The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010 - amending the Genetically Modified Organisms (Contained Use) Regulations 2000

On the 21 December 2010 three minor changes will be made to the existing Genetically Modified Organisms (Contained Use) Regulations 2000 (the 2000 Regulations) to insert requirements set out in European Directive 2009/41/EC but not included in the original Regulations.

This email explains what these changes are, what (if any) action you will need to take and answers some questions. It also provides background information on the changes and the reason for them.

The changes to the Regulations are:

1. Including "the disposal of waste and effluent" in the existing list of matters to be considered by your assessment of the risks to human health and the environment.
2. A clarification of the characteristics of genetically modified micro-organisms which it will be appropriate to include as Class (1), i.e. 'no or negligible risk' micro-organisms, has been added to the steps to be taken when carrying out a risk assessment (see below).
3. An explicit requirement for biohazard signs to be displayed on the doors of the facility where Class 2, 3 or 4 activities are being undertaken.

It is HSE's view that the existing guidance produced by the Scientific Advisory Committee on Genetic Modification covers these matters and therefore it is unlikely that you will need to make any changes.

A copy of the amending Regulations is available at:
http://www.legislation.gov.uk/uksi/2010/2840/contents/made

Further information
These changes are being made because the 2000 Regulations are requirements of a European Directive and the European Commission is of the view that the Regulations did not adequately implement three aspects of that Directive. The UK faced a possible significant fine if we did not act. HSE consulted on the proposals for these amending Regulations in April and May 2010. You can obtain a copy of the consultation document and summary of responses from HSE's website:
http://www.hse.gov.uk/consult/condocs/cd231.htm

In response to comments received, HSE hopes the following may be helpful:

Waste disposal

You are unlikely to need to change your existing risk assessment because of the inclusion of an explicit reference in the Regulations to assessing the risks arising from disposal of waste and effluent. The SACGM guidance on risk assessment (part 2) refers to the need to consider waste disposal (especially in relation to potential environmental impacts) and covers appropriate measures to be taken to ensure that waste is inactivated before disposal (part 3, section 3.5).

Where you or other people at your facility use a standard format to record your GM risk assessments you may wish to consider whether it should include a specific prompt to consider disposal of waste and effluent, if it does not do so already. However, this is not compulsory, as the format for recording risk assessments is not specified.

Clarification of Class 1 - Meaning of the term 'recipient or parental micro-organism'

The clarification of Class 1 genetically modified micro-organisms in full is: "recognition that, in general, only activities involving genetically modified micro-organisms which show the following characteristics are 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 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;".

The above clarification of the meaning of Class 1 refers to the 'recipient or parental micro-organism'. This description is taken directly from the Directive and is consistent with the description in the 2000 Regulations of information that should be notified to HSE. The terms 'recipient' and 'parental' micro-organisms are considered to be interchangeable, and refer to the organism into which 'donor DNA' or 'insert' is being cloned via a vector system. For the majority of work involving genetic modification it will be clear which organism is the donor and which is the recipient/parental organism.

An example of work that will meet the criteria for class 1 is cloning many sequences from a pathogenic micro-organism (the insert from the donor microorganism) into a disabled strain of E coli (the recipient or parental strain e,g,K12) if the final genetically modified micro-organism is unlikely to cause disease to humans, animals or plants and is unlikely to have deleterious effects on the environment.

Display of biohazard signs

If you are carrying out Class 2, 3 or 4 activities, you must ensure there is a biohazard sign on the doors of the facility. This sign should be the standard biohazard sign (as below); use of a written hazard warning in addition is optional:

If the facility is within a larger building, other areas of which are not used for Class 2, 3 or 4 activities, it will be appropriate to put the sign only on the door at the entrance to the facility itself e.g. specific laboratories/ controlled areas. However, you should

also consider whether all appropriate parts of the facility have been included – for example, where waste or effluent treatment equipment is located outside of the immediate work area.

Use of the biohazard sign for containment level 1 facilities is not required.

If you have any further queries about how this affects your own work, please contact HSE on:
Tel: 0151 951 4468
Fax: 0151 951 3474
Email: germs.gmos@hse.gsi.gov.uk