A Guide to the Genetically Modified Organisms (Contained Use) Regulations, 1992.

HSE
Health & Safety Executive

A guide to the Genetically Modified Organisms (Contained Use) Regulations 1992

GUIDANCE
ON REGULATIONS

Health and Safety Executive

A Guide to the Genetically Modified Organisms (Contained Use) Regulations 1992

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Contents

Introduction

1 This booklet gives practical guidance on the Genetically Modified Organisms (Contained Use) Regulations 1992 (SI 1992/3217), which are designed to ensure the safe use and handling of genetically modified organisms under containment.

2 The Regulations repeal and replace the earlier legislation in this field, the Genetic Manipulation Regulations 1989. They implement within Great Britain EC Directive 90/219/EEC on the contained use of genetically modified micro-organisms, which was adopted on 23 April 1990 (OJ No L 117, 8.5.90, p1). The Regulations came into force on 1 February 1993.

3 The Regulations have been made under the powers of the Health and Safety at Work etc Act 1974 (the HSW Act) and the European Communities Act 1972 and are concerned with protecting both human health and the environment. They require, with certain exceptions, that anyone carrying out any activity involving genetic modification must do so in conditions of contained use which satisfy the Regulations. Among other things this means carrying out a risk assessment, submitting a notification to the Health and Safety Executive, and in certain circumstances receiving the Executive's formal consent.

4 For genetically modified micro-organisms the Regulations cover both human health and environmental risks. For larger genetically modified organisms, such as plants and animals, they cover human health risks only. The environmental risks associated with work with larger organisms are covered separately by section 108(1)(a) of the Environmental Protection Act 1990 (the EP Act) which came into force for this purpose on 1 February 1993 (see paragraph 20 below). This section requires anyone creating a genetically modified organism which is not an approved product under the Deliberate Release Regulations (see below), or obtaining one from elsewhere, to carry out an assessment of the environmental risks and make it available for inspection.

Other relevant legislation

5 Note that this guidance does not cover other legislation which may also have a bearing on work with genetically modified organisms. That legislation includes, for example, controls on: human and veterinary medicines, under the Medicines Acts 1968 and 1971; pesticides, under the Food and Environment Protection Act 1985; plant pathogens under the Plant Health (Great Britain) Order 1987; transgenic animals under the Animals (Scientific Procedures) Act 1986; genetically modified material and plants under the Plant Health (Great Britain) Order 1987; and the introduction of novel species under the Wildlife and Countryside Act 1981. All this legislation remains in force and is not affected by the Genetically Modified Organisms (Contained Use) Regulations 1992, ("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, including, where appropriate, the Control of Substances Hazardous to Health Regulations 1988.

Legislation on the deliberate release of genetically modified organisms

6 A second EC Directive, 90/220/EEC, deals with the deliberate release of genetically modified organisms. Regulations to implement this directive (the Genetically Modified Organisms (Deliberate Release) Regulations 1992) have been introduced under the EP Act. Separate guidance on the Act and Regulations is to be produced.

Enquiries on the Contained Use Regulations

7 If, after reading this guidance, you need further advice on the procedures in the Contained Use Regulations for risk assessment, notification and consent, you should contact:

Health and Safety Executive
Health Policy Division
Room 536
Baynards House
1 Chepstow Place
London W2 4TF
Tel: 071 243 6149
Fax: 071 243 6293

Technical enquiries on matters such as containment practices and the reporting of accidents etc should be made to :

Health and Safety Executive
Technology and Health Sciences Division, Branch C6
Magdalen House
Stanley Precinct
Bootle
Merseyside L20 3QZ
Tel: 051 951 4831
Fax: 051 922 7918

Summary

1 The main requirements of the Contained Use Regulations provide for:

- human health and environmental risk assessment;
- records of risk assessments;
- establishment of a local genetic modification safety committee to advise on risk assessments;
- categorisation of work on the basis of risks to human health and safety and of damage to the environment, taking into account the nature of the organism and the type of activity;
- advance notification to the Health and Safety Executive (HSE) of an intention to use premises for activities involving genetic modification for the first time and, for some activities, consent from the Executive before work can start;
- notification to HSE of individual activities involving genetic modification, and, for some activities, consent from HSE before they can proceed;
- standards of occupational and environmental safety and levels of containment;
- notification of accidents and, where appropriate, the drawing up of emergency plans;
- disclosure of information and public registers, with provision for confidentiality;
- fees for notifications.

2 The activities covered by the Contained Use Regulations include laboratory operations, housing and/or breeding of modified animals in animal houses or farm animals restrained by appropriate fencing, the use of growth rooms and glasshouses of appropriate specification, and the use of fermenters. All such activities are prohibited unless they are carried out in contained use conditions which comply with the Regulations.

3 'Contained use' is defined as any operation in which organisms are genetically modified or in which genetically modified organisms (GMOs) are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers, or physical barriers combined with chemical or biological barriers or both, are used to limit their contact with the general population and the environment. Note that physical barriers appropriate to the GMO must always be present. But in some cases physical barriers alone may not limit contact with the environment sufficiently; for example, some designs of glasshouse may not adequately contain plant pollen.

4 The Contained Use Regulations cover the breeding on of a transgenic plant or animal, as well as 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 consisting of or containing GMOs. These activities are covered by the EP Act and the Deliberate Release Regulations.

5 So long as the use of a product is as specified by an approval under the Deliberate Release Regulations in the conditions for marketing, and no further genetic modification is undertaken, it will not be covered by the Contained Use

Regulations. 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 Regulations or the Contained Use Regulations.

6 Waste streams from contained facilities also fall under the Contained Use Regulations. They are not regulated by the Deliberate Release Regulations.

Administrative arrangements

7 The Contained Use Regulations are administered jointly by HSE and the Department of the Environment (DOE), but duty-holders have a single point of contact in HSE. All notifications under the Contained Use Regulations should be made to HSE, which has a duty to pass copies to the Secretary of State for Environment (or the Secretary of State for Scotland or Wales as appropriate). The agreement of the Secretary of State must be obtained before HSE can issue a consent, insofar as it relates to environmental protection. Inter-departmental arrangements have been made in addition to ensure that on environmental matters in general HSE will co-operate with the Secretary of State in putting the Regulations into effect. Where further information is required by either the Secretary of State or HSE it will be requested by HSE.

8 Notifications and consent applications must be made in a form approved by the Executive and submitted to:

Health and Safety Executive
Health Policy Division
Room 536
Baynards House
1 Chepstow Place
London W2 4TF
Tel: 071 243 6149
Fax: 071 243 6293

Model forms for the applications can be obtained free from the above address.

Enforcement

9 Enforcement of the Contained Use Regulations is the responsibility of HSE under the powers of the HSW Act. HSE inspectors have extensive powers under this Act, including powers to enter premises and to require the provision of information relevant to their purposes and the production of documents.

Guidance from the Advisory Committee on Genetic Modification

10 The Advisory Committee on Genetic Modification (ACGM) has prepared a series of guidance notes (ACGM/HSE/DOE Notes 1-11) on individual subjects related to the contained use of GMOs. The guidance notes are referred to where appropriate in the regulation-by-regulation guidance that follows and a list of current titles is at Appendix 2. The notes will be updated from time to time. Copies of the notes may be obtained from HSE at the address given at paragraph 8 above.

Regulation 1

Citation and commencement

Regulation 1

These Regulations may be cited as the Genetically Modified Organisms (Contained Use) Regulations 1992 and shall come into force on 1 February 1993.

Guidance 1

11 There are special transitional arrangements for activities which were already notified under the Genetic Manipulation Regulations 1989 or are notified in the period immediately after the new Regulations come into force. They are in regulation 23 (see note on that regulation below).

Regulation 2

Interpretation

Regulation

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

"the 1989 Regulations" means the Genetic Manipulation Regulations 1989[a];

"accident" means any 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;

"approved" means approved in writing for the time being by the Executive;

"activity involving genetic modification" means any operation involving the contained use of a genetically modified organism;

"contained use" means any operation in which organisms are genetically modified or in which such genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers or a combination of physical barriers with chemical or biological barriers or both, are used to limit their contact with the general population and the environment;

"the contained use Directive" means Council Directive No. 90/219/EEC[b] on the contained use of genetically modified micro-organisms;

"the Executive" means the Health and Safety Executive;

"genetic modification" in relation to an organism means the altering of the genetic material in that organism by 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 1; and

(b) the techniques listed in Part II of that Schedule are not considered to result in genetic modification,

and "genetically modified" shall be construed accordingly;

(a) S.I. 1989/1810.
(b) OJ No L 117, 8.5.90, p.1.

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Regulation

"genetic modification safety committee" means the committee established in accordance with regulation 11;

"micro-organism" means a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material including animal or plant cell cultures;

"organism" means a biological entity capable of replication or of transferring genetic material and includes a micro-organism;

"self-cloning" means the removal of nucleic acid from a cell or organism, followed by the re-insertion of all or part of that nucleic acid - with or without further enzymic, chemical or mechanical steps - into the same cell type (or cell-line) or into a phylogenetically closely related species which can naturally exchange genetic material with the donor species;

"Type A operation" means any activity involving genetically modified micro-organisms for the purposes of teaching, research, development, or for non-industrial or non-commercial purposes on a scale at which the practices and conditions of the operations relative to the culture volume and numbers of organisms involved is such that -

(a) the system used to keep the organisms under containment reflects good microbiological practice and good occupational safety and hygiene; and

(b) it is possible easily to render the organisms inactive by standard laboratory decontamination techniques;

"Type B operation" means any activity involving the genetic modification of micro-organisms other than a Type A operation.

(2) Genetically modified organisms shall be classified -

(a) in the case of micro-organisms -

(i) as Group I micro-organisms if they comply with such of the criteria set out in Part I of Schedule 2 as are applicable to the particular case, determined in accordance with the guidelines set out in Part II of that Schedule which gives effect to Commission Decision 91/448/EEC[(a)], or

(ii) as Group II micro-organisms if they do not comply with the said criteria; or

(b) in the case of genetically modified organisms other than micro-organisms, in accordance with the criteria set out in Part III of Schedule 2.

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

(a) a reference to a numbered Part, regulation or Schedule is a reference to the Part, 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.

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(a) OJ No L 239, 28.8.91, p 23.

Guidance

12 This regulation deals with definitions. Particular points to note are:

- "**contained use**" covers any operation involving GMOs under conditions of containment;

  the containment must be provided by physical barriers, whether or not they are *supplemented* by chemical or biological ones;

  the containment must limit the contact of the genetically modified organism with the general population and the environment;

- the "**genetic modification**" definition is similar to that for genetic manipulation contained in the Genetic Manipulation Regulations 1989 (now repealed). Techniques included in the definition are listed in Schedule 1 Part I. However:

  the list in Schedule 1 Part I is not exhaustive;

  gene deletions or the insertion of multiple copies of a gene are considered to be genetic modification if they are brought about using any listed technique (see also "self-cloning" below);

  cell fusion is considered to be a technique of genetic modification. This is a change from the 1989 Regulations (but see note on regulation 3 below);

- Schedule 1 Part II contains techniques which are not considered to fall within the definition of genetic modification if they do not involve the use of recombinant DNA molecules or genetically modified organisms. So, for example, the transformation of cells with DNA or the transformation of cells with viruses do not count as genetic modification unless modified DNA or modified viruses are employed or the recipient is itself genetically modified. Schedule 1 Part III lists techniques which *are* considered to be genetic modification but which are excluded if they do not involve the use of genetically modified organisms as recipient or parental organisms;

- "**micro-organism**" covers all micro-organisms. The term includes viruses and viroids, the uncharacterised agent responsible for transmissible spongiform encephalopathy, cell cultures and tissue cultures, including those from plants, animals and humans. It does not cover naked DNA or naked plasmids;

- "**organism**" covers, in addition to all micro-organisms, all multicellular organisms not defined as micro-organisms, including plants and animals;

- "**self-cloning**" is one of the techniques referred to in Schedule 1 Part III. This term, as defined, covers the re-insertion of an organism's nucleic acid into the same species. The nucleic acid may have been subject to modification by enzymic, chemical or mechanical steps so as to produce a novel order, to remove sequences, to produce multiple gene copies etc, but may not contain foreign gene sequences beyond short oligonucleotide linker sequences such as those used for the purpose of introducing restriction endonuclease sites. Self-cloning which meets the following criteria is exempt from the Regulations:

  - only non-pathogenic micro-organisms which meet the criteria for Group I status, or non-pathogenic organisms which are as safe as any recipient or parental organism, are used. For micro-organisms, both the donor and recipient must meet the criteria for Group I status. Guidance on Group I status is given below;

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- the vector is poorly mobilisable, well characterised and free from harmful sequences;

- the modified nucleic acid does not contain genes known to affect pathogenicity, toxicity or which could affect the capacity of the organism to harm human health or the environment;.

- "**Type A operation**" - to qualify as a Type A operation, an activity must fulfil two conditions:

  (1) it must be for teaching, research or development, or for non-industrial or non-commercial purposes,

  (2) it must be on a scale at which operations related to culture volume and numbers of organisms are such that:

  (a) the containment system reflects good microbiological practice and good occupational safety and hygiene;

  (b) the organism can easily be rendered inactive by standard laboratory decontamination techniques.

  In determining whether these conditions are fulfilled the following should be taken into account:

  the system of operations used to contain the organisms should comply with the methods set out in ACGM/HSE/DOE Note 8 taking into account ACGM/HSE/DOE Note 6 where appropriate;

  it should be possible to limit the possibility of contact with man and the environment both in the event of spillage and in the removal of waste for safe disposal. A figure of 10 litres is given in the EC Directive 90/219/EEC as indicative of appropriate volume, but it is recognised that this cannot be used as a fixed figure;

- Type A operations are typically characterised by work with small numbers of organisms. The work can be basic science or applied research, carried out either in a laboratory in an academic institution or in the laboratory of a commercial firm with the aim of creating a process for subsequent industrial or commercial exploitation;

- **Type B operation -** classified as any operation which does not fulfil the criteria for Type A. Type B operations will in the main be carried out under industrial conditions. Usually the production volume is considerably greater than in Type A operations and operational conditions are different, but all operations which produce an industrial or commercial product are Type B operations even though they may be carried out at small volume. A Type B operation which is industrial production is likely to be a process or series of processes repeated again and again with little or no change in process conditions, and leading to a product that is either put on the market or used as a raw material elsewhere in the production process;

- **classification of micro-organisms**. The Regulations define two hazard groups of genetically modified micro-organisms, **Group I** and **Group II**. All persons undertaking any contained use with a genetically modified micro-organism must classify it into one of these groups.

  Schedule 2 Part I sets out the criteria that a micro-organism must meet

(to the extent that they are applicable) to be classified as Group I. Part II of the Schedule sets out the guidelines published in a European Commission Decision, No 91/448/EEC, for the further interpretation of the criteria in Part I.

There are qualifying terms such as "appropriate", "if necessary", and "as much as possible", which call for judgments to be made. For instance, Part II paragraph 7 lists the areas to be "taken into account" in considering whether or not the insert is well characterised. The level of information needed for this may vary from case to case. If the precise structure of the insert were unknown, but it had been derived from a non-pathogenic, non-harmful organism (to human health or the environment), the lack of information would be less critical to the classification than if it were derived from a pathogenic or harmful organism. Clearly, if the insert were derived from a pathogenic or harmful organism (such as a human or plant pathogen) it would be important to the classification to know whether or not the insert contained potentially harmful sequences. Non-harmful sequences derived from a pathogenic organism would not automatically mean that the GMO would have to be classified as Group II. Conversely, if the insert did contain potentially harmful sequences the GMO would necessarily have to be classified as Group II. However, for Type A operations, *if* those genes constituted an essential part of the insert without, under any circumstances, resulting in a harmful or pathogenic phenotype of the GMO, Group II classification may not be necessary.

Group I organisms may not be based upon recipients with pathogenic characteristics or those which may harm the environment. *As a general guide,* the following recipient micro-organisms will not qualify for Group I status and are therefore automatically considered to be Group II:

> micro-organisms listed in hazard groups 2,3 or 4 in the Advisory Committee on Dangerous Pathogens (ACDP) guidance document *Categorisation of pathogens according to hazard and categories of containment*, 1990, 2nd Ed;
>
> organisms listed in the Plant Health (Great Britain) Order 1987, or any other plant pathogen or pest;
>
> *Agrobacterium* strains that retain all of the plant interactive genes of the wild type plasmid;
>
> pathogens of animals, poultry, fish, or bees controlled by the Agriculture Departments (listed in Appendix N of the above ACDP publication);
>
> any other micro-organism capable of harming the environment by any means including the production of metabolites.

Disabled strains of pathogenic species such as *E coli* K12 may satisfy the host/vector criteria for Group I status set out in Schedule 2.

Agrobacterium tumefaciens strains which carry modified plasmids deficient in all tumorigenic genes may satisfy the host/vector criteria for Group I as long as the plasmid has not also been altered to increase pathogenicity or alter the host range. For any insert sequences the factors set out in Schedule 2 Part II paragraph 7 (1-5) should also be considered before final categorisation is determined. MAFF/SOAFD licence requirements under the Plant Health legislation for genetic modification involving plant pests or pathogens, including *Agrobacterium* species, must also be met irrespective of Group I or Group II status;

Guidance

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- **classification of organisms other than micro-organisms.** Part III of Schedule 2 sets out the criteria for classification of higher organisms. There are two categories; which one a particular genetically modified organism falls into depends upon whether or not it is as safe to man or the environment as the parental organism.

Regulation 3

Application

Regulation

-(1) These Regulations shall have effect with a view to protecting persons against risks to their health, whether immediate or delayed, and for the protection of the environment, arising from activities involving genetically modified organisms.

(2) Regulations 8 to 12 shall not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.

(3) These Regulations shall not apply to the genetic modification of organisms solely by any of the techniques referred to in Part III of Schedule 1 or to any organisms so modified.

(4) Insofar as these Regulations relate to the protection of the environment, they shall only apply to genetically modified micro-organisms.

(5) Nothing in these Regulations shall prejudice any requirement imposed by or under any enactment which relates to public health or the protection of the environment.

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

Guidance

13 This regulation specifies that the Regulations apply both to risks to human health and protection of the wider environment, and that they apply to all activities involving the contained use of genetically modified organisms with the following exceptions:

- the transport of genetically modified organisms is subject only to the requirements for risk assessment in regulation 7 and the provisions of regulation 13 onwards. In carrying out a risk assessment for transport the parameters in Schedule 3 need be applied only as far as they are relevant to transport. The requirements for notification in regulations 8-12 do not apply;

- the Regulations do not apply to GMO activities involving solely the techniques of genetic modification listed in Schedule 1, Part III. This lists techniques which are excluded so long as the parental or recipient organism is not itself a genetically modified organism. Such techniques include some self-cloning (see guidance to regulation 2) and cell fusion of plant cells where the resulting organism could be produced using traditional breeding methods. Interpretation of the term "**traditional breeding methods**" has been agreed by the Competent Authorities of EC member States to mean:

  Traditional breeding refers to practices which use one or more of a number of methods, including physical and/or chemical means and control of physiological processes, which can lead to successful crosses between plants of the same botanical family.

3

Guidance
3

14 The Regulations do not apply in Northern Ireland, where separate, matching provisions will implement the EC Directive.

Regulation 4

Meaning of "work" and "at work"

Regulation
4

For the purpose of these Regulations and Part I of the Health and Safety at Work etc Act 1974[(a)] the meaning of "work" shall be extended to include any activity involving genetic modification and the meaning of "at work" shall be extended accordingly.

(a) 1974 c.37.

Guidance
4

15 This 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 work who does not fall into one of these categories, such as a research student. All such activities are covered both by the general duties in Part I of the Act and by the Contained Use Regulations.

Regulation 5

Modification of section 3(2) of the Health and Safety at Work etc Act 1974

Regulation
5

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

Guidance
5

16 This regulation modifies section 3(2) of the HSW Act, which requires self employed persons to conduct their undertakings in such a way as to ensure, so far as is reasonably practicable, that persons other than employees are not exposed to risks to their health and safety. Under regulation 5, this requirement is extended, in relation to an activity involving genetic modification, to anyone who is not an employer or an employee.

Regulation 6

Prohibition of certain work with genetically modified organisms outside containment

Regulation
6

-(1) Subject to paragraph (2), any operation in which organisms are genetically modified or in which such genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of is prohibited unless it is undertaken in conditions of contained use in accordance with these Regulations.

(2) Paragraph (1) shall not apply to any operation in which -

Regulation

6

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

(i) a consent granted by the Secretary of State under section 111(1) of the Environmental Protection Act 1990[a], or

(ii) a written consent given by another competent authority of a member 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, the operation is conducted in accordance with any conditions or limitations attached to that consent;

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

(3) 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) O.J. No L117, 8.5.90, p15

Guidance

6

17 Regulation 6 prohibits any work with genetically modified organisms unless:

- the work is carried out under contained conditions in accordance with the Contained Use Regulations, or
- the organisms are or are contained in an "approved product" under the Deliberate Release Regulations, or
- the activity is a deliberate release to the environment carried out under a consent issued under the EP Act andDeliberate Release Regulations.

Regulation 7 Risk assessment

Regulation

7

-(1) A person shall not -

(a) use any premises for activities involving genetic modification for the first time; or

(b) undertake any activity involving genetic modification,

unless he has ensured that, before commencing that use or activity, as the case may be, a suitable and sufficient assessment of the risks created thereby to human health and the environment has been made.

(2) Without prejudice to the generality of paragraph (1), the purposes of the assessment undertaken under that paragraph shall include -

(a) classifying any genetically modified organisms involved in the activity in accordance with the provisions of Schedule 2; and

(b) where appropriate, making decisions about the levels of containment required for the activity concerned.

(3) In making the assessment required by paragraph (1) the person undertaking that assessment shall -

Regulation

7

(a) in particular, take due account of the parameters set out in Schedule 3 in as far as they are relevant; and

(b) in a case in which the Executive has approved a method in relation to the activity involving genetic modification concerned or in relation to a particular element of that assessment, undertake the assessment in accordance with that method.

(4) The assessment shall be reviewed forthwith if -

(a) there is reason to suspect that the assessment is no longer valid; or

(b) there has been a significant change in the activity to which the assessment relates.

(5) The person making the assessment shall make a record of it and of any subsequent review and shall keep that record for at least 10 years from the date on which use of the premises or the activity, as the case may be, to which the assessment related, ceased.

Guidance

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18 This regulation requires that a risk assessment, taking account of the parameters set out in Schedule 3 to the Regulations so far as they are relevant, must be made before any premises can be used for genetic modification activities or any such activities are undertaken. Under regulation 7(2), two of the purposes of the risk assessment are to classify the organisms involved, in accordance with Schedule 2, and make decisions about appropriate levels of containment. (See also the guidance on regulation 12.)

19 Risk assessments made for the purpose of notifying a general intention to use premises will necessarily be less specific than those made for the purpose of notifying individual activities.

Guidance on risk assessment is contained in:

> ACGM/HSE/DOE Note 6, ACGM/HSE/DOE Note 7 and, in relation to eukaryotic viral vectors, ACGM/HSE/DOE Note 5.

HSE may approve a risk assessment method for particular activities or particular aspects of the assessment, and where it has, that method must be used. Methods approved by HSE will be based on ACGM/HSE/DOE guidance.

20 The Contained Use Regulations do not cover the environmental risks associated with the contained use of GMOs that are not micro-organisms - whole plants and animals for example. (See Introduction, paragraph 4). The contained use of large GMOs is, however, covered by section 108(1)(a) of the EP Act, which requires that anyone who makes or obtains (the term "acquire" in the Act embraces both these meanings) a GMO of this kind must make an assessment of the environmental risks. For this purpose section 108(1)(a) has been applied to the same range of genetic modification techniques as the Contained Use Regulations, and may be treated as an extension of them[a]. In practice, the assessment will normally be combined with the one required by regulation 7, and the same considerations should be taken into account. (Note that the Regulations do cover the human health risks associated with large GMOs, and for those risks the notification requirements in particular apply in the normal way.)

21 Under regulation 7(4), it is necessary to review the assessment where there is reason to suspect that the original assessment is no longer valid or

(a) This has been brought about by the Environmental Protection Act 1990 (Commencement No 12) Order 1992, which activates section 108(1)(a) of the EP Act, and the Genetically Modified Organisms (Contained Use) Regulations 1993, which limit the application of section 108(1)(a) to the activities and risks described in paragraph 20.

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where there has been a significant change in the activity to which the assessment relates. In this context significant change could include:

- 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 in the environment etc.

22 Under regulation 7(5), records of risk assessments are required to be kept for at least 10 years from the date on which use of the premises or activity to which the assessment related has ceased.

23 Under regulation 11, any persons undertaking a risk assessment for the purposes of the Regulations must establish a genetic modification safety committee to advise them in relation to that assessment. See paragraphs 34-35 for further guidance on such committees.

Regulation 8

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

Regulation

8

-(1) Subject to the following paragraphs of this regulation and regulation 10, no person shall undertake any activity involving genetic modification at any premises for the first time, unless he has notified the Executive of his intention to do so at least 90 days in advance or before such shorter time as the Executive may approve and with that notification has furnished the particulars specified in Schedule 4.

(2) In the case of activities involving the genetic modification of micro-organisms, separate notifications shall be made of an intention to use the premises for activities involving genetically modified micro-organisms of Group I or Group II.

(3) In the case of activities involving genetically modified micro-organisms of Group II, the premises shall only be used for those activities after the Executive has given its consent.

(4) In any other case, the use of the premises for the activity may be commenced at or after the end of the period of 90 days or such shorter period as the Executive may have approved in pursuance of paragraph (1) unless the Executive objects in writing before the end of the relevant period.

(5) In any case in which a consent is required under paragraph (3), the Executive shall communicate its decision on the application in writing within 90 days after the application was received.

(6) Nothing in this regulation shall prevent a person from notifying under regulation 9 an individual activity which he intends to undertake in the premises at the same time as making a notification under this regulation; in such a case he shall not commence the activity except in accordance with the time periods specified in this regulation.

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24 Under both this regulation and regulation 9, notification is required by the person undertaking or intending to undertake the activity involving genetic modification. In practice, the "person" will generally be a corporate body such as a company, university or research institute.

Guidance

25 Notification under regulation 8 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) 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. Advice in individual cases can be obtained from HSE.

26 Notification is required 90 days in advance of any intended activities or later with the agreement of HSE. Under regulation 10(6), notification under regulation 8 must be made in a form approved by HSE and a model form for this purpose can be obtained free from HSE at the address given at paragraph 8 above. The information to be notified is specified in Schedule 4 to the Regulations.

27 For activities involving micro-organisms, notifiers must indicate whether Group I or Group II micro-organisms are to be used and separate notifications are required for each Group. Where a notification of intention to undertake activities involving Group I micro-organisms has been made and it is subsequently the intention to undertake activities involving Group II micro-organisms, or vice versa, then a further notification is required.

28 For activities with Group I micro-organisms, or organisms other than micro-organisms, the activities may proceed at the end of 90 days or any shorter time that HSE may have approved provided that no objection is raised by HSE. For notification of intention of activities with Group II micro-organisms, the activities may proceed only with the consent of HSE, which will be granted only with the agreement of the Secretary of State for Environment (or Scotland or Wales) in relation to environmental protection. Notifiers will be informed of the outcome of consideration of consent applications within 90 days of the receipt of the application.

29 The regulation also provides that notification of intention to use premises for the first time under regulation 8 and notification of individual activities under regulation 9 (see below) can be submitted at the same time. The notifications will be considered together, with relevant time periods running concurrently. In accordance with regulation 8, individual activities, if notified at the same time as an intention to use premises for the first time, can only be commenced after a period of 90 days unless HSE approves a shorter time.

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Regulation 9

Notification of individual activities involving genetic modification

Regulation

-(1) Subject to the following paragraphs of this regulation and regulation 10, no person shall undertake any activity involving genetic modification unless he has notified the Executive of his intention to do so at least 60 days in advance or before such shorter time as the Executive may approve and has furnished the particulars specified in the following paragraphs of this regulation and, except in the case of an activity to which paragraph (5) applies, the activity may be commenced after the expiry of the relevant period if by then the Executive has not objected in writing.

(2) In the case of an activity which is -

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Regulation

(a) a Type A operation involving only micro-organisms classified as Group I; or

(b) an activity involving genetically modified organisms other than micro-organisms and which satisfy the criteria set out in Part III of Schedule 2,

it shall be a sufficient compliance with paragraph (1) if the person undertaking the activity keeps a record of such activities and forthwith after the end of each calendar year notifies the Executive-

(i) of the total number of risk assessments under regulation 7 undertaken during that year;

(ii) where appropriate, that he is intending to continue to undertake such activities; and

(iii) that the information notified to the Executive in accordance with regulation 8 remains correct.

(3) In the case of an activity which is a Type B operation involving only micro-organisms classified as Group I, the specified particulars for the purposes of paragraph (1) shall be those specified in Part I of Schedule 5.

(4) In the case of an activity which is -

(a) a Type A operation involving genetically modified micro-organisms classified as Group II; or

(b) an activity involving genetically modified organisms other than micro-organisms and which do not satisfy the criteria set out in Part III of Schedule 2,

the specified particulars for the purposes of paragraph (1) shall be those specified in Parts I and II of Schedule 5.

(5) In the case of an activity which is a Type B operation involving genetically modified micro-organisms classified as Group II, the specified particulars for the purposes of paragraph (1) shall be those specified in Parts I, II and III of Schedule 5 and the activity shall only be commenced with the consent of the Executive.

(6) In any case in which a consent is required under paragraph (5), the Executive shall communicate its decision on the application in writing within 90 days after the application was received.

(7) The Executive may accept as a single notification a connected programme of work covering more than one activity involving genetic modification at one site, or a single activity carried on by the same person at more than one site.

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Guidance

30 This regulation deals with notification of specific activities involving genetic modification. Under regulation 9(7), HSE may accept as a single notification a connected programme of work covering more than one activity. To be treated in this way the work covered by the notification should form a coherent and integrated programme. It should not be simply everything that happens to be taking place on one site. To avoid having to renotify different phases or elements of a particular activity notifiers should consider the project as a whole, and the notification should cover all foreseeable aspects of the intended work. For example, a project to clone and analyse the function of a gene might include the following stages: the construction of a gene library; the

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screening of the library; the subcloning of the gene of interest into, say, *E coli*; and investigation of its expression in another organism.

31 Under regulation 10(6) notification under regulation 9 must be made in a form approved by HSE and model forms for this purpose can be obtained free from HSE at the address given at paragraph 8 above. The information to be notified, the time period for notification, and whether a consent is required depend on the nature of the activity and can be summarised as follows:

Type A operations involving Group I micro-organisms or operations involving organisms other than micro-organisms which satisfy the criteria in Schedule 2, Part III - regulation 9(2)

In these cases, advance notification of individual activities is not required (but first-use notification under regulation 8 must still be given). Instead, records of activities need to be kept available for inspection. At the end of each calendar year HSE should be notified forthwith of the total number of risk assessments required under regulation 7 undertaken during that year, whether the activities are to be continued and of changes to any particulars previously notified. A model form for the annual retrospective return is available free from HSE at the address given at paragraph 8 above.

Type B operations involving Group I micro-organisms - regulation 9(3)

The information specified in Part I of Schedule 5 should be notified 60 days in advance of the proposed activity, or later with the agreement of HSE. The activity may proceed at the end of the notification period provided that no objection is raised by HSE, and in accordance with any conditions imposed by HSE.

Note that the information submitted with Group I, Type B notifications should demonstrate that environmental harm will not be caused as a result of effluent discharge. If it does not then HSE is likely to ask for more information (see regulation 10). If the additional information provided indicates that contact of genetically modified micro-organisms with man or the environment is not sufficiently limited, HSE will object and the activity, as contained use, will not be permitted. (In such a case it follows that the organism probably does not satisfy the criteria for Group I.)

Type A operations involving Group II micro-organisms and operations involving organisms other than micro-organisms which do not satisfy the criteria in Schedule 2, Part III - regulation 9(4)

The information specified in Parts I and II of Schedule 5 should be notified 60 days in advance of the proposed activity or later with the agreement of HSE. The activity may proceed at the end of the notification period provided that no objection is raised by HSE, in accordance with any conditions imposed by HSE.

Type B operations involving Group II micro-organisms - regulation 9(5)

The information specified in Parts I, II and III of Schedule 5 should be notified. The activity can proceed only with the consent of HSE. HSE will not grant a consent relating to environmental protection without the agreement of the Secretary of State. Notifiers will be informed of the outcome of their applications within 90 days of their receipt.

Regulation 10

Additional provisions relating to notifications and consents

Regulation

-(1) Where necessary for the purpose of evaluating a notification made under regulation 8 or 9, the Executive may require in writing the person making the notification to give such additional information relating to the proposal as it may specify and in such a case the person making the notification shall not proceed with the activity involving genetic modification until the Executive gives its approval and the period between the time when the Executive requires the information and the notifier responds to the satisfaction of the Executive shall not be taken into account in calculating the periods of days referred to in the provisions concerned.

(2) Any consent granted by the Executive under regulation 8 or 9 may be granted subject to conditions or to a limit of time and may be revoked or varied at any time and in such a case the person undertaking the activity shall comply with those conditions.

(3) In so far as they relate to the protection of the environment, the Executive shall not grant, vary or revoke a consent under regulation 8 or 9, or give its approval under paragraph (1) without the agreement of the Secretary of State.

(4) Where a person making a notification in pursuance of regulation 8 or 9 subsequently makes a significant change in any premises or activity to which the notification relates or becomes aware of any new information which would affect the particulars previously notified, he shall forthwith notify the Executive thereof.

(5) If information subsequently becomes available to the Executive which could have significant consequences for the risks to health or the environment created by an activity involving genetic modification which has been notified to it, it may require the notifier to modify the conditions under which the activity is carried out, or to suspend or terminate the activity.

(6) Notifications made in pursuance of regulations 8 and 9 shall be in a form approved by the the Executive.

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Guidance

32 This regulation, which is largely self-explanatory, deals with:

- requests by HSE for additional information, which stop the clock as far as the specified time periods are concerned. When additional information is asked for the activity may not be started until HSE has given its approval, but note that this is quite separate from "consent" as required by regulations 8(3) and 9(5);
- provision for conditions to be specified as part of a consent, or for a consent to be varied or revoked;
- the need for notification of any significant changes in premises or activities or new information which would affect the particulars previously notified. This is not in itself a new notification calling for the payment of a further fee, though it may lead to the variation or revocation of an existing consent or indicate that the category of the work has changed sufficiently for a new full notification to be necessary;
- provision for HSE to require modification, suspension or termination of activities in the light of new information; and
- the need to make notifications under regulations 8 and 9 in a form approved by HSE.

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Guidance

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33 For guidance on what would constitute a "significant" change in relation to regulation 10(4), the guidance in paragraph 21 above also applies. HSE should also be informed of changes in notified personnel and it is particularly important that HSE is informed of cessation of work involving genetic modification.

Regulation 11

Establishment of a genetic modification safety committee

Regulation

11

A person who undertakes an assessment made for the purposes of regulation 7(1) shall establish a genetic modification safety committee to advise him in relation to that assessment.

Guidance

11

34 There should be a properly constituted and representative genetic modification safety committee at each centre where activities involving genetic modification are undertaken. As for notifications under regulations 8 and 9, the person setting up the safety committee will more usually be the "body corporate". In considering notifications under the Regulations, HSE will take into account comments made by such committees. Advice on their constitution and functions is contained in ACGM/HSE/DOE Note 11.

35 (Note that other sources of advice may also be necessary. Regulation 6 of the Management of Health and Safety at Work Regulations 1992 requires that employers appoint competent persons 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 him or her for that purpose, as regards work with GMOs.)

Regulation 12

Standards of occupational and environmental safety and containment

Regulation

12

-(1) For any activity involving genetically modified micro-organisms of Group I, the principles of good microbiological practice and the following principles of good occupational safety and hygiene shall apply -

(a) to keep workplace and environmental exposure to any physical, chemical and biological agent adequately controlled;

(b) to exercise engineering control methods at source and to supplement these with appropriate personal protective clothing and equipment where necessary;

(c) to test and maintain control measures and equipment;

(d) to test, when necessary, for the presence of viable process organisms outside the primary physical containment;

(e) to provide training of personnel; and

Regulation

(f) to formulate and implement local rules for the safety of personnel.

(2) For the purpose of paragraph (1) "adequate" in relation to the control of an agent means adequate having regard only to the nature of the agent and the nature and degree of exposure to such an agent and "adequately" shall be construed accordingly.

(3) For any activities involving genetically modified micro-organisms of Group II in Type A operations, in addition to the principles set out in paragraph (1) the containment measures shall be determined by a method approved by the Executive.

(4) For any activities involving genetically modified micro-organisms of Group II in Type B operations, in addition to the principles set out in paragraph (1) the containment measures set out in Schedule 6 shall be applied at an appropriate level so as to ensure a high level of health and safety and environmental protection.

(5) For any activities involving genetically modified organisms other than micro-organisms, the principles set out in paragraph (1) shall be applied in as far as they are appropriate.

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Guidance

36 Regulation 12 sets out standards of occupational and environmental safety and containment which must be achieved for all work with genetically modified organisms. Requirements for each group of organism and type of operation are detailed in turn.

37 For work with Group I micro-organisms, control measures must be taken in accordance with principles of good microbiological practice and good occupational safety and hygiene, as set out in regulation 12(1) and (2). These principles are intended to protect both human health and safety and the environment. Level 1 laboratory containment as defined in ACGM/HSE/DOE Note 8 (see paragraph 38 below), when applied together with the principles of good occupational safety and hygiene, will normally be appropriate for work with Group I GMOs. This correspondence should not be assumed and the classification of the GMO and the derivation of containment level should be carried out independently, but if the GMO classification is Group I and the assessed level of containment is higher than level 1 then both should be checked to make sure that they are correct. ACGM/HSE/DOE Note 6 deals with the safe operation of scale-up work.

38 For work with Group II micro-organisms in Type A operations, regulation 12(3) requires, in addition to observance of the above principles, containment measures, determined by a method approved by HSE. The approved method is the application at an appropriate level, based on the risk assessment, of the measures set out in ACGM/HSE/DOE Note 8, which contains advice on safe systems of work in laboratories. Four physical containment levels are defined, numbered 1 to 4 in ascending order of thoroughness. All ACGM levels are in accordance with the principles of good microbiological practice.

39 Containment provisions to be used for work with Group II micro-organisms in Type B operations are set out in Schedule 6, at three levels: B2, B3 and B4. (These were previously in use under the 1989 Regulations for large scale categories LS1, LS2 and LS3 and they are set out in ACGM/HSE/DOE Note 6).

40 For genetically modified organisms other than micro-organisms, the principles set out in regulation 12(1) must be applied as appropriate. Standards for physical containment for work with transgenic animals are contained in ACGM/HSE/DOE Note 9, and ACGM/HSE/DOE Note 10 contains standards for glasshouse work.

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Regulation 13

Emergency plans

Regulation

-(1) Where the assessment made in accordance with regulation 7(1) shows that as a result of any reasonably foreseeable accident the health or safety of persons outside the premises in which an activity involving genetic modification is carried on is liable to be affected or there is a risk of damage to the environment, the person undertaking the activity shall ensure that a suitable emergency plan is prepared with a view to securing the health and safety of those persons and the protection of the environment.

(2) The person preparing the plan shall consult such persons, bodies and authorities as are appropriate and shall inform the emergency services in writing of the plan and of the hazards to which the plan relates.

(3) The person undertaking the activity involving genetic modification which is the subject of the emergency plan shall take appropriate measures to inform persons who are liable to be affected by an accident of the safety measures and the correct behaviour to adopt in the event of an accident.

(4) The information required to be given in pursuance of paragraph (3) shall be repeated and brought up to date at appropriate intervals and shall be made publicly available.

13

Guidance

41 Regulation 13 contains a requirement to draw up an emergency plan if the risk assessment undertaken in accordance with regulation 7(1) indicates that, as a result of any foreseeable accident, the health and safety of persons outside the premises may be affected or if there is any risk to the environment. In practice the drawing up of an emergency plan is unlikely to be necessary for any operations other than for those Type B operations involving Group II micro-organisms. Nevertheless it is advisable that the emergency services should at least 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, the fighting of 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 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.

42 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, including 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 National Rivers Authority and the company appointed for the local water supply, and in Scotland the appropriate regional offices of the Scottish Water and Sewerage Authorities (part of the Regional/Islands Councils), and River Purification Boards or Islands Councils who are responsible for the control of environmental pollution.

43 The plan should include the following *where appropriate*:

(i) the types of incidents to people or the environment to be taken into account and the immediate steps to be taken;

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Guidance

(ii) organisations involved, including key personnel, their responsibilities and liaison arrangements between them;

(iii) communication links including arrangements for giving information to people liable to be affected by any accident and for making such information publicly available;

(iv) special equipment, including damage control and repair items;

(v) technical information such as nature of the organism, characteristics of the plant and other hazards which may be present;

(vi) information about the site including likely locations of personnel and hazardous organisms;

(vii) evacuation arrangements;

(viii) contacts and arrangements for obtaining further advice and assistance, eg meteorological information, medical services, water and agricultural authorities;

(ix) arrangements for dealing with the media;

(x) longer-term clean up.

44 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.

13

Regulation 14 Notification of accidents

Regulation

-(1) Where an accident occurs, the person undertaking the activity involving genetically modified organisms shall forthwith notify the Executive of it and shall provide the following information -

(a) the circumstances of the accident;

(b) the identity and quantity of genetically modified organisms released;

(c) any information necessary to assess the effects of the accident on the health of the general population and on the environment; and

(d) the emergency measures taken.

(2) Where the Executive receives a notification in pursuance of paragraph (1), the Executive shall -

(a) ensure that any emergency, medium and long term measures are taken;

(b) immediately inform any other member State that could be affected by the accident;

(c) collect, where possible, the information necessary for a full analysis of the

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Regulation

14

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 the information provided for under paragraph (1), together with an analysis of the accident and details of any recommendations made to avoid similar accidents in the future and to limit their effects.

Guidance

45 This regulation requires notification to HSE of an accident, defined in regulation 2 as any incident involving a significant and unintended release of GMOs which presents a hazard, immediate or delayed, to either human health and safety or to the environment.

The regulation specifies that the notification should be made forthwith and that it should contain the following information:

(a) the circumstances of the accident;

(b) the identity and quantity of genetically modified organisms released;

(c) any information necessary to assess the effects of the accident on the health of the general population and on the environment;

(d) the emergency measures taken.

In accordance with Community wide guidelines agreed by member States, the information should be set out as in Appendix 3.

The notification should be made to:

Health and Safety Executive
Technology and Health Sciences Division, Branch C6
Magdalen House
Stanley Precinct
Bootle
Merseyside L20 3QZ
Tel: 051 951 4831
Fax: 051 922 7918

46 Spillages of Group I micro-organisms are unlikely to count as significant releases of genetically modified organisms which present a hazard, and they will not routinely require notification. This may not be true, however, for spillages of Group II micro-organisms.

47 On receipt of an accident notification, HSE is required to:

(a) ensure that appropriate emergency measures are taken;

(b) inform any other member State that could be affected by the accident;

(c) carry out an analysis of accidents and make recommendations to avoid similar occurrences and to limit their effects; and

(d) send to the European Commission accident details as specified above together with an analysis and any recommendations.

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Regulation 15 Disclosure of information notified

Regulation

15

-(1) Information notified in pursuance of regulations 8 to 10 shall not be treated as relevant information for the purposes of section 28 of the Health and Safety at Work etc Act 1974.

(2) Where a person making a notification in pursuance of regulations 8 to 10 indicates that it contains certain information the disclosure of which might harm his competitive position and should be kept confidential, full justification for that indication shall be given and in such a case after consulting the notifier the Executive shall decide which information shall be kept confidential and shall inform the notifier of its decision.

(3) Nothing in paragraph (2) shall apply to the following information which shall not be kept confidential -

(a) the name and address of the notifier and the location of the activity involving genetic modification;

(b) the purpose of the activity;

(c) the description of the genetically modified organism involved;

(d) methods and plans for monitoring the genetically modified organism and for emergency response; and

(e) the evaluation of foreseeable effects and in particular pathogenic effects and ecologically disruptive effects.

(4) Notwithstanding paragraph (3), where the Executive is satisfied on the basis of detailed 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 Executive shall withhold that information to the extent and for so long as it is necessary to protect those rights.

(5) Information which is kept confidential in accordance with paragraph (2) or withheld in accordance with paragraph (4) shall be disclosed only -

(a) to the Secretary of State;

(b) to the European Commission or the competent authority for Northern Ireland or another member State;

(c) for the purpose of any legal proceedings;

(d) with the consent of the notifier; or

(e) to the extent necessary to evaluate the notification.

(6) A person who receives information in accordance with sub-paragraph (e) of paragraph (5) shall not use that information except for a purpose of the Executive or the Secretary of State.

(7) Where the notifier has requested that certain information in the notification shall be kept confidential in accordance with paragraph (2) or withheld in accordance with paragraph (4), the Executive shall not disclose any of that information (except in accordance with paragraph (5)) until at least 14 days after it

Regulation

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has reached a decision under the relevant paragraph.

(8) After consulting the notifier, the Executive may review any decision made under paragraph (2) or (4) and shall inform the notifier of the result of that review.

(9) Where, for whatever reason, the notifier withdraws the notification, the Executive shall not thereafter disclose any of the information supplied.

Guidance

48 This regulation determines whether HSE may disclose the information submitted as part of a notification or must withhold it. The regulation begins by disapplying section 28 of 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 to cover the case of a GMO notification.

49 For any of the information submitted *except the items listed in regulation 15(3)* the notifier may ask that it should be kept confidential, on the grounds that disclosure would harm his or her competitive position. If HSE accepts the claim, which must be supported by a full justification, the information in question will not be disclosed. Separately, the notifier may ask that any of the information covered by regulation 15(3) should be withheld if disclosure would damage his or her intellectual property rights. This includes damage to the future patentability of an invention, and notifers who are in doubt about the effect of disclosure on future patents are strongly advised to seek professional advice before making their notifications. 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.

50 The status of information which HSE agrees not to disclose for either of the reasons set out above will be reviewed at intervals, and if the grounds for withholding it have disappeared then it will become disclosable. An argument that absolutely everything covered by regulation 15(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 his or her 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 persons will *not* be revealed.

51 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 their proposals confidentially and informally with HSE officials before submitting their notifications.

52 Some limited disclosure will always be necessary to meet HSE's statutory obligations and so that the notification can be evaluated. This is provided for in regulation 15(5). Information may be given in particular to members of ACGM, whose opinion will be taken into account by HSE in its decisions on consent or objection. Anyone receiving information in this way may not use it except for the purpose for which it was given.

53 If at any time a notifier withdraws a notification, disclosure of any information associated with it will cease, though of course by that time some of it may already be in the public domain. But information which the notifier has asked HSE to withhold will not be disclosed until the notifier's case has been assessed and a decision reached, and if necessary the notifier has been given the opportunity to withdraw the notification.

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Regulation 16 Register of notifications

Regulation

-(1) The Executive shall maintain a register of notifications to which regulation 8(3) or 9(5) relate (for which the consent of the Executive is required) and that register shall be open to inspection by members of the public at any reasonable time.

(2) The register referred to in paragraph (1) shall contain in relation to each such notification -

(a) such of the information referred to in regulation 15(3) as has not been withheld in accordance with paragraph (4) of that regulation; and

(b) a statement as to whether or not the consent of the Executive has been granted.

(3) The information referred to in sub-paragraph (a) of paragraph (2) shall be entered in the register within 14 days of its receipt by the Executive and the information referred to in sub-paragraph (b) of that paragraph within 14 days of the decision whether or not to grant the consent having been made, except that where the notifier has requested that certain information specified in regulation 15(3) be withheld in accordance with regulation 15(4), that information shall only be entered in the register not less than 14 days but not more than 28 days after the Executive has made a decision not to withhold that information.

(4) Copies of the register shall be maintained at -

(a) the area office of the Executive in whose area the notifier is situated; and

(b) Baynards House, 1 Chepstow Place, Westbourne Grove, London W2 4TF,

(c) Magdalen House, Stanley Precinct, Bootle, Merseyside, L20 3QZ.

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Guidance

54 This regulation requires HSE to maintain a public register of notifications requiring *consent* (ie notifications of intention to use premises for activities involving Group II micro-organisms for the first time and individual Type B operations involving Group II micro-organisms). The information to be placed on the register is that specified by regulation 15(3), that is, the information for which a case for confidentiality may not be made on competitiveness grounds, but any of it which HSE has agreed to withhold under regulation 15(4), to protect the notifier's intellectual property rights, will not be placed on the register. Information subject to a request for non-disclosure will not be placed on the register while the request is being considered, and if HSE does not accept the case being made, until the notifier has been given the opportunity to withdraw the notification.

55 The approved notification form for consent applications contains a separate section for the register information. To avoid delay arising from inadequate proposed entries, notifiers should provide in this section as full and precise a description of the organism, the purpose of the activity and the evaluation of forseeable effects on human health and the environment as they can, subject to the considerations set out in the guidance on regulation 15 above. It should precis the information contained in the main notification document in sufficient detail to enable a user of the register to make an informed judgment about possible risks to the public and the environment.

16

56 Copies of the register are maintained at the area office of HSE in whose area the notifier is situated (addresses of HSE's local offices are given in general

Guidance

telephone directories, under 'Health and Safety Executive') and at Head Offices of HSE. The Head Office addresses are:

Health and Safety Executive
Health Policy Division
Room 536
Baynards House
1 Chepstow Place
Westbourne Grove
London W2 4TF
Tel: 071 243 6149

and

Health and Safety Executive
Technology and Health Sciences Division, Branch C6
Magdalen House
Stanley Precinct
Bootle
Merseyside L20 3QZ
Tel: 051 951 4831

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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.

Regulation 17

Duties on receiving notifications

Regulation

17

The Executive shall examine a notification under regulation 8 or 9 for -

(a) the conformity with the requirements of these Regulations;

(b) the accuracy and completeness of the information given;

(c) the correctness of the classification of the organisms to which the notification relates in accordance with Schedule 2; and

(d) where appropriate, the adequacy of the waste management, safety and emergency response measures.

Guidance

17

57 This regulation, which is largely self-explanatory, places requirements on HSE to scrutinise notifications received to ensure:

- conformity with the requirements of the Contained Use Regulations;
- accuracy and completeness of notified information;
- the correctness of classifications of organisms and micro-organisms; and
- where appropriate, adequacy of waste management, safety and emergency response measures.

Regulation 18

Information to be sent to the Secretary of State

Regulation

18

Forthwith after receipt, the Executive shall send to the Secretary of State a copy in each case of -

(a) any notification received under regulation 8 or 9;

(b) any requirement for further information under regulation 10(1) and the response thereto; and

(c) any notification relating to an accident under regulation 14,

and if requested to do so by the Secretary of State shall require additional information under regulation 10(1).

Guidance

18

58 This regulation requires HSE to pass to the Secretary of State copies of notifications, any requests it makes for further information and responses to such requests, and accident notifications. It formalises cooperation between HSE and the Secretary of State on environmental matters.

Regulation 19

Reports to the European Commission

Regulation

19

The Executive shall send to the European Commission reports of notifications for which a consent is required under regulation 9(5) and summary reports of the application of these Regulations in accordance with Article 18 of the contained use Directive.

Guidance

19

59 Regulation 19 requires HSE to send reports to the European Commission in accordance with Article 18 of the Contained Use Directive (90/219/EEC). Under Article 18, member States are required to send to the Commission summary reports of notifications of individual activities for which a consent is required ie Type B operations involving Group II organisms. These reports include the description, proposed uses and risks of the micro-organisms. In addition, every three years, member States are required to submit a report on their experience of the operation of the Directive. The Commission publishes a summary based on these reports.

Regulation 20

Exemption certificates

Regulation

20

-(1) Subject to paragraph (2) and to any provisions imposed by the Communities in respect of the control and regulation of genetically modified organisms, the Executive may, with the agreement of the Secretary of State in so far as the exemption relates to the environment, by a certificate in writing, exempt any person or class of persons, genetically modified organism or class of genetically modified organisms from all or any of the requirements 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 Executive shall not grant any such exemption unless, having regard to the circumstances of the case and in particular to -

Regulation

20

(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 that the health and safety of persons who are likely to be affected by the exemption or the protection of the environment will not be prejudiced in consequence of it.

Guidance

20

60 This regulation sets out the powers of HSE to make exemptions from the requirements of the Regulations. Before making any such exemption HSE will consider the circumstances of the case and will need to be satisfied that the health and safety of persons and the protection of the environment 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.

Regulation 21 Enforcement and civil liability

Regulation

21

-(1) Insofar as any provision of regulations 6 to 14 is made under section 2 of the European Communities Act 1972[(a)] -

(a) the provisons of the Health and Safety at Work etc. Act 1974 relating to enforcement and offences shall apply to that provision as if that provision had been made under section 15 of that Act; and

(b) in the event of a breach of duty imposed by that provision, it shall confer a right of action in civil proceedings if that breach of duty causes damage.

(2) Notwithstanding regulation 3 of the Health and Safety (Enforcing Authority) Regulations 1989[(b)], the enforcing authority for these Regulations shall be the Executive.

(a) 1972 c.68
(b) S.I. 1989/1903

Guidance

21

61 The effect of regulation 21(1) is that the provisions of the 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 HSW Act. The provisions of the HSW Act in relation to matters such as 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.

62 Under regulation 21(2) HSE is the enforcing authority for the Contained Use Regulations in respect of both human health and environmental protection in all premises concerned, including those where local authorities enforce other HSW Act regulations.

Regulation 22 Fees for notifications

Regulation

-(1) Fees shall be payable in accordance with paragraph (2) by a notifier to the Executive in relation to any matter referred to in that paragraph.

(2) The fees referred to in paragraph (1) shall be -

(a) subject to sub-paragraph (b), on each notification of the intention to use premises for activities involving genetic modification for the first time under regulation 8, £100;

(b) on each notification of the intention to use premises for activities involving genetic modification for the first time, where a consent is required under regulation 8(3), £130;

(c) subject to sub-paragraph (d), on each notification of individual activities involving genetic modification under regulation 9, £180;

(d) on each notification of individual activities involving genetic modification for which a consent is required under regulation 9(5), £270.

(3) This regulation shall not apply to any notification made for the purposes of regulation 23(1) or (3) (which relates to transitional provisions).

22

Guidance

63 A fee is charged to cover the cost of processing all notifications except the annual retrospective summaries permitted by regulation 9(2). There is a fixed scale of charges with four different fees in it: the one to be paid depends upon the type of notification being made. Payment should be made when the notification is submitted. **NOTE: The scale of charges will be updated annually, and notifiers should check with HSE if they are unsure what the current rates are.**

64 Where a notification covers a connected programme of work covering more than one activity, as permitted by regulation 9(7), only one fee is required, however many separate activities it includes.

22

Regulation 23 Transitional provisions

Regulation

-(1) Where before 1st February 1993 a person had notified the Executive of his intention to undertake activities involving genetic modification which complied with regulation 5(1) and (2)(a) of the 1989 Regulations as then in force, that notification shall be treated as satisfying the requirements of regulation 8 except that regulation 8(3) shall apply to that activity on or after 1st February 1994.

(2) Before 2nd May 1993 it shall be a sufficient compliance with regulation 8 if the notifier commences the activity having notified his intention to do so 30 days in advance or such shorter time in advance as the Executive may approve and regulation 8(3) shall not apply to activities commenced before 2nd May 1993 until 1st February 1994.

(3) Where before 1st February 1993 a person had notified the Executive of his intention to undertake activities involving genetic modification which complied with regulation 5(1) and (2)(b) of the 1989 Regulations as then in force, that notification shall be treated as satisfying the requirements of regulation 9 except that regulation

23

Regulation

23

9(5) shall apply to that activity on or after 1st February 1994.

(4) Before 2nd April 1993 it shall be a sufficient compliance with regulation 9 if the notifier of an activity involving genetic modification had notified it in accordance with that regulation 30 days in advance or such shorter time in advance as the Executive may approve and regulation 9(5) shall not apply to activities commenced before 2nd April 1993 until 1st February 1994.

(5) Regulation 10 shall apply to any notification made on or after 1st February 1993.

Guidance

23

65 The aim of the transitional provisions is to ensure that those who have notified under the Genetic Manipulation Regulations 1989 may continue with as little disturbance as possible but also to ensure that those activities notified under the 1989 Regulations which are subject to consent are brought within the new regime.

66 Where a notification of first use or a notification of an individual activity was made under the 1989 Regulations then no further notification need be made unless, under the Contained Use Regulations, a consent is required - that is, for premises used for activities involving Group II organisms or individual activities involving Group II organisms in Type B operations. Where consent is required, those undertaking the activities have until one year after the new Regulations come into force either to obtain a consent or to cease the activity.

67 For the first 90 days after the Contained Use Regulations come into force a notifier may begin the activity in question provided that notification has been made 30 days in advance. This is to avoid creating a period when it would not be possible for new work to begin. For work beginning within the first 30 days after the Contained Use Regulations come into force notification would have to have been made under the Genetic Manipulation Regulations 1989, the notification period then bridging the two sets of Regulations. For activities subject to consent the notifier has until one year after the Contained Use Regulations come into force to obtain that consent.

68 Where notifiers are given up to one year to obtain consents under transitional arrangements, they will need to ensure that consent applications are submitted within 9 months of the Regulations coming into force to ensure that work does not have to cease while waiting up to 90 days for consents to be granted.

Regulation 24 Extension outside Great Britain

Regulation

24

These Regulations shall apply in relation to premises and activities outside Great Britain to which sections 1 to 59 and 80 to 82 of the Health and Safety at Work etc. Act 1974 apply by virtue of the Health and Safety at Work etc. Act 1974 (Application Outside Great Britain) Order 1989[(a)] as they apply to premises and activities within Great Britain.

(a) S.I. 1989/840

Guidance

24

69 The Regulations apply to those premises and activities specified in the Health and Safety at Work etc Act 1974 (Application Outside Great Britain) Order 1989 as they apply within Great Britain. Notification is therefore required of any activity which takes place on an offshore installation which is in

Guidance
24

territorial waters or areas designated under the Continental Shelf Act 1964 which includes 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 25 Revocation

Regulation
25

The 1989 Regulations are revoked.

Guidance
25

70 This regulation revokes the Genetic Manipulation Regulations 1989.

Schedule 1 Definition of genetic modification

Regulations 2(1) and 3(3)

Schedule 1

Part I

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 DNA techniques consisting of the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside the cell, into any virus, bacterial plasmid or other vector system so as to allow their incorporation into a host organism in which they do not occur naturally but in which they are capable of continued propagation;

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

(c) cell fusion (including protoplast 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.

Part II

Techniques which are not considered to result in genetic modification

2 The following techniques are not considered to result in genetic modification if they do not involve the use of recombinant-DNA molecules or genetically modified organisms -

(a) in vitro fertilisation;

(b) conjugation, transduction, transformation or any other natural process; and

(c) polyploidy induction.

Part III

Techniques to which these Regulations do not apply

3 These Regulations shall not apply to the following techniques of genetic modification if they do not involve the use of genetically modified organisms as recipient or parental organisms -

(a) mutagenesis;

(b) the construction and use of somatic hybridoma cells (for example for the production of monoclonal antibodies);

(c) cell fusion (including protoplast fusion) of plant cells where the resulting organisms can also be produced by traditional breeding methods;

(d) self-cloning of non-pathogenic naturally occurring micro-organisms which fulfil the criteria of Group I for recipient micro-organisms; and

(e) self-cloning of non-pathogenic naturally occurring organisms other than micro-organisms which fulfil the criteria of Part III of Schedule 2.

Schedule 2

Criteria for the classification of organisms

Regulation 2(2)

Part I

Criteria as applicable for classification of micro-organisms in Group I

1 Recipient or parental organism

(a) non-pathogenic;

(b) no adventitious agents;

(c) proven and extended history of safe use or built-in biological barriers, which, without interfering with optimal growth in the reactor or fermenter, confer limited survivability and replicability, without adverse consequences in the environment.

2 Vectors/Insert

(a) well characterised and free from known harmful sequences;

(b) limited in size as much as possible to the genetic sequences required to perform the intended function;

(c) should not increase the stability of the construct in the environment (unless that is a requirement of intended function);

(d) should be poorly mobilisable;

(e) should not transfer any resistance markers to micro-organisms not known to acquire them naturally (if such acquisition could compromise use of drugs to control disease agents).

3 Genetically modified micro-organisms

(a) non-pathogenic;

(b) as safe in the reactor or fermenter as recipient or parental organism, but with limited survivability and/or replicability without adverse consequences in the environment.

4 Other genetically modified micro-organisms that could be included in Group I if they meet the conditions in paragraph 3

(a) those constructed entirely from a single prokaryotic recipient (including its indigenous plasmids and viruses) or from a single eukaryotic recipient (including its chloroplasts, mitochondria, plasmids, but excluding viruses);

(b) those that consist entirely of genetic sequences from different species that exchange these sequences by known physiological processes.

Part II

Guidelines as applicable for classification of micro-organisms in Group I

For classification into Group I the following guidelines should be used to further interpret Part I of this Schedule.

5 Characteristics of the recipient or parental organism(s)

(1) Non-pathogenic

The recipient or parental organisms can be classified as non-pathogenic if they satisfy the conditions of one of the following sub-paragraphs -

(a) the recipient or parental strain should have an established record of safety in the laboratory and/or industry, with no adverse effects on human health and the environment;

(b) the recipient or parental strain does not meet the conditions of sub-paragraph (a) above but it belongs to a species for which there is a long record of biological work including safety in the laboratory and/or industry, showing no adverse effects on human health and the environment;

(c) if the recipient or parental organism is a strain which does not satisfy the conditions of sub-paragraph (a) above and belongs to a species for which there is no record of biological work including safe use in the laboratory and/or industry, appropriate testing (including, if necessary, animals) must be carried out, in order to establish non-pathogenicity and safety in the environment;

(d) if a non-virulent strain of an acknowledged pathogenic species is used, the strain should be as deficient as possible in genetic material that determines virulence so as to ensure no reversion to pathogenicity. In the case of bacteria, special attention should be given to plasmid or phage-borne virulence determinants.

(2) No adventitious agents

The recipient or parental strain/cell line should be free of known biological contaminating agents (symbionts, mycoplasms, viruses, viroids, etc), which are potentially harmful.

(3) The recipient or parental strain/cell line should have proven and extended history of safe use or built-in biological barriers, which, without interfering with optimal growth in the reactor or fermenter, confer limited survivability and replicability, without adverse consequences in the environment (applicable only for Type B operations).

Schedule 2

6 Characteristics of the vector

(1) The vector should be well characterised

For this purpose the following characteristics should be taken into account.

(a) Information on composition and construction

(i) the type of the vector should be defined (virus, plasmid, cosmid, phasmid, transposable element, minichromosome, etc);

(ii) the following information on the constituent fragments of the vector should be available -

(aa) the origin of each fragment (progenitor genetic element, strain of organism in which the progenitor genetic element naturally occurred),

(bb) if some fragments are synthetic, their functions should be known;

(iii) the methods used for construction should be known.

(b) Information on vector structure

(i) the size of the vector should be known and expressed in basepairs or D;

(ii) the function and relative positions of the following should be known -

(aa) structural genes,

(bb) marker genes for selection (antibiotic resistance, heavy metal resistance, phage immunity, genes coding for degradation of xenobiotics, etc),

(cc) regulatory elements,

(dd) target sites (nic-sites, restriction endonuclease sites, linkers, etc),

(ee) transposable elements (including provirus sequences),

(ff) genes related to transfer and mobilisation function (eg with respect to conjugation, transduction or chromosomal integration),

(gg) replicon(s).

(2) The vector should be free from harmful sequences

The vector should not contain genes coding for potentially harmful or pathogenic traits (eg virulence determinants, toxins, etc.) unless for Type A operations, such genes constitute an essential feature of the vector without, under any conditions or circumstances, resulting in a harmful or pathogenic phenotype of the genetically modified micro-organism.

(3) The vector should be limited in size as much as possible to the genetic sequences required to perform the intended function.

(4) The vector should not increase the stability of the genetically modified micro-organism in the environment (unless that is a requirement of the intended function).

(5) The vector should be poorly mobilisable

(a) If the vector is a plasmid -

(i) it should have a restricted host-range;

(ii) it should be defective in transfer-mobilisation factors eg Tra^- Mob^+, for Type A operations or Tra^-, Mob^-, for Type B operations.

(b) If the vector is a virus, cosmid or phasmid -

(i) it should have a restricted host-range;

(ii) it should be rendered non-lysogenic when used as a cloning vector (eg defective in the cI-lambda repressor).

(6) It should not transfer any resistance markers to micro-organisms not known to acquire them naturally (if such acquisition could compromise use of drugs to control disease agents).

7 Required characteristics of the insert

(1) The insert should be well characterised

For this purpose, the following characteristics should be taken into account.

(a) The origin of the insert should be known (genus, species, strain).

(b) The following information on the library from which the insert originated, should be known -

(i) the source and method for obtaining the nucleic acid of interest (cDNA, chromosomal, mitochondrial, etc);

(ii) the vector in which the library was constructed (eg lambda gt11, pBR322, etc) and the site in which the DNA was inserted;

(iii) the method used for identification (colony, hybridization, immuno-blot, etc);

(iv) the strain used for library construction.

(c) If the insert is synthetic, its intended function should be identified.

(d) The following information on the structure of the insert is required -

(i) information on structural genes, regulatory elements;

(ii) size of the insert;

(iii) restriction endonuclease sites flanking the insert;

(iv) information on transposable elements and provirus sequences.

(2) The insert should be free from harmful sequences

(a) The function of each genetic unit in the insert should be defined (not applicable for Type A operations);

(b) the insert should not contain genes coding for potentially harmful or pathogenic traits (eg virulence determinants, toxins, etc.), (unless for Type A operations, such genes constitute an essential part of the insert without, under any circumstances resulting in a harmful or pathogenic phenotype of the genetically modified micro-organism).

(3) The insert should be limited in size as much as possible to the genetic sequences required to perform the intended function.

(4) The insert should not increase the stability of the construct in the environment (unless that is a requirement of intended function).

(5) The insert should be poorly mobilisable

For instance, it should not contain transposing or transferrable provirus sequences and other functional transposing sequences.

8 Required characteristics of the genetically modified micro-organism

(1) The genetically modified micro-organism should be non-pathogenic

This requirement is reasonably assured by compliance with all the requirements above.

(2) (a) The genetically modified micro-organism should be as safe (to man and the environment) as the recipient or parental strains (applicable only for Type A operations);

(b) the genetically modified micro-organisms should be as safe in the reactor or fermenter as the recipient or parental strains, but with limited survivability and/or replicability outside the reactor or fermenter without adverse consequences in the environment (applicable only for Type B operations).

9 Other genetically modified micro-organisms that could be included in Group I if they meet the conditions in paragraph 8 above

(1) Those constructed entirely from a single prokaryotic recipient (including its indigenous plasmids and viruses) or from a single eukaryotic recipient (including its chloroplasts, mitochondria, plasmids, but excluding viruses).

(2) Those that consist entirely of genetic sequences from different species that exchange these sequences by known physiological processes.

Part III

Criteria for the classification of organisms other than micro-organisms

10 An organism which satisfies the criteria of this Part is a genetically modified organism -

(a) which is not a genetically modified micro-organism: and

(b) which is as safe in the containment facility as any recipient or parental organism.

Schedule 3

Parameters to be taken into account in risk assessments, as far as they are relevant, under regulation 7

Regulation 7(3)

Schedule 3

Characteristics of the donor, recipient or (where appropriate) parental organism

1 The following matters shall be investigated and assessed in relation to any organism which is or will be a donor, recipient or parental organism -

(a) the name, species, subspecies and strain of the organism;

(b) the degree of relatedness between the donor, recipient (and where appropriate the parental) organism in relation to which the assessment is being carried out;

(c) the sources of the organism;

(d) the reproductive cycle of the organism;

(e) history of prior genetic modifications to the organism;

(f) the stability of the genetic traits of the organism;

(g) the nature of the pathogenicity, virulence, infectivity, toxicity, and vectors of disease transmission of the organism;

(h) the base sequence, frequency of mobilisation and specificity of the organism's indigenous vectors;

(i) the presence in the organism of genes which confer resistance;

(j) the host range of an organism which is a parasite or pathogen;

(k) the organism's other potentially significant physiological traits, and the stability of those traits;

(l) the organism's natural habitat and geographic distribution;

(m) the climatic characteristics of the organism's natural habitat;

(n) the significant involvement of the organism in environmental processes, including nitrogen fixation and pH regulation;

(o) the interaction of the organism with other organisms in the environment and its effect on those organisms, including its likely competitive or symbiotic properties;

(p) the ability of the organism to form survival structures, including seeds, spores or sclerotia.

Characteristics of the modified organism

2 The following matters shall be investigated and assessed in relation to an organism in relation to which a risk assessment under regulation 7 is carried out -

(a) the description of the modification, including the technique used or proposed to be used to introduce a vector or insert into the organism;

Schedule 3

(b) the nature and source of the vector introduced into the organism;

(c) the function of the genetic modification and/or of the new nucleic acid;

(d) the structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organism;

(e) the stability of the genetic traits introduced into the organism;

(f) the frequency of mobilisation of inserted vector or genetic transfer capability;

(g) the rate and level of expression of the new genetic material in the organism, and the method and sensitivity of measurement of that rate and level;

(h) the activity of the expressed protein.

Health considerations

3 The following matters shall be investigated and assessed in relation to an organism in relation to which a risk assessment under regulation 7 is carried out -

(a) toxic or allergenic effects of non-viable organisms and/or their metabolic products;

(b) product hazards;

(c) comparison of the modified micro-organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

(d) capacity for colonization;

(e) if the organism is pathogenic to humans who are immunocompetent -

(i) diseases caused and mechanism of pathogenicity including invasiveness and virulence,

(ii) communicability,

(iii) infective dose,

(iv) host range, possibility of alteration,

(v) possibility of survival outside of human host,

(vi) presence of vectors or means of dissemination,

(vii) biological stability,

(viii) antibiotic-resistance patterns,

(ix) allergenicity,

(x) availability of appropriate therapies.

Environmental considerations

4 The following matters shall also be investigated and assessed in relation to an organism in relation to which a risk assessment under regulation 7 is carried out -

Schedule 3

(a) the factors affecting survival, multiplication and dissemination of the modified organism in the environment;

(b) the available techniques for detection, identification, and monitoring of the modified organism in the environment;

(c) the available techniques for detecting transfer of the new genetic material to other organisms;

(d) the known and predicted habitats of the modified organism;

(e) the ecosystems to which the modified organism could be disseminated as a result of an escape;

(f) the anticipated mechanism and result of interaction between the modified organism and the organisms which might be exposed in case of the escape of the organism;

(g) the known or predicted effects of the organism on plants and animals, including pathogenicity, infectivity, toxicity, virulence, vector or pathogen allergenicity, colonisation, predation, parasitism, symbiosis and competition;

(h) the known or predicted involvement of the organism in biogeochemical processes, including nitrogen fixation and pH regulation;

(i) the availability of methods for decontamination of the area in case of release to the environment.

Schedule 4

Information required for a notification under regulation 8(1)

Regulation 8(1)

Schedule 4

1 A notification required for the purposes of regulation 8(1) shall include the following information -

(a) the name and address of the person responsible for carrying out the activity and the names of persons responsible for supervision, monitoring and safety together with details of their training and qualifications;

(b) address of the premises where the activity is to be carried on and its grid reference and, where appropriate, a description of the sections of the installation;

(c) a description of the nature of the activity to be undertaken, the likely scale of the operation and in particular, in the case of micro-organisms, their classification (whether in Group I or Group II);

(d) a summary of the risk assessment undertaken in accordance with regulation 7;

(e) the names and capacities of the members of the genetic modification safety committee;

(f) comments made by the genetic modification safety committee on the local arrangements for risk assessment;

Schedule 4

(g) the names of the biological and deputy biological safety officers concerned with the intended activities (if any);

(h) the name of the supervisory medical officer (if any);

(i) the arrangements for health surveillance (if any); and

(j) any other information the Executive needs for the purpose of maintaining the register referred to in regulation 16.

Schedule 5

Information required for a notification under regulation 9

Regulation 9

Part I

Schedule 5

Information required under regulation 9(3)

1 A notification required for the purposes of regulation 9(3) shall include the following information -

(a) the name and address of the person responsible for carrying out the activity;

(b) address of the premises where the activity is to be carried out;

(c) the date of the notification referred to in regulation 8(1);

(d) the parental organism used, or where applicable the host-vector system used;

(e) the source and the intended function of the genetic material involved in the modification;

(f) the identity and characteristics of the genetically modified organism;

(g) the purpose of the activity including the expected results;

(h) where appropriate the culture volumes to be used or the scale of the activity;

(i) details of waste treatment including levels of live genetically modified micro-organisms in the waste; and

(j) a summary of the risk assessment required in accordance with regulation 7 and of the comments of the genetic modification safety committee on it.

Part II

Additional information required under regulation 9(4)

2 In addition to the information required under Part I a notification made for the purposes of regulation 9(4) shall contain the following information -

(a) a description of the sections of the installation involved and the methods for handling the organisms;

Schedule 5

(b) a description of the predominant meteorological conditions and the potential sources of danger arising from the location of the installation;

(c) a description of the protective and supervisory methods to be applied throughout the duration of the activity; and

(d) in the case of micro-organisms, the containment level to which the micro-organism has been allocated in accordance with the risk assessment made in accordance with regulation 7(1) and in any case the safety precautions to be observed.

Part III

Additional information required under regulation 9(5)

3 In addition to the information required under Parts I and II a notification made for the purposes of regulation 9(5) shall contain the information specified in paragraph 5.

4 If it is not technically possible, or if it does not appear necessary to give the information specified in paragraph 5, the reason shall be stated. The level of detail required in response to each subset of considerations is likely to vary according to the nature and scale of the proposed activity. In the case of information already submitted to the Executive by the notifier under these Regulations (or the 1989 Regulations) reference can be made to that information by him.

5 The additional information required is -

(a) information about the genetically modified micro-organisms -

(i) the identity and characteristics of the genetically modified micro-organisms,

(ii) the purpose of the contained use or the nature of the product,

(iii) the host-vector system to be used where applicable,

(iv) the culture volume to be used,

(v) behaviour and characteristics of the micro-organisms in the case of changes in the conditions of containment or release into the environment,

(vi) overview of the potential hazards associated with the release of the micro-organisms into the environment, and

(vii) substances which are or may be produced in the course of use of the micro-organisms other than the intended product;

(b) information about personnel -

(i) the maximum number of persons working in the installation, and

(ii) the number of persons who will work directly with the micro-organisms;

(c) information about the installation -

(i) the activity in which the micro-organisms are to be used,

(ii) the technological processes used,

Schedule 5

(iii) a description of the sections of the installation involved, and

(iv) the predominant meteorological conditions and specific hazards arising from the location of the installation;

(d) information about waste management -

(i) types, quantities and potential hazards arising from the use of the micro-organisms,

(ii) waste management techniques used including recovery of liquid or solid wastes and the inactivation techniques used, and

(iii) ultimate form and destination of inactivated wastes;

(e) information about accident prevention and emergency response plans -

(i) the sources of hazards and conditions under which accidents might occur,

(ii) the preventive measures applied such as safety equipment, alarm systems, containment methods and procedures and available resources,

(iii) a description of information given to workers, and

(iv) the information necessary for the Executive to evaluate any emergency plan prepared in accordance with regulation 13;

(f) the full risk assessment referred to in regulation 7; and

(g) any other information the Executive needs for the purpose of maintaining the register referred to in regulation 16.

Schedule 6

Containment measures for micro-organisms of Group II

Regulation 12(4)

Schedule 6

1 The containment measures for Type B operations using micro-organisms from Group II shall be chosen by the user from the levels in the Table below as appropriate to the micro-organism and the operation in question in order to ensure the protection of health of the general population and the environment.

2 Type B operations shall be considered in terms of their unit operations. The characteristics of each operation will dictate the physical containment to be used at that stage. This will allow the selection and design of process, plant and operating procedures best fitted to ensure adequate and safe containment. Two important factors to be considered when selecting the equipment needed to implement the containment are the risk of, and the effects consequent on, equipment failure. Engineering practice may require increasingly stringent standards to reduce the risks of failure as the consequence of that failure becomes less tolerable.

Schedule 6

	Specifications	*Containment Levels*		
		B2	*B3*	*B4*
1	Viable micro-organisms should be contained in a system which physically separates the process from the environment (closed system)	Yes	Yes	Yes
2	Exhaust gases from the closed system should be treated so as to:	Minimise release	Prevent release	Prevent release
3	Sample collection, addition of materials to a closed system and transfer of viable micro-organisms to another closed system, should be performed so as to:	Minimise release	Prevent release	Prevent release
4	Bulk culture fluids should not be removed from the closed system unless the viable micro-organisms have been:	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5	Seals should be designed so as to:	Minimise release	Prevent release	Prevent release
6	Closed systems should be located within a controlled area	Optional	Optional	Yes, and purpose-built
	(a) Biohazard signs should be posted	Optional	Yes	Yes
	(b) Access should be restricted to nominated personnel only	Optional	Yes	Yes, via airlock
	(c) Personnel should wear protective clothing	Yes,work clothing	Yes	Yes A complete change
	(d) Decontamination and washing facilities should be provided for personnel	Yes	Yes	Yes
	(e) Personnel should shower before leaving the controlled area	No	Optional	Yes
	(f) Effluent from sinks and showers should be collected and inactivated before release	No	Optional	Yes

Schedule 6

		Containment Levels		
	Specifications	*B2*	*B3*	*B4*
	(g) The controlled area should be adequately ventilated to minimise air contamination	Optional	Optional	Yes
	(h) The controlled areas should be maintained at an air pressure negative to atmosphere	No	Optional	Yes
	(i) Input air and extract air to the controlled area should be HEPA filtered	No	Optional	Yes
	(j) The controlled area should be designed to contain spillage of the entire contents of the closed system	Optional	Yes	Yes
	(k) The controlled area should be sealable to permit fumigation	No	Optional	Yes
7	Effluent treatment before final discharge	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated physical means

Appendix 1 Notification requirements

Appendix 2 Current titles in the ACGM guidance note series

ACGM/HSE/DOE Note 1.	(2nd Revision) - Guidance on construction of recombinants containing potentially oncogenic nucleic acid sequences.
ACGM/HSE/DOE Note 2.	Disabled host/vector systems (now incorporated in Note 7).
ACGM/HSE/DOE Note 3.	The intentional introduction of genetically manipulated organisms into the environment.
ACGM/HSE/DOE Note 4.	Guidelines for the health surveillance of those involved in genetic manipulation at laboratory and large-scale.
ACGM/HSE/DOE Note 5.	Guidance on the contained use of eukaryotic viral vectors in genetic modification.
ACGM/HSE/DOE Note 6.	Guidelines for the large-scale use of genetically manipulated organisms.
ACGM/HSE/DOE Note 7.	Guidelines for the risk assessment of operations involving the contained use of genetically modified micro-organisms.
ACGM/HSE/DOE Note 8.	Laboratory containment facilities for genetic manipulation.
ACGM/HSE/DOE Note 9.	Guidelines on work with transgenic animals.
ACGM/HSE/DOE Note 10.	Guidelines on work involving the genetic manipulation of plants and plant pests.
ACGM/HSE/DOE Note 11.	Genetic manipulation safety committees.

Appendix 3

Format for information to be supplied with accident notification* (regulation 14)

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:
Grid reference:
Principal Activity of installation . . . . . .
. . . . . .
Type of activity (Type A or Type B):
Classification of organism (Group I or Group II)

2 *Type of accident*
Failure of equipment (breakage/leakage etc.)
Fire
Explosion
Maloperation of equipment (human/mechanical)
Other (specify) . . . . . .

3 *Organisms released*
Identity of genetically modified organisms released:
Quantity of genetically modified organisms released:
Form and/or concentration in which organisms released:

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*

* As agreed by the Committee of National Competent Authorities

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