EXPLANATORY MEMORANDUM TO

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

2005 No. 2466

1. This explanatory memorandum has been prepared by the Health and Safety Executive (HSE) on behalf of the Department for Work and Pensions and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments

2. Description

2.1 These Regulations amend the Genetically Modified Organisms (Contained Use) Regulations 2000.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 In the first report of 2001 The Joint Committee on Statutory Instruments reported the Genetically Modified Organisms (Contained Use) Regulations 2000 (S.I. 2000/2831). Regulations 13(1)(b), 15(2)(g), 15(5), 29(8)(b)(ii) and 30 were reported for defective drafting, paragraphs 1(b), 2(b), and 3(b) of Schedule 6 as requiring elucidation, paragraph 9(4) of Schedule 11 for making an unexpected use of enabling powers and paragraph 9(6) of Schedule 11 for failing to conform to proper drafting practice. The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005 make changes to regulations 13, 15, 29, Schedules 6 and 11 and omit regulation 30 of the Genetically Modified Organisms (Contained Use) Regulations 2000.

4. Legislative Background

4.1 These Regulations are made under the Health and Safety at Work etc. Act 1974 (the 1974 Act) and section 2(2) of the European Communities Act 1972.

4.2 Changes were required to the regulations as a result of the JCSI report; in order to include a provision on the collection of information on transboundary movements of class 3 and 4 genetically modified organisms so that the UK can pass this information to the EC and the Biological Clearing House as required by Regulation 1946/2003/EC of the European Parliament and the Council on transboundary movement of genetically modified organisms and; to alter the disclosure of information provisions so that they align with the Environmental Information Regulations 2004 (S.I. 2004/3391) and the Environmental Information (Scotland) Regulations 2004 (S.S.1. 2004/520), which implement Council Directive 2003/4/EC on public access to environmental information.

4.3 In addition to the changes set out in Para 4.2, the opportunity was taken to update references to other legislation, to reflect changes in government organisation, to remove 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. Regulation 14 of the Health and Safety (Fees) Regulations 2005 has been amended so that applicants are not charged as a result of the changes to the containment measures.

5. Extent

This instrument applies to Great Britain. The Northern Ireland Office has been notified of the proposed revocations.

6. European Convention on Human Rights

As the Instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The Genetically Modified Organisms (Contained Use) Regulations 2000 (S.I.2000/2831) revoke similarly entitled 1992 regulations and implement Council Directive 90/219/EEC on the contained use of genetically modified organisms as amended by Council Directive 98/81/EC. The 2000 Regulations make provision to protect individuals and the environment from risks arising from activities involving the contained use of genetically modified micro-organisms and, in the case of individuals, from the risks where the organisms are not micro-organisms (eg genetically modified plants and animals). The Regulations require users to make a risk assessment for all genetic modification activities; the application of appropriate containment measures and controls; notification to HSE (on behalf of the Competent Authority) of all premises where genetic modification is to take place; and prior notification to HSE of certain higher risk activities – consents being required before work can begin for the highest risk activities.

7.2 There are currently 522 Genetic Modification centres registered with HSE. The work is carried out within a range of universities, hospitals and private firms.

7.3 The changes are not politically sensitive. 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. Results of the public consultation are set out in Appendix B of the RIA. 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 the press release will highlight where this guidance can be found.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

8.2 The impact on the public sector is negligible.

9. Contact

Colin Dunn at the Health and Safety Executive can answer any queries regarding the instrument.
Tel: 020 7717 6623 or
E-mail: colin.dunn@hse.gsi.gov.uk

ANNEX 1

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

Contact point

Colin Dunn
Biological Agents and Genetically Modified Organisms Policy Unit
7NW
Health and Safety Executive
Rose Court
2 Southwark Bridge
London SE1 9HS
020 7717 6348
e-mail: colin.dunn@hse.gsi.gov.uk

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

Appendix B

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.