

**Proposals for the Genetically Modified Organisms (Contained Use)
(Amendment) Regulations 2005**

This consultative document is issued by the Health and Safety Commission in compliance with its duty to consult, under Sections 16(2) and 50(3) of the Health and Safety at Work etc. Act 1974, bodies which appear to it to be appropriate before submitting proposals for the making of Regulations and the issue of Approved Codes of Practice.

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to reach her no later than 31 March 2005

The Commission tries to make its consultation procedure as thorough and open as possible. Responses to this Consultative Document will be lodged in the Health and Safety Executive's Information Centres after the close of the consultation period where they can be inspected by members of the public or be copied to them on payment of the appropriate fee to cover costs.

Responses to this Consultative Document are invited on the basis that any person submitting them agrees to their response being dealt with in this way. Responses, or part of them, will be withheld from the Information Centres only at the express request of the person making them (where this allowed under the Freedom of Information Act 2000 and the Data Protection Act 1998). In such cases a note will be put in the index to the responses identifying those who have commented and have asked that their views, or part of them, be treated as confidential.

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Consultative Document on proposals for the Genetically Modified Organisms (Contained Use) Regulations (Amendment) Regulations 2005

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PROPOSALS FOR THE GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS (AMENDMENT) REGULATIONS 2005

Introduction and summary

1. This Consultative Document sets out the Health and Safety Commission's (HSC) proposals for regulations to amend the Genetically Modified Organisms (Contained Use) Regulations 2000 (GMO(CU)) by:

- a. removing the provisions for extension of the Regulations outside Great Britain;
- b. making technical amendments required by the Joint Committee on Statutory Instruments (JCSI);
- c. removing the references to the Minister for Agriculture, Fisheries and Food;
- d. clarifying the National Assembly for Wales' power to issue deliberate release consents under the Environmental Protection Act 1990 in regulations 3(3)(a)(i)(aa) and 3(3)(b);
- e. including a reference to the EC Regulation 1829/2003 on Genetically Modified Food and Feed;
- f. removing the regional versions of the public register in England and Wales;
- g. providing for the collection of information required under the EC Regulation on transboundary movements of GMOs;
- h. changing the Directive reference in reg 3(3)(a)(i)(bb);
- i. deleting regs 22 and 23 on the disclosure of information as they are superseded by the provisions of the Environmental Information Regulations 2004;
- j. amending containment measures in Schedule 8 so as to clarify requirements for waste inactivation; control of contaminated water in plant growth facilities; and for animals in isolators.

2. The regulations are being made primarily to satisfy the requirements of the Joint Committee on Statutory Instruments (JCSI). It is also necessary to amend the regulations to align with the Environmental Information Regulations 2004. Both these requirements must be implemented as the first is required by Parliament and the second is required under an EU Directive.

3. The opportunity is also being taken to remove the regional versions of the public register kept under the Regulations, which are scarcely ever consulted (by the public) and to amend some of the containment measures to

provide greater clarity to those reading the Regulations. HSC/E considers these amendments desirable, but consultees' views are invited on how useful they are and whether they are the best way of achieving their aims.

4. The opportunity is also being taken to update references to other legislation in the Regulations and to remove outdated references to the MAFF Minister.

5. Guidance to the amending regulations will be given in the HSE's GM newsletter which is sent to all GM centres and published on HSE's internet site. Amendment of the full guide to the Regulations is planned but will probably not be published in the near future. When it is revised, it will incorporate guidance to both this set of amending regulations and the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002.

6. A glossary of abbreviations and terms used in this Consultative Document is at Annex A.

7. The proposals will be of most interest to GM centres. They will be particularly interested in the revised containment measures as they will need to review their risk assessments when the regulations come into force and if necessary request a derogation from these containment measures from the CA or re-notify an activity. A list of those to whom this Consultative Document is being sent directly is at Annex D. Comments from others are, of course, welcome.

8. The detailed proposals are set out in paras 21-73 below and the draft regulations are attached at Annex B.

Invitation to comment

9. The Health and Safety Commission (HSC) has a statutory duty to consult to elicit stakeholder's views on proposals. HSC believes that this enables an open and transparent approach to decision-making which is essential if policies and decisions are to have widespread ownership and reflect the needs and aspirations of the people they will affect. The Commission then decides on the best way forward based on an interpretation and analysis of the results of the exercise.

10. This Consultative Document is being sent to a wide range of organisations who are concerned with work with genetically modified organisms in contained use and a list of the organisations and individuals concerned is at Annex D. The consultative document can be freely photocopied, and is also available on the HSE web-site at www.hse.gov.uk/condocs/. Alternatively, further copies can be obtained free from HSE Books at the address on the back cover. However, if you want more than one copy, a charge will be made to cover the cost of packaging and handling.

11. The HSC would welcome your response to the questions raised in this consultative document. For convenience, all the questions concerned appear in bold type in the main text of the document, and to make things easier, they are also set out on the reply form at Annex E that you may find helpful to use when replying, but you can let us have your comments in any form. If you are replying on behalf of an organisation, it would be helpful if you would tell us what that organisation does, what its aims are and the size of the organisation (ie no of employees). Please attach additional pages if necessary. We will acknowledge all responses and give full consideration to the substance of arguments in the development of proposals; we may contact you again if, for example, we have a query.

12. HSC would particularly like comments on the following aspects of the regulations:

Removal of extension outside Great Britain - Whether you are content for the provision for extension outside Great Britain to be removed (see paras 21-23 and reg 3(10)).

Application of the regulations - the changes to regs 3(3)(a)(i)(aa) and (bb) and 3(3)(b) (see paras 25-27 and draft reg 3(3)(a)-(f)).

The regional registers - Whether you are content for the legal provision for the regional registers in England and Wales to be removed from reg 24(9) and whether you are also content for guidance to make provision for maintaining the register relating to Wales (see paras 28-33 and draft reg 3(3)(8)(c)).

The collection of information on transboundary movements of GMOs - the way it is proposed to implement collection of the information required under the EU Regulation on transboundary movements (see paras 34-37 and draft reg 3(2)).

Clarification of some of the additional notification requirements in reg 15 - the changes to reg 15 (see paras 38-41 and draft reg 3(3)(6)).

The disclosure of information provisions - the proposal to delete regs 22 and 23 and amend reg 24, which are superseded by the Environmental Information Regulations 2004 (see paras 42-49 and draft regs 3(7) and (8)).

Appeals procedures - the changes to the appeals procedures (see paras 50-53 and draft regs 3(17)).

The containment measures -

the revised containment measure for waste inactivation (see paras 55-57 and draft reg 3(12));

the revised containment measures for control of contaminated run-off water and procedures for transfer of living material between the plant growth facilities and protective structure and the laboratory (see paras 58-62 and draft regs 3(13) and (14));

the revised containment measure for animals in isolators (see paras 63-67 and draft regs 3(15) and (16)).

The transitional period - the length of the transitional period (see paras 68-73 and draft reg 4).

The Partial Regulatory Impact Assessment - whether the amending regulations will adversely affect small businesses and to comment on any other aspect of the RIA (see paras 74-76 and Annex C).

13. To help consultees these questions and opportunities to comment are set out in a questionnaire attached at Annex E, but comments in any form are acceptable. Responses should reach HSE by **31 March 2005**. Please write or send an e-mail to:

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The Health and Safety Executive will be happy to meet with GM stakeholders and other interested parties during the consultation period, so that consultees can gain a better understanding of the proposals before responding to them.

Publication of consultation responses

14. If you reply to this Consultative Document in a personal capacity, rather than as a post holder of an organisation, you should be aware that information you provide may constitute 'personal data' in the terms of the Data Protection Act 1998. For the purposes of this Act, HSE is the 'data controller' and will process the data for health, safety and environmental purposes. HSE may disclose this data to any person or organisation for the purposes for which it was collected, or where the Act allows disclosure. You have the right to ask for a copy of the data and to ask for inaccurate data to be corrected.

15. HSE tries to make its consultation procedure as thorough and as open as possible. Copies of the responses to this consultative document will be lodged at HSE's Information Centres after the close of the consultation period. Members of the public may inspect them or obtain copies on payment of the

appropriate fee to cover our costs. The two HSE Information Centres are located at:

Bootle Information
Magdalen House
Stanley Precinct, Bootle
Merseyside L20 3QZ

Sheffield Information Centre
Broad Lane
Sheffield S3 7HQ

16. Responses to this Consultative Document are invited on the basis that anyone submitting them agrees to them being dealt with in this way. Responses, or parts of them, will be withheld from the Information Centres only at the express request of the person making them. In such cases a note will be put in the index to the responses identifying those who have commented and asked that their views, or part of them, be treated as confidential.

17. You should also be aware that there may be circumstances in which HSE will be required to communicate information to third parties on request in order to comply with its obligations under the Freedom of Information Act 2000, the Environmental Information Regulations 2004 and the proposed Civil Contingencies Act 2004 (Contingency Planning) Regulations 2005.

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How to complain if you are not satisfied with conduct of consultation

19. This consultation has been prepared in accordance with the Cabinet Office's Code of Practice on Written Consultation available at www.cabinet-office.gov.uk.

20. If you are not satisfied with the way in which this consultation exercise has been conducted you can complain by contacting Liz Gibby, Head of Hazards and Technical Policy Division, 5NW, Health and Safety Executive, Rose Court, 2 Southwark Bridge, London SE1 9HS. We aim to reply to all complaints within 10 working days. If you are not satisfied with the outcome of your complaint, you can raise the matter with the Director-General of HSE, Timothy Walker, at the same address. You can also write to ask your MP to take up the case with us. Your MP may refer the matter to the Parliamentary Commissioner for Administration (the Ombudsman) who will investigate your complaint.

The proposals

Removal of existing provisions (reg 30 of GMO(CU))

21. When the JCSI examined GMO(CU) they found that there was a need to define the competent authority in relation to premises and activities outside Great Britain referred to in reg 30, ie offshore. The effect of reg 30 is to extend the Regulations so that they apply in relation to activities and premises outside GB to which provisions of the Health and Safety at Work etc. Act 1974 (HSWA) apply. However, the Regulations did not go on to define a competent authority for premises and activities involving genetic modification outside Great Britain.

22. The Health and Safety at Work etc. Act (Application Outside Great Britain) Order 2001 (SI 2001/2127) (which re-enacts with amendments the 1995 Order) extends the sections of the 1974 Act referred to in the Order to certain premises and activities in territorial waters and designated areas outside Great Britain (Great Britain being England, Scotland and Wales). The offshore premises covered by the Order are limited to places such as oil rigs, wells, and pipelines. No GM activities take place on any of these premises.

23. HSE has reviewed the purpose of reg 30 and concluded that it is extremely unlikely that anyone would set up a GMO activity offshore and even more unlikely that any would take place on an oil rig. It is therefore proposed to remove reg 30.

Consultees are invited to comment on the proposal to remove reg 30.

Definitions (reg 2 of GMO(CU))

24. The reference to the Minister for Agriculture, Fisheries and Food (a post which no longer exists) is also being deleted in reg 14(4) which requires the Executive to request additional information relating to notifications if requested to do so by the Secretary of State or the Scottish Ministers.

Application of the Regulations (reg 3 of GMO(CU))

Clarification of the National Assembly for Wales' power to issue deliberate release consents under the Environmental Protection Act 1990 in regulations 3(3)(a)(i)(aa) and 3(b) of GMO(CU)

25. Regs 3(3)(a)(i)(aa) and 3(3)(b) of GMO(CU) exclude from the Regulations consents granted by the Secretary of State, or, as regards Scotland, by the Scottish Ministers under section 111(1) of the Environmental Protection Act 1990 (EPA) and GMOs released or marketed in cases or circumstances in which those Ministers' consent is required under section 111(1) of EPA. Deliberate release is devolved for both Scotland and Wales and there should therefore be a reference to the National Assembly for Wales in these regulations as well as to the Secretary of State and the Scottish

Ministers. The omission of the reference in GMO(CU) was an oversight at the time of drafting.

Change to Directive reference in reg 3(3)(a)(i)(bb) of GMO(CU)

26. Article 13(4) of Council Directive 90/220/EEC has now been replaced by Articles 15(3), 17(6) and 18(2) of Council Directive 2001/18/EC. The opportunity is therefore being taken to update the reference in reg 3(3)(a)(i)(bb) which exempts from the Regulations products marketed in pursuance of written consent given by the competent authority of an EEA State in accordance with these Articles.

Inclusion of references to Regulation (EC) 1829/2003 on Genetically Modified Food and Feed

27. Regulation (EC) 1829/2003 on Genetically Modified Food and Feed applies to GMOs for food use, food containing or consisting of GMOs, and food and feed produced from or containing ingredients produced from GMOs. These GMOs have to be authorised under EC Regulation 1829/2003. In order to avoid GMOs under these Regulations being assessed twice, provision is being inserted into the CU amendment regulations to disapply the GMO(CU) regulations to GMOs for food use, food containing or consisting of GMOs or food and feed produced from or containing ingredients produced from GMOs marketed in accordance with the provision of EC Regulation 1829/2003. The reference to the Novel Foods Regulation 258/97 is deleted as authorisations under this Regulation will now be subsumed into EC Regulation 1829/2003.

Consultees are asked for any comments on the changes to regs 3(3)(a) and (b).

Removal of the regional versions of the public register in England

28. The public register gives details of all premises and activities notified to the competent authority under GMO(CU). Hard copies of the full register (with the exception of details of activities which the Secretary of State has required to be kept confidential in the interests of national security) are available for inspection by the public in HSE's London and Bootle offices.

29. At present each regional office of HSE also maintains a copy of the public register showing the entries relating to premises and activities in its region. There have been no requests to view any of the regional registers in the last two years and only a limited number over the last ten years. One enquirer was told where his nearest regional register was, but in the event he chose to inspect the full register in London. HSE is concerned about the balance between the administrative burden and cost to the tax-payer involved in maintaining these regional registers and their use by members of the public. The requirement for regional versions of the register was originally put into GMO(CU) because it was felt it would help the public to have access to information within their own regions. However, enquiries for the information at

regional offices have proved negligible and it is now considered that the cost of administering the regional registers far outweighs any benefits. It is therefore proposed that the requirement at reg 24(9) of GMO(CU) to keep the regional registers should be removed.

30. This change will not affect the copies of the public register at HSE's London and Bootle head offices. These copies of the public register will continue to be maintained and made available for inspection by the public. The edition of the register relating to Scotland will continue to be kept and this will continue to be provided for in reg 24(8). Because England and Wales form one competent authority (whereas Scotland has a separate competent authority) under GMO(CU), it would be inconsistent with the legal reality to treat Wales differently from the English regions and to provide for legal retention of its separate part of the public register whilst removing those for the English regions. However, it is recognised that Wales has its own identity with its own Assembly Government and, for this reason, may wish to keep its own register. It is therefore proposed to provide, in guidance, for the part of the public register relating to Wales to be kept.

31. HSE is committed to placing a simplified version of the public register on the Internet in the not too distant future, showing GM centre numbers, the name and address of the notifier (including the postcode) and all activity titles listed against each GM centre number (except those withheld in the interests of national security) to be available hopefully in early 2005. It is proposed that the list will be updated monthly but any new Class 3 and 4 notifications will be added to the Internet as they are received (thus allowing members of the public to make any representations within 30 days of the date on which the acknowledgement letter was sent to the notifier). Regardless of the progress that is made in making the public register available on-line, full information on activities will continue to be available to enquirers on request, subject to the limitations on disclosure set out in regs 23A and 24A of GMO(CU) and the Environmental Information Regulations 2004 (ie information withheld in the interests of national security and information which the notifier has asked to be kept confidential and where the competent authority has agreed the request or is yet to make a decision).

32. The proposal was put to the Advisory Committee on Genetic Modification (ACGM) at their meeting in November 2002 and they supported the proposal so long as the information was still publicly available. Other members of the UK competent authority (including representatives of the Scottish Executive and Welsh Assembly) have been consulted and they are content with the proposals.

33. Consultees are asked to comment as to whether they are content for the requirement for the regional registers to be removed from reg 24(9) and whether they are also content for guidance to make provision for maintaining the register relating to Wales.

The collection of information on transboundary movements of GMOs

34. The EC Regulation on Transboundary Movements of Genetically Modified Organisms (Regulation 1946/2003) requires Member States to inform the Biological Clearing House and the European Commission of any final decision taken by them on the use of GMOs within the Member State. This includes decisions on contained use classified in risk class 3 or 4 of GMOs which are likely to be subject to transboundary movements. Transboundary movements are those entering or leaving the EC.

35. At present no information is collected on the possible transboundary movement of class 3 and 4 organisms. One option is to include a provision in the amending regulations to allow the competent authority to collect this information. This could be done easily by placing another tick box about transboundary movements on the CU notification of activities form which is almost invariably used by notifiers (though they are of course free to make their notifications in other ways).

36. As the competent authority for GMO(CU) approves class 3 and 4 GMO activities this seems the easiest way of collecting the information in order that the UK can forward it to the EC. However, it is arguable whether GMO(CU) is the right place in UK legislation for the provision. Regulation 1946/2003 limits the provision to decisions in accordance with Articles 11 and 20(3)(d) of the Cartagena Protocol on Biosafety. Article 11 deals only with food and feed and Article 20(3)(d) concerns final decisions regarding the importation or release of living modified organisms. It might, therefore, be felt more appropriate to put the provision in legislation dealing with food and feed and/or deliberate release, but this might mean using separate legislation rather than putting the provision in regulations which are already being made. Consultees' views are therefore sought on this issue.

37. Consultees are asked to comment as to whether they consider via the GMO(CU) regulations is the most appropriate way of collecting information required by the EC on transboundary. If they do not feel this is the appropriate place, they are asked to suggest how it might be collected.

Clarification of some of the additional notification requirements in reg 15

Additional premises

38. Reg 15(2) requires a notifier who has submitted a notification under any of regs 9 to 12 to inform the competent authority of certain changes in the information supplied or in the circumstances in which the activity in question is undertaken. Para (g) of reg 15(2) requires details to be provided of any use made of additional premises in connection with a particular activity carried on by the notifier at more than one site, provided that he has submitted a notification under reg 9(1). The purpose of reg 15(2)(g) is to allow a permitted activity to be undertaken at an additional site without the need for a further

notification under reg 10, 11 or 12, provided that (ie on condition that) the additional site is notified under reg 9(1). The JCSI considered that the intention was not clearly conveyed by reg 15(2)(g), which appeared to provide that the additional notification was required only where reg 9(1) had been complied with. They recommended that the intention would have been made clear if reg 15(2)(g) had been expressed to be without prejudice to reg 9(1). Reg 15(2)(g) is therefore being amended to make it clear that the requirement to notify additional premises is without prejudice to reg 9(1) which requires the notification of first use of premises for activities involving genetic modification.

Significant changes

39. Reg 15(3)(a) requires a notifier to provide information to the competent authority where he makes changes to his premises or activity which may have significant consequences for the risks arising from the activity. Where the change would require a notification of a class 3 or 4 activity to be made under reg 11(1), reg 15(4) prohibits the making of the change until the requirements of reg 11 have been satisfied (ie the notification has been made to the competent authority and the written consent of the competent authority has been received). Reg 15(5) then disapplies reg 15(4) where the activity is carried on with a consent granted under reg 11(1). The effect of reg 11(1) is to prohibit a person from undertaking any activity in class 3 or 4 without his having submitted a notification and received consent under that regulation. The effect of reg 15(4) is to prohibit the making of a change which would attract the requirements of reg 11(1) until those requirements have been met, and reg 15(5) dispenses with those requirements.

40. The JCSI considered that reg 15(5) did not adequately implement the intention, since it disapplied only reg 15(4) and not reg 11(1) itself. They considered the intended result would have been achieved more simply if reg 15(3) had been expressed to be without prejudice to reg 11 and reg 15(5) had disapplied reg 11. Reg 15(4) could then have been omitted. Changes are therefore being made to regs 15(2), (3), (4) and (5) to reflect these recommendations.

41. Consultees are invited to comment on the changes to reg 15.

Disclosure of information - regs 22 and 23 of GMO(CU)

42. There are two ways information held under GMO(CU) can get into the public domain:

- placing it on the public register held under the Regulations;
- as a result of a request from a member of the public.

43. Regs 22 and 23 of GMO(CU) which deal with the disclosure of information quote the Environmental Information Regulations 1992 (EIR 92). These latter regulations are being updated by the Environmental Information Regulations 2004 (EIR 2004) and equivalent Scottish regulations, which are expected to come into force on 1 January 2005. These regulations implement

provisions relating to access of information of the Aarhus convention and provisions of Council Directive 2003/4/EC on public access to information and repealing Council Directive 90/313/EEC.

The draft regulations, together with further information about them may be found on the Defra website at

<http://www.defra.gov.uk/corporate/consult/envinfo/index.htm>.

44. Under the current provisions in GMO(CU) notifiers inform the competent authority of the information they wish to be kept confidential and the competent authority then decides whether the information can be kept confidential. The Freedom of Information Act 2000 and EIR 2004 have a different starting basis for the provision of information. The Act:

- provides two related rights - the right to be told whether the information exists and the right to receive the information;
- imposes an obligation on public bodies to comply, subject to certain exemptions.

45. HSE (acting on behalf of the competent authority) is a public body as defined in the Act and therefore is obliged to comply with the Act and EIR 2004. It is also obliged to comply with the EC obligations from which these derive. Under EIR 2004, public bodies are obliged to give information unless it is covered by one of the exemptions in regs 12(4) and (5) of the Regulations. These exemptions are broadly the same as those in EIR 1992 which are used under the present regime under regs 22 and 23 of GMO(CU).

46. Reg 12 of EIR 2004 enables HSE not to disclose where a request is made. Together with reg 4(4) EIR 2004, it also enables information to be kept confidential. A decision on whether reg 12 applies to the information would have to be taken for it to be kept confidential under reg 4(4) in order to decide that the information should not be placed on the public register.

47. The EC information regime in 2003/4 supersedes any EC information provisions that regs 22 and 23 implemented. The domestic implementation in the EIR 2004 takes precedence. Regs 22 and 23 are superseded and are therefore being deleted as serving no future useful purpose. However, this will not mean that information will be disclosed which it would be inappropriate for HSE to pass on. When a request for information is received HSE will have to decide whether that information is covered by any of the exceptions in EIR 2004. In making this decision HSE will be obliged by reg 12(1) of EIR 2004 to weigh up whether the public interest in maintaining the exception outweighs the public interest in disclosing the information. In order to help the competent authority do this, guidance will be issued to notifiers asking them to indicate whether they consider that any of the information supplied should be kept confidential under the provisions of EIR 2004. It will then be possible for the competent authority to make a decision which takes into account the notifier's view. Effectively, this will mean that there will be little difference with the current process for dealing with confidential information.

48. To keep HSE's procedures in line with EIR 2004, there are some changes to reg 24, namely:

- The provisions in regulations 24(3)(d) and 24(4) for notifiers to request that information be withheld from the register and for information which the competent authority has decided cannot be withheld to be kept off the public register for 14 days from the date the decision is sent to the notifier have been deleted and are replaced by the exception provisions of reg 12 of EIR 2004.
- The provision in reg 24(5) for the competent authority to remove withdrawn information from the public register has been removed.

49. Consultees are asked for any comments on the revised disclosure of information provisions.

Appeals procedures - reg 29 of GMO(CU)

50. Reg 29 of GMO(CU) makes provision for appeals against certain decisions of the competent authority. Reg 29(8)(b)(ii)(aa) provides for appeals relating to the undertaking of an activity in both England and Scotland. This is aimed at cases where a notification has been submitted to the joint competent authority under reg 13(1) concerning premises or activities. The intention in these regulations was to allow for cases where a single premises straddle the border of both England and Scotland.

51. When JCSI reported on GMO(CU) it considered that the drafting of these regulations did not make clear the intention to cater for cases where premises straddle the English/Scottish border. Amendments are therefore being made to regs 13(1) and 29(8)(b)(ii)(aa) to clarify the position.

52. Para 9(4) of Schedule 11 has been removed as it was criticised by the JCSI for limiting the rights of a body corporate to be represented by any person of its choosing. Para 9(6) of Schedule 11 has been removed as the JCSI criticised it for adding nothing to the meaning of the Schedule.

53. Consultees are asked for any comments on this amendment.

Amendment of the containment measures in Schedule 8 of GMO(CU)

54. During the three years that GMO(CU) has been in force, it has become clear that some of the containment provisions display ambiguities and are not as clear as they might be. The opportunity is therefore being taken to clarify the points which have been found to be less clear than they might be and thereby assist notifiers in achieving the right level of health and safety. The proposed changes are set out below.

Waste inactivation - Schedule 8, Table 1a, point 17 of GMO(CU)

55. Table 1a applies to all laboratories, whatever work they are undertaking.

Current 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 |

Proposed amendment

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

56. The current requirement in relation to the inactivation of waste is of limited value because the requirement is the same across all the containment levels (required by validated means). The aim of the amendment is to achieve a stepwise requirement which ensures that waste is inactivated on site at increasing proximity to the place where the activity takes place in line with the level of risk. This will therefore make it easier for GM centres to decide how 'required by validated means' should be interpreted at each level. At level 1 it will still be permissible to send waste for off-site incineration by a waste contractor provided the waste is stored and transported in a way that does not increase the risk. This will be made clear in guidance.

57. Consultees are invited to comment on the revised containment measure for inactivation of GMMs in contaminated material and waste by validated means.

Control of contaminated run-off water and procedures for transfer of living material between the plant growth facilities, protective structure and the laboratory - Schedule 8, Table 1b, points 3 and 6 of GMO(CU)

58. Table 1b applies only in respect of plant growth facilities and sets out the additional requirements that those facilities need to comply with in addition to those set out in Table 1a.

Current 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 |

Proposed amendment

| 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 minimise run-off | required so as to prevent run-off | required so as to prevent run-off |

Current 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 |

Proposed amendment

| 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 |

59. The changes to the containment measures for activities involving genetic modification of micro-organisms in plant growth facilities are intended to make a more distinct difference between containment levels 2 and 3. The changes will, in fact, bring the UK 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). When the Directive was originally transposed into UK legislation, a higher standard than the Directive was set at level 2 in GMO(CU). At the time it was considered that this was necessary to maintain compatibility between GMO(CU) and the plant licensing regime, which also covers work with plant pests and that the word 'prevent' more accurately reflected the

practices required for a Plant Health Licence under the Plant Health (Great Britain) Order 1993. However, on reconsideration and reflecting on the experience over the three years that GMO(CU) has been in force, it now seems clear that, in fact, the requirements relating to transit of waste and run-off water, which are included in plant licences, can actually be considered to be measures that minimise rather than prevent exposure.

60. The lack of distinction between levels 2 and 3 in the current Regulations also makes it more difficult for centres to decide whether they ought to notify work as class 2 or class 3. The proposed differentiation between levels 2 and 3 will make it easier for notification at the correct level, thus ensuring that only more hazardous work is classified as class 3.

61. The proposed change was discussed and endorsed by a meeting of the ACGM Technical Sub-Committee in November 2002 and has been agreed by technical experts of the competent authority namely those from the Central Science Laboratory, the Department for the Environment, Food and Rural Affairs (Defra), HSE, and the Scottish Agricultural Science Agency (SASA) in February 2003.

62. Consultees are invited to comment on the revised containment measures for control of contaminated run-off water and procedures for transfer of living material between the plant growth facilities and protective structure and the laboratory

Animals in isolators

63. Table 1c applies only in respect of animal units and sets out the additional requirements that those facilities need to comply with in addition to those set out in Table 1a.

Current 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 |

Proposed amendment - 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 |

Proposed additional 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 |

64. The amendments are being made to make it clear at what containment level the possibility of using an isolator needs to be actively considered, as opposed to other containment facilities such as cages, pens or tanks. It should be noted that in making this judgement the size of the animals being studied will clearly need to be taken into account in terms of the reasonable practicability of using an isolator. This is covered in paragraph 66 below. The current requirement does not provide any indication of when the use of an isolator may be appropriate on safety grounds. This is seen as a shortcoming as the use of isolators is probably the main distinguishing feature that applies to high risk work. The amendment therefore splits the current point 8 by taking the containment measure 'isolators' out of the list of other containment facilities and creating a separate point 9 showing when the use of an isolator should be actively considered.

65. The containment levels then go on to show that isolators are only required at levels 1 and 2 where the risk assessment shows they are necessary, but making clear that they are more likely to be required at levels 3 and 4 where 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*.

66. It is current practice only to use isolators for small animals and the competent authority is likely to view favourably applications for derogation from the requirement so that large animals can be kept in isolated rooms rather than isolators. Thus the amendment is not necessarily intended to bring about any change in the containment measures that actually need to be implemented for work with large animals, but rather it is aimed at providing a clearer indication as to when the use of an isolator should be actively considered.

67. Consultees are invited to comment on the revised containment measure for animals in isolators.

Transitional arrangements

68. The changes in the regulatory requirements largely reflect current practice and it is therefore not anticipated that they will have a great deal of impact on existing projects. It is not envisaged that notifiers will need to buy new equipment as a result of the changes as they clarify requirements rather than impose new ones. However, the changes to the containment measures will mean that those undertaking activities involving GM will need to consider whether their notifications and risk assessments will remain up to date in the light of the revised containment measures and take appropriate action in the light of their conclusions.

69. It is proposed to allow a three month transitional period specifically for the amended containment measures only. All other aspects of the amending regulations will come into effect on the date they come into force. The transitional period will apply to both those working on current activities, where the three amendments set out in paras 56-67 apply, and anyone who submitted a relevant notification immediately before the amendments came into force. Thus all laboratories will be expected to comply with the amended legislation by the end of the transitional period. This should not be particularly burdensome as the new standards largely reflect current practice. Moreover, since the containment measures that are in place for existing projects will, in general terms at least, already have been approved when the work was originally notified there should be few, if any, cases where new equipment or procedures are required.

70. Reg 8(1)(a) of GMO(CU) requires those undertaking activities to review their risk assessments where there is reason to suspect that the assessment is no longer valid. Those undertaking activities affected by the revised containment measures will need to review their risk assessments and notifications, as they may no longer cover all the necessary issues. For all the containment measures all laboratories currently working on activities will be required to apply the new standards (which largely reflect current practice anyway). As it will not be practical to change the conditions of a long-term experiment part way through as this could affect results, centres may need to apply for derogation to continue the activity using the current containment measures if, having reviewed their risk assessment, they find they are no longer valid in the light of the changes to the Regulations. The competent

authority will already have approved the measures being undertaken for the activity in question and it is therefore unlikely that such requests will be refused. An example of where this might be the case is where waste at class 2 or 3 is currently inactivated off-site and the notifier wishes to continue this practice for the activity in question.

71. In a very few cases it will be necessary to submit a new notification for the activity. Examples of this might be where the risk assessment identifies that the contaminated run off water should be prevented rather than minimised - currently preventing run off water is a requirement at Class 2, whereas under the amendments this will rise to Class 3; isolators are not used for animals in an activity which would in future fall into class 3. Reg 18(3) of GMO(CU) requires notifiers to review containment measures if they suspect the containment measures are no longer adequate; the class identified in the risk assessment is no longer appropriate; or the risk assessment is no longer valid in the light of new scientific or technical knowledge. In the very few cases where the containment measure is no longer valid and the activity moves from class 2 to class 3 it will be necessary for the notifier to submit a new notification in accordance with reg 11 of GMO(CU).

72. Under the transitional provisions provided in reg 4 of the amending regulations, the usual fee will be waived if the application for a derogation or the notification of a change from class 2 to class 3 is made in the first two months of the three month transitional period. The reason the application needs to be made 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 provision will only apply where the derogation or notification is made purely because of the changes to the containment measures in Schedule 8.

73. Consultees are invited to comment on whether the 3 months' transitional period is the appropriate length. In considering the question they will need to consider the length of time it will take to review their notifications and risk assessments and submit an application for a derogation or a new notification.

Regulatory impact assessment

74. A Partial Regulatory Impact Assessment is attached at Annex C. No information is collected on the size of firms in which GM centres are based. The research facility is likely to be part of an organisation, rather than comprise the organisation itself. HSE is therefore unaware of any small businesses that will be affected by these amendments. However, HSE would welcome information from consultees on any small business that might be affected.

75. Consultees' opinions are invited on whether any small businesses will be adversely affected by the amending regulations.

76. Consultees are invited to comment on all aspects of the initial RIA.

Timing

77. Following the close of this consultation, all comments will be considered and the draft regulations will be revised as necessary to take account of them. Revised draft regulations will be put to the Health and Safety Commission in the summer of 2005 and, subject to their approval, will be forwarded to the Secretary of State for Work and Pensions for signature shortly afterwards. It is proposed that the regulations should be laid before Parliament and come into force in the autumn of 2005.

Glossary of terms and abbreviations used in this consultative document

Defra - Department for the Environment, Food and Rural Affairs

EIR - Environmental Information Regulations

EPA - Environmental Protection Act 1990 (1990 c.43)

GM centres - Premises notified to the competent authority under GMO(CU) which undertake activities involving genetic modification in contained use.

GMO(CU) - The Genetically Modified Organisms (Contained Use) Regulations 2000 (SI 2000/2831).

GMOs – genetically modified organisms.

HSC - Health and Safety Commission

HSE - Health and Safety Executive

JCSI – the Joint Committee on Statutory Instruments (the Parliamentary body which scrutinises all legislation to ensure that it meets legislative standards).

MAFF - Ministry of Agriculture, Fisheries and Food

SASA - Scottish Agricultural Science Agency

2005 No.

Annex B

HEALTH AND SAFETY

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

| | |
|---|----------|
| <i>Made</i> - - - - | [] 2005 |
| <i>Laid before Parliament</i> | [] 2005 |
| <i>Coming into force</i> | |
| <i>for the purpose of Regulation 3(12) to 3(16)</i> [3 months after c.i.f.date] 2005 | |
| <i>for all other purposes</i> | [] 2005 |

The Secretary of State, being the Minister designated(a) under section 2(2) of the European Communities Act 1972(b) in relation to the control and regulation of genetically modified organisms and in the exercise of the powers conferred upon him by the said section 2(2)(c) and sections 15(1) and (2) and 43(2), (4), (5) and (6) and 82(3)(a) of, and paragraphs 1(1)(b) and (c), (2), 11 and 15(1) of Schedule 3 to, the Health and Safety at Work etc. Act 1974(d) (“the 1974 Act”) and of all powers enabling him in that behalf and for the purpose of giving effect without modifications to proposals submitted to him by the Health and Safety Commission under section 11(2)(d) of the 1974 Act after the carrying out by the said Commission of consultations in accordance with section 50(3) of that Act, hereby makes the following Regulations:

Citation, Commencement and Interpretation

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005 and for the purposes of regulations 3(12) to 3(16) shall come into force on [insert date 3 months after coming into force date] 2005 and for all other purposes on [insert coming into force date] 2005.

2. In these Regulations, “the 2000 Regulations” means the Genetically Modified Organisms (Contained Use) Regulations 2000(e).

(a) S.I. 1991/755.

(b) 1972 c.68; the enabling powers conferred by section 2(2) were extended by virtue of section 1 of the European Economic Area Act 1993 (c.51).

(c) As regards Scotland, see also section 57(1) of the Scotland Act 1998 (c.46), which provides that, despite the transfer to the Scottish Ministers by virtue of that Act of functions in relation to observing and implementing obligations under community law, any function of a Minister of the Crown in relation to any matter shall continue to be exercisable by him as regards Scotland for the purposes specified in section 2(2) of the European Communities Act 1972.

(d) 1974 c.37; sections 11(2), 15(1) and 50 were amended by section 116 of, and paragraphs 4, 6 and 16 respectively of Schedule 15 to, the Employment Protection Act 1975 (c.71).

(e) S.I. 2000/2831, as amended by S.I. 2002/63.

Amendment of the 2000 Regulations

- 3.—(1) The 2000 Regulations shall be amended as follows.
- (2) In regulation 2(1)—
- (a) for the definition of “competent authority” remove the words “, the Minister of Agriculture, Fisheries and Food”;
 - (b) after the definition of “notifier”, insert—

““non-Party” means any country or regional economic integration organisation not being a party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity^(a)”;
 - (c) after the definition of “organism”, insert—

““Party” means any country or regional economic integration organisation being a party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;

“transboundary movement” means the intentional or unintentional movement of a genetically modified organism between one Party or non-Party and another Party or non-Party, excluding intentional movements between Parties within the Community”.
- (3) In regulation 3—
- (a) in sub-paragraph (3)(a)(i)(aa), after the word “Ministers,” add “or, as regards Wales, by the National Assembly for Wales,”;
 - (b) after sub-paragraph (3)(a)(i)(aa), insert as a new sub-paragraph (3)(a)(i)(bb), “a consent granted by the Northern Ireland Department of the Environment under Article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991^(b), or”;
 - (c) renumber the existing sub-paragraph (3)(a)(i)(bb) as (3)(a)(i)(cc), and after “Article 13(4) of Council Directive 90/220/EEC” insert “or Articles 15(3), 17(6), or 18(2) of Council Directive 2001/18/EC^(c)”;
 - (d) for sub-paragraph (3)(a)(iii) substitute, “food or feed authorised in accordance with the provisions of Council Regulation (EC) No.1829/2003 of the European Parliament and Council^(d)”;
 - (e) insert as sub-paragraph (3)(a)(iv), “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 Council Regulation (EC) No.1829/2003 of the European Parliament and Council”;
 - (f) in sub-paragraph (3)(b),
 - (i) after the word “Ministers,” add “or, as regards Wales, by the National Assembly for Wales,”;
 - (ii) after “1990”, add “or 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”.
- (4) In regulation 13(1)—
- (a) in sub-paragraph (a) for the words “in both England and Scotland”, substitute “on the border of England and Scotland”; and

(a) O.J. No L201, 31.7.02, p.48 - Council Decision of 25 June 2002 approves the Cartagena Protocol on Biosafety. The Protocol is at Annex A to the Council Decision.

(b) S.I. 1991/1714 (N.I.19).

(c) O.J. No. L106, 17.04.01, p.1 as supplemented by Commission Decision 2002/623/EC (O.J. L200, 30.07.02, p.22).

(d) O.J. No. L268, 18.10.2003, p1.

- (b) in subparagraph (b), for the words “to take place in both England and Scotland”, substitute “to be undertaken at premises situated on the border of England and Scotland.”.
- (5) In regulation 14(4) the words “, the Minister of Agriculture, Fisheries and Food” shall be omitted.
- (6) In regulation 15—
- (a) in paragraph (2) sub-paragraph (g), for the words “, provided that a notification has been submitted by him in accordance with”, substitute “and without prejudice to”;
- (b) in paragraph (3), for the words “subject to paragraphs (4) and (5)”, substitute “Without prejudice to regulation 11 and subject to paragraph (5)”;
- (c) paragraph (4) shall be omitted; and
- (d) in paragraph (5)—
- (i) for the words “Paragraph (4)”, substitute “Regulation 11”, and
- (ii) after the words “regulation 11(1)(b) and”, insert “, but for this paragraph,”.
- (7) Regulations 22 and 23 shall be omitted.
- (8) In regulation 24—
- (a) in paragraph (3) for the words “regulation 22(2) (b) or shall be withheld under regulations 22(8)” substitute “ the provisions of the Environmental Information Regulations 2004(a) or the Environmental Information (Scotland) Regulations 2004(b).”;
- (b) for paragraph (4) substitute—
- “(4) Information shall be entered in the register within 14 days of its receipt by the competent authority.”;
- (c) paragraphs (5) and (9) shall be omitted.
- (9) In regulation 29(8) for sub-paragraph (b)(ii), substitute the following sub-paragraph—
- “(ii) an appeal under paragraph (2)(a) or (b) against a request or instruction relating to—
- (aa) the undertaking or proposed undertaking of an activity involving genetic modification in premises situate, or
- (bb) premises which are the subject of a notification under regulation 9(1) and are situate
- wholly in Scotland or on the border between England and Scotland, as the case may be.”.
- (10) Regulation 30 shall be omitted.
- (11) In paragraph 2 of Schedule 6—
- (a) The word “and” at the end of sub-paragraph (n)(vi) shall be omitted;
- (b) For sub-paragraph (o), substitute—
- “(o) a copy of the assessment referred to in regulation 6(1); and
- (p) whether the genetically modified organism is likely to be subject to transboundary movement.”.
- (12) In Schedule 8, in Table 1a for point 17, substitute—

“

(a) S.I. 2004/****.
 (b) S.I. 2004/****.

| | <i>1</i> | <i>2</i> | <i>3</i> | <i>4</i> |
|---|-----------------------------|---|---|---|
| Inactivation of GMMs in contaminated material and waste | required by validated means | required by validated means, with waste inactivated within the building | required by validated means, with waste inactivated within the laboratory suite | required by validated means, with waste inactivated within the laboratory |

”.

(13) In Schedule 8, in Table 1b point 3 (control of contaminated run-off water), for containment level 2, for the word “prevent” substitute “minimise”.

(14) In Schedule 8, in Table 1b point 6 (procedures for transfer of living material), for containment level 2, for the word “prevent” substitute “minimise”.

(15) In Schedule 8, in Table 1c for point 8, substitute—

“

| | | <i>1</i> | <i>2</i> | <i>3</i> | <i>4</i> | <i>Additional</i> |
|---|--|---|---|---|---|-------------------|
| 8 | Animals kept in appropriate containment facilities, such as cages, pens or tanks but not 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 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 | Additional |

”.

(16) In Schedule 8, in Table 1c, after point 8, insert—

“

| | | <i>1</i> | <i>2</i> | <i>3</i> | <i>4</i> | <i>Additional</i> |
|---|---------------------------|---|---|----------|----------|-------------------|
| 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 | Additional |

”.

(17) Paragraphs 9(4) and 9(6) of Schedule 11 shall be omitted.

Amendment of the Health and Safety (Fees) Regulations 2005

4. Regulation [16] of the Health and Safety (Fees) Regulations 2005(a) shall be amended as follows–

(1) at the beginning of paragraph (1) there shall be inserted the following words “Subject to paragraph (1A) below;

(2) after paragraph (1) there shall be inserted the following paragraph–

“(1A) No Fee shall be payable by a notifier to the competent authority for a notification of an activity involving genetic modification in class 3 under regulation 11(1) or an application for the written agreement of that authority under regulation 18(2) of the 2000 Regulations in circumstances where–

- (a) the notifier is of the view, and makes a statement in writing to the effect, that the containment measure for the activity in question has changed as a result of an amendment to any of the containment measures that has been effected by the Genetically Modified Organisms (Contained Use)(Amendment) Regulations 2005(b); and
- (b) the application was submitted to the authority no later than [] 2005.”.

Signed by authority of the Secretary of State for Work and Pensions

Address
Date

Jane Kennedy
Minister of State
Department for Work and Pensions

(a) S.I. 2005/****.
(b) [insert SI number].

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations amend the Genetically Modified Organisms (Contained Use) Regulations 2000, as amended. The principal amendments are as follows.
2. Regulation 3 makes changes to correct errors, including provisions in respect of Wales, provision for notifications and appeals relating to premises and activities that are situated partly in Scotland.
3. Paragraph 7 of regulation 3 revokes regulations 22 and 23 and paragraph 8 amends regulation 24. These amendments implement the provisions of Council Directive 2003/4/EC(a) on public access to environmental information and repealing Council Directive 90/313/EEC(b). The existing provisions in these Regulations implemented the provisions of Article 19 of Council Directive 90/219/EEC(c) as amended by Council Directive 98/81/EC(d). These provisions have been superseded by Council Directive 2003/4/EC which is implemented by the Environmental Information Regulations 2004(e) and the Environmental Information (Scotland) Regulations 2004(f).
4. Paragraph 10 of regulation 3 removes regulation 30 so that the Regulations are no longer extended outside Great Britain.
5. Paragraph 11 of regulation 3 requires additional information for notifications. This is necessary in order to fully comply with the requirements of Regulation (EC) 1946/2003.
6. Paragraphs 12 to 16 of regulation 3 amend the containment levels for specified containment measures.
7. Regulation 4 amends the Fees Regulations 2005(g). No fee shall be charged in respect of notifications under regulation 11(1) or applications under regulation 18(2) of the 2000 Regulations that have arisen as a result of the changes to containment measures in regulation 3.
8. A copy of the regulatory impact assessment prepared in respect of these Regulations may be obtained from the [] Health and Safety Executive, Rose Court, 2 Southwark Bridge, London SE1 9HS. A copy has been placed in the library of each House of Parliament.

(a) O.J. No. L 41, 14.2.2003, p.26.
(b) O.J. No. L158, 23.6.1990, p56.
(c) O.J. No. L 117, 8.5.1990, p1.
(d) O.J. No. L 330, 5.12.98, p13.
(e) S.I.2004/****.
(f) S.I. 2004/****.
(g) S.I.2005/****.

**PARTIAL REGULATORY IMPACT ASSESSMENT FOR THE PROPOSED
GENETICALLY MODIFIED ORGANISMS (CONTAINED USE)
(AMENDMENT) REGULATIONS 2005**

Title of proposed regulation

1. It is proposed to call the regulations the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005. They will amend the Genetically Modified Organisms (Contained Use) Regulations 2000 (GMO(CU))(SI 2000/2831).

Purpose and intended effect of measure

Objective

2. The proposed regulations are intended to:
- remove the provisions for extension of the Regulations offshore;
 - make technical amendments required by the Joint Committee on Statutory Instruments (JCSI);
 - remove references to the Minister for Agriculture, Fisheries and Food;
 - clarify the National Assembly for Wales' power to issue deliberate release consents under the Environmental Protection Act 1990 in regulations 3(3)(a)(i)(aa) and 3(b);
 - add a provision for the regulations not to apply where authorisations have been issued under the EC Food and Feed Regulations;
 - remove the regional versions of the public register in England;
 - change the Directive reference in reg 3(3)(a)(i)(bb);
 - enable the Competent Authority (CA) to collect information on proposed transboundary movements of class 3 and 4⁽¹⁾ genetically modified organisms (GMOs) so that they can forward the information to the European Commission as required by the EU Regulation implementing the Cartagena protocol;
 - make changes to the provisions on the disclosure of information in order to bring the regulations into line with the Environmental Information Regulations 2004;
 - amend 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.
3. The competent authority will be affected by the changes to the provisions for disclosure of information. The containment proposals could potentially affect the 522 GM centres in Great Britain.

Background

4. It is necessary to make amending regulations to satisfy the requirements of the JCSI. It is necessary to make changes to align provisions in the regulations with those in the Environmental Information Regulations 2004 and equivalent Scottish regulations. During the 3 years that GMO(CU) has been in force it has become clear to HSE's specialist inspectors who enforce the Regulations that some of the containment measures need clarifying to help GM centres understand what is expected of them. The regional registers are not being used and it is therefore proposed to remove them to save the administrative cost of keeping them. The opportunity is also being taken to update references to other legislation and correct an error.

Risk assessment

5. The risks to health and safety from the genetic modification of micro-organisms are already addressed in GMO(CU). The amendments to the Regulations will not affect the level of health and safety already achieved by them.

6. Regulations have to be made in order to avoid the risk of further reports from the JCSI for not acting on their recommendations. They also have to be made to align the 2000 Regulations with the Environmental Information Regulations 2004 in order to avoid infraction proceedings from the EC for not fully implementing the EC Directive on environmental information. Guidance would not be considered an acceptable alternative to regulatory amendment by either the JCSI or the EC and would not be an acceptable alternative to changing the Regulations to align with the new Environmental Information Regulations 2004 as the Freedom of Information Act 2000 provides power for the Secretary of State to require changes. The other amendments are considered desirable to help clarity and correctness, but HSE would be unlikely to be criticised for not implementing them.

Options

7. Removal of extension offshore. An option would be to leave the provision in and include a definition of the offshore competent authority as suggested by JCSI. However, as there are no GM activities taking place offshore and the limited scope of the regulation makes it unlikely that any could take place, removing the regulation seems a better option.

8. JCSI requirements. There is no option but to implement the JCSI requirements as HSE has been criticised for the original drafting of the Regulations.

9. Collection of information required under Cartagena protocol. The UK Government is not at present in possession of the information required under the protocol and has no authority to collect it. There is therefore no alternative but to provide legislatively for the collection of this information. One option is

for HSE to collect the information under GMO(CU) as it already approves class 3 and 4 GMO activities. The alternative option would be to provide for collection of the information by way of other legislation.

10. Alignment of the Regulations with the Environmental Information Regulations 2004. Section 75 of the Freedom of Information Act 2000 gives the Secretary of State power to demand the amendment of legislation which does not comply with FOI (under which EIR 2004 is made). It is inevitable that the Regulations will have to be changed to align with FOI/EIR and it makes sense to do so whilst other amendments are being made rather than to have to do so later. EIR will take precedence over the current GMO(CU) provisions – it is unlikely that it would be seen as acceptable not to make the changes when GMO(CU) is being amended anyway.

11. Regional versions of the public register. One option is to do nothing and continue to provide copies of the public register in all regions – this would mean continued administrative costs for HSE to provide information which is not being used. The alternative of providing the information in the form of a complete electronic register has been considered and HSE is working towards implementing at least a partial electronic register with key information (backed up by the public being able to contact HSE for full information) by early 2005. One consideration is that an electronic register might be cumbersome to search and people might still prefer to browse a paper copy.

12. Containment measures. One option is to do nothing. This would mean that GM centres might still be unclear in some cases as to what was required. It would also mean that, because the measures were not as clear in the Regulations, inspectors could find it difficult to enforce the requirements and would be spending more time in explaining requirements, rather than concentrating on their key activities. One alternative is to issue further guidance. This would go some way towards meeting the problem, but would not provide the legal backing. The alternative is to clarify the requirements legislatively and this is considered the best option by HSE and the other members of the competent authority. Making the changes in law would leave no doubt as to what the requirement at each containment level is and remove any doubts that enforcement action might be appropriate.

Costs and benefits

Business sectors affected

13. On 22 January 2004, there were 522 GM centres registered with HSE (who are notified on behalf of the CA). Of these 177 centres carry out only class 2 work; 6 centres carry out only class 3 work, 47 centres carry out both class 2 and 3 work and 3 centres carry out a mixture of class 2, 3 and 4 work⁽¹⁾. Out of the total number of centres, 4 centres are working on genetically modified micro-organisms that infect plants and 9 centres are working on projects involving class 3 GMMs infecting animals. The work is carried out within a range of universities, hospitals and private firms. It is, however, difficult to break these down exactly from the notifications as there is

wide cross-over between sectors, eg university hospitals, charities/research bodies who operate in conjunction with hospitals and universities and companies, eg on cancer research. Also some institutions have one GM centre, others have several. No information is collected on the number of people working in each centre, or the organisation(s) to which they are attached, and it is therefore impossible to say how many, if any, are small firms

Assumptions

14. The changes to the containment measures largely reflect current practice, and it is therefore thought unlikely that many businesses will be directly affected by the changes.

Benefits

15. No direct health and safety benefits will be derived from making the amending regulations. The clarification of the containment measures will increase transparency of the Regulations by making it clearer to those undertaking activities what is required of them.

16. Implementing the JCSI requirements and aligning the regulations with the Environmental Information Regulations 2004 will be a benefit to HSE and the CA as external requirements will be satisfied.

17. The savings to HSE of the notification team not having to filter out the information to make up the regional registers is estimated at £696 per annum. This is made up of 24 hours' administrator (HSE band 6) time based on 210 forms x 7 minutes per form. The 7 minutes is made up of looking up the region, photocopying the form, addressing the envelope, e-mailing subsequent changes to the public register contacting the region, keeping the contact list up to date and any ad hoc correspondence. In addition 4 administrators (band 6s) in the regions will save a small amount of time maintaining the regional registers - estimated at 3-4 hours per year for each of the 5 centres at a total cost of £435-580 per annum (based on figures from HSE's staff ready reckoner for 2003-4, which includes full staff costs including non-salary costs, for Band 6 national (£29). The ten year present value of all HSE's savings is £10,000 to £11,000.

18. Implementing the containment measures will benefit GM centres insofar as they will be clearer about what is required of them. This will benefit HSE as clarity will make enforcement of the Regulations easier and inspectors will need to spend less time explaining what the regulations mean thus freeing up more time for their core activities.

19. 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.

20. Updating of references will make it clearer for readers what documents they need to refer to, thus saving their time by avoiding searching for out of date documents only to find they have been updated.

Costs

Total costs

21. Total costs of implementing the regulations are expected to be small. There will be a saving in administrative time and stationery involved by no longer keeping the regional registers.

Costs for businesses/GMO centres

22. Each GMO centre will require a short amount of time to become familiar with the amendments. HSE assumes that each of the 522 GMO centres would require one hour of a scientist's time (assumed to cost £20⁽²⁾) to achieve this. This total estimated one-off cost is £10,000.

23. The cost to industry, universities and public sector organisations is expected to be small. The containment measures largely reflect current practice. However, the effect of the changed regulations will be that GM centres affected by the changes will need to review their risk assessments. All activities at class 2 will already have been approved by HSE and for activities at classes 3 and 4 the specific consent of HSE will have been given⁽¹⁾. In some cases, HSE will have granted derogations under reg 18(2) of GMO(CU) to allow notifiers not to apply the full containment measures given in Schedule 8 if the risk assessment has provided a full justification for not applying them⁽³⁾. In some cases, as a result of reviewing the risk assessment, notifiers will need to apply to HSE for a derogation under reg 18(2) in order to continue the work which has already been approved by HSE as a direct result of the changes being made to the containment measures in Schedule 8. In a very few (no more than 6) cases it may be necessary to re-notify a current class 2 activity as a class 3 activity. In both these cases, the amending regulations will allow the waiving of the derogation or notification fee provided the application is made in the first two months of the three month transitional period, so there will be no additional cost to the notifier. It is not envisaged that notifiers will need to buy new equipment as a result of the changes, as they clarify requirements, rather than impose new ones.

24. It is estimated that the average time taken to review a risk assessment would at most be 3 days for those who would need to apply for derogations or re-notify an activity and 1 day for those who do not need to do so. HSE estimates that the cost per day would be £163⁽⁴⁾. All the 228 centres carrying out class 2 work will need to review their waste inactivation arrangements, but as in virtually all cases waste is inactivated in the building, this will require nothing more than reading the amendment and deciding there is no need to do anything. It is expected that applications for derogations relating to waste treatment will be required for about 30 projects. Such derogations will be needed to allow the continued inactivation of class 2 waste

outside of the building in which it is generated ie elsewhere on the site or at a remote incinerator. There are about 14 projects involving genetically modified micro-organisms that infect plants where there will be a need to review the assessments as a result of the amendments, but it is not expected that any of these will need to apply for a derogation. There are about 16 class 3 projects involving animals and it is estimated that in about 10 of these cases it will be necessary to make derogation requests as a result of the amendments. In total, it is therefore estimated that 60 notifications will need to be reviewed in detail. In 40 of these cases it will be necessary to apply for a derogation, but in 6 of these 40 cases it may be necessary to submit a new notification rather than seek a derogation. The total cost to industry of the amendments to the containment measures is therefore estimated to be £25,000. These would be one-off costs because of a specific change in regulation. Centres are expected to review their risk assessments regularly in any case.

Costs for a typical business

25. It is very difficult to define a typical business in the area covered by the Regulations. The work affected concerns that in research laboratories where genetic modification takes place as part of the activity. The work is spread across a wide range of organisations which do not split conveniently down into specific categories. For example, there are university hospitals, charities/research bodies who operate in conjunction with hospitals and universities and companies eg cancer research. Also some institutions have one GM centre whilst others have several. No information is collected on how many people are employed per centre. In view of the small proportion of businesses likely to be affected, it would be unrealistic to quantify the regulations in terms of a typical business.

Costs for HSE

26. There are currently 134 class 3 activities and 6 class 4 activities notified to HSE⁽¹⁾. We do not know how many of these are likely to be subject to transboundary movements. The cost of collecting the information required by the EC Regulation will be minimal as it will be built into HSE's current systems. It will involve an administrator (HSE band 4) checking all new class 3/4 risk assessments, copying the appropriate ones and forwarding them to the EC. The measure will apply only to new notifications - approximately 15 class 3/4 notifications are received each year. The total cost to HSE is therefore likely to be £600 (based on HSE staff ready reckoner cost (including non-salary costs) for national Band 4 of £40 per hour). For industry there will be virtually no cost as they will only need to tick an additional box on the notification form and (possibly) send an additional copy of the risk assessment.

27. The cost to HSE in loss of revenue from waiving the derogation and notification fees where application is made as a direct result of the legislative changes being made is estimated to be limited to no more than £19,000. It is anticipated that at most 40 applications will be made for such notifications and

derogations. The charge for these derogations is £432 and £624 for a class 3 notification (2003 rates). This will be a one-off cost to HSE.

Environmental costs

28. None has been identified

Summary of costs and benefits

| | One off costs | Ten year present value |
|-----------------------|---------------|---------------------------|
| Benefits | | |
| Benefits to business | Unquantified | Unquantified |
| Benefits to HSE | | £10,000 to £11,000 |
| Total benefits | | £10,000 to £11,000 |
| Costs | | |
| Costs to business | £35,000 | £35,000 |
| Costs to HSE | £19,000 | £19,000 |
| Total costs | | £54,000 |

29. Total quantified estimated benefits are £10,000 to 11,000. Note that this does not include potential benefits that business will enjoy as a result of greater clarity in the GMO contained uses regulations. Total estimated compliance costs are £54,000.

Equity and fairness

30. GMO(CU) applies to all GM activities carried out in contained use. No key groups are therefore likely to be disproportionately affected.

Small Firms' Impact Test

31. No information is collected on the size of firms in which GM centres are based. The research facility is likely to be part of an organisation, rather than comprise the organisation itself. HSE is therefore unaware of any small businesses that will be affected by these amendments. However, HSE would welcome information from consultees on any small business that might be affected.

Competition assessment

32. Much of the work that is done on genetically modified organisms in contained use is research which may lead to other products, eg medicines or is initial research to support subsequent deliberate release applications. The only areas with a high degree of concentration in a small number of establishments are plant and animal work. At the moment we believe the number of companies who are actually supplying GM products for use in other contained use facilities (eg GM tests kits) is minimal. Obviously the research costs will impact on the competitive nature of UK companies which could

compete with overseas companies. The costs themselves are so minimal (even before potential benefits to business due to greater clarity are factored in) that, in HSE's view, there is no possibility that the amendments will create adverse competition effects.

Enforcement and sanctions

33. The regulations will be enforced by HSE's specialist inspectors who enforce GMO(CU) in the course of their routine inspections. No special enforcement programme will be undertaken in connection with the amending regulations.

Consultation

Within government

34. The proposals have been agreed with the other members of the CA and with other government departments who attend the meetings of the UK CA.

Public consultation

35. The proposal will be put to public consultation on 31 December 2004 with a closing date for comments of 31 March 2005. Consultees will be asked to comment on the partial Regulatory Impact Assessment.

Monitoring and review

36. GMO(CU) is to be evaluated in 2005/6. As the amendments do not have a significant impact on GMO(CU) as a whole, it is intended to include the amending regulations in that evaluation.

Summary and recommendation

37. It is proposed to make amendments to GMO(CU) as outlined in para 2 above. It is recommended to make the amendments as required by JCSI, and to make the changes necessary to align GMO(CU) with EIR 2004 as these requirements are being laid upon HSC/E. It is proposed to amend the containment measures as this will provide clarity for GM centres as to what is expected of them.

Ministerial declaration

[38. I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Jane Kennedy
2004]

Contact point

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Notes

(1) GMO(CU) requires the classification of all activities involving genetically modified micro-organisms into one of four classes which are related to the containment levels appropriate to control the degree of risk. Class 1 covers activities of no or negligible risk; class 2 activities of low risk; class 3 activities of moderate risk; and class 4 those of high risk to people and the environment. Risk is assessed by risk assessment, which reg 6(1) says must be carried out before activity is commenced.

First use of premises for activities must be notified to HSE - activities may commence as soon as HSE acknowledges receipt of the notification and the premises have complied with notification requirements for the first intended activity. Activities at class 1 do not have to be notified to HSE.

Activities of classes 2, 3 and 4 must be notified to the HSE. The first class 2 activity at a premises must be notified 45 days before it is intended to begin (unless consent has already been granted for Class 3 or Class 4 activities, in which case the activity may begin as soon as HSE acknowledges receipt of the notification). Subsequent class 2 activities must be notified, but may begin as soon as HSE acknowledges receipt of the notification.

First class 3 or 4 activities at a premises must be notified 90 days before it is intended to begin work. In this case HSE has to issue consent - or let the notifier know why consent is being withheld - within 30 to 90 days. Subsequent class 3 and 4 activities must be notified 45 days before they are intended to begin. In this case, HSE must issue a consent - or let the notifier know why consent is being withheld - within 30 to 45 days.

(2) Based on New Earnings Survey 2002 SOC 201 'Biological Scientists and Biochemists' plus 30% for non-wage costs.

(3) Schedule 8 of GMO(CU) sets out the containment measures for activities involving genetic modification of micro-organisms in laboratories. For each containment measure (eg laboratory sealable for fumigation), the containment level is given for each class. Reg 15(3)(b) requires notifiers to send HSE (on behalf of the CA) full details of significant changes to specific ongoing activities where they become aware of new information which may have significant consequences for the risks arising from that activity. Reg 18(2) allows application to be made to the HSE for agreement not to apply a particular containment measure of the appropriate containment level where the risk assessment shows that it is not necessary for the activity involving genetic modification to which the assessment relates. HSE (on behalf of the competent authority) gives approval in the form of derogations for which a charge is made under the Health and Safety Fees Regulations.

(4) Based on New Earnings Survey 2002 SOC 201 'Biological Scientists and Biochemists' plus 30% for non-wage labour costs.

**LIST OF COMPANIES AND ORGANISATIONS TO BE
CONSULTED ON THE PROPOSED GENETICALLY MODIFIED
ORGANISMS (CONTAINED USE) (AMENDMENT) REGULATIONS**

EMPLOYERS' ORGANISATIONS AND COMPANIES

Alliance of Independent Retailers and Businesses
Allied Lyons Retailing Plc
Association of Independent Businesses
Association of British Chambers of Commerce
Association of British Insurers
Association of British Plant Breeders
Bio Industry Association
Brewers and Licensed Retailers Association
British Safety Industry Federation
British Sugar Plc
British Sugarbeet and Seed Organisation
British Veterinary Association
Committee of Vice Chancellors and Principals
Confederation of British Industry
Confederation of British Industry Smaller Firms' Council
Croner Publications
Du Pont (UK) Plc
Federation of Small Businesses
Fisons Plc
Food and Drink Federation
Forum of Private Business
Institute of Management
John Innes Centre
KMZ Chemicals
Minerva Health Group, Sedgwick Group
National Association of Waste Disposal Contractors
National Federation of Self-Employed and Small Businesses Ltd
National Specialist Contractors' Council
Premier Poultry

The Independent Food Retailers' Confederation
The Union of Independent Companies
United Kingdom Science Park Association
Water Companies' Association
Water Services Association of England and Wales
Water Utilities' Association
Waterers Landscape Ltd
Zeneca Pharmaceuticals

TRADES UNIONS

Advisory/Co-ordinator Offshore - Trades Union Congress
Amalgamated Engineering & Electrical Union(AEEU)
Association of Teachers and Lecturers
Bakers, Food and Allied Workers Assn. (BFAWA)
Banking, Insurance and Finance Union (BIFU)
British Institute of Occupational Hygienists
British Medical Association
General, Municipal, Boilermakers & Allied Trades Union (GMB)
Institution of Professionals, Managers and Specialists
Inter-Union Offshore Oil Committee
Manufacturing, Science and Finance Union
National Association of Fire Officers
National Farmers Union
National Union of Teachers
National Union of Rail, Maritime and Transport Workers (RMT)
Scottish Trades Union Congress
Trades Union Congress
Transport and General Workers' Union (TGWU)
UNISON

OIL INDUSTRY ASSOCIATIONS

The UK Offshore Operators Association (UKOOA)
International Marine Contractors Association (IMCA)
International Association of Drilling Contractors (IADC)

British Rig Owners Association (BROA)
Offshore Contractors Association
Well Servicing Contractors Association
The Emergency Response & Rescue Vessel Association (ERRVA)

PROFESSIONAL BODIES & OTHER REPRESENTATIVE BODIES

Association of Chief Police Officers
Association of Local Authorities of Northern Ireland
Association of London Authorities
Association of Occupational Health Nurse Practitioners (UK)
British Health and Safety Society
British Insurance and Investment Brokers Assn. (BIIBA)
British Safety Council
British Transport Police
Campaign for the Freedom of Information
Cancer Research UK
Chartered Institute of Environmental Health Officers
Chartered Institute of Water and Environmental Management
Chief & Assistant Chief Fire Officers' Association
Citizens Advice Scotland
Consumers' Association
Convention of Scottish Local Authorities
Council of Independent Inspecting Authorities
Engineers and Managers' Assn. (EMA)
English Nature
Freight Transport Association
Friends of the Earth
GeneWatch
General Law Society England and Wales
Green Alliance
Greenpeace
Institute for Animal Health
Institute of Biology
Institute of Cancer Research

Institute of Directors
Institute of Environmental Health Officers
Institute of Occupational Health and Safety
Institute of Occupational Medicine
Institute of Safety in Technology and Research
Institute of Trading Standards Administration
Institute of Waste Management
Institute of Water & Environment Management
Institution of Professionals, Managers and Specialists (IPMS)
Law Society
Law Society of Scotland
Local Government Association
London Boroughs Association
National Association of Citizens Advice Bureaux
National Chamber of Trade
National Consumer Council
National Council of Women
National Institute for Medical Research
National Institute for Standards and Control
National Institute of Biological Standards
National Specialist Contractors Association
National Specialist Contractors Council
Pharmaceutical Society of Great Britain
Royal Agricultural Society of England
Royal College of Nursing
Royal College of Nursing Society of Occupational Health Nurses
Society of Occupational Medicine
Royal Environmental Health Institute of Scotland
Royal Society of Chemistry
Royal Society for the Prevention of Accidents
Scottish Consumer Council
Society of Occupational Medicine
The British Hygiene Society

United Kingdom Environmental Law Association (Biotechnology Working Group)

EDUCATIONAL & RESEARCH ESTABLISHMENTS

Advisory Council for Research and Development
AFRC Institute for Animal Health
Agricultural and Food Research Council
Biotechnology and Biological Sciences Research Council
Cancer Research Campaign
Consortium of Local Education Authorities for the Provision of School Science
Council of Science and Technology
Department of Epidemiology and Public Health
Economic and Social Research Council
Imperial Cancer Research Fund
Medical Research Council
National Environment Research Council
Royal College of Physicians
Royal Environmental Health Institute - Scotland
Science Research Council
Scottish Schools Equipment Research Centre
The Association for Science Education

GM CENTRES

All GM centres involved in activities notified under GMO(CU)

GOVERNMENT DEPARTMENTS AND AGENCIES

British Airports Authority
British Pharmacopoeia Commission
Cabinet Office
Central Office of Information
Civil Aviation Authority
Countryside Commission
Department of Enterprise, Trade and Investment, Northern Ireland
Department of Health (including NHS Executive)

Department of Trade and Industry
Department for Constitutional Affairs
Department for Education and Skills
Department for Environment, Food and Rural Affairs
Department for Work and Pensions
Environment Agency
Environment Council
Foreign and Commonwealth Office
Government of Gibraltar
Health and Safety Executive Northern Ireland
Health Protection Agency (including Centre for Applied Microbiology
Research, Porton Down)
HM Customs and Excise
HM Treasury
Home Office
House of Commons Library
House of Lords Library
Laboratory of the Government Chemist
Law Commission
Maritime and Coastguard Agency
Medicines Commission
Ministry of Defence (including Defence, Science and Technology Laboratory,
Porton Down)
National Assembly for Wales
Northern Ireland Department of Economic Development, Health and Safety
Division
Northern Ireland Office
Office of the Deputy Prime Minister
Rural Development Commission
Scottish Environment Protection Agency
Scottish Executive
Scottish Law Commission
Scottish National Heritage Agency
Scottish Parliament Information Centre

Scottish Office
Small Business Service
UK Permanent Representative to the European Union
Welsh Assembly Government
Welsh Development Agency
Wales Office

GOVERNMENT ADVISORY COMMITTEES

Advisory Committee on Genetic Modification and its Technical Sub-Committee (ceased to exist in December 2003 but its former members are all being consulted)
Advisory Committee on Dangerous Pathogens
Advisory Committee on Releases into the Environment
Animal Procedures Committee
Animal Welfare Advisory Council
Defence Scientific Advisory Council
Gene Therapy Advisory Committee
Scientific Advisory Committee on Genetical Modification (Contained Use)
Secretariat of Advisory Committee on Novel Foods and Processes
Secretariat of Agriculture and Environment Biotechnology Commission

OTHER ORGANISATIONS

British Broadcasting Corporation
Council for Science and Technology
Horticultural Development Council
Medical Research Council
Sandwell MBC
Welsh Pharmaceutical Committee

**PROFORMA FOR COMMENTS ON THE PROPOSALS TO AMEND
THE GENETICALLY MODIFIED ORGANISMS (CONTAINED USE)
REGULATIONS 2000**

We should like you to tell us what you think about the proposals set out in this Consultative Document. You are welcome to comment on any aspect of the proposals, but we are particularly interested in your views on those set out in this proforma. You may find it useful to place your comments in the spaces provided, but you are free to submit comments in whatever way you prefer.

We shall acknowledge all responses and give full consideration to them in the development of the proposals. In some instances, we may contact you to discuss your comments further.

The Commission tries to make its consultation procedure as thorough and open as possible. After the close of the consultation period, responses to this consultation letter will be lodged in the Health and Safety Executive's Information Centres in Bootle and Sheffield where they can be inspected by members of the public, or copied to them on payment of a fee to cover the costs of doing so.

Responses are invited on the basis that anyone submitting them agrees to them being dealt with as described above. Responses, or parts of them, will be withheld from the Information Centres only at the express request of the person submitting them. In such cases, a note will be put in the index to the responses to identify those who have commented but asked for some or all of their views to be kept confidential.

Many business e-mail systems now automatically append a paragraph stating the message is confidential. If you are responding to this CD by e-mail and you are content for your responses to be made publicly available, please make clear in the body of your response that you do not wish any standard confidentiality statement to apply.

If you are dissatisfied with the way in which this consultation exercise has been carried out, you have the right to complain.

| |
|------|
| Name |
|------|

| |
|---------|
| Address |
|---------|

Telephone, Fax, Email

Aims of organisation

Size of organisation (ie no of employees)

PTO for question sheets

Removal of reg 30

Question 1:

Do you agree with the removal of reg 30?

- Yes
- Yes with reservations
- No

(Please tick)

Please add any comments you wish to make.

Application of the Regulations including National Assembly for Wales' power to issue deliberate release consents

Question 2:

Do you agree with the changes to regs 3(3)(a) and 3(3)(b)?

- Yes
- Yes with reservations
- No

(Please tick)

Please add any comments you wish to make.

The regional registers

Question 3a:

Are you content for the legal provision for the regional registers in England and Wales to be removed from reg 24(9)?

- Yes
- Yes with reservations
- No

(Please tick)

Please add any comments you wish to make.

Question 3b:

Are you content for guidance to make provision for maintaining the register relating to Wales?

- Yes
- Yes with reservations
- No

(Please tick)

Please add any comments you wish to make.

The collection of information on transboundary movements of GMOs

Question 4a:

Do you believe that via GMO(CU) is the most appropriate way to collect the information on transboundary movements of GMOs required by the EU by way of the GMO(CU) Regulations?

- Yes
- Yes with reservations
- No

(Please tick)

Please add any comments you wish to make.

Question 4b:

Can you suggest a better alternative way of collecting the information on transboundary movements of GMOs required by the EU?

- Yes
- Yes with reservations
- No

(Please tick)

Please add any comments you wish to make.

Clarification of the additional notification requirements in reg 15

Question 5: Are you content with the way the additional notification requirements have been clarified?

- Yes
- Yes with reservations
- No

(Please tick)

Please add any comments you wish to make.

Disclosure of information

Question 6: Are you content with the deletion of regs 22 and 23 and related changes to reg 24?

- Yes
- Yes with reservations
- No

(Please tick)

Please add any comments you wish to make.

ppeals procedures

Question 7:

Are you content with the changes to the appeals procedures?

Yes

Yes with reservations

No

(Please tick)

Please add any comments you wish to make.

The containment measures

Question 8a:

Are you content with the revised containment measure for waste inactivation?

- Yes
- Yes with reservations
- No

(Please tick)

Please add any comments you wish to make.

Question 8b:

Are you content with the revised containment measures for control of contaminated run-off water and procedures for transfer of living material between the plant growth facilities and protective structure and the laboratory?

- Yes
- Yes with reservations
- No

(Please tick)

Please add any comments you wish to make.

Question 8c:

Are you content with the revised containment measure for animals in isolators?

Yes

Yes with reservations

No

(Please tick)

Please add any comments you wish to make.

The transitional period

Question 9:

Are you content with the length of the transitional period?

- Yes
- Yes with reservations
- No

(Please tick)

If you consider that it is too short, please tell us how long you think it should be and why, and add any other comment you wish to make.

The partial regulatory impact assessment

Question 10a:

Do you know of any small businesses that will be adversely affected by the amending regulations?

- Yes
- Yes with reservations
- No

(Please tick)

Please add any comments you wish to make.

Question 10b:

Do you have any other comments on the partial Regulatory Impact Assessment?

Yes

No

(Please tick)

Please add any comments you wish to make.

