



<b>Health and Safety Executive</b>		<b>Operational Circular</b>	
		<b>OC 349/6</b>	
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<b>Version No &amp; Date</b>	2: 05/03/2004	<b>Author Unit/Section</b>	HID CD6

**See [OC 167/11](#) for information on keeping public registers and databases available to the public in connection with the Contained Use of Genetically Modified Organisms**

Target Audience:  
All HSE Inspectors

## **THE GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS 2000 and other regulations relating to the contained use of GMOs**

This OC provides information on details of enforcement arrangements the Genetically Modified Organisms (Contained Use) Regulations 2000, SI 2000 No 2831 (both in file 349). Details of the scope of the regulations are given at [Appendix 1](#).

### BACKGROUND

1 The regulations are enforced solely by HID CD6. However, enforcement of general health and safety issues remain the remit of FOD, or in a few premises to HID or NSD. Where reference to FOD is made, this should be read to apply to HID/NSD when appropriate. This OC sets out the division of responsibilities, liaison arrangements and gives background information on the regulations in the [Appendix](#).

### ARRANGEMENTS FOR INSPECTION

#### **Primary inspection responsibilities**

2 FOD is responsible for the primary inspection of most work activities allocated for HSE enforcement which includes health risks from biological agents. However, CD6 inspectors are responsible for primary inspection of biological aspects in those parts of premises involved in the use or production of GMOs. **It should be noted that FOD retains primary inspection responsibilities for all other aspects of health and safety in the premises where CD6 has the primary inspection lead for GM work.**

#### **Liaison where dual primary inspection responsibilities exist**

3 Where GM work is carried out, both FOD and CD6 inspectors each have primary inspection responsibilities. Good liaison arrangements are therefore necessary between FOD and CD6 to ensure that inspection arrangements are properly co-ordinated, and to minimise the duplication of activity. In some cases joint approaches may be necessary.

4 Before visiting to inspect under the Contained Use Regulations, CD6 will notify the FOD principal inspector (PI) on FI 2507. The PI should advise CD6 of any reason to defer a planned inspection, or of the need for a joint visit.

5 CD6 inspectors are responsible for making recommendations on improving standards in relation to their inspection activities including written advice directly to the premises concerned. A copy of any correspondence and a file note will be sent to the PI following each visit. The CD6 inspector will also give relevant information to the employees or their representatives.

6 In areas for which they have inspection responsibility, CD6 will inform the FOD PI of any health and safety defects that they notice in non-GM topics. FOD inspectors wishing to inspect non-GM matters should consult CD6 before visiting parts where high risk work is undertaken. In general, FOD inspectors should enter these parts only when the areas have been made safe for them. FOD field staff must be conversant with the FOD Safety Policy supplement *Microbiological and genetic modification hazards* (file 22) before undertaking this kind of work.

7 Safety representatives or others who raise GM matters with the FOD inspector should be referred to CD6; and non-GM matters which are raised with the CD6 inspector should be referred to the FOD inspector. If responsibility is unclear it should be resolved by consultation between the 2 inspectors in the first instance and in some circumstances a joint approach may be necessary.

#### FORMAL ENFORCEMENT

8 Formal enforcement action, ie notices and prosecutions for non-GM breaches is the responsibility of FOD inspectors. CD6 inspectors will, however, issue enforcement notices under the appropriate legislation relating to biological safety in GM work. The notices may be under the Contained Use Regulations and/or under HSW Act, the Control of Substances Hazardous to Health Regulations 2002 or the Management of Health and Safety at Work Regulations 1999. Where practicable, before issuing any notice, CD6 inspectors should consult the FOD PI and in all cases should send a copy of the notice to the FOD group.

9 CD6 inspectors are responsible for any follow up action in connection with notices they have issued.

10 Responsibility for initiating prosecutions for GM breaches rests with CD6 but consultation with the area should normally take place before such action is taken.

11 It should be noted that only CD6 inspectors hold warrants to enforce the Environmental Protection Act s.108(1) which is required for some GM work.

#### ACCIDENT OR OTHER INVESTIGATION

12 The Contained Use Regulations require notification to CD6 of any incident involving a significant and unintended release of GMOs which presents a hazard, immediate or delayed, to either human health and safety or to the environment. CD6 will copy any notifications to the FOD PI for information and will advise the PI of the result of any investigation. Any such incidents first notified to FOD should be referred to CD6 without delay. These may be on a form CU3 or in any other written format.

13 Accidents or dangerous occurrences (DOs) with respect to human health and safety are still required to be reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR). These should be actioned through the Incident Contact Centre. Any RIDDORS sent to FOD by the Incident Contact Centre which relate to areas of CD6 enforcement responsibility should be forwarded to HID CD6.

## REQUESTS FOR ADVICE

14 Requests from occupiers for additional information and advice on the procedures in the Contained Use Regulations concerning risk assessment, notification and consent, should be directed to;

Health and Safety Executive  
Central Division 6  
Biological Agents Unit  
Room 443  
Magdalen House  
Trinity Road  
Bootle  
L20 3QZ  
Tel:0151 951 3779  
Fax:0151 951 3474

15 Enquiries from occupiers on technical matters such as containment practices and the reporting of accidents (under the Contained Use Regulations) should be directed to the address above.

16 If any problems arise concerning liaison arrangements, inspectors should contact CD6.

## CANCELLATION OF INSTRUCTIONS

17 OC 349/6 version 1 - **cancel** and **destroy**

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APPENDIX 1  
(para 1)

1 **The Genetically Modified Organisms (Contained Use) Regulations 2000** repeal and replace the earlier legislation in this field. They implements the Great Britain EC Directive 90/219/EEC as amended by Directive 94/51/EEC and 98/81/EC on the contained use of genetically modified micro-organisms. The Contained Use Regulations 2000 came into force in November 2000.

Note: Unless otherwise stated, the phrase "Contained Use Regulations" refers to the 2000 Regulations.

2 The Contained Use Regulations have been made under the powers of the Health and Safety at Work etc Act 1974 (HSW Act) and the European Communities Act 1972 and are concerned with protecting **both human health and the environment**. They require, with certain exceptions, that anyone carrying out any activity involving genetic modification (GM) must do so in conditions of contained use which satisfy the Contained Use Regulations. For genetically modified **micro-organisms** the Contained Use Regulations cover both human health and environmental risks. For larger genetically modified organisms (GMOs), such as plants and animals, they cover human health risks only.

3 The Contained Use Regulations are administered jointly by HSE and the Department for the Environment, Food and Rural Affairs (DEFRA) for England and Wales; HSE and Scottish Executive (SE) for Scotland. However, notification of intention to carry out GMO work is to be made only to HSE. Enforcement also falls only to HSE, including those premises where local authorities enforce other HSW Act provisions. An interdepartmental memorandum and agency agreement have been drawn up to enable HSE to enforce the Regulations. A copy of the *Memorandum of understanding on the control and regulation of contained use and deliberate release of genetically modified organisms (GMOs)* and associated annexes is available in file 349.

4 The environmental risks associated with work with larger organisms are covered separately by the **Environmental Protection Act 1990** (the EP Act) s.108(1)(a) which came into force for this purpose on 1 February 1993 by Commencement Order No 12 and by the Contained Use Regulations 1992. EP Act s.108(1) requires anyone creating a GMO which is not an approved product under the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (Deliberate Release Regulations) (see para 5), or obtaining one from elsewhere, to carry out an assessment of the environmental risks, make it available for inspection and keep it for 10 years. They also provide that EP Act s.108(1)(a) does not apply to matters which are controlled by the Contained Use Regulations (see also para 27). Inspection is carried out by HID CD6 under agency agreements with Department for the Environment, Food and Rural Affairs (DEFRA), the Welsh Assembly Government (WAG) and the Scottish Executive (SE).

5 EC Directive, 2001/18/EC, deals with the deliberate release and marketing of GMOs. **The Deliberate Release Regulations** have been introduced under the EP Act to implement this directive. Information on the Deliberate Release Regulations is available in OC 349/7(Rev).

### Scope of the Contained Use Regulations

6 GM involves altering the genetic structure of organisms to change some of their

characteristics. It opens the way for advances in science, and in the production of food, pharmaceuticals and other products, and in pollution control. Often it is little more than an extension of the traditional drive to develop better strains of plants and animals and to use the properties of micro-organisms in useful processes, like the production of bread, wine or cheese.

7 The Contained Use Regulations interpret GM as "the altering of the genetic material in that organism by a way that does not occur naturally by mating or natural recombination or both". Schedule 2 lists examples of techniques that are regarded as GM. Thus, GM includes certain:

- 1) recombinant DNA techniques;
- 2) techniques involving the direct introduction into an organism of heritable material; and
- 3) cell fusion techniques where live cells with new combinations of heritable genetic material are formed by means of methods that do not occur naturally.

8 Schedule 1 then qualifies the included techniques by giving examples which are not considered to be techniques which result in GM, such as:

- 1) *in vitro* fertilization;
- 2) conjugation, transduction, transformation or any other natural process; and
- 3) polyploidy induction.

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

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

In the above paragraph

- (a) 'self-cloning' means the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent), whether or not altered by enzymic or mechanical processes, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by homologous recombination; and

- (b) self-cloning may include the use of recombinant vectors, with an extended history of safe use in the particular organism, to manipulate and reinsert the nucleic acid sequences, but the vectors shall not consist of any genetic elements other than those designed for vector structure, vector replication, vector maintenance or marker genes.

10 'Contained use' means any operation involving GMOs under conditions of containment. The containment must be provided by biological, physical and chemical barriers. The containment must limit the contact of the GMO with the general population and the environment.

11 The activities covered by the Contained Use Regulations include laboratory operations, housing and/or breeding of modified animals in animal houses or farms, animals restrained by appropriate fencing, the use of growth rooms and glasshouses of appropriate specification, and the use of fermenters. Waste streams from contained facilities also fall under the Contained Use Regulations.

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

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

Guidance on the Contained Use Regulations is provided in the HSE Book A guide to the Genetically Modified Organisms (Contained Use) Regulations 2000 (L29) (file 349). The guidance booklet also reproduces the Regulations. A summary can be found in two HSE booklets; Contained use of genetically modified organisms IND86(rev2) and Contained use of genetically modified organisms. Excluding information from the Public Register INDG357.

13 The Contained Use Regulations modify the meaning of self employed so that these Regulations also apply to any person who is neither an employer nor an employee. For example, they apply to research students who are engaged in any GM activity.

### Notifications

14 Notifications of activities under the Contained Use Regulations are made to CD6 who will copy them as appropriate to:

- 1) DEFRA;
- 2) SE;
- 3) WAG;
- 4) The Following divisions; Wales and South West, East and South East London, Midland, Yorkshire and north East, NorthWest and Scotland.

15 Some of the work falling under the Contained Use Regulations requires **consent** before that work may begin.

There are 3 notification forms:

- (1) CU1 *Notification of intention to use premises for activities involving genetic modification for the first time.*
- (2) CU2 *Notification of individual activities involving genetic modification*
- (3) CU3 *Notification of accidents involving genetic modified organisms*

16 The Contained Use Regulations require that part of the information contained in those notifications which require a consent be made available to the public on request. (See OC 167/7 for the procedure for keeping information on public registers).

17 Transitional arrangements were made for activities notified under the previous Genetic Manipulation Regulations.

### Emergency plans

18 The Contained Use Regulations require that the operator draw up an emergency plan if their risk assessment indicates that, as a result of any foreseeable accident, the health and safety of persons **outside** the premises may be affected, or if there is a risk to the environment. The plan has to be drawn up in consultation with the emergency services and other interested bodies.

19 Some of the premises subject to the Contained Use Regulations will also be subject to the Control of Major Accident Hazards Regulations 1999 (COMAH). Onsite and offsite emergency plans to comply with CIMAH must include adequate safeguards for the security of GM hazards. CD6 inspectors will monitor arrangements made as regards GM hazards.

