. In practice it is often helpful to decide this at the same time as making the risk assessment. Notification requirements are not determined in the same way as for activities involving GMMs. Instead, the consideration involves whether or not the genetically modified organisms themselves have a greater degree of potential to cause harm to humans than the non-modified equivalent organism. Activities will be notifiable where there is a greater potential for harm to **humans**. For instance, if a mouse was to be genetically modified to contain the polio virus receptor it could act as a new reservoir for human disease and so have a greater potential to cause harm to humans. However, if the mouse had just been modified to change its colour this would not increase the potential to cause harm to humans over that of other mice. The activity involving the mice now susceptible to the polio virus would be notifiable, the colour change activity would not. (See also regulation 12 - notification requirements for genetically modified non-micro-organisms.)

7(1)-(2)

Regulation 8 Review and recording of risk assessments

Regulation

(1) Where -

(a) there is reason to suspect that the assessment is no longer valid; or
(b) there has been a significant change in the activity involving genetic modification to which an assessment relates,

the person undertaking the activity involving genetic modification to which the assessment relates shall ensure that the assessment is reviewed forthwith.

(2) The person undertaking an activity involving genetic modification -

(a) shall keep a record of the assessment relating to that activity, and any review of that assessment, for at least 10 years from the date of the cessation of that activity; and
(b) shall make such record available to the competent authority when requested to do so.

(3) In this regulation, "assessment" means an assessment carried out for the purposes of regulation 6 or regulation 7.

8(1)-(2)

Guidance

50 Under regulation 8(1), it is necessary to review the risk assessment, made under either regulation 6 or regulation 7, where there is reason to suspect that the original assessment is no longer valid or where there has been a significant change in the activity to which the assessment relates. In this context significant change could include, for example:

- change of scale of operation;
- change in containment conditions used;
- change of waste treatment procedures;
- new data on the behaviour of the organism, eg data on the toxicity of the gene product; on the level of gene expression; on the ability of the organism to cause harm to humans or the environment etc.

8(1)-(2)

51 Regulation 8(2) requires that records of risk assessments are kept for at least

Guidance

10 years from the date on which the activity to which the assessment related ceased. In practice, the very act of undertaking a risk assessment will usually generate a record of some sort. The record should be sufficient to serve two important purposes:

- to allow the persons involved in the activity to check the risk assessment and review it as necessary;
- to provide enforcing authority inspectors with a way of seeing what has been done in the past.

52 An adequate record will therefore contain facts and data and the conclusions of the risk assessment and the reasoning behind them. How much is needed on any particular point will depend on its importance in the assessment and the extent to which it is generally accepted material in published and peer reviewed sources.

53 Under regulation 16, any persons undertaking a risk assessment (as opposed to ensuring that one has been undertaken - see paragraphs 39 and 46) for the purposes of the Regulations must establish a genetic modification safety committee to advise them in relation to that assessment. See the guidance to regulation 16 for further information on such committees.

8(1)-(2)

Regulation 9 Notification of the intention to use premises for the first time for activities involving genetic modification

Regulation

(1) No person shall use premises for the first time for the purpose of undertaking an activity involving genetic modification, unless -

(a) he has submitted to the competent authority a notification informing it of his intention to do so and containing the information specified in Schedule 5; and

(b) he has received an acknowledgement from the Executive of receipt of that notification.

(2) Within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1), the Executive shall send to the notifier an acknowledgement of receipt.

9(1)-(2)

Guidance

54 Regulations 9 to 13 set out the notification procedures required to be fulfilled by the person intending to undertake activities involving genetic modification. In practice, the 'person' will generally be a body such as a company, university or research institute.

55 Notification under regulation 9 is required when premises are to be used for the first time for activities involving genetic modification. The extent to which groups of premises (for example, different laboratories within the same research institution or university; geographically separate parts of an institute/ company etc) may be the subject of a single notification, will depend largely on the way in which the management structure of the body making the notification is organised. The key factor will be that there is a single person (ie body) which has ultimate management responsibility over all of the parts being notified. Also, it is increasingly common for premises to be occupied by several different bodies. In cases of multiple occupancy, each managerially separate entity will need to separately notify. Advice on individual cases can be obtained from HSE Technology Division, for contact details see paragraph 20.

9(1)-(2)

Guidance

56 Premises notification must be made before any activities involving genetic modification have been carried out. HSE acts as the post box on behalf of the competent authority for the Regulations and notifications should be sent to the Technology Division at the address in paragraph 20. The notification must contain the information specified in Schedule 5. HSE will acknowledge the notification within 10 working days of receipt (again on behalf of the competent authority). This acknowledgement does not imply that the information is either complete or satisfactory. You are advised to keep the acknowledgement with your records. If you wish, class 1 activities or activities involving non-notifiable GM animals or plants can start immediately on receipt of the acknowledgement.

57 Where the first activity to be undertaken at a premises is either a class 1 activity involving GMMs, or involves genetically modified organisms other than micro-organisms and for which the activity is **not** notifiable under regulation 12, a summary of the risk assessment relating to the first activity to be undertaken must be supplied with the premises notification. (That is, if the first activity is not notifiable you have to supply a summary of the risk assessment for it with the premises notification.) For first class 1 activities involving GMMs, information on waste management must also be supplied.

58 It is possible to notify premises at the same time that any notification of an individual activity (under regulation 10, 11 or 12) or a connected programme (regulation 13) is made. In such cases only the fee payable for the individual activity or connected programme is required. (Effectively, the premises notification, when combined with activity notifications, is free.) For instance, the premises notification may be made with a notification under regulation 12 in respect of a class 3 activity or a connected programme notification of a class 3 with an associated activity involving a genetically modified plant under regulation 13. However, it is important to note that the information required by each regulation must be supplied and all of the notification requirements fulfilled. For instance, in the examples just given, the class 3 activity could not be started until consent had been given (which would be between 30 and 90 days of the notification) and the activity involving the genetically modified plant could not be started until 45 days had elapsed from the date of the acknowledgement, or earlier with the agreement of the competent authority.

59 Users are free to supply the information to be notified in any format they wish, although electronic notifications cannot be accepted at present. However, model forms are available free on request from HSE or (for electronic versions) on the HSE Internet website. These forms (copies of which are at Appendix 5) have been designed to help notifiers comply with the information requirements and also form the basis for the entry onto the public register (see regulation 24 and related guidance). The forms are also designed to allow easy identification of information being claimed as confidential. (See regulation 22 on disclosure of information.)

9(1)-(2)

Regulation 10 Notification of class 2 activities involving genetic modification of micro-organisms

Regulation

(1) Subject to the following paragraphs of this regulation, no person shall undertake any activity involving the genetic modification of micro-organisms in class 2 unless he has submitted a notification to the competent authority informing it of his intention to do so and containing the information specified in Part I of Schedule 6.

(2) Within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1), the Executive shall send to the notifier an acknowledgement of receipt.

10(1)-(7)

Regulation

(3) The competent authority shall ensure that any emergency plan has been prepared.

(4) No person shall undertake -

(a) for the first time an activity referred to in paragraph (1) at the premises referred to in a notification submitted in accordance with that paragraph unless -

(i) at least 45 days, or such shorter period of time as the competent authority may approve in writing, have elapsed since the date on which the acknowledgement was sent in accordance with paragraph (2) and the competent authority has not within the said period of 45 days or the shorter period of time approved by the competent authority, as the case may be, informed the notifier that he shall not undertake the activity in question, or

(ii) he has received the acknowledgement required by paragraph (2) and consent for activities involving genetic modification in class 3 or 4 has already been granted in respect of the premises to which the notification submitted in accordance paragraph (1) refers;

(b) for the second or subsequent times an activity referred to in paragraph (1) at the premises referred to in a notification submitted in accordance with that paragraph unless he has received the acknowledgement required by paragraph (2).

(5) Where a person submits a notification in accordance with paragraph (1) in respect of an activity referred to in that paragraph which is not to be undertaken for the first time at the premises referred to in the notification, with the notification that person may request that the competent authority makes a decision whether or not to agree to his undertaking the activity in question.

(6) The competent authority shall make a decision requested in accordance with paragraph (5) within 45 days of the date on which the acknowledgement was sent in accordance with paragraph (2).

10(1)-(7)

Guidance

60 Notification is required of all class 2 activities involving GMMs. Notifications must include the information set out in Part I of Schedule 6 and should be sent to HSE, Technology Division (address at paragraph 20). HSE, on behalf of the competent authority, will acknowledge receipt of the notification within 10 working days. (Acknowledgement will not imply that the information is adequate - simply that it has been received.)

61 For the first class 2 activity, and when the notifier does not already hold a consent[41] in respect of a class 3 or 4 activity at the same premises, the activity cannot commence until:

- 45 days after the date on which the acknowledgement was sent by HSE (so long as HSE has not informed the notifier that the activity should not be started); or
- the competent authority has approved in writing that work may commence before the 45 day notification period has ended.

62 Where a consent for a class 3 or 4 activity is already held, the notifier may start the class 2 activity immediately on receipt of the acknowledgement.

10(1)-(7)

41 When the notifier has a consent for one or more class 3 or 4 activity the first class 2 activity is treated as if it where a subsequent class 2 activity; see paragraphs 62 and 63.

Guidance

63 For subsequent class 2 activities the notifier may commence work as soon as the acknowledgement has been received. If the notifier wishes, they can request that subsequent class 2 activities are subject to a 45 day notification period and formal authorisation from the competent authority. In such cases, the work could not commence unless and until the competent authority has authorised the work. The response will be given by the authorities within 45 days of the acknowledgement of receipt.

64 Where the notification included a request to the competent authority to allow a lower level of containment than the minimum required for class 2 activities (ie level 2; see regulation 18), the competent authority will confirm the decision on whether or not to allow this derogation. For those class 2 activities which may start immediately on receipt of the acknowledgement (see regulation 12 for details) the full containment level 2 requirements must be applied, unless and until the derogation is confirmed.

10(1)-(7)

Regulation 11 Notification of class 3 or class 4 activities involving genetic modification of micro-organisms

Regulation

(1) Subject to the following paragraphs of this regulation, no person shall undertake an activity involving genetic modification of micro-organisms in class 3 or class 4 unless he has -

(a) submitted to the competent authority a notification informing it of his intention to do so and containing the information specified in Part II of Schedule 6; and
(b) received the written consent of the competent authority to undertake the activity in question.

(2) Within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1), the Executive shall send to the notifier an acknowledgement of receipt.

(3) Where a person proposes to undertake an activity referred to in paragraph (1) for the first time at the premises referred to in a notification submitted in accordance with that paragraph, the competent authority shall inform that person in writing of its decision to grant or refuse consent to undertake the activity in question not more than 45 days after the acknowledgement was sent in accordance with paragraph (2).

(4) Where a person proposes to undertake an activity referred to in paragraph (1) for the second or subsequent times at the premises referred to in a notification submitted in accordance with that paragraph, the competent authority shall inform that person in writing of its decision to grant or refuse consent to undertake the activity in question not than 45 days after the acknowledgement was sent in accordance with paragraph (2).

(5) Before granting a consent under either paragraph (3) or paragraph (4), the competent authority shall ensure that any emergency plan has been prepared.

(6) Before deciding whether to grant or refuse a consent under either paragraph (3) or paragraph (4), the competent authority shall take into account any representations made to it by any person within 30 days of the date on which the Executive sent the acknowledgement of receipt in accordance with paragraph (2).

11(1)-(7)

Regulation 11(1)-(7)

(7) A consent granted pursuant to this regulation may be granted subject to conditions.

Guidance

65 Notification is required of all class 3 and class 4 activities involving GMMs. Notifications must include the information set out in Part II of Schedule 6 and should be sent to HSE, Technology Division (address at paragraph 20). HSE, on behalf of the competent authority, will acknowledge receipt of the notification within 10 working days. (Acknowledgement will not imply that the information is adequate or acceptable.)

66 For the first class 3 or 4 activity at the premises, the activity cannot commence until:

- the competent authority has given its written consent to the activity. The decision on whether or not to issue a consent will not be given before 30 days after the date on which the acknowledgement was sent by HSE have elapsed, but will be given no later than 90 days after the date of acknowledgement.

67 For subsequent class 3 or 4 activities, ie where the notifier already holds one or more consents for either class 3 or class 4 activities, the activity cannot commence until:

- the competent authority has given its written consent to the activity. As for the first class 3 or 4 activity, the decision on whether or not to issue a consent will be given within the period 30 to 45 days after the date on which the acknowledgement was sent by HSE.

68 Where the notification included a request to the competent authority to allow a lower level of containment than the minimum required for class 3 or class 4 activities (ie level 3 or level 4 respectively; see regulation 18), the competent authority will confirm the decision on whether or not to allow this derogation at the same time as giving the decision on whether or not to grant the consent. Conditions may be placed on the consent by the competent authority.

11(1)-(7)

Regulation 12 Notification of activities involving genetic modification of organisms other than micro-organisms

Regulation

(1) Subject to the following paragraphs of this regulation, no person shall undertake an activity involving genetic modification of organisms other than micro-organisms unless he has submitted to the competent authority a notification informing it of his intention to do so and containing the information specified in Part III of Schedule 6.

(2) Paragraph (1) shall not apply to an activity involving genetic modification of organisms where that genetic modification results in a genetically modified organism (other than a micro-organism) which poses no greater risk to humans than its unmodified parental organism.

(3) Within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1), the Executive shall send to the notifier an acknowledgement of receipt.

(4) No person shall undertake any activity referred to in paragraph (1), unless at least 45 days, or such shorter period of time as the competent authority may approve in writing, have elapsed since the date on which the acknowledgement

12(1)-(4)

Regulation

12(1)-(4)

was sent in accordance with paragraph (3) and the competent authority has not within the said period of 45 days or the shorter period of time approved by the competent authority, as the case may be, informed the notifier that he shall not undertake the activity in question.

Guidance

12(1)-(4)

69 All activities involving genetically modified organisms other than micro-organisms (eg genetically modified plants and animals) where the GMO has a greater degree of potential to cause harm to humans (see Schedule 4, Part I, 2a - d for examples of harm) than the equivalent non-modified organism, must be notified. (See also paragraph 49 in the risk assessment section.) Notifications must include the information set out in Part III of Schedule 6 and should be sent to HSE, Technology Division (address at paragraph 20). HSE, on behalf of the competent authority, will acknowledge receipt of the notification within 10 working days. (Acknowledgement will not imply that the information is adequate or acceptable.) Notifiers may find it helpful to use the forms in Appendix 5 - although these are not mandatory.

70 The notifier may commence the activity 45 days after the date on which the acknowledgement was sent, unless the competent authority has approved in writing that work may commence before the 45 day notification period has ended.

Regulation 13 Notifications to the joint competent authority and of connected programmes of work

Regulation

13(1)-(4)

(1) Where a notification is required -

(a) under regulation 9(1) in respect of premises which are situated in both England and Scotland; or
(b) under regulation 10(1), 11(1) or 12(1) in respect of an activity involving genetic modification which is to take place in both England and Scotland,

the notifier shall submit a single notification under the regulation in question to the joint competent authority.

(2) The competent authority may accept a single notification submitted under regulation 10(1), 11(1) or 12(1) in respect of a connected programme of work undertaken by the same person at -

(a) one site; or
(b) more than one site.

(3) The competent authority may accept a single notification submitted under regulation 10(1), 11(1) or 12(1) in respect of a single activity involving genetic modification undertaken by the same person at more than one site.

(4) In this regulation -

(a) "connected programme of work" means a series of activities involving genetic modification which form a coherent and integrated programme;
(b) "site" means premises of which the competent authority has been notified in accordance with regulation 9(1).

Guidance

13(1)-(4)

71 If a user wants to notify premises which occupy both sides of the border between England and Scotland, the notification has to be made to the joint competent authority (ie HSE, the Secretary of State and the MAFF Minister for England and Wales, and HSE and Scottish Ministers for Scotland). In practice, just

Guidance

one copy of the notification should be sent to the HSE Technology Division which will arrange distribution to the other parts of the competent authorities. The user is advised, however, to indicate in a covering note that the notification is being made to the joint competent authority. The same requirement applies if a notifiable activity is to be undertaken at premises which occupy both sides of the border. The competent authority may accept a single notification covering a connected programme of work. This might involve a programme covering more than one activity at a single notified premises or more than one activity carried out by a single person at more than one notified premises. (This might apply, for example, where an institution or company has several notified premises which all collaborate on connected work.) The competent authority may also accept a single notification covering a single activity which is to be undertaken by the same person at more than one notified premises.

72 Activities covered by a connected programme of work notification may involve[42] any combination of class 2, class 3 or class 4 activities and any notifiable activities involving genetically modified organisms which are not micro-organisms (eg genetically modified plants and animals). However, to form a connected programme they must all be part of a coherent and integrated programme of work. That is, they should all form part of a specific scientific/research goal. One good indicator of whether the activities are sufficiently connected is if they would be acceptable as a single, standard research grant application or a single budgetary submission to a company board or similar body.

73 Notifications in respect of connected programmes must contain all of the information required under regulation 10, 11 or 12 (as applicable) for each individual activity.

74 The relevant notification requirements (eg notification periods and consents etc) stipulated in regulations 10, 11 and 12 must be complied with for each individual activity within a connected programme. For instance, consider a connected programme consisting of activities in classes 2 and 3 which are to be undertaken at a premises where previous class 2 activities have been undertaken, but where no class 3 (or 4) activities have been undertaken. The class 2 activities may be commenced as soon as the acknowledgement has been received from HSE. However, the class 3 activities cannot be started until the competent authority has issued a consent. For a first time class 3 activity this could take up to 90 days. Similarly, derogations from minimum containment levels cannot be commenced until written agreement has been received.

75 The advantages to users of connected programme notifications are:

- only a single notification fee is payable even though the notification covers several activities;
- there is some saving derived from not having to duplicate certain information in the notification.

76 Where users wish to commence an additional activity under a previously notified connected programme, the appropriate notification must be made under regulations 10, 11 or 12. If users wish to add several new activities to a connected programme these could be notified together under regulation 13, in the same way as the original set of activities.

13(1)-(4)

42 They may also, of course, involve class 1 activities or non-notifiable activities involving GM animals or plants, but none of these need to be included in the notification.

Guidance

13(1)-(4)

77 Regulation 15(2) and 15(3) apply to any changes to previously notified activities, including those notified as part of connected programmes. (See paragraphs 81-88 for further explanation.) This regulation cannot, however, be used to add on new activities.

Regulation 14 Duties on receiving notifications and additional information

Regulation

(1) The competent authority shall examine a notification submitted under regulation 9(1), 10(1), 11(1) or 12(1) for -

(a) conformity with the requirements of these Regulations;
(b) the accuracy and completeness of the information provided;
(c) the correctness of the assessment carried out pursuant to regulation 6(1) or 7(1) and submitted to the competent authority with the notification;
(d) the adequacy of the waste management and emergency response measures submitted with the notification; and
(e) in the case of a notification submitted under regulation 10(1) or regulation 11(1), the correctness of the class assigned to the activity involving genetic modfication of micro-organisms.

(2) For the purpose of carrying out an examination of a notification in accordance with paragraph (1), the Executive may request in writing the notifier to provide such additional information relating to the notification as it may specify, and, in such a case, when so requested by the Executive, the notifier shall not begin nor, subject to paragraph (3), continue, as the case may be, the activity involving genetic modification until the competent authority has given its approval in writing.

(3) Where the person who submitted a notification pursuant to regulation 9(1), 10(1), or 12(1) has commenced the activity involving genetic modification before the Executive requests additional information in accordance with paragraph (2) -

(a) the Executive may give to that person instructions concerning the cessation of the activity involving genetic modification;
(b) that person shall comply with any such instructions;
(c) subject to any such instructions, that person shall continue the activity involving genetic modification only to the extent necessary in order to store or destroy all genetically modified organisms resulting from the activity since its commencement.

(4) If requested to do so by the Secretary of State, the Minister of Agriculture, Fisheries and Food or the Scottish Ministers, the Executive shall request additional information under paragraph (2).

(5) Within 10 working days, the Executive shall acknowledge receipt of all additional information provided in response to a request made by the Executive under paragraph (2).

(6) The period of time between the date when the Executive requests additional information in accordance with paragraph (2) and the date when the Executive receives that additional information shall not be taken into account in calculating the period of days referred to in regulations 10(4), 10(6), 11(3), 11(4), or 12(4), as the case may be.

14(1)-(7)

Regulation

14(1)-(7)

(7) Where -

(a) a notifier under regulation 9(1) has not commenced any activity involving genetic modification, or a notifier under regulation 10(1), 11(1) or 12(1), has not commenced the activity relating to genetic modification to which his notification relates; and
(b) the Executive requests additional information pursuant to paragraph (2); and
(c) the notifier in question does not provide that information within a period of six months of the date on which the Executive sent the request,

the competent authority may return the notification to the notifier.

Guidance

78 This regulation sets out duties on the competent authority relating to receipt of a notification of either first use of premises or individual activity. The regulation also gives the competent authority the right to request additional information in relation to notifications. In practice, HSE will request any additional information on behalf of the other members of the competent authority and on its own behalf. HSE, again on behalf of the competent authority, will acknowledge receipt of the additional information within 10 working days. (Acknowledgement will not imply that the information is adequate or acceptable.)

79 When additional information is asked for, and the activity is not one that is permitted to be started as soon as acknowledgement is received, the competent authority may instruct the notifier not to start the activity until it has given its written approval. In the case of activities which had already started they may be requested to be stopped while the additional information is obtained and considered. While the activity is suspended the GMOs must either be stored or destroyed, or handled in such a way as the competent authority directs. Requests for additional information stop the clock as far as the specified time periods for the competent authorities to respond to class 3 or 4 activities are concerned. The clock will re-start on receipt of the information. Because of the requirement for approval, requests for additional information also effectively impose on the competent authority the 45 day notification periods imposed by regulations 9 and 10. Requests for additional information will therefore stop the clock on this 45 day period (re-starting it on receipt of the information). Note that any required 'approval' is quite separate from 'consent' as required by regulation 11 for class 3 and 4 activities.

80 Note also that a time limit of 6 months is given for responses to requests for additional information in relation to first class 2 activities, activities involving notifiable GM animals and plants, and class 3 or 4 activities. If the information is not supplied within this time period the notification will be returned[43] (but not the fee). The situation for premises notifications and subsequent class 2 activities is slightly different in that the activity could already have started by the time additional information was requested. In these cases, if the additional information was not forthcoming the competent authority would use its powers in regulation 15(1) to suspend or terminate the activity. (In fact, in certain circumstances this might be done while the additional information was being sought.) The notification, however, will not be returned for activities which had already commenced as the information would have to remain with the competent authorities and be available for potential public disclosure.

14(1)-(7)

43 A new notification and new fee would then be required if the user wished to restart the notification process.

Regulation 15 Additional provisions relating to notifications

Regulation

(1) The competent authority may at any time by notice in writing to the person undertaking or proposing to undertake an activity involving genetic modification -

(a) set a limit of time for, or impose conditions with regard to, that activity;
(b) require that person to suspend, to terminate or not to commence that activity, as the case may be;
(c) revoke or vary a consent granted to that person under regulation 11,

and the person to whom the notice is addressed shall comply with that notice.

(2) A notifier shall forthwith send to the competent authority full details in writing of -

(a) any change in the information specified in paragraphs (a), (d) or (e) of Schedule 5 and provided by him in accordance with regulation 9(1);
(b) any new building -

(i) added by the notifier to the premises notified by him in accordance with regulation 9(1), and
(ii) under his control;

(c) any decision by him no longer to use premises notified by him in accordance with regulation 9(1) for the purposes of undertaking any activity involving genetic modification;
(d) any cessation for the time being of all activity involving genetic modification at premises notified by him in accordance with regulation 9(1);
(e) any cessation of an activity involving genetic modification notified by him in accordance with regulation 10(1), 11(1) or 12(1);
(f) any re-commencement by him of an activity involving genetic modification at premises in respect of which details of a cessation had previously been given by him under sub-paragraph (d) above;
(g) any use by him of additional premises in connection with a single activity involving genetic modification carried on solely by him at more than one site, provided that a notification has been submitted by him in accordance with regulation 9(1) in respect of the additional premises;
(h) any change in the information specified in -

(i) paragraphs (b) and (c) of Schedule 5 and provided by him in accordance with regulation 9(1), or
(ii) paragraph 1(c) or (d) of Part I of Schedule 6 and provided by him in accordance with regulation 10(1).

(3) Subject to paragraphs (4) and (5), where a notifier subsequently -

(a) makes a change in the premises or the activity involving genetic modification to which his notification relates which may have significant consequences for the risks arising from that activity, or
(b) becomes aware of any new information which may have significant consequences for the risks arising from that activity,

15(1)-(8)

Regulation

he shall forthwith send to the competent authority in writing full details of the change or the new information, as the case may be.

(4) Subject to paragraph (5), where a change referred to in paragraph (3)(a) would require a person to submit a notification in accordance with regulation 11(1), that person shall not make the change until -

(a) he has submitted a notification in accordance with that regulation, and
(b) he has received the written consent of the competent authority pursuant to regulation 11(1)(b).

(5) Paragraph (4) shall not apply where a person undertakes an activity involving genetic modification with the written consent of the competent authority granted pursuant to regulation 11(1)(b) and the change referred to in paragraph (3) would require that person to make a further notification under regulation 11(1).

(6) A notifier may withdraw his notification by giving written notice to the competent authority, provided that the notifier has not commenced the activity involving genetic modification to which the notification relates.

(7) In this regulation, the word "site" has the same meaning as it has in regulation 13.

(8) Anything required to be submitted or sent to the competent authority pursuant to these Regulations shall be submitted or sent in writing to the competent authority at Magdalen House, Stanley Precinct, Bootle, Merseyside L20 3QZ.

15(1)-(8)

Guidance

81 Regulation 15 (1) allows the competent authority to impose conditions on any contained use activity or proposed contained use activity. This could include time-limiting the activity, ordering it to stop or be halted temporarily, or not to start. The competent authority may also revoke or vary any consent, setting conditions or imposing time limits as necessary.

82 Regulation 15 requires users to notify the competent authority of significant changes to information supplied as part of either premises or individual activity notifications *and* any new information which could significantly affect the level of risk from a particular notified activity. Note that it is specifically required that the competent authority be informed that activities have ceased. The information to be notified is divided into two types, which can be generally described as:

- administrative (eg changes to people responsible, address/premises changes, cessation of an activity, cessation of all activities, closure of a facility, notification of when claims for confidentiality are no longer justified under regulation 22);
- ongoing activity specific (significant changes to the risk of ongoing activities including - changes to the GMOs involved, new information about the level of risk, changes to containment and control measures including requests for agreement not to apply the full containment related to the class of activity, changes to procedures being undertaken).

83 Risk means risk to human health or the environment in the case of activities involving GMMs, but for activities involving genetically modified animals and plants, it means risk to human health only. 'Significant' changes are any modification or new information which leads to the need to reconsider/review the original risk assessment. Notifications of administrative change do not attract a fee. Notifications of changes to ongoing activities do attract a fee. (See regulation 27.) To minimise the numbers of changes users have to notify in relation to activities -

15(1)-(8)

Guidance

15(1)-(8)

and fees to be paid - the scope of the initial notification should be considered very carefully. For instance, if there is a possibility that alternative hosts, vectors and gene sources could be used, as well as the 'first choice' ones, include them in the notification to avoid having to submit numerous significant change notifications.

84 It is also important to note that where the change is such that a consent is required, where there had not previously been one (eg a class 2 activity becoming class 3) the change cannot be notified under regulation 15. Rather, a complete new notification under regulation 11 must be made. In such cases the change cannot be made until the consent has been received. This may sometimes mean temporary suspension of the activity (apart from storage or destruction) is necessary.

85 There is no notification period - changes may be put into effect immediately[42] - nor is there a prescribed set of information requirements under regulation 15. However, for changes to ongoing activities where there have been significant changes or significant new information such that the risk assessment has been reviewed, it would normally be the case that the revised risk assessment should be sent to the competent authority (via HSE, Technology Division). The reference number for the original notification and title of the activity should be clearly indicated where possible. HSE, on behalf of the competent authority, will acknowledge receipt of the information within 10 working days.

86 It is not acceptable to notify **new** activities under regulation 15, even when they are to be part of a connected programme (see paragraphs 70 to 75). New activities must be notified under regulation 10, 11, or 12 (as appropriate) including as connected programmes.

87 **It is permissible for a notifier to withdraw a notification, but only before the activity (or activities) has commenced. Once notifications have been withdrawn the information will not be disclosed by the competent authority and any register entry will be removed. However, notifiers should be aware that some information may already have entered the public domain before the notification was withdrawn even if the work had not started.**

88 Regulation 15(8) requires all information, including notifications, to be supplied to the competent authority 'in writing'. This can include typescript and manuscript - although typescript is preferable. All information should be sent to the competent authority via the HSE, Technology Division, Bootle. (Address at paragraph 20.)

Part III Conduct of activities involving genetic modification

Regulation 16 Establishment of a genetic modification safety committee

Regulation 16

A person who carries out an assessment pursuant to regulation 6 or 7 shall establish a genetic modification safety committee to advise him in relation to that assessment.

Guidance

16

89 The only statutory purpose of a genetic modification safety committee (GMSC) is to advise on risk assessments made in compliance with regulations 6 or 7 (as appropriate). A particular safety committee may have other functions, advisory or representative, but these fall outside the scope of the Regulations.

Guidance

90 Here, as elsewhere in the Regulations, a 'person' may be a body such as a company, university or research institute. It is not a requirement that every researcher sets up such a committee. It will normally be the corporate body or institution that sets one up to advise on all risk assessments undertaken at the centre. It is possible for GMSCs to advise more than one centre - especially where notified premises are on split sites.

91 A GMSC does not itself have the duty to make a risk assessment, or any of the other duties placed by the Regulations on a person undertaking activities involving genetic modification.

92 In practice, someone will have to assess risk to comply with regulations 6 or 7 in almost all establishments carrying out activities involving genetic modification, and a GMSC will be required. There may be cases however where:

- the activity in question is a minor one ancillary to a major activity carried out by another organisation (eg storage, freeze drying or irradiation of GMOs produced elsewhere, and which remain the property of the producer);
- a risk assessment is made by the other organisation to cover both the major and ancillary activities, with advice from its own GMSC;
- the risk assessment is made available to the secondary establishment where the ancillary activity is carried out.

93 In such cases a GMSC need not be set up in the secondary establishment (at least not for this particular activity alone), as the risk assessment is not undertaken there. But the person (ie body/institution) carrying out the activity should still be satisfied that the assessment is suitable and sufficient.

94 There may be instances where within a single institution there are several, *separately notified*, GM premises. In cases where activities are to be transferred between different premises the risk assessment should be reviewed to ensure that the risk takes account of the new local circumstances. There will also be a requirement for the GMSC which has been set up by the new premises to be consulted on the risk assessment, even when the risk assessment had been advised on by the GMSC in the previous notified premises. Of course, there may be cases where there is a shared GMSC. In such a case, the GMSC would still need to be asked to advise on the reviewed risk assessment.

95 There are no hard and fast rules governing the make-up of a GMSC. It should ideally be constituted to represent both management and employees with its members also being representative of all people having access to the genetic modification facilities or who might otherwise be exposed to such work. It is important to include members who will not benefit directly from the decisions of the GMSC (eg technical staff). The GMSC should have enough members, with sufficient depth and range of knowledge and experience to:

- understand the risks to both human health and the environment arising from the proposed activity, and the extent to which those risks are uncertain. Where GMSCs are considering activities involving genetically modified animals and plants the coverage is, strictly speaking, just human health. However, it is strongly recommended - *but not a requirement* - that GMSCs also advise on the environmental risk assessments required under the Environmental Protection Act and associated regulations;
- judge the adequacy of the risk assessment made under regulation 6 or 7;
- where appropriate, test its emerging conclusions by discussion so that the advice given is genuinely that of a committee and not an individual.

Guidance

96 Additional advice on the possible constitution and functions of GMSCs and similar committees is given in the ACGM Compendium of Guidance. (See Appendix 2).

97 Note that other sources of advice may also be necessary. Regulation 6 of the Management of Health and Safety at Work Regulations 1999 (MHSWR) requires that employers appoint competent people to assist them in complying with health and safety legislation. Where there is a sufficiently competent biological safety officer the employer may wish to appoint the officer for that purpose, as regards work with GMOs.

98 The requirement for a GMSC under the Contained Use Regulations in no way affects the rights of safety representatives appointed under the Safety Representatives and Safety Committees Regulations 1977[45] (as amended by the MHSWR 1999) to request their employer to establish a safety committee under the 1977 Regulations. Such committees have the function of keeping health and safety measures under review, which could include measures relating to genetic modification. It is essential, therefore, that the relationship between any such committee and the GMSC is clearly defined. For example, the GMSC may be a sub-committee of the main safety committee. Local circumstances and the wishes of those represented on the main safety committee will have to be taken into account in determining the best arrangement. **Where there are appointed safety representatives these should have the right to sit on the GMSC if they wish.**

99 More recently, the Health and Safety (Consultation with Employees) Regulations 1996[46] have been introduced. These place a statutory duty on management to consult staff on issues which impinge on health and safety where there are no recognised trade union representatives to be consulted. The employer must allow time to give the employees or their representatives information about what is proposed. The employer must also give the employees or their representatives the chance to express their views. Then the employer must take account of these views before they reach a decision in relation to health and safety matters.

16

45 S.I. 1977/5000 as amended by S.I. 1992/2051 46 S.I. 1996/1513

Regulation 17 Principles of occupational and environmental safety

Regulation

(1) Any person who undertakes an activity involving genetic modification shall ensure that -

(a) the exposure of humans and the environment to genetically modified micro-organisms is reduced to the lowest level that is reasonably practicable; and
(b) harm to humans arising from an activity involving genetic modification of organisms other than micro-organisms is reduced to the lowest level that is reasonably practicable.

(2) For any activity involving genetic modification of micro-organisms, the measures to be taken in order to comply with the duty under paragraph (1) shall include the general principles of good microbiological practice and of good occupational safety and hygiene set out in Schedule 7.

(3) For any activity involving genetic modification of organisms other than micro-organisms, the general principles set out in Schedule 7 shall be applied insofar as they are appropriate.

17(1)-(3)

Guidance

100 There is a fundamental requirement for people to limit contact of GMOs with humans and the environment (see paragraphs 26 and 27 on the definition of contained use) to provide a high level of safety. The degree of limitation necessary must be consistent with the level of risk. The basic aim is to minimise harm to humans or the environment in the case of genetically modified micro-organisms, and humans in the case of GM animals and plants. To achieve this, regulation 17(1) requires people to reduce exposure, of humans or the environment, to GMMs to the lowest reasonably practicable level.

101 For activities involving genetically modified micro-organisms, in addition to the standard containment levels set out in Schedule 8 (see also regulation 18), 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. Application of these principles will contribute to the achievement of limited contact with people outside the containment facility and the environment, but will also aid protection of those undertaking the work within the containment facility.

102 All of these principles must be applied in all cases. However, some of the individual principles are qualified by references to what is appropriate etc. In these cases the degree to which they need to be applied will vary. Where there is some flexibility in applicability the decision must relate to the risk of the activity. The following further explains the principles:

- **keeping workplace and environmental exposure to any genetically modified micro-organism to the lowest reasonably practicable level.** The key to the application of this principle is the use of good practice to achieve a low level of exposure to GMMs. The level of exposure should be such that it is unlikely that harm will occur to either people or the environment. The concept of 'reasonable practicability' is one based on risk, but takes into account the cost (in terms of money, time or trouble) of controlling that risk. If the risk is significant, or uncertain, you should err on the side of safety in weighing up the cost of action against safety benefits. Only where risks are negligible, and the cost of control measures is grossly disproportionate to the safety benefit, do you not have to apply the measures. Such overt consideration of cost and safety benefit is rarely necessary on a day-to-day basis. Rather, standard good practice, such as that set out in the ACGM Compendium of Guidance (see Appendix 2) will normally constitute accepted levels of lowest reasonable practicability;
- **exercising engineering control measures at source and supplementing these with appropriate personal protective clothing and equipment where necessary.** This echoes the hierarchy of control measures set out in COSHH[47] which requires that if exposure cannot be prevented (by elimination or substitution) exposure is controlled through primary containment in the first instance. For activities involving GMMs protective clothing is always required, although in some cases this is work clothing rather than specialist laboratory coats or overalls. This is actually a slightly different emphasis to the normal control hierarchy for non-microbial substances. Furthermore, microbiological safety cabinets (ie engineering control) may not always be required - even though protective clothing is. More specialist personal protective equipment (such as breathing apparatus) is a secondary line of defence;
- **testing adequately and maintaining control measures and equipment.** It is important to ensure the integrity of containment and that other control measures (including management and work methods) are being applied appropriately. A particularly important aspect to monitor for effectiveness is waste inactivation. The inactivation procedure used must be validated

17(1)-(3)

47 COSHH - the Control of Substances Hazardous to Health Regulations, S.I. 1999/437

Guidance

and monitoring data kept. This should include data on the level of kill (if not 100%) and the numbers of live GMMs in waste material being disposed of. The frequency and degree of testing/examination of equipment and control measures will be dependent on the level of risk and nature of the activity. As an indication, COSHH requires examination of safety equipment at least every 14 months;

- **testing, where necessary, for the presence of viable process organisms outside the primary physical containment.** Where the risk assessment shows that monitoring for GMMs outside the primary containment (eg culture vessel) is necessary to ensure effective control, this must be undertaken. Monitoring could include both monitoring within the workplace and also in the surrounding environment. In particular, monitoring of waste, especially at the point of disposal, for the presence of viable GMMs is likely to be necessary when there is any possibility that harm might result from any escape;
- **providing appropriate training of personnel.** The level of training should be appropriate to the level of risk and the complexity of the operations being undertaken (see also Schedule 8 for specific requirements);
- **formulating and implementing local codes of practice for the safety of personnel, as required.** The content and form of local codes of practice will be dependent on the level of risk and nature of activities being undertaken. They might include: operating instructions for particular equipment; management issues; systems of work; maintenance regimes;
- **displaying biohazard signs where appropriate.** The requirements for biohazard signs are further detailed in Schedule 8;
- **providing washing and decontamination facilities for personnel.** What constitutes appropriate facilities would be dependent on the risk and nature of the work. (See also Schedule 8 for specific requirements);
- **keeping adequate records.** Regulation 8 requires the keeping of records of risk assessment. In addition (and not least) you should keep records of work that has been undertaken and any modifications to the risk assessment or control measures;
- **prohibiting in the work area eating, drinking, smoking, applying cosmetics or the storing of food for human consumption**;
- **prohibiting mouth pipetting**;
- **providing written standard operating procedures where appropriate to ensure safety.** Appropriateness should be with regard to the level of risk and nature of the activity and equipment;
- **having effective disinfectants and specified disinfection procedures available in case of spillage of genetically modified organisms.** (Only really applicable to GMMs.) The ACGM Compendium of Guidance contains further advice about disinfection methods. Disinfection should reduce the numbers of live GMMs by at least 99.999% - ie a 5 log reduction;
- **providing safe storage for contaminated laboratory equipment and materials where appropriate.** Appropriateness must be decided based on the risk.

103 For activities involving genetically modified animals and plants the GMP and GOSH principles must be applied where appropriate to protect human health and safety.

17(1)-(3)

Regulation 18 Containment and control measures for activities involving genetic modification of micro-organisms

Regulation

(1) Subject to paragraph (2), a person who undertakes an activity involving genetic modification of micro-organisms shall apply the containment measures set out in the applicable Table in Schedule 8, where and to the extent required in the column of the appropriate containment level.

(2) Where a risk assessment, or any review of that assessment carried out in accordance with regulation 8, shows that a particular containment measure of the appropriate containment level is not necessary for the activity involving genetic modification of micro-organisms to which the assessment relates, the person undertaking that activity, after providing full justification to, and with the written agreement of, the competent authority, need not apply that containment measure for the activity in question.

(3) A person who undertakes an activity involving genetic modification of micro-organisms shall review the containment measures applied by him in accordance with paragraph (1) -

(a) at suitably regular intervals; and
(b) forthwith if that person suspects that -

(i) the containment measures are no longer adequate,
(ii) the class in relation to the activity involving genetic modification of micro-organisms identified in the risk assessment is no longer appropriate, or
(iii) in the light of new scientific or technical knowledge, the risk assessment is no longer valid.

(4) In this regulation, "risk assessment" means an assessment carried out pursuant to regulation 6.

18(1)-(4)

Guidance

104 When undertaking activities involving genetically modified micro-organisms, in addition to applying the principles of GMP and GOSH as set out in Schedule 7, users must also apply the appropriate containment and control measures from Schedule 8.

105 Schedule 8 details four levels of containment (level 1 - level 4) and is divided up into four tables:

- Table 1a sets out measures in respect of activities which are normally considered to be 'laboratory type' both in terms of scale and nature;
- Table 1b contains additional measures and modifications to Table 1a in respect of activities undertaken in plant growth facilities (including glasshouses and growth rooms). The measures in Table 1a should also be applied. The sorts of activities where it is appropriate to consider Table 1b are those where plants are infected with, or grown along side, genetically modified micro-organisms (GMMs). *It is important to note that Table 1b concerns containment of the GMMs only*, not the plant itself (although, of course, there will be consequent containment of the plant). Should the plant be genetically modified other containment measures might also be appropriate. (Specific containment and control measures for genetically modified plants are not set out in the Contained Use Regulations 2000. However, guidance may be found in the ACGM Compendium);

18(1)-(4)

Guidance

- Table 1c contains additional measures and modifications to Table 1a in respect of activities undertaken in animal units. The measures in Table 1a should also be applied. The sorts of activities where it is appropriate to consider Table 1c are those where animals are infected with or exposed to genetically modified micro-organisms (GMMs). It is important to note that Table 1c concerns containment of the GMMs only. Although there will be consequent containment of the animals, further consideration should be given to requirements should the animals also be genetically modified. (Specific containment and control measures for genetically modified animals are not set out in the Contained Use Regulations 2000. However, guidance may be found in the ACGM Compendium);
- Table 2 sets out containment and control measures for large scale activities (termed 'other'), where laboratory type measures are not appropriate. Such measures will be used for large scale research and development, as well as large scale industrial production. It is important to note that the distinction between Tables 1a and 2 is the applicability of the containment measures to the nature of the activity. It is not related to the purpose of the activity. The requirements in Table 1a might be more appropriate for some small scale industrial production.

106 When deciding appropriate containment, the minimum which must be applied is (but see paragraphs 107 and 108 below concerning derogations):

- level 1 for class 1 activities;
- level 2 for class 2 activities;
- level 3 for class 3 activities;
- level 4 for class 4 activities.

'Required where and to extent the risk assessment shows it is required', means that application of the particular measure must be determined by the risk assessment. If this indicates that the measure is necessary to control the risk, then it must be applied.

107 Regulation 18(2) allows users to seek agreement from the competent authority to not apply a measure, or measures, in the containment level corresponding to the activity class. Such requests must be justified by the risk assessment and will normally be made at the same time as activities are notified (see regulations 10, 11 and 12). HSE, on behalf of the competent authority, will inform users of whether the derogation has been agreed when responding to the notification. Unless, or until, written agreement has been received the full containment level must be applied.

108 In some cases users may decide to request such derogations from containment after the activity has been notified or for activities which do not require notification (ie class 1). If so, users should notify the competent authority (via HSE, Technology Division). In most cases this would involve supplying a (revised) risk assessment which justifies the request. The reduced containment measures should not be applied unless and until the competent authority has agreed in writing. Note that such a notification would constitute a significant change to an activity (see regulation 15). It would therefore be subject to a notification fee. To save both time and money it would be sensible to apply for any derogation from full containment at the time that the original activity notification is made. Even if this derogation is not used, it would give flexibility to change the control measures without having to make a separate request to the competent authorities.

109 It should be noted that all containment levels, at whatever scale of activity, require that material and waste [48] contaminated with GMMs must be inactivated

18(1)-(4)

48 For the lower containment levels, this does not apply to waste from handwashing basins and showers, extract air or exhaust gases.

Guidance

before discharge/waste disposal. The level of kill that must be achieved by the inactivation methods must be commensurate with the risk and the need to limit contact of the GMMs with humans and the environment. (See the definition of 'inactivation' in Schedule 8, Part I, paragraph 1.) For more hazardous GMMs 100% kill must be achieved. This would normally involve heat inactivation. For lower hazard GMMs chemical disinfection, sometimes combined with heat treatment or other methods, may be acceptable. Inactivation by chemical disinfection would normally give at least 99.999% kill (ie a 5 log reduction in viability). If any live GMMs are present in the waste to be disposed of this must be justified by the risk assessment, particularly if viability is reduced by less than 99.999%. Consideration must be given to the form and amount of waste and the method of its disposal (eg landfill, controlled water, sewage etc).

110 Previous legislation did not overtly stipulate inactivation for low risk GMMs, although in practice it was routinely done. What the change will mean is that if users wish to dispose of untreated, non-inactivated waste they must seek the agreement of the competent authority before doing so. It is highly unlikely that serious consideration would be given to such a derogation except for the lowest risk GMMs in class 1 activities and where the GMM can be shown to have limited survivability in the environment and no harm will be caused by the disposal. As for other derogations from containment, and as described in paragraph 108 above, users seeking the derogation from inactivation should supply a thorough risk assessment which justifies the intended action to the competent authority.

111 There is a general duty on users to keep under review the containment measures. This is required to be undertaken at 'suitable regular intervals' and in specific instances. The specific instances are:

- it is suspected that they are no longer adequate;
- the activity classification has changed; or
- there is new scientific knowledge which shows that the risk assessment is inadequate.

Interpretation of 'suitable regular intervals' needs to take into account the risk and nature of the particular activity. For low risk, routine activities a suitable interval might be every couple of years. For high risk, less routine activities, especially where non-standard operations are involved, the review interval will be much less and might range from monthly to annually. The appropriate review interval should be considered when the risk assessment is undertaken. Staff changes might also trigger a review. It would be useful to record the review interval and other triggers on the risk assessment itself.

112 Certain GMMs may also fall within the definition of 'biological agent' under the COSHH Regulations 1999. Under COSHH, the selection of control measures for biological agents is prescribed according to their risk to human health, while the Contained Use Regulations 2000 set out containment measures appropriate to both human health **and environmental** protection. Where there is a mismatch, the stricter requirements must be applied. This may arise, for example, for a genetically modified biological agent which presents a low risk of disease in humans, but which is environmentally harmful; in which case, the risk management measures to ensure environmental protection must be applied.

18(1)-(4)

Regulation 19 Containment and control measures for activities involving genetic modification of organisms other than micro-organisms

Regulation

19(1)-(2)

(1) A person who undertakes an activity involving genetic modification of organisms other than micro-organisms shall apply the containment measures selected in accordance with the assessment made pursuant to regulation 7(1).

(2) That person shall review the containment measures applied by him in accordance with paragraph (1) -

(a) at suitably regular intervals; and
(b) forthwith if that person suspects that -

(i) the containment measures applied are no longer adequate; or
(ii) in the light of new scientific or technical knowledge, the assessment referred to in paragraph (1) is no longer valid.

Guidance

19(1)-(2)

113 Regulation 19 requires that people undertaking activities involving genetically modified animals and plants apply the appropriate containment identified by the risk assessment undertaken in accordance with regulation 7. This means that measures appropriate to protect human health and safety must be put in place.

114 The Contained Use Regulations 2000 do not detail containment requirements for genetically modified animals and plants, other than requiring that GMP and GOSH principles be applied as appropriate. However, further guidance on appropriate containment can be found in the ACGM Compendium of Guidance. (See Appendix 2.)

115 There is a general duty on users to keep under review the containment measures. This should particularly be so if it is suspected that they are no longer adequate, or there is new scientific knowledge which shows that the risk assessment is inadequate.

Regulation 20 Emergency plans

Regulation

20(1)-(4)

(1) Where an assessment carried out pursuant to regulation 6(1) shows that, as a result of any reasonably foreseeable accident -

(a) the health or safety of persons outside the premises in which an activity involving genetic modification is carried on is liable to be seriously affected; or
(b) there is a risk of serious damage to the environment;

the person undertaking that activity shall ensure that, before the activity to which the assessment relates begins, a suitable plan is prepared with a view to securing the health and safety of those persons and the protection of the environment.

(2) Where an assessment carried out pursuant to regulation 7(1) shows that, as a result of any reasonably forseeable accident, the health or safety of persons outside the premises in which an activity involving genetic modification is undertaken is liable to be seriously affected, the person undertaking that activity shall ensure that, before the activity to which the assessment relates begins, a suitable plan is prepared with a view to securing the health and safety of those persons.

Regulation

(3) Every emergency plan -

(a) shall include the measures to be taken in the event of accident to which the plan relates; and
(b) shall be reviewed and, where necessary, revised at suitably regular intervals.

(4) The person undertaking the activity involving genetic modification which is the subject of an emergency plan shall -

(a) inform the emergency services and any body or authority liable to be affected by an accident to which the plan relates of the contents of the plan and of any relevant revisions made in pursuance of paragraph (3); and
(b) make the plan and any such revisions publicly available.

20(1)-(4)

Guidance

116 An emergency plan must be prepared if the risk assessment, carried out under regulation 6(1) in respect of activities involving genetically modified micro-organisms or 7(1) in respect of GM animals and plants, indicates that, as a result of any foreseeable accident (involving significant and unintended release of GMOs), the health and safety of people **outside** the premises may be seriously affected, or (for GMMs only) if there is any serious risk to the environment. In practice, an emergency plan is unlikely to be necessary for most small scale activities or those involving low risk organisms.

117 Nevertheless, it is advisable for the emergency services to be informed of the nature of any potentially harmful organisms, even if the risk assessment indicates no potential for harm outside the premises, as this may affect their strategy in carrying out their duties. For example, fighting a fire at the premises may need special tactics as water used to extinguish it may carry organisms into the environment; emergency vehicles and other equipment may also need to be cleaned in a particular way to avoid transporting organisms outside the site; or the police may need to follow special procedures if the premises are burgled.

118 Where an emergency plan is produced, it should be a written document, kept up to date to reflect changes in risk procedures and personnel. Anyone on the site who is affected by the plan should be aware of its relevant provisions; not only people who may have duties under it but also those who may need to be evacuated from the site in an emergency. This should include contractors and visitors. The plan should be drawn up in consultation with appropriate organisations including the emergency services (fire, police and ambulance), the local authority emergency planning officer and Environmental Health Department, and relevant parts of the health service network. In England and Wales, the plan should also be brought to the attention of the Environment Agency in relation to possible pollution of water courses and the company appointed for the local water supply. (In Scotland, the appropriate water authority and the Scottish Environment Protection Agency, which is responsible for the control of environmental pollution.)

119 Examples of information which could be recorded in an emergency plan include:

- the types of incidents to people or the environment to be taken into account and the immediate steps to be taken;
- organisations involved, including key personnel, their responsibilities and liaison arrangements between them;
- communication links, including arrangements for giving information to people liable to be affected by any accident and for making such information publicly available;

20(1)-(4)

Guidance

20(1)-(4)

- special equipment, including damage control and repair items;
- technical information such as the nature of the organism(s), characteristics of the plant and other hazards which may be present;
- information about the site including likely locations of personnel and hazardous organisms;
- evacuation arrangements;
- contacts and arrangements for obtaining further advice and assistance, eg meteorological information, medical services, water and agricultural authorities;
- arrangements for dealing with the media;
- longer-term clean up.

120 Steps to make the information in the emergency plan publicly available should be taken in consultation with the local authority, which may be able to offer advice and assistance with the provision of public information, for example by allowing information to be placed in public buildings such as libraries, civic centres and town halls.

Regulation 21 Information relating to accidents

Regulation

21(1)-(2)

(1) Where an accident occurs, the person undertaking the activity involving genetic modification shall forthwith notify the competent authority of the accident and shall provide the following information -

(a) the circumstances of the accident;
(b) the identity and quantity of the genetically modified organisms concerned;
(c) any information necessary to assess the effects of the accident on the health of the general population and on the environment; and
(d) any measures taken in response to the accident.

(2) Where the competent authority is informed of an accident in pursuance of paragraph (1), it shall -

(a) ensure that any necessary measures are taken;
(b) immediately inform those EEA States which could be affected by the accident;
(c) collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit their effects; and
(d) send to the European Commission -

(i) the information provided under paragraph (1)(a), (b) and (d),
(ii) information on the effectiveness of the measures taken in response to the accident, and
(iii) an analysis of the accident, including recommendations to limit its effects and to avoid similar accidents in the future.

Guidance

21(1)-(2)

121 This regulation requires immediate notification to the competent authority of any accident, defined in regulation 2 as any incident involving a significant and unintended release (outside of primary containment) of genetically modified organisms which present a hazard, immediate or delayed, direct or indirect, to either human health and safety, or to the environment. (In respect of GM animals and plants this is limited to consideration of effects on human health and safety.) This requirement is in addition to the requirement under RIDDOR to report accidents. Note that the 'unintended release' may be confined to within the laboratory/facility. Therefore, consideration has to be given to protection of the people inside the containment facility as well as to the general population and wider

Guidance

environment. (Compare this to the trigger for emergency plans which hinges on possible serious effects on people or the environment **outside** the containment facility.)

122 Minor spillages within the containment facility of micro-organisms being used in class 1 activities are unlikely to count as significant releases of genetically modified micro-organisms, and they will not routinely require notification. This is because they would be highly unlikely to affect people within the facility and will be easily dealt with so that they do not reach the environment. The same may not be true, however, for spillages of GMMs being used in class 2, 3 or 4 activities, or for large scale spillages of GMMs from some class 1 activities. For large scale class 1 activities a significant loss of containment (eg 5 - 10% plus of total volume), where there is no agreement that inactivation is not required before disposal, could constitute an accident and require notification. It is also possible, although less likely, that escapes of GM animals or plants may also constitute an 'accident' with potential for harm to humans.

123 It is recommended that information in notifications of accidents be set out as in Appendix 4. Accident notifications should be sent to HSE, Technology Division (who will receive notifications on behalf of the competent authority) at the address shown in paragraph 20. Although details would need to be notified in writing (letter, fax or e-mail) you would be advised, for serious accidents, to inform HSE of any occurrence by telephone - followed by written confirmation.

21(1)-(2)

124 Note that accident notifications are subject to the disclosure provisions set out in regulation 23.

Part IV Disclosure of information and publicity

Regulation 22 Disclosure of information notified pursuant to regulations 9 to 15

Regulation

(1) The information provided pursuant to regulations 9 to 15 shall not be treated as relevant information for the purposes of section 28 of the 1974 Act.

*(2) Subject to paragraph (3), where, either in a notification submitted under regulation 9(1), 10(1), 11(1) or 12(1), or in response to a request made in pursuance of regulation 14(2) or when providing information in accordance with regulation 15(2) or 15(3), a person indicates that he is providing information which should be kept confidential on one or more of the grounds set out in regulation 4(2)(a) to (c) and (e) of the Environmental Information Regulations 1992**(a)** -*

(a) that person shall give full justification for that indication to the competent authority; and
(b) after consulting that person, the competent authority shall decide which, if any, information shall be kept confidential and shall inform him of its decision.

(3) Subject to paragraph 8, paragraph (2) shall not apply to the following information which shall not be kept confidential -

(a) the name and address of the notifier;

22(1)-(12)

(a) S.I. 1992/3240, as amended by S.I. 1998/1447

Regulation

(b) in the case of a notification relating to an activity involving genetic modification of a micro-organism -

(i) the location of the activity,
(ii) the general characteristics of the genetically modified micro-organism,
(iii) the class of the activity involving genetic modification of the micro-organism,
(iv) the containment measures, and
(v) the evaluation of foreseeable effects, in particular any harmful effects on human health and the environment.

(4) Information which a notifier has indicated should be kept confidential and in relation to which the competent authority has not yet made a decision under paragraph (2)(b) and information which the competent authority has decided shall be kept confidential shall not be disclosed except -

(a) to the extent necessary to evaluate the notification; and
(b) to the European Commission.

(5) Where the competent authority has made a decision under paragraph (2)(b) that certain information shall not be kept confidential, that information shall not be disclosed until there has elapsed a period of 14 days following the day on which the competent authority informed the person providing the information of its decision except -

(a) to the extent necessary to evaluate the notification; and
(b) to the European Commission.

(6) A person who receives information by virtue of paragraph 4(a) or 5(a) shall not use that information except for the purposes of the competent authority.

(7) Information contained in a notification which has been withdrawn shall not be disclosed after the competent authority has received written notice in accordance with regulation 15(6).

(8) Notwithstanding paragraph (3), where the competent authority is satisfied on the basis of evidence submitted to it by the notifier and, where appropriate, after consultation with the notifier, that it is necessary to withhold, for the time being, certain of the information specified in paragraph (3) in order to protect his intellectual property rights, the competent authority shall withhold that information to the extent that, and for so long as, it is necessary to protect those rights.

(9) Subject to paragraph (10), where, pursuant to paragraph (2) or (8), a notifier has indicated that -

(a) he has provided confidential information; or
(b) withholding information is necessary in order to protect his intellectual property rights,

he shall forthwith inform the competent authority in writing of any change in circumstances which may affect the justification given under paragraph (2)(a) or the evidence submitted under paragraph (8), as the case may be.

22(1)-(12)

(10) Paragraph (9) shall not apply if the competent authority has informed the notifier that the information in question is not to be kept confidential or withheld.

Regulation

(11) Where -

(a) the competent authority has decided to keep information confidential pursuant to paragraph (2)(b) or has withheld information pursuant to paragraph (8); and
(b) the notifier has informed the competent authority of any change in circumstances pursuant to paragraph (9),

the competent authority shall, after consulting the notifier where appropriate, review whether the information in question should continue to be kept confidential or withheld and shall inform the notifier of the result of that review.

(12) For the purposes of this regulation, "general characteristics" in relation to a genetically modified micro-organism, means characteristics other than genus, species, genotype, serotype and strain.

22(1)-(12)

Guidance

125 Regulation 22 determines whether the competent authority may disclose[49] the information submitted as part of a notification or must withhold it. The regulation begins by disapplying section 28 of the HSW Act, so that the information submitted is not subject to the disclosure restrictions imposed by that section. It goes on to specify new restrictions specific to the Contained Use Regulations 2000. **It should be noted that unless the competent authority accepts a claim of confidentiality (or the notification is withdrawn before the activity has commenced[50] - see regulation 15) all information supplied to the competent authority, and which is required by the legislation, will be potentially disclosable on request to anyone who asks to see it.** The exception to this rule is personal information (ie names, addresses and qualifications of individual people). This information would be subject to the provisions of the Data Protection Act and would normally[51] only be disclosed with the explicit written permission of the individual concerned.

126 For any of the information submitted **except the items listed in regulation 22 (3)** the notifier may ask that it should be kept confidential on the grounds that it falls within certain of the categories allowed by the Environmental Information Regulations (EIR)1992,[52] as amended in 1998.[53] These categories are information the disclosure of which:

- would affect international relations, national defence or public security;
- would affect matters which are, or have been, an issue in any legal proceedings or in any enquiry (including any disciplinary enquiry), or are the subject matter of any investigation undertaken with a view to any such proceedings or enquiry;
- would affect the confidentiality of the deliberations of any relevant person;
- would affect the confidentiality of matters to which any commercial or industrial confidentiality attaches, including intellectual property.

49 A fee will be charged for disclosure in some cases - contact HSE (address at paragraph 20) for details.
50 This has important implications for anyone claiming confidentiality. If the activity had already commenced before the decision whether or not to grant confidentiality was made, it would not be possible to withdraw the notification, even if the claim for confidentiality were not accepted. In such cases, the information **would** be disclosable. It may, therefore, be advisable to wait for the decision on a confidentiality claim before commencing work, even in those cases where immediate starts are permitted. This will allow full protection of all the notified information if the notification is withdrawn before any work has commenced. (The EIR will not apply if a notification is withdrawn before work is commenced as there would be no possible effect on the environment).
51 The Act does have some specific cases in which disclosure may be permitted without the agreement of the person concerned, for instance if there was a legal duty to do so. However, this is unlikely to be the case for the information notified under the Contained Use Regulations.
52 S.I. 1992/3240
53 S.I. 1998/1447

22(1)-(12)

Guidance

127 In practice it is likely that only some of these categories will be relevant. That is, information relating to commercial confidentiality, intellectual property rights, personal information (which in any case is protected - see paragraph 125), or information whose disclosure could lead to harm to public security (which might include the location of animal facilities). Each claim of confidentiality must be supported by a full justification. Information claimed to be confidential should also be limited as far as possible. That is, confidential information should be identified precisely and kept to the minimum amount necessary to afford protection. For instance, the precise strain or species may be commercially sensitive, but the genus may be disclosable. Similarly the location of an animal house itself may be claimed as confidential, but for large sites (eg the whole university campus) it is unlikely that a claim that the whole notified premises should be confidential would succeed without very good justification. Similarly, an argument that absolutely everything covered by regulation 22(3) should be withheld will not succeed: it should be assumed that some information, if necessary in broad and general terms, can always be disclosed. Whenever a case is being made for non-disclosure, the notifier should indicate at the same time the nature of the information which **could** be disclosed without harm to their interests. The identity of the notifier, however, will be disclosed only as the name of the organisation or corporate body carrying out the work. The names of individual people will not be revealed. The only exception to this is where the person making the premises notification is an actual individual, rather than an institution or company or other organisation. However, this is likely to be extremely rare.

128 If the competent authority accepts any claim for confidentiality, the information in question will not be disclosed.

129 Separately, the notifier may ask that **any** of the information covered by regulation 22(3) should be withheld if disclosure would damage their intellectual property rights. This includes damage to the future patentability of an invention, and notifiers who are in doubt about the effect of disclosure on future patents are strongly advised to seek professional advice before making their notification. Again, a full and detailed justification must be given to support a request of this kind. Where the justification depends to some degree on the protection of patentability it should preferably be supported by evidence based on the opinion of a patent agent.

130 The status of information which the competent authority agrees not to disclose for any of the reasons set out in paragraph 126 will be reviewed at intervals, and if the grounds for withholding it have disappeared then it will become disclosable. There is a requirement in regulation 22(8) for the notifier to inform the competent authority as soon as there is no longer any justification for withholding information. (This will not attract a fee.)

131 If notifiers are in doubt about the application to them of these parts of the Regulations, and to avoid later delays during the processing of the notification itself, they may find it helpful to discuss, on a confidential and informal basis, their proposals relating to confidentiality with HSE officials in the Technology Division, before submitting their notification (contact details at paragraph 20). If a person is dissatisfied with the judgement of the competent authority regarding confidentiality and disclosure, then that person can appeal against the decision. (See regulation 29 - appeals.)

132 Some limited disclosure outside of the competent authority will often be necessary to evaluate the notification. This is provided for by regulation 22(4). In particular information may be given to members of the ACGM or its Technical Sub-Committee, whose opinion will be taken into account in decisions on consent or objection. Anyone receiving information in this way may not use it except for

22(1)-(12)

Guidance

22(1)-(12)

the purpose for which it was given. The competent authority can also exclude committee members with a direct conflict of interest from receiving particular notifications.

133 If a notifier has claimed confidentiality for any information notified, that information will not be disclosed until the notifier's case has been assessed and a decision reached and the notifier informed. In cases where a claim has not been accepted the information in question will not be placed on the public register for 14 days after the decision. The notifier may choose to withdraw the notification so long as the work has not started (see 15(3)) and all of the information in the notification will be kept confidential from that time. Similarly, even if no confidentiality claim has been made and the notifier has withdrawn the notification in accordance with regulation 15 (3), the information will be treated as confidential from the time of withdrawal. However, notifiers should be aware that in either case some information (which was not subject to a claim for confidentiality) may already have entered the public domain.

Regulation 23 Disclosure of information provided pursuant to regulation 21

Regulation

23(1)-(11)

(1) The information provided pursuant to regulation 21 shall not be treated as relevant information for the purposes of section 28 of the 1974 Act.

(2) Subject to paragraph (3), where a person indicates that information provided by him pursuant to regulation 21 should be kept confidential on one or more of the grounds set out in regulation 4(2)(a) to (c) and (e) of the Environmental Information Regulations 1992 -

- *(a) he shall give full justification for that indication to the competent authority; and*
- *(b) after consulting that person, the competent authority shall decide which, if any, information shall be kept confidential and shall inform that person of its decision.*

(3) Subject to paragraph (7), paragraph (2) shall not apply to the following information, which shall not be kept confidential -

- *(a) the name and address of the person providing the information;*
- *(b) in the case of an accident relating to an activity involving the genetic modification of a micro-organism -*
  - *(i) the location of the accident,*
  - *(ii) the general characteristics of the genetically modified micro-organism,*
  - *(iii) the class of the activity involving genetic modification of the micro-organism;*
  - *(iv) the containment measures; and*
  - *(v) the evaluation of actual and foreseeable effects, in particular any harmful effects on human health and the environment.*

(4) Information which the person providing that information has indicated should be kept confidential and in relation to which the competent authority has not yet made a decision under paragraph (2)(b) and information which the competent authority has decided shall be kept confidential shall not be disclosed except to the extent necessary to enable the competent authority to comply with its obligations under regulation 21(2).

Regulation

(5) Where the competent authority has made a decision under paragraph (2)(b) that certain information shall not be kept confidential, that information shall not be disclosed until there has elapsed a period of 14 days following the day on which the competent authority informed the person providing the information of its decision, except to the extent necessary to enable the competent authority to comply with its obligations under regulation 21(2).

(6) A person who receives information by virtue of paragraph (4) or (5) shall not use that information except for the purposes of the competent authority.

(7) Notwithstanding paragraph (3), where the competent authority is satisfied on the basis of detailed evidence submitted to it by the person providing the information and, where appropriate, after consultation with that person, that it is necessary to withhold, for the time being, certain of the information specified in paragraph (3) in order to protect his intellectual property rights, the competent authority shall withhold that information to the extent that, and for so long as, it is necessary to protect those rights.

(8) Subject to paragraph (9), where, pursuant to paragraph (2) or (7), a person has indicated -

(a) that certain information is confidential; or
(b) withholding information is necessary in order to protect his intellectual property rights,

he shall forthwith inform the competent authority in writing of any change in circumstances which may affect the justification given under paragraph (2)(a) or the evidence submitted under paragraph (7), as the case may be.

(9) Paragraph (8) shall not apply if the competent authority has informed the person providing the information that the information in question is not to be kept confidential or withheld.

(10) Where-

(a) the competent authority has decided to keep information confidential pursuant to paragraph (2)(b) or has withheld information pursuant to paragraph (7), and
(b) the person who provided the information has informed the competent authority of a change in circumstances pursuant to paragraph (8),

the competent authority shall, after consulting that person where appropriate, review whether the information in question should continue to be kept confidential, and shall inform that person of the result of that review.

(11) In this regulation, "general characteristics" in relation to a genetically modified micro-organism has the same meaning as it has in regulation 22.

23(1)-(11)

Guidance

134 This regulation provides the same balance of protection for confidential information and availability of information for disclosure for notification of accidents as there is under regulation 22 for premises and activity notifications. Because of the similarity, this part of the guide gives only an outline of the provisions. You are advised to read it in parallel with the guide to regulation 22.

135 As does regulation 22, regulation 23 starts by disapplying section 28 of the HSW Act. It then proceeds to allow claims for confidentiality to be made on the same basis as for notifications of premises and activities. (See paragraphs 126 and

23(1)-(11)

Guidance

127 for details.)

136 Certain information is listed in regulation 23(3) which cannot be kept confidential. The list is similar to that in 22(3). For accidents involving GMMs the following cannot be kept confidential:

- *location of the accident*;
- *general characteristics of the GMM*. This has the same meaning as for regulation 22. It is important to emphasise two points: (a) the full, precise and detailed information must be supplied to HSE, including confidential information where it is necessary for evaluation of safety, (b) any claims for confidentiality must be fully justified. As much information as possible, without compromising confidentiality, must be available for disclosure;
- *the class of the activity*, as it was before the accident;
- *containment measures* - this will include both the measures which were in place before the accident and the remedial measures used following the accident;
- *the evaluation of actual and foreseeable effects, in particular any harmful effects on human health and the environment*.

137 The competent authority will consider any claim for confidentiality and shall not disclose any information (subject to a claim) while the decision is being taken or if the claim is agreed. If the competent authority does not accept the claim the information will not be disclosed for 14 days after the notifier has been informed of the decision. The only exceptions to this are where some disclosure is necessary to fulfil the requirements for informing other member States and the European Commission or if disclosure is necessary to ensure that safety measures are taken (see regulation 21(2)). Users may appeal against decisions on confidentiality (see regulation 29).

138 Separately, it is possible to claim all notified information (including that set out in regulation 23(3) to be confidential on the basis of intellectual property rights. (See paragraph 129 for further advice.)

139 As for confidentiality claims in respect of premises and activity notifications, notifiers of accidents have to inform the competent authority if the claim for confidentiality is no longer valid. The competent authority may also review confidentiality claims from time to time.

23(1)-(11)

Regulation 24 Register of notifications

Regulation

(1) The competent authority shall maintain a register of every notification submitted under regulations 9 to 12.

(2) The register referred to in paragraph (1) shall contain -

(a) in relation to every notification submitted under regulations 9 to 12-

(i) the name, address and telephone number and any fax number and any e-mail address of the notifier,
(ii) the date on which the receipt of the notification was acknowledged by the Executive, and
(iii) if the competent authority receives details of a matter referred to in sub-paragraphs (a) to (g) of regulation 15(2) or in regulation 15(3), confirmation that such details have been received;

24(1)-(11)

Regulation

(b) in relation to each notification submitted under regulation 10(1), 11(1) or 12(1), the date of any cessation of the activity involving genetic modification to which the notification relates.

(3) The register referred to in paragraph (1) shall also contain -

(a) in relation to each notification submitted under regulation 9(1) -

(i) the information specified in paragraphs (d) to (g), (h)(ii) and (h)(iii) of Schedule 5, and
(ii) if the competent authority has been informed of an accident under regulation 21 at the premises to which the notification relates, confirmation that the information has been received;

(b) in relation to each notification submitted under regulation 10(1), the information specified in paragraph 1(e) to (l) of Part I of Schedule 6;
(c) in relation to each notification submitted under regulation 11(1) -

(i) the information specified in paragraph 2(e) to (m) of Part II of Schedule 6 and,
(ii) if appropriate, confirmation that a consent under regulation 11(3) or regulation 11(4), as the case may be, has been granted;

(d) in relation to each notification submitted under regulation 12(1), the information specified in paragraph 3(e) to (k) of Part III of Schedule 6, but the register shall not contain any information which the competent authority has decided shall be kept confidential under regulation 22(2)(b) or shall be withheld under regulation 22(8).

(4) Information shall be entered in the register within 14 days of its receipt by the competent authority, except that, where a notifier has requested that certain information -

(a) be kept confidential in accordance with regulation 22(2); or
(b) be withheld in accordance with regulation 22(8),

that information shall be entered in the register not less than 14 days and not more than 28 days following the day on which the competent authority informed the notifier of its decision not to keep that information confidential or not to withhold that information, as the case may be.

(5) Where a person withdraws a notification under regulation 15(6), information relating to that notification, which has been entered in the register, shall be removed from the register by the competent authority.

(6) The competent authority may remove from the register -

(a) information relating to an activity involving genetic modification ten years after being notified in accordance with regulation 15(2)(d) or (e) that the activity has ceased; and
(b) information relating to premises ten years after being notified in accordance with regulation 15(2)(c) of a decision no longer to use such premises for the purposes of undertaking any activity involving genetic modification.

24(1)-(11)

(7) Copies of the register as regards Great Britain shall be maintained at the offices of the Executive at -

Regulation

(a) Rose Court, 2 Southwark Bridge, London SE1 9HS; and
(b) Magdalen House, Stanley Precinct, Bootle, Merseyside L20 3QZ.

(8) Copies of that part of the register maintained in accordance with this regulation by the competent authority as regards Scotland and the joint competent authority shall be maintained at the offices of the Executive at Belford House, 59, Belford Road, Edinburgh EH4 3UE.

(9) A copy of that part of the register which relates to -

(a) premises in respect of which a notification has been submitted in accordance with regulation 9(1) situated in an area served by a main office of the Executive; and
(b) an activity involving genetic modification, in respect of which a notification has been submitted in accordance with regulation 10(1), 11(1) or 12(1), undertaken at such premises,

shall be maintained at that main office.

(10) The copies of the register shall be open to inspection by members of the public at any reasonable time.

24(1)-(11)

Guidance

140 This regulation requires the competent authority to maintain a public register. It will allow members of the public access to information about all notified activities. Comments in relation to the risk and control measures may be made to the competent authorities and these will be considered and action taken if appropriate. The register will be of notifications made under regulations 9 to 13 in respect of:

- first use of premises;
- class 2 activities involving genetically modified micro-organisms;
- class 3 or 4 activities involving genetically modified micro-organisms; and
- notifiable activities involving genetically modified animals and plants.

141 All of the information notified will be placed on the public register, apart from the risk assessment and any information which has been accepted by the competent authority as confidential under regulation 22. Although the risk assessment itself will not be included, a statement of the evaluation of foreseeable harmful effects on human health or the environment will be included. *This will allow people to decide whether they wish to request to see the full risk assessment*. (See the notification forms in Appendix 5 - these illustrate the information which will be placed on the public register and that which will not.)

142 Information subject to a request for non-disclosure will not be placed on the register while the request for non-disclosure is being considered, and if the competent authority does not accept the case being made, not until 14 days after the decision has been made to not accept the claim. Where notifiers have withdrawn a notification in accordance with regulation 15(3), any information already on the register will be removed. (Remember that this applies only where activities have not commenced.) The competent authorities may also remove information from the register if it is more than 10 years since the activity ended.

143 Although users are free to supply the necessary information to comply with notification requirements in any format they wish, it is advisable that notifiers take account of the public register requirements when making a notification and structure their notification in a way that allows for easy removal of the risk assessment and confidential information. A notification format (paper or electronic

24(1)-(11)

Guidance

versions[54]) is available free from HSE which has been devised to help people to both ensure that the required information is notified and to simplify the identification of information to be placed on the public register. (Copies are also in Appendix 5.)

144 Copies of the entire register are maintained at the head offices of HSE. The head office addresses are:

Health and Safety Executive
Health Directorate, Division B2
Rose Court
2 Southwark Bridge
London SE1 9HS
Tel: 0207 717 6297/6348
Fax: 0207 717 6199

Health and Safety Executive
Technology Division
Magdalen House
Stanley Precinct
Bootle
Merseyside L20 3QZ
Tel: 0151 951 4772
Fax: 0151 951 3474

and

A copy of the register covering all notified premises and activities in Scotland is maintained at HSE's office in Edinburgh whose address is:

Belford House
59 Belford Road
Edinburgh
EH4 3UE
Tel: 0131 247 2000 Fax: 0131 247 2121

Each main office of HSE maintains a copy of that part of the register covering all notified premises and activities in the area served by that office. Addresses of HSE's offices are given in general telephone directories under 'Health and Safety Executive'.

145 Registers are open to inspection by members of the public during normal office hours, but those wishing to inspect them are advised to telephone first.

24(1)-(11)

54 Unfortunately electronic notifications cannot be accepted at present

Part V Miscellaneous and general

Regulation 25 Exemption certificates

Regulation

(1) Subject to paragraph (2), the competent authority may, by a certificate in writing, exempt -

(a) any person or class of persons; or
(b) any genetically modified organism, or class of genetically modified organisms,

from all or any of the requirements of, or prohibitions imposed by, these Regulations and any such exemption may be granted subject to conditions and to a limit of time and may be revoked by a certificate in writing at any time.

(2) The competent authority shall not grant an exemption unless, having regard to the circumstances of the case and in particular to -

25(1)-(3)

Regulation

(a) the conditions, if any, that it proposes to attach to the exemption; and
(b) any requirements imposed by or under any enactments which apply to the case,

it is satisfied about the matters referred to in paragraph (3).

(3) The matters about which the competent authority shall be satisfied for the purposes of paragraph (2) are -

(a) that the health and safety of persons who are likely to be affected by the exemption will not be prejudiced in consequence of it; and
(b) that the environment will not be prejudiced in consequence of the exemption where the exemption is concerned with a requirement of, or a prohibition imposed by, these Regulations which relates to an activity involving genetic modification of a micro-organism.

25(1)-(3)

Guidance

146 This regulation sets out the powers of the competent authority to make exemptions from the requirements of the Regulations. Before making any exemption, the competent authority will consider the circumstances of the case and will need to be satisfied that the health and safety of people and the protection of the environment (in the case of genetically modified micro-organisms) will not be prejudiced by it. Exemptions will also be subject to any provisions imposed by the European Communities in respect of the control and regulation of genetically modified organisms.

147 It is possible for a person to whom an exemption certificate has been granted subject to conditions to appeal against those conditions. Similarly it is possible to appeal against the revocation of an exemption certificate. (See regulation 29.)

25(1)-(3)

Regulation 26 Enforcement and civil liability

Regulation

(1) Subject to paragraph (2) and to the extent they would not otherwise do so, the provisions of -

(a) sections 16 to 26 (approved codes of practice and enforcement), sections 33 to 42 (provisions as to offences) and section 47 (civil liability) of the 1974 Act; and
*(b) the Health and Safety (Training for Employment) Regulations 1990**(a)***

shall apply to these Regulations as if they were health and safety regulations for the purposes of that Act, and any function of the Health and Safety Commission under any other provision of the 1974 Act which is exercisable in relation to any function of the Executive under or in respect of health and safety regulations (including their enforcement) shall be exercisable as if these Regulations were, to the extent they would not otherwise be so, health and safety regulations for the purposes of that Act.

(2) A failure to discharge a duty -

(a) placed on the competent authority or the Executive by these Regulations; or
(b) placed on any other person by Schedule 11,

shall not be an offence, and section 33(1)(c) of the 1974 Act shall have effect accordingly.

26(1)-(3)

Regulation

26(1)-(3)

*(3) Notwithstanding regulation 3 of the Health and Safety (Enforcing Authority) Regulations 1998**(b)**, the enforcing authority for these Regulations shall be the Executive.*

(a) S.I. 1990/1380
(b) S.I. 1998/494

Guidance

26(1)-(3)

148 The effect of regulation 25(1) is that the provisions of these Regulations made under the European Communities Act 1972, including provisions in relation to the protection of the environment, are treated as if they were made under the HSW Act. The provisions of the HSW Act in relation to matters such as the ability to make Approved Codes of Practice and enforcement and serving of notices therefore apply, and rights of action in civil proceedings are conferred, as in the case of regulations made under the HSW Act.

149 Under regulation 25(3) HSE is the enforcing authority for the Contained Use Regulations 2000 in respect of both human health and environmental protection in all premises concerned, including those where local authorities enforce other HSW Act regulations.

Regulation 27 Fees for notifications and applications

Regulation

27(1)-(2)

(1) The fee specified in column 2 of the table in Schedule 9 shall be payable by a notifier to the competent authority in relation to any notification or application referred to in the corresponding entry in column 1 of that table.

(2) No fee shall be returned to a notifier where the competent authority returns a notification pursuant to regulation 14(7) or a notifier withdraws his notification pursuant to regulation 15(6).

Guidance

27(1)-(2)

150 A fee is charged to cover the cost to HSE of processing all notifications (on behalf of the competent authority) made under regulations 9 - 12 and some notifications made under 15(2). That is, notifications in respect of premises, individual activities, connected programmes and activity specific significant changes (including changes to connected programmes) which affect the risk assessment. There are fixed fees as set out in Schedule 9:

Notification/application type	**Fee (£)**
premises (regulation 9)	200
class 2 activities (regulation 10)	400
class 3 activities (regulation 11)	430
class 4 activities (regulation 11)	500
GM animals and plants (regulation 12)	400
connected programmes (regulation 13) - the fee payable is the one for the highest class of activity in the connected programme. GM animals and plants are counted as equivalent to class 2 for these purposes	400, 430 or 500
notification of significant changes relating to activities (regulation 15)	300
application under regulation 18(2) for the agreement not to apply the full containment level required by the class of activity (no fee required if this application is made at the same time as the original notification)	300

Guidance

151 Payment should be made when the notification is submitted. Cheques should be made payable to 'Health and Safety Executive' and addressed to:

Notifications Finance Officer
Technology Division
Health and Safety Executive
DST Unit E6
Magdalen House
Stanley Precinct
Bootle L20 3QZ

152 Note that the fees are updated annually and notifiers should check with HSE, Technology Division, if they are unsure what the current level of fee is.

153 Where a notification covers a connected programme of work (see regulation 13) including more than one activity, only one fee is required irrespective of the number of separate activities it includes. Where premises are notified (under regulation 9) at the same time as individual activities (under regulation 10, 11 or 12) or even a connected programme the activity fee only is charged.

154 It should be noted that notifications made under the transitional provisions in regulation 28 do not attract a fee, but only for the time period stipulated for the transitional provisions.

155 Where the competent authority returns a notification under regulation 14(7) because a request for additional information has not been answered within 6 months, the fee will not be returned. Similarly if a notifier withdraws a notification under regulation 15(6) the fee will not be returned.

27(1)-(2)

Regulation 28 Transitional provisions

Regulation 28

Schedule 10 shall have effect.

Guidance

Background

156 The transitional provisions (as set out in Schedule 10) are necessary to ensure that all users comply with the full requirements of the Contained Use Regulations 2000, especially in those respects where they differ from the Regulations which they replace. The key differences are that the Contained Use Regulations 2000 require:

- risk assessment to take specified matters into account and the inclusion of certain steps in the risk assessment procedure. For GMMs this includes the classification of activities into classes 1, 2, 3 or 4;
- certain additional information to be supplied for premises notifications (see below for details);
- for notification of individual activities, certain additional information requirements (see below for details for each type of notification);
- consents in respect of all activities classified as 3 or 4. (Previously activity consents were only required for Group II / Type B activities).

157 In addition there may also be a few instances of some activities which involved Group I GMMs in Type A activities (ie non-notifiable) under the previous Contained Use Regulations, which will now be classified as class 2 (and hence notifiable). The number of such activities is likely to be small, but the transitional provisions have to bring these into line.

28

Guidance

Deadlines for fulfilling transitional provisions

158 Apart from ensuring that the risk assessments of all ongoing activities have been revised in the light of the Contained Use Regulations 2000 (see paragraph 162 below), all actions to be taken by users to fulfil the transitional provisions must be completed by 15 February 2001.[55]

159 No fees will be charged in respect of any notification of information under the transitional provisions. Also, ongoing work, which had previously fulfilled the notification requirements of the Contained Use Regulations 1992, as amended in 1996 and 1998, need not be suspended while notifications are made under the transitional provisions. **However, if you fail to meet the deadline of 15 February 2001 (or 15 January 2001 in the case of class 3 or 4 activities) you will have to halt work (apart from storage or destruction of the GMMs) and the only way to recommence will be following a full notification under the procedure set out in regulation 9, 10, 11 or 12 (as appropriate). This will include the payment of the relevant fee.**

160 When considering the transitional provisions you only need to include those activities which will continue to be undertaken after 14 February 2001. There will be no need to supply any information in respect of activities which had been previously notified, but which ceased (or will cease) before this date. However, you should be aware that notifications made under the Contained Use Regulations 1992 will still be subject to disclosure provisions, although from the coming into force date these will be those provisions in regulation 22 of the Contained Use Regulations 2000. Similarly, the new provisions relating to the competent authorities' powers to impose conditions on activities and the notifier's right to withdraw a notification (but only where the activity has not commenced) are extended to notifications made under the Contained Use Regulations 1992. These provisions will impinge particularly on those activities which are still being undertaken on the coming into force date but which will cease before 15 February 2001.

Confidentiality claims

161 While preparing to fulfil the transitional provisions would be a good time to review confidentiality claims and notify any changes. In particular, for activities notified some years ago the original justification for confidentiality may no longer be valid or require updating.

Risk assessments and classification

162 All ongoing activities involving GMMs and GM animals and plants will have to be risk assessed in accordance with the matters to take into account and the procedure set out in Schedule 3 (for GMMs) or Schedule 4 (GM animals and plants). This needs to be completed before 15 December 2000. However, both the matters for consideration and the procedure set out in the Schedules are very similar to that found in the ACGM Compendium of Guidance. Therefore, if you have already been following the Compendium guidance, it is very unlikely that you will need to reassess the risk of existing activities.

163 One aspect of the GMM risk assessment procedure that will have to be undertaken in all cases is to classify the activity into class 1, 2, 3 or 4 as set out in Schedule 3, Part II. In essence this will involve considering the containment and control measures required to control the risk against the containment levels set out in Schedule 9. (For more detail see the guidance at paragraphs 43 and 44.) Classification into the new classes should be a simple process.

55 Note that for consents to be granted by 15 February 2001 for Class 3 or 4 activities, notifications must be made by 15 January 2001 (see paragraphs 180-182).

Guidance

Notification of premises

164 The transitional provisions (paragraph 2) allow premises notifications under the Contained Use Regulations 1992 to be treated as if they were notifications under the Contained Use Regulations 2000, provided that certain information is supplied to the competent authority. This information is that which was not required for premises notifications under the 1992 legislation, namely:

- the class of the activities undertaken;
- information on waste management;
- *if an emergency plan is required* (very unlikely for class 1 activities - see paragraphs 116 to 120), confirmation that the emergency services and other relevant authorities have been informed of the plan and any revisions.

165 For notification of premises you must also include:

- the name of the organisation, and address;
- the premises (GM centre) reference number assigned by HSE (eg GM 111).

166 This information may be supplied in any written format. HSE will issue proformas to all centres to aid the collation of the information in relation to both the premises and activity notifications under the transitional provisions. (You do not have to use them - just if you would find them helpful.) In fact, where you have previously supplied the required information, it is permissible simply to refer back to it rather than physically re-sending the data. This might particularly apply in the case of information on waste management (which is very often included in the risk assessment).

Notification of activities

167 Activities now classified as class 1 will not require notification under the transitional provisions.

168 Activities involving GM animals and plants, which would under the Contained Use Regulations 2000 require notification under regulation 12, will not need to be notified under the transitional provisions so long as they were notified under the Contained Use Regulations 1992.

169 Class 2, 3 or 4 activities will all require notification of at least some information under the transitional provisions. The extent of the information requirements depends on both the classification under the 1992 Regulations (ie Group I/II, Type A/B) and the new class (class 2, 3 or 4). Each case is detailed, as follows:

Notifications of class 2 activities

170 Class 2 activities can be divided into three sets, depending on the classification under the Contained Use Regulations 1992:

- Class 2 which were previously Group I/Type A;
- Class 2 which were previously either Group I/Type B or Group II/Type A;
- Class 2 which were previously Group II/Type B.
- Information requirements for each of these three sets differ and are set out as follows:

(i) *Information requirements for class 2 which were previously Group I/Type A.*

171 Under the Contained Use Regulations 1992 there was no requirement for notification of Group I / Type A activities. This means that none of the information

Guidance

requirements in respect of class 2 activities will have been met. Therefore, all of the information in Schedule 6, Part I will have to be notified as if the activity is a new one under the Contained Use Regulations 2000. You may find it helpful to use the notification form for individual activities in Appendix 5. (No fee will be charged provided that the notification is received before 15 February 2001.)

172 In addition you will also need to supply the following. (This is mainly for the purpose of placing information on the public register, ensuring contact details are up to date and that the competent authorities can cross reference to existing information):

- the name of the organisation and address;
- the premises (centre) reference number given by HSE (eg GM 111);
- a short description (or title) of the activity to which the notification relates. (One or two sentences to give a flavour of the activity - similar to that which might be used for the title of a research grant application).

173 Obviously the first two of these will have been supplied in respect of the premises notification, and therefore need not be duplicated unless the notifications are made at different times.

(ii) *Information requirements for class 2 which were previously Group I/Type B or Group II/Type A.*

174 All of these activities were required to have been notified under the Contained Use Regulations 1992 and therefore the information now required to be notified under the transitional provisions is that which was not previously required. Namely:

- the names of people responsible for supervision and safety and information on their training and qualifications;
- a description of the containment and other protective measures which are applied;
- information on waste management (type, form, treatment, ultimate form and destination);
- (if applicable) justification for not applying any containment measure at level 2;
- a copy of the risk assessment (rather than the summary previously required);
- (if applicable) information for the competent authority to evaluate any emergency response plans and confirmation that emergency services and other relevant authorities have been informed of the contents of the plan and any revisions.

175 You must also supply the information set out at paragraph 172. But in addition, the activity reference assigned by HSE (eg GM111/97/1) and dates of any correspondence proposing changes in the activity.

176 Some of the information required may have been supplied previously. In such cases it is permissible simply to refer back to it rather than physically re-send the data. Equally some of the information might duplicate that required for the premises notification under the transitional provisions. This need not be duplicated.

(iii) *Information requirements for class 2 activities which were previously Group II/ Type B.*

177 All of these activities were required to have been notified under the Contained Use Regulations 1992 and therefore the information now required to be notified under the transitional provisions is that which was not previously required. Namely:

28

Guidance

- the names of people responsible for supervision and safety and information on their training and qualifications;
- (if applicable) justification for not applying the full level 2 containment;
- (if applicable) confirmation that emergency services and other relevant authorities have been informed of the contents of the plan and any revisions.

178 You must also supply the information set out at paragraph 172, and, in addition the activity reference assigned by HSE (eg GM 111/97/1), and dates of any correspondence proposing changes in the activity.

179 As described previously, it is permissible to refer back to information already notified. Similarly, information required by the premises notification need not be duplicated.

Notifications of class 3 or 4 activities

180 The transitional provisions take a different approach to notification of class 3 or 4 activities, compared to that for class 2. These differences relate to the fact that the competent authority needs to grant formal consent to class 3 and 4 activities by 15 February 2001. The key differences are therefore:

- notifications have to be made by 15 January 2001 (to allow sufficient time for consents to be issued);
- all of the information set out in Schedule 6, Part II must be sent to the competent authority. (It will not be sufficient to cross refer to information already supplied).

181 In addition, as for all notifications of activities, the information set out in paragraph 172 will also have to be supplied, together with the activity reference assigned by HSE (eg GM111/97/1) and dates of any correspondence proposing changes in the activity.

182 Rather than having to produce a completely new set of information to satisfy the requirements of Schedule 6, Part II, it is quite likely that in most cases you would be able to photocopy information from your existing records. However, certain information will need to be added, as it was not relevant to the previous legislation, including:

- the class of activity;
- justification for not applying any containment measure at level 3 (for class 3) or at level 4 (for class 4).

Where to send notifications

183 All notifications under the transitional provisions should be sent to HSE, Technology Division (address at paragraph 20) who will receive the notifications on behalf of the competent authority.

Information to be placed on the public register

184 Certain information from all premises and activities notified under the transitional provisions will be placed on the public register. Namely:

For premises notifications:

- the name and address of the notifier (normally the institution, company or other organisation); and
- the centre reference number, eg GM111;
- information about waste management.

Guidance

28

For activities:

- the name and address of the notifier (normally the institution, company or other organisation);
- a short description or title of the activity;
- the reference number assigned by HSE (eg GM111/97/1)
- an indication of whether any significant changes have been notified.

185 Information related to premises will be placed on the register by 15 March 2001. Information relating to activities will be placed on the register by 15 April 2001. It should be noted that, subject to the confidentiality provisions of regulation 22, all notified information is open to disclosure to the public on request.

Regulation 29 Appeals

Regulation

29(1)-(8)

(1) Any person who is aggrieved by a decision of the competent authority -

(a) that he shall not undertake an activity involving genetic modification referred to in regulation 10(1), 11(1) or 12(1);
(b) not to agree pursuant to regulation 18(2) that he need not apply a particular containment measure for the activity involving genetic modification in question;
(c) to revoke an exemption certificate granted to him pursuant to regulation 25(1);
(d) to grant to him an exemption certificate subject to a condition or a limit of time pursuant to regulation 25(1),

may appeal to the appropriate person.

(2) Any person who is aggrieved by -

(a) a request to him made pursuant to regulation 14(2);
(b) an instruction given to him pursuant to regulation 14(3);
(c) a notice given to him pursuant to regulation 15(1),

may appeal to the appropriate person.

(3) Any person who is aggrieved by a decision of the competent authority -

(a) made pursuant to regulation 22(2)(b) or regulation 23(2)(b), not to keep confidential information provided by that person to the competent authority in accordance with these Regulations;
(b) made pursuant to regulation 22(8) or regulation 23(7), not to withhold information, may appeal to the appropriate person.

(4) The provisions of Schedule 11 shall apply where an aggrieved person appeals to the appropriate person.

(5) Where an appeal is brought under this regulation, none of the following, that is to say -

(a) a decision of the competent authority other than a decision referred to in paragraph (3);
(b) an instruction given pursuant to regulation 14(3);
(c) the operation of paragraphs (2) or (6) of regulation 14;

Regulation

(d) a notice given pursuant to regulation 15(1),

shall be suspended pending the final determination of the appeal.

(6) Where an appeal is brought under paragraph (3) in respect of any information provided pursuant to regulation 21, pending the final determination of the appeal, the information shall not be disclosed except to the extent necessary to enable the competent authority to comply with its obligations under paragraph (2) (a), (b) and (d) of that regulation.

(7) Where an appeal is brought in accordance with paragraph (3) in respect of information provided pursuant to regulations 9 to 15 -

(a) pending the final determination of the appeal, the information shall not be disclosed except -

(i) to the extent necessary to evaluate the notification, and
(ii) to the European Commission;

(b) if -

(i) the appeal is finally determined in favour of the competent authority, and
(ii) the information is required to be entered in the register maintained in accordance with regulation 24,

the information shall be entered in that register within fourteen days following the day on which the appeal is finally determined.

(8) In this regulation, "the appropriate person" means -

(a) the Secretary of State, in the case of -

(i) an appeal under paragraph (1), (2)(c) or (3) against a decision of, or a notice given by, the competent authority as regards England and Wales, or
(ii) an appeal under paragraph (2)(a) or (b) against a request or instruction relating to -

(aa) the undertaking or proposed undertaking of an activity involving genetic modification, or
(bb) premises which are the subject of a notification under regulation 9(1) and which are situate,

in England or Wales;

(b) the Secretary of State and the Scottish Ministers acting jointly, in the case of -

(i) an appeal under paragraph (1), (2)(c) or (3) against a decision of, or a notice given by, the competent authority as regards Scotland or the joint competent authority, or
(ii) an appeal under paragraph 2(a) or (b) against a request or instruction relating to -

(aa) the undertaking or proposed undertaking of an activity involving genetic modification, or
(bb) premises which are the subject of a notification under

29(1)-(8)

Regulation 29(1)-(8)

regulation 9(1) and which are situate,

in Scotland or in both England and Scotland, as the case may be.

Guidance

186 This regulation introduces an appeals mechanism for any notifier who is aggrieved by certain decisions of the competent authority. The decisions against which people may appeal are, the competent authority:

- not permitting a class 2, class 3, class 4 activity to take place, or not permitting an activity involving notifiable GM animals or plants to take place;
- imposing conditions, suspending, terminating or time limiting any activity;
- revoking or varying a consent for a class 3 or 4 activity;
- not allowing derogation from the full containment level which corresponds to the class of activity;
- revoking an exemption certificate;
- placing conditions or time limit on an exemption certificate;
- requiring additional information in respect of a premises or activity notification, and any instructions (such as cessation, destroying or storing the GMOs) associated with the request for additional information;
- not agreeing to a confidentiality claim in respect of premises, activity or accident notifications;
- not agreeing to withhold information claimed as confidential because of intellectual property rights (again in respect of premises, activity or accident notifications.)

187 For England and Wales, if a notifier is aggrieved about any of the above, they may appeal to the Secretary of State. For Scotland, appeals may be made to the Secretary of State and Scottish Ministers.

188 The system for appeals is based on that found in section 44 of the Health and Safety at Work etc. Act 1974, but with modifications such that the Secretary of State (or, in Scotland, the Secretary of State and Scottish Ministers acting jointly) will appoint another person to determine the appeal.

189 Not all appeals will require a hearing to be held. If both the appellant and the competent authority agree, the appointed person can determine the appeal without a hearing. However, if either the appellant or the competent authority wish it they must be given the opportunity to appear and be heard by the appointed person. In such cases the rules and procedures set out in Schedule II will apply.

190 The conditions and procedure set out in these rules include:

- the setting of a hearing date - with sufficient notice being given to all parties;
- the possibility that a hearing may be made public;
- prior exchange of written statements and lists of documents which will be put forward by either party. It is also required that the documents listed are made available for scrutiny by the other party;
- a right for both the appellant and the competent authority to appear at the hearing, either in person, through an appointed officer or counsel or solicitor;
- once the appointed person has determined the appeal the decision is communicated in writing.

191 Hearings related to claims for confidentiality will be taken in private.

192 Where an appeal has been made the decision of the competent authority will stand unless and until there is a decision to the contrary. The exceptions to this are where the appeal is in relation to a claim for confidentiality, or protection of intellectual property rights. In such cases the information in question will remain confidential until the decision has been made. However, it should be noted that

29(1)-(8)

Guidance

29(1)-(8)

some limited disclosure may be permitted. For accident notifications this would be where duties to inform other Member States or the European Commission must be fulfilled or where disclosure is necessary for the competent authority to ensure safety. (See also regulation 23.) For premises and activity notifications limited disclosure may be necessary to evaluate the notification or provide information to the European Commission. (See also regulation 22.)

Regulation 30 Extension outside Great Britain

Regulation

30

These Regulations shall apply in relation to premises and activities involving genetic modification outside Great Britain to which sections 1 to 59 and 80 to 82 of the 1974 Act apply by virtue of the Health and Safety at Work etc. Act 1974 (Application Outside Great Britain) Order 1995[(a)] as they apply to premises and activities involving genetic modification within Great Britain.

(a) SI. 1995/263

Guidance

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193 The Regulations apply to premises and activities specified in the Health and Safety at Work etc. Act 1974 (Application Outside Great Britain) Order 1995. Notification is therefore required of any 'premises' on an offshore installation which is in territorial waters or areas designated under the Continental Shelf Act 1964, including the British North Sea oil fields. The Order, and therefore the Regulations, does not, however, apply to vessels in, or aircraft flying over, territorial waters or designated areas.

Regulation 31 Revocations, amendments and savings

Regulation

31(1)-(6)

(1) The following are revoked -

*(a) the Genetically Modified Organisms (Contained Use) Regulations 1992**(b)**;*
*(b) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1996**(c)**;*
*(c) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1998**(d)**.*

*(2) In paragraph 3(h) of regulation 8 of the Genetically Modified Organisms (Deliberate Release) Regulations 1992**(e)**, for the words "under regulation 11 of the Genetically Modified Organisms (Contained Use) Regulations 1992", there shall be substituted the words "under regulation 16 of the Genetically Modified Organisms (Contained Use) Regulations 2000".*

*(3) The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996**(f)** shall be amended as follows -*

(a) in regulation 1(3), in the definition of "the Contained Use Regulations", for the words "the Genetically Modified Organisms (Contained Use) Regulations 1992", there shall be substituted the words "the Genetically Modified Organisms (Contained Use) Regulations 2000";
(b) in paragraph (2)(b)(i) of regulation 3, for the words "Schedule 1", there shall be substituted the words "Schedule 2"; and
(c) in paragraph (2)(b)(ii) of regulation 3, for the words "regulation 3(3) of, and Part III of Schedule 1", there shall be substituted the words "regulation 3(2) of, and Part III of Schedule 2".

Regulation

31(1)-(6)

*(4) In paragraph 12(5) of Schedule 3 to the Control of Substances Hazardous to Health Regulations 1999**(g)**, for the words "Genetically Modified Organisms (Contained Use) Regulations 1992", there shall be substituted the words "Genetically Modified Organisms (Contained Use) Regulations 2000".*

*(5) In the Health and Safety (Fees) Regulations 2000**(h)**, regulation 17 and Schedule 14 shall be omitted.*

(6) Every record required to be kept under regulation 7(5) of the Genetically Modified Organisms (Contained Use) Regulations 1992 shall, notwithstanding paragraph (1), be kept in the same manner and for the same period as specified in that regulation as if these Regulations had not been made.

(b) S.I. 1992/3217
(c) S.I. 1996/967
(d) S.I. 1998/1548
(e) S.I. 1992/3280. Paragraph (3) of regulation 8 was amended by S.I. 1995/304; there are other amendments not relevant to these Regulations.
(f) S.I. 1996/1106, to which there are amendments not relevant to these Regulations.
(g) S.I. 1999/437
(h) S.I. 2000/2482

Schedule 1 Classes of activity involving genetic modification

Schedule

1

Regulation 2(1)

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

Schedule 2 Part I

Schedule

2

Regulation 2(1)

Examples of techniques constituting genetic modification

1 Examples of the techniques which constitute genetic modification which are referred to in sub-paragraph (a) of the definition of "genetic modification" in regulation 2(1) are -

(a) 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;

(b) techniques involving the direct introduction into an organism of heritable genetic material prepared outside the organism, including micro-injection, macro-injection and micro-encapsulation;

(c) cell fusion or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

Schedule

Part II

Regulation 2(1)

Techniques which are not considered to result in genetic modification

2 The following techniques are not considered to result in genetic modification provided that they do not involve the use of genetically modified organisms made by techniques other than those listed in Part III or the use of recombinant nucleic acid molecules, namely -

(a) in vitro fertilisation;
(b) natural processes including conjugation, transduction or transformation;
(c) polyploidy induction.

Part III

Regulation 3(2)

Techniques to which these Regulations do not apply

3 These Regulations (except regulation 17) shall not apply to the following techniques of genetic modification, provided that they do not involve the use of recombinant nucleic acid molecules or of genetically modified organisms other than those recombinant nucleic acid molecules or genetically modified organisms produced by one or more of the following techniques of genetic modification -

(a) mutagenesis;
(b) cell fusion (including protoplast fusion) of prokaryotic species which can exchange genetic material through homologous recombination;
(c) cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions;
(d) self-cloning where the resulting organism is unlikely to cause disease or harm to humans, animals or plants.

4 In paragraph 3 -

(a) "self-cloning" means the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent), whether or not altered by enzymic or mechanical processes, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by homologous recombination; and
(b) self-cloning may include the use of recombinant vectors, with an extended history of safe use in the particular organism, to manipulate and reinsert the nucleic acid sequences, but the vectors shall not consist of any genetic elements other than those designed for vector structure, vector replication, vector maintenance or marker genes.

2

Schedule

Schedule 3

Part I

Regulation 6(2)

Matters to be taken into account in carrying out an assessment for the purposes of regulation 6

1 The following matters shall be taken into account in carrying out an assessment for the purposes of regulation 6 -

(a) any potentially harmful effects, in particular those associated with -

(i) the recipient micro-organism,
(ii) the inserted genetic material (originating from the donor organism),
(iii) the vector,
(iv) the donor micro-organism (where that donor micro-organism is used during the activity involving genetic modification), and
(v) the resulting genetically modified micro-organism;

(b) the characteristics of the activity;
(c) the severity of the potentially harmful effects; and
(d) the likelihood of the potentially harmful effects being realised.

2 In paragraph 1, "potentially harmful effects" includes -

(a) disease to humans including allergenic or toxic effects;
(b) disease to animals or plants;
(c) adverse effects resulting from the inability to treat disease or offer an effective prophylaxis;
(d) adverse effects resulting from establishment or dissemination of the genetically modified micro-organisms in the environment;
(e) adverse effects resulting from the natural transfer of genetic material to or from other organisms;
(f) adverse effects resulting from the likely interaction of the genetically modified micro-organism with other organisms at the premises where the activity involving genetic modification is to be conducted.

Part II

Regulation 6(2)

Steps to be included when carrying out an assessment for the purposes of regulation 6

3 An assessment carried out for the purposes of regulation 6 shall include -

(a) identification of any harmful properties of the recipient and, where appropriate, the donor micro-organism;
(b) identification of any harmful properties associated with the vector or inserted material, including any alteration in the recipient's existing properties;
(c) consideration of relevant Community legislation, including Council Directive

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Schedule

90/679/EEC**(a)** on the protection of workers from risks related to exposure to biological agents at work, other classification schemes referring to plant and animal pathogens, and other international and national classification schemes for genetically modified micro-organisms;

(d) identification of the provisional level of risk associated with the genetically modified micro-organism;

(e) consideration of -

(i) the characteristics of the environment likely to be exposed,

(ii) the characteristics of the activity involving genetic modification of micro-organisms, and

(iii) any activities involving genetic modification of micro-organisms which cannot be adequately controlled by standard laboratory procedures, and which present risks which require controls for each individual case;

(f) adjustment of the provisional level of risk in the light of the matters referred to in sub-paragraph (e) above;

(g) selection of the appropriate containment measures from those specified in the applicable Table in Schedule 8 on the basis of the provisional level of risk as adjusted in accordance with sub-paragraph (f) above;

(h) assignment of the activity involving genetic modification of micro-organisms to the appropriate containment level, in accordance with paragraph 4;

(i) classification of that activity in the class of the same number as that of the appropriate containment level; and

(j) review and reconsideration of classification in the light of the completed assessment.

4 To assign an activity involving genetic modification of micro-organisms to the appropriate containment level for the purposes of paragraph 3(h), the person carrying out the assessment for the purposes of regulation 6 shall -

(a) first identify for each selected containment measure the column in the applicable Table in Schedule 8 having the lowest number in which that selected containment measure is shown as being required, regardless of whether or not such requirement is subject to any qualification;

(b) then select, the highest number of all the columns identified in accordance with sub-paragraph (a) above; and

(c) then assign the activity involving genetic modification in question to the containment level of that highest number.

5 In paragraph 4, “selected containment measure” means an appropriate containment measure selected in accordance with paragraph 3(g).

(a) OJ No. L374, 31.12.90, p.1, as amended by Council Directive 93/88/EEC (OJ No. L268, 29.10.93, p.71), Commission Directive 95/30/EC (OJ No. L155, 6.7.95, p.41) Commission Directive 97/59/EC (OJ No. L282, 15.10.1997, p.33) and Commission Directive 97/65/EC (OJ No. L335, 6.12.1997, p.17).

3

Schedule

Schedule 4 Part I

Regulation 7(2)

Matters to be taken into account in carrying out an assessment for the purposes of regulation 7

1 The following matters shall be taken into account in carrying out an assessment for the purposes of regulation 7 -

(a) the identification of any potentially harmful effects, in particular those associated with -

(i) the recipient organism,
(ii) the inserted genetic material (originating from the donor organism),
(iii) the vector,
(iv) the donor organism, and
(v) the resulting genetically modified organism;

(b) the characteristics of the activity involving genetic modification;
(c) the severity of the potentially harmful effects; and
(d) the likelihood of the potentially harmful effects being realised.

2 In paragraph 1, "potentially harmful effects" includes -

(a) disease to humans including allergenic or toxic effects;
(b) acting as a human disease vector or reservoir;
(c) adverse effects to humans arising from change in behaviour or in physical nature;
(d) adverse effects arising from the inability to treat human disease or offer effective prophylaxis.

Part II

Regulation 7(2)

Steps to be included when carrying out an assessment for the purposes of regulation 7

3 An assessment carried out for the purposes of regulation 7 shall include -

(a) identification of the harmful properties of the recipient and, where appropriate, the donor organism;
(b) identification of any harmful properties associated with the vector or inserted material, including any alteration in the existing properties of the recipient;
(c) identification of the provisional level of risk associated with the genetically modified organisms;
(d) selection of containment and other protective measures on the basis of -

(i) the provisional level of risk, and
(ii) the characteristics of the activity involving genetic modification;

(e) adjustment of the level of risk in the light of the matters referred to in sub-paragraph (d) above; and

Schedule 4

(f) review and reconsideration of the containment and other protective measures in the light of the steps required by sub-paragraphs (a) to (e) above.

Schedule 5 Information required for a notification under Regulation 9(1)

Schedule 5

Regulation 9(1), 15(2) and 24(3)

A notification required for the purposes of regulation 9(1) shall contain the following information -

(a) the name, address, and telephone number and any fax number and any e-mail address of the notifier;
(b) the name of the employee of the notifier with specific responsibility for the supervision and safety of activities involving genetic modification;
(c) information on the training and qualifications of that employee;
(d) details of the genetic modification safety committee established pursuant to regulation 16;
(e) the address of the premises where the activity involving genetic modification is to be carried out and a general description of the premises;
(f) the nature of the work to be undertaken;
(g) the class of any activity involving genetic modification of micro-organisms;
(h) where the first activity to be carried out in those premises is an activity involving genetic modification in class 1 -

    (i) a summary of the assessment of that activity made for the purposes of regulation 6(1),
    (ii) any advice received in relation to that assessment from the genetic modification safety committee established pursuant to regulation 16;
    (iii) information on waste management, and
    (iv) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of the emergency plan and of any relevant revisions made in pursuance of regulation 20(3); and

(i) where the first activity to be carried out in those premises involves genetic modification of organisms which are not micro-organisms and that activity is not notifiable under regulation 12(1) -

    (i) a copy of the assessment made for the purposes of regulation 7(1), and
    (ii) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of the plan and of any relevant revisions made in pursuance of regulation 20(3).

Schedule 6

Part I

Regulations 10(1), 15(2) and 24(3)

Information required for a notification under Regulation 10(1)

1 A notification required for the purposes of regulation 10(1) shall contain the following information -

(a) the name, address and telephone number and any fax number and any e-mail address of the notifier;
(b) the centre number allocated by the competent authority in respect of the premises at which the activity involving genetic modification of micro-organisms is to be undertaken and the date of the notification required by regulation 9(1) relating to those premises;
(c) the name of the employee of the notifier with specific responsibility for supervision and safety;
(d) information on the training and qualifications of that employee;
(e) the recipient or parental micro-organism to be used;
(f) the donor micro-organism to be used;
(g) where applicable, the host-vector system to be used;
(h) the source and intended function of the genetic material involved in the modification;
(i) the identity and characteristics of the genetically modified micro-organism;
(j) the purpose of the activity involving genetic modification of micro-organisms, including its expected results;
(k) the approximate culture volumes to be used;
(l) a description of the containment and other protective measures to be applied, including -

  (i) information on waste management, including the type and form of wastes to be generated, their treatment, ultimate form and destination, and
  (ii) justification for not applying any containment measure at containment level 2;

(m) a copy of the assessment carried out pursuant to regulation 6(1);
(n) any advice received in relation to that assessment from the genetic modification safety committee established pursuant to regulation 16;
(o) the information necessary for the competent authority to evaluate any emergency plan; and
(p) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of the plan and of any relevant revisions made in pursuance of regulation 20(3).

Schedule

Part II

Regulation 11(1), 15(2) and 24(3)

Information required for a notification under Regulation 11(1)

2 A notification required for the purposes of regulation 11(1) shall contain the following information -

(a) the name, address and telephone number and any fax number and any e-mail address of the notifier;
(b) the centre number allocated by the competent authority in respect of the premises at which the activity involving genetic modification of micro-organisms is to be undertaken and the date of the notification required by regulation 9(1) relating to those premises;
(c) the name of the employee of the notifier with specific responsibility for supervision and safety;
(d) information on the training and qualifications of that employee;
(e) the recipient or parental micro-organism to be used;
(f) the donor micro-organism to be used;
(g) where applicable, the host-vector system to be used;
(h) the source and intended function of the genetic material involved in the modification;
(i) the identity and characteristics of the genetically modified micro-organism;
(j) the culture volumes to be used;
(k) a description of the containment and other protective measures to be applied, including -

  (i) information on waste management, including the type and form of wastes to be generated, their treatment, ultimate form and destination,
  (ii) in the case of activities involving genetic modification of micro-organisms in class 3, justification for not applying any containment measure at containment level 3, and
  (iii) in the case of activities involving genetic modification of micro-organisms in class 4, justification for not applying any containment measure at containment level 4;

(l) the purpose of the activity involving genetic modification of micro-organisms, including its expected results;
(m) a description of the parts of the installation;
(n) information on any accident prevention and emergency plans, including -

  (i) any specific hazards arising from the location of the installation,
  (ii) the preventive measures applied, including safety equipment, alarm systems and containment methods,
  (iii) procedures and plans for verifying the continuing effectiveness of the containment measures,
  (iv) a description of the information provided to workers,
  (v) the information necessary for the competent authority to evaluate any emergency plan, and
  (vi) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of that plan and of any relevant revisions made in pursuance of regulation 20(3); and

(o) a copy of the assessment referred to in regulation 6(1).

Part III

Regulation 12(1), 15(2) and 24(3)

Information required for a notification under Regulation 12(1)

3 A notification required for the purposes of regulation 12(1) shall contain the following information -

(a) the name, address and telephone number and any fax number and any e-mail address of the notifier;
(b) the centre number allocated by the competent authority in respect of the premises at which the activity involving genetic modification of organisms other than micro-organisms is to be undertaken and the date of the notification required by regulation 9(1) relating to those premises;
(c) the name of the employee of the notifier with specific responsibility for supervision and safety;
(d) information on the training and qualifications of that employee;
(e) the recipient or parental organism to be used;
(f) the donor organism to be used;
(g) where applicable, the host-vector system to be used;
(h) the sources and intended functions of the genetic material involved in the modification;
(i) the identity and characteristics of the genetically modified organism;
(j) the purpose of the activity involving genetic modification of organisms other than micro-organisms, including its expected results;
(k) a description of the containment and other protective measures to be applied, including information on waste management, including the type and form of wastes to be generated, their treatment, ultimate form and destination;
(l) a copy of the assessment referred to in regulation 7(1);
(m) the information necessary for the competent authority to evaluate any emergency plan; and
(n) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of that plan and of any relevant revisions made in pursuance of regulation 20(3).

Schedule 7 General principles of good microbiological practice and of good occupational safety and hygiene

Schedule

Regulation 17(2) and (3)

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;

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(e) providing appropriate training of personnel;
(f) formulating and implementing local codes of practice for the safety of personnel, as required;
(g) displaying biohazard signs where appropriate;
(h) providing washing and decontamination facilities for personnel;
(i) keeping adequate records;
(j) prohibiting in the work area eating, drinking, smoking, applying cosmetics or the storing of food for human consumption;
(k) prohibiting mouth pipetting;
(l) providing written standard operating procedures where appropriate to ensure safety;
(m) having effective disinfectants and specified disinfection procedures available in case of spillage of genetically modified micro-organisms; and
(n) providing safe storage for contaminated laboratory equipment and materials where appropriate.

Schedule 8 Containment measures

Schedule

Regulations 2(3) and 18(1)

Part I

1 In this Schedule -

"GMMs" means genetically modified micro-organisms;

"HEPA" means High Efficiency Particulate Air;

"inactivation" means the complete or partial destruction of GMMs so as to ensure that any contact between the GMMs and humans or the environment is limited to an extent commensurate with the risks identified in the risk assessment and to provide a high level of protection for humans and the environment;

"plant growth facilities" means a structure, whether permanent or impermanent, designed and used principally for growing plants in a controlled and protected environment; and

"risk assessment" means the assessment carried out in accordance with regulation 6.

2 For the purposes of this Schedule, where, in the final column of Table 1b or 1c, a measure is specified as -

(a) a modification, it shall be read as an addition to the measures in Table 1a;
(b) additional, it shall be read as an addition to the measures in Table 1a, subject to the substitution, where appropriate, of an individual measure in Table 1a by a measure specified as a modification in the Table in question.

3 For the purposes of this Schedule -

(a) Table 1a describes containment measures applicable to activities involving genetic modification of micro-organisms in laboratories;
(b) Table 1a, read with Table 1b, describes containment measures applicable to activities involving genetic modification of micro-organisms in plant growth facilities;

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Schedule

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(c) Table 1a, read with Table 1c, describes containment measures applicable to activities involving genetic modification of micro-organisms in animal units;
(d) Table 2 describes containment measures applicable to activities involving genetic modification of micro-organisms in premises other than those referred to in Tables 1a, 1b and 1c.

Schedule

Part II

Table 1a: Containment Measures for Activities Involving Genetic Modification of Micro-organisms in Laboratories

Containment Measures		Containment Levels			
		1	**2**	**3**	**4**
1	Laboratory suite: isolation **(Note 1)**	not required	not required	required	required
2	Laboratory: sealable for fumigation	not required	not required	required	required
	Equipment				
3	Surfaces impervious to water, resistant to acids, alkalis, solvents, disinfectants and decontamination agents and easy to clean	required for bench	required for bench	required for bench and floor	required for bench and floor, ceiling and walls
4	Entry to lab via airlock **(Note 2)**	not required	not required	required where and to extent the risk assessment shows it is required	required
5	Negative pressure relative to the pressure of the immediate surroundings	not required	required where and to extent the risk assessment shows it is required	required	required
6	Extract and input air from the laboratory shall be HEPA filtered	not required	not required	HEPA filters required for extract air	HEPA filters required for input and extract air **(Note 3)**
7	Microbiological safety cabinet/enclosure	not required	required where and to extent the risk assessment shows it is required	required, and all procedures with infective materials required to be contained within a cabinet/ enclosure	Class III cabinet required

Schedule

	Containment Measures	Containment Levels			
		1	2	3	4
8	Autoclave	required on site	required in the building	required in the laboratory suite **(Note 4)**	double ended autoclave required in laboratory
	System of work				
9	Access restricted to authorised personnel only	not required	required	required	required (via airlock key procedure)
10	Specific measures to control aerosol dissemination	not required	required so as to minimise	required so as to prevent	required so as to prevent
11	Shower	not required	not required	required where and to extent the risk assessment shows it is required	required
12	Protective clothing	suitable protective clothing required	suitable protective clothing required	suitable protective clothing required; footwear required where and to extent the risk assessment shows it is required	complete change of clothing and footwear required before entry and exit
13	Gloves	not required	required where and to extent the risk assessment shows they are required	required	required
14	Efficient control of disease vectors (eg rodents and insects) which could disseminate GMMs	required where and to extent the risk assessment shows it is required	required	required	required
15	Specified disinfection procedures in place	required where and to extent the risk assessment shows they are required	required	required	required

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Schedule

	Containment Measures	Containment Levels			
		1	2	3	4
	Waste				
16	Inactivation of GMMs in effluent from handwashing sinks and showers and similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
17	Inactivation of GMMs in contaminated material and waste	required by validated means	required by validated means	required by validated means	required by validated means
	Other Measures				
18	Laboratory to contain its own equipment	not required	not required	required so far as is reasonably practicable	required
19	An observation window or alternative is to be present so that occupants can be seen	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required	required
20	Safe storage of GMMs	required where and to extent the risk assessment shows it is required	required	required	secure storage required
21	Written records of staff training	not required	required where and to extent the risk assessment shows they are required	required	required

Notes

1 In the Table above, "isolation" means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.

2 Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

3 Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.

4 Where the autoclave is outside the laboratory in which the activity involving genetic modification of micro-organisms is being undertaken, but within the laboratory suite, there shall be validated procedures for the safe transfer of material

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Schedule 8

into that autoclave, which provide a level of protection equivalent to that which would achieved by having an autoclave in that laboratory.

Table 1b: Containment Measures for Activities Involving Genetic Modification of Micro-organisms in Plant Growth Facilities (to be read with Table 1a as indicated in paragraph 3)

	Containment Measures	Containment Levels				Additional/ modification
		1	2	3	4	
	Building					
1	Permanent structure **(Note 1)**	required where and to extent the risk assessment shows it is required	required	required	required	Modification
	Equipment					
2	Entry via a separated room with two interlocking doors	not required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required (via airlock key procedure)	Additional
3	Control of contaminated run-off water	required where and to extent the risk assessment shows it is required	required so as to prevent run-off	required so as to prevent run-off	required so as to prevent run-off	Additional
	System of Work					
4	Effective control of disease vectors such as insects, rodents and arthropods which could disseminate GMMs	required	required	required	required	Additional
5	Effective control of pollen, seeds and other plant material which could disseminate GMMs	required where and to extent the risk assessment shows it is required	required so as to minimise dissemination	required so as to prevent dissemination	required so as to prevent dissemination	Additional
6	Procedures for transfer of living material between the plant growth facilities, protective structure and laboratory shall control dissemination of GMMs	required so as to minimise dissemination	required so as to prevent dissemination	required so as to prevent dissemination	required so as to prevent dissemination	Additional

Note

1 A permanent structure refers to a fixed structure with walls, a roof and a floor. Where the permanent structure is a greenhouse, that structure shall also have a continuous waterproof covering and self-closing lockable outer doors, and be located on a site designed to prevent the entry of surface run-off water.

Table 1c: Containment Measures for Activities Involving Genetic Modification of Micro-organisms in Animal Units (to be read with Table 1a as indicated in paragraph 3)

	Containment Measures	Containment Levels				Additional/ modification
		1	2	3	4	
	Facilities					
1	Isolation of animal unit **(Note 1)**	required where and to extent the risk assessment shows it is required	required	required	required	Modification
2	Animal facilities **(Note 2)** separated by lockable doors	required where and to extent the risk assessment shows they are required	required	required	required	Additional
3	Animal facilities (cages, etc) designed to facilitate decontamination (waterproof and easily washable material)	required where and to extent the risk assessment shows they are required	required where and to extent the risk assessment shows they are required	required	required	Additional
4	Floor, walls and ceiling easily washable	required where and to extent the risk assessment shows they are required	required for floor	required for floor and walls	required for floor, walls and ceiling	Modification
5	Appropriate filters on isolators or isolated rooms **(Note 3)**	not required	required where and to extent the risk assessment shows they are required	required	required	Additional
6	Incinerator for disposal of animal carcasses	required to be accessible	required to be accessible	required to be accessible	required to be on site	Additional
7	Appropriate barriers at the room exit, and at drains or ventilation duct work	required	required	required	required	Additional
8	Animals kept in appropriate containment facilities, such as cages, pens, tanks or isolators	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	Additional

Notes

1 In the Table above, "animal unit" means a building, or separate area within a building, containing an animal facility and other areas including changing rooms, showers, autoclaves and food storage areas.

2 In the Table above and in Note 1 above, "animal facility" means a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures on animals.

3 In the Table above, "isolators" means transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

Table 2: Containment Measures for Activities Involving Genetic Modification of Micro-organisms in Premises other than those referred to in Tables 1a, 1b and 1c

Containment Measures		Containment Levels			
		1	2	3	4
	General				
1	Viable micro-organisms shall be contained in a system which separates the process from the workplace and wider environment (closed system)	required where and to extent the risk assessment shows it is required	required	required	required
2	Closed systems located within a controlled area	not required	required where and to extent the risk assessment shows they are required	required	required and required to be purpose built
3	Control of exhaust gases from the closed system	not required	required so as to minimise release	required so as to prevent release	required so as to prevent release
4	Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	required where and to extent the risk assessment shows it is required	required so as to minimise release	required so as to prevent release	required so as to prevent release
5	Inactivation of bulk culture fluids before removal from the closed system	required where and to extent the risk assessment shows it is required	required by validated means	required by validated means	required by validated means
6	Seals shall be designed so as to minimise or prevent release	not required	required so as to minimise release	required so as to prevent release	required so as to prevent release
7	The controlled area designed to contain spillage of the entire contents of the closed system	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required	required

	Containment Measures		Containment Levels		
8	The controlled area sealable to permit fumigation	not required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required
		1	**2**	**3**	**4**
9	Biohazard signs posted	required where and to extent the risk assessment shows it is required	required	required	required
	Equipment				
10	Entry via airlock	not required	not required	required where and to extent the risk assessment shows it is required	required
11	Surfaces resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents and easy to clean	required for any bench	required for any bench	required for floor and any bench	required for bench, floor, ceiling and walls
12	Specific measures to adequately ventilate the controlled areas in order to minimise air contamination	required where and to extent the risk assessment shows they are required	required where and to extent the risk assessment shows they are required	required where and to extent the risk assessment shows they are required	required
13	The controlled area maintained at an air pressure negative to the immediate surroundings	not required	not required	required where and to extent the risk assessment shows it is required	required
14	Extract and input air from the controlled area shall be HEPA filtered	not required	not required	required for extract air, optional for input air	required for input and extract air
	System of Work				
15	Access restricted to authorised personnel only	not required	required	required	required
16	Decontamination and washing facilities provided for personnel	required	required	required	required
17	Personnel shall shower before leaving the controlled area	not required	not required	required where and to extent the risk assessment shows it is required	required

	Containment Measures		Containment Levels		
18	Personnel shall wear protective clothing	work clothing required	work clothing required	required	complete change required before exit and entry
19	Written procedures and records of staff training	not required	not required	required	required
		1	**2**	**3**	**4**
	Waste				
20	Inactivation of GMMs in effluent from handwashing sinks and showers or similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
21	Inactivation of GMMs in contaminated material and waste including those in process effluent before final discharge	required by validated means	required by validated means	required by validated means	required by validated means

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Schedule 9 Fees for notification and applications

Regulation 27(1)

Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1).	£200
Notification of an activity involving genetic modification in class 2 under regulation 10(1), except a notification to which paragraph 4(1) or paragraph 5(1) of Schedule 10 applies.	£400
Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1) at the same time as notification of an activity involving genetic modification in class 2 under regulation 10(1).	£400
Notification of an activity involving genetic modification in class 3 under regulation 11(1), except a notification to which paragraph 4(2) or paragraph 5(2) of Schedule 10 applies.	£430
Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1) at the same time as notification of an activity involving genetic modification in class 3 under regulation 11(1).	£430
Notification of an activity involving genetic modification in class 4 under regulation 11(1), except a notification to which paragraph 4(2) or paragraph 5(2) of Schedule 10 applies.	£500
Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1) at the same time as notification of an activity involving genetic modification in class 4 under regulation 11(1).	£500
Notification of an activity involving genetic modification of organisms other than micro-organisms under regulation 12(1).	£400
Notification of the intention to use premises for the first time for the purpose of undertaking activities involving genetic modification under regulation 9(1) at the same time as notification of an activity involving genetic modification of organisms other than micro-organisms under regulation 12(1).	£400
Notification of additional information under regulation 15(3).	£300
Application for the written agreement of the competent authority under regulation 18(2) where the application is made after a notification has been submitted pursuant to regulation 9(1), 10, 11 or 12(1).	£300

Schedule 10 Transitional provisions

Schedule

Regulation 28

Interpretation

1 In this Schedule -

(a) "the 1992 Regulations" means the Genetically Modified Organisms (Contained Use) Regulations 1992 **(a)**;
(b) "the relevant date" means the date on which these Regulations come into force; and
(c) a reference to a numbered sub-paragraph is a reference to the sub-paragraph so numbered in the paragraph in which that reference occurs.

Risk assessment

2 (1) Where a person undertakes an activity involving genetic modification of micro-organisms which he commenced before the relevant date, he shall ensure that an assessment is carried out in accordance with regulation 6 as if the date of the commencement of that activity were 15th December 2000.

(2) Where a person undertakes an activity involving genetic modification of organisms other than micro-organisms which he commenced before the relevant date, he shall ensure that an assessment is carried out in accordance with regulation 7 as if the date of the commencement of that activity were 15th December 2000.

Notification of premises

3 Where before the relevant date a person had notified the Executive in accordance with regulation 8(1) of the 1992 Regulations of his intention to undertake an activity involving genetic modification at premises for the first time, the requirements of regulation 9 shall be deemed to be satisfied, provided that, before 15th February 2001, that person submits to the competent authority a notification containing -

(a) the information specified in paragraph (g) of Schedule 5; and
(b) the information specified in paragraph (h)(iii) and (iv) of Schedule 5 where the activity involving genetic modification is a class 1 activity to be undertaken on or after 15th February 2001 at the premises referred to in the notification submitted pursuant to regulation 8(1) of the 1992 Regulations.

Notification of activities involving genetic modification

4 (1) Where a person had notified the Executive of his intention to undertake an activity involving genetic modification of micro-organisms in accordance with regulation 9(1) of the 1992 Regulations and immediately before the relevant date that person was entitled under the 1992 Regulations to undertake that activity, and where that activity involving genetic modification of micro-organisms is in class 2, the requirements of regulation 10 shall be deemed to be satisfied in relation to that activity, provided that before 15th February 2001 that person submits to the competent authority a notification containing -

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(a) S.I. 1992/3217 as amended by S.I. 1996/967, 1998/1548

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(a) in the case of an activity referred to in regulation 9(2)(a) of the 1992 Regulations, the information specified in Part I of Schedule 6;
(b) in the case of an activity referred to in regulation 9(3) or regulation 9(4)(a) of the 1992 Regulations, the information specified in paragraphs (c), (d), (l), (m), (o) and (p) of Part I of Schedule 6; and
(c) in the case of an activity referred to in regulation 9(5) of the 1992 Regulations, the information specified in paragraphs (c), (d), (l)(ii) and (p) of Part I of Schedule 6.

(2) Where a person had notified the Executive of his intention to undertake an activity involving genetic modification of micro-organisms in accordance with regulation 9(1) of the 1992 Regulations and immediately before the relevant date that person was entitled under the 1992 Regulations to undertake that activity, and where that activity involving genetic modification of micro-organisms is in class 3 or class 4, the requirements of regulation 11 shall be deemed to be satisfied in relation to that activity, provided that -

(a) before 15th January 2001, that person submits to the competent authority a notification containing the information specified in Part II of Schedule 6; and
(b) before 15th February 2001, the competent authority gives its consent in writing to continue to undertake the activity involving genetic modification of micro-organisms in question.

(3) Where a person had notified the Executive of his intention to undertake an activity involving the genetic modification of organisms other than micro-organisms in accordance with regulation 9(1) of the 1992 Regulations and immediately before the relevant date that person was entitled under the 1992 Regulations to undertake that activity, the requirements of regulation 12 shall be deemed to be satisfied.

(4) Where a person submits a notification in accordance with this paragraph, he shall at the same time provide the competent authority with a short description of the activity involving genetic modification to which the notification relates.

Notification of proposed activities involving genetic modification

5 (1) Where a person had notified the Executive of his intention to undertake an activity involving genetic modification of micro-organisms in accordance with regulation 9(1) of the 1992 Regulations but immediately before the relevant date that person was not entitled under the 1992 Regulations to undertake that activity for any reason other than the reason mentioned in sub-paragraph (4), and where the activity involving genetic modification of micro-organisms is in class 2, that person may submit to the competent authority a notification containing -

(a) in the case of an activity referred to in regulation 9(2)(a) of the 1992 Regulations, the information specified in Part I of Schedule 6;
(b) in the case of an activity referred to in regulation 9(3) or regulation 9(4)(a) of the 1992 Regulations, the information specified in paragraphs (c), (d), (l), (m), (o) and (p) of Part I of Schedule 6; and
(c) in the case of an activity referred to in regulation 9(5) of the 1992 Regulations, the information specified in paragraphs (c), (d), (l)(ii) and (p) of Part I of the Schedule 6,

in which case the provisions of these Regulations shall apply as if that person had submitted a notification pursuant to regulation 10(1) on the date he submitted the

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notification pursuant to this sub-paragraph, save that regulation 24 shall apply as modified in accordance with paragraph 10.

(2) Where a person had notified the Executive of his intention to undertake an activity involving genetic modification of micro-organisms in accordance with regulation 9(1) of the 1992 Regulations but immediately before the relevant date that person was not entitled under the 1992 Regulations to undertake that activity for any reason other than the reason mentioned in sub-paragraph (4), and where that activity involving genetic modification of micro-organisms is in class 3 or 4, that person may submit a notification containing the information specified in Part II of Schedule 6, in which case the provisions of these Regulations shall apply as if that person had submitted a notification pursuant to regulation 11(1) on the date he submitted the notification pursuant to this sub-paragraph, save that regulation 24 shall apply as modified in accordance with paragraph 10.

(3) Where a person had notified the Executive of his intention to undertake an activity involving the genetic modification of organisms other than micro-organisms in accordance with regulation 9(1) of the 1992 Regulations but immediately before the relevant date that person was not entitled under the 1992 Regulations to undertake that activity for any reason other than the reason referred to in sub-paragraph (4), the provisions of these Regulations shall apply as if that person had submitted a notification in accordance with regulation 12 on the relevant date, save that regulation 24 shall apply as modified in accordance with paragraph 10.

(4) The reason referred to in sub-paragraphs (1), (2) and (3) is that the Executive has informed the person who submitted the notification in question that he may not commence the activity involving genetic modification to which the notification relates.

(5) Where a person submits a notification in accordance with this paragraph, he shall at the same time provide the competent authority with a short description of the activity involving genetic modification to which the notification relates.

Duties on receiving notifications and additional information

6 Regulation 14(1) to (5) shall apply to a notification submitted pursuant to the 1992 Regulations which, by virtue of paragraph 4 of this Schedule, is treated as satisfying the requirements of these Regulations as it applies to a notification submitted pursuant to these Regulations.

Additional provisions relating to notification

7 Regulation 15 shall apply in cases where a notification has been submitted pursuant to regulation 8 or 9 of the 1992 Regulations as it applies where a notification has been submitted pursuant to these Regulations.

Emergency plans

8 Where before the relevant date a person had ensured that a plan had been prepared in accordance with regulation 13 of the 1992 Regulations, that plan shall be treated as satisfying the requirements of regulation 20, provided that, immediately following the assessment to be carried out in accordance with paragraph 2, the plan is reviewed and, where necessary, revised pursuant to regulation 20(3).

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Disclosure of information

9 Regulations 22 and 23 shall apply to information notified or provided under the 1992 Regulations as they apply to information notified under these Regulations.

Register of notifications

10 (1) Subject to sub-paragraph (2), regulation 24 shall apply to a notification submitted in accordance with paragraphs 3,4 and 5 as it applies to a notification submitted in accordance with regulations 9(1), 10(1), 11(1) and 12(1).

(2) Paragraphs (2), (3) and (4) of regulation 24 shall not apply to a notification submitted in accordance with paragraphs 3, 4 and 5 and shall be replaced by the following provisions, namely -

(a) in relation to a notification submitted in accordance with paragraph 3, the register shall contain the name and address of the person who submitted that notification, and the reference number given by the Executive to the notification under the 1992 Regulations of the premises in question;
(b) in relation to a notification submitted in accordance with paragraph 4, the register shall contain -

(i) the name and address of the person who submitted that notification,
(ii) a short description of the activity involving genetic modification to which the notification relates, and any reference number given by the Executive to the notification of that activity under the 1992 Regulations,
(iii) the date on which any information had been notified under regulation 10(4) of the 1992 Regulations, and
(iv) where appropriate, confirmation that a consent has been granted under paragraph 4(2)(b); and

(c) in relation to a notification submitted in accordance with paragraph 5, the register shall contain -

(i) the name and address of the person who submitted that notification,
(ii) a short description of the activity involving genetic modification to which the notification relates, and any reference number given by the Executive to the notification of that activity under the 1992 Regulations,
(iii) the date on which any information had been notified under regulation 10(4) of the 1992 Regulations, and
(iv) where appropriate, confirmation that a consent has been granted under paragraph 11(3) or 11(4).

(3) The competent authority shall include in the register -

(a) by 15th March 2001, the information referred to in sub-paragraph (2)(a);
(b) by 15th April 2001, the information referred to in sub-paragraph (2)(b); and
(c) within fourteen days of the receipt of a notification submitted under paragraph 5, the information referred to in sub-paragraph 2(c).

Reference to previous notification

11 Where a person submits a notification in accordance with paragraph 3, 4 or 5, he shall at the same time provide the competent authority with the following information -

(a) his name, address and telephone number and any fax number and any e-mail address; and either

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(b) in the case of a notification submitted in accordance with paragraph 3 -

(i) the date of,
(ii) any reference number given by the Executive to, and
(iii) the date of any information notified to the Executive under regulation 10 of the 1992 Regulations relating to,

the notification in question submitted under regulation 8(1) of the 1992 Regulations; or

(c) in the case of a notification submitted in accordance with paragraph 4 or 5 -

(i) the date of,
(ii) any reference number given by the Executive to, and
(iii) the date of any information notified to the Executive under regulation 10 of the 1992 Regulations relating to,

the notification in question submitted under regulation 9(1) of the 1992 Regulations.

Schedule 11 Appeals

Schedule

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Regulation 29

Part I

1 In this Schedule -

(a) "appeal" means an appeal under regulation 29;

"appellant" means a person who has brought an appeal;

"appointed person" means a person appointed in accordance with paragraph 2;

"appropriate person" has the same meaning as in regulation 29;

"authority" means the competent authority in the case of an appeal under regulation 29(1), (2)(c) or (3) and the Executive in the case of an appeal under regulation 29(2)(a) or (b);

"hearing" means a hearing to which Part II of this Schedule applies;

"the parties" means the appellant and the authority;

"site" means premises at which the activity involving genetic modification to which the appeal relates is, or is proposed to be, undertaken; and

(b) a reference to a numbered sub-paragraph is a reference to the sub-paragraph so numbered in the paragraph in which that reference occurs.

2 The appropriate person shall direct that an appeal shall be determined by a person appointed by him for the purpose and the appropriate person shall notify the parties in writing of the name of the appointed person.

3 Before the determination of an appeal, the appointed person shall ask the parties whether they wish to appear and be heard on the appeal and -

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(a) the appeal may be determined without a hearing of the parties if both of them express a wish not to be heard as aforesaid;
(b) the appointed person shall, if either of the parties expresses a wish to appear and be heard, afford both of them an opportunity of so doing, in which case the provisions of Part II of this Schedule shall apply.

4 An appointed person may give such directions as he thinks appropriate to give effect to his determination.

5 The appropriate person may pay to an appointed person such remuneration and allowances as the appropriate person may, with the approval of the Minister for the Civil Service, determine.

Part II

6 An appeal brought pursuant to regulation 29(3) shall be heard in private.

7 (1) Subject to the following sub-paragraphs of this paragraph, a date, time and place for the holding of the hearing shall be fixed, and may be varied, by the appointed person, who shall give not less than 42 days' notice in writing of such date, time and place to the parties.

(2) With the consent of the parties, the appointed person may give such lesser period of notice as shall be agreed with the parties and in that event he may specify a date for service of the statement referred to in paragraph 8(1) later than the date determined in accordance with that paragraph.

(3) Where it becomes necessary or advisable to vary the time or place fixed for the hearing, the appointed person shall give such notice of the variation as may appear to him to be reasonable in the circumstances.

(4) Without prejudice to the foregoing provisions of this paragraph, the appointed person may require the authority to take one or more of the following steps, namely: -

(a) to publish in one or more newspapers circulating in the locality in which the site is situated such notice of the hearing and in such form as he may direct;
(b) to serve such notice of the hearing, in such form and on such persons or classes of persons as he may direct;
(c) to give such other notice of the hearing and in such form as he may direct,

and the requirements as to the period of notice contained in sub-paragraph (1) shall not apply to any such notices.

8 (1) Not later than 28 days before the date of the hearing, or such later date as the appointed person may specify in accordance with paragraph 7(2), the authority shall serve on the appellant a written statement of any submission which the authority proposes to put forward at the hearing and shall supply a copy of the statement to the appointed person.

(2) Where a government department has expressed in writing to the authority a view in support of the decision of the authority and the authority proposes to rely on such expression of view in its submission at the hearing, the authority shall include the expression of view in its statement and shall supply a copy of the statement to the government department concerned.

(3) Where the authority intends to refer to or put in evidence at the

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hearing, documents (including photographs, maps and plans), the statement of the authority shall be accompanied by a list of such documents, together with a written notice stating the times and place at which the documents may be inspected by the appellant; and the authority shall afford the appellant a reasonable opportunity to inspect and, where practicable, to take copies of the documents.

(4) If so required by the appointed person, the appellant shall -

(a) serve on the authority and on the appointed person, within such time before the hearing as the appointed person may specify, a written statement of the submissions which he proposes to put forward at the hearing; and such statement shall be accompanied by a list of any documents (including photographs, maps and plans) which the appellant intends to refer to or put in evidence at the hearing; and

(b) afford the authority a reasonable opportunity to inspect and, where practicable, to take copies of such documents as are referred to in the foregoing provision.

9 (1) The parties shall be entitled to appear at the hearing.

(2) Any other person may appear at the discretion of the appointed person provided that he has, not later than 7 days before the date of the hearing, served on the authority a statement of his proposed submissions.

(3) The authority shall send a copy of every statement served on it in accordance with sub-paragraph (2) to the appointed person and to the appellant.

(4) A body corporate may appear by its clerk or secretary or by any other officer appointed for the purpose by that body, or by counsel or a solicitor.

(5) A person may appear on his own behalf or be represented by counsel, a solicitor or any other person.

(6) Where there are two or more persons having a similar interest in the subject matter of the hearing, the appointed person may allow one or more persons to appear for the benefit of some or all persons so interested.

10 (1) Where a government department has expressed in writing to the authority a view in support of the decision of the authority and the authority has included this view in the statement referred to in paragraph 8(1), the appellant may apply in writing to the appointed person, not later than 14 days before the date of the hearing, for a representative of the government department concerned to be made available at the hearing.

(2) The appointed person shall send any application made to him under sub-paragraph (1) to the government department concerned who shall make a representative of the department available to attend the hearing.

(3) A representative of a government department who, in pursuance of this paragraph, attends a hearing shall be called as a witness by the authority and shall state the reasons for the view expressed by his department and included in the statement of the authority under paragraph 8(1) and shall give evidence and be subject to cross-examination to the same extent as any other witness.

(4) Nothing in the last foregoing paragraph shall require a representative of a government department to answer any question which in the opinion of the appointed person is directed to the merits of government policy or to

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matters which affect the safety of the State and the appointed person shall disallow any such question.

11 (1) Except as otherwise provided in this Part of this Schedule, the procedure at the hearing shall be such as the appointed person shall in his discretion determine and the appointed person shall -

(a) state at the commencement of the hearing the procedure which, subject to consideration of any submission by the parties, he proposes to adopt; and
(b) shall inform the parties what he proposes as regards any site inspection arising out of the hearing.

(2) Unless in any particular case the appointed person with the consent of the appellant otherwise determines -

(a) in the case of an appeal to the Secretary of State, the appellant shall be heard first and shall have the right of final reply; and
(b) in the case of an appeal to the Secretary of State and the Scottish Ministers acting jointly -

(i) the appellant shall be heard first,
(ii) the other persons entitled or permitted to appear shall be heard in such order as the appointed person may determine, and
(iii) any closing statements shall be made in the same order, unless the appointed person otherwise determines.

(3) The parties shall be entitled to make an opening statement, to call evidence and to cross-examine persons giving evidence, but any other person appearing at the hearing may do so only to the extent permitted by the appointed person.

(4) Subject to sub-paragraph (5), any evidence may be admitted at the discretion of the appointed person, who may direct that documents tendered in evidence may be inspected by any person entitled or permitted to appear at the hearing and that facilities be afforded him to take or obtain copies thereof.

(5) The appointed person shall not require or permit the giving or production of any evidence, whether written or oral, which would be contrary to the public interest.

(6) The appointed person may allow the authority or the appellant, or both of them, to alter or add to the submissions contained in any statement served under paragraph 8(1) or (4), or to any list of documents which accompanied such statement, so far as may be necessary for the purpose of determining the questions in controversy between the parties, but shall (if necessary by adjourning the hearing) give the appellant or the authority, as the case may be, an adequate opportunity of considering any such fresh submission or document.

(7) If any person entitled to appear at the hearing fails to appear, the appointed person may proceed with the hearing at his discretion.

(8) The appointed person shall be entitled (subject to disclosure thereof at the hearing) to take into account any written representations or statements received by him before the hearing from any person.

(9) The appointed person may from time to time adjourn the hearing, and where he does so, shall give reasonable notice to every person entitled or permitted to appear at the hearing of the date, time and place of the adjourned hearing.

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12 (1) The appointed person may make an inspection of the site before or during the hearing after having given notice to the parties of the date and time at which he proposes to do so.

(2) The appointed person may, and shall if so requested by either party before or during the hearing, inspect the site after the close of the hearing and, in all cases where he intends to make such an inspection, shall announce during the hearing the date and time at which he proposes to do so.

(3) The parties shall be entitled to accompany the appointed person on any inspection under this paragraph, but the appointed person shall not be bound to defer his inspection if any person entitled to accompany him is not present at the time appointed.

13 (1) Where, after the close of the hearing, the appointed person proposes to take into consideration -

(a) any new evidence, including expert opinion on a matter of fact; or
(b) any new issue of fact, not being a matter of government policy or a matter affecting the safety of the State,

which was not raised at the hearing and which he considers to be material to his decision, he shall not come to a decision without first notifying the parties of the substance of the new evidence or of the new issue of fact and affording them an opportunity of making representations thereon in writing within 21 days or of asking within that time for the re-opening of the hearing.

(2) If he thinks fit, the appointed person may cause the hearing to be re-opened and shall cause it to be re-opened if asked to do so in accordance with sub-paragraph (1).

(3) Where the hearing is re-opened, paragraphs 7(1) and 7(4) shall apply as they applied to the original hearing with the substitution in paragraph 7(1) of “28” for “42”.

14 The appointed person shall notify the decision on the appeal, and the reasons therefor, in writing to the parties and to any person who, having appeared at the hearing, has asked to be notified of the decision.

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Appendix 1 European risk assessment guidance

The amended Contained Use Directive requires the European Commission to produce risk assessment guidance to further explain and underpin the risk assessment procedure set out in Annex III to the Directive. The guidance has to be formally adopted by a qualified majority of Member States under a regulatory committee procedure. The deadline for completion of the guidance was 5 June 2000. Unfortunately the timing has meant that the guidance cannot be included in this publication. However, once it is available, it will be circulated to all GM centres, and others who may be interested, via the ACGM Newsletter.

Appendix 2 Contents list of ACGM compendium of guidance

- Preface
- Acronyms
- Part 1 - Risk assessment of contained use activities involving genetic modification: interaction with other legislation
- Part 1A - Health and Safety legislation
- Part 1B - Environmental Protection legislation
- Part 2 - Risk assessment of genetically modified organisms
- Part 2A - Risk assessment of genetically modified micro-organisms other than eukaryotic viruses
- Part 2B - Risk assessment of genetically modified human and animal viruses and viral vectors
- Part 2C - Risk assessment of genetically modified plant viruses
- Part 2D - Risk assessment of work with genetically modified plants
- Part 2E - Risk assessment of activities involving genetically modified animals
- Part 3 - Regulatory requirements for determining GMO containment and control measures and general guidance
- Part 3A - Selection of containment and control measures for laboratory and large scale activities involving GMMs
- Part 3B - Selection and containment and control measures for work with genetically modified plants
- Part 3C - Selection of containment and control measures for activities involving plants infected or associated with GMMs.
- Part 3D - Selection of containment and control measures for activities involving genetically modified animals.
- Part 3E - Selection of containment and control measures for animals infected with, or in association with genetically modified micro-organisms.

Appendix 3 Example risk assessments

[The format used for these examples is *not* generally recommended for normal use: they are designed to *illustrate* the process rather than to provide a suitable standardised format]

The following examples are designed to show:

- the requirements of the Contained Use Regulations as regards matters to be considered and the steps that must be included in a risk assessment; and
- classification of activities involving GMMs (which forms part of the risk assessment.)

It should be noted that the risk assessments are presented in a somewhat artificial way to more clearly illustrate the process; so technical detail and justification have been kept to a minimum. 'Real' risk assessments should be 'suitable and sufficient' with the appropriate level of detail included.

Note that it is expected that statements will be justified. This may be by use of suitable references to the scientific literature.

The example risk assessments should not appear radically different from those prepared following previous editions of the ACGM Compendium. One point of difference is that the bacterial example given does not use the 'Access', 'Expression' and 'Damage' system of assessment (sometimes referred to as the 'Brenner' system). This is because the approach does not now fulfil the requirements of the Contained Use Regulations in terms of both procedure and matters to consider. That said, if you wish to use 'Access', 'Expression' and 'Damage', in addition to the procedure now required, you are free to do so.

E. coli K-12 derivative (eg DH5α) expressing human growth hormone

Overview

(Not required by the legislation - but useful to set the scene)

The aim of the project is to clone and express the human growth hormone in an *E. coli* K-12 derivative, DH5α. The insert will be carried on the vector pUC 18. The construct will be grown at a pilot plant scale of 200 litres.

Hazard identification in respect of human health and environmental safety. (Consider host, vector, insert and final GMM.)

E. coli K-12 derivatives, such as, DH5α, are recognised as non-colonising and disabled, and may be considered to be equivalent to ACDP biological agents hazard group 1. They are not considered pathogenic to humans or animals. They are expected to have limited survivability in the environment and often have auxotrophic requirements, which are unlikely to be satisfied outside laboratory culture.

The vector pUC 18 is considered to be non-mobilisable. It has a safe history of use. The marker gene codes for an antibiotic which is not used clinically.

Estimation of the severity or consequence of the harmful effect were it to occur.

The human growth hormone is expressed as a fusion protein, which forms insoluble inclusion bodies within bacterial cells. The initially expressed product is thus biologically inactive and it requires treatment by several *in vitro* laboratory steps to produce active protein *(reference or supporting data required)*. Therefore, while human growth hormone could exert harmful effects if delivered in a biologically active form, for the purposes of the risk assessment, the expressed gene product can be considered non-harmful.

Provisional containment level (in particular taking account of the biological agents hazard group and other classification scheme for pathogens.)

The cloned protein is unlikely to alter the pathogenicity of the cloning host, and is likely to reduce its survivability/fitness. The host is biological agents hazard group 1, for which containment level 1 is appropriate.

This step will often involve considering the containment level necessary to control the risk of the host and making a judgement about whether the modification will result in a GMM which is more hazardous, less hazardous or about the same. Sometimes it might help to compare the GMM with the relative hazard presented by other organisms.

Provisional containment level 1

Environment and activity considerations.

This includes an estimation of the likelihood that hazards will be realised. Given that the provisional containment level has already been decided, it helps to bear this in mind when deciding how likely a harmful event is.

The genetically modified micro-organism (GMM) is being grown at large scale (200 litres), under mono-septic conditions. It is being grown in a closed stainless steel fermenter, and will be harvested by centrifugation. The paste will be passed through a cell disrupter, and the insoluble inclusion bodies harvested. The centrate, containing cell debris and a low titre of viable cells will be heat-inactivated and discharged.

E. coli K-12 derivative (eg DH5α) expressing human growth hormone (continued)

Use these considerations of likelihood to revise the provisional containment level so that all risks are controlled to low or effectively zero.	Although the fermenter will be completely contained, with appropriate seals being used and with off-gases being filtered, these measures are primarily to prevent contamination, and are in excess of what would be required for the purposes of protection of human health or the environment.
Double check that all hazards are properly controlled by the proposed containment.	In the event of spillage from the fermenter, the area can be effectively disinfected. The fermenter is housed within a process building, and the wider environment is unlikely to become contaminated.
Assign activity Class.	For laboratory operations a standard containment level 1 facility, and the use of good microbiological practice will be sufficient to limit contact with humans and the environment.
This is done by comparing the containment and control measures identified as necessary *to control the risk* with the tables of containment in Schedule 8 to the Regulations.	For the large-scale operations, the process equipment used will be sufficient to limit contact. The organism is unlikely to cause harm to either workers or the environment, so filtration of the off-gases and the use of a closed system are not required as safety measures. None of the measures in containment level 2 of Table 2 (of Schedule 8) for safety reasons, even though they will be used for process reasons. **The activity is therefore Class 1**

1 In all examples *E.coli* denotes *Escherichia coli*.

Construction of an adenoviral vector with a modified tissue tropism

Overview

(Not required by the legislation - but useful to set the scene)

The aim of this project is to develop a replication competent adenoviral vector with a modified fibre gene which targets the virus to leukaemic cells. The long-term aim is to use the virus in the treatment of leukaemia.

Hazard identification in respect of human health and environmental safety. (Consider host, vector, insert and final GMM.)

The vector under development will be based on adenovirus serotype 5 (Ad5). Ad5 is a respiratory pathogen and in vivo infections are generally limited to the epithelial cells lining the respiratory tract. Unmodified Ad5 is classified in biological agents hazard group 2. Ad5 is generally associated with mild respiratory infections in children, and it is thought that the majority of the population is likely to have antibodies to the wild-type virus *(reference or supporting data required)*.

Estimation of the severity or consequence of the harmful effect were it to occur.

Cells that are susceptible to adenovirus carry the receptor protein CAR. Spikes that protrude from the adenovirus capsid surface are responsible for the initial interaction of the virus with host cells. The end of each spike is folded into a knob domain that specifically interacts with CAR. The protein which forms these spikes is the viral fibre protein and the gene encoding this protein is a prime target for attempts to modify the tissue tropism of adenoviral vectors.

There are some cell types (eg lymphocytes and smooth muscle cells) on which CAR is either absent or present at very low levels. Existing adenoviral vectors are not suitable for gene transfer into such cells. This has stimulated efforts to redirect the adenovirus tropism from its natural receptor to specifically selected surface proteins.

The basis of the project is the knowledge that there is a particular protein that is expressed at very high levels on the surface of leukaemic cells which is an attractive target for viral gene therapy. This protein is also expressed at a lower but significant level on the surface of normal lymphocytes.

The project will involve the replacement of the fibre gene with a modified version in which the sequence in the knob region has been modified. The modification of the knob region will involve the insertion of a binding site for the protein that is present at high levels on the surface of leukaemic cells. This will mean that the virus should have a broadened tissue tropism *in vivo*. It is predicted that the construct will target with high efficiency a surface protein that is expressed at high levels in leukaemic cells. However, this surface protein may also be present at lower levels on normal lymphocytes. Therefore, the construct may infect normal lymphocytes at a higher efficiency than wild-type adenovirus, which does not normally infect blood cells *in vivo*.

It is not thought that the modified virus would pose a serious risk to the environment. There is no evidence that human adenoviruses can infect animals, and replication is only seen at low levels *in vitro*, for example in mouse cell lines *(reference or supporting data required)*. The virus is however, non-enveloped and relatively resistant to desiccation. The main environmental risk would be to susceptible children. The containment measures in place should minimise any risk.

Provisional containment level (in particular taking account of the biological agents hazard group and other classification scheme for pathogens.)

This step will often involve considering the containment level necessary to control the risk of the host and making

Although the unmodified virus is biological agents hazard group 2, the modified virus is potentially more hazardous.

Provisional containment level 3.

Construction of an adenoviral vector with a modified tissue tropism (continued)

a judgement about whether the modification will result in a GMM which is more hazardous, less hazardous or about the same.

Environment and activity considerations.

This includes an estimation of the likelihood that hazards will be realised. Given that the provisional containment level has already been decided, it helps to bear this in mind when deciding how likely a harmful event is.

The modified virus may not be transmissible through the airborne route, although there is no scientific certainty that this will be the case. In light of the discussions above, and the fact that the virus will be replication-competent, it is appropriate for all manipulations involving this virus to be undertaken within a safety cabinet in a laboratory where access is restricted to authorised personnel only. Moreover, staff would need to be specifically trained in the safety aspects of this work with written training records being kept. An inward airflow would be required and the laboratory would have to be sealable for fumigation. All waste materials should be autoclaved, with the autoclave situated within the laboratory or in the laboratory suite. Appropriate, validated disinfectants should be used to decontaminate exposed work areas. These containment and control measures will protect both the workers and the environment.

Use these considerations of likelihood to revise the provisional containment level so that all risks are controlled to low or effectively zero.

Double check that all hazards are properly controlled by the proposed containment.

Assign activity Class.

This is done by comparing the containment and control measures identified as necessary *to control the risk* with the tables of containment in Schedule 8 to the Regulations.

The requirements for a microbiological safety cabinet to be used for all operations and for the laboratory to have inward airflow and to be sealable for fumigation are all features of level 3 containment. Restricting access to authorised personnel, requiring written training records, and an autoclave in the laboratory/laboratory suite further confirm that level 3 is appropriate.

Full containment level 3 will be applied, final classification Class 3, Notification and consent required.

Genetic manipulation of foot-and-mouth disease virus

Overview

(Not required by the legislation - but useful to set the scene)

The aim of the project is to introduce mutations into foot and mouth disease virus (FMDV) to study the function of targeted genes.

Hazard identification in respect of human health and environmental safety.
(Consider host, vector, insert and final GMM.)

Live FMDV will be recovered from full-length cDNA clones of the RNA genome. Critical residues will be mutated, and the effect on the recovered virus will be analysed.

The FMDV can be considered to be both the host and the vector.
FMDV is an Aphthovirus, and is predominantly considered to be an animal pathogen. It is classified as requiring MAFF containment level 4. It infects most species of domestic and wild cloven-hooved animals, such as cattle, pigs and deer, as well as rodents. It is highly infectious through ingestion and the airborne aerosol route. Symptoms include fever and the formation of vesicles on the feet and mouth.

Infection in humans has been reported, and some cases of laboratory acquired infection recorded. Symptoms in humans are generally mild, and include fever and malaise, followed by blistering around the mouth and feet. Full recovery is normal.

The modifications being made to the virus involve mutating, or introducing deletions into genes to study function in vitro. At a later stage, these constructs may be introduced into animals; however, a separate notification will be made for such studies. The modifications are expected to have an adverse effect on the virus, reducing its fitness (*reference or supporting data required*). However, as the studies are aimed at elucidating the function of genes, it cannot be certain that all modifications will lead to a less harmful virus.

Estimation of the severity or consequence of the harmful effect were it to occur.

The main concern with FMDV is environmental. It causes serious disease in animals, and severe economic losses in terms of meat and milk production. Human exposure can lead to symptoms, but not serious disease. It has a history of safe use. The marker gene codes for an antibiotic which is not used clinically.

Provisional containment level (in particular taking account of the biological agents hazard group and other classification scheme for pathogens.)

This step will often involve considering the containment level necessary to control the risk of the host and making a judgement about whether the modification will result in a GMM which is more hazardous, less hazardous or about the same.

FMDV is a MAFF Category 4 pathogen. The containment requirements are aimed primarily at protecting the environment through preventing escape of pathogens from the laboratory, rather than protecting the health of workers.

However, all work with live virus should be carried out in a safety cabinet to reduce worker exposure. Air from the laboratory should be extracted via two HEPA filters in series, and the supply air filtered through a single HEPA filter. Entrance to and exit from the facility should be via an airlock which should be ventilated through an air exhaust system. The laboratory must be maintained at negative pressure; a full change of clothes must be worn, all waste must be autoclaved through a double ended autoclave; the laboratory must be sealable for fumigation.

It is not thought that the modifications will increase the pathogenicity of the virus, so additional measures above those for the wild type virus are not required.

Provisional containment level 4

Environment and activity considerations.

This includes an estimation of the likelihood that hazards will be realised. Given that the provisional containment

If all the precautions listed as MAFF containment level 4 are implemented, it is unlikely that the environment surrounding the facility will be exposed to the virus, and the risk can be considered to be effectively zero. There is a possibility that workers could transmit the virus from the laboratory, and it could be spread into the wider environment. The use of gloves, safety cabinets, showering out, as well as local rules on contact with animals should mitigate this.

Genetic manipulation of foot-and-mouth disease virus (continued)

level has already been decided, it helps to bear this in mind when deciding how likely a harmful event is.	
Use these considerations of likelihood to revise the provisional containment level so that all risks are controlled to low or effectively zero.	As the virus is not considered to be a serious human pathogen, a Class III cabinet is not considered necessary for handling live virus.
Double check that all hazards are properly controlled by the proposed containment.	The virus is primarily an animal pathogen, and protection of the environment is the primary concern. Full implementation of the MAFF level 4 containment should protect the environment.
Assign activity Class. This is done by comparing the containment and control measures identified as necessary to control the risk with the tables of containment in Schedule 8 to the Regulations.	A number of the key containment measures required for handling the virus are consistent with those in containment level 4 - the filtering of input and extract air, the complete change of clothing, and the double-ended autoclave The operation should therefore be notified as a class 4 activity. Full level 4 (such as the use of a Class III cabinet) may not be required, as the virus is not a serious human pathogen and written permission not to implement all of the measures listed as containment level 4 must be obtained from the regulatory authorities. **Class 4, but seek permission not to apply full level 4 containment.**

Genetic modification of pathogenic plant RNA viruses

Overview

(Not required by the legislation - but useful to set the scene)

The aim of the project is to construct viral chimeras containing genes from pea early browning (PEBV) and tobacco rattle virus (TRV) to determine which genes are involved in symptom elicitation. Full-length cDNAs will be cloned into *E. coli* strain DH5α using the vector pUC 18. Sections will be replaced by genes from heterologous isolates. Infectious transcripts will be produced and susceptible plants will be infected with either the transcripts or the plasmids.

Hazard identification in respect of human health and environmental safety. (Consider host, vector, insert and final GMM.)

E. coli K-12 derivatives, such as DH5α, are recognised as non-colonising and disabled, and may be considered to be equivalent to ACDP hazard group 1. They are not considered pathogenic to humans or animals. They are expected to have limited survivability in the environment and often have auxotrophic requirements which are unlikely to be satisfied outside laboratory culture.

The vector pUC 18 is considered to be non-mobilisable. It has a history of safe use. The marker gene codes for an antibiotic which is not used clinically.

The viral inserts are unlikely to be harmful to humans or animals; however, both viruses cause disease to plants. Both are tobraviruses and are already present in the UK *(reference or supporting data required)*. The disease symptoms caused are mild. Both viruses are normally transmitted by nematodes and are not transmitted by insects *(reference or supporting data required)*.

The modified viruses are likely to be less fit than wild-type; however, the chimeras may have novel properties which could alter pathogenicity.

Estimation of the severity or consequence of the harmful effect were it to occur.

Both viruses cause mild symptoms. The modified viruses are likely to be less fit than wild-type and unlikely to alter the route of transmission, although this cannot be ruled out. The greenhouse is free from nematodes, so transmission via this route is unlikely.

Provisional containment level (in particular taking account of the biological agents hazard group and other classification scheme for pathogens.)

This step will often involve considering the containment level necessary to control the risk of the host and making a judgement about whether the modification will result in a GMM which is more hazardous, less hazardous or about the same.

A MAFF licence is required for both viruses, and although no classification system is generally used for viruses, conditions for use are included in the licence conditions.

Access to the facility must be restricted to authorised personnel only, and contaminated run-off water must be contained to prevent run-off. Both of these measures are features of containment level 2.

E. coli parts of the project will be carried out in a standard laboratory, whilst work with whole plants will be undertaken in a secure level 2 glasshouse.

Effective vector control is required, and the facility should afford secure containment. Transport of waste from the facility for destruction etc. must be in secure closed containers.

Provisional containment level 2.

Genetic modification of pathogenic plant RNA viruses (continued)

Environment and activity considerations.

This includes an estimation of the likelihood that hazards will be realised. Given that the provisional containment level has already been decided, it helps to bear this in mind when deciding how likely a harmful event is.

Use these considerations of likelihood to revise the provisional containment level so that all risks are controlled to low or effectively zero.

Double check that all hazards are properly controlled by the proposed containment.

The viruses are plant pathogens, and protection of the environment is the primary concern. Close adherence to standard operating procedures (SOPs), training of staff, and rigorous implementation of containment measures should protect the environment.

Assign activity Class.

This is done by comparing the containment and control measures identified as necessary *to control the risk* with the tables of containment in Schedule 8 to the Regulations.

The containment measures required for handling the viruses are consistent with those in containment level 2. The operation should, therefore, be notified as a class 2 activity.

Final activity classification: Class 2

Appendix 4 Format for information to be supplied with accident notification

1 *General data*

Date and time of the accident:

Name and address of person responsible for carrying out the activity:

.....

.....

Address of premises where activity is carried out:

.....

.....

Principal activity of installation

.....

.....

Classification of activity (Class 1, 2, 3 or 4).....

2 *Type of accident*

Failure of equipment (breakage/leakage etc)

Fire

Explosion

Maloperation of equipment (human/mechanical)

Other (specify).....

3 *Organisms involved*

Identity of genetically modified organisms involved:

Approximate quantity of genetically modified organisms involved:

Form and/or concentration in which organisms involved:

4 *Description of the circumstances of the accident*

5 *Was there any emergency plan drawn up in advance?*

Yes No

If yes, by whom?.....

6 *Emergency measures taken*

(a) Inside the installation.....

.....

(b) Outside the installation .....

.....

7 *Assumed or established cause(s) of accident* (If not known, information should be supplied as soon as possible).

8 *Nature and extent of exposure*

(a) Within the installation: provide information on the following:

- persons exposed to the accident
- casualties
- damage to health
- material damage
- damage affecting the containment equipment
- whether the danger is still present
- if danger still exists, it should be specified

(b) Outside the installation / to the environment: provide information on the following:

- persons exposed to the accident
- casualties
- damage to health
- types of environments exposed (water, sewage systems, agricultural land, natural environments)
- material damage
- damage affecting the containment equipment
- damage to the environment
- whether the danger is still present
- if danger still exists it should be specified

9 *Member States already informed bilaterally of the accident*

Appendix 5 Notification forms (not mandatory)

HSE
Health & Safety Executive

Premises notification

The Genetically Modified Organisms (Contained Use) Regulations 2000

Notification of intention to use premises for contained use activities

- The public register sections MUST be understandable without reference to the risk assessment or other supporting documents.
- Please return your completed form to the Health and Safety Executive at the address given in Notes for Guidance.
- Please do not feel constrained by the box sizes - expand them or continue on separate sheets if necessary.
- Important - please refer to Notes for Guidance where identified.

FOR HSE USE ONLY									
GM centre reference: GM			Date notification acknowledged: / /20			Date premises ceased to be used for GM / /20			Public Register
Dates on which additional information submitted									
Date on which accident notification submitted									

1. Name of organisation (Note 1)

Address

Telephone number

Fax number

e: mail

Public Register

2. Address(es) of the premises where the activities will actually be conducted (if different from that at Section 1). (Note 2)

Public Register

3. Tick to confirm that you have established a genetic modification safety committee to advise on risk assessments of contained use activities ☐

Give brief details of the genetic modification safety committee **(Note 3)**

Public Register

4. Please indicate the nature of the premises, or sections of the premises, where the contained use activities are to be carried out. (Tick all applicable). (Note 4)

	Laboratory	Animal Unit	Growth room	Glasshouse	Large scale (ie activities to which Table 2 of Schedule 8 is appropriate)
Level 1 (GMMs)					
Level 2 (GMMs)					
Level 3 (GMMs)					
Level 4 (GMMs)					
Non-microbial, eg work with transgenic plants or animals					
Other (please specify)					

Public Register

5. Nature of work to be undertaken at the premises. (Tick all boxes which apply). (Note 5)

i. Bacteriology ☐
ii. Virology ☐
iii. Mycology ☐
iv. Parasitology ☐
v. Transgenic animals ☐
vi. Transgenic invertebrates ☐
vii. Transgenic birds ☐
viii. Transgenic fish ☐
ix. Transgenic plants ☐
x. Microbiology research ☐
xi. Gene therapy ☐
xii. Other (please specify) ☐

Public Register

6. For Class 1 activities involving GMMs, describe the waste management measures which you will apply to the activity. (Notes 6 & 7)

Public Register

7. Please tick to confirm that you are attaching a summary of the risk assessment for Class 1 activities involving GMMs or non - notifiable activities involving non-micro-organisms (Notes 6 & 8) ☐

(Please tick if you are claiming exemption from disclosure for sections of the risk assessment ☐)

Public Register

8. Please enter comments of the genetic modification safety committee on the risk assessment (Notes 6 & 9)

Public Register

PERSONAL INFORMATION Premises notification

9. Name of person responsible for supervision and safety of GM activities at the premises.

Training and qualifications

Telephone No Fax No e:mail

Confidential Information

10. Name of the Biological Safety Officer (if any). (Note 10)

Training and qualifications

Confidential Information

Address (if different from that in section 1)

Telephone No Fax No e:mail

Confidential Information

11. Contact name - if different from Biological Safety Officer (or other named person). (Note 11)

Address (if different from that in section 1)

Telephone No Fax No e:mail

Confidential Information

12. Please enter in this section any information required in sections 1 - 8 for which you are claiming confidentiality, together with full justification for that claim. (Note 12)

Confidential Information

Confidential Information

Confidential Information

13. Declaration

I am notifying an intention to use premises for contained use of genetically modified organisms with the authority and approval of the person (organisation or individual) named in section 1 of this form.

Name

Position in organisation

Signed **(Note 13)** Date

THE GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS 2000 NOTIFICATION OF INTENT TO USE PREMISES FOR CONTAINED USE ACTIVITIES

Notes for Guidance

Data Protection Act 1998

This Act requires the Health and Safety Executive (HSE) to inform you that this form may include information about you (this is called "personal data" in the Act) and that we are a "data controller" for the purposes of the Act. HSE will process the data for health, safety and environmental purposes. HSE may disclose these data to any person or organisation for the purposes for which they were collected or where the Act allows disclosure. As data subject, you have the right to ask for a copy of the data and to ask for any inaccurate data to be corrected.

All the information given in sections 1 to 8 of this form will be placed on HSE's public register of notifications within 14 days of receipt. You may consider that there is information relevant to these sections whose disclosure would harm your organisation's competitive position or which you wish to keep confidential on other grounds referred to in regulation 22(2); please see paragraph 126 of the Guide to the Regulations. If so, you should enter such information in section 12 with a full justification for its exemption from disclosure.

Subject to the following paragraph, there are some sections for which you must provide at least some information for disclosure. This is because the Regulations specify certain categories of information for which exemption from disclosure cannot be claimed on any grounds other than, exceptionally, harm to intellectual property rights. It should always be possible to provide information in these categories without risk of harm to competitive position or any of the other grounds referred to in regulation 22(2). If there are particular details, necessary for evaluation of the notification, for which you wish to claim confidentiality, these should be entered in section 12 with the necessary justification.

You may request exemption from disclosure for any information if you can demonstrate that it is necessary to protect your intellectual property rights. Such information should be entered in section 12 with a full justification for its exemption from disclosure.

Personal information will not be disclosed unless the individual concerned has given his or her explicit written permission.

Note 1
This will normally be the University, Institution, Company or Organisation. Only rarely will it be necessary to include an individual's name.

Note 2
If you intend to carry out activities involving GMMs, you must not leave this section blank unless you are claiming exemption from disclosure to protect intellectual property rights. If you are claiming the precise address of the premises where activities with GM animals or plants are to be carried out as confidential, you must include this, together with the justification, in section 12.

Note 3
NB: In relation to health and safety matters, you must also comply with the Safety Representatives and Safety Committees Regulations 1977 and, where any employees are not in groups covered by trade union safety representatives, you must consult such employees according to the Health and Safety (Consultation with Employees) Regulations 1996.
Brief details of the genetic modification safety committee might include its composition, operating procedures and frequency of meeting. No names of individuals need to be given - refer to job titles, positions and representative functions instead. Any information claimed as confidential should be entered in section 12 together with justification.

Note 4
Please tick all applicable boxes on the grid. Any information claimed as confidential should be entered in section 12 together with justification.

Note 5
Please tick all boxes applicable. Any information claimed as confidential should be entered in section 12 together with justification.

Note 6
If you are notifying your intention to use premises for genetic modification, and the first activity which you intend to undertake is in Class 1 OR is a non-notifiable activity involving non-micro-organisms (ie GM animals or plants), complete sections 6-8. Otherwise go straight to section 9. If the first activity which you intend to undertake is in Class 2, 3 or 4 or a notifiable activity involving GM animals or plants, you should submit a separate activity notification form with this premises notification. In such cases, the fee payable will be only that related to the activity notification.

Note 7
Any information claimed as confidential should be entered in section 12 together with justification.

Note 8
For activities involving GMMs, the risk assessment must cover risks to humans and the environment. For activities involving GM animals and plants, assessment of risks to humans only is required to be sent in. However, note that you are required under Part VI of the Environmental Protection Act 1990 and the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996, as amended, to make an assessment in respect of environmental protection from GM animals and plants. You must keep a record of this assessment but **do not send it in.**
Tick the lower box if any of the sections of the risk assessment are claimed as confidential. The confidential information does not need to be entered in section 12, but justification for any claims of confidentiality must be given with the risk assessment.
The risk assessment will not at present be placed on the public register, but will be open to disclosure (subject to confidentiality provisions). If, as hoped, an electronic public register is set up in the future, this may allow for inclusion of the risk assessment on the register.

Note 9
Any information claimed as confidential should be entered in section 12 together with justification.

Note 10
If the details of the Biological Safety Officer were given at section 9, simply refer.

Note 11
Please give details of the person to whom general correspondence (eg Newsletters issued by the Advisory Committee on Genetic Modification) should usually be sent, if different from the Biological Safety Officer.

Note 12
Please enter in this section any information, required in sections 1-8, which you wish to be exempt from public disclosure on grounds that

a) disclosure would harm your organisation's competitive position; or
b) disclosure would compromise your intellectual property rights; or
c) the information falls into one of the other categories for exemption in regulation 22(2) - state which.

For each piece of information entered you must:

d) state clearly which of the grounds applies. In particular, state which category of exemption allowed by the Environmental Information Regulations 1992, as amended in 1998, applies, namely:-

- international relations, national defence, public security, legal proceedings, confidentiality of deliberation, commercial / industrial confidentiality, intellectual property;

e) indicate the section of the form to which it is relevant; and
f) provide a full justification, explaining why the stated ground for exemption applies.

You do not need to enter any personal information as this will automatically be treated as confidential.

Note 13

Send the completed form to:
Notifications Officer
Health and Safety Executive
Rm 443, TD6
Magdalen House
Stanley Precinct Bootle
Merseyside, L20 3QZ
Tel: 0151 951 4772 Fax: 0151 951 3474

Activity notification

HSE Health & Safety Executive

The Genetically Modified Organisms (Contained Use) Regulations 2000

Notification of intention to conduct individual contained use activities

- The public register sections MUST be understandable without reference to the risk assessment or other supporting documents.
- Please return your completed form to the Health and Safety Executive at the address given in Notes for Guidance.
- Please do not feel constrained by the box sizes - expand them or continue on separate sheets if necessary.
- Important - please refer to Notes for Guidance where identified.

FOR HSE USE ONLY									
GM centre reference: GM			Date notification acknowledged: / / 20			Date activity ceased: / / 20			
Dates on which additional information submitted									
Date on which accident notification submitted									
Consent granted (Class 3/4) *please tick box* ☐									

Public Register

1. Name of organisation (Note 1)

Address

Public Register

Telephone number

Fax number

e: mail

Public Register

2. Date of premises notification (Note 2)

HSE centre number GM

3. Please tick box if notifying a connected programme of work (Note 3) ☐

4. Class(es) of activity - tick all relevant boxes (Note 4)

Class 2 ☐

Class 3 ☐

Class 4 ☐

Activity involving notifiable non-micro-organisms ☐

Public Register

5. Please give a short descriptive title of the activity (or activities)

Public Register

6. Purpose of the contained use (Note 5)

Public Register

7. Characteristics of the GMO(s) including the evaluation of foreseeable effects (Note 6)

Recipient or parental organism

Public Register

Host / vector system

Public Register

Origins and intended functions of the genetic material involved

Public Register

Evaluation of foreseeable effects

Public Register

Public Register

8. Containment and control measures for GMOs that are not micro-organisms (eg GM animals and plants) (Note 7)

Public Register

Public Register

9. Maximum culture volumes per experiment - <u>for GMMs only</u> (Note 8)

(i) Class 2 activities, state approximate culture volume

Public Register

(ii) For Class 3 or Class 4 activities, specify the culture volume

10. For GMMs only, indicate the level of containment that will be applied (please tick appropriate box(es)). (Note 9)

Public Register

	Level 2	Level 3	Level 4
Laboratory activities			
Glasshouses			
Growthrooms			
Animal units			
Large scale activities (ie activities to which Table 2, Schedule 8 containment is appropriate)			
Human clinical applications			

Public Register

11. For GMMs only - application for any derogation from full containment for the Class of activity. (Measures and justification) (Note 10)

Public Register

12. Describe the waste management measures which you will apply to the activity (including the type and form, treatment, ultimate form and fate). (Note 11)

Public Register

13. Is an emergency plan required according to regulation 20? Yes ☐ No ☐

If Yes, please tick to confirm that it is attached to this form. ☐

14. Please tick to confirm that you have attached a risk assessment to this form (Note 12) ☐

Tick if you are claiming exemption from disclosure for sections of the risk assessment ☐

Public Register

15. Please enter comments of the genetic modification safety committee on the risk assessment. (Note 13)

Public Register

PERSONAL INFORMATION

16. Name of person responsible for supervision and safety of GM activities at the premises.

Training and qualifications

Confidential Information

CONFIDENTIAL INFORMATION

17. Enter in this section any information required in sections 1-15 for which you are claiming confidentiality, together with full justification for that claim. (Note 14)

Confidential Information

18. Declaration

I am notifying an intention to carry out an activity involving contained use of genetically modified organisms with the authority and approval of the person (organisation or individual) named in section 1 of this form.

Confidential Information

Name

Position in organisation

Signed **(Note 15)** Date

Activity notification

THE GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS 2000 NOTIFICATION OF INTENTION TO CONDUCT INDIVIDUAL CONTAINED USE ACTIVITIES

Notes for Guidance

Data Protection Act 1998

This Act requires the Health and Safety Executive (HSE) to inform you that this form may include information about you (this is called "personal data" in the Act) and that we are a "data controller" for the purposes of the Act. HSE will process the data for health, safety and environmental purposes. HSE may disclose these data to any person or organisation for the purposes for which they were collected or where the Act allows disclosure. As data subject, you have the right to ask for a copy of the data and to ask for any inaccurate data to be corrected.

All the information given in sections 1 to 15 of this form will be placed on HSE's public register of notifications within 14 days of receipt. You may consider that there is information relevant to these sections whose disclosure would harm your organisation's competitive position or which you wish to keep confidential on other grounds referred to in regulation 22(2); please see paragraph 126 of the Guide to the Regulations. If so, you should enter such information in section 17 with a full justification for its exemption from disclosure.

Subject to the following paragraph, there are some sections for which you must provide at least some information for disclosure. This is because the Regulations specify certain categories of information for which exemption from disclosure cannot be claimed on any grounds other than, exceptionally, harm to intellectual property rights. It should always be possible to provide information in these categories without risk of harm to competitive position or any of the other grounds referred to in regulation 22(2). If there are particular details, necessary for evaluation of the notification, for which you wish to claim confidentiality, these should be entered in section 17 with the necessary justification.

You may request exemption from disclosure for any information if you can demonstrate that it is necessary to protect your intellectual property rights. Such information should be entered in section 17 with a full justification for its exemption from disclosure.

Personal information will not be disclosed unless the individual concerned has given his or her explicit written permission.

Compliance with other legislation

It is important to note that compliance with the provisions of the Contained Use Regulations does not constitute compliance with other relevant legislation. For example, you may also need to apply separately for licences or permits under legislation controlling plant health, animal health, animal scientific procedures, or the introduction of non-indigenous species. For clinical trials involving gene therapy you will need approval from the Gene Therapy Advisory Committee.

Even if you have fulfilled the requirements of the Contained Use Regulations, and have any necessary consents or approvals under that legislation, you cannot begin the activity unless you also have the relevant licences / permit under any other applicable legislation.

Note 1
This will normally be the University, Institution, Company or Organisation. Only rarely will it be necessary to include an individual's name.

Note 2
If you have previously notified your premises, indicate the date of the notification and the HSE reference number assigned (eg GM111). If you have not notified your premises, you will not have a reference - so leave blank. Note that, if not previously notified, you will also need to complete a premises notification - using the form provided if you wish - and submit it at the same time as this activity notification. The fee payable in such cases will only be that related to the activity notification.

Note 3
It is permissible to notify a connected programme of work using this form. However, you must included details of all of the component activities in sections 4-15. The fee payable in relation to connected programmes is the fee for the highest Class of activity involved. (Notifiable activities involving GM animals and plants are equivalent to Class 2 for this purpose).

Note 4
Please tick all applicable boxes. Confidentiality in relation to the Class of activities involving GMMs may not be claimed - unless disclosure would harm intellectual property rights. Any information claimed as confidential should be entered in section 17 together with justification.

Note 5
Any information claimed as confidential should be entered in section 17 together with justification.

Note 6
For activities involving GMMs, this section cannot be left blank unless you have a justified claim in respect of protection of intellectual property rights (IPR). If you are not making a claim in respect of IPR, you must at least include general characteristics of the GMMs involved in the intended activity. Where there are no justifiable claims for confidentiality, you must include precise details. An evaluation of the foreseeable effects must also be included, in as precise detail as possible. The evaluation of forseeable effects should include the identity and characteristics of the GMMs indicated by the risk assessment. Include information on hazards to human health and the environment with particular reference to those arising from the modification as opposed to being inherent properties of the host micro-organism. (A fuller account of these details will be included in the risk assessment).

For activities involving GMOs which are not micro-organisms (eg GM animals and plants) it is permissible to claim confidentiality for any of the required information, but the second section should still be completed in as precise detail as possible without endangering confidentiality. The evaluation of foreseeable effects is required to consider only human health and safety aspects. Any information claimed as confidential should be entered in section 17 together with justification.

Note 7
For activities involving GMOs which are not micro-organisms (eg GM animals and plants), describe the containment and control measures which you will apply to the activity. These should be justified by reference to the risk assessment. Any information claimed as confidential should be entered in section 17 together with justification.

Note 8
Any information claimed as confidential should be entered in section 17 together with justification.

Note 9
You must not leave this section blank. For activities with GMMs confidentiality may only be claimed if disclosure would harm your intellectual property rights.

Note 10
For activities involving GMMs, you will normally need to apply all the measures specified as requirements for the relevant containment level. If, however, your risk assessment indicates that any of those measures are unnecessary, you may ask for permission to omit them. Indicate any such measures with a brief justification that includes reference to the relevant parts of the risk assessment. You cannot claim confidentiality for the actual containment measures (except if your intellectual property rights might be affected) BUT the justification may be claimed as confidential. If any claim is made for confidentiality, the confidential information must be included in section 17 together with justification.

Note 11
Waste management measures which will be applied to the activity must be described. You should take into consideration only the waste consisting of or containing viable GM material. You must specify the type and form of waste(s) generated, their treatment, ultimate form and fate. Include an indication of the numbers of viable GMOs remaining after treatment (if any).

For activities involving GMMs, this section cannot be left blank unless you are claiming protection for reasons of intellectual property rights. Even if this is not the case, it is permissible not to give precise details if claims for confidentiality can be justified. For instance, you could say that inactivation is by heat treatment to give100% kill, but the precise detail of how this is achieved may be commercially confidential information. If any claim is made for confidentiality, the confidential information must be included in section 17 together with justification.

Note 12
You must attach the risk assessment of the activity to this form. The risk assessment will not at present be placed on the public register, but will be open to disclosure to members of the public on request (subject to confidentiality provisions). If, as hoped, an electronic public register is set up in the future, this may allow for inclusion of the risk assessment on the register.

If you wish to claim exemption from disclosure for any sections of the risk assessment, please indicate those sections clearly on the risk assessment and set out a full justification for exemption. If your justification is accepted, the risk assessment will be disclosed with the exempt sections removed. You are advised to submit a second version of the risk assessment from which those sections have already been removed. Such a version of the risk assessment should indicate precisely where information has been removed.

Note 13
NB: remember that, as well as consulting the genetic modification safety committee on the risk assessment, you must also comply with the Safety Representatives and Safety Committees Regulations 1977 and, where any employees are not in groups covered by trade union safety representatives, you must consult such employees according to the Health and Safety (Consultation with Employees) Regulations 1996.

If any claim is made for confidentiality, the confidential information must be included in section 17 together with justification.

Note 14
Please enter in this section any information, required in sections 1-15, which you wish to be exempt from public disclosure on grounds that

a) disclosure would harm your organisation's competitive position;
b) disclosure would compromise your intellectual property rights; or
c) the information falls into one of the other categories for exemption in regulation 22(2) - state which.

For each piece of information entered you must:

d) state clearly which of the grounds applies. In particular, state which category of exemption allowed by the Environmental Information Regulations 1992, as amended in 1998, applies, namely:

   - international relations, national defence, public security, legal proceedings, confidentiality of deliberation, commercial / industrial confidentiality, intellectual property;

e) indicate the section of the form to which it is relevant; and

f) provide a full justification, explaining why the stated ground for exemption applies.

You do not need to enter any personal information as this will automatically be treated as confidential.

Note 15

Send the completed form to:

Notifications Officer
Health and Safety Executive
Rm 443, TD6
Magdalen House
Stanley Precinct Bootle
Merseyside, L20 3QZ
Tel: 0151 951 4772 Fax: 0151 951 3474

Appendix 6 Departmental contacts

Health and Safety Executive (HSE) Health Directorate, Division B Rose Court 2 Southwark Bridge London SE1 9HS Tel: 020 7717 6234/6297/6348 Fax: 020 7717 6199	For advice on general policy and interpretation relating to the Contained Use Regulations 2000.
Health and Safety Executive (HSE) Technology Division 6 Magdalen House Stanley Precinct Bootle Merseyside L20 3QZ Tel: 0151 951 4772 Fax: 0151 951 4374	Address for submission of all notifications and information under the Contained Use Regulations 2000. Advice about notifications, inspection and enforcement matters; technical advice relating to matters such as risk assessment, containment measures and safety management systems.
Department of the Environment, Transport and the Regions (DETR) Biotechnology Unit Ashdown House 123 Victoria Street London SW1E 6DE Tel: 020 7890 5275/5285 Fax: 020 7890 5259	All enquiries relating to deliberate release or marketing of GMOs (except for food safety and medicinal/veterinary products aspects). DETR operate the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (as amended in 1995 and 1997) and the related sections of the Environmental Protection Act 1990 Part VI. DETR also approve introductions of non-indigenous species under the Wildlife and Countryside Act 1981.
Department of Health Biotechnology Unit Room 531b Skipton House 80 London Road Elephant and Castle London SE1 6LW Tel: 0171 972 5347 Fax: 0171 972 5155 For food safety in particular: Tel: 020 7972 5314 Fax: 020 7972 5134	General enquiries relating to human health and food safety aspects of GMOs.
Medicines Control Agency c/o Information Centre Central Enquiry Point. Tel: 020 7273 0000 Fax: 020 7273 0353	Enquiries relating to clinical trials of human medicines and the marketing of medicinal products under the European Council Regulation No. 2309/93.

Gene Therapy Advisory Committee (GTAC), Secretariat Department of Health Room 401 Wellington House 135 - 155 Waterloo Road London SE1 8UG Tel: 020 7972 4021 Fax: 020 7972 4196	Guidance and advice on all clinical trials involving gene therapy in humans. GTAC operates an approvals system for all gene therapy trials.
United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA) Department of Health, Area 311 Wellington House 133 - 155 Waterloo Road London SE1 8UG Tel: 020 7972 4921/4822 Fax: 020 7972 4852	Guidance and advice on xenotransplantation. UKXIRA regulates all xenotransplantation activities.
Ministry of Agriculture, Fisheries and Food (MAFF) Genetic Modification and Agriculture Group Co-ordination Division (GM and AGC) Room 410 Whitehall Place (East Block) London SW1A 2HH Tel: 020 7270 8138 Fax: 020 7270 8933	MAFF is responsible for the agricultural and fisheries implications of GMOs (eg plant variety and seeds legislation, plant and animal health aspects, pesticide controls and general impact on agriculture). GM and AGC Division co-ordinates MAFF's interests in this area and is responsible for dealing with GMO contained use and deliberate release consent applications.
Food Standards Agency Novel Foods Division Room 239c, Ergon House PO Box 31037, Horseferry Road London SW1P 3WG Tel: 020 7238 6379 Fax: 020 7238 6382	The Food Standards Agency was established in April 2000 and is responsible for the safety and labelling of GM food and the application of the EC Regulation on Novel Foods and Novel Food Ingredients.
Home Office Animals, By-Laws and Coroners Unit 50 Queen Anne's Gate London SW1 9AT Tel: 020 7273 2861 Fax: 020 7273 2423	The Home Office is responsible for regulating the use of protected animals (all vertebrate animals and Octopus vulgaris) for experimental or other scientific purposes, including the production and use of genetically modified animals. Regulation is by certificates and licences issued under the Animals (Scientific Procedures) Act 1986. The Home Office maintains an active inspection programme of licensed work.

The Scottish Executive Rural Affairs Department
Genetic Modification Co-ordination Team
Area 1 - H76
Victoria Quay
Edinburgh
EH6 6QQ
Tel: 0131 244 7578
Fax: 0131 244 4071

The Scottish Executive is responsible for the release and marketing of GMOs in Scotland. It is also responsible for any plant health aspects relating to GMOs in containment or otherwise.

The National Assembly for Wales
Environment Division 5
Cathays Park
Cardiff
Tel: 01222 825 111
Fax: 01222 823 658

The National Assembly is responsible for the release and marketing of GMOs in Wales.

Department of Trade and Industry (DTI)
Chemicals and Biotechnology Directorate
151 Buckingham Palace Road
London SW1W 9SS
Tel: 020 7215 2914
Fax: 020 7215 1379

DTI has overall responsibility for sponsoring the industrial application of biotechnology and for ensuring that Government policies take account of their impact on industrial competitiveness in this area. An important component of this is to encourage the development of biotechnology through support for innovation through schemes such as LINK, SMART, SPUR, EUREKA and the EU Framework programme on biotechnology. DTI publishes a BioGuide providing the biotechnology community with an essential summary of current regulations and procedures and of support available to the sector, both from Government and elsewhere. Copies are available from DTI.

Environment Agency
Head Office
Rio House
Waterside Drive
Aztec West
Almondsbury
Bristol
BS32 4UD
Tel: 01454 624400
Fax: 01454 624409

General Enquiry Line:
Tel: 0845 9333111 (this will automatically connect you with your local Agency office)

Emergency Hotline for reporting all environmental incidents relating to air, land and water:
Tel: 0800 807060

The Environment Agency's overall aim is to protect and improve the environment and make a contribution towards the delivery of sustainable development through the integrated management of air, land and water.

Its statutory responsibilities include regulation of

- industrial processes with the greatest pollution potential, whether to land, air or water;
- the treating, keeping, movement and disposal of waste; and
- discharges to controlled waters.

For advice and enquiries in respect of disposal of wastes arising from GM operations, or any aspects of the Agency's work, please contact your local office, or use the general enquiry line.

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Further information

For information about health and safety ring HSE's Infoline Tel: 0845 345 0055 Fax: 0845 408 9566 Textphone: 0845 408 9577 e-mail: hse.infoline@natbrit.com or write to HSE Information Services, Caerphilly Business Park, Caerphilly CF83 3GG.

HSE priced and free publications can be viewed online or ordered from www.hse.gov.uk or contact HSE Books, PO Box 1999, Sudbury, Suffolk CO10 2WA Tel: 01787 881165 Fax: 01787 313995. HSE priced publications are also available from bookshops.

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