HSE
Health and Safety Executive

The Genetically Modified Organisms (Contained Use) Regulations 2014

Guidance on Regulations

L29 (Fifth edition)
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The Genetically Modified Organisms (Contained Use) Regulations 2014 came into force on 1 October 2014. This fifth edition of L29 provides practical advice to help dutyholders comply with their legal duties in relation to working with GMOs in contained facilities. It describes the law that applies, sets out the containment measures and other controls that need to be considered and explains the role of the competent authority. The guidance covers carrying out the risk assessment, classifying the contained use work, notifying to the competent authority, applying the relevant control measures and accident reporting.

Changes have been made to the guidance to:

- reflect the legislative changes to the 2014 Regulations;
- simplify and clarify the text;
- take account of advances in technology, for example synthetic biology;
- provide clearer distinction between duties on the user and duties on the competent authority;
- remove some of the technical advice, which will be updated and included in *The SACGM Compendium of Guidance*;
- remove the appeals process and provide clearer, standalone guidance on the appeals procedure;
- improve the advice on significant changes, the genetic modification safety committee, and how the Regulations interact with Control of Substances Hazardous to Health Regulations 2002 (COSHH).

HSE Books

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Second edition 1993
Third edition 1996
Fourth edition 2000
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This guidance is issued by the Health and Safety Executive. Following the guidance is not compulsory, unless specifically stated, and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance.

Contents

Introduction

1 This publication contains guidance on the Genetically Modified Organisms (Contained Use) Regulations 2014,[1] ('the Regulations'). The Regulations consolidate, revoke and replace:

(a) the Genetically Modified Organisms (Contained Use) Regulations 2000;
(b) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002;
(c) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005;
(d) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010.

2 The Regulations are made under the powers of the Health and Safety at Work etc Act 1974[2] ('the HSW Act') and the European Communities Act 1972[3] and are concerned with the prevention of harm to human health that arises from contained use involving genetically modified micro-organisms (GMMs), genetically modified (GM) animals and GM plants, and the prevention of harm to the environment arising from contained use involving GMMs. GM animals, plants and insects are collectively known as larger genetically modified organisms (GMOs).

3 The Regulations transpose and implement European Council Directive 2009/41/EC on the contained use of genetically modified micro-organisms ('the Directive').[4] Larger GMOs are not covered by the Directive, but have been included in the Regulations.

4 The competent authority responsible for the Regulations consists of the Health and Safety Executive (HSE) and the Secretary of State for the Environment, Food and Rural Affairs (Defra) in England and Wales (www.gov.uk/government/organisations/department-for-environment-food-rural-affairs). In Scotland, HSE and the Scottish Ministers are the competent authority. HSE takes the lead on their behalf and acts as the point of contact for notifications, enquiries and inspections.

5 The guidance applies to contained use, whether in a work context or not, including contained use by private individuals (eg DIY biologists) and contained use in an educational setting.

6 This guidance is aimed at dutyholders and health and safety professionals, but managers and health and safety representatives may also find it useful. It describes both the provisions of the Regulations and the legal duties placed on dutyholders and the competent authorities. These include:

(a) the requirement to carry out an assessment of the risks to human health and the environment (or human health for larger GMOs) and to obtain competent advice on that assessment before any contained use can start;
(b) the requirement to make a notification to the competent authority before starting a contained use with GMOs, in respect of the first use of a premises as well as contained uses of low, moderate and high risk;

(c) the requirement for the competent authority to examine notifications for compliance with the Regulations and where they are content, issue consent for contained uses of moderate and high risk;
(d) the requirement for a person who undertakes contained use to adhere to the safety principles and apply containment and control measures appropriate to that contained use to protect human health and the environment;
(e) the requirement to inform the competent authority when accidents happen;
(f) the requirement for the competent authority to maintain a register of the notifications and make this available for public inspection;
(g) provisions relating to keeping certain information confidential (eg on grounds of national security);
(h) provision of a range of powers to the competent authority to administer and enforce the Regulations;
(i) provision of a right of appeal for any person who is aggrieved by certain decisions of the competent authority.

7 The requirements of the Regulations also apply to 'synthetic biology', ie the use of techniques that involves incorporating synthesised DNA or RNA into an organism. It is inserting the synthetic material into an organism that makes it a 'contained use' and not the process of the DNA synthesis.

8 Protection of the environment from contained uses involving larger GMOs is achieved through relevant sections of the Environmental Protection Act 1990[5] ('the EPA') and associated regulations, the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996,[6] as amended by the Genetically Modified Organisms (Deliberate Release and Risk Assessment – Amendment) Regulations 1997.[7] Defra is responsible for this legislation.

9 Taken together, the Regulations and the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996 (as amended) and the EPA require, with certain exceptions, that anyone carrying out any contained use involving genetic modification does so in a way which satisfies the Regulations. Among other things, this means carrying out a risk assessment for both human health and environmental protection, and in certain circumstances submitting a notification to the competent authority, and in some cases receiving the competent authority's formal consent.

10 All work activities, including those concerned with genetic modification and synthetic biology, are covered by the HSW Act and relevant regulations made under that Act. These include, where appropriate, the Control of Substances Hazardous to Health Regulations 2002[8] (COSHH) and the Management of Health and Safety at Work Regulations 1992[9] ('the Management Regulations'). Where the provisions of COSHH and the Regulations both apply, the risk assessment must consider the requirements of both sets of Regulations when determining the most appropriate control measures for the work. In circumstances where the relative requirements under COSHH and the Regulations differ, the higher standard (ie the more stringent control measure) must be applied. Where inconsistencies exist between the two sets of Regulations, these have been highlighted and addressed in the guidance.

Legislation

11 This guidance does not cover all legislation that may have a bearing on work with GMOs. Other areas of legislation that may be relevant include, eg:

(a) environmental protection (including plant, wildlife, water and waste);

(b) transport of dangerous goods;
(c) use of human tissue;
(d) animal welfare;
(e) human and veterinary medicines;
(f) national security;
(g) marketing authorisation.

12 It is the responsibility of the dutyholder to ensure compliance with the relevant regulations and any other legislation that comes to bear on their activities.

Enforcement

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

14 HSE also enforces the sections of the EPA relevant to contained use and associated regulations under an Agency Agreement and Memorandum of Understanding with Defra and the Devolved Administrations.

Guidance from the Scientific Advisory Committee on Genetic Modification

15 The Scientific Advisory Committee on Genetic Modification (Contained Use) (SACGM(CU)) is a non-statutory scientific advisory committee established in 2004. SACGM(CU) provides scientific advice to the competent authorities on the contained use of GMOs, particularly in respect of hazard identification and risk assessment. HSE, with advice from the SACGM(CU), has prepared a compendium of guidance[10] on subjects related to the contained use of GMOs. The compendium provides useful advice on how to comply with the Regulations and is referred to, where appropriate, in this guidance.

PART 1 Interpretation and general

Regulation 1 Citation and commencement

Regulation 1

These Regulations may be cited as the Genetically Modified Organisms (Contained Use) Regulations 2014 and come into force on 1st October 2014.

Regulation 2 Interpretation

Regulation 2

(1) In these Regulations—

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

"the 2000 Regulations" means the Genetically Modified Organisms (Contained Use) Regulations 2000;

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

"class" in relation to a contained use involving micro-organisms, means one of the four classes set out in Schedule 1;

"competent authority" means in relation to premises situated in, or contained use taking place in—

(a) England and Wales, the Secretary of State and the Executive, acting jointly; or
(b) Scotland, the Scottish Ministers and the Executive, acting jointly,

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

"contained use" means an activity in which organisms are genetically modified or in which genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which physical, chemical or biological barriers, or any combination of such barriers, are used to limit their contact with, and to provide a high level of protection for, humans and the environment;

"emergency plan" means a plan required by regulation 21;

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

"genetic modification" in relation to an organism means the altering of the genetic material in that organism in a way that does not occur naturally by mating or natural recombination (or both) and within the terms of this definition—

Regulation 2

(a) *genetic modification occurs at least through the use of the techniques listed in Part 1 of Schedule 2; and*
(b) *the techniques set out in Part 2 of Schedule 2 are not considered to result in genetic modification,*

and "genetically modified" is to be construed accordingly;

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

"larger GMO" means an organism which is genetically modified or is the subject of genetic modification which is not a micro-organism;

"micro-organism" means a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, and includes a virus, a viroid, and an animal or plant cell in culture;

"notifier" means, except in regulation 14, the person who submits or has submitted a notification to the competent authority under regulation 9(2), 10(2), 11(2), 12(2) or 33(3);

"organism" means a biological entity capable of replication or of transferring genetic material and includes a micro-organism, but does not include a human, human embryo or human admixed embryo and for the purposes of this definition—

(a) *"human admixed embryo" has the same meaning as in the Human Fertilisation and Embryology Act 1990 by virtue of section 4A(6) and (11) of that Act; and*
(b) *"human embryo" has the same meaning as "embryo" in the Human Fertilisation and Embryology Act 1990 (apart from section 4A) by virtue of section 1(1) and (6) of that Act;*

"person responsible for contained use" or "person responsible for the contained use" means—

(a) *a person who has the authority to determine whether a particular contained use takes place, or*
(b) *a person who has control of the planning or conduct (or both) of that contained use, and there may be more than one person responsible for the same contained use;*

"premises" means both single buildings and a site made up of more than one building;

"risk assessment" means, in the context of contained use involving—

(a) *genetically modified micro-organisms, an assessment carried out as required by regulation 5(1); or*
(b) *larger GMOs, an assessment carried out as required by regulation 6(1);*

"transboundary movement" has the meaning assigned to it by Article 3 of Regulation (EC) No 1946/2003 of the European Parliament and the Council on transboundary movements of genetically modified organisms;

"user" means a person who undertakes or proposes to undertake a contained use;

Regulation 2

"working day" means any day other than a Saturday, a Sunday, Christmas Day or Good Friday, or a bank holiday specified in Schedule 1 to the Banking and Financial Dealings Act 1971.

(2) A reference in these Regulations to the competent authority is to be construed as a reference to the joint competent authority in relation to premises or contained use where the relevant notification is required to be submitted to the joint competent authority in accordance with regulation 9(5) or 13(1).

(3) In these Regulations—

(a) a reference to an appropriate containment level is a reference to the containment level assigned to a contained use involving micro-organisms in accordance with paragraphs 3(i) and 4 of Part 2 of Schedule 3;
(b) any reference to a contained use in a numbered class is a reference to a contained use involving micro-organisms which has been classified as belonging to the class of that number in accordance with paragraph 3(j) and (k) of Part 2 of Schedule 3.

(4) The measures in—

(a) Part 2 of Schedule 8 are to be applied in accordance with Part 1 of that Schedule; and
(b) Tables 1a, 1b and 1c in Part 2 of Schedule 8 are to be applied in accordance with the notes set out at the end of the table in question.

Guidance 2

16 Regulation 2 defines the terms used throughout the Regulations. The definitions include the concepts central to the legislation. This guidance aims to provide further explanation, using examples where possible to help with interpretation and understanding of how to comply with the Regulations.

17 ***Organism:*** This term covers all organisms, including multicellular organisms, such as animals, plants, insects, nematodes, ie larger GMOs, as well as micro-organisms (including those made synthetically). The definition does not include humans, human embryos and human admixed embryos, which are excluded from these Regulations.

18 ***Micro-organism:*** This term covers bacteria, fungi and viruses, as well as cell and tissue cultures from plants, animals or humans. Naked nucleic acid, oligonucleotides, synthetic DNA, plasmids or liposomes are not considered to be micro-organisms. However, full-length copies of the genomes of viruses (whether recombinant or synthetically made) that have the potential to be infectious in their own right are considered to be micro-organisms (even when they are not encapsulated or enveloped). In the case of negative strand viruses, the notion of having the potential to be infectious should include situations where the infectivity of the genome is dependent on the presence of an exogenous source of polymerase. Plant pollen, animal ova and sperm are not considered to be micro-organisms. However, where they are from larger GMOs, the same controls apply for minimising dissemination of larger GMOs.

19 ***Genetic modification:*** Means any alteration of the genetic material of an organism (ie DNA or RNA), which does not occur naturally (by mating or recombination) and which has been achieved through one of the techniques set out in Part 1 of Schedule 2. The techniques listed are examples and are indicative of the types of alterations that fall within the Regulations. The requirements of the Regulations (eg risk assessment, application of control measures) apply to the activity in which GMOs are created, used or disposed of rather than the techniques themselves.

Guidance 2

20 These techniques involve introducing and incorporating new combinations of genetic material (whether derived from an existing organism or synthetically made) into a recipient organism in which they do not naturally occur. The introduced genetic material must be capable of stable incorporation and/or continued propagation in the recipient organism. Techniques considered to be genetic modification include:

(a) any technique which alters the genetic material in an organism using a method that does not occur by natural mating or recombination (eg synthetic generation of artificial chromosomes in yeast);
(b) introduction of foreign or synthetic genetic material into an organism via transfection, recombinant bacteriophage transduction (eg to make gene libraries), transformation, particle bombardment or other gene delivery systems (eg liposomes);
(c) gene deletions or the insertion of multiple copies of a gene in an organism count as genetic modification if they are brought about using any listed technique or other artificial method;
(d) stable introduction of synthetically generated DNA or RNA (eg 'biobricks') into an organism;
(e) techniques that involve directly introducing heritable genetic material (eg particle bombardment of plant tissues, directly injecting naked DNA into an animal and liposomes) only where the introduced genetic material is intended to be incorporated into the organism's genetic material in a stable way.

21 Genetic modification of larger GMOs includes not only their generation but also their breeding on (even if one of the parents was not itself a GMO and the cross was by natural means). This also includes situations where only some of the cells contain the modification (ie mosaics).

22 Part 2 of Schedule 2 lists techniques that are not considered to fall within the definition of genetic modification but only where these techniques do not involve using recombinant or synthetic DNA or RNA or organisms that are themselves GMOs. Techniques that are not considered to be genetic modification include:

(a) organisms generated using methods based on natural mating or recombination;
(b) somatic cell nuclear transfer ('cloning') provided no GM material is present and the donor/recipient organisms are able to interbreed;
(c) artificial transfer of pollen from one flower to another (considered to be natural fertilisation);
(d) hybrid or reassortant viruses generated by natural recombination or trans-encapsidation during co-infection of a cell;
(e) DNA vaccination, where naked or synthetic DNA is introduced into animals to elicit an immune response against antigens encoded by that material, with no intention of stable integration.

23 Although not listed, DNA synthesis is not considered to be a contained use. It only falls within the Regulations, where the synthesised DNA is incorporated into an organism.

24 ***Contained use:*** Any activity involving GMOs where barriers are used to limit contact with and protect humans and the environment. Barriers used must provide a high level of safety for humans and the environment. These barriers can be:

(a) **physical:** This would normally take the form of a building, a room, a container, an obstruction, equipment or physical process (eg ventilation, UV irradiation) used to prevent escape or exposure to the GMO;

Guidance 2

(b) **chemical:** This can be interpreted as the use of chemicals to inactivate/ destroy a GMO before waste disposal, or the use of chemicals to prevent escape of larger GMOs (eg a chemical moat used to contain GM insects);

(c) **biological:** Where a GMO has inherent or engineered characteristics that mean it is attenuated, disabled or rendered unable to survive outside of a specialised environment, this is considered to provide a biological barrier. Where such barriers are included in the risk assessment, these characteristics should be well understood and robust, eg be stable, unable to be complemented and the result of multiple mutations.

25 It is likely that a combination of barriers will be used to provide several layers of protection. The use of physical, chemical or biological barriers must be applied in the context of regulation 18, which requires that exposure of humans and the environment to GMOs is reduced to the lowest level reasonably practicable. In most situations, there will be some physical separation (eg when work is undertaken in a laboratory) and implementing containment based purely on biological or chemical barriers would be unusual.

26 Contained use includes the actual process of genetic modification. It also includes any use of the constructed GMO including storage, transport, destruction and disposal. For example, while laboratory workers will be involved with constructing and using GMOs, those involved in commercial disposal of waste (containing GMOs) also need to comply with the Regulations.

27 ***Class:*** Contained uses are classified into one of four classes, as described in Schedule 1, based on the risk that the contained use presents to human health and the environment. These are referred to as class 1 (no or negligible risk), class 2 (low risk), class 3 (moderate risk) and class 4 (high risk). The contained use class is derived from the outcome of the risk assessment and is only applicable to GMMs and is not used for larger GMOs.

28 ***Person responsible:*** This term refers to the body or person, to which the duties within the Regulations are most applicable. For large organisations this will be the employer, who will assign tasks to various individuals to help them comply with the requirements to ensure that risk assessments are completed, notifications submitted and that the work is conducted safely.

29 ***User:*** This term is used to describe the person undertaking the contained use. For small companies or individuals, the user may also be the person responsible for the contained use. While the user is the person undertaking the contained use, they are also likely to be significantly involved in developing risk assessments for the contained use.

30 ***Notifier:*** This term is used to describe the person who has submitted a notification under the Regulations.

31 ***Accident:*** This term is defined as significant and unintended release. Consequently, it is incumbent on the person responsible and the user to determine if incidents meet this criteria and whether any immediate or delayed hazard could arise. The term is applicable to both GMMs in respect of harm to human health or the environment; and to larger GMOs but only in respect of human health. However, accidents involving the escape of a larger GMO, which could cause harm to the environment, are covered by the EPA, consequently users are advised to inform the competent authority of such accidents.

Regulation 3 Application

Regulation 3

(1) These Regulations (except regulation 18) do not apply to the genetic modification of organisms solely by any of the techniques referred to in Part 3 of Schedule 2 nor to any organisms so modified.

(2) These Regulations do not apply to any activity in which—

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

(i) the consent of any of the following granted under section 111(1) of the Environmental Protection Act 1990—

(aa) the Secretary of State;

(bb) the Scottish Ministers, as regards Scotland;

(cc) the Welsh Ministers, as regards Wales;

(ii) a consent granted by the Northern Ireland Department of the Environment under article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991;

(iii) a written consent given by the competent authority of an EEA state in accordance with Article 15(3), 17(6), or 18(2) of Directive (EC) No 2001/18 of the European Parliament and the Council on the deliberate release into the environment of genetically modified organisms,

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

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

(i) a medicinal product for human or veterinary use marketed in accordance with Regulation (EC) No 726/2004 of the European Parliament and the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

(ii) food or feed authorised in accordance with the provisions of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed; or

(iii) food products notified to the Commission in accordance with the provisions of Article 8.1, or feed products notified to the Commission in accordance with the provisions of Article 20.1, of Regulation (EC) No 1829/2003 of the European Parliament and the Council;

(c) genetically modified organisms are released or marketed in cases or circumstances in which—

(i) the consent of any of the following is required under section 111(1) of the Environmental Protection Act 1990—

(aa) the Secretary of State;

(bb) the Scottish Ministers, as regards Scotland;

(cc) the Welsh Ministers, as regards Wales;

(ii) the consent of the Northern Ireland Department of the Environment is required under article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991.

(3) Regulations 7, 9 to 17, 18(2) and (4), 19, 20, and 23 to 25 do not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.

Regulation 3

(4) Regulation 5 applies to the transport of genetically modified organisms by road, rail, inland waterway, sea or air, except that, in making the assessment required by regulation 5(1) the person undertaking that assessment is not required to include the steps set out in paragraph 3(i) to (k) of Part 2 of Schedule 3.

(5) These Regulations do not extend to Northern Ireland.

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

Guidance 3

32 Regulation 3 sets out the circumstances where the Regulations (or parts of them) do not apply to genetic modification or GMOs. Part 3 of Schedule 2 provides a list of genetic modification techniques to which the Regulations (except regulation 18) do not apply. This is only the case where the parental or recipient organisms are not themselves GM or synthetic. Regulation 18 places a responsibility on the user to ensure the risks are reduced to the lowest level reasonably practicable and to take appropriate measures to comply with this duty. The techniques excluded are explained as follows:

(a) ***mutagenesis:*** The use of chemicals or radiation to induce random mutagenesis is excluded from the Regulations. However, the situation is complicated by existing methodology that allows site-directed mutagenesis to be undertaken. During such site-directed mutagenesis, precise sequence changes are introduced either via synthetic DNA or by DNA editing techniques. These latter techniques involve using protein complexes that are capable of recognising a particular DNA sequence and then introducing change at a specific base pair. Where this could be achieved by random mutagenesis, the Regulations do not apply. However, where this is achieved by a series of mutations (eg a combination of three or four different mutations designed to introduce a new function), then the Regulations do apply;

(b) ***prokaryotic cell or protoplast fusion:*** The fusion of prokaryotic cells that naturally inherit each other's genomic DNA through homologous recombination and integration. This does not include the exchange of synthetic genomes demonstrated in bacteria;

(c) ***eukaryotic cell or protoplast fusion:*** The fusion of cells from any eukaryotic species, including the production of somatic animal (including human) hybridomas;

(d) ***self-cloning:*** The term self-cloning covers the removal of DNA or RNA from a cell of an organism, which may be followed by the reinsertion of all or part of it into the same species. The techniques used to undertake self-cloning may include those in Part 1 of Schedule 2.

33 In the case of self-cloning, the inserted genetic material can be made synthetically, but must be from an organism of the same or a closely related species and which is known to exchange genetic material naturally by homologous recombination. Vector sequences may also be permitted with certain restriction. The nucleic acid insert can be altered by enzymatic or mechanical processes and inserted into recombinant vectors (eg a plasmid or cosmid) before reinsertion. For the self-cloned organism to remain exempt, any recombinant vector must have a long history of safe use in the recipient organism. It is permissible for all or some of the vector to remain in the final GMO and the vector itself need not be composed entirely of DNA/RNA from the same or closely related species. However, it is important to note that there are limitations as to what sequences may be present in the vector. The vector may contain sequences required for its construction, maintenance and replication (eg origins of replication, molecular cloning sites, marker genes to identify or select transformants). The foreign sequences inserted in the vector are not considered to be part of the vector itself.

Guidance 3

34 The self-cloning exemption only applies where the resultant self-cloned GMO is unlikely to cause harm to humans or the environment (in the case of larger GMOs, harm to human health). Vectors that contain full-length copies of viral genomes that are infectious in their own right are not covered by the self-cloning exemption. Self-cloned GMOs are not exempt from the Genetically Modified Organisms (Deliberate Release) Regulations 2002[11] (which implement Directive 2001/18/EC[12] and parts of the EPA) ('the Deliberate Release Regulations'). Therefore, even though they are exempted from most of the provisions of the Regulations, they must still be used under the contained conditions outlined in regulation 19, unless consent to release has been obtained.

35 The Regulations do not apply to GMOs for which marketing approval has been obtained (eg marketing under the EPA, other product marketing legislation (human/veterinary medicines) or European Community procedures) provided no further genetic modification is planned (unless specifically allowed by the marketing consent conditions). The consent conditions normally apply to the product itself and not its manufacture, which may constitute a contained use. Some products may be sold without consent on condition that they are sold for use in contained facilities, in which case these Regulations would apply in full. Larger GMOs sold for research (eg animals) will be subject to these Regulations.

36 The Deliberate Release Regulations regulate activities where GMOs are intentionally released from someone's control into the environment (either experimentally or marketed). Before release, the GMOs will be kept under control using containment applied on the basis of these Regulations.

37 ***Transportation exemptions:*** The transport of GMOs is exempt from some regulations (including notification and the application of the containment measures set out in Schedule 8). However, a number of requirements still apply, including risk assessment and access to competent advice. The risk assessment must follow the requirements of Schedule 3 for GMMs and Schedule 4 for larger GMOs and take particular account of risks associated with transport itself. This would include the use of appropriate packaging and labelling, supplying appropriate information to the person transporting the GMOs, and accounting for possible accidents by putting in place appropriate emergency measures. The duty to control the risks to humans and the environment from GMMs to the lowest reasonably practicable level still remains. Where appropriate an emergency plan should be in place. In the event of an accident during transport, this should be reported to the competent authority. The provisions to ensure safe packaging, labelling and transport within the transport regulations will also apply (eg the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009).[13]

38 GMOs may also be subject to other legislation, depending on the nature of the construct. For example, if the GMO is an animal or plant pathogen encompassed by any of the Specified Animal Pathogen Order(s)[14] or Plant Health Order(s),[15] then a licence will be required before the GMO can be held. Similarly, Part 7 of the Anti-terrorism Crime and Security Act 2001[16] (ATCSA) will apply to certain GMOs where their storage and use is subject to additional security provisions and must be notified to the Home Office. The HSE website provides signposting to further information on these associated regulatory requirements.

Regulation 4 Meaning of 'work' and 'at work' and modification of the 1974 Act

Regulation 4

(1) For the purpose of these Regulations and Part I of the 1974 Act, the meaning of "work" is extended to include any contained use and the meaning of "at work" is extended accordingly.

(2) Sections 2(1), (2) and (3) and 7 of the 1974 Act are modified in relation to contained use as follows—

(a) those sections have effect as if a reference to—
(i) an employer includes a reference to an educational establishment providing a course of study; and
(ii) an employee includes a reference to a student undertaking contained use in that educational establishment to the extent that the contained use is under the control of that educational establishment.

(3) Section 3(2) of the 1974 Act is modified in relation to contained use so as to have effect as if the reference in that section—

(a) to a self-employed person were a reference to any person (except a student) undertaking contained use who is not an employer or an employee; and
(b) to that person's undertaking includes a reference to that contained use.

(4) In this regulation—

"educational establishment" means a university, college, school or similar educational or technical institute; and

"student" means any person studying at an educational establishment.

Guidance 4

39 Regulation 4 ensures that all contained uses, irrespective of who carries them out, fall within the scope of the Regulations and general duties of the HSW Act. This is achieved by extending the HSW Act meaning of 'work' and 'at work' to include any contained use. The effect of these provisions is that at least one of the general duties in sections 2(1), 2(2), 2(3), s3 and s7 of the HSW Act will apply to all people in control of, or undertaking, contained use.

40 Students (including visiting students) are considered as employees of the educational establishment in which they are studying and undertaking contained use. This means that responsibility for their safety as well as the safe conduct of contained use, rests with the educational establishment, but also that students are required to take reasonable care for their own health and safety as well as that of any other person who may be affected by their actions (or inactions). Educational establishment has a very broad interpretation and includes schools, universities, and training providers.

41 The self-employed, or anyone else undertaking contained use in a non-work situation, are required to ensure, so far as is reasonably practicable, that others are not exposed to risks arising from that contained use.

PART 2 Risk assessment and notification of contained use

Regulation 5 Risk assessment of contained use involving micro-organisms

Regulation 5

(1) Before any contained use involving micro-organisms is commenced, a person responsible for the contained use must ensure that a suitable and sufficient assessment of the risks to human health and the environment created by the contained use is carried out.

(2) The assessment required by paragraph (1) must take into account the matters set out in Part 1, and include the steps set out in Part 2, of Schedule 3.

Guidance 5

42 Regulation 5 sets out the duties of the person responsible to ensure that contained use involving GMMs is assessed before any work starts, that any relevant risks are identified and controls assigned. These include risks (whether immediate or delayed) to the health of humans and the environment, arising from the contained use of GMMs.

43 Regulation 5(1) requires the person responsible to ensure that a suitable and sufficient risk assessment is carried out. It is important that those most familiar or who understand the risks are involved in the process. In most cases, this will involve the user. It is acceptable for a third party to undertake the assessment, but the person responsible for the contained use must ensure that the risk assessment is adequate. This can occur where an ancillary activity is undertaken by a contractor (eg contract research organisation), or where connected programmes of work take place at multiple sites. Where the contained use is identical at the multiple sites (eg in a clinical trial), the same risk assessment may apply to all the sites. In such circumstances, variations in local procedures and rules must be taken into account. Similarly, when contained use is transferred or shared between premises the local arrangements must be considered and, if necessary, the risk assessment adjusted.

44 The risk assessment must take full account of all aspects of the planned work, including handling, transport, work area decontamination, inactivation of GMMs, disposal and waste management including where waste contractors are used. Regulation 5(2) and Part 1 of Schedule 3 set out what to consider as part of the risk assessment. The key aspects to consider include:

(a) identification of any potentially harmful effects;
(b) characteristics of the proposed activity;
(c) the severity of any potentially harmful effects;
(d) the likelihood of them occurring; and
(e) disposal of waste and effluent.

45 The amount of detail in the risk assessment should be proportionate, providing sufficient detail to assess the hazards (potential for harm), the means by which harm could be realised, the likelihood of this occurring and the control measures

Guidance 5

that are needed to prevent the harm being realised. Risk assessments for simple contained use involving no/low hazard, well-known and well-understood micro-organisms can be less detailed than those for a complex contained use involving moderate/high hazard and less familiar micro-organisms. For example, work involving routine cloning of mammalian genes using a series of well-defined non-mobilisable vectors and well-characterised disabled strains of *Escherichia coli* K-12 can be concise, with cross references to established guidance. Furthermore, these could be covered using a generic risk assessment, provided the hazards associated with all vectors, host strains and inserts to be used are considered.

46 Work involving GMMs that are more hazardous will require more detail. For instance, work on a pathogenic virus that involves substituting genes from another pathogenic virus would require careful assessment to draw conclusions about the hazards present and how best to control the risks. This is particularly pertinent where the modified virus could be endowed with properties of an altered tropism, infectivity or immune modulation.

47 SACGM(CU) provides independent advice to the competent authorities on risk assessment for contained use. *The SAGCM compendium of guidance* has detailed advice on risk assessment for GMMs and larger GMOs. This has incorporated explanatory guidance on the risk assessment procedure produced by the European Commission.

48 In addition to what to consider, regulation 5(2), and Part 2 of Schedule 3 also set out the steps to take when completing a risk assessment. The key steps include:

(a) hazard identification (eg harmful properties of recipient and donor micro-organisms, vectors or inserted material, consulting the Approved List) and assigning a provisional level of risk associated with the GMM;
(b) consideration of how and where the contained use will be undertaken (including any non-standard procedures or higher risk environments) and adjusting the provisional level of risk accordingly;
(c) selection of the appropriate containment measures (from the most applicable table in Schedule 8) based on the provisional level of risk and assigning the contained use to the appropriate containment level and classifying the activity according to that level; and
(d) reviewing and reconsidering the classification in light of the completed assessment.

49 The initial step in the risk assessment is to consider the hazardous properties of the micro-organism. Cross referencing to national categorisation lists (eg *The Approved List of biological agents;*[17] the list of Specified Animal Pathogens)[18] is an important starting point. Consideration is then given to how the micro-organism is being modified (including possible enhancement of function, altered tropism or altered routes of transmission) and the impact on its hazardous properties (ie more pathogenic, attenuated or left unchanged). Consideration is then given to the nature of the contained use (eg scale of work, whether it involves non-standard procedures, where the contained use will be undertaken).

50 Having completed the hazard identification step the risk assessment should then consider the most appropriate containment measures to ensure the risks are adequately controlled. Schedule 8 sets out the containment requirements in four tables (Table 1a relates to laboratories; Table 1b relates to plant growth units; Table 1c relates to animal units; and Table 2 relates to other premises (eg large-scale manufacturing)). The risk assessment should select containment measures from the most appropriate table and in line with the provisional level of risk assigned. See

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guidance on regulation 19 for further details about the containment measures required at different risk levels in each working environment.

51 Having selected the appropriate containment and control measures for controlling the risks, the risk assessment process then classifies the contained use into one of four risk classes based on the highest containment level selected. For example, the risk assessment may show that work requires inward airflow and HEPA filtration of extract air. In consulting the tables in Schedule 8, these measures are required at a minimum of containment level (CL) 3. Consequently, the risk assessment would conclude that CL3 is required for the work and the contained use would be classified as class 3.

Table 1 Containment levels and the corresponding risk classification

Containment necessary to control the risk	Risk classification
Level 1	Class 1
Level 1 with the addition of measures from Level 2 or Level 2 (without additional measures)	Class 2
Level 2 with the addition of measures from Level 3 or Level 3 (without additional measures)	Class 3
Level 3 with the addition of measures from Level 4 or Level 4 (with or without additional measures)	Class 4

52 Where the containment tables in Schedule 8 contain the phrase 'required where and to extent the risk assessment shows it is necessary', this means that the measure is not an absolute requirement at that containment level. Rather, the control measure is only required for that containment level if the risk assessment deems it necessary. For instance, the need for insect vector control is 'required where and to extent the risk assessment shows it is necessary' at CL2 and required at CL3. If this measure is deemed necessary, it would be acceptable for the work to be undertaken at CL2 and classified as class 2. In contrast, the need for inward airflow is not required at CL2 but is required at CL3 where there is an airborne route of transmission. If this measure is deemed necessary, the work should be undertaken at CL3 and classified as class 3.

53 Note that the classification is based on **the level of containment required to control the risk**, not necessarily the level of containment at which the work is planned to be done. For example, the work may be classified as class 1 based on the containment required to control the risk, but if all the laboratories meet CL2 requirements, this does not mean that it becomes risk class 2.

Guidance 5

54 If there is evidence-based justification that a control measure shown in the table in Schedule 8 from the containment level at which the contained use will be conducted is not necessary, or alternative measures are more appropriate that provide an equivalent level of protection, users can request a derogation from applying the relevant control measure (see paragraphs 125-127 for guidance on derogations). Any such request must be supported by appropriate explanation and justification. In such circumstances, all measures at the required containment level must be applied until written consent for the derogation is received from the competent authority.

55 The final stage in the risk assessment process is to review and reconsider the classification of the work in light of the completed assessment. This is particularly pertinent to ensure that the assessment is adequate and appropriate. For example, class 1 contained use is defined as 'of no or negligible risk', so it is not acceptable to classify any GMM that retains pathogenicity for humans, plants or animals as a class 1 contained use. Similarly, where the genetic modification will result in the hazardous properties of the GMM being equivalent to the unmodified parental micro-organism, the contained use should be classified in line with the categorisation of the parental micro-organism.

Regulation 6 Risk assessment of contained use involving larger GMOs

Regulation 6

(1) Before any contained use involving larger GMOs is commenced, a person responsible for the contained use must ensure that a suitable and sufficient assessment of the risks to human health created by the contained use is carried out.

(2) The assessment required by paragraph (1) must take into account the matters set out in Part 1, and include the steps set out in Part 2, of Schedule 4.

Guidance 6

56 Regulation 6 requires the person responsible to ensure that contained use involving larger GMOs is assessed before any work commences, that any relevant risks are identified and controls assigned. These include risks (whether immediate or delayed) to the health of humans from the contained use of larger GMOs.

57 Part 1 of Schedule 4 sets out what to consider in the risk assessment for larger GMOs. The key aspects to consider include:

(a) identification of any potentially harmful effects;
(b) characteristics of the proposed activity;
(c) the severity of any potentially harmful effects; and
(d) the likelihood of them occurring.

58 Risk assessments need only provide enough detail to draw conclusions about the hazards present. For a larger GMO that presents no hazard to humans and would be unable to survive in the receiving environment (ie the immediate environment surrounding the facility) a detailed assessment would not be expected. Conversely, a larger GMO that does present harm to humans (eg by acting as a disease vector or by being toxic when consumed) and that could survive in the receiving environment would require more detailed consideration and careful application of control measures.

59 In addition to the matters to consider, regulation 6(2), and Part 2 of Schedule 4 also sets out the steps to take when completing a risk assessment. The key steps include:

Guidance 6

(a) hazard identification (eg harmful properties of recipient and donor, vectors or inserted material) and assigning a provisional level of risk for the larger GMO;
(b) considering the characteristics of the contained use to be undertaken (including any non-standard procedures or higher risk environments) and adjusting the provisional level of risk accordingly;
(c) selecting the appropriate containment and other protective measures; and
(d) reviewing and reconsidering the containment and protective measures in light of the completed assessment.

60 For larger GMOs, there is no requirement to consult the containment tables in Schedule 8 or classify the contained use. However, the risk assessment should consider whether the larger GMO is more hazardous to human health than the non-modified parental organism. If this is the case, notification to the competent authority is required (see regulation 12 for further information on the notification of contained use involving larger GMOs).

61 While these Regulations are concerned with the risks to human health from contained use with larger GMOs, users should note that the EPA requires risks to the environment to be considered. Consequently it is recommended that both the risks to human health and the environment are considered in the risk assessment for larger GMOs, including risks arising from the escape of animals or escape of viable pollen from plants. This enables users to adopt the most suitable containment and protective measures to minimise damage to the environment as well as harm to human health.

62 Guidance on risk assessment and appropriate containment measures for larger GMOs can be found in *The SACGM compendium of guidance*.

Regulation 7 Review and recording of risk assessments

Regulation 7

(1) A person responsible for contained use must ensure that the risk assessment is reviewed immediately where—

(a) there is reason to suspect that the risk assessment is no longer valid; or
(b) there has been a significant change in the contained use to which the risk assessment relates.

(2) A person responsible for contained use must—

(a) keep a record of the risk assessment and any review of the risk assessment, for at least 10 years from the date the contained use stops; and
(b) make the record available to the competent authority when requested to do so.

Guidance 7

63 Regulation 7 requires that the person responsible for contained use ensures that the risk assessments completed in respect of regulations 5 and 6 are reviewed where there is reason to believe that the contained use has changed significantly or where the assessment is no longer valid. It is sensible to include a periodic review of risk assessments as part of a management system to identify risk assessments which are no longer applicable to the contained use being undertaken. The period between successive reviews will depend on the level of risk, the nature of the work and the likelihood of changes occurring.

Guidance 7

64 Regulation 7 also requires that the risk assessments are recorded and retained. There is no statutory risk assessment format, however, thought should be given to the headings in the risk assessment document, to ensure it elicits the relevant information and in the appropriate level of detail. Key assumptions in the risk assessment should be supported by evidence. The recorded risk assessment should be considered a 'living' document, ie one that is kept relevant and up to date. The risk assessment record should be sufficient to inform people involved with the work about the risks and the control measures necessary to mitigate these risks.

Regulation 8 Advice from a genetic modification safety committee

Regulation 8

(1) Subject to paragraph (2), a person responsible for contained use must obtain advice on a risk assessment from either—

(a) a person, or
(b) a genetic modification safety committee,

with expertise in risk assessment relating to contained use.

(2) Where the risk assessment indicates that the contained use is classified as class 2 or above the advice must be obtained from a genetic modification safety committee.

Guidance 8

65 Regulation 8 requires the person responsible to ensure that expert advice on risk assessments is obtained. It is proportionate in many circumstances that such advice on class 1 risk assessments can be provided by a competent individual (eg Biological Safety Officer/Advisor), but for other activities including class 2 and above, the advice must be provided by a committee. The individual or committee providing the advice on risk assessment should:

(a) have enough knowledge and experience to understand the risks to both human health and the environment arising from the proposed contained use;
(b) understand the extent to which those risks are uncertain;
(c) be able to judge the adequacy of the risk assessment made under regulation 5 or 6; and
(d) where appropriate and necessary, test emerging conclusions by discussion with relevant experts, either within or outside their institution.

66 It is likely that institutions which already have an established genetic modification safety committee (GMSC) will continue to use the committee for all contained uses. Similarly, there may be circumstances where it is more appropriate for a committee rather than an individual to provide expert opinion for class 1 risk assessments (eg a clinical environment). Where a committee is used, there are no specific rules governing its make-up. It should ideally represent both management and employees with representatives of all people with access to the genetic modification facilities or who might otherwise be exposed to such work. It is important to include members who will not benefit directly from the decisions of the committee (eg technical staff) and to ensure the discussion is that of the group rather than a particular individual. It is acceptable for the committee to consider other health and safety matters and not just genetic modification contained uses (eg biological safety committee), provided the committee has the appropriate expertise.

Guidance 8

67 Where there is no established committee, it is possible for this advice to be provided by a shared committee or another institution's GMSC, provided there are written agreements in place confirming the arrangements for provision of this advice. It is not a requirement that every corporate body or institution sets up a committee to advise on all risk assessments undertaken at the centre. It is possible for GMSCs to advise more than one centre – especially where notified premises are on split sites.

68 There may be instances where within a single institution there are several, separately notified GM premises. In such cases, there may be multiple committees, but it is also acceptable for a single committee to cover all premises. The same approach can be adopted where there are multiple GM centres working at a single building or location. Once again it may be appropriate for a single committee to cover all contained uses at the premises. Where contained uses are to be transferred between different premises or employers, the risk assessment should be reviewed before work starts to ensure that the risk assessment takes account of the new local circumstances.

Regulation 9 Notification of premises to be used for contained use

Regulation 9

(1) A user must not use premises for contained use unless the premises have been notified to the competent authority in accordance with this regulation.

(2) Before premises are used for contained use for the first time, a person responsible for the contained use must—

(a) submit a notification to the competent authority containing the information specified in Schedule 5; and
(b) have received an acknowledgement of receipt of the notification from the Executive.

(3) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving the notification.

(4) A single notification may include more than one premises.

(5) Where the notification includes more than one premises and at least one of those premises is situated in England or Wales and at least one of those premises is situated in Scotland the notification must be submitted to the joint competent authority.

(6) The notifier must nominate one address which is to be the principal address for the purposes of a notification under paragraph (4) or (5).

Guidance 9

69 Regulation 9 requires that premises are notified before any contained use can begin. The person responsible must ensure that the premises are notified by submitting the information set out in Schedule 5 (using the online forms on the HSE website). If the first contained use is non-notifiable (ie class 1 contained uses, larger GMOs that are not notifiable under regulation 12) a summary of the risk assessment for that contained use should be submitted, as well as information on waste management arrangements and details of any expert advice received.

70 Groups of premises (eg different laboratories or facilities within the same research institution, geographically separate parts of an organisation etc) can be

Guidance 9

submitted as a single notification. Where this is the case, it is important that the management structure is such that the person responsible (ie body, employer, coordinator) has suitable management oversight of all of the parts being notified. However, it is required that in such instances, a single contact address is provided that covers all notified premises. It is increasingly common for a single building or set of premises to be occupied by several different organisations. In the case of multiple occupancies, a person responsible for the contained use carried out in each organisation will need to notify separately.

71 HSE will send an acknowledgement within 10 days of receiving a premises notification. Where this is for class 1 contained use or involves larger GMOs, the user can commence with the contained use on receipt of the acknowledgement. For class 2 and above contained use, a further notification is required under regulation 10, 11 or 12 (as appropriate) before the contained use can begin.

72 Where a premises notification is submitted at the same time as a notification of a contained use under regulations 10, 11 or 12, only the fee for the contained use is required making the premises notification free. However, it is important that the information required by each regulation is supplied and all of the notification requirements fulfilled, including the stipulated time delay before the contained use can start.

Regulation 10 Notification of class 2 contained use

Regulation 10

(1) A user must not undertake a contained use involving micro-organisms classified as class 2 unless the provisions of this regulation have been complied with.

(2) A person responsible for the contained use must submit a notification to the competent authority containing the information specified in Schedule 6.

(3) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving the notification.

(4) Where the premises in the notification have not previously been notified for class 2 or a higher class of contained use, a user may undertake the class 2 contained use if—

(a) 45 days have elapsed since the acknowledgement of receipt was received, provided that the competent authority has not informed the notifier that the class 2 contained use may not be undertaken; or
(b) the competent authority has agreed in writing that the class 2 contained use may commence sooner.

(5) Where the premises in the notification have—

(a) previously been notified for class 2 contained use; or
(b) already been granted consent for class 3 or class 4 contained use,

a user may undertake the class 2 contained use if the notifier has received the acknowledgement of receipt.

(6) Where a notifier submits a notification for a class 2 contained use which is to be undertaken for the second or subsequent time at the premises in the notification, the notifier may request that the competent authority provide a written agreement that the contained use may be undertaken.

Regulation 10

(7) The competent authority must make a decision and, if they agree, provide the written agreement requested under paragraph (6), within 45 days of the date on which the acknowledgement of receipt was sent to the notifier.

Guidance 10

73 Regulation 10 requires that all class 2 contained uses are notified before the contained use can begin. The person responsible must ensure that class 2 contained uses are notified by submitting all the information set out in Schedule 6 (using the online forms on the HSE website). This will include a copy of the risk assessment, details of containment and protective measures (specifically related to waste management arrangements) and any details of expert advice received from the GMSC.

74 HSE will send an acknowledgement within 10 working days of receiving a class 2 notification. Notifiers are advised to keep a record of the acknowledgement. The timescale for starting work will depend on the following:

(a) the first class 2 contained use with GMMs cannot start until 45 days after the date on which the acknowledgement was sent by HSE; or
(b) the competent authority has agreed in writing that the contained use can start in a shorter period;
(c) for subsequent class 2 contained uses with GMMs (or where consent for class 3 or 4 contained uses has already been received), the contained use may start as soon as the HSE acknowledgement has been received.

75 If the notification includes a derogation request to not apply a required containment measure from CL2, HSE will confirm in writing the decision on whether or not to allow this derogation. For those class 2 contained uses which may start immediately on receipt of the acknowledgement, the full CL2 requirements must be applied, unless and until the derogation is confirmed.

Regulation 11 Notification of class 3 or class 4 contained use

Regulation 11

(1) A user must not undertake a contained use involving micro-organisms classified as class 3 or class 4 unless written consent for that contained use has been granted by the competent authority.

(2) A person responsible for the contained use must submit a notification to the competent authority containing the information specified in Schedule 6.

(3) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving the notification.

(4) Where the premises in the notification have not previously been notified for class 3 or class 4 contained use, the competent authority must inform the notifier, in writing, of its decision to grant or refuse consent for the class 3 or class 4 contained use, within 90 days of the date on which the acknowledgement of receipt was sent to the notifier.

(5) Where the premises in the notification have previously been notified for class 3 or class 4 contained use and all relevant conditions of existing consents have been complied with, the competent authority must inform the notifier, in writing, of its decision to grant or refuse consent for the class 3 or class 4 contained use, within 45 days of the date on which the acknowledgement of receipt was sent to the notifier.

Regulation 11

(6) Before granting consent, the competent authority must ensure that an emergency plan has been prepared where the risk assessment shows an emergency plan is required.

(7) Before deciding whether to grant or refuse consent, the competent authority must take into account any representations made to it by any person within 30 days of the date on which the acknowledgement of receipt was sent to the notifier.

(8) A consent granted under this regulation may be granted subject to conditions.

Guidance 11

76 Regulation 11 requires consent from the competent authority before class 3 or 4 contained use can begin. The person responsible must ensure that class 3 and 4 contained uses are notified by submitting all the information set out in Schedule 6 (using the online forms on the HSE website). This will include a copy of the risk assessment, details of containment and protective measures (specifically related to waste management arrangements), an emergency plan (where the risk assessment deems this to be necessary) and details of any expert advice received from the GMSC. There is an additional requirement to indicate if the class 3 or 4 GMMs may be sent outside the EC, so would be subject to transboundary movements and the requirements of the Cartagena Protocol.[19,20]

77 An emergency plan must be prepared if the risk assessment indicates that a failure of containment and control measures could lead to serious harm to humans and/or susceptible animals outside the premises and/or to the environment (see regulation 21). Where deemed necessary, the formulated plan must be submitted to HSE as part of an individual contained use notification.

78 HSE will send an acknowledgement within 10 working days of receiving a class 3 or 4 contained use notification. Notifiers are advised to keep a record of the acknowledgement. The timescale for starting work will depend on the following:

(a) For the first class 3 or 4 contained use with GMMs at the premises, the user cannot start the contained use until HSE has issued a consent, within 90 days after the HSE acknowledgement was sent;
(b) For subsequent class 3 or 4 contained uses with GMMs at the premises, the user cannot begin the contained use until HSE has issued a consent, within 45 days after the HSE acknowledgement was sent.

79 HSE will consider any representations made concerning class 3 or 4 contained use notifications from any source if they are received within 30 days of acknowledging receipt of the notification. They will be considered as part of the decision whether or not to issue consent for the contained use.

80 In issuing consent, HSE may attach certain conditions to the contained use. For contained uses where the notification includes a derogation request to allow a lower level of containment than the minimum required for class 3 or 4 contained use, HSE will confirm whether or not to allow this derogation at the same time as the decision whether or not to grant consent to the contained use.

Regulation 12 Notification of contained use involving larger GMOs

Regulation 12

(1) A user must not undertake a contained use involving larger GMOs unless the provisions of this regulation have been complied with.

(2) A person responsible for the contained use must submit a notification to the competent authority containing the information specified in Schedule 6.

(3) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving the notification.

(4) A user may undertake the contained use if—

(a) 45 days have elapsed since the acknowledgement of receipt was received, provided the competent authority has not informed the notifier that the contained use may not be undertaken; or
(b) the competent authority has agreed in writing that the contained use may commence sooner.

(5) This regulation does not apply to a contained use which results in a larger GMO that poses no greater risk to humans than its unmodified parental organism.

Guidance 12

81 Regulation 12 requires the person responsible for a contained use involving larger GMOs to notify the competent authority where the larger GMO presents a greater risk to humans than the non-modified parental organism. Examples of risks of harm from larger GMOs include:

(a) causing disease in humans, including allergenic or toxic effects;
(b) acting as a reservoir or vector for micro-organisms affecting humans;
(c) adverse effects on humans arising from changes in behaviour or in physical nature.

82 The person responsible must submit a notification of contained use of larger GMOs which includes the information set out in Schedule 6.

83 HSE will send an acknowledgement of receipt within 10 working days of receiving the notification for contained use involving larger GMOs. The timescale for starting work will depend on the following:

(a) the contained use involving larger GMOs cannot begin until 45 days after the date on which the acknowledgement was received from HSE;
(b) the competent authority has agreed in writing that the contained use can begin within a shorter period.

Regulation 13 Single notifications to the joint competent authority and for connected programmes of work

Regulation 13

(1) Where a notification is required under regulation 10(2), 11(2) or 12(2) in respect of a contained use which is to take place in premises that fall within regulation 9(5) the notifier must submit the notification for that contained use to the joint competent authority.

(2) A competent authority, or where paragraph (1) applies the joint competent authority, may accept a single notification submitted under regulation 10(2), 11(2) or 12(2) in respect of a connected programme of work undertaken at—

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

(3) A competent authority, or where paragraph (1) applies, the joint competent authority, may accept a single notification submitted under regulation 10(2), 11(2) or 12(2) in respect of a single contained use undertaken at more than one premises.

(4) In this regulation—

"connected programme of work" means a series of activities involving contained use which form a coherent and integrated programme.

Guidance 13

84 Regulation 13 allows the person responsible for contained use to submit a single notification for premises in different geographical locations, eg where one premises is in Scotland and the other is in England or Wales.

85 If the contained use is to be carried out by one organisation but in more than one premises, and one or more of the premises is in England or Wales and one or more in Scotland then the application for that contained use must be submitted to the joint competent authority (although the application will be submitted to HSE, as is the same for any other notification).

86 Regulation 13 also allows the person responsible to submit a single notification covering a connected programme of work. This might involve a programme covering more than one contained use at a single notified premises or more than one contained use carried out by a single person or organisation at more than one notified premises. This might apply, eg where an institution or company has several notified premises, which all collaborate on connected work. The competent authority may also accept a single notification covering a single contained use which is to be undertaken by the same person at more than one notified premises. This could include a clinical trial involving a GMM being carried out at a number of different premises across GB.

87 To form a connected programme of work, all contained uses must be part of a coherent and integrated programme of work, ie the different types of contained use should all form part of a common scientific/research goal.

88 Connected programme notifications must contain all of the information required under regulation 10, 11 or 12 (as applicable) for each contained use. To achieve this you should provide an overview that defines the purpose and overall scope of the programme (ie that sets boundaries on the range of work forming the programme). Other key information will be an outline of the range of vectors and

Guidance 13

inserts that will be used and a detailed risk assessment of the most hazardous GMMs that will be made as part of the programme. The notification should also mention any variations in the controls that are required to control different risks. It may be that as a connected programme develops the experimental plans are refined which necessitates the construction of slightly different GMMs from those planned at the outset. In such circumstances, a brief additional risk assessment should be undertaken and reviewed at local level. However, as long as the new work fell in the scope of the notified connected programme (and did not increase the risk), there would be no need for further notification. The person responsible should also consider whether a similar brief risk assessment is necessary for new work at class 1 or non-notifiable contained uses involving larger GMOs.

89 The relevant notification requirements must be complied with (eg notification periods and consents etc) as stipulated in regulations 10, 11 and 12 for each contained use within a connected programme. For instance, if a planned connected programme consisted of contained uses in class 2 and 3 at premises where previously contained use had been done at class 2, but not at class 3 (or 4), the class 2 contained use could start as soon as acknowledgement is received from HSE, but the class 3 contained use could not start until HSE has issued a consent. For a first time class 3 contained use this could take up to 90 days. Similarly, derogations from minimum containment levels cannot be applied until written agreement has been received.

90 The advantages of connected programme notifications are:

(a) only a single notification fee is payable even though the notification covers several contained uses (the fee would be for the highest class of contained use);
(b) there is some saving derived from not having to duplicate certain information in the notification.

91 This regulation cannot be used to cover new work that falls outside the original scope of the notified connected programme. In such circumstances appropriate notification must be made under regulations 10, 11 or 12. Similarly, if several new contained uses are planned, these could be notified together under regulation 13, in the same way as the original set of contained uses.

92 Where the circumstances associated with or the consequences arising from previously notified connected programmes change, then the requirements under regulations 14 and 15 should be considered to decide whether further notification is required.

Regulation 14 Changes of circumstances relating to notifications

Regulation 14

(1) Full details in writing must be sent immediately to the competent authority of—

(a) any change in the information specified in paragraph (a), (d) or (e) of Schedule 5 in relation to premises previously notified in accordance with regulation 9(2);
(b) any new building—
(i) added to premises previously notified in accordance with regulation 9(2); and
(ii) under the notifier's control;

Regulation 14

(c) premises notified under regulation 9(2) that will no longer be used for contained use;
(d) any cessation, for the time being, of all contained use at premises notified under regulation 9(2);
(e) any cessation of a contained use notified in accordance with regulation 10(2), 11(2) or 12(2);
(f) any recommencement of contained use at premises in respect of which the notifier had previously given details of a cessation under sub-paragraph (d);
(g) any use of additional premises in connection with a single contained use where a single notification for that contained use was accepted by the competent authority under regulation 13(3);
(h) any change in the information specified in paragraph (b) or (c) of Schedule 5 as provided by the original notifier in accordance with regulation 9(2);
(i) any change in the information specified in paragraph (c) or (d) of Schedule 6 as provided by the original notifier in accordance with regulation 10(2), 11(2) or 12(2).

(2) Where—

(a) a notifier has informed the competent authority of additional premises under paragraph (1)(g); and
(b) that information, taken together with the notification for that single contained use accepted under regulation 13(3), provides all the information required for notification of those premises under regulation 9(2);

the provision of that information will be treated as notification of those premises for the purposes of regulation 9(2).

(3) The details required by paragraph (1) must be provided by—

(a) the original notifier;
(b) a person responsible for the premises notified under regulation 9(2); or
(c) a person responsible for the contained use notified under regulation 10(2), 11(2) or 12(2).

(4) In this regulation—

"notifier" means the person who sends the details required by paragraph (1) to the competent authority; and

"original notifier" means the person who submitted the notification of the premises under regulation 9(2) or the contained use under regulation 10(2), 11(2) or 12(2).

Guidance 14

93 Regulation 14 requires the competent authority to be notified about changes to the information supplied as part of either premises or contained use notifications. It is concerned with information considered to be administrative and does not relate to changes of a technical nature. More specifically, the type of changes covered by regulation 14 include changes to the details of the person making the notification, the person responsible for supervising the contained use, the address and description of the premises where the contained use is undertaken, cessation of a contained use, cessation of all contained uses and closure of a facility. Notifying cessation of contained use under regulation 14 will provide the start date for later removal of data from the public register (see regulation 28).

Guidance 14

94 Regulation 14 also permits notification of additional buildings that are added to those already notified under regulation 9 (eg this could include adding premises at another geographical site or another building in the same campus). The regulation also permits new premises to be added to those that are being used for a single contained use (eg this permits the same contained use to be undertaken at more than one premises). Where the information relates to additional premises for a single contained use, as long as sufficient details have been provided, the information about the new premises submitted under regulation 14 will be treated as a premises notification and no separate notification under regulation 9 will be required.

95 Notifications can be made either by the original notifier, the person currently responsible for the contained use or a person responsible for the premises that are the subject of the additional information. The submission of information relating to these administrative changes is not charged a fee and should be sent to HSE at the address identified for this purpose on its website.

Regulation 15 Duty to notify significant changes affecting risks

Regulation 15

(1) Where, after submitting a notification, a notifier—

(a) makes a change in the premises or the contained use to which the notification relates which may have significant consequences for the risks arising from the contained use; or
(b) becomes aware of any new information which may have significant consequences for the risks arising from the contained use,

the notifier must immediately send to the competent authority full details in writing of the change or the new information.

(2) As long as the change or new information does not affect the class of the contained use, the notifier need not submit a further notification under regulation 10(2), 11(2) or 12(2), and the change or new information will be treated as a modification of the original notification.

Guidance 15

96 Regulation 15 requires a notifier to inform the competent authority of any significant changes affecting the risks associated with a notified contained use. It is not acceptable to notify a **new** contained use under regulation 15. It can sometimes be difficult to determine when minor changes to a contained use become a shift to a new contained use. For clarity, the descriptive title and purpose of the contained use or connected programme should be used to help define the scope of the work being notified (ie to set boundaries on the work covered). Further clarification can then be provided by setting out the scientific rationale, intended end product and range of organisms, inserts and techniques to be used. When setting these boundaries, users should be aware of how the contained use can be effectively managed and monitored. Where the contained use extends beyond these boundaries then the change would be considered to be a new contained use and must be notified under regulation 10, 11, or 12 (as appropriate).

97 To minimise the number of notifications (and fees to be paid) the purpose of the initial notification should be considered very carefully. For instance, if there is a possibility that alternative hosts, vectors and gene sources could be used, include them in the notification with appropriate details to avoid having to submit numerous significant change notifications.

Guidance 15

98 Where changes are necessary to the ongoing contained use, regulation 15 requires the notifier to inform the competent authority where these changes are deemed to be 'significant', specifically where these changes increase or present different risks from the notified work. Risk means risk to human health or the environment in the case of contained uses involving GMMs, but for contained uses involving larger GMOs it means risk to human health only. 'Significant' changes are any proposed modification to the ongoing work or where new information emerges that changes the rationale upon which the risk assessment is based. These changes are significant if they lead to the user having to change the way they work (eg containment or control measures) or they present different or increased hazards/risks to those undertaking the work (eg inherent properties of the GMM). Many of the changes associated with ongoing contained uses will not meet these criteria but rather will involve alterations having little or no effect on the hazards or risks associated with the work. In such circumstances, it is acceptable for these changes to be dealt with through the local risk assessment process, without notification to the competent authority.

99 Where the type of changes to the ongoing contained use involve those in Table 2, it is more likely that these changes will be deemed 'significant'. The user needs to use their judgement to decide if such changes are 'significant'.

Table 2 Types of changes to ongoing contained use that would be deemed a significant change

Type of change	Example
Changes to containment and control measures	Risk-based need to implement additional controls (within same containment level), eg small to large-scale culture volume, necessitating applying the containment measures in Table 2 of Schedule 8. Changes to procedures, such as different research procedures/techniques that increase the risks to users (eg type of filtration; centrifugation; use of sharps)
Use of different organisms or strains of organisms with different inherent characteristics	Relevant characteristics include route of transmission, pathogenicity, tropism, availability of treatment or prophylaxis: this would include moving from attenuated to virulent strains (eg replacement of vaccine strains, replication incompetent strains, strains with a different host range)
Use of different vector, recipient organisms or genetic inserts for GM work	Using inserts with more harmful properties/extending host range; using vectors with fewer disabling mutations; using a host organism able to persist in the environment
Change in nature of the work	Moving from *in vitro* to *in vivo* work; changing the *in vivo* model (eg mice to birds) being studied
Changes to any consent conditions	For class 3 and 4 contained use, consents may have conditions attached to them (eg derogation of control measures, limits of the scope of the work)
New information emerges that changes the consequences of exposure	New information may be from scientific literature or preliminary research findings, which affects the rationale upon which the risk assessment for the work is based (eg virulence function ascribed to a previously unknown gene; research demonstrates more severe pathogenicity than envisaged at the outset)

Guidance 15

100 Notifications of significant changes to an ongoing contained use are charged a fee. There is no notification period – changes may be put into effect immediately – nor is there a prescribed set of information requirements under regulation 15. However, one way of making such a notification is to update the risk assessment and then send it to HSE with the amended sections highlighted. The reference number for the original notification and title of the contained use should be clearly indicated where possible. HSE will acknowledge receipt of the information within 10 working days.

Regulation 16 Action of notifier and user on receipt of request for additional information

Regulation 16

(1) If additional information relating to a notification is requested by the Executive under regulation 24(1), a user must not commence the contained use that is the subject of the notification until the competent authority has given its approval in writing.

(2) Subject to paragraphs (3) and (4), if the contained use has commenced before the Executive requests additional information, a user may not continue the contained use until the competent authority has given its approval in writing.

(3) The Executive may give the notifier instructions concerning the cessation of the contained use and the notifier and any user undertaking the contained use must comply with the instructions.

(4) Subject to any instructions, the notifier or user may continue the contained use only to the extent necessary to store or destroy all genetically modified organisms resulting from the contained use.

Guidance 16

101 Regulation 16 sets out the actions, which must be taken by the notifier and the user on receipt of a request for further information. The request for additional information arises generally from the need for further clarification on the proposed contained use and the risk assessment surrounding this. Consequently, on receipt of the request, the contained use must not begin. If it has already started (ie because it is class 1 or class 2 contained use and the waiting period has expired), HSE may give specific instructions for the contained use to stop. Where no such instructions are given, the contained use should only continue to the extent necessary to store or destroy the material.

102 HSE will acknowledge receipt of the additional information within 10 working days, but this does not imply that the information is adequate or acceptable and the user must not restart the contained use until they have received written approval from HSE to do so.

Regulation 17 Withdrawal of notification

Regulation 17

A notifier may withdraw a notification by giving written notice to the competent authority, provided that the contained use to which the notification relates has not commenced.

Guidance 17

103 Regulation 17 allows a notifier to withdraw a notification, but only where the contained use has not started. Once a notification has been withdrawn HSE will not disclose any further information and any entry on the public register will be removed (see regulation 28). However, some information may already have entered into the public domain before the notification was withdrawn. The fee is not returned where a notifier withdraws their notification.

PART 3 Conduct of contained use

Regulation 18 Principles of occupational and environmental safety

Regulation 18

(1) A user who undertakes a contained use involving micro-organisms must ensure that the risks to human health and the environment arising from the contained use are reduced to the lowest level that is reasonably practicable.

(2) The measures to be taken in order to comply with the duty under paragraph (1) must include the general principles of good microbiological practice and of good occupational safety and hygiene set out in Schedule 7.

(3) A user who undertakes a contained use involving larger GMOs must ensure that the risks to human health arising from the contained use are reduced to the lowest level that is reasonably practicable.

(4) For contained use involving larger GMOs, the general principles set out in Schedule 7 must be applied to the extent that they are appropriate.

Guidance 18

104 A fundamental requirement of the Regulations is to apply barriers to limit contact of GMOs with humans and the environment. The nature and extent of these barriers should be consistent with the level of risk, so that a high level of safety is afforded and, in the case of GMMs, exposure of humans or the environment must be reduced to the lowest level reasonably practicable. To achieve this, control measures must include the principles of good microbiological practice (GMP) and good occupational safety and hygiene (GOSH) which are set out in Schedule 7. Application of all these principles is mandatory in all cases. Several individual principles are qualified by reference to what is appropriate etc. For some specific measures, the degree to which they need to be applied is conditional and will vary depending on the containment level being used. In such circumstances, the application should be based on the outcome of the risk assessment for the contained use. The following paragraphs provide further explanation of these principles.

105 ***Keeping workplace and environmental exposure to any GMM to the lowest reasonably practicable level.*** This sets out the overarching philosophy of the Regulations to minimise contact between GMMs, people and the environment, ensuring that it is unlikely there will be harm to either people or the environment. The concept of 'reasonable practicability' is based on risk, but also takes into account the cost (in terms of money, time or trouble) of controlling that risk. If the risk is significant, or uncertain, a precautionary approach should be taken, with safety benefits taking precedence over the cost of action. These measures can only be discounted if risks are negligible and the cost of control measures is grossly disproportionate to the safety benefit. When deciding what constitutes an accepted level of lowest reasonable practicability, *The SACGM compendium of guidance* provides examples of how to comply with the Regulations.

Guidance 18

106 ***Exercising engineering control measures at source and supplementing these with appropriate personal protective clothing and equipment where necessary.*** This reflects the hierarchy of control measures set out in COSHH, which requires that exposure is primarily controlled using physical containment, if it cannot be wholly prevented (by elimination or substitution). Given this hierarchy, the use of specialised personal protective equipment (PPE) (such as respirators or breathing apparatus) should be only viewed as a supplementary or secondary control. An exception to the overall hierarchy is the use of protective clothing (eg laboratory coats or overalls). The Regulations require using protective clothing on a precautionary basis at all containment levels, whereas at the lowest levels of containment engineering controls are not required.

107 ***Testing adequately and maintaining control measures and equipment.*** You must ensure the integrity of containment and that other control measures (including management and work methods) are applied and perform appropriately. This involves devising and implementing planned preventative maintenance regimes for containment and control measures and any equipment used as part of the contained use.

108 The frequency and extent of testing/examination of equipment and control measures is dependent on the level of risk and nature of the contained use. In the case of local exhaust ventilation (which includes ventilation systems, microbiological safety cabinets and HEPA filters), it must be thoroughly examined and tested, as a minimum, every 14 months, by a competent person.

109 In addition to testing and maintenance, the containment and control measures should be subject to appropriate checks for defects or deterioration before each use. This may involve visual checks, measurements or other forms of monitoring. Similarly, equipment should only be used for the purpose it was intended. Checks should include assessment of whether the containment/control measures and equipment are being used appropriately and correctly.

110 All PPE, including respirators, should be checked regularly to ensure it continues to function and provide protection, in accordance with the manufacturer's instructions. PPE that has deteriorated significantly, or is faulty, should be effectively repaired or disposed of safely.

111 ***Testing, where necessary, for the presence of viable process organisms outside the primary physical containment.*** In some exceptional cases the risk assessment may show that monitoring for GMMs outside the primary containment (eg culture vessel, safety cabinet, containment laboratory) is necessary to ensure effective control. In such circumstances, monitoring could be done both within the workplace and in the surrounding environment. Monitoring of waste, especially at the point of disposal, for the presence of viable GMMs is likely to be necessary where harm will result from an escape. Other proactive monitoring methods are preferable (eg monitoring performance of control measures), as they allow users to take action before a release can take place.

112 ***Providing appropriate training of personnel.*** All users must be given suitable and sufficient information, instruction and training, appropriate to the level of risk and the complexity of the operations being undertaken (see also Schedule 8 for specific requirements in relation to written records of training). Trained individuals should be able to demonstrate competence, which should be subject to review and provision of refresher training or additional training where necessary.

113 ***Formulating and implementing local codes of practice for the safety of personnel, as required.*** The content and form of local codes of practice will

Guidance 18

depend on the level of risk and nature of the contained use. This might include operating instructions for particular equipment, management arrangements, a list of authorised users, systems of work or maintenance regimes. Users should be able to demonstrate their familiarisation and understanding of these documents.

114 ***Displaying biohazard signs where appropriate***. The requirements for biohazard signs are set out in the containment tables in Schedule 8.

115 ***Providing washing and decontamination facilities for personnel.*** What constitutes appropriate facilities will depend on the risk and nature of the work. Hand washbasins and a supply of antimicrobial soap should always be supplied. Showering facilities might also be needed if work is to take place at containment level 3 or 4.

116 ***Keeping adequate records.*** Under regulation 7 it is required that records of risk assessments are kept. Furthermore, records of work that have been undertaken and any modifications to the risk assessment or control measures should be kept. The retention and maintenance of training records for staff is recommended.

117 ***Prohibiting in the work area eating, drinking, smoking, applying cosmetics or the storing of food for human consumption.*** This measure is intended to minimise the risk of hand to mouth (or eye) contact and thus prevent potential exposure to GMMs through ingestion or mucosal route.

118 ***Prohibiting mouth pipetting.*** This measure is intended to minimise the risk of ingesting GMMs.

119 ***Providing written standard operating procedures where appropriate to ensure safety.*** The level of detail in standard operating procedures and the flexibility they allow in practice should be proportionate to the level of risk involved, taking into account the complexity of the equipment used and procedures being undertaken (see Table 2, Schedule 8 for some specific requirements).

120 ***Having effective disinfectants and specified disinfection procedures available in case of spillage of GMOs.*** This is primarily applicable to GMMs. The disinfectants and procedures should include appropriate surface disinfectants and instructions for their effective use, as well as a procedure for effectively dealing with spillages. For all disinfectants used for these purposes, their effectiveness should be validated or verified. For class 1 and 2 contained use, it may be enough to use manufacturer's data provided that the manufacturer tests are representative of the conditions in which the disinfectant will be used. The type of disinfectant should be chosen carefully to ensure it is effective against the GMM in use. The effectiveness of chemical disinfection is affected by many factors, including the presence of organic matter, contact time and concentration. For high-risk contained use, disinfectants may not be sufficient to ensure that all residual risk is removed and may be used in combination with physical methods or fumigation. *The SACGM compendium of guidance* also contains further advice about chemical inactivation.

121 ***Providing safe storage for contaminated laboratory equipment and materials where appropriate.*** The requirements for storage of GMMs are set out in the containment tables in Schedule 8. Additional security requirements may be necessary for storage of GM versions of micro-organisms listed in Schedule 5 of ATCSA. Safe storage in this context means that the GMMs are stored in a way that will not result in their release, the contents can be identified, an inventory is maintained, so all the material is accounted for, and access is restricted to trained and competent people. Secure storage adds an extra layer of security and accountability, to ensure material is not removed either inadvertently or deliberately.

Regulation 19 Containment and control measures for contained use involving micro-organisms

Regulation 19

(1) A user who undertakes a contained use involving micro-organisms must apply the containment measures set out in the applicable table in Part 2 of Schedule 8, where and to the extent required in the column of the appropriate containment level.

(2) A user need not apply a containment measure required for the appropriate containment level where—

(a) the risk assessment, or any review of the risk assessment, shows that the containment measure is not necessary or practicable for a specific activity;
(b) the notifier of the contained use has provided justification in writing to the competent authority; and
(c) the notifier has received the written agreement of the competent authority that the containment measure need not be applied.

(3) A person responsible for the contained use must review the containment measures applied—

(a) at suitably regular intervals; and
(b) immediately, if that person suspects that—
(i) the containment measures are no longer adequate;
(ii) the class assigned to the contained use in the risk assessment is no longer appropriate; or
(iii) in the light of new scientific or technical knowledge, the risk assessment is no longer valid.

Guidance 19

122 In addition to applying the principles of GMP and GOSH, as set out in Schedule 7, users must also employ all measures identified by risk assessments made under regulation 5. Schedule 8 defines the minimum containment measures required for contained use with GMMs.

123 As explained in paragraph 51, contained use of GMMs is classified as part of the risk assessment to one of four risk classes; class 1, 2, 3 or 4. The class is determined by which of the four levels of containment are necessary to control the risk. The containment measures are set out in the tables in Schedule 8. There are four tables in the Regulations that provide details of the containment measures required when working at each containment level. Each table relates to different working circumstances:

(a) **Table 1a** sets out measures for contained uses considered 'laboratory type' in terms of scale and nature. Although not strictly defined, laboratory type contained use may typically involve use of Petri dishes, flasks and culture bottles, also small bench-top chemostats and fermenters.
(b) **Table 1b** contains additional measures and modifications to Table 1a with respect to contained use undertaken in plant growth facilities. This would normally apply where plants are infected with, or grown alongside, GM plant pathogens in glasshouses, polytunnels and growth rooms. The measures in Table 1a that are not amended by Table 1b should also be applied. It is important to note that Tables 1a and 1b concern containment of GMMs only, not the plants, although there will be some containment of the plants as a consequence. If the plant is GM, other containment measures might also be appropriate.

Guidance 19

(c) **Table 1c** contains additional measures and modifications to Table 1a with respect to contained uses undertaken in animal houses or similar facilities. This would normally apply where animals are infected with, or exposed to, GMMs in an animal house or animal experimentation unit. The measures in Table 1a that are not amended by Table 1c should also be applied. It is important to note that Tables 1a and 1c concern containment of GMMs only and not the animals, although there will be some containment of the animals as a consequence. If the animals are also GM, other containment measures might also be appropriate.

(d) **Table 2** sets out containment and control measures for contained uses carried out in 'other' premises. All premises that do not fall within the categories in the other tables are covered by Table 2, but the types of premises that most commonly fall in this 'other' category are those where large-scale work is undertaken, eg industrial production, pilot plant facilities. There is no strict distinction between 'laboratory type' and 'large-scale' contained use, but the terminology used in Table 2 is more applicable to the latter. There is reference to a closed system, with seals and measures to control exhaust gases. Given this, the distinction between Tables 1a and 2 lies in how applicable the containment measures are to the **nature** of the work rather than its **purpose**.

124 Taking into consideration all the control measures from Schedule 8, the containment level identified as appropriate then specifies the contained use class. Therefore, the minimum that must be applied is:

(a) Containment level 1 for class 1 contained use;
(b) Containment level 2 for class 2 contained use;
(c) Containment level 3 for class 3 contained use;
(d) Containment level 4 for class 4 contained use.

125 As explained in paragraph 52, some control measures in the tables in Schedule 8 use the term *'required where and to extent the risk assessment shows it is required'*. This means the control measure must be applied only if the risk assessment indicates that the measure is necessary to control a hazard. All measures shown to be necessary by the risk assessment, including any not in the tables, should be implemented, but only those specified in the table will affect the contained use classification and notification requirements.

126 If there is evidence-based justification that a control measure shown in the table is not necessary or practicable for the contained use (either not appropriate or equally effective alternatives are available), it may be possible to obtain a derogation under regulation 19(2) from the competent authority, ie for it not to be applied. To avoid incurring additional notification fees, derogation requests should be made at the same time that the contained use is notified. The justification must be set out in writing to HSE (usually as part of the risk assessment). The competent authority will inform users if they consent to the request when responding to the notification. Until written agreement has been received, all measures at the required containment level must be applied.

127 Derogations from containment measures can also be sought after the contained use has been notified, and for those contained uses that do not require notification, ie class 1 work with GMMs. In these cases, users should contact the competent authority to apply for the derogation, supplying justification and a revised risk assessment to support the request together with the appropriate fee. As before, all containment measures indicated in the tables must be applied unless and until the competent authority has agreed to the derogation request in writing.

Guidance 19

128 There is a general duty for users to keep containment measures under review. This must be done at 'suitable regular intervals' and when other certain instances arise, specifically when:

(a) it is suspected that containment measures are no longer adequate;
(b) the contained use classification has changed; or
(c) there is new scientific knowledge showing that the risk assessment is no longer adequate.

129 'Suitable regular intervals' is not strictly defined, so should be applied by taking into account the risks involved and the nature of the particular contained use. For lower risk, routine work, a suitable interval might be every three or four years. For higher risk work, especially where work is non-standard, the review interval will be much shorter and it might be appropriate to undertake an annual review. The appropriate review interval should be established when the risk assessment is undertaken. Staff changes might also trigger a review. It would be useful to record on the risk assessment itself the review interval and/or date last reviewed and next due date, and what triggers would prompt a review.

130 Certain GMMs may also fall within the definition of 'biological agent' under COSHH. The selection of control measures for biological agents under COSHH is prescribed according to their risk to human health, while these Regulations set out containment measures appropriate to both human health **and environmental** protection. Paragraph 10 explains that where control measures under COSHH differ to these Regulations, the more stringent requirements must be applied. For example, while the Regulations allow flexibility regarding the method used for waste inactivation across all containment levels, including class 4 contained uses, the requirement under COSHH is stricter in that animal carcases infected with a micro-organism classified as a hazard group 4 biological agent would have to be incinerated on site. For class 4 work with GMMs, where classification is based on risks to the environment, alternative equally effective means are acceptable.

131 In Table 1a the requirement for a microbiological safety cabinet/enclosure is identical at CL3 and CL4. This allows flexibility, as many GMMs will be classified as class 4 on the basis of environmental protection, rather than worker protection. However, where the classification is based on risks to workers, the expectation is that stringent controls will be applied (ie a close-fronted microbiological safety cabinet or an open-fronted cabinet supplemented by a suited system).

132 In Table 1a, the requirement for several containment measures at CL3 is risk based. For example, the need for HEPA filtration of extract air and the provision of an inward airflow is dependent on the ability of the organism to be transmitted via the airborne route. The *Approved list of biological agent*s helpfully identifies, with an asterix, which micro-organisms are not normally transmitted via an airborne route. This information should be used in the first instance to inform the risk assessment. The actual specifics of the contained use then need to be considered to make a final decision on the extent to which it is necessary to protect workers from exposure to airborne GMMs. For example, propagation of blood-borne viruses such as Hepatitis B virus is unlikely to require room air to be extracted through a HEPA filter or an inward airflow into the room, but would require the use of a microbiological safety cabinet. However, other containment requirements will still necessitate the laboratory being designated as CL3.

133 In Table 1a, the requirement for an observation window at CL3 is risk-based. COSHH does not allow such flexibility, so an observation window is required for class 3 contained use involving a GMM that presents a risk to human health.

Guidance 19

134 Contained uses will generate contaminated waste, which must be inactivated by a validated means at class 2, 3 and 4. Inactivation at class 1 is not required only where all of the following criteria are met:

(a) do not have the potential to cause harm to human health or the environment;
(b) must be biologically contained (eg possess multiple disabling mutations or restrictive nutrient requirements that cannot be met outside the laboratory);
(c) do not have the capacity to establish and multiply in the environment; and
(d) do not have capacity to transfer genetic material to other micro-organisms (eg non-mobilisable plasmid).

135 The risk assessment should conclude whether inactivation of waste at class 1 is required and the methods for achieving this. For the purposes of the Regulations, any of the following methods, ie disinfection, off-site treatment (eg rotaclave, incinerator) or autoclave may be considered to be validated means and comply with the Regulations. This is provided appropriate steps are taken to confirm the efficacy of the method, the appropriate control measures are put in place for the safe transport and storage of the waste material and the process is completed in a safe manner.

Regulation 20 Containment and control measures for contained use involving larger GMOs

Regulation 20

(1) A user who undertakes a contained use involving larger GMOs must apply the containment measures selected in the risk assessment for the contained use.

(2) A person responsible for the contained use must review the containment measures applied—

(a) at suitably regular intervals; and
(b) immediately, if that person suspects that—
(i) the containment measures are no longer adequate; or
(ii) in the light of new scientific or technical knowledge, the risk assessment is no longer valid.

Guidance 20

136 While contained use with larger GMOs requires the application of the principles of occupational and environmental safety (Schedule 7), unlike GMMs there are no specific containment tables for work with larger GMOs. However, users are required to apply appropriate containment and control measures for contained use of larger GMOs to safeguard human health and safety. The appropriate containment and control measures should be identified by a risk assessment under regulation 6. Further information on appropriate containment for larger GMOs can be found in *The SACGM compendium of guidance*.

137 The Regulations do not cover environmental hazards arising from contained use with larger GMOs. However, environmental risk assessments are required under the EPA and suitable containment and control measures must be applied to prevent escape and to protect the environment.

Regulation 21 Emergency plans

Regulation 21

(1) Where an assessment carried out under regulation 5(1) shows that, as a result of any reasonably foreseeable accident—

(a) the health or safety of persons outside the premises in which the contained use is undertaken is liable to be seriously affected; or
there is a risk of serious damage to the environment from the contained use,

a person responsible for the contained use must ensure that, before the contained use commences, a suitable emergency plan is prepared with a view to securing the health and safety of those persons or the protection of the environment or both.

(2) Where an assessment carried out under regulation 6(1) shows that, as a result of any reasonably foreseeable accident, the health or safety of persons outside the premises in which the contained use is undertaken is liable to be seriously affected, a person responsible for the contained use must ensure that, before the contained use commences, a suitable emergency plan is prepared with a view to securing the health and safety of those persons.

(3) An emergency plan must—

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

(4) A person responsible for the contained use which is the subject of an emergency plan must—

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

Guidance 21

138 The provision of an emergency plan is aimed at safeguarding human health or the environment in the event of a foreseeable accident. Therefore, the formulation of an emergency plan is required to cover incidents involving GMOs where the failure of containment and control measures could lead to serious harm to humans outside the premises and/or to the environment. The ultimate need for an emergency plan is therefore based on those risks associated with the GMOs themselves and contained uses.

139 An emergency plan must be prepared if risk assessments carried out under regulations 5 or 6 indicate that, as a result of any foreseeable accident (involving significant and unintended release of GMOs), the health and safety of people **outside** the premises may be seriously affected. With regard to contained uses involving GMMs, an emergency plan is also required if a foreseeable accident might result in a serious risk to the environment. In practice, an emergency plan should only be prepared for work with organisms that pose the highest hazards to humans or the environment.

140 If an emergency plan is required, this should be submitted to the competent authority as part of a contained use notification.

Guidance 21

141 Where an emergency plan is produced, it should be a written document that is kept up to date to reflect any changes in safety procedures, premises and personnel. Examples of information that could be recorded in an emergency plan include:

(a) the types of incident to be taken into account and the immediate steps to be taken if the scenario is realised;
(b) organisations involved, including key personnel, their responsibilities and liaison arrangements between them;
(c) communication links, including arrangements for giving information to people liable to be affected by any accident and for making such information publicly available;
(d) specialised equipment available for damage control and repair;
(e) technical information such as the nature of the organism(s), characteristics of the plant and other hazards which may be present;
(f) information about the site, including likely locations of personnel and hazardous organisms;
(g) evacuation arrangements;
(h) contacts and arrangements for obtaining further advice and assistance, eg meteorological information, medical services, local authorities;
(i) arrangements and procedures for dealing with the media and external enquiries;
(j) long-term clean-up procedures.

142 Anyone on the site affected by the plan should be familiar with its relevant provisions. This will involve those who have duties under it as well as those who will need to be evacuated in the event of an emergency (including contractors and visitors). The plan should be drawn up in consultation with appropriate organisations, including emergency services (fire, police and ambulance), the local authority emergency planning officer, the environmental health department and relevant parts of the health services. In England and Wales, the plan should be brought to the attention of the Environment Agency and the utility company that handles the local water supply with regard to possible pollution of watercourses. Likewise, in Scotland, the plan should be brought to the attention of the Scottish Environment Protection Agency and the appropriate utility company.

143 Information about the emergency plan should be made publicly available. The local authority should be consulted, and it may be able to offer advice and assistance with the provision of public information, for instance by allowing information to be placed in public buildings such as libraries, civic centres and town halls.

Regulation 22 Information relating to accidents

Regulation 22

If an accident occurs, a person responsible for the contained use must immediately inform the competent authority of the accident and must provide the following information—

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

Guidance 22

144 The Regulations provide a definition of what constitutes an accident. This does not include all unintended incidents, only those which result in a significant and unintended release and which presents an immediate or delayed risk to human health or the environment. Where this criteria is met, the person responsible for the contained use must inform the competent authority (via HSE) of the accident as soon as possible. In the first instance, it may be appropriate to convey the information by telephone and submit further written details using the online form on the HSE website. You should provide all the information requested, including the circumstances of the accident (including characteristics and quantity) and the measures taken in response to the accident.

145 Where the GMO presents a risk to human health, there are additional reporting requirements under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013[21] (RIDDOR).

146 Where a GMO is unintentionally released from primary containment, it may remain confined to the laboratory/facility, but protecting people inside the containment facility must be considered as well as the general population and wider environment. This contrasts with the risk-based trigger for an emergency plan which should only be initiated based on possible serious effects on human health or the environment **outside** the facility.

147 Clearly, not every incident with a GMO should be notified under regulation 22. In deciding what is notifiable, it should be noted that the competent authority is duty-bound under the Contained Use Directive to inform the European Commission of notified accidents. The EC are only interested in those accidents where human health or the environment could realistically have come to serious harm. This should encourage decisions on reporting to be made in a pragmatic and risk-based way. Consequently, minor spillages where there is no significant risk to human health or the environment are not reportable under the Regulations. Conversely, any breach of the primary containment of class 4 GMMs is reportable.

PART 4 Duties and powers of the competent authority

Regulation 23 Duties of competent authority on receiving a notification

Regulation 23

The competent authority must examine a notification and accompanying documentation submitted under regulation 9(2), 10(2), 11(2), or 12(2) for—

(a) conformity with the requirements of these Regulations;
(b) the accuracy and completeness of the information provided;
(c) the adequacy and correctness of the risk assessment or summary of the risk assessment;
(d) the adequacy of the waste management and emergency response measures;
(e) in the case of a notification submitted under regulation 10(2) or 11(2), the correctness of the class assigned to the contained use; and
(f) the inclusion of an emergency plan where the risk assessment indicates that such a plan is necessary.

Guidance 23

148 On receiving a notification, the competent authority has responsibilities to assess the information provided to ensure that, among other things, the risk assessment is sufficient and the classification of the work is appropriate to protect human health and the environment.

149 The assessment is used by the competent authority in reaching a decision on what subsequent action is necessary (eg issuing consent for class 3 and 4 contained use). The period assigned for the assessment is included in the timescales set out in regulations 9, 10, 11 and 12.

Regulation 24 Requests for additional information

Regulation 24

(1) For the purpose of carrying out an examination of a notification in accordance with regulation 23 the Executive may, on behalf of the competent authority, request the notifier to provide such additional information relating to the notification as it may specify.

(2) If requested to do so by the Secretary of State or the Scottish Ministers, the Executive must request additional information under paragraph (1).

(3) A request for additional information must be made in writing.

(4) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of receipt of all of the additional information.

(5) The period of time beginning with the date on which the Executive requests additional information and ending with the date on which the Executive

Regulation 24

receives all of that additional information will not be taken into account in calculating the period of days referred to in regulation 10(4), 10(7), 11(4), 11(5) or 12(4).

(6) The competent authority may return a notification to the notifier where—

(a) the Executive has requested additional information;
(b) the notifier has not provided all the additional information requested within six months of the date on which the Executive sent the request; and
(i) contained use has not commenced at the premises to which a notification made under regulation 9(2) relates; or
(ii) the contained use referred to in the notification has not commenced.

Guidance 24

150 Having assessed a notification submitted under regulations 9, 10, 11 or 12, HSE may decide that the criteria set out in regulation 23 have not been met. Consequently, regulation 24 sets out the process by which HSE on behalf of (or as instructed by) the competent authority will request further information from the notifier, to enable the assessment criteria to be met. A user must not start or continue contained use if they receive a request for further information. See guidance on regulation 16 for further information.

151 HSE, on behalf of the competent authority, will acknowledge receipt of the additional information within 10 working days. Requests for additional information 'stop the clock' in respect of statutory timescales for the competent authority to respond to contained use notifications and it will restart when the information is received. The notification will continue to be held by HSE during this period and placed on the public register within 14 days of receipt (see regulation 28).

152 A time limit of six months is given for the notifier to respond to requests for additional information. If the information is not supplied within this time period, the notification will be returned but the notification fee will not be refunded.

Regulation 25 Powers of competent authority in relation to contained use

Regulation 25

The competent authority may at any time by notice in writing to a notifier—

(a) set a time limit for, or impose conditions with regard to, a particular contained use;
(b) require the notifier and any user to suspend, terminate or not to commence a particular contained use;
(c) revoke or vary a consent granted to the notifier under regulation 11,

and the notifier and any user undertaking the contained use must comply with that notice.

Guidance 25

153 Regulation 25 provides the competent authority with a number of powers in relation to contained use, either at the notification stage or when the contained use is in progress. This includes setting time limits, applying conditions, suspending, terminating or instructing not to start a particular contained use. The competent authority will exercise this power in writing. The competent authority also has the power to vary or revoke consents.

154 Exercising these powers is most likely to arise in light of information provided as part of a notification or where new information emerges that suggests the risks

Guidance 25

from the work may not be adequately controlled or managed. Anyone undertaking the contained use has a duty to comply with any such instruction from the competent authority.

Regulation 26 Exemption certificates

Regulation 26

(1) A competent authority may, by a certificate in writing, exempt—

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

from all or any of the requirements of, or prohibitions imposed by, these Regulations.

(2) An exemption may be granted subject to conditions and to a time limit and may be revoked by a certificate in writing at any time.

(3) A competent authority must not grant an exemption unless, having regard to the circumstances of the case and in particular to—

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

it is satisfied about the matters referred to in paragraph (4).

(4) The matters are—

(a) that the health or safety of persons who are likely to be affected by the exemption will not be prejudiced in consequence of it; and
(b) where the exemption relates to a contained use involving a micro-organism, that the environment will not be prejudiced in consequence of the exemption.

Guidance 26

155 The competent authority can issue an exemption for a particular GMM, contained use or person from some or all the requirements of the Regulations. However, this is only where the exemption will not adversely affect human health or the protection of the environment. Situations which qualify for exemptions are limited. One example may be to implement a direction from the EC that a specific GMM meets the criteria for exemption from the Directive – an exemption certificate could be used to implement this measure.

156 In order to issue an exemption, the competent authority will require valid justification and supporting evidence. Any exemption certificate may have conditions attached, including a time limit, if applicable. The competent authority can revoke the exemption at any time by informing the notifier in writing and this would take effect immediately.

Regulation 27 Duties of competent authority on receipt of information about accidents

Regulation 27

Where the competent authority is informed of an accident in accordance with regulation 22, it must—

(a) ensure that any necessary measures are taken;
(b) immediately inform those EEA states which could be affected by the accident;
(c) collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit their effects; and
(d) send to the European Commission—
(i) the information provided under regulation 22(a), (b) and (d),
(ii) information on the effectiveness of the measures taken in response to the accident; and
(iii) an analysis of the accident, including recommendations to limit its effects and to avoid similar accidents in the future.

Guidance 27

157 Upon receiving an accident notification, the competent authority will decide whether the accident meets the criteria defined in the Regulations. Where this is the case, the competent authority will inform the European Commission. This will include details of the accident, the effectiveness of the measures taken and the recommendations to avoid similar accidents recurring.

158 The competent authority will ascertain the circumstances of the accident and decide, based on published investigation selection criteria, whether the accident warrants further investigation. As a minimum, the information provided in relation to the accident should include enough detail for the competent authority to consider whether adequate measures have been taken to limit the effects of the accident and prevent a recurrence.

Regulation 28 Register of notifications

Regulation 28

(1) This regulation is subject to regulation 29.

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

(3) Subject to paragraph (4) the register must contain—

(a) in relation to each notification submitted under regulation 9(2), 10(2), 11(2) or 12(2)—
(i) the name, address and telephone number and any fax number and any e-mail address of the notifier;
(ii) the date on which the Executive acknowledged receipt of the notification; and
(iii) where the competent authority receives details of a matter referred to in sub-paragraphs (a) to (g) of regulation 14(1) or in regulation 15(1) confirmation that such details have been received;
(b) in relation to each notification submitted under regulation 10(2), 11(2), or 12(2), the date of any cessation of the contained use to which the notification related;
(c) in relation to each notification submitted under regulation 9(2)—
(i) the information specified in paragraphs (d) to (g), (h)(ii) and (h)(iii) of Schedule 5;

Regulation 28

(ii) if applicable, the fact that the competent authority has been informed of an accident at those premises under regulation 22;

(d) in relation to each notification submitted under regulation 10(2), the information specified in paragraphs (e) to (k) and (m)(i) and (ii) of Schedule 6;

(e) in relation to each notification submitted under regulation 11(2)—

(i) the information specified in paragraphs (e) to (j), (l), (m)(i), (iii) and (iv) and (r) of Schedule 6,

(ii) if applicable, confirmation that consent for the contained use has been granted under regulation 11(4) or 11(5);

(f) in relation to each notification submitted under regulation 12(2), the information specified in paragraphs (e) to (j) and (m)(i) of Schedule 6.

(4) The competent authority must omit information from the register where—

(a) the information falls within one of the exceptions to disclosure in—

(i) regulation 12(5) or 13(1) of the Environmental Information Regulations 2004; or

(ii) regulation 10(5) or 11(1) of the Environmental Information (Scotland) Regulations 2004;

(b) the notifier has requested that the competent authority treat the information as confidential; and

(c) the competent authority has decided that the information is to be kept confidential.

(5) The competent authority may not keep the following information confidential if it was submitted in accordance with the requirements of 9(2), 10(2) or 11(2)—

(a) the general characteristics of any genetically modified micro-organisms, the name and address of the notifier, and the location of use;

(b) the class of contained use and the containment measures;

(c) the evaluation of foreseeable effects, in particular any harmful effects on human health and the environment.

(6) Information must be entered in the register within 14 days of its receipt by the competent authority.

(7) The competent authority may remove from the register details of—

(a) premises which are no longer used for contained use, ten years after being informed of this under regulation 14(1)(c);

(b) premises where all contained use has ceased for the time being, ten years after being informed of this under regulation 14(1)(d), provided no notice of recommencement under regulation 14(1)(f) has been received;

(c) a contained use that has ceased, ten years after being informed of this under regulation 14(1)(e).

(8) A copy of the register must be made available for inspection to members of the public by the Executive, by such means as it considers appropriate, which may include publication on its website.

Guidance 28

159 HSE maintains a register of premises and contained uses notified under regulations 9, 10, 11 or 12. Information is placed on the register within 14 days of receipt, provided all the administrative requirements (eg payment) have been made. A version of the register is made publically available on the HSE website. Access to this version is not restricted and the public register is updated on a monthly basis. Each entry contains summary information taken from the notification rather than the

Guidance 28

more detailed information that is often presented in the risk assessment. The key elements of this summary information include:

(a) the name and address of the notifier, and the location of use;
(b) the title of each notifiable project undertaken at the premises;
(c) the purpose of each notifiable project;
(d) the general characteristics of any GMMs;
(e) the class of contained use and the containment measures;
(f) the evaluation of foreseeable effects, in particular any harmful effects on human health and the environment.

160 Where a notifier considers that information that would otherwise be placed on the register would be exempt from disclosure under the Freedom of Information Act 2000,[22] (FOI) or Environmental Information Regulations 2004[23] (or if in Scotland the Environmental Information (Scotland) Regulations 2004)[24] (collectively EIR) they should indicate this in their notification. A full explanation of why the notifier considers the information to be exempt should be supplied (a list of the grounds for exemption/exceptions to disclosure are set out in the relevant provisions of FOI and EIR). The competent authority will consider this request, and if it agrees with the notifier it will withhold the information from the register. Note that certain information cannot be withheld from the register (see regulation 29).

161 The risk assessment submitted with a notification is not placed on the register. However, this could be the subject of a request for disclosure under FOI or EIR. Again, if a notifier considers that the risk assessment or other information supplied with the application, but which is not placed on the register, would be exempt under FOI or EIR they should indicate this when submitting the notification as this will assist the competent authority if they receive any requests for disclosure. Under FOI and EIR the competent authority must form its own judgment as to whether information is exempt/excepted from the relevant legislation and may not agree with the notifier.

162 Users are advised to notify using the online forms on the HSE website, as this presents the notification data to HSE in a structure that allows for easy removal of the information that is not to be placed on the public register. If notifications are made using any other format, notifiers are advised to clearly identify the information that they consider should not be placed on the public register.

163 HSE will remove details of notifications from the public register 10 years after being informed that the contained use has ceased. Only if a notifier withdraws their notification **before** the contained use starts (in accordance with regulation 17) will information not be placed on the public register. If the request for withdrawal is made before starting but after information has already been placed on the public register, it will be removed as soon as possible.

Regulation 29 Information not to be included in the register

Regulation 29

(1) No information may be included in the register if and so long as, in the opinion of the Secretary of State, the inclusion in the register of that information, or information of that description, would be contrary to the interests of national security.

(2) For the purpose of securing the exclusion from the register of information to which paragraph (1) applies, the Secretary of State may give the competent

Regulation 29

authority directions—

(a) specifying information, or descriptions of information, to be excluded from the register; or
(b) specifying descriptions of information to be referred to the Secretary of State for his or her determination.

(3) No information referred to the Secretary of State under paragraph (2)(b) may be included in the register unless the Secretary of State determines that it should be included.

(4) The competent authority must notify the Secretary of State of any information it excludes from the register in accordance with directions given to it under paragraph (2).

(5) A person may give a written notice to the Secretary of State specifying information which appears to that person to be information to which paragraph (1) may apply and stating why it should not be included in the register.

(6) If a person gives a written notice under paragraph (5), at the same time that person must give written notice to the competent authority that they have done so.

(7) No information notified under paragraph (5) may be included in the register unless the Secretary of State determines that it should be included.

Guidance 29

164 Regulation 29 provides for the Secretary of State to direct HSE not to include information on the register which would be contrary to the interests of national security. The Secretary of State has directed that information about the location or work with pathogens and toxins listed in Schedule 5 of ATCSA should be excluded from the public register on this basis. This exclusion also extends to the details of individual projects involving pathogens and toxins listed in Schedule 5.

165 If any person thinks that any information in a submitted notification may present a risk to national security they should give notice to the Secretary of State identifying what the information is, where it is in the notification (if known) and why they think it should be considered for exclusion from the public register. The Secretary of State will decide if it should be included in the register and this information will not be placed in the public register until a decision has been reached that does not present a risk to national security. For details of how to give notice to the Secretary of State please see the Pathogens and Toxins section of the National Counter Terrorism and Security Office website (www.nactso.gov.uk/hazardous-materials) or contact NaCTSO directly (pathogens@homeoffice.gsi.gov.uk).

PART 5 Miscellaneous and general

Regulation 30 Enforcement

Regulation 30

(1) This regulation applies to the extent that any part of these Regulations are not health and safety regulations within the meaning of section 15 of the 1974 Act.

(2) The following provisions apply to the whole of these Regulations as if they were health and safety regulations for the purposes of that Act—

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

(3) Every function of the Executive under any provision of the 1974 Act, or under health and safety regulations, is exercisable in relation to these Regulations as if the whole of these Regulations were health and safety regulations for the purposes of that Act.

(4) Despite section 33(1)(c) of the 1974 Act a failure to discharge a duty placed on the competent authority or the Executive by these Regulations is not an offence.

(5) Despite regulation 3 of the Health and Safety (Enforcing Authority) Regulations 1998, the enforcing authority for these Regulations is the Executive.

Guidance 30

166 The effect of regulations 30(2) and (3) is that the provisions of these Regulations that rely on powers in the European Communities Act 1972, including provisions in relation to the protection of the environment, are treated as if they were made under the HSW Act. The provisions of the HSW Act in relation to matters such as the ability to make Approved Codes of Practice and serving of notices therefore apply, as in the case of regulations made under the HSW Act.

167 Under regulation 30(5) HSE is the enforcing authority for these 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 31 Appeals

Regulation 31

(1) A person responsible for contained use who is aggrieved by any of the following may appeal to the appropriate person—

(a) a decision by the competent authority—
(i) to refuse to provide a written agreement requested under regulation 10(6);

Regulation 31

(ii) to refuse consent for a class 3 or class 4 contained use notified under regulation 11(2);
(iii) to refuse to provide written agreement under regulation 19(2)(c) that a particular containment measure need not be applied for a specific activity;
(iv) to refuse to grant an exemption certificate under regulation 26(1) or to revoke such a certificate;
(v) to impose a condition or a time limit on an exemption certificate issued under regulation 26(1).

(b) an instruction concerning the cessation of a contained use under regulation 16(3);

(c) a request for additional information by the Executive under regulation 24(1);

(d) a notice from the competent authority under regulation 25.

(2) The appropriate person may direct that an appeal be determined on their behalf by one or more persons appointed for that purpose.

(3) The appropriate person may pay such remuneration and allowances to an appointed person as the appropriate person may determine.

(4) An appointed person may decide the procedure to be followed on the appeal and may give such directions as are appropriate to give effect to the determination of the appeal.

(5) Where an appeal is brought under this regulation—

(a) the following remain valid pending the final determination of the appeal—
(i) a decision of the competent authority referred to in paragraph (1)(a);
(ii) a request for additional information made under regulation 24(1);

(b) the following are not suspended pending the final determination of the appeal—
(i) the operation of regulation 16 and any instructions given under regulation 16(3);
(ii) a notice issued under regulation 25.

(6) The period of time beginning with the date on which an appeal is lodged and ending with the date on which that appeal is determined will not be taken into account in calculating the period of days referred to in regulation 10(4), 10(7), 11(4), 11(5) or 12(4).

(7) In this regulation,

"appointed person" means the person appointed by the appropriate person to determine an appeal;

"appropriate person" means—

(a) the Secretary of State, in the case of—
(i) an appeal under paragraph (1)(a) or (d) against a decision of, or a notice issued by, the competent authority as regards England and Wales; or
(ii) an appeal under paragraph (1)(b) or (c) against a request or instruction relating to—
(aa) the undertaking or proposed undertaking of a contained use; or
(bb) premises which are the subject of a notification under regulation 9(2),

Regulation 31

in England or Wales;

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

(i) an appeal under paragraph (1)(a) or (d) against a decision of, or a notice issued by, the competent authority as regards Scotland or the joint competent authority; or

(ii) an appeal under paragraph (1)(b) or (c) against a request or instruction relating to—

(aa) the undertaking or proposed undertaking of a contained use; or

(bb) premises which are the subject of a notification under regulation 9(2) or 9(5), in Scotland.

Guidance 31

168 This regulation provides a mechanism by which a person responsible for contained use can appeal against decisions made by the competent authority. Decisions against which an appeal can be made include:

(a) not permitting a class 3 or 4 contained use to take place;
(b) imposing conditions, suspending, terminating or time limiting any contained use;
(c) revoking or varying a consent for a class 3 or 4 contained use;
(d) not allowing derogation from the full containment;
(e) revoking an exemption certificate;
(f) placing conditions or a time limit on an exemption certificate;
(g) requiring additional information about a premises or contained use notification, and any instructions (such as stopping, destroying or storing the GMOs) associated with the request for additional information.

169 Where an appeal is lodged, the Secretary of State or, where the premises or contained use are in Scotland, the Secretary of State and Scottish Ministers acting jointly, decide whether to determine the appeal themselves or appoint an independent person or persons (termed appointed person(s)) to determine the appeal. An appointed person will determine the appeal procedure which may be different in each case depending on the nature of the issues that need to be decided. For further information on how to appeal and the process that will be followed, see www.hse.gov.uk/biosafety/gmo/notifications/appeals.htm.

170 If there is an appeal, the original decision of the competent authority will stand pending the outcome.

171 The timescales specified in regulations 10(4), 10(7), 11(4), 11(5) or 12(4) in relation to notifications will be suspended for the duration of the period between when an appeal is lodged (related to that notification) and its resolution.

Regulation 32 Competent authority address

Regulation 32

Anything required to be submitted or sent to a competent authority under these Regulations must be sent to the Executive at the address published for this purpose on its website, which may be, or include, an address for submission by electronic means.

Guidance 32

172 Where possible, all information, including notifications, should be submitted electronically using the online forms on the HSE website. If contact by email or submission of paper documents is required, details of how this can be done are also provided on the website.

Regulation 33 Saving and transitional provisions

Regulation 33

(1) Subject to paragraph (3) the following continue to have effect and are deemed to have been made, granted or imposed under these Regulations—

(a) a notification made under any of regulations 9 to 13 of the 2000 Regulations, provided that the notification complied with the provisions of those Regulations, as if the notification had been made by a notifier under the corresponding regulation of these Regulations;
(b) a consent granted by the competent authority under regulation 11 of the 2000 Regulations as if it were granted under regulation 11 of these Regulations;
(c) an agreement by the competent authority under regulation 18(2) of the 2000 Regulations that a specific containment measure need not be applied to a contained use, as if it were made under regulation 19(2) of these Regulations;
(d) a request for additional information made under regulation 14(2) of the 2000 Regulations, as if it were made under regulation 24(1) of these Regulations;
(e) a condition, limit of time or other requirement imposed by the competent authority under regulation 15(1) of the 2000 Regulations, as if it were imposed under regulation 25 of these Regulations.

(2) Every record required to be kept under regulation 8(2) of the 2000 Regulations must be kept in the same manner and for the same period as specified in that regulation as if the requirement were imposed under regulation 7(2) of these Regulations.

(3) A person responsible for contained use involving micro-organisms must submit a notification to the competent authority in the following circumstances–

(a) the contained use was being undertaken in accordance with the 2000 Regulations before the date on which these Regulations come into force;
(b) the appropriate containment level for the contained use is different under these Regulations to the appropriate containment level under the 2000 Regulations; and
(c) as a result the contained use is classified under these Regulations at a higher class than under the 2000 Regulations.

(4) The notification must be submitted to the competent authority within the specified period.

(5) Subject to paragraphs (6) to (8) the notification must be treated as a notification required under regulation 10(2) or 11(2) of these Regulations.

(6) The notification must contain the information in Schedule 6 that is specified for the new class of contained use, unless the competent authority exempts the notifier from some or all of the requirements of Schedule 6.

(7) Where a notification is submitted for a contained use that requires consent as class 3 or class 4 contained use, the competent authority must inform the notifier of its decision whether or not to grant consent within 90 days of receipt of the notification.

(8) The contained use referred to in paragraph (3) may continue provided that—

(a) the notification is submitted within the specified period;

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(b) the risk assessment shows no increase in the risks to human health or the environment created by the contained use;
(c) the competent authority does not require the notifier to suspend or terminate the contained use under regulation 25 of these Regulations; and
(d) the competent authority has not refused consent for the contained use.

(9) In this regulation—

"specified period" means the 90 days beginning with the date on which these Regulations come into force.

Guidance 33

173 The transitional arrangements enable (with limited exceptions) existing contained uses notified in compliance with the 2000 Regulations to be transferred across to the 2014 Regulations without the need to renotify. Any conditions or derogations attached to the notified contained use will also still apply.

174 However, the person responsible for the contained use should review their risk assessment and contained use to ascertain whether changes to the containment measures in the 2014 Regulations have resulted in an increase in class of the existing contained use. If this is the case, a revised notification should be submitted to HSE within 90 days of the new Regulations coming into force. The contained use may continue in the meantime unless the risk assessment shows that the risks have increased or HSE does require the user to stop the contained use.

Regulation 34 Consequential amendments

Regulation 34

(1) The Health and Safety (Fees) Regulations 2012 are amended as follows.

(2) In regulation 13—

(a) in the heading, for "2000" substitute "2014";
(b) in paragraph (1), for "2000" substitute "2014";
(c) for paragraph (2) substitute—
"(2) No fee is to be returned to a notifier where the notifier withdraws a notification under regulation 17 of the 2014 Regulations or the competent authority returns a notification under regulation 24(6) of the 2014 Regulations.";
(d) in paragraph (3) in both instances, for "2000" substitute "2014".

(3) In regulation 24(16)(b) for "2000" substitute "2014".

(4) In Schedule 10—

(a) in the heading, for "2000" substitute "2014";
(b) In column 1 of the table—
(i) for paragraph (a) substitute "Notification of premises to be used for contained use for the first time under regulation 9(2)";
(ii) for paragraph (b) substitute "Notification of class 2 contained use under regulation 10(2)";
(iii) for paragraph (c) substitute "Notification of premises to be used for contained use for the first time under regulation 9(2) at the same time as notification of class 2 contained use under regulation 10(2)";
(iv) for paragraph (d) substitute "Notification of class 3 contained use under regulation 11(2)";
(v) for paragraph (e) substitute "Notification of premises to be used for

Regulation 34

contained use for the first time under regulation 9(2) at the same time as notification of class 3 contained use under regulation 11(2)";

(vi) for paragraph (f) substitute "Notification of class 4 contained use under regulation 11(2)";

(vii) for paragraph (g) substitute "Notification of premises to be used for contained use for the first time under regulation 9(2) at the same time as notification of class 4 contained use under regulation 11(2)";

(viii) for paragraph (h) substitute "Notification of contained use under regulation 12(2)";

(ix) for paragraph (i) substitute "Notification of premises to be used for contained use for the first time under regulation 9(2) at the same time as notification of contained use under regulation 12(2)";

(x) for paragraph (j) substitute "Notification of a change or new information affecting risks under regulation 15(1)";

(xi) in paragraph (k) for "18(2)" substitute "19(2)" and for "9(1), 10(1), 11(1) or 12(1)" substitute "9(2), 10(2), 11(2) or 12(2)".

Guidance 34

175 The Health and Safety (Fees) Regulations 2012[25] previously referred to the 2000 Regulations. These amendments ensure that the Fees Regulations refer to the 2014 Regulations. The fees themselves will not change under the new Regulations.

Regulation 35 Revocations

Regulation 35

The following are revoked—

(a) the 2000 Regulations;

(b) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002;

(c) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005;

(d) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010.

Guidance 35

176 Starting from the date the new Regulations come into force, the 2000 Regulations as well as the 2002, 2005 and 2010 amendments are revoked but the requirements for record keeping still apply.

Schedules

Schedule 1 Classes of contained use

Schedule 1

Regulation 2(1)

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

Schedule 2

Schedule 2

Regulation 2(1) and 3(1)

Part 1 Techniques constituting genetic modification

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

(a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;
(b) techniques involving the direct introduction into an organism of heritable genetic material prepared outside the organism, including micro-injection, macro-injection and micro-encapsulation;
(c) cell fusion or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

Schedule 2

Part 2 Techniques which are not considered to result in genetic modification

2 The following techniques are not considered to result in genetic modification provided that they do not involve the use of recombinant nucleic acid molecules or of genetically modified organisms made by techniques other than those listed in Part 3—

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

Part 3 Techniques to which these Regulations do not apply

3 These Regulations (except regulation 18) do not apply to the following techniques of genetic modification, provided that they do not involve the use of recombinant nucleic acid molecules or of genetically modified organisms other than those made by one or more of the following techniques—

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

4 In paragraph 3—

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

Schedule 3

Schedule 3

Regulation 2(3), 3(4) and 5

Part 1 Matters to be taken into account in carrying out an assessment for the purposes of regulation 5

1 The following matters must be taken into account in carrying out an assessment for the purposes of regulation 5—

(a) any potentially harmful effects, in particular those associated with—
  (i) the recipient micro-organism;
  (ii) the inserted genetic material (originating from the donor organism);
  (iii) the vector;
  (iv) the donor micro-organism (where that donor micro-organism is used during the contained use);
  (v) the resulting genetically modified micro-organism;
(b) the characteristics of the contained use;
(c) the severity of the potentially harmful effects;
(d) the likelihood of the potentially harmful effects being realised;
(e) the disposal of waste and effluents.

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

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

Part 2 Steps to be included when carrying out an assessment for the purposes of regulation 5

3 An assessment carried out for the purposes of regulation 5 must include—

(a) identification of any harmful properties of the recipient and, where appropriate, the donor micro-organism;
(b) identification of any harmful properties associated with the vector or inserted material, including any alteration in the existing properties of the recipient;
(c) recognition that, in general, only contained use which shows the following characteristics is appropriate for inclusion in class 1 as described in Schedule 1—
  (i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants;
  (ii) the nature of the vector and the insert is such that they do not endow the genetically modified micro-organism with a phenotype likely to cause

Schedule 3

disease to humans, animals or plants, or likely to cause deleterious effects on the environment; and

(iii) the genetically modified micro-organism is unlikely to cause disease to humans, animals or plants and is unlikely to have deleterious effects on the environment;

(d) consideration of relevant EU legislation, including Directive (EC) 2000/54 of the European Parliament and of the Council on the protection of workers from risks related to exposure to biological agents at work, other classification schemes referring to plant and animal pathogens, and other international and national classification schemes for genetically modified micro-organisms;

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

(f) consideration of—

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

(ii) the characteristics of the contained use involving micro-organisms;

(iii) any contained use of micro-organisms which cannot be controlled adequately by standard laboratory procedures, and which presents risks which require controls for each individual case;

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

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

(i) assignment of the contained use to the appropriate containment level, in accordance with paragraph 4;

(j) classification of the contained use in the class of the same number as that of the appropriate containment level;

(k) review and reconsideration of that classification in the light of the completed risk assessment.

4 To assign a contained use to the appropriate containment level for the purposes of paragraph 3(i), the person carrying out the risk assessment must—

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

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

(c) then assign the contained use to the containment level of that highest number.

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

Schedule 4

Schedule 4

Regulation 6

Part 1 Matters to be taken into account in carrying out an assessment for the purposes of regulation 6

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

(a) any potentially harmful effects, in particular those associated with—
  (i) the recipient organism;
  (ii) the inserted genetic material (originating from the donor organism);
  (iii) the vector;
  (iv) the donor organism;
  (v) the resulting genetically modified organism;
(b) the characteristics of the contained use;
(c) the severity of the potentially harmful effects;
(d) the likelihood of the potentially harmful effects being realised.

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

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

Part 2 Steps to be included when carrying out an assessment for the purposes of regulation 6

3 An assessment carried out for the purposes of regulation 6 must include—

(a) identification of any harmful properties of the recipient and, where appropriate, the donor organism;
(b) identification of any harmful properties associated with the vector or inserted material, including any alteration in the existing properties of the recipient;
(c) identification of the provisional level of risk associated with the genetically modified organisms;
(d) selection of containment and other protective measures on the basis of—
  (i) the provisional level of risk; and
  (ii) the characteristics of the contained use;
(e) adjustment of the level of risk in the light of the matters referred to in sub-paragraph (d);
(f) review and reconsideration of the containment and other protective measures in the light of the steps required by sub-paragraphs (a) to (e).

Schedule 5 Information required for a notification under regulation 9(2)

Schedule 5

Regulation 9(2), 14(1) and 28(3)

A notification required for the purposes of regulation 9(2) must contain the following information—

(a) the name, address and telephone number and any fax number and any e-mail address of the notifier;
(b) the name of the person with specific responsibility for the supervision and safety of contained use;
(c) information on the training and qualifications of that person;
(d) details of the arrangements for obtaining advice on risk assessments in accordance with regulation 8, including details of any genetic modification safety committee if established;
(e) the address of the premises where the contained use is to be carried out and a general description of the premises, together with, if required by regulation 9(6), the principal address of the premises;
(f) the nature of the work to be undertaken;
(g) the class of any contained use involving micro-organisms;
(h) where the first contained use to be carried out in those premises is a class 1 contained use—
  (i) a summary of the risk assessment of that contained use;
  (ii) any advice received in relation to the risk assessment from a person or genetic modification safety committee in accordance with regulation 8;
  (iii) information on waste management;
  (iv) confirmation that the emergency services, and any body or authority liable to be affected by an accident to which any emergency plan relates, will be informed of the contents of the emergency plan and of any relevant revisions;
(i) where the first contained use to be carried out in those premises is a contained use involving larger GMOs and that contained use is not notifiable under regulation 12(2)—
  (i) a copy of the risk assessment made for the purposes of regulation 16(1); and
  (ii) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates, will be informed of the contents of the emergency plan and of any relevant revisions.

Schedule 6 Information required for a notification under regulations 10(2), 11(2) or 12(2)

Schedule 6

Regulation 10(2), 11(2), 12(2), 14(1), 28(3) and 33(6)

A notification required for the purposes of regulations 10(2), 11(2) or 12(2) must contain the following information except where it is required only for a specified regulation—

(a) the name, address and telephone number and any fax number and any e-mail address of the notifier;
(b) any centre number allocated by the competent authority in respect of the premises at which the contained use is to be undertaken and the date of the notification required by regulation 9(2) relating to those premises;

Schedule 6

(c) the name of the person with specific responsibility for supervision and safety of contained use;
(d) information on the training and qualifications of that person;
(e) the recipient or parental micro-organism to be used;
(f) the donor micro-organism to be used;
(g) where applicable, the host-vector system to be used;
(h) the source and intended function of the genetic material involved in the modification;
(i) the identity and characteristics of the genetically modified organism;
(j) the purpose of the contained use, including its expected results;
(k) for regulation 10(2) the approximate culture volumes to be used;
(l) for regulation 11(2) the culture volumes to be used;
(m) a description of the containment and other protective measures to be applied, including—
  (i) information on waste management, including the type and form of wastes to be generated, their treatment, ultimate form and destination; and
  (ii) for regulation 10(2) justification for not applying any containment measure at containment level 2;
  (iii) for regulation 11(2), for class 3 contained use, justification for not applying any containment measure at containment level 3;
  (iv) for regulation 11(2), for class 4 contained use, justification for not applying any containment measure at containment level 4;
(n) for regulations 10(2) and 11(2) a copy of the risk assessment;
(o) for regulations 10(2) and 11(2) the advice received in relation to that assessment from a genetic modification safety committee;
(p) for regulation 12(2) a copy of the risk assessment;
(q) information in relation to any accident prevention and emergency plans including—
  (i) the information necessary for the competent authority to evaluate any emergency plan;
  (ii) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates, will be informed of the contents of the emergency plan and of any relevant revisions;
  (iii) for regulation 11(2), in addition—
    (aa) any specific hazards arising from the location of the installation;
    (bb) the preventive measures applied, including safety equipment, alarm systems and containment methods;
    (cc) procedures and plans for verifying the continuing effectiveness of the containment measures;
    (dd) a description of the information provided to workers;
(r) for regulation 11(2) a description of the parts of the installation;
(s) for regulation 11(2) whether the genetically modified organism is likely to be subject to transboundary movement.

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

Schedule 7

Regulation 18

The general principles of good microbiological practice and of good occupational safety and hygiene are as follows—

(a) keeping workplace and environmental exposure to any genetically modified micro-organism to the lowest reasonably practicable level;
(b) exercising engineering control measures at source and supplementing these with appropriate personal protective clothing and equipment where necessary;
(c) testing adequately and maintaining control measures and equipment;
(d) testing, where necessary, for the presence of viable process organisms outside the primary physical containment;
(e) providing appropriate training of personnel;
(f) establishing a genetic modification safety committee, if required;
(g) formulating and implementing local codes of practice for the safety of personnel, as required;
(h) displaying biohazard signs where appropriate;
(i) providing washing and decontamination facilities for personnel;
(j) keeping adequate records;
(k) prohibiting in the work area eating, drinking, smoking, applying cosmetics or the storing of food for human consumption;
(l) prohibiting mouth pipetting;
(m) providing written standard operating procedures where appropriate to ensure safety;
(n) having effective disinfectants and specified disinfection procedures available in case of spillage of genetically modified micro-organisms;
(o) providing safe storage for contaminated laboratory equipment and materials where appropriate.

Schedule 8

Schedule 8

Regulation 2(2) and 19(1)

Part 1 General

1 In this Schedule—

"GMMs" means genetically modified micro-organisms;

"HEPA" means High Efficiency Particulate Air;

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

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

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

(a) a modification, it is to be read in substitution for the relevant measure in Table 1a;
(b) additional, it is to be read as an addition to the measures in Table 1a, and any measure which has been substituted for a measure in Table 1a, in accordance with paragraph 2(a).

3 For the purposes of this Schedule—

(a) Table 1a describes containment measures applicable to contained use involving micro-organisms in laboratories;
(b) Table 1a, read with Table 1b, describes containment measures applicable to contained use involving micro-organisms in plant growth facilities;
(c) Table 1a, read with Table 1c, describes containment measures applicable to contained use involving micro-organisms in animal units;
(d) Table 2 describes containment measures applicable to contained use involving micro-organisms in premises other than those referred to in Tables 1a, 1b and 1c.

Part 2 Containment measures

Table 1a Containment measures applicable to contained use involving micro-organisms in laboratories

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

8	Autoclave	required on site	required in the building	required in the laboratory suite[4]	double ended autoclave required in laboratory

System of work					
9	Access restricted to authorised personnel only	not required	required	required	required (via airlock key procedure)
10	Biohazard sign on door	not required	required	required	required
11	Specific measures to control aerosol dissemination	not required	required so as to minimise	required so as to prevent	required so as to prevent
12	Shower	not required	not required	required where and to extent the risk assessment shows it is required	required
13	Protective clothing	suitable protective clothing required	suitable protective clothing required	suitable protective clothing required; footwear required where and to extent the risk assessment shows it is required	complete change of clothing and footwear required before entry and exit
14	Gloves	not required	required where and to extent the risk assessment shows they are required	required	required
15	Efficient control of disease vectors (eg rodents and insects) which could disseminate GMMs	required where and to extent the risk assessment shows it is required	required	required	required
Waste					
16	Inactivation of GMMs in effluent from hand-washing sinks and showers and similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
17	Inactivation of GMMs in contaminated material and waste	required by validated means where and to extent the risk assessment shows it is required	required by validated means	required by validated means, with waste inactivated within the laboratory suite	required by validated means, with waste inactivated within the laboratory

Other measures					
18	Laboratory to contain its own equipment	not required	not required	required, so far as is reasonably practicable	required
19	An observation window or alternative is to be present so that occupants can be seen	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required
20	Safe storage of GMMs	required where and to extent the risk assessment shows it is required	required	required	secure storage required
21	Written records of staff training	not required	required where and to extent the risk assessment shows it is required	required	required

1 “isolation” means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.

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

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

4 Where the autoclave is outside the laboratory in which the contained use is being undertaken, but within the laboratory suite, there must be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

Table 1b Containment measures applicable to contained use involving micro-organisms in plant growth facilities (to be read with Table 1a as indicated in paragraph 3(b) of Part 1)

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

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

Table 1c Containment measures applicable to contained use involving micro-organisms in animal units (to be read with Table 1a as indicated in paragraph 3(c))

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

8	Animals kept in isolators	not required	required where and to extent the risk assessment shows it is required	required	required	modification

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

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

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

Table 2 Containment measures applicable to contained use involving micro-organisms in premises other than those referred to in Tables 1a, 1b and 1c

Containment Measures		*Containment Levels*			
		1	*2*	*3*	*4*
General					
1	Viable micro-organisms must be contained in a system which separates the process from the workplace and wider environment (closed system)	required where and to extent the risk assessment shows it is required	required	required	required
2	Closed systems located within a controlled area	not required	required where and to extent the risk assessment shows it is required	required	required
3	Control of exhaust gases from the closed system	not required	required so as to minimise release	required so as to prevent release	required so as to prevent release
4	Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	required where and to extent the risk assessment shows it is required	required so as to minimise release	required so as to prevent release	required so as to prevent release

5	Inactivation of bulk culture fluids before removal from the closed system	required where and to extent the risk assessment shows it is required	required by validated means	required by validated means	required by validated means
6	Seals must be designed so as to minimise or prevent release	not required	required so as to minimise release	required so as to prevent release	required so as to prevent release
7	The controlled area designed to contain spillage of the entire contents of the closed system	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required	required
8	The controlled area sealable to permit fumigation	not required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required
9	Biohazard signs posted	not required	required	required	required
Equipment					
10	Entry via airlock	not required	not required	required where and to extent the risk assessment shows it is required	required
11	Surfaces resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents and easy to clean	required for any bench	required for any bench	required for any bench and floor	required for any bench, floor, ceilings and walls
12	Specific measures to ventilate adequately the controlled areas in order to minimise air contamination	required where and to extent the risk assessment shows they are required	required where and to extent the risk assessment shows they are required	required where and to extent the risk assessment shows they are required	required
13	The controlled area maintained at an air pressure negative to the immediate surroundings	not required	not required	required where and to extent the risk assessment shows it is required	required
14	Extract and input air from the controlled area must be HEPA filtered	not required	not required	required for extract air, required where and to extent the risk assessment shows it is required for input air	required for input and extract air

System of work					
15	Access restricted to authorised personnel only	not required	required	required	required
16	Personnel must shower before leaving the controlled area	not required	not required	required where and to extent the risk assessment shows it is required	required
17	Personnel must wear protective clothing	work clothing required	work clothing required	required	complete change required before exit and entry
18	Written procedures and records of staff training	not required	required where and to extent the risk assessment shows they are required	required	required
Waste					
19	Inactivation of GMMs in effluent from hand-washing sinks and showers or similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
20	Inactivation of GMMs in contaminated material and waste including those in process effluent before final discharge	required by validated means where and to extent the risk assessment shows it to be required	required by validated means	required by validated means	required by validated means

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Further information

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