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# HEALTH AND SAFETY COMMISSION

## Proposed Amendments to the Genetically Modified Organisms (Contained Use) Regulations 2000 – Results of the Public Consultation and Recommendations

**A Paper by Colin Dunn**

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**Cleared by Giles Denham and Jonathan Rees**

### Issue

1. Approval of draft regulations to amend the Genetically Modified Organisms (Contained Use) Regulations 2000 following public consultation.

### Timing

2. Regulations to be in force on the next common commencement date of 1 October 2005. This will enable the UK to comply with European legislation already in force, and to minimise potential confusion for the GM industry over conflicting regulatory confidentiality requirements.

### Recommendation

3. That the Commission:

- note the results of the public consultation at **Annex A,** including the widespread support for these uncontroversial amendments, and the associated recommendations;
- approve the draft regulations at **Annex B** for submission to Lord Hunt;
- note the final Regulatory Impact Assessment at **Annex C**.

### Background

**4** The Genetically Modified Organisms (Contained Use) Regulations 2000 protect workers, the public and the environment from risks arising from activities involving the contained use of genetically modified micro-organisms and, in the case of people, from the risks where the organisms are not micro-organisms (eg genetically modified plants and animals). The Regulations are EU driven. They require users to:

- make a risk assessment for all genetic modification activities;
- apply appropriate containment measures and controls;

- notify HSE (on behalf of the UK Competent Authority) of all premises where genetic modification is to take place; and
- notify HSE of certain higher risk activities – consents being required before work can begin for the highest risk activities.

5. Changes to the Regulations are necessary to address legal drafting improvements identified by the Joint Committee on Statutory Instruments in completing the 2000 Regulations. However, we are also using this opportunity to follow the principles of better regulation by simplifying the Regulations, in particular on disclosure of information on GM activities.

6. HSC consulted on proposed changes to the Regulations (CD 201; HSC/04/22) from December 2004 to March 2005:

- to meet the technical requirements of the Joint Committee on Statutory Instruments (JCSI);
- in order to include a provision on the collection of information on transboundary movements of class 3 and 4 genetically modified organisms (GMOs) so that the UK can pass this information to the EC and the Biological Clearing House as required by EC law;
- to alter the disclosure of information provisions so that they align with the Environmental Information Regulations 2004 and equivalent Scottish regulations;
- to update references to other legislation in the Regulations; removal of the regional versions of the public register and to amend some of the containment measures set out in Schedule 8 of the regulations to provide greater clarity.

7. Details on the amendments and the results of the public consultation are set out in Annex A.

**Argument**

8. Arising from the consultation exercise, no major complaints were received about removing the regional versions of the public register. Almost all respondees considered HSE to be the appropriate body to collect transboundary movements of class 3 and 4 GMOs and pass this information to the EC and Biological Clearing House.

9. The main concern from consultees was a change to one of the containment measures set out in schedule 8. This proposed in laboratories that GMMs (genetically modified micro-organisms) in contaminated material and waste should be inactivated within the building where they had been created/modified for containment level 2. A number of establishments inactivated the waste within the site but not necessarily in the same building, by transporting the waste in sealed containers to a building with an autoclave. There were issues surrounding the cost of installing an autoclave within the same building or of having to apply for a derogation ( ie seeking HSE's written permission) each time before the activity was carried out. As a result of these comments, it is proposed to alter the wording back to "require by validated means" This will not impinge on the acceptability of how waste is inactivated or the degree of information with which HSE is provided with, since means of waste inactivation is assessed as part of the notification review for all Class 2 activities.

## Consultation

10. HSC/04/22 set out the organisations that received hard copies of the CD. This included all GM centres involved in activities notified under these regulations. In addition the CD was published on the web and details of its publication appeared in the scientific journals.

11. There were 27 substantive responses. 9 came from the bio-tech industry, 5 from other Government organisations, 7 from universities/research organisations and 6 others. A list of those who responded is on Annex D.

## Presentation

12. The new regulations will be announced in a press release that will be sent to a wide range of scientific journals concerned with genetic modification. Additional guidance to publicise the changes and set out their requirements will be posted on the HSE web-site and mention will be made in a press release where this guidance can be found.

## Costs and Benefits

13. Concern was expressed about the costs of installing an autoclave within the building for containment level 2 GMMs, if the proposal to inactivate these within the building was adopted. However by reverting to the current requirement "required by validated means" as set out in paragraph 9 this will not be an issue. As a result the Regulatory Impact Assessment (RIA) has been amended, as the numbers required to apply for a derogation will be reduced. Total costs for industry as a result are estimated to fall from £35 000 to £19 000. The amendments to schedule 8 will provide a clearer understanding of the containment measures.

14. Other comments on the RIA suggested the costs of a scientist's time at £20 per hour was too low and the time to become familiar with the amendments would take longer than the one hour stipulated in the RIA. The scientist's costs were based on the New Earnings survey for 2003 plus 30% for non-wage costs. With guidance on these Regulations to be posted on the HSE website, we believe an hour will be an adequate time to become familiar with the changes.

15. Information on transboundary movements can be collected by placing another tick box on the CU notification of activities form which is almost invariably used by notifiers and therefore no additional costs are expected for GM centres to comply with this requirement.

## Financial/Resource Implications for HSE

16. The cost to HSE on drawing up these proposals were approximately £61 200 and came within budget. The total cost through loss of revenue by waiving the derogation and notification fees for HSE is expected to be no more than £5 000 on one-off costs. This is £14 000 less than originally envisaged HSE would waive in collection, as numbers applying for a derogation will fall (see para 9). The costs of collecting and passing on information on transboundary movements of class 3 and 4 GMOs to the EC will be minimal, at around £600 per year. Against this HSE will be saving approximately £10-11

000 over a ten year period as result of removing the regional registers. Enforcement will be done as part of routine inspections. The costs to HSE are therefore negligible.

**Environmental Implications**

17. The effect on the environment will be minimal; as all the work is already well-contained and new approvals/consents will require equal standards.

**Other Implications**

18. Responses to the CD indicated that small businesses would not be adversely affected by the amending regulations.

**Action**

19. The Commission is asked to endorse the draft regulations at annex B and their submission to Lord Hunt for agreement.

**ANNEX A**

**Questions, summary of responses and UK Competent Authority recommendations on proposed changes to the Genetically Modified Organisms (Contained Use) Regulations 2000.**

## Question 1

**Removal of regulation 30 so that the regulations do not extend or apply in relation to premises and activities outside Great Britain referred to in regulation 30, ie offshore.**

96.15 % in favour (3.85% with reservations - one respondent )
3.85% against (one respondent )

**Recommendation** - The one response against, cited the example of pirate radio stations operating offshore in the 1960s & 1970s. It is HSE's view that it is extremely unlikely that anyone would set up a GMO activity offshore. This was also one the amendments requested by the Joint Committee on Statutory Instruments as the regulations did not go on to define a competent authority for premises and activities involving genetic modification outside Great Britain. The Control of Substances Hazardous to Health Regulations 2002 would still apply. There would be a legal requirement to assess and control exposure to any biological agents, which includes GMOs. Remove as suggested.

## Question 2

**Changes to regulations 3(3) (a) and (b) to enable the National Assembly for Wales power to issue deliberate release consents under the Environmental Protection Act 1990. 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 Scottish Ministers. The omission of the reference in GMO (CU) was an oversight at the time of drafting.**

100 % in favour

**Recommendation** – Remove as suggested

## Question 3a

**Legal Provision for the regional registers in England and Wales to be removed from reg 24(9). This would enable HSE to withdraw from its Regional offices and from its office in Cardiff the public register showing the entries relating to premises and activities in its region. Hard copies of the full register would still be available for inspection by the public in HSE's London & Bootle offices and HSE is planning to place the full register in the internet by late summer. The edition of the register relating to Scotland will continue to be kept as Scotland has a separate competent authority.**

96.15% in favour
3.85% against (one respondent)

**Recommendation** - There was one against this proposal and in essence was not related to the question but about identification of entries in register. Remove as suggested.

**Question 3b**

**Guidance to make provision for maintaining the register relating to Wales. Because Wales and England form one competent authority it would be inconsistent to treat Wales separately from the English regions and for it legally to retain its own register. However, it is recognised that Wales has its own identity with its own assembly and may wish to keep its own register. We are therefore proposing to provide, in guidance for Wales to keep its part of the public register**.

96.15% in favour
3.85% against (one respondent)

**Recommendation** – The one against, cited the unnecessary cost. The guidance will be short and simple and will not involve a great deal of time and expense for HSE to produce. The Welsh Assembly wish to maintain their own public register. Provide guidance as suggested.

**Question 4a**

**Is GMO(CU) the most appropriate way to collect the information on transboundary movements (ie those entering or leaving the EC) of GMOs classified in risk class 3 or 4, as required by the EU.**

96.15% in favour (7.7% with reservations – 2 respondents)
3.85% against (one respondent)

**Recommendation** - The objection was that it was a" just in case information" and any increase in bureaucracy may hinder (time-critical) work. However as an EU requirement has to be done and 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. The Department for the Environment, Food and Rural Affairs (DEFRA) are also in favour of HSE collecting this information. This can be easily done by placing another tick box about transboundary movements on the CU notification of activities form, which is almost invariably used by notifiers. Alter the regulations to include a provision for this.

**Question 5**

**Are you content with the deletion of regulations 22 &23 and related changes to reg 24. Regulations 22 &23 have been superseded by the Environmental Information Regulations (EIR) 2004 and the Scottish equivalent and regulation 24 requires to be changed in keep in line with these regulations.**

100% in favour (15.4% with reservations – 4 respondents)

**Recommendation** - There were reservations, about putting information on the register without comeback from the notifier. 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 reg12(1) of EIR 2004 to weigh up whether the public interest in maintaining the exception outweighs the public interest in disclosing this information. In order to help 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 HSE 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. These changes are required because of EIR requirements.

**Question 6**

**Are you content for changes to the Appeals Procedures to make clear the intention to cater for appeal cases where premises straddle the English/ Scottish border, amendments to regs 13(1) and 29)( 8). Also removal of schedule 11 Para 9 (4 & 6) which will allow the rights of the body corporate to be represented by any person of its choosing. These changes were requested by JCSI.**

100% in favour

**Recommendation** – Change as set out.

**Question 7a**

**Are you content with the revised containment measures for waste inactivation (Schedule 8, table 1a point 17)**

77.8 % yes (29.6 % with reservations – 8 respondents)
22.2 % no ( 6 respondents)

**Recommendation -** The main concern from consultees was the proposals in laboratories for inactivation of GMMs (genetically modified micro-organisms) in contaminated material and waste to be inactivated within the building for containment level 2. A number of establishments set out that the waste is inactivated within the site but not necessarily the same building by transporting the waste in sealed containers to the building with an autoclave. There were issues surrounding the cost of installing an autoclave within the same building or of having to apply for a derogation ( ie seeking HSE's written permission) each time before the activity was carried out. As a result of these comments, it is

proposed to alter the wording back to “require by validated means” for containment level 2. This will not impinge on the acceptability of how waste is inactivated or the degree of information with which HSE are provided with, since means of waste inactivation is assessed as part of the notification review for Class 2 activities. The proposed amendments to containment level 3 to say “required by validated means, with waste inactivated within the laboratory suite” and for containment levels 4 to say ”required by validated means, with waste inactivated within the laboratory” will remain.

**Question 7b**

**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 of the laboratory (Schedule 8, Table 1b, points 3 & 6)**

92.3 % yes (7.7% with reservations – 2 respondents)
7.7 % no (2 respondents)

**Recommendation** - It was suggested that the revised wording of Schedule 8, table 1a, point 17 GMMs at containment level 2 (Question 7a) and revised wording of schedule 8, table 1b using GMMs at containment level 2 appears to be contradictory as far as working with plant pathogens is concerned. On the one hand requiring that all class 2 GMMs should be inactivated within the building while on the other hand implying that this need not be the case as transfer of GM plant pathogens between structures is allowed and dissemination needs only to be minimised during the transfer of material. By removing the location of inactivation from Class 2 in 7a and saying “required by validated means” we would remove any perceived contradiction with 7b. So revise as set out.

**Question 7c**

**Are you content with the revised containment measure for animals in isolators (Schedule 8, table 1a, point 8)**

96.15% in favour (27% with reservations - 7 respondents)
3.85% against (one respondent)

Recommendation - It was pointed out that for large animals that it may not be practicable to use an isolator and that details of the alternative means of protecting the operator and environment should be provided. We have therefore added to the derogation in regulation 18 the words “or practicable” This has the effect of applying the possibility of a derogation to all containment measurers but it is only with the written agreement of the competent authority. We will make it clear in the guidance that accompanies the amendments that this new derogation ground is aimed at animals too large for an isolator.

**Question 8**

**Are you content with the length of the transitional period. 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 schedule 8 apply and anyone who has submitted a relevant notification immediately before the amendments come onto force**.

85.2 % yes ( 14.8% with reservations – 4 respondents)
14.8% no ( 4 respondents)

**Recommendation** - There were a few points made on the need for new equipment, especially an autoclave in the building to deal with inactivation of GMMs in contaminated material for containment level 2 (see question 7a). However as it is proposed to change the wording back to "required by validated means" this would now not be an issue. HSE do not see the changes as particularly burdensome as the new standards 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. Information on when the regulations come into force and the transitional period ends will be made known to all GM centres. Keep length of transitional period as suggested.

**Question 9a**

**Do you know if any small businesses that will be adversely affected by the amending regulations**

Points Made – There was one significant response was on the costs of installing an autoclave within the building. See response to question 7a. However by reverting to the current wording "required by validated means " this would not now be an issue.

**Question 9b**

**Any other comments on the partial RIA**

Points made - There was one response re wage costs for scientists unrealistically low at £20 per hour. It was also suggested it would take more than one hour to become familiar with the amendments. Economists confirmed that the scientists costs was based on the New Earnings Survey for 2003 and with guidance on the amendments to be posted on the HSE website, we still believe an hour will be adequate time to become familiar with the changes.

D R A F T  S T A T U T O R Y  I N S T R U M E N T S - 2 / 6 / 0 5

# 2005 No.

# HEALTH AND SAFETY

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

*Made - - - -* *[ ] 2005*

*Laid before Parliament* *[ ] 2005*

*Coming into force*

*for the purpose of regulation 2(12) to 3(16)* *1st January 2006*

*for all other purposes* *1st October 2005*

The Secretary of State, being the Minister designated(**1**) under section 2(2) of the European Communities Act 1972(**2**) 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)(**3**) 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(**4**) ("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 and commencement**

**1.** These Regulations may be cited as the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005 and for the purpose of regulation 2(12) to (16) shall come into force on 1st January 2006 and for all other purposes on 1st October 2005.

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

**2.**—(1) The Genetically Modified Organisms (Contained Use) Regulations 2000(**5**) shall be amended as follows.

(2) In regulation 2(1)—

(a) after the definition of "organism", insert—

(**1**) S.I. 1991/755.
(**2**) 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).
(**3**) 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.
(**4**) 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).
(**5**) S.I. 2000/2831, as amended by S.I. 2002/63.

""transboundary movement" has the meaning assigned to it by Article 3 of Council Regulation 1946/2003/EC of 15 July 2003 on transboundary movements of genetically modified organisms(**6**)**"**.

(3) In regulation 3—

(a) in (3)(a)(i)(aa), after the word "Ministers," add "or, as regards Wales, by the National Assembly for Wales,";

(b) after (3)(a)(i)(aa), insert as a new (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(**7**), or";

(c) renumber the existing (3)(a)(i)(bb) as (3)(a)(i)(cc) and after "Article 13(4) of Council Directive 90/220/EEC" insert "or Article 15(3), 17(6), or 18(2) of Council Directive 2001/18/EC(**8**)";

(d) for (3)(a)(iii) substitute, "food or feed authorised in accordance with the provisions of Council Regulation (EC) No.1829/2003 of 22 September 2003 on genetically modified food and feed(**9**)";

(e) insert as (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 on genetically modified food and feed";

(f) in (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 subparagraph (a) for the words "in both England and Scotland", substitute "on the border of England and Scotland"; and

(b) in subparagraph (b), for the words "both England and Scotland", substitute "premises situated on the border of England and Scotland.".

(5) In regulation 15—

(a) in paragraph (2)(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) omit paragraph (4); 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,".

(6) In regulation 18(2), after "necessary", insert "or practicable".

(7) Omit regulations 22 and 23 and 23A.

(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(**10**) or the Environmental Information (Scotland) Regulations 2004(**11**).";

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(**6**) OJ L 287/1 5.11.2003.
(**7**) S.I. 1991/1714 (N.I.19).
(**8**) 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).
(**9**) OJ No. L268, 18.10.2003, p1.
(**10**) S.I. 2004/3391.
(**11**) S.I. 2004/520.

(b) for paragraph (4) substitute—

**"**(4) Information shall be entered in the register within 14 days of its receipt by the competent authority.**"**

**;**

(c) omit paragraphs (5) and (9).

(9) In regulation 29—

(a) omit paragraph (3);

(b) for paragraph (8)(b)(ii), substitute the following—

"(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) Omit Regulation 30.

(11) In paragraph 2 of Schedule 6—

(a) omit the word "and" at the end of sub-paragraph (n)(vi);

(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—

"

| | *1* | *2* | *3* | *4* |
|---|---|---|---|---|
| Inactivation of GMMs in contaminated material and waste | required by validated means | required by validated means | 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—

"

| | | *1* | *2* | *3* | *4* | *Additional* |
|---|---|---|---|---|---|---|
| 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—

"

| | | *1* | *2* | *3* | *4* | *Additional* |
|---|---|---|---|---|---|---|
| 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) In Schedule 11, paragraph 9(4), after "a solicitor" add "or any other person".

(18) Omit paragraph 9(6) of Schedule 11.

**Amendment of the Health and Safety (Fees) Regulations 2005**

**3.**—(1) Regulation 14 of the Health and Safety (Fees) Regulations 2005(**12**) shall be amended as follows.

(2) at the beginning of paragraph (1) insert "Subject to paragraph (1A) below";

(3) after paragraph (1) insert–

"(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; and

(b) the application was submitted to the authority no later than 30 November 2005.**"**.

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

*Lord Hunt*
Parliamentary Under Secretary
Department for Work and Pensions

Address
Date

(**12**) S.I. 2005/676.

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

1. These Regulations amend the Genetically Modified Organisms (Contained Use) Regulations 2000 (S.I. 2000/2831) ("the 2000 Regulations"), as amended by the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002 (S.I. 2002/63). The principal amendments are as follows.

2. Paragraph 7 of regulation 2 revokes regulations 22 and 23 and paragraph 8 amends regulation 24. Paragraph 9(a) removes appeal provisions relating to regulations 22 and 23. These amendments implement the provisions of Council Directive 2003/4/EC of 28 January 2003 on public access to environmental information (O.J. No. L41, 14.2.2003, p.26) and repealing Council Directive 90/313/EEC of 7 June 1990 on the freedom of access to information on the environment (O.J. No. L158, 23.6.1990, p. 56). The existing provisions in the 2000 Regulations implemented the provisions of Article 19 of Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms (O.J. No. L117, 8.5.1990, p. 1) as amended by Commission Directive 94/51/EC of 7 November 1994 (O.J. L297, 18.11.94, p. 29) and Council Directive 98/81/EC of 26 October 1998 (O.J. No. L330, 5.12.98, p. 13). These provisions have been superseded by Council Directive 2003/4/EC which is implemented by the Environmental Information Regulations 2004 (S.I. 2004/3391) and the Environmental Information (Scotland) Regulations 2004 (S.S.I. 2004/520).

3. Paragraph 10 of regulation 2 removes regulation 30 so that the Regulations are no longer extended outside Great Britain.

4. Paragraph 11 of regulation 2 requires additional information for notifications. This is necessary in order to fully comply with the requirements of Council Regulation 1946/2003/EC of 15 July 2003 on transboundary movements of genetically modified organisms (O.J. No. L287, 5.11.2003, p. 1).

5. Paragraphs 12 to 16 of regulation 2 amend the containment levels for specified containment measures.

6. The remaining paragraphs of regulation 2 make changes to correct errors, including provisions for representation at appeals, provisions in respect of Wales and provisions for notifications and appeals relating to premises and activities that are situated partly in Scotland.

7. The Regulations also amend the Health and Safety (Fees) Regulations 2005 (S.I. 2005/676). Under regulation 3, 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 2.

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.

**Annex C**

# 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);
- 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. It is also necessary to make provision for the UK to collect information on transboundary moves of GMOs as required by the EC Regulation implementing the Cartagena protocol.

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.

Rationale for Government Intervention

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 further criticism from the JCSI. They also have to be made to align the 2000 Regulations with the Environmental Information Regulations 2004 which implement Council Directive 2003/4/EC on public access of environmental information. Together with the provisions for collection of information in accordance with the requirements of Regulation 1946/2003/EC, these provisions are necessary in order to avoid infraction proceedings from the EC. Guidance would not be considered an acceptable alternative to regulatory amendment by either the JCSI or the EC. The other amendments are considered desirable to help clarity and correctness.

## Consultation

Within government

7. A list of Government Departments and Agencies and Government Advisory Committees consulted is attached at Appendix A. The proposals have been agreed with other government departments who attend the meetings of the UK Competent Authority – Department of Environment, Food and Rural Affairs, National Assembly for Wales, Scottish Executive are members and the Department of Health, Department of Trade and Industry and the Northern Ireland Department of Economic Development attend as observers.

Public consultation

8. The proposals were put out to public consultation on 20 December 2004 with a closing date for comments of 12 March 2005. 27 substantive responses were received. Consultees were asked to comment on the partial Regulatory Impact Assessment. The results of the public consultation are attached at Appendix B.

## Options

9. 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.

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

11. 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.

12. 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.

13. 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 by late summer 2005.

14. 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

15. Presently there are 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

16. 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. The base year for costs quoted is 2003

Benefits

17. 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.

18. 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.

19. The savings to HSE of the notification team not having to filter out the information to make up the regional registers are 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.

20. 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.

21. 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.

22. 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*

23. 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*

24. 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.

25. 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.

26. 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)]. 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 30 notifications will need to be reviewed in detail. In 10 of these cases it will be necessary to apply for a derogation, but in 6 of these 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 £9 000. 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*

27. 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*

28. 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 additional 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 per year (based on HSE staff ready reckoner cost (including non-salary costs) for national Band 4 of £40 per hour). This amounts to £5 000 in ten year present value. For industry there will be virtually no additional 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.

29. 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 £5 000. It is anticipated that at most 10 applications will be made for such notifications and derogations. The charge for these derogations is £432 and for a class 3 notification £624 (2003 rates). This will be a one-off cost to HSE.

Environmental costs

30. 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* | *£19 000* | *£19 000* |
| *Costs to HSE* | *£5 000* | *£10 000* |
| ***Total Costs*** | ***£24 000*** | ***£29 000*** |

31. 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 which will be administrative are £29 000.

**Equity and fairness**

32. 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**

33. 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.

**Competition assessment**

34. 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 and monitoring**

35. 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.

**Implementation and Delivery Plan**

36. It is planned for the regulations to come into force on the next common commencement date of 1 October 2005. The changes to the regulations in containment measures will come into force 3 months later. The regulations will be announced in a press release that will be sent to a wide range of scientific journals concerned with genetic modification. Additional guidance to publicise the changes and set out their requirements will be posted on the HSE web-site and mention will be made in the press release where guidance can be found.

**Post – Implementation and review**

37. 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**

38. 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**

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

2005]

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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 2003 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 2003 SOC 201 'Biological Scientists and Biochemists' plus 30% for non-wage labour costs.

Appendix A

**GOVERNMENT DEPARTMENTS AND AGENCIES WHO WERE CONSULTED**

British Airports Authority

British Pharmocopoeia 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

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 Comission

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 Committee

Defence Scientific Advisory Committee

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

**For Appendix B of the Regulatory Impact Assessment see Annex A of Commission Paper.**

**Annex D**

List Of Respondees

Viragen (Scotland) Ltd
MRC Laboratory of Molecular Biology
John Francis
Centre for Ecology and Hydrology (Dorset), Natural Environmental Research Council
GE Healthcare, Bio-Sciences
London School of Hygiene & tropical Medicine
Queen Mary's School of Medicine & Dentistry
AstraZenca UK Ltd
Gene Therapy Advisory Committee
University of West London – Genetic Modification Safety Committee
ML Laboratories PLC
Schering-Plough Animal Health
B & K Universal Ltd
University of Sheffield
East Malling Research
Scottish Agricultural Science Agency
Corbra Bio Manufacturing PLC
Institute of Animal Health
University of Glasgow
National Health Institute for Biological Standards & Control
Moredun Research Institute
John Innes Centre
Department for Environment Food & Rural Affairs
Genewatch UK
DSTL – Ministry of Defence
Hammersmith Hospitals HNS Trust
University of Cambridge