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## HEALTH AND SAFETY COMMISSION

### PROPOSED AMENDMENTS TO THE GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS 2000

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#### Issue

1. Amendment of the Genetically Modified Organisms (Contained Use) Regulations 2000.

#### Timing

2. The Commission is asked to agree to the publication of the draft Consultation Document (CD) attached at Appendix 1 for a three month consultation period. It is intended to publish the CD at the end of December.

#### Recommendation

3. That the Commission:
  - agree to publication of the draft consultation document attached;
  - agree that the standard consultation period of 12 weeks should be used;
  - agree to allowing the waiving of derogation and notification fees during the transitional period.

#### Background

4. Review of the Genetically Modified Organisms (Contained Use) Regulations 2000 (GMO(CU)) by the Joint Committee on Statutory Instruments (JCSI) revealed the omission of an offshore competent authority and the need for some technical amendments (see paras 21-23, 38-41, and 50-53 of draft CD at Appendix 1). Amending regulations therefore have to be made. A provision is needed for the collection of information on transboundary movements of class 3 and 4 genetically modified organisms (GMOs) in order that HSE can pass this information on to the EC and the Biological Clearing House as required by the newly introduced (11 September 2003) Regulation of the European Parliament of the Council on transboundary movements of GMOs which implements the Cartagena protocol on transboundary movements of GMOs (EU Regulation 1946/2003) (see paras 34-37 of CD and reg

3(2)). It is also necessary to delete the disclosure of information provisions in current regulations 22 and 23 of GMO(CU) because they are overtaken by the new regime under the Environmental Information Regulations 2004 and equivalent Scottish regulations (see paras 42-49 of CD and regs 3(7) and (8)).

## Argument

5. The changes required and described in para 4 have to be done and the opportunity is also being taken to introduce other changes. The arguments for all the amendments are set out in paras 21-73 of the attached draft Consultation Document at Appendix 1. The changes will:
  - remove the extension of the Regulations offshore (see paras 21-23 of draft CD and reg 3(10));
  - remove references to the MAFF Minister (see para 24 of CD and regs 3(2)(a) and (5));
  - clarify the National Assembly for Wales' power to issue deliberate release consents under the Environmental Protection Act 1990 in regs 3(3)(a)(i)(aa) and 3(3)(b) of GMO(CU) (see paras 25 of CD and reg 3(3)(f));
  - update references to other legislation which has been amended (see paras 26-27 of CD and regs 3(3)(b)-(e));
  - remove the regional versions of the public register in England which are not being used by the public (see paras 28-33 of CD and reg 3(3)(8)(c));
  - amend some of the containment measures in Schedule 8 so as to clarify requirements for waste inactivation; control of contaminated water in plant growth facilities; procedures for transfer of living material between plant growth facilities; and for animals in isolators. This is not expected to have a significant impact as most notifiers are using similar measures already (see paras 57-67 of CD and regs 3(12)-(16)).
6. At present no information is collected on the possible transboundary movements of class 3 and 4 GMOs as required by EU Regulation 1946/2003. An option is to include a provision in the amending regulations to collect this information. However, the provisions in the original protocol on which the EC requirements are based only relate to food and feed, deliberate release and import of GMOs. Consultees are therefore being asked for their views on where to place these provisions in UK regulations.
7. The effect of the amending regulations will be that some notifiers will need to apply for derogations or re-notify activities in order to carry on already approved activities legally. It would seem unfair to ask them to pay a derogation or notification fee for work already in hand which just needs to be re-authorised as a result of changes in the wording of the regulations designed to clarify the requirements. It is therefore proposed to allow for the waiving of fees for applications for derogations or re-notifications made during the first two months of the three month transitional period. The requirement to apply during the first two months of the transitional period is to allow time for the administrative procedures to be completed by the end of the transitional period. This would apply only to derogations and re-notifications resulting purely from the changing of the wording in the regulations. This approach was used when the GMO(CU) Regulations 2000 were made; the HSC gave their approval for the waiving of fees for new notifications required as the result of the Regulations during the transitional period.

The Commission is asked to agree the provision for this at reg 4. Only a very small number of notifications (probably about 40 out of an annual total of 200-250) will be involved.

## **Consultation**

8. The Advisory Committee on Genetic Modification agreed to the policy proposals being worked up into draft regulations at their meeting in November 2002. The detailed proposals have been agreed with the members of the UK Competent Authority (including the devolved administrations) for GMO(CU) and with other relevant Government Departments.

9. While a number of stakeholders and Government Departments have been involved in dialogue up to now, it is proposed to formally consult all relevant Government Departments; devolved administrations; the former members of the Advisory Committee on Genetic Modification; the members of the new Scientific Advisory Committee on Genetic Modification appointed to advise the competent authority and HSE on technical matters relating to GMOs in contained use; all GM centres; relevant pressure groups; bodies concerned with the offshore industry; the TUC; CBI and Scottish TUC and other interested parties. A full consultation list is attached at Annex D of Appendix 1. The CD will be published on the web and details of it will also appear in the next GM newsletter. Meetings to discuss the proposals with GM stakeholders and other interested parties will be offered when the CD is launched.

## **Presentation**

10. The CD will be announced in a press notice which will be sent to a wide range of scientific journals concerned with genetic modification.

## **Costs and Benefits**

11. The costs to industry are likely to be minimal (on average less than £100 per centre) - in total £35,000, comprising only £10,000 to read the amendment regulations and decide whether action is needed and £25,000 to review current notifications and apply for derogations as necessary. Industry will benefit by having a clearer understanding of the containment measures and this will benefit HSE by freeing up inspector time from giving advice allowing more time for their core duties. A preliminary Regulatory Impact Assessment is attached at Annex C of Appendix 1.

## **Financial/Resource Implications for HSE**

12. The total cost for HSE is expected to be no more than £19,000 one-off costs for waiving the derogation and notification fees. Against this HSE will be saving approximately £10-11,000 as a result of removing the regional registers. All these figures take into account staff costs. Enforcement will be done as part of routine inspections. The costs to HSE are therefore negligible.

## **Environmental Implications**

13. The effect on the environment is expected to be minimal, as all the work is already well contained and new approvals/consents will require equal standards.

## **Other Implications**

14. As well as the amendments required by the JCSI, it is necessary to align the disclosure of information provisions with the Environmental Information Regulations 2004 or HSC/E could be criticised for not fully implementing EU legislation.

15. The provision for the removal of the regional versions of the public register includes removal of the register in Wales. It is considered desirable to keep the register relating to Wales since Wales is a separate legal/political entity with its own administration. However, GMOs in contained use are not devolved to Wales so including this provision in the regulations would be inconsistent with the legal reality. As the option for areas to retain a register will remain, it is therefore proposed to resolve this problem by providing guidance recommending that the Welsh Register be retained for the above reasons.

16. HSE is unaware of any small business that would be disproportionately affected by these amendments.

## **Action**

17. It is proposed to publish the CD at the end of December 2004 with a view to coming back to the Health and Safety Commission with revised proposals in July/August 2005 and making amending regulations in October/November of 2005.

18. The Commission is invited to:

- agree to the publication of the consultation document attached at Appendix 1;
- agree that the standard consultation period of 12 weeks should be used;
- agree to waiving of the derogation and re-notification fees during the transitional period.