# The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005

The Genetically Modified Organisms (Contained Use) Regulations 2000 have been amended by the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005.

# 1 When do the Regulations come into force?

These amendments came into force on 1 October 2005, except for a three-month transitional period for the amended containment measures set out in Schedule 8. The transitional period will apply both to those working on current relevant activities and to anyone submitting a relevant notification immediately before the amendments come into force. All GM centres should have complied with the Schedule 8 amendments by 1 January 2006.

# 2 What are the amendments?

- wording refinements to address comments by the Joint Committee on Statutory Instruments (the Parliamentary body which scrutinises all legislation);
- provision to collect information on transboundary movements of class 3 & 4 GMOs ( in accordance with European Commission requirements);
- removal of the confidentiality provisions in regulations 22 and 23 which have been superseded by the provisions of the Environmental Information Regulations 2004 and equivalent Scottish Regulations;
- removal of the regional versions of the public register in England;
- changes to three of the containment measures set out in Schedule 8.

# 3 How will these changes affect me?

Perhaps the two changes which are most likely to affect you are, firstly, those made to containment measures in Schedule 8 and secondly, the new requirement concerning transboundary movements.

## 3 (i) Changes to the containment measures

The three changes to the containment measures in Schedule 8 are:

**(A)** Table 1a, which applies to all laboratories, whatever work is undertaken, point 17 concerning *waste inactivation* has been changed from:

**Former requirement**

| Containment Measures | Containment Levels | | | |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4 |
| 17. Inactivation of GMMs in contaminated material and waste | Required by validated means | Required by validated means | Required by validated means | Required by validated means |

to:

**New requirement**

| Containment Measures | Containment Levels | | | |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4 |
| 17. Inactivation of GMMs in contaminated material | Required by validated means | Required by validated means | Required by validated means, with waste inactivated in the laboratory suite | Required by validated means, with waste inactivated within the laboratory |

The former requirement was of limited value because the requirement is the same across all the containment levels (i.e. 'required by validated means'). For containment level 2, it was originally proposed to amend this so that waste would be required to be inactivated within the building. However a number of containment level 2 stakeholders pointed out that they do not, at present, inactivate waste within the building but within the site by transporting the waste in sealed containers to a building which has an autoclave. This method will, in fact, continue to be allowed without the need for derogation as will sending the waste for offsite incineration by a waste contractor, provided the waste is stored and transported in a way that does not increase risk. There are, however, changes to containment levels 3 & 4 which provide clarification for GM centres and interpret what 'required by validated means' entails.

**(B)** Schedule 8, table 1b: Containment Measures for Activities involving Genetic Modification of Micro-organisms in Plant Growth Facilities.

**Former requirement**

| Containment Measures | Containment Levels | | | |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4 |
| 3. Control of contaminated run-off water | Required where and to extent the risk assessment shows it is required | Required so as to prevent run-off | Required so as to prevent run-off | Required so as to prevent run-off |

to**:**

**New requirement**

| Containment Measures | Containment Levels | | | |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4 |
| 3. Control of contaminated run-off water | Required where and to extent the risk assessment | Required so as to minimise run-off | Required so as to prevent run-off | Required so as to prevent run-off |

| | | | | |
|---|---|---|---|---|
| | shows it is required | | | |

**Former requirement**

| Containment Measures | Containment Levels | | | |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4 |
| 6. Procedures for transfer of living material between the plant growth facilities, protective structure and laboratory shall control dissemination of GMMs | Required so as to minimise dissemination | Required so as to prevent dissemination | Required so as to prevent dissemination | Required so as to prevent dissemination |

to

**New requirement**

| Containment Measures | Containment Levels | | | |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4 |
| 6. Procedures for transfer of living material between the plant growth facilities, protective structure and laboratory shall control dissemination of GMMs | Required so as to minimise dissemination | Required so as to minimise dissemination | Required so as to prevent dissemination | Required so as to prevent dissemination |

The changes at points 3 and 6 of the containment measures for activities involving genetic modification of micro-organisms in plant growth facilities make a more distinct difference between containment levels 2 and 3, ensuring that only more hazardous work is classified as class 3. They bring the GB legislation back into line with the EU Directive which GMO (CU) implements *(Council Directive 98/81/EC amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms).*

**(C)** Schedule 8, Table 1c: Containment Measures for activities involving Genetic Modification of Micro-organisms in Animal Units

**Former requirement - point 8**

| Containment Measures | Containment Levels | | | |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4 |
| 8. Animals kept in appropriate containment facilities, such as cages, pens, tanks or isolators | Required where and to extent the risk assessment shows it is required | Required where and to extent the risk assessment shows it is required | Required where and to extent the risk assessment shows it is required | Required where and to extent the risk assessment shows it is required |

to:

**New requirement - point 8**

| Containment Measures | Containment Levels | | | |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4 |
| 8. 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 |

**New point 9**

| Containment Measures | Containment Levels | | | |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4 |
| 9. Animals kept in isolators | Required where and to the extent the risk assessment shows it is required | Required where and to the extent the risk assessment shows it is required | Required | Required |

This amendment makes clear when the possibility of using an isolator needs to be actively considered. At containment levels 1 & 2 isolators are required where the risk assessment shows they are necessary. The new point 9 means they are required at levels 3 & 4 because the risk is much higher. An example of the type of work where animals need to be kept in isolators might be mice and other rodents infected with mycobacterium tuberculosis. You can apply to HSE for a derogation from this requirement giving a full justification and providing details of the alternative containment for example using appropriate air-fed suits in conjunction with appropriate containment facilities such as cages, pens & tanks.

**How do these Schedule 8 changes affect me–**

In relation to all three changes to Schedule 8, you will need to examine any relevant notifications and risk assessments to see if they comply with the new requirements. We do not expect you to change the conditions of an experiment part-way through as this could affect the results. You may therefore need to apply for a derogation to continue the activity using the current containment measures if, having reviewed your risk assessment, you find it is no longer valid. This might happen, for example, where you currently inactivate waste at level 3 off-site and wish to continue this practice for the activity in question.

In a very few cases, after examining your risk assessment, you may find it necessary to submit a new notification. This might happen, for example, if your risk assessment identifies that the contaminated run-off water should be prevented rather than minimised - previously preventing run-off water was a requirement at Class 2, whereas now it has risen to Class 3; or isolators are not used for animals in an activity, which now falls into Class 3.

Following the introduction of the Amending Regulations, there was a three-month transitional period in which to apply for a derogation for which the usual fee was waived. If your application for derogation is out with this timeframe, the usual derogation fee or notification fee will be charged – the current fees can be found at:

http://www.hse.gov.uk/biosafety/gmo/acgm/acgmwarn.htm

**Where do I send my application?**

You should send your application for derogation or a new notification, and the appropriate fee, to the notification team at:

***Notification Officer***
***HID SI4, Biological Agents Unit***
***1.2 Redgrave Court***
***Merton Road***
***Bootle***
***Merseyside L20 7HS***

## 3 (ii) Collection of Information on Transboundary Movements of class 3 and 4 Genetically Modified Micro-organisms (GMOs)

EC Regulation 1946/2003 of the European Parliament and Council on transboundary movements of GMOs requires Member States to inform the Biological Clearing House (BCH) and the European Commission (EC) of any decisions on class 3 and class 4 contained use activities involving GMOs that are likely to be subject to transboundary movements. Transboundary movements are those entering or leaving the EC. In order for the Competent Authority (CA) to carry this out function, an additional point was added to Schedule 6 of the regulations requiring notifiers of class 3 or 4 GMOs to notify the CA on whether it is likely to be subject to transboundary movement. If your class 3 or 4 GMOs are likely to be subject to such transboundary movements you need to tell us in your notification. As from 1 October 2005, a new tick box is included on the CU2 activity notification form to help you do this. Your *risk assessment should also cover the movement of the GMOs*. Although there is no legal requirement to do so, if you have notified us of your activity and subsequently find that your class 3 or 4 GMOs will be subject to transboundary

movements we would like to pass this information to the BCH and EC. Therefore we would be grateful if you could inform the Notifications Officer at the address below, quoting the appropriate GM Centre Reference number.

Notifications Officer
HSE, Biological Agents Unit
1.2 Redgrave Court, Merton Road
Bootle, Merseyside
L207HS
Tel: 0151 951 3085 or by e.mail - notificationofficer@hse.gsi.gov.uk

## 3 (iii) Removal of the regional versions of the public register in England

*How will I obtain information on GM contained use activities in future?*

Paper copies of the register will continue to be held in HSE's offices in London and Bootle, and versions relating to Scotland and Wales will be held in Edinburgh and Cardiff respectively (see address details below). Copies of the public register are available for viewing during normal office hours. If you wish to see a copy of the public register at one of the offices below, please telephone the relevant number to arrange a suitable appointment. In addition to the hardcopy registers, the register is available in electronic form on the Internet at the following link: http://www.hse.gov.uk/biosafety/gmo/publicregister.htm

**The public register for the whole GB is held at**:

*HSE*
*Rose Court*
*2 Southwark Bridge*
*London*
*SE1 9HS*
*Tel 0207 717 6623*

*HSE*
*Redgrave Court*
*Merton Road*
*Bootle*
*Merseyside*
*L20 7HS*
*Tel 0151 951 3085*

**The public register for Scotland is held at:**

*HSE*
*Belford House*
*59 Belford Road*
*Edinburgh*
*EH4 3UE*
*Tel 0131 247 2000*

**The public register for Wales is held at:**

*HSE*

*Government Buildings*
*Ty Glas*
*Llanishen*
*Cardiff*
*Wales*
*CF14 5SH*
*Tel 02920 263000*

Anyone wishing to obtain information about notifications, including requests to see risk assessments and any other information not on the public register should contact the Notification Officer, HSE, Biological Agents Unit, Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS, telephone 0151 951 3085 or by e:mail - notificationofficer@hse.gsi.gov.uk

## 3 (iv) Disclosure of Information

The confidentiality provisions in Regulations 22 and 23 have now been removed as these have been superseded by the provisions of the Environmental Information Regulations 2004 and equivalent Scottish Regulations. The criteria for non-disclosure are basically the same, however, the Competent Authority does have to consider a public interest test when considering disclosure of any information at the time of the request.
For more detailed information on changes to requirements on the disclosure of information, please refer to separate guidance on this subject which can be found at http://www.hse.gov.uk/biosafety/gmo/guidance/disclosureguidance.pdf

## 3 (v) Changes required by the Joint Committee on Statutory Instruments

These should have no or little impact on your business or activities. Changes required by the Joint Committee on Statutory Instruments are:

- removal of the provisions for extension of the Regulations offshore – there are no GM activities taking place offshore and it is extremely unlikely that anyone would wish to do so;
- clarification of some of the additional notification requirements set out in regulation 15;
- removal of para 9(4) of Schedule 11 which enables a body corporate to be represented by any person of its choosing in appealing against a decision by the competent authority;
- clarification of appeals procedures to make clear the intention to cater for cases where premises straddle the English/Scottish border