Consultation on Proposal to Consolidate the Genetically Modified Organisms (Contained Use) Regulations 2000 and the three amending Regulations of 2002, 2005 and 2010

This consultative document is issued by the Health and Safety Executive in compliance with its duty to consult under section 16 of the Health and Safety at Work etc Act 1974.

Comments should be sent to:

GMO Consolidation Team
Health and Safety Executive
5S2 Redgrave Court
Merton Road
Bootle
Merseyside L20 7HS

E-mail: gmoconsolidation@hse.gsi.gov.uk

to reach there no later than 20 December 2013.

The Executive tries to make its consultation procedure as thorough and open as possible. Responses to this consultation document will be lodged in the Health and Safety Executive’s Knowledge Centre after the close of the consultation period where they can be inspected by members of the public.

Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004 (EIR)). Statutory Codes of Practice under the FOIA and EIR also deal with confidentiality obligations, among other things.

If you would like us to treat any of the information you provide, including personal information, as confidential, please explain your reasons for this in your response. If we receive a request under FOIA or EIR for the information you have provided, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will be disregarded for these purposes. Requests for confidentiality should be made explicit within the body of the response.

HSE will process all personal data in accordance with the DPA. This means that personal data will not normally be disclosed to third parties and any such disclosures will only be made in accordance with the Act.
Proposal to consolidate the Genetically Modified Organisms (Contained Use) Regulations 2000 and the three amending Regulations of 2002, 2005 and 2010

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Consultation by the Health and Safety Executive

HSE has a statutory duty to consult stakeholders to seek their views on its proposals. It believes that public consultation provides an open and transparent approach to decision-making. Following consultation, HSE will make a recommendation to the Secretary of State on the best way forward.

How to Respond

A summary of the proposal and the questionnaire can be found on the HSE website [www.hse.gov.uk/consult/condocs/cd263.htm](http://www.hse.gov.uk/consult/condocs/cd263.htm). You are welcome to comment on any issue raised by this document.

You can:

- Complete the online questionnaire [www.hse.gov.uk/consult/condocs/cd263.htm](http://www.hse.gov.uk/consult/condocs/cd263.htm); or
- Respond by email – you should send this to gmoconsultation@hse.gsi.gov.uk;
- Respond on paper – you can do this either by:
  - Printing the online questionnaire; or
  - Making a written response in whatever format you wish.

Send your completed response to:

GMO Consolidation Team, Health and Safety Executive, 5S2 Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS

We would be grateful if you could send an email address when you provide your response, so that we can inform you of when the HSE intends to publish information concerning consultation responses on the HSE website. Responses must be received by **20 December 2013**.

Further information on the consolidation can be obtained by joining the HSE GMO consolidation online community. To request an invitation to the community please send an email to lyndsey.bennett@hse.gsi.gov.uk.

If you require a more accessible format of this document please send details to creative@hse.gsi.gov.uk and your request will be considered.

**What happens next?**

We will acknowledge all responses and give full consideration to the substance of arguments in the proposals; we may contact you again if, for example we have a query in respect of your response.

We will tell you when the HSE will publish information concerning the consultation responses. We will provide a summary of those who responded to this consultation and we will produce a summary of the views expressed to each question; this information will be placed on the HSE’s website.
**Code of Practice on Consultation**

HSE is committed to best practice in consultation and to the Government's Consultation Principles. The Government is improving the way it consults by adopting a more proportionate and targeted approach, so that the type and scale of engagement is proportional to the potential impacts of the proposal. The emphasis is on undertaking the effects of a proposal and focussing on real engagement with key groups rather than following a set process.

The key Consultation Principles are:

- departments will follow a range of timescales rather than defaulting to a 12-week period, particularly where extensive engagement has occurred before;
- departments will need to give more thought to how they engage with and consult with those who are affected;
- consultation should be by ‘digital by default’, but other forms should be used where these are needed to reach the groups affected by a policy;
- the principles of the Compact between government and the voluntary sector will continue to be respected.
- Additional guidance can be found at: [www.cabinetoffice.gov.uk/resource-library/consultation-principlesguidance](http://www.cabinetoffice.gov.uk/resource-library/consultation-principlesguidance)

**How your responses will be handled**

We will acknowledge all responses and give full consideration to the substance of arguments in the development of proposal. HSE will then decide on how best to take the regulations forward based on an interpretation and analysis of the consultation responses.

**Queries and complaints**

If you have any comments or complaints about the way this consultation exercise has been conducted, please contact the HSE Consultation Co-ordinator by writing or sending an email to:

**Teresa Farnan**, Health and Safety Executive, 7th Floor, Caxton House, Tothill Street, London, SW1H 9NA; email [teresa.farnan@hse.gsi.gov.uk](mailto:teresa.farnan@hse.gsi.gov.uk)

We aim to reply to all complaints within 10 working days. If you are not satisfied with the outcome, you can raise the matter with HSE’s Acting Chief Executive, Kevin Myers, at Health and Safety Executive, Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS. You can also write and ask your MP to take up your case with us or with Ministers. Your MP may also ask the Independent Parliamentary Commissioner for Administration (the Ombudsman) to review your complaint.
Summary of proposed changes

1. The following table contains a summary of the proposed changes to the current regulations

<table>
<thead>
<tr>
<th>Change</th>
<th>Reference in current regulations</th>
<th>Subject of regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-1</td>
<td>Table 1a (measure 15)</td>
<td>Specified disinfection procedures in place</td>
</tr>
<tr>
<td>A-2</td>
<td>Table 1c (measure 6)</td>
<td>Incinerator for disposal of animal carcasses containing GMMs</td>
</tr>
<tr>
<td>A-3</td>
<td>Table 2 (measure 16)</td>
<td>Decontamination and washing facilities provided for personnel</td>
</tr>
<tr>
<td>B-1</td>
<td>Table 1a (measure 5)</td>
<td>Negative pressure relative to surroundings at CL2 and CL3</td>
</tr>
<tr>
<td>B-2</td>
<td>Table 1a (measure 6)</td>
<td>HEPA filtration at CL3</td>
</tr>
<tr>
<td>B-3</td>
<td>Table 1a (measure 7)</td>
<td>Microbiological safety cabinet at CL4</td>
</tr>
<tr>
<td>B-4</td>
<td>Table 1a (measure 17)</td>
<td>Inactivation of waste at CL1 - laboratories</td>
</tr>
<tr>
<td>B-5</td>
<td>Table 1a (measure 19)</td>
<td>Observation window at CL3</td>
</tr>
<tr>
<td>B-6</td>
<td>Table 1c (measure 9)</td>
<td>Use of isolators at CL1</td>
</tr>
<tr>
<td>B-7</td>
<td>Table 2 (measure 2)</td>
<td>Controlled areas purpose built at CL4</td>
</tr>
<tr>
<td>B-8</td>
<td>Table 2 (measure 9)</td>
<td>Biohazard signs at CL1</td>
</tr>
<tr>
<td>B-9</td>
<td>Table 2 (measure 19)</td>
<td>Written procedures and training records</td>
</tr>
<tr>
<td>B-10</td>
<td>Table 2 (measure 21)</td>
<td>Inactivation of waste at CL1 – other facilities</td>
</tr>
<tr>
<td>C-1</td>
<td>Regulations 10(3), 11(5), Schedules 5 &amp; 6</td>
<td>Emergency plans</td>
</tr>
<tr>
<td>C-2</td>
<td>Regulation 10(1), Schedule 6</td>
<td>Information required for a Class 2 notification</td>
</tr>
<tr>
<td>C-3</td>
<td>Regulation 24(7), (8)</td>
<td>Register of notifications</td>
</tr>
<tr>
<td>D-1</td>
<td>Regulation 16</td>
<td>Requirement to establish a genetic modification safety committee</td>
</tr>
<tr>
<td>E-1</td>
<td>Restructure</td>
<td>Separating the duties on the competent authority and the users</td>
</tr>
<tr>
<td>E-2</td>
<td>Change of term used</td>
<td>Contained use</td>
</tr>
<tr>
<td>E-3</td>
<td>Change of term used</td>
<td>'user'</td>
</tr>
<tr>
<td>E-4</td>
<td>Replace term used</td>
<td>Larger GMOs (LGMOs)</td>
</tr>
<tr>
<td>E-5</td>
<td>Schedule 6</td>
<td>Notification requirements</td>
</tr>
<tr>
<td>E-6</td>
<td>Regulation 29 &amp; Schedule 11</td>
<td>Right of appeal and procedure</td>
</tr>
</tbody>
</table>
Introduction

2. This consultative document (CD) seeks views on proposals to introduce a new set of regulations, provisionally titled ‘The Genetically Modified Organisms (Contained Use) Regulations 2014’, which consolidates ‘The Genetically Modified Organisms (Contained Use) Regulations 2000’ and its three amending regulations made in 2002, 2005 and 2010 (collectively referred to in this CD as ‘the GMO regulations’). The aim is to produce a single simplified set of up-to-date regulations, and thereby assist employers to comply with the legislation. The proposed changes will not compromise safety or increase risks to the environment.

3. HSE is consulting stakeholders as required under s.50 of the Health and Safety at Work etc. Act 1974 (HSWA) on the proposed changes to the GMO regulations to seek views on:

- whether they agree with the proposed changes;
- whether there are any unforeseen implications resulting from the proposed changes;
- what users may have to do differently; and
- the costs and benefits of the proposed changes.

4. The consultation questions are set out throughout the document and for convenience in Annex E.

5. The consultation will be conducted over an 8 weeks period from 28th October to 20th December 2013, which falls in line with the Government’s guidance on Consultation Principles.

6. The GMO regulations cover the whole of Great Britain. HSE is the joint Competent Authority for the regulation of contained use of GMOs with Defra (in England and Wales) and with the Scottish Government (in Scotland). Northern Ireland has equivalent regulations. For administrative purposes, HSE acts as a single point of contact for users. This consultation relates to regulations that will apply in England, Scotland and Wales.

Background

7. The GMO regulations are concerned with the protection of the environment and prevention of harm to human health from activities involving genetically modified micro-organisms (GMMs) used in laboratories and other ‘contained use’ facilities. They also provide for the protection of humans from the contained use of genetically modified plants and animals. They implement the relevant requirements of European Directive 2009/41/EC on the contained use of genetically modified micro-organisms and other EU requirements concerning access to environmental information. Directive 2009/41/EC is itself a consolidation (recast) of the previous three Directives covering this issue.

8. Genetic modification (GM) in relation to an organism means altering the genetic material (either DNA or RNA) in that organism in a way that does not occur naturally by mating and/or recombination. Typically, this involves the removal of the genetic material, its manipulation outside the cell and reinsertion into the same or
another organism. The aim is often to introduce a new or altered characteristic to the target organism.

9. Contained use activities (for the purposes of these regulations) cover any activity involving Genetically Modified Organisms (GMOs), encompassing microorganisms and larger organisms (e.g. animals, plants, and insects) under the containment conditions laid down by the regulations. Barriers are required to be in place to limit contact between GMOs and humans and the environment, with the intention to provide a high level of safety for humans and the environment. For GMMs, these barriers can be provided by physical, biological or chemical means, or a combination of these. This includes the destruction and disposal of GMMs. For both GMMs and larger GMOs, these barriers are described in the extensive guidance\(^1\) from the Scientific Advisory Committee on Genetic Modification (SACGM).

10. The regulations set out the way in which GMMs are to be risk assessed and classified, and specifies waste management and containment requirements. The GMM activity classifications are:

- **Class 1** – Activities of no or negligible risk, for which containment level 1 is appropriate to protect human health and the environment.
- **Class 2** – Activities of low risk, for which containment level 2 is appropriate to protect human health and the environment.
- **Class 3** – Activities of moderate risk, for which containment level 3 is appropriate to protect human health and the environment.
- **Class 4** – Activities of high risk, for which containment level 4 is appropriate to protect human health and the environment.

11. Since 2000, when the regulations first came into force, there have been three amending regulations, introduced in 2002, 2005 and 2010. These regulations are supported by a HSE guide (L29\(^2\)).

**Why are the Regulations being amended?**

12. The consolidation of the GMO regulations is one of the recommendations of the L"ofstedt review of health and safety, published on the 28 November 2011. The L"ofstedt review recommended that a consolidation of GMO legislation should:

- ensure the regulations reflect current industry practices;
- limit the extent to which UK health and safety legislation has enhanced EU Directives (gold-plated); and
- simplify the regulations (for example by reducing any duplication).

13. At the same time, the Government has emphasised that the consolidation process should not reduce the protections provided by the existing legislation. Instead, the opportunity has been taken to make a number of changes that make the

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\(^1\) The SACGM Compendium of guidance – This is guidance prepared, in consultation with HSE, by the Scientific Advisory Committee for Genetic Modification, which meets the Government principles for scientific advisory committees. [www.hse.gov.uk/biosafety/gmo/acgm/acgmcopl/](http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcopl/)

\(^2\) A guide to the Genetically Modified Organisms (Contained Use) Regulations 2000 (L29) HSE Books
regulations more risk based and proportionate and reflect experience of applying these regulations since 2000. The opportunity has also been taken to remove potential hurdles that may impede the longer term goal of producing a single regulatory framework for human and animal pathogens and GMOs.

14. There are in the region of 600 premises in the UK carrying out contained use of microorganisms. The majority of GMO contained use work is being undertaken at Class 1, deemed to be of nil or negligible risk, with very few employers undertaking work at Class 4 (e.g. work with ebola virus, foot and mouth disease virus), deemed to present a high risk to human health or the environment.

<table>
<thead>
<tr>
<th>Containment Level</th>
<th>Number of GM Centres</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>CL1</td>
<td>342</td>
<td>57%</td>
</tr>
<tr>
<td>CL2</td>
<td>179</td>
<td>30%</td>
</tr>
<tr>
<td>CL3</td>
<td>71</td>
<td>12%</td>
</tr>
<tr>
<td>CL4</td>
<td>6</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>598</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

*Breakdown of employers and premises by class of activity (at 1 August 2013)*

15. Some of the proposed changes affect all or different risk classes. However many of the measures relate to Class 1 activities, which will therefore not affect safety and should have the greatest impact on reducing unnecessary regulatory burden and making the requirements proportionate to the risk.

16. HSE proposes to introduce the new consolidated regulations by 1 October 2014. The outcome of this consolidation will contribute to the Government’s wider commitment to remove or improve health and safety regulations, making them more risk based and proportionate and thereby encourage growth.

17. A draft statutory instrument of the Genetically Modified Organisms (Contained Use) Regulations 2014 (GMO(CU) 2014) can be found at Annex A. This incorporates the proposed structural and procedural changes explained in this consultation document. The annexed draft GMO(CU) 2014 regulations are not the final version and will be amended further to ensure that they are technically sound and, where appropriate, developed to reflect the outcome of the consultation.

**Summary of current provisions**

18. The current GMO regulations already closely follow the European Directive on which they are based. Similarly previous consultation exercises have been supportive of the current GMO regulations. However, the existing legislation can be simplified and would benefit from changes to improve clarity, proportionality and remove unnecessary requirements on low risk activities.
19. The current provisions in the GMO regulations can be broadly grouped into
the following areas:

- Risk assessment and classification of work
- Notification and provision of information
- Containment and control measures to be applied

20. It is also hoped that the consolidation will provide for greater consistency in
standards between GMOs and non-modified microorganisms. Work with non-
modified human pathogens is covered by the Control of Substances Hazardous to
Health Regulations (COSHH) 2002 (as amended) and underpinned by the Biological
Agents Directive 2000/54/EC. Work with specified animal pathogens is covered by
the relevant Specified Animal Pathogen Orders (SAPO 2008, 2009) in England,
Scotland and Wales.

21. These GMO regulations are solely concerned with the contained use of
GMOs and do not cover the deliberate release into the environment of GMOs (e.g.
field trials with genetically modified plants). Defra and Devolved Governments
regulate the latter as part of the Genetically Modified Organisms (Deliberate

Proposed Changes to the Regulations

22. The changes proposed as part of the consolidation broadly fall into the
following areas:

23. **Part 1 Control measures** – These are changes to the provisions within the
containment tables and include amendments involving notifications and
administrative arrangements.

24. **Part 2 Restructure and technical tidy-up** – These refer to changes to the
language and layout of the consolidated regulations. These changes have no impact
on the legal duties under the regulations but should assist users with compliance.

25. Changes to the control measures are considered individually in Part 1. There
is an explanation as to why the change is being proposed, followed by a question, or
questions, asking whether you agree with the change. There is also an opportunity
to qualify your answer and make any comments on the potential effects of the
change including any costs/benefits likely to ensue.

26. We will be seeking specific data to help us determine the potential financial
impact (either costs or savings) of the proposed changes in parallel to this
consultation. If contacted, and you do not have an accurate figure at hand, a best
estimate will be helpful.

27. Changes to the structure and layout of the regulations are described in Part 2.
The revised GMO(CU) 2014 regulations (see Annex A) have been reorganised into
more logical ‘Parts’ including interpretation, risk assessment and notification, conduct
of activities, duties & powers of Competent Authority and miscellaneous. This
structure is intended to separate the duties on users and the Competent Authority to
add clarity and make the regulations more accessible. Contact references have
been updated and obsolete terms have been removed as part of the technical tidy-up.
PART 1: Control Measures

28. The proposed changes to the control measures reflect experience of applying the regulations since 2000 and are risk based, with no foreseeable reduction in the protection afforded to human health or the environment. Two approaches have been taken to introduce these changes. Where the control measure is a domestic provision, it can be removed in its entirety. Where the control measure is a Directive provision, the change will only apply to the measure at a specific containment level (CL) and most often reverts to the equivalent standard in the Directive.

29. The following table lists those proposals (A-1 to A-3) which will remove a control measure in its entirety from the containment tables.

Table A – proposals to remove control measures from containment tables

<table>
<thead>
<tr>
<th>Change</th>
<th>Reference in current regulations</th>
<th>Containment measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-1</td>
<td>Table 1a (measure 15)</td>
<td>Specified disinfection procedures in place</td>
</tr>
</tbody>
</table>

Regulation 17 requires application of the general principles of microbiological and occupational safety and hygiene. Schedule 7 (of the regulations) sets out these principles of which principle (m) places an absolute requirement for this control measure regardless of the class of activity. Principle (m) will remain unaltered; hence, there is no need to repeat this requirement in the containment table. Removing this measure from the table will simplify the Table 1a by reducing the overall number of containment measures and remove its risk-based application at CL1 (which may under implement the Directive). Overall, this will remove duplication from the regulations.

| A-2    | Table 1c (measure 6)           | Incinerator for disposal of animal carcasses containing GMMs |

The regulations require inactivation of GMMs in contaminated material and waste. The Directive makes no separate provision for animal carcasses as this is encompassed within the term contaminated material and waste. Consequently, the regulations are overly prescriptive in requiring an incinerator to dispose of animal carcasses. There are alternative modern technologies available (e.g. autoclaves, tissue digesters, rotaclaves) that provide effective means of inactivation and are more environmentally friendly. Specifically, the requirement to have an incinerator on site at CL4 may preclude the development of new facilities in certain geographical areas (due to environmental permissions) or within certain institutions (where cost would be prohibitive). The requirement to inactivate animal carcasses will remain (within the term contaminated material and waste), however, the prescriptive requirement for an incinerator will be removed, enabling greater flexibility in the inactivation method used. Removing this measure from the table will simplify the Table 1c by reducing the overall number of containment measures. For human pathogens, the requirement for an incinerator specified in COSHH will still apply. The intention would be to amend the Biological Agents Directive, when the opportunity arises.

| A-3    | Table 2 (measure 16)           | Decontamination and washing facilities provided for personnel |

Regulation 17 requires application of the general principles of microbiological and occupational safety and hygiene. Schedule 7 (of the regulations) sets out these principles of which principle (h) places an absolute requirement for this control measure regardless of the class of activity. Principle (h) will remain unaltered; hence, there is no need to repeat this requirement in the containment table. Removing this measure from the table will simplify Table 2 by reducing the overall number of containment measures and will remove duplication from the regulations.
30. Please can you answer the following questions in relation to the proposed changes in Table A:

Q1(a) Should containment measure 15 (disinfection procedures) of Table 1a be removed as suggested?

Q1(b) Should containment measure 6 (incinerator) of Table 1c be removed as suggested?

Q1(c) Should containment measure 16 (decontamination facilities) of Table 2 be removed as suggested?

Q1(d) Please provide some comments to support your answers including any costs or benefits that these changes may cause.

31. The following tables (B-1 to B-10) explain the proposed changes to specific measures at particular containment levels. These amendments address areas where reflected experience of applying these regulations since 2000, permits a more risk based and proportionate approach (in the areas where the current regulations go beyond the Directive). For reference the requirements at the four different containment levels is shown for the containment measure. The containment level affected by the change is shaded and the proposed changed wording is shown in bold.

Table B-1: change to Table 1a (measure 5)

<table>
<thead>
<tr>
<th></th>
<th>CL1</th>
<th>CL2</th>
<th>CL3</th>
<th>CL4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current wording</td>
<td>Negative pressure relative to the pressure of the immediate surroundings</td>
<td>Not required</td>
<td>Required where and to extent the risk assessment shows it is required</td>
<td>Required</td>
</tr>
<tr>
<td>Proposed wording</td>
<td>Negative pressure relative to the pressure of the immediate surroundings</td>
<td>Not required</td>
<td>Not required</td>
<td>Required except for activities where transmission does not occur via airborne route</td>
</tr>
</tbody>
</table>

32. This containment measure refers to the need for inward airflow into the laboratory, providing protection to those outside who may be exposed to a biological agent. The current requirement at CL2 goes beyond the standard in the Directive. There are very few situations, where this measure is required at CL2, which by definition covers low risk activities. It is difficult to envisage activities, which require this measure that would not also require other CL3 associated measures (e.g. HEPA filter of extract; room sealability). Consequently, it is more appropriate for this measure only to be required at CL3. The proposed change has the benefit of creating a greater distinction between containment levels and provides consistency in the requirement for measure 13 in Table 2 of the regulations.
33. The current wording at CL3 goes beyond the standard in the Directive. For CL3, the proposal is to revert to the Directive, which indicates that this measure is required except for activities where transmission does not occur via airborne route. This change means that the control measure is only required when it is needed to control airborne infection.

Q2(a) Should containment measure 5 (inward airflow) of Table 1a be amended as suggested at CL2?

Q2(b) Should containment measure 5 (inward airflow) of Table 1a be amended as suggested at CL3?

Q2(c) Please provide some comments to support your answers including any costs or benefits that either of these changes may cause.

Table B-2: change to Table 1a (measure 6)

<table>
<thead>
<tr>
<th>Containment Measure</th>
<th>CL1</th>
<th>CL2</th>
<th>CL3</th>
<th>CL4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current wording</td>
<td>Extract and input air from the laboratory shall be HEPA filtered</td>
<td>Not required</td>
<td>HEPA filters required for extract air</td>
<td>HEPA filters required for extract and input air</td>
</tr>
<tr>
<td>Proposed wording</td>
<td>Extract and input air from the laboratory shall be HEPA filtered</td>
<td>Not required</td>
<td>Required except for activities where transmission does not occur via airborne route</td>
<td>HEPA filters required for extract and input air</td>
</tr>
</tbody>
</table>

34. This control measure is required to ensure that air is filtered before leaving (and at CL4, entering) the laboratory. The current requirement at CL3 goes beyond the standard in the Directive, which indicates that this measure is required except for activities where transmission does not occur via airborne route. This change means that the control measure is only required when it is needed to control airborne infection.

Q3(a) Should containment measure 6 (HEPA filtration) of Table 1a be amended as suggested at CL3?

Q3(b) Please provide some comments to support your answer including any costs or benefits that this change may cause.
Table B-3: change to Table 1a (measure 7)

<table>
<thead>
<tr>
<th>Containment Measure</th>
<th>Current wording</th>
<th>Proposed change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbiological safety cabinet / enclosure</td>
<td>Not required</td>
<td>Required where and to extend the risk assessment shows it is required</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>CL1</th>
<th>CL2</th>
<th>CL3</th>
<th>CL4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current wording</td>
<td></td>
<td>Required, and all procedures with infective materials required to be contained within a cabinet / enclosure</td>
<td></td>
<td>Class III cabinet required</td>
</tr>
<tr>
<td>Proposed change</td>
<td></td>
<td>Required, and all procedures with infective materials required to be contained within a cabinet / enclosure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

35. This containment measure is intended primarily to offer operator protection proportionate to the level of risk presented. At CL4, the regulation goes beyond the Directive (and the Biological Agents Directive) in prescribing a particular type of microbiological safety cabinet (MSC) (i.e. Class III MSC is a fully enclosed glove box). The proposed change is to revert more closely to the standard in the Directives and include the same wording as for CL3. The selection of the most appropriate MSC to provide high levels of operator and environmental protection will be based upon risk assessment and the benchmark set out in industry guidance. This approach makes the requirement less prescriptive and more closely aligned with the relevant Directives. This flexibility recognises that not all CL4 work (e.g. foot and mouth disease virus does not present a risk to the operator) requires a Class III MSC and also accommodates the use of alternative containment approaches for human pathogens (e.g. positive pressure suited systems), where a Class III MSC is not practicable. When combined with other MSC types (e.g. Class I MSC – open fronted cabinet), the suited systems can offer an equal level of protection.

Q4(a) Should containment measure 7 (microbiological safety cabinet) of Table 1a be amended as suggested at CL4?

Q4(b) Please provide some comments to support your answer including any costs or benefits that this change may cause.
### Table B-4: change to Table 1a (measure 17)

<table>
<thead>
<tr>
<th>Current wording</th>
<th>Containment Measure</th>
<th>CL1</th>
<th>CL2</th>
<th>CL3</th>
<th>CL4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inactivation of GMMs in contaminated material and waste</td>
<td>Required by validated means</td>
<td>Required by validated means</td>
<td>Required by validated means, with waste inactivated within the laboratory suite</td>
<td>Required by validated means, with waste inactivated within the laboratory suite</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Proposed wording</th>
<th>Containment Measure</th>
<th>CL1</th>
<th>CL2</th>
<th>CL3</th>
<th>CL4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inactivation of GMMs in contaminated material and waste</td>
<td><strong>Required by a validated means where and to the extent the risk assessment shows it is required</strong></td>
<td>Required by validated means</td>
<td>Required by validated means, with waste inactivated within the laboratory suite</td>
<td>Required by validated means, with waste inactivated within the laboratory suite</td>
<td></td>
</tr>
</tbody>
</table>

36. The Directive emphasises the need to assess the routes of disposal and means of inactivation for material contaminated with GMMs. The current requirement at CL1 goes beyond the standard specified in the Directive. The proposed change will revert to the standard in the Directive and make the requirement for inactivation of waste at CL1 to be determined by the risk assessment. This change would permit flexibility on the means and method by which inactivation is undertaken and remove the perceived mandatory use of an autoclave for this purpose. The proposed change in this containment measure will be supplemented by guidance to explain under what circumstances (i.e. where the GMM is biologically contained and therefore cannot survive, replicate, spread or transfer genetic material) it is permissible to dispose of waste without inactivation (see Annex B).

| Q5(a) | Should containment measure 17 (waste inactivation) of Table 1a be amended as suggested at CL1? |
| Q5(b) | Does the related guidance in Annex B clarify the requirements for inactivation of waste at CL1? |
| Q5(c) | Please provide some comments to support your answers including any benefits or costs that this change may cause. |
Table B-5: change to Table 1a (measure 19)

<table>
<thead>
<tr>
<th>Reference</th>
<th>Containment Measure</th>
<th>CL1</th>
<th>CL2</th>
<th>CL3</th>
<th>CL4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current wording</td>
<td>An observational window or alternative is to be present so that occupants can be seen</td>
<td>Required where and to extent the risk assessment shows it is required</td>
<td>Required where and to extent the risk assessment shows it is required</td>
<td>Required where and to extent the risk assessment shows it is required</td>
<td>Required where and to extent the risk assessment shows it is required</td>
</tr>
<tr>
<td>Proposed wording</td>
<td>An observational window or alternative is to be present so that occupants can be seen</td>
<td>Required where and to extent the risk assessment shows it is required</td>
<td>Required where and to extent the risk assessment shows it is required</td>
<td>Required where and to extent the risk assessment shows it is required</td>
<td>Required where and to extent the risk assessment shows it is required</td>
</tr>
</tbody>
</table>

37. The observation window (or equivalent) provides a means of viewing the occupants of the laboratory. At CL3, this goes beyond the standard in the Directive. The proposed change will revert to the Directive so that the observational window requirement would be determined by the risk assessment. This would bring the requirements in line with the Biological Agents Directive, where an observation window is only recommended at CL3 (i.e. not an absolute requirement). The current measure is often at odds with other regulatory requirements (e.g. security measures) and so the proposed change will allow equally effective alternatives (e.g. personal alarms, buddy systems, management procedures) that do not compromise the security of the laboratory.

Q6(a) Should containment measure 19 (observation window) of Table 1a be amended as suggested at CL3?

Q6(b) Please provide some comments to support your answer including any costs or benefits that this change may cause.
### Table B-6: change to Table 1c (measure 9)

<table>
<thead>
<tr>
<th>Containment Measure</th>
<th>CL1</th>
<th>CL2</th>
<th>CL3</th>
<th>CL4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current wording</td>
<td>Animals kept in isolators</td>
<td>Required where and to extent the risk assessment shows it is required</td>
<td>Required where and to extent the risk assessment shows it is required</td>
<td>Required</td>
</tr>
<tr>
<td>Proposed change</td>
<td>Animals kept in isolators</td>
<td><strong>Not required</strong></td>
<td>Required where and to extent the risk assessment shows it is required</td>
<td>Required</td>
</tr>
</tbody>
</table>

38. Isolators are intended to contain infected animals and afford a level of protection to users. It is not apparent in what situation this containment measure would be required at CL1. Consequently, it is more appropriate for this measure only to be required at CL2 and above. This is an entirely domestic requirement not in the Directive tables. However, the proposed change is limited to CL1, where isolators will not be required. This change reflects the HEPA requirements for isolators (Measure 5, Table 1c) and provides a greater distinction between CL1 and CL2.

**Q7(a)** Should containment measure 9 (isolators) of Table 1c be amended as suggested at CL1?

**Q7(b)** Please provide some comments to support your answer including any costs or benefits that this change may cause.
**Table B-7: change to Table 2 (measure 2)**

<table>
<thead>
<tr>
<th>Containment Measure</th>
<th>CL1</th>
<th>CL2</th>
<th>CL3</th>
<th>CL4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current wording</td>
<td>Closed systems located within a controlled area</td>
<td>Not required</td>
<td>Required where and to extent the risk assessment shows they are required</td>
<td>Required and required to be purpose built</td>
</tr>
<tr>
<td>Proposed wording</td>
<td>Closed systems located within a controlled area</td>
<td>Not required</td>
<td>Required where and to extent the risk assessment shows they are required</td>
<td>Required</td>
</tr>
</tbody>
</table>

39. The requirement relates to specifically building a controlled area to house a closed system at CL4 (rather than, for example, using an existing controlled area). This goes beyond the standard in the Directive. The proposed change will retain the need for a controlled area but remove the requirement for this area to be purpose built. Although this change will create an inconsistency between the GMO regulations and COSHH in the UK, there are currently no CL4 facilities of this type working with human pathogens and only one working with a specified animal pathogen. The intention would be to amend the Biological Agents Directive, when the opportunity arises.

**Q8(a)** Should containment measure 2 (controlled area) of Table 2 be amended as suggested at CL4?

**Q8(b)** Please provide some comments to support your answer including any costs or benefits that this change may cause.
Table B-8: change to Table 2 (measure 9)

<table>
<thead>
<tr>
<th>Reference</th>
<th>Containment Measure</th>
<th>CL1</th>
<th>CL2</th>
<th>CL3</th>
<th>CL4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current wording</td>
<td>Biohazard signs posted</td>
<td>Required where and to extent the risk assessment shows it is required</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Proposed change</td>
<td>Biohazard signs posted</td>
<td>Not required</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
</tr>
</tbody>
</table>

40. The intention of the biohazard sign is to inform those entering the facility of relevant hazards that may be present. At CL1, the current requirement goes beyond the standard in the Directive. The proposed change is to remove the need for a biohazard sign at CL1, which is of nil/negligible risk hence the biohazard sign is not necessary.

Q9(a) Should containment measure 9 (biohazard sign) of Table 2 be amended as suggested at CL1?

Q9(b) Please provide some comments to support your answer including any costs or benefits that this change may cause.
### Table B-9: change to Table 2 (measure 19)

<table>
<thead>
<tr>
<th>Containment Measure</th>
<th>CL1</th>
<th>CL2</th>
<th>CL3</th>
<th>CL4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current wording</td>
<td>Written procedures and records of staff training</td>
<td>Not required</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proposed wording</td>
<td>Written procedures and records of staff training discharge</td>
<td>Not required</td>
<td>Required where and to extent the risk assessment shows it is required</td>
<td>Required</td>
</tr>
</tbody>
</table>

41. The requirement for written procedures and training records arises in the Directive from the principles of good microbiological practice. The containment table is used in addition to the general principle to clarify this requirement. Currently at CL2, this measure is not required, however this is inconsistent with the similar requirement in measure 21 of Table 1a. By amending the requirement, to be risk based, this will remove inconsistencies in the containment tables and will not increase regulatory requirements unless the risk assessment indicates this is necessary.

Q10(a) Should containment measure 19 (records of training) of Table 2 be amended as suggested at CL2?

Q10(b) Please provide some comments to support your answer including any costs or benefits that this change may cause.
<table>
<thead>
<tr>
<th>Containment Measure</th>
<th>CL1</th>
<th>CL2</th>
<th>CL3</th>
<th>CL4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current wording</td>
<td>Required by validated means</td>
<td>Required by validated means</td>
<td>Required by validated means</td>
<td>Required by validated means</td>
</tr>
<tr>
<td>Proposed wording</td>
<td>Required by a validated means where and to extent the risk assessment shows it is required</td>
<td>Required by validated means</td>
<td>Required by validated means</td>
<td>Required by validated means</td>
</tr>
</tbody>
</table>

42. The Directive emphasises the need to assess the routes of disposal of and means of inactivation for material contaminated with GMMs. The current requirement at CL1 goes beyond the standard specified in the Directive. The proposed change will revert to the standard in the Directive and make the requirement for inactivation of waste at CL1 determined by the risk assessment. The proposed change in this containment measure will be supplemented by guidance to explain under what circumstances (i.e. where the GMM is biologically contained and therefore cannot survive, replicate, spread or transfer genetic material) it is permissible to dispose of waste without inactivation (see Annex B).

Q11(a) Should containment measure 21 (waste inactivation) of Table 2 be amended as suggested at CL1?

Q11(b) Please provide some comments to support your answer including any costs or benefits that this change may cause.
Table C: changes to the notification requirements and register

<table>
<thead>
<tr>
<th>Change</th>
<th>Reference in current regulations</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-1</td>
<td>Regulations 10(3) &amp; Schedules 5 &amp; 6</td>
<td>Information required in relation to an emergency plan</td>
</tr>
</tbody>
</table>

The requirement for an emergency plan is based upon the risk assessment determining that a foreseeable accident is liable to result in either the health of people outside the premises being seriously affected or a risk of serious damage to the environment. Currently the regulations place a duty on the Competent Authority to ensure an emergency plan is in place but is not explicitly risk based. Consequently, the amendments will clarify and make it explicit that the emergency plan should only be confirmed where the risk assessment identifies a need for one.

| C-2    | Regulation 10(1), Schedule 6 | Information required for a notification of Class 2 activities - provision of a risk assessment versus a summary of the risk assessment |

The current information required for a notification of a Class 2 activity requires the user to provide a risk assessment for the proposed activity. This goes beyond the information requirements within the Directive, which stipulates the provision of a summary of the assessment. It is unclear whether changing the requirement to reflect the Directive will reduce or increase regulatory burden, as this requires the user to create an appropriate summary containing all the relevant information to provide to the Competent Authority to allow them to judge the conformity and adequacy of the assessment. The current requirement simply requires provision of the risk assessment, which the user already has to undertake as a requirement of the regulations. On balance, it is proposed to keep the current provision.

| C-3    | Regulation 24(7), (8) | Register of notification – change from a paper copy to an electronic copy only |

The notifications made under the GMO regulations are maintained on a public register, which is held in HSE offices (in Bootle and Edinburgh) as a paper copy register and as an electronic document on the HSE website. The proposal is to withdraw the paper copy register and retain only an online electronic version. This change will not affect the accessibility by the public who may wish to inspect the register. The proposal will remove the administration costs involved in maintaining a paper copy in these two locations.

Q12(a) Should the emergency plan provisions be amended as suggested?

Q12(b) Would you prefer to a) submit a full risk assessment for Class 2 activities; or b) would you prefer to submit a summary of the assessment for Class 2 activities?

Q12(c) Do you have any objections to remove the hardcopy register of notifications and move to an electronic version (only)?

Q12(d) Please provide some comments to support your answers including any costs or benefits that these changes may cause.
Table D: requirements for a genetic modification safety committee (GMSC)

<table>
<thead>
<tr>
<th>D-1</th>
<th>Reference in current regulations</th>
<th>genetic modification safety committee (GMSC)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Regulation 16</td>
<td>A person who carries out an assessment pursuant to regulation 6 or 7 shall establish a genetic modification safety</td>
</tr>
<tr>
<td></td>
<td></td>
<td>committee to advise him in relation to that assessment</td>
</tr>
<tr>
<td></td>
<td>Proposed wording</td>
<td>(1) A user who carries out an assessment under regulation 6 or 7 must obtain advice on that assessment from either –</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(a) a person, or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) a genetic modification safety committee, with expertise in risk assessment relating to contained use.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(2) Where the risk assessment indicates that contained use will be at class 2 or above the user must obtain the</td>
</tr>
<tr>
<td></td>
<td></td>
<td>advice required under paragraph (1) from a genetic modification safety committee.</td>
</tr>
</tbody>
</table>

The proposal is to retain the requirement to obtain expert advice on risk assessments for GM activities but to introduce flexibility on whether this is provided by a competent individual or committee for Class 1 activities. This is proportionate to the level of risk at Class 1 and reduces the regulatory burden on smaller, start up companies who may not have the resources or the range of competencies in-house to make up a GMSC.

43. Users are required to establish a GMSC, which is required to provide advice on risk assessments made under the GMO regulations. The Directive is less prescriptive in that as part of the general principles, it requires that a biological safety committee or subcommittees should be established ‘if required’. The proposed change will permit advice on risk assessments for Class 1 activities to be obtained elsewhere (e.g. biological safety advisor, other organisations) and by a committee who’s remit is not solely focused on GM activities but has the appropriate expertise (e.g. biological safety committee). The requirement to establish a committee (if required) will be inserted into the general principles in Schedule 7(f) to provide consistency with the Directive. It is envisaged that collectively these changes will ensure adequate oversight is maintained but reduce the time spent by the committee discussing activities of nil or negligible risk. This change will be supplemented by additional explanation in the guide to the regulations (See Annex C).
| Q13(a) | Should the source of advice on risk assessments be amended as suggested for Class 1 risk assessments? |
| Q13(b) | Provided the committee has appropriate expertise, do you agree with multi-functional committees providing advice on GM risk assessments? |
| Q13(c) | Does the related guidance in Annex C clarify the requirements for the Genetic Modification Safety Committee? |
| Q13(d) | Please provide some comments to support your answer including any benefits or costs that these changes may cause. |
PART 2: Restructure and Tidy Up

44. One of the key objectives of the Löfstedt recommendation was to consolidate the four pieces of GMO(CU) legislation into one set of modern regulations, which technically and presentationally required changes to the structure and layout. As part of this restructure, the opportunity has been taken to reorganise some of the ‘Parts’ of the regulations to help differentiate between duties on the user and the Competent Authority (CA). This format clearly directs the user to the relevant requirements. The parts are:

- Part 1 – Interpretation and General
- Part 2 – Risk Assessment and Notification Activities Involving Genetic Modification
- Part 3 – Conduct of Activities Involving Genetic Modification
- Part 4 – Duties and Powers of the Competent Authority
- Part 5 – Miscellaneous and General
- Schedules

45. A copy of the proposed Statutory Instrument is at Annex A.

46. Table E below describes the main changes made to the GMO(CU) 2014 regulations with a view to reducing, simplifying and clarifying the legislation.
<table>
<thead>
<tr>
<th>Reference</th>
<th>Change</th>
<th>Reasoning</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-1</td>
<td>Separating the duties on the competent authority and the users</td>
<td>This change will assist users to navigate through the regulations and find the parts most relevant to them. The change reduces confusion and helps direct the user to their legal requirements. It should assist with compliance and aid transparency of the Competent Authority’s requirements under the regulations.</td>
</tr>
<tr>
<td>E-2</td>
<td>To replace the term “activity involving genetic modification” with “contained use”</td>
<td>Contained use is defined in the regulations as an activity in which organisms are genetically modified, consequently the use of the term “contained use” is shorter and clearer language.</td>
</tr>
<tr>
<td>E-3</td>
<td>To replace the term “person undertaking an activity involving genetic modification” with the term “user”. “User” will be defined as “person who undertakes or proposes to undertake contained use.”</td>
<td>Use of simple language</td>
</tr>
<tr>
<td>E-4</td>
<td>To replace the terms “GMOs other than micro-organisms” and “genetically modified animals and plants” with the term “larger GMOs (LGMOs)</td>
<td>Allows the use of one, shortened and simplified term instead of two interchanging terms</td>
</tr>
<tr>
<td>E-5</td>
<td>Streamlining of Schedule 6 for information required for notification of a Class 2, 3 or 4 contained use of micro-organisms, or contained use of larger GMOs</td>
<td>The information requirements in this Schedule have not changed. Much of the information required for notification of each class of contained use was duplicated in each part of the Schedule. The parts have been merged into a more streamlined format.</td>
</tr>
<tr>
<td>E-6</td>
<td>To remove or simplify Schedule 11 on the appeals process and use the procedure set out in s44 of the HSWA</td>
<td>The right to appeal against a decision by the CA will remain in the main body of the regulations, but the appeal process will either be removed from the Schedule or simplified to bring it in line with the approach for other permissioning/licensing regimes that fall under the Health and Safety at Work Act. This will make the procedure more transparent and consistent and can be more readily updated or amended without the need to change the legislation.</td>
</tr>
<tr>
<td></td>
<td>To remove out of date references to the rights of appeal against the decision to include information on the register</td>
<td>This right of appeal was removed following the 2005 Amendment Regulations, but some references were unintentionally left in and need to be removed.</td>
</tr>
</tbody>
</table>
Q14(a) Do you agree or disagree with the proposed changes to the structure and language of the regulations? If you disagree, please state which change you disagree with and why?

Q14(b) Should the term genetically modified organisms other than micro-organisms be amended as suggested? Are there alternatives that would be more appropriate?

Additional Matters

The saving and transitional arrangements

47. The saving and transitional arrangements are set out in Regulation 34 of the draft statutory instrument (annex A). These are intentionally brief as the changes introduced by the consolidation are limited and are unlikely to alter existing working practices. Whilst considered unlikely, several users may need to revise their activity classification, hence require notification to the Competent Authority. These notifications should be made within the 90 day transitional period. The approach taken in respect of the saving and transitional arrangements has been to accommodate any foreseeable eventuality in the least burdensome but most appropriate way. Additional guidance will be set out on the HSE website to support any user who is required to re-classify work as a result of the consolidation.

Q15(a) Are you content that the savings and transitional arrangements are adequate to cover the changes arising from the new regulations?

Q15(b) Please provide some comments to support your answer including whether you will be required to re-classify your work or notify under the transitional arrangements?

Application to synthetic biology

48. As set out in the UK’s published Synthetic Biology Roadmap, synthetic biology is the design and engineering of biological based parts, novel devices and systems as well as the redesign of existing, natural biological systems. Synthetic biology has the potential to deliver important new applications and improve existing industrial processes, which will potentially contribute to future economic growth and development. Areas of particular promise for synthetic biology include pharmaceuticals and environmentally sustainable fuels.

49. Currently, synthetic biology falls within the definition of genetic modification set out in the Directive 2009/41/EC (contained use) hence is encompassed within the GMO regulations and evidence shows that these provisions are adequate. However, future products of synthetic biology may increasingly challenge current risk assessment methodologies and their application may be outside of traditional contained use sectors or facilities. For the purposes of this consolidation, we do not

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propose to make any changes with respect to the application of the GMO regulations to synthetic biology. However views would be welcome on any difficulties this approach may present, particularly in terms of future applications and any longer term views on alternative regulatory approaches.

16(a) Does the application of GMO contained use regulations to synthetic biology present any practical problems?

16(b) Considering future applications (or products) of synthetic biology outside those of the traditional contained use sector, do you have views on any better-fit regulatory models suitable for the effective and responsible regulation of synthetic biology?

Impact Assessment

50. This consolidation, as one of the Löfstedt recommendations, falls under the ‘fast track’ criteria, which means the initial impact assessment stage can be bypassed to expedite the process for introducing new/revised legislation. However, given the nature of the consolidation and the proposed changes, it was felt appropriate to include the preliminary impact assessment (Annex D). Additional information is required in relation to some of the proposed changes to assess their impact. This will be gathered separately.

Q17(a) Do you have any views on any aspect of the preliminary impact assessment?

Q17(b) Are there any costs or benefits related to the proposed changes which have not been included in the impact assessment?

Guide to the Regulations

51. The subject matter of the regulations is highly technical. The guide to the current regulations has an amalgamation of regulatory and technical guidance, which makes the document dense, long and difficult for the user to navigate. Consequently, the intention is to provide a slim-line guide to the regulations restricted to explaining the regulatory requirements and moving the technical content to the Scientific Advisory Committee for Genetic Modification (SACGM) compendium of guidance.

52. In response to the feedback during informal consultation with practitioners, the guide to the regulations will include expanded sections on how to notify groups (rather than single) genetic modification activities (referred to in the regulations as ‘Connected Programmes of Work’) and when to notify ‘Significant Changes to Notifications’. Further explanation will also be provided in the SACGM compendium of guidance. There will also be specific explanatory guidance in relation to the changes to waste inactivation and the requirement for a GMSC. Stakeholders will be involved in the drafting of the guide including via the HSE’s on-line community established for the consolidation.

53. The intention is to replace the existing hard copy guide to the regulations (L29) with an on-line version only.
Q18(a) Do you have any objections to replacing the hardcopy of the guide to the regulations (L29) with an electronic on-line version (only)?

Q18(b) Please provide some comments to support your answer including any costs or benefits that this change may cause.

List of Annexes

**ANNEX A** – Draft Statutory Instrument of the Genetically Modified Organisms (Contained Use) Regulations 2014

**ANNEX B** – Supplementary guidance on the inactivation of waste at Class 1

**ANNEX C** – Supplementary guidance on the establishment of a GMSC

**ANNEX D** – Preliminary Impact Assessment

**ANNEX E** – Consultation Question Set
The Secretary of State, has been designated for the purposes of section 2(2) of the European Communities Act 1972(a) in relation to the control and regulation of genetically modified organisms.(b)

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972 and by sections 15(1) and (2) and 82(3)(a) of, and paragraphs 1(1)(b) and (c) and (3), 6(1) and 13(1) of Schedule 3 to, the Health and Safety at Work etc Act 1974(c) (“the 1974 Act”).

The Regulations give effect without modifications to proposals submitted to the Secretary of State by the Health and Safety Executive under section 11(3) of the 1974 Act.

Before submitting those proposals to the Secretary of State, the Health and Safety Executive consulted the bodies that appeared to be appropriate as required by section 50(3) of the 1974 Act.

PART 1

Interpretation and General

Citation and Commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) Regulations 2014 and come into force on 1st October 2014.

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

(a) 1972 c. 68.
(b) S.I. 1991/755.
(c) 1974 c 37. Section 15(1) was amended by the Employment Protections Act 1975 (c.71), Schedule 15, paragraphs 6 and 16 respectively. Section 15 was further amended by S.I. 2002/794. Section 50(3) was [further why?] amended by the Health Protection Agency Act 2004 (c.17), Schedule 3, paragraph 5(1) and (3) and by S.I. 2008/960, which also substituted section 11.
“the 1974 Act” means the Health and Safety at Work etc Act 1974;

“the 2000 Regulations” means the Genetically Modified Organisms (Contained Use) Regulations 2000;

“accident” means an incident involving a significant and unintended release of genetically modified organisms in the course of a contained use which presents an immediate or delayed hazard to human health or to the environment;

“class”, in relation to a contained use of micro-organisms, means one of the four classes described in Schedule 1;

“competent authority” means—

(a) as regards England and Wales, the Secretary of State and the Executive, acting jointly; and
(b) as regards Scotland, the Scottish Ministers and the Executive, acting jointly,

and the expressions “competent authority as regards England and Wales” and “competent authority as regards Scotland” are to be construed accordingly;

“contained use” means an activity in which organisms are genetically modified or in which genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which physical, chemical or biological barriers, or any combination of such barriers, are used to limit their contact with, and to provide a high level of protection for, humans and the environment;

“EEA State” means a State, other than the United Kingdom, which is a Contracting Party to the Agreement on the European Economic Area signed at Oporto on 2nd May 1992, as adjusted by the Protocol signed at Brussels on 17th March 1993 and adopted as respects the United Kingdom by the European Economic Area Act 1993(a);

“emergency plan” means a plan required by virtue of regulation 22;

“emergency services” means the police, fire and ambulance services;

“the Executive” means the Health and Safety Executive;

“genetic modification” in relation to an organism means the altering of the genetic material in that organism in a way that does not occur naturally by mating or natural recombination or both and within the terms of this definition—

(a) genetic modification occurs at least through the use of the techniques listed in Part I of Schedule 2; and
(b) the techniques listed in Part 2 of Schedule 2 are not considered to result in genetic modification,

and “genetically modified” are to be construed accordingly;

“human admixed embryo” has the same meaning as it has in the Human Fertilisation and Embryology Act 1990 by virtue of section 4A(6) and (11) of that Act;

“human embryo” means an embryo within the meaning given in the provisions of the Human Fertilisation and Embryology Act 1990 (apart from section 4A) by virtue of section 1(1) and (6) of that Act;

“joint competent authority” means the competent authority as regards England and Wales and the competent authority as regards Scotland, acting jointly;

“larger GMO” means an organism which is the subject of genetic modification which is not a micro-organism;

“micro-organism” means a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, and includes a virus, a viroid, and an animal or plant cell in culture;

(a) 1993 c. 51.
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“notifier” means a person who has submitted a notification to the competent authority under regulation 9(1), 10(1), 11(1), 12(1) or 13(1);
“organism” means a biological entity capable of replication or of transferring genetic material and includes a micro-organism, but does not include a human, human embryo or human admixed embryo;
“transboundary movement” has the meaning assigned to it by Article 3 of Regulation 1946/2003/EC of the European Parliament and of the Council on transboundary movements of genetically modified organisms;
“user” means a person who undertakes or proposes to undertake a contained use;
“working day” means any day other than a Saturday, a Sunday, Christmas Day or Good Friday, or a bank holiday within the meaning given by the Banking and Financial Dealings Act 1971.

(2) In these Regulations—
(a) in relation to a contained use, any reference to an appropriate containment level is a reference to the containment level assigned to that activity in accordance with paragraphs 3(h) and 4 of Part 2 of Schedule 3;
(b) any reference to a contained use in a numbered class is a reference to a contained use of micro-organisms which has been classified as belonging to the class of that number in accordance with paragraph 3(i) and (j) of Part 2 of Schedule 3; and
(c) in relation to a notification submitted in accordance with regulation 13 any reference to the competent authority is to be construed as a reference to the joint competent authority.

(3) The provisions in—
(a) Part 2 of Schedule 8 are to be applied in accordance with Part 1 of that Schedule; and
(b) Tables 1a, 1b and 1c in Part 2 of Schedule 8 are to be applied in accordance with the notes set out at the end of the Table in question.

Application

3.—(1) These Regulations have effect with a view to—
(a) protecting persons against risks to their health, whether immediate or delayed, arising from contained use; and
(b) protecting the environment against harm from contained use of micro-organisms.

(2) These Regulations (except regulation 19) do not apply to the genetic modification of organisms solely by any of the techniques referred to in Part 3 of Schedule 2 nor to any organisms so modified.

(3) These Regulations do not apply to any activity in which—
(a) genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used, where such organisms are or are contained in—
(i) a product marketed in accordance with—
(aa) a consent granted by the Secretary of State, or, as regards Scotland, by the Scottish Ministers, or, as regards Wales, by the National Assembly for Wales, under section 111(1) of the Environmental Protection Act 1990, or
(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(a), or
(cc) a written consent given by the competent authority of an EEA State in accordance with Article 13(4) of Council Directive 90/220/EEC or Article 15(3), 17(6), or 18(2) of Directive 2001/18/EC of the European Parliament

(a) 1991 No. 1714 (N.I.19).
and Council on the deliberate release into the environment of genetically modified organisms,

and, in each case, that activity is conducted in accordance with any conditions or limitations attached to that consent,

(ii) a medicinal product for human or veterinary use marketed in accordance with Council Regulation (EEC) No 2309/93 or Regulation (EC) No 726/2004 of the European Parliament and the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, or

(iii) food or feed authorised in accordance with the provisions of Regulation 1829/2003/EC of the European Parliament and of the Council on genetically modified food and feed, or

(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 Regulation 1829/2003/EC;

(b) genetically modified organisms are released or marketed in cases or circumstances in which the consent of the Secretary of State, or, as regards Scotland, the Scottish Ministers, or, as regards Wales, by the National Assembly for Wales, is required under section 111(1) of the Environmental Protection Act 1990 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) Regulations 8 to 17, 19(2) and (4), 20, 21, 24 to 26 do not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.

(5) Regulation 6 applies to the transport of genetically modified organisms by road, rail, inland waterway, sea or air, except that, in making the assessment required by regulation 6(1), the person undertaking that assessment is not required to include the steps set out in paragraph 3(i) to (k) of Part 2 of Schedule 3.

(6) These Regulations do not extend to Northern Ireland.

(7) In this regulation, “product” means a product consisting of or containing a genetically modified organism or a combination of genetically modified organisms.

Meaning of “work” and “at work”

For the purpose of these Regulations and Part I of the 1974 Act, the meaning of “work” is extended to include any contained use and the meaning of “at work” is extended accordingly.

Modification of the Health and Safety at Work etc Act 1974

(1) Sections 2(1), (2) and (3) and 7 of the 1974 Act are modified in relation to a contained use so as to have effect as if the reference to an employer in those sections includes a reference to an educational establishment providing a course of study, and the reference to an employee in those sections includes a reference to a student of that educational establishment and that student is treated as the employee of that educational establishment, to the extent that the contained use is under the control of that educational establishment.

(2) Section 3(2) of the 1974 Act is modified in relation to a contained use so as to have effect as if the reference in that section to a self-employed person is a reference to any person (except a student) who is not an employer or an employee and the reference in that section to that person’s undertaking includes a reference to such an activity.

(3) In this regulation—

“educational establishment” means a university, college, school or similar educational or technical institute; and

“student” means any person studying at an educational establishment.
PART 2
Risk Assessment and Notification of Contained Use

Risk assessment of contained use involving micro-organisms
6.—(1) Before commencing any contained use of micro-organisms the user must ensure that a suitable and sufficient assessment of the risks created to human health and the environment by the contained use has been carried out.
(2) The assessment required by paragraph (1) must take account of the matters set out in Part 1 of, and include the steps set out in, Part 2 of, Schedule 3.

Risk assessment of contained use involving larger GMOs
7.—(1) Before commencing any contained use involving larger GMOs the user must ensure that a suitable and sufficient assessment of the risks created to human health by the contained use has been carried out.
(2) The assessment required by paragraph (1) must take into account the matters set out in Part 1 of, and include the steps set out in Part 2 of, Schedule 4.

Review and recording of risk assessments
8.—(1) Where—
(a) there is reason to suspect that an assessment is no longer valid; or
(b) there has been a significant change in the contained use to which an assessment relates,
the user must ensure that the assessment is reviewed immediately.
(2) The user must—
(a) keep a record of the assessment relating to that activity, and any review of that assessment, for at least 10 years from the date that activity stops; and
(b) make the record available to the competent authority when requested to do so.
(3) In this regulation, “assessment” means an assessment carried out for the purposes of regulations 6 or 7.

Notification of the intention to use premises for the first time for contained use
9.—(1) A user must not use premises for the first time for a contained use, unless they have—
(a) submitted a notification to the competent authority that contains the information specified in Schedule 5; and
(b) received an acknowledgement from the Executive of receipt of that notification.
(2) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1).

Notification of class 2 activities involving contained use of micro-organisms
10.—(1) A user must not undertake a contained use of micro-organisms in class 2 unless they have submitted a notification to the competent authority that contains the information specified in Schedule 6 and the provisions of paragraph (3) or (4) have been fulfilled.
(2) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving the notification submitted in accordance with paragraph (1).
(3) Where the premises at which the class 2 contained use is to take place have not been the subject of a previous notification for contained use at class 2 or above the notifier may undertake contained use at class 2 if—
   (a) 45 days have elapsed since the date of the receipt of the acknowledgement referred to in paragraph (2) without the competent authority informing the notifier that they must not undertake the class 2 contained use in question; or
   (b) the competent authority has agreed in writing that the class 2 contained use may begin within a shorter period.

(4) Where the premises at which class 2 contained use notified under paragraph (1) is to take place have—
   (a) previously been notified for contained use at class 2; or
   (b) already been granted consent for contained use at class 3 or 4;
the notifier may undertake contained use at class 2 if the notifier has received the acknowledgement referred to in paragraph (2).

(5) Where a user submits a notification in accordance with paragraph (1) for a contained use which is to be undertaken for the second or subsequent time at the premises referred to in the notification, at the same time the user may request that the competent authority makes a decision whether or not to agree to their undertaking the contained use in question.

(6) The competent authority must make a decision requested in accordance with paragraph (5) within 45 days of the date on which the acknowledgement was sent in accordance with paragraph (2).

Notification of class 3 or class 4 contained use of micro-organisms

11.—(1) A user must not undertake a contained use of micro-organisms in class 3 or class 4 unless they have—
   (a) submitted to the competent authority a notification containing the information specified in Schedule 6; and
   (b) received the written consent of the competent authority to undertake the contained use in question.

(2) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1).

(3) Where the premises in the notification have not been the subject of a previous notification for contained use at class 3 or 4 the competent authority must inform the notifier in writing of its decision to grant or refuse consent for the contained use notified under paragraph (1) not more than 90 days after the acknowledgement was sent in accordance with paragraph (2).

(4) Where the premises in the notification have been the subject of a previous notification for contained use at class 3 or 4 and all relevant conditions have been complied with, the competent authority must inform the notifier in writing of its decision to grant or refuse consent for the contained use notified under paragraph (1) not more than 45 days after the acknowledgement was sent in accordance with paragraph (2).

(5) Before granting a consent under either paragraph (3) or paragraph (4), the competent authority must ensure that an emergency plan has been prepared where the risk assessment shows an emergency plan is required.

(6) Before deciding whether to grant or refuse a consent under either paragraph (3) or paragraph (4), the competent authority must take into account any representations made to it by any person within 30 days of the date on which the Executive sent the acknowledgement of receipt in accordance with paragraph (2).

(7) A consent granted under this regulation may be granted subject to conditions.
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Notification of contained use of larger GMOs

12.—(1) A user must not undertake a contained use of larger GMOs unless they have submitted a notification to the competent authority containing the information specified in Schedule 6 and either—

(a) 45 days have elapsed since the date of the receipt of acknowledgement referred to in paragraph (2) without the competent authority informing the notifier that that they must not undertake the contained use in question; or

(b) The competent authority has agreed in writing that the contained use may begin within a shorter period.

(2) The Executive must send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1).

(3) This regulation does not apply to a contained use of organisms which results in a larger GMO that poses no greater risk to humans than its unmodified parental organism.

Single notifications to the joint competent authority and of connected programmes of work

13.—(1) Where a notification is required—

(a) under regulation 9(1) in respect of premises which are situated on the border of England and Scotland; or

(b) under regulation 10(1), 11(1) or 12(1) in respect of a contained use which is to take place in premises situated on the border of England and Scotland,

the notifier must submit a single notification under the regulation in question to the joint competent authority.

(2) The competent authority may accept a single notification submitted under regulation 10(1), 11(1) or 12(1) in respect of a connected programme of work undertaken by the same person at—

(a) one site; or

(b) more than one site.

(3) The competent authority may accept a single notification submitted under regulation 10(1), 11(1) or 12(1) in respect of a single contained use undertaken by the same person at more than one site.

(4) In this regulation—

(a) “connected programme of work” means a series of activities involving contained use which form a coherent and integrated programme;

(b) “site” means premises of which the competent authority has been notified in accordance with regulation 9(1).

Action of notifier on receipt of request for further information

14.—(1) If further information is requested by the Executive under regulation 25(1), the notifier must not begin nor, subject to paragraph (2), continue the contained use until the competent authority has given its approval in writing.

(2) In the case of a notification under regulation 9(1), 10(1) or 12(1) if the notifier has commenced the contained use before the Executive requests additional information under regulation 25(1)—

(a) the Executive may give the notifier instructions concerning the cessation of the contained use;

(b) the notifier must comply with any such instructions;

(c) subject to any such instructions, the notifier may continue the contained use only to the extent necessary in order to store or destroy all genetically modified organisms resulting from the contained use.
Changes of circumstances relating to notifications

15.—(1) A notifier must immediately send to the competent authority full details in writing of—
   (a) any change in the information specified in paragraphs (a), (d) or (e) of Schedule 5 and provided by the notifier in accordance with regulation 9(1);
   (b) any new building—
      (i) added by the notifier to the premises previously notified by them in accordance with regulation 9(1), and
      (ii) under their control;
   (c) any decision by the notifier to cease using premises notified under regulation 9(1) for the purposes of a contained use;
   (d) any cessation for the time being of all contained use at premises notified under regulation 9(1);
   (e) any cessation of a contained use notified in accordance with regulation 10(1), 11(1) or 12(1);
   (f) any recommencement by the notifier of a contained use at premises in respect of which they had previously given details of a cessation under sub-paragraph (d) above;
   (g) any use by the notifier of additional premises in connection with a single contained use at more than one site where a single notification for that contained use was submitted under regulation 13(3);
   (h) any change in the information specified in—
      (i) paragraphs (b) and (c) of Schedule 5 and provided by the notifier in accordance with regulation 9(1), or
      (ii) paragraph (c) or (d) of Schedule 6 and provided by the notifier in accordance with regulation 10(1).

(2) Where—
   (a) a notifier has informed the competent authority of additional premises under paragraph (1)(g); and
   (b) those details, taken together with the notification for that single contained use submitted under regulation 13(3), provide all the information required for notification of those premises for the purposes of regulation 9(1)

the provision of such information will be treated as notification of those premises for the purposes of regulation 9(1).

(3) In this regulation “site” has the same meaning as it has in regulation 13.

Duty to notify of significant changes affecting risks

16.—(1) Where a notifier subsequently—
   (a) makes a change in the premises or the contained use to which their notification relates which may have significant consequences for the risks arising from the contained use; or
   (b) becomes aware of any new information which may have significant consequences for the risks arising from the contained use,

they must immediately send to the competent authority in writing full details of the change or the new information.

(2) Where the notifier—
   (a) undertakes a contained use with the written consent of the competent authority granted under regulation 11(1)(b) and,
   (b) has complied with the requirements of paragraph (1),
they need not make a further notification under regulation 11(1) relating to the change in
contained use referred to in paragraph (1).

Withdrawal of Notification

17. A notifier may withdraw their notification by giving written notice to the competent authority,
provided that the notifier has not commenced the contained use to which the notification relates.

PART 3
 Conduct of Contained Use

Establishment of a genetic modification safety committee

18.―(1) A user who carries out an assessment under regulation 6 or 7 must obtain advice on that
assessment from either—
(a) a person, or
(b) a genetic modification safety committee,
with expertise in risk assessment relating to contained use.

(2) Where the assessment indicates that contained use will be at class 2 or above the user must
obtain the advice required under paragraph (1) from a genetic modification safety committee.

Principles of occupational and environmental safety

19.―(1) A user who undertakes a contained use of micro-organisms must ensure that the exposure
of humans and the environment to genetically modified micro-organisms is reduced to the lowest
level that is reasonably practicable.

(2) For any contained use involving micro-organisms, the measures to be taken in order to
comply with the duty under paragraph (1) must include the general principles of good
microbiological practice and of good occupational safety and hygiene set out in Schedule 7.

(3) A user who undertakes a contained use of larger GMOs must ensure that harm to humans
arising from that activity is reduced to the lowest level that is reasonably practicable.

(4) For any contained use of larger GMOs, the general principles set out in Schedule 7 must be
applied insofar as they are appropriate.

Containment and control measures for contained use involving micro-organisms

20.―(1) Subject to paragraph (2), a user who undertakes a contained use of micro-organisms must
apply the containment measures set out in the applicable Table in Schedule 8, where and to the
extent required in the column of the appropriate containment level.

(2) The user need not apply a particular containment measure required for the appropriate
containment level where—
(a) a risk assessment, or any review of that assessment carried out in accordance with
regulation 8, shows that the particular containment measure is not necessary or
practicable for that activity;
(b) they have provided full justification in writing to the competent authority, and
(c) they have received the written agreement of the competent authority not to use that
containment measure.

(3) A user who undertakes a contained use of micro-organisms must review the containment
measures applied by them in accordance with paragraph (1)—
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(a) at suitably regular intervals; and

(b) immediately if that person suspects that—
   (i) the containment measures are no longer adequate,
   (ii) the class in relation to the contained use of micro-organisms identified in the risk assessment is no longer appropriate, or
   (iii) in the light of new scientific or technical knowledge, the risk assessment is no longer valid.

(4) In this regulation, “risk assessment” means an assessment carried out under regulation 6.

**Containment and control measures for contained use involving larger GMOs**

21.—(1) A user who undertakes a contained use of larger GMOs must apply the containment measures selected in accordance with the assessment made under regulation 7(1).

(2) The user must review the containment measures applied by them in accordance with paragraph (1)—
   (a) at suitably regular intervals; and
   (b) immediately if the user suspects that—
      (i) the containment measures applied are no longer adequate, or
      (ii) in the light of new scientific or technical knowledge, the assessment referred to in paragraph (1) is no longer valid.

**Emergency plans**

22.—(1) Where an assessment carried out under regulation 6(1) shows that, as a result of any reasonably foreseeable accident—
   (a) the health or safety of persons outside the premises in which a contained use is carried on is liable to be seriously affected; or
   (b) there is a risk of serious damage to the environment,

the user must ensure that, before the activity to which the assessment relates begins, a suitable plan is prepared with a view to securing the health and safety of those persons and the protection of the environment.

(2) Where an assessment carried out under regulation 7(1) shows that, as a result of any reasonably foreseeable accident, the health or safety of persons outside the premises in which a contained use is undertaken is liable to be seriously affected, the user must ensure that, before the activity to which the assessment relates begins, a suitable plan is prepared with a view to securing the health and safety of those persons.

(3) Every emergency plan must—
   (a) include the measures to be taken in the event of an accident to which the plan relates; and
   (b) be reviewed and, where necessary, revised at suitably regular intervals.

(4) The user undertaking the contained use which is the subject of an emergency plan must—
   (a) inform the emergency services and any body or authority liable to be affected by an accident to which the plan relates of the contents of the plan and of any relevant revisions made in accordance with paragraph (3)(b)22(2); and
   (b) make the plan and any such revisions publicly available.

**Information relating to accidents**

23. Where an accident occurs, the user must immediately inform the competent authority of the accident and must provide the following information—
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(a) the circumstances of the accident;
(b) the identity and quantity of the genetically modified organisms concerned;
(c) any information necessary to assess the effects of the accident on the health of the general population and on the environment; and
(d) any measures taken in response to the accident.

PART 4
Duties and powers of the competent authority

Duties on the competent authority on receiving notifications

24. The competent authority must examine a notification submitted under regulation 9(1), 10(1), 11(1), 12(1) or 13(1) for—
   (a) conformity with the requirements of these Regulations;
   (b) the accuracy and completeness of the information provided;
   (c) the correctness of the assessment carried out under regulation 6(1) or 7(1) and submitted to the competent authority with the notification;
   (d) the adequacy of the waste management and emergency response measures submitted with the notification; and
   (e) in the case of a notification submitted under regulation 10(1) or regulation 11(1) the correctness of the class assigned to the contained use of micro-organisms.
   (f) The inclusion of an emergency plan where the assessment carried out under regulation 6(1) or 7(1) indicates that such a plan is necessary.

Requests for further information

25.—(1) For the purpose of carrying out an examination of a notification in accordance with regulation 24, the Executive may request in writing the notifier to provide such additional information relating to the notification as it may specify.

   (2) If requested to do so by the Secretary of State or the Scottish Ministers, the Executive must request additional information under paragraph (1).

   (3) Within 10 working days, the Executive must acknowledge receipt of all additional information provided in response to a request made by the Executive under paragraph (1).

   (4) The period of time between the date when the Executive requests additional information in accordance with paragraph (2) and the date when the Executive receives that additional information will not be taken into account in calculating the period of days referred to in regulations 10(3), 10(4)10(6), 11(3), 11(4) or 12(1).

   (5) Where—
      (a) a notifier under regulation 9(1) has not commenced any contained use at the premises to which the notification relates, or a notifier under regulation 10(1), 11(1) or 12(1) has not commenced the contained use to which their notification relates;
      (b) the Executive requests additional information under paragraph (1); and
      (c) the notifier in question does not provide that information within a period of six months of the date on which the Executive sent the request,
       the competent authority may return the notification to that notifier.

Powers of competent authority in relation to activities which must be notified

26. The competent authority may at any time by notice in writing to a user—
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(a) set a time limit for, or impose conditions with regard to, a particular contained use;
(b) require the user to suspend, to terminate or not to commence a particular contained use;
(c) revoke or vary a consent granted to the user under regulation 11,
and the user must comply with that notice.

Register of notifications

27.—(1) This regulation is subject to regulation 28.

(2) The competent authority must maintain a register of every notification submitted under regulations 9 to 12.

(3) Subject to paragraph (4) the register must contain—

(a) in relation to every notification submitted under regulations 9 to 12—
   (i) the name, address and telephone number and any fax number and any e-mail address
       of the notifier
   (ii) the date on which the receipt of the notification was acknowledged by the Executive,
       and
   (iii) where the competent authority receives details of a matter referred to in sub-
       paragraphs (a) to (g) of regulation 15(1) or in regulation 16(1), confirmation that
       such details have been received;
(b) in relation to each notification submitted under regulation 10(1), 11(1) or 12(1), the date
    of any cessation of the contained use to which the notification relates;
(c) in relation to each notification submitted under regulation 9(1)—
   (i) the information specified in paragraphs (d) to (g), (h)(ii) and (h)(iii) of Schedule 5,
   and
   (ii) confirmation of receipt of required information if the competent authority has been
    informed of an accident under regulation 23 at the premises to which the notification
    relates;
(d) in relation to each notification submitted under regulation 10(1), the information
    specified in paragraphs (e) to (k) and (m)(i) and (ii) of Schedule 6;
(e) in relation to each notification submitted under regulation 11(1)—
   (i) the information specified in paragraphs (e) to (j), (1), (m)(i)(iii) and (iv) and (r) of
       Schedule 6 and
   (ii) if appropriate, confirmation that a consent under regulation 11(3) or 11(4) as the case
       may be, has been granted;
(f) in relation to each notification submitted under regulation 12(1), the information
    specified in paragraphs (e) to (j) and (m)(i) of Schedule 6.

(4) The register must not contain any information which the competent authority has decided
must be kept confidential under the provisions of the Environmental Information Regulations
2004 or the Environmental Information (Scotland) Regulations 2004.

(5) Information must be entered in the register within 14 days of its receipt by the competent
authority.

(6) The competent authority may remove from the register—

(a) information relating to a contained use ten years after being notified in accordance with
    regulation 15(1)(d) or (e) that the contained use has ceased; and
(b) information relating to premises ten years after being notified in accordance with
    regulation 15(1)(c) of a decision to cease to use such premises for the purposes of
    undertaking any contained use.
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(7) A copy of the register will be made available to members of the public by the Executive by such means as it considers appropriate which may include by publishing on its website.

(8) In this regulation, “the register” means the register maintained by the competent authority in accordance with paragraph (2).

Information not to be included in the register

28.—(1) No information may be included in the register if and so long as, in the opinion of the Secretary of State, the inclusion in the register of that information, or information of that description, would be contrary to the interests of national security.

(2) For the purpose of securing the exclusion from the register of information to which paragraph (1) applies, the Secretary of State may give to the competent authority directions—

(a) specifying information, or descriptions of information, to be excluded from the register; or

(b) specifying descriptions of information to be referred to the Secretary of State for their determination.

(3) No information referred to the Secretary of State under paragraph (2)(b) may be included in the register until the Secretary of State determines that it should be so included.

(4) The competent authority must notify the Secretary of State of any information it excludes from the register in accordance with directions given to it under paragraph (2).

(5) A person may give a written notice to the Secretary of State—

(a) specifying information which appears to that person to be information to which paragraph (1) may apply; and

(b) indicating its apparent nature.

(6) If a person gives a written notice under paragraph (5), at the same time that person must give written notice to the competent authority that they have done so.

(7) No information notified under paragraph (5) may be included in the register until the Secretary of State has determined that it may be so included.

Exemption certificates

29.—(1) Subject to paragraph (2), the competent authority may, by a certificate in writing, exempt—

(a) any person or class of persons; or

(b) any genetically modified organism or class of genetically modified organisms, from all or any of the requirements of, or prohibitions imposed by, these Regulations and any such exemption may be granted subject to conditions and to a time limit and may be revoked by a certificate in writing at any time.

(2) The competent authority must not grant an exemption unless, having regard to the circumstances of the case and in particular to—

(a) the conditions, if any, that it proposes to attach to the exemption; and

(b) any requirements imposed by or under any enactments which apply to the case, it is satisfied about the matters referred to in paragraph (3).

(3) The matters about which the competent authority must be satisfied for the purposes of paragraph (2) are—

(a) that the health and safety of persons who are likely to be affected by the exemption will not be prejudiced in consequence of it; and

(b) where the exemption relates to a contained use of a micro-organism, that the environment will not be prejudiced in consequence of the exemption.
Duties on receipt of information about accidents

30. Where the competent authority is informed of an accident in accordance with regulation 23, it must—

(a) ensure that any necessary measures are taken;
(b) immediately inform those EEA States which could be affected by the accident;
(c) collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit their effects; and
(d) send to the European Commission—
   (i) the information provided under regulation 23(a), (b) and (d),
   (ii) information on the effectiveness of the measures taken in response to the accident, and
   (iii) an analysis of the accident, including recommendations to limit its effects and to avoid similar accidents in the future.

PART 5
Miscellaneous and General

Enforcement

31.—(1) Subject to paragraph (2) and to the extent they would not otherwise do so, the provisions of—

(a) sections 16 to 26 (approved codes of practice and enforcement) and sections 33 to 42 (provisions as to offences) of the 1974 Act; and
(b) the Health and Safety (Training for Employment) Regulations 1990,

apply to these Regulations as if they were health and safety regulations for the purposes of that Act, and any function of the Health and Safety Executive under any other provision of the 1974 Act under or in respect of health and safety regulations (including their enforcement) are exercisable as if these Regulations were, to the extent they would not otherwise be so, health and safety regulations for the purposes of that Act.

(2) A failure to discharge a duty placed on the competent authority or the Executive by these Regulations is not an offence, and section 33(1)(c) of the 1974 Act has effect accordingly.

(3) Notwithstanding regulation 3 of the Health and Safety (Enforcing Authority) Regulations 1998, the enforcing authority for these Regulations is the Executive.

Appeals

32.—(1) A user may appeal to the appropriate person about the following—

(a) A decision by the competent authority—
   (i) that the user may not undertake a contained use referred to in regulation 10(1), 11(1) or 12(1);
   (ii) to refuse to agree under regulation 20(2) that the user need not apply a particular containment measure for a contained use;
   (iii) to revoke an exemption certificate granted to the user under regulation 29(1); or
   (iv) to impose conditions or a time limit on an exemption certificate issued to the user under regulation 29(1),
(b) an instruction to the user from the Executive under regulation 14(2)(a);
(c) a request to the user for additional information by the Executive under regulation 25(1); or

(d) a notice given to the user by the competent authority under regulation 26.

(2) Sub-sections (2) to (6) of section 44 of the 1974 Act apply for the purposes of paragraph (1) as they apply to an appeal under section 44(1) of that Act with the modification that references to the Secretary of State are to be read as references to the appropriate person.

(3) Where the Secretary of State is the appropriate person the England and Wales Procedure Rules apply with the modification that references to a licensing authority are to be read as references to the competent authority.

(4) Where the Secretary of State and the Scottish Ministers are the appropriate person and the appeal relates either to premises or contained use which are situated in Scotland the Scotland Procedure Rules apply with the modification that references to a licensing authority are to be read as references to the joint competent authority.

(5) Where the Secretary of State and the Scottish Ministers are the appropriate person and the appeal relates to premises or contained use which are situated on the borders between England and Scotland—

(a) the appropriate person will determine whether the England and Wales Procedure Rules or the Scotland Procedure Rules apply to that appeal; and

(b) in either case the Rules will apply with the modification that references to a licensing authority are to be read as references to the joint competent authority.

(6) Where an appeal is brought under this regulation, none of the following are suspended pending the final determination of the appeal—

(a) a decision of the competent authority;

(b) an instruction given under regulation 14(2)(a)

(c) the operation of regulations 14(1) or 25(3);

(d) a notice given under regulation 26.

(7) In this regulation, “the appropriate person” means—

(a) the Secretary of State, in the case of—

(i) an appeal under paragraph (1)(a) or (d) against a decision of, or a notice given by, the competent authority as regards England and Wales, or

(ii) an appeal under paragraph (1)(b) or (c) against a request or instruction relating to—

(aa) the undertaking or proposed undertaking of a contained use, or

(bb) premises which are the subject of a notification under regulation 9(1) and which are situated,

in England or Wales;

(b) the Secretary of State and the Scottish Ministers, acting jointly, in the case of—

(i) an appeal under paragraph (1)(a) or (d) against a decision of, or a notice given by, the competent authority as regards Scotland or the joint competent authority, or

(ii) an appeal under paragraph (1)(b) or (c) against a request or instruction relating to—

(aa) the undertaking or proposed undertaking of a contained use in premises situated, or

(bb) premises which are the subject of a notification under regulation 9(1) and are situated,

wholly in Scotland or on the border between England and Scotland.

(8) In this regulation—

(a) the “England and Wales Procedure Rules” mean the Health and Safety Licensing Appeals (Hearings Procedure) Rules 1974; and
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(b) the “Scotland Procedure Rules” mean the Health and Safety Licensing Appeals (Hearing Procedure) (Scotland) Rules 1974.

Competent authority address

33. Anything required to be submitted or sent to the competent authority under these Regulations must be submitted to the address published from time to time on the website of the Executive, which may be, or include, an address for submission by electronic means.

Saving and Transitional provisions

34.—(1) Subject to paragraph (2) the following continue to have effect and will be deemed to have been made or done under these Regulations as follows;

(a) a notification made by a user under regulations 9 to 13 of the 2000 Regulations, as long as the notification complied with the provisions of those Regulations, as if the notification had been made by a user under the corresponding regulation of these Regulations;

(b) a consent granted by the competent authority under regulation 10 or 11 of the 2000 Regulations as if it were granted under the corresponding regulation of these Regulations;

(c) An agreement by the competent authority under regulation 18(2) of the 2000 Regulations that a user need not apply a specific containment measure, as if it were made under regulation 20(2) of these Regulations;

(d) a request for information made under regulation 14(2) of the 2000 Regulations, as if it were made under regulation 25(1) of these Regulations;

(e) a condition, limit of time or other requirement imposed by the competent authority under regulation 15(1) of the 2000 Regulations as if it were imposed under regulation 26 of these Regulations.

(2) Where—

(a) a user was undertaking contained use before the relevant date in accordance with the 2000 Regulations; and

(b) under the new Regulations a change in one or more of the required containment measures in Schedule 8 increases the class of that contained use,

the user must submit a notification to the competent authority containing the information required in Schedule 6 that is applicable to the new class of contained use.

(3) The notification must be submitted to the competent authority within the specified period.

(4) The competent authority may exempt a user referred to in (2) above from some or all of the requirements of Schedule 6.

(5) Where a notification is submitted under paragraph (2) for a contained use that requires consent at class 3, the competent authority must inform the user of its decision whether or not to grant consent within 90 days of receipt of the notification.

(6) The provisions of regulations 25 to 28 of these Regulations apply to a notification submitted under paragraph (2) as if it were a notification under regulations 9 to 13.

(7) The contained use referred to in paragraph (2) may continue as long as;

(a) The notification is submitted within the specified period;

(b) The risk assessment shows no change in the risks associated with the contained use;

(c) The competent authority does not require the user to suspend or terminate the contained use under regulation 24 of these Regulations;

(d) The competent authority has not refused consent for the contained use.
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(8) Where the competent authority grants consent for a class 3 activity with conditions which are not already imposed on that contained use, the competent authority may allow an additional period of time for the user to comply with those conditions.

(9) In this regulation

“relevant date” is the date on which these Regulations come into force

“specified period” is the period of 90 days beginning with the relevant date.

(10) Every record required to be kept under regulation 8(2) of the 2000 Regulations must be kept in the same manner and for the same period as specified in that regulation as if these Regulations had not been made.

Revocations,

35. The following are revoked—

(a) the 2000 Regulations,
(b) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002(a),
(c) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005(b), and
(d) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010(c).

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

Name: Minister of State

Date: Department for Work and Pensions

SCHEDULE 1

Regulation 2(1)

Classes Of Contained Use

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Activities of no or negligible risk, for which containment level 1 is appropriate to protect human health and the environment.</td>
</tr>
<tr>
<td>2</td>
<td>Activities of low risk, for which containment level 2 is appropriate to protect human health and the environment.</td>
</tr>
<tr>
<td>3</td>
<td>Activities of moderate risk, for which containment level 3 is appropriate to protect human health and the environment.</td>
</tr>
<tr>
<td>4</td>
<td>Activities of high risk, for which containment level 4 is appropriate to protect human health and the environment.</td>
</tr>
</tbody>
</table>

(a) S.I. 2002/63
(b) S.I. 2005/2466
(c) S.I. 2010/2840
SCHEDULE 2

PART 1
Examples of Techniques Constituting Genetic Modification

1. Examples of the techniques which constitute genetic modification which are referred to in subparagraph (a) of the definition of "genetic modification" in regulation 2(1) are—
   (a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;
   (b) techniques involving the direct introduction into an organism of heritable genetic material prepared outside the organism, including micro-injection, macro-injection and micro-encapsulation;
   (c) cell fusion or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART 2
Techniques which are not Considered to Result in Genetic Modification

2. The following techniques are not considered to result in genetic modification provided that they do not involve the use of genetically modified organisms made by techniques other than those listed in Part 3 or the use of recombinant nucleic acid molecules, namely—
   (a) in vitro fertilisation;
   (b) natural processes including conjugation, transduction or transformation;
   (c) polyploidy induction.

PART 3
Techniques to which These Regulations do not Apply

3. These Regulations (except regulation 19) do not apply to the following techniques of genetic modification, provided that they do not involve the use of recombinant nucleic acid molecules or of genetically modified organisms other than those recombinant nucleic acid molecules or genetically modified organisms produced by one or more of the following techniques of genetic modification—
   (a) Mutagenesis;
   (b) cell fusion (including protoplast fusion) of prokaryotic species which can exchange genetic material through homologous recombination;
   (c) cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions;
   (d) self-cloning, where the resulting organism is unlikely to cause disease or harm to humans, animals or plants.

4. In paragraph 3—
   (a) "self-cloning" means the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent), whether or not altered by enzymic or mechanical processes, into
cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by homologous recombination; and

(b) self-cloning may include the use of recombinant vectors, with an extended history of safe use in the particular organism, to manipulate and reinsert the nucleic acid sequences, but the vectors must not consist of any genetic elements other than those designed for vector structure, vector replication, vector maintenance or marker genes.

SCHEDULE 3 Regulations 2(2), 3(5) and 6(2)

PART 1

Matters to be Taken into Account in Carrying Out an assessment for the Purposes of Regulation 6

1. The following matters must be taken into account in carrying out an assessment for the purposes of regulation 6—
   (a) any potentially harmful effects, in particular those associated with—
      (i) the recipient micro-organism,
      (ii) the inserted genetic material (originating from the donor organism),
      (iii) the vector,
      (iv) the donor micro-organism (where that donor micro-organism is used during the contained use), and
      (v) the resulting genetically modified micro-organism;
   (b) the characteristics of the activity;
   (c) the severity of the potentially harmful effects;
   (d) the likelihood of the potentially harmful effects being realised; and
   (e) the disposal of waste and effluents.

2. In paragraph 1, "potentially harmful effects" includes—
   (a) disease to humans including allergenic or toxic effects;
   (b) disease to animals or plants;
   (c) adverse effects resulting from the inability to treat disease or offer an effective prophylaxis;
   (d) adverse effects resulting from establishment or dissemination of the genetically modified micro-organisms in the environment;
   (e) adverse effects resulting from the natural transfer of genetic material to or from other organisms;
   (f) adverse effects resulting from the likely interaction of the genetically modified micro-organism with other organisms at the premises where the contained use is to be conducted.

PART 2

Steps to be Included When Carrying out an Assessment for the Purposes of Regulation 6

3. An assessment carried out for the purposes of regulation 6 must include—
   (a) identification of any harmful properties of the recipient and, where appropriate, the donor micro-organism;
(b) identification of any harmful properties associated with the vector or inserted material, including any alteration in the recipient's existing properties;

(c) recognition that, in general, only contained uses which show the following characteristics are appropriate for inclusion in class 1 as described in Schedule 1—
   (i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants,
   (ii) the nature of the vector and the insert is such that they do not endow the genetically modified micro-organism with a phenotype likely to cause disease to humans, animals or plants, or likely to cause deleterious effects on the environment, and
   (iii) the genetically modified micro-organism is unlikely to cause disease to humans, animals or plants and is unlikely to have deleterious effects on the environment;

(d) consideration of relevant EU legislation, including Council Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work, other classification schemes referring to plant and animal pathogens, and other international and national classification schemes for genetically modified micro-organisms;

(e) identification of the provisional level of risk associated with the genetically modified micro-organism;

(f) consideration of—
   (i) the characteristics of the environment likely to be exposed,
   (ii) the characteristics of the contained use of micro-organisms, and
   (iii) any contained use of micro-organisms which cannot be adequately controlled by standard laboratory procedures, and which presents risks which require controls for each individual case;

(g) adjustment of the provisional level of risk in the light of the matters referred to in subparagraph (f) above;

(h) selection of the appropriate containment measures from those specified in the applicable Table in Schedule 8 on the basis of the provisional level of risk as adjusted in accordance with sub-paragraph (f) above;

(i) assignment of the contained use of micro-organisms to the appropriate containment level, in accordance with paragraph 4;

(j) classification of that activity in the class of the same number as that of the appropriate containment level; and

(k) review and reconsideration of that classification in the light of the completed assessment.

4. To assign a contained use of micro-organisms to the appropriate containment level for the purposes of paragraph 3(h), the person carrying out the assessment for the purposes of regulation 6 must—

   (a) first identify for each selected containment measure the column in the applicable Table in Schedule 8 having the lowest number in which that selected containment measure is shown as being required, regardless of whether or not such requirement is subject to any qualification;
   (b) then select the highest number of all the columns identified in accordance with subparagraph (a) above; and
   (c) then assign the contained use in question to the containment level of that highest number.

5. In paragraph 4, "selected containment measure" means an appropriate containment measure selected in accordance with paragraph 3(h).
SCHEDULE 4

PART 1

Matters to be Taken into Account in Carrying out an Assessment for the Purposes of Regulation 7

1. The following matters must be taken into account in carrying out an assessment for the purposes of regulation 7—
   (a) the identification of any potentially harmful effects, in particular those associated with--
       (i) the recipient organism,
       (ii) the inserted genetic material (originating from the donor organism),
       (iii) the vector,
       (iv) the donor organism, and
       (v) the resulting genetically modified organism;
   (b) the characteristics of the contained use;
   (c) the severity of the potentially harmful effects; and
   (d) the likelihood of the potentially harmful effects being realised.

2. In paragraph 1, "potentially harmful effects" includes—
   (a) disease to humans including allergenic or toxic effects;
   (b) acting as a human disease vector or reservoir;
   (c) adverse effects to humans arising from change in behaviour or in physical nature;
   (d) adverse effects arising from the inability to treat human disease or offer effective prophylaxis.

PART 2

Steps to be Included When Carrying out an Assessment for the Purposes of Regulation 7

3. An assessment carried out for the purposes of regulation 7 must include—
   (a) identification of the harmful properties of the recipient and, where appropriate, the donor organism;
   (b) identification of any harmful properties associated with the vector or inserted material, including any alteration in the existing properties of the recipient;
   (c) identification of the provisional level of risk associated with the genetically modified organisms;
   (d) selection of containment and other protective measures on the basis of--
       (i) the provisional level of risk, and
       (ii) the characteristics of the contained use;
   (e) adjustment of the level of risk in the light of the matters referred to in sub-paragraph (d) above; and
   (f) review and reconsideration of the containment and other protective measures in the light of the steps required by sub-paragraphs (a) to (e) above.
SCHEDULE 5  Regulations 9(1), 15(1) and 27

Information Required for a Notification Under 9(1)

A notification required for the purposes of regulation 9(1) must contain the following information—

(a) the name, address and telephone number and any fax number and any e-mail address of the notifier;
(b) the name of the employee of the notifier with specific responsibility for the supervision and safety of contained use;
(c) information on the training and qualifications of that employee;
(d) details of any genetic modification safety committee established under regulation 18;
(e) the address of the premises where the contained use is to be carried out and a general description of the premises;
(f) the nature of the work to be undertaken;
(g) the class of any contained use of micro-organisms;
(h) where the first activity to be carried out in those premises is a contained use in class 1—
   (i) a summary of the assessment of that activity made for the purposes of regulation 6(1),
   (ii) any advice received in relation to that assessment from a genetic modification safety committee,
   (iii) information on waste management, and
   (iv) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of the emergency plan and of any relevant revisions made in accordance with regulation 22(3); and
(i) where the first activity to be carried out in those premises involves genetic modification of larger GMOs and that activity is not notifiable under regulation 12(1)—
   (i) a copy of the assessment made for the purposes of regulation 7(1), and
   (ii) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of the plan and of any relevant revisions made in accordance with regulation 22(3).

SCHEDULE 6  Regulations 10(1), 11(1), 12(1)

Information Required for Notifications other than under Regulation 9

A notification required for the purposes of regulations 10(1), 11(1) and 12(1) must contain the information below except where it is required only for a specified regulation—

(a) the name, address and telephone number and any fax number and any e-mail address of the notifier;
(b) the centre number allocated by the competent authority in respect of the premises at which the contained use is to be undertaken and the date of the notification required by regulation 9(1) relating to those premises;
(c) the name of the employee of the notifier with specific responsibility for supervision and safety;
(d) information on the training and qualifications of that employee;
(e) the recipient or parental micro-organism to be used;
(f) the donor micro-organism to be used;
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(g) where applicable, the host-vector system to be used;
(h) the source and intended function of the genetic material involved in the modification;
(i) the identity and characteristics of the genetically modified micro-organism;
(j) the purpose of the contained use, including its expected results;
(k) for regulation 10(1) the approximate culture volumes to be used;
(l) for regulation 11(1) the culture volumes to be used;
(m) a description of the containment and other protective measures to be applied, including—
   (i) information on waste management, including the type and form of wastes to be generated, their treatment, ultimate form and destination, and
   (ii) for regulation 10(1) justification for not applying any containment measure at containment level 2;
   (iii) for regulation 11(1) where the contained use is at class 3 justification for not applying any containment measure at containment level 3;
   (iv) for regulation 11(1) where the contained use is at class 4 justification for not applying any containment measure at containment level 4;
(n) for regulations 10(1) and 11(1) a copy of the assessment carried out under regulation 6(1);
(o) for regulation 10(1) any advice received in relation to that assessment from the genetic modification safety committee established under regulation 16;
(p) for regulation 12(1) a copy of the assessment carried out under regulation 7(1);
(q) information in relation to any accident prevention and emergency plans to include;
   (i) the information necessary for the competent authority to evaluate any emergency plan;
   (ii) confirmation that the emergency services and any body or authority liable to be affected by an accident to which any emergency plan relates will be informed of the contents of the plan and of any relevant revisions made in accordance with regulation 22(3).
   (iii) for regulation 11(1) this should also include
      (aa) any specific hazards arising from the location of the installation,
      (bb) the preventive measures applied, including safety equipment, alarm systems and containment methods,
      (cc) procedures and plans for verifying the continuing effectiveness of the containment measures,
      (dd) a description of the information provided to workers;
(r) for regulation 11(1) a description of the parts of the installation; and
(s) for regulation 11(1) whether the genetically modified organism is likely to be subject to transboundary movement.

SCHEDULE 7

Regulation 19

General Principles of Good Microbiological Practice and of Good Occupational Safety and Hygiene

The general principles of good microbiological practice and of good occupational safety and hygiene are as follows—

(a) keeping workplace and environmental exposure to any genetically modified micro-organism to the lowest reasonably practicable level;
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(b) exercising engineering control measures at source and supplementing these with appropriate personal protective clothing and equipment where necessary;
(c) testing adequately and maintaining control measures and equipment;
(d) testing, where necessary, for the presence of viable process organisms outside the primary physical containment;
(e) providing appropriate training of personnel;
(f) establishing a genetic modification safety committee, if required;
(g) formulating and implementing local codes of practice for the safety of personnel, as required;
(h) displaying biohazard signs where appropriate;
(i) providing washing and decontamination facilities for personnel;
(j) keeping adequate records;
(k) prohibiting in the work area eating, drinking, smoking, applying cosmetics or the storing of food for human consumption;
(l) prohibiting mouth pipetting;
(m) providing written standard operating procedures where appropriate to ensure safety;
(n) having effective disinfectants and specified disinfection procedures available in case of spillage of genetically modified micro-organisms; and
(o) providing safe storage for contaminated laboratory equipment and materials where appropriate.

SCHEDULE 8 Regulations 2(3) and 20(1)

Containment Measures

PART 1

1. In this Schedule—

"GMMs" means genetically modified micro-organisms;
"HEPA" means High Efficiency Particulate Air;
"inactivation" means the complete or partial destruction of GMMs so as to ensure that any contact between the GMMs and humans or the environment is limited to an extent commensurate with the risks identified in the risk assessment and to provide a high level of protection for humans and the environment;
"plant growth facilities" means a structure, whether permanent or impermanent, designed and used principally for growing plants in a controlled and protected environment; and
"risk assessment" means the assessment carried out in accordance with regulation 6.

2. For the purposes of this Schedule, where, in the final column of Table 1b or 1c, a measure is specified as—

(a) a modification, it is to be read in substitution for the relevant measure in Table 1a;
(b) additional, it is to be read as an addition to the measures in Table 1a, subject to the substitution, where appropriate, of an individual measure in Table 1a by a measure specified as a modification in the Table in question.
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3. For the purposes of this Schedule—
   (a) Table 1a describes containment measures applicable to contained use of micro-organisms in laboratories;
   (b) Table 1a, read with Table 1b, describes containment measures applicable to contained use of micro-organisms in plant growth facilities;
   (c) Table 1a, read with Table 1c, describes containment measures applicable to contained use of micro-organisms in animal units;
   (d) Table 2 describes containment measures applicable to contained use of micro-organisms in premises other than those referred to in Tables 1a, 1b and 1c.

PART 2

Table 1a: Containment Measures for Contained Use of Micro-organisms in Laboratories

<table>
<thead>
<tr>
<th>Containment Measures</th>
<th>Containment Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Laboratory suite; isolation <strong>(Note 1)</strong></td>
<td>not required</td>
</tr>
<tr>
<td>Laboratory: sealable for fumigation</td>
<td>not required</td>
</tr>
<tr>
<td><strong>Equipment</strong></td>
<td></td>
</tr>
<tr>
<td>Surfaces impervious to water, resistant to acids, alkalis, solvents, disinfectants and decontamination agents and easy to clean</td>
<td>required for bench</td>
</tr>
<tr>
<td>Entry to lab via airlock <strong>(Note 2)</strong></td>
<td>not required</td>
</tr>
<tr>
<td>Negative pressure relative to the pressure of the immediate surroundings</td>
<td>not required</td>
</tr>
<tr>
<td>Extract and input air from the laboratory must be HEPA filtered</td>
<td>not required</td>
</tr>
<tr>
<td>Microbiological safety cabinet/enclosure</td>
<td>not required</td>
</tr>
</tbody>
</table>

**Note 1:**
- 

**Note 2:**
- 

**Note 3:**
-
## Draft Regulations

<p>| | | | | |</p>
<table>
<thead>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Autoclave</td>
<td>required on site</td>
<td>required in the building</td>
<td>required in the laboratory suite (Note 4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>System of work</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Access restricted to authorised personnel only</td>
<td>not required</td>
<td>required</td>
<td>required</td>
</tr>
<tr>
<td>9A</td>
<td>Biohazard sign on door</td>
<td>not required</td>
<td>required</td>
<td>required</td>
</tr>
<tr>
<td>10</td>
<td>Specific measures to control aerosol dissemination</td>
<td>not required</td>
<td>required so as to minimise</td>
<td>required so as to prevent</td>
</tr>
<tr>
<td>11</td>
<td>Shower</td>
<td>not required</td>
<td>not required</td>
<td>required where and to extent the risk assessment shows it is required</td>
</tr>
<tr>
<td>12</td>
<td>Protective clothing</td>
<td>suitable protective clothing required</td>
<td>suitable protective clothing required</td>
<td>suitable protective clothing required; footwear required where and to extent the risk assessment shows it is required</td>
</tr>
<tr>
<td>13</td>
<td>Gloves</td>
<td>not required</td>
<td>required where and to extent the risk assessment shows they are required</td>
<td>required</td>
</tr>
<tr>
<td>14</td>
<td>Efficient control of disease vectors (eg rodents and insects) which could disseminate GMMs</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required</td>
<td>required</td>
</tr>
<tr>
<td><strong>Waste</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Inactivation of GMMs in effluent from hand-washing sinks and showers and similar effluents</td>
<td>not required</td>
<td>not required</td>
<td>required where and to extent the risk assessment shows it is required</td>
</tr>
<tr>
<td>17</td>
<td>Inactivation of GMMs in contaminated material and waste</td>
<td>required by validated means where and to extent the risk</td>
<td>required by validated means</td>
<td>required by validated means, with waste inactivated within the</td>
</tr>
</tbody>
</table>
Other measures

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>Laboratory to contain its own equipment</td>
<td>not required</td>
<td>not required</td>
</tr>
<tr>
<td>19</td>
<td>An observation window or alternative is to be present so that occupants can be seen</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required where and to extent the risk assessment shows it is required</td>
</tr>
<tr>
<td>20</td>
<td>Safe storage of GMMs</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required</td>
</tr>
<tr>
<td>21</td>
<td>Written records of staff training</td>
<td>not required</td>
<td>required where and to extent the risk assessment shows it is required</td>
</tr>
</tbody>
</table>

NOTES

1. In the Table above, "isolation" means, in relation to a laboratory, separation of the laboratory from other areas in the same building, or being in a separate building.

2. Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

3. Where viruses are not retained by the HEPA filters, extra requirements will be necessary for extract air.

4. Where the autoclave is outside the laboratory in which the contained use of micro-organisms is being undertaken, but within the laboratory suite, there must be validated procedures for the safe transfer of material into that autoclave, which provide a level of protection equivalent to that which would be achieved by having an autoclave in that laboratory.

Table 1b: Containment Measures for Contained Use of Micro-organisms in Plant Growth Facilities (to be read with Table 1a as indicated in paragraph 3)

<table>
<thead>
<tr>
<th>Containment Measures</th>
<th>Containment Levels</th>
<th>Additional/ modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Permanent structure (Note 1)</td>
<td>required where and to extent the risk assessment shows it is required</td>
</tr>
<tr>
<td>Equipment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
NOTES

1. A permanent structure refers to a fixed structure with walls, a roof and a floor. Where the permanent structure is a greenhouse, that structure must also have a continuous waterproof covering and self-closing lockable outer doors, and be located on a site designed to prevent the entry of surface run-off water.

Table 1c: Containment Measures for Contained Use of Micro-organisms in Animal Units (to be read with Table 1a as indicated in paragraph 3)

<table>
<thead>
<tr>
<th>Containment Measures</th>
<th>Containment Levels</th>
<th>Additional/ modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facilities</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>1 Isolation of animal unit (Note 1)</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Containment Levels</th>
<th>Additional/ modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Modification</td>
</tr>
</tbody>
</table>

Table 1c: Containment Measures for Contained Use of Micro-organisms in Animal Units (to be read with Table 1a as indicated in paragraph 3)
Draft Regulations

<table>
<thead>
<tr>
<th></th>
<th>Animal facilities (Note 2) separated by lockable doors</th>
<th></th>
<th></th>
<th>Additional</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required</td>
<td>required</td>
<td>required</td>
</tr>
<tr>
<td>3</td>
<td>Animal facilities (cages, etc) designed to facilitate decontamination (waterproof and easily washable material)</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required</td>
<td>required</td>
</tr>
<tr>
<td>4</td>
<td>Floor, walls and ceiling easily washable</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required for floor</td>
<td>required for floor and walls</td>
</tr>
<tr>
<td>5</td>
<td>Appropriate filters on isolators or isolated rooms (Note 3)</td>
<td>not required</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required</td>
</tr>
<tr>
<td>7</td>
<td>Appropriate barriers at the room exit, and at drains or ventilation duct work</td>
<td>required</td>
<td>required</td>
<td>required</td>
</tr>
<tr>
<td>8</td>
<td>Animals kept in appropriate containment facilities, such as cages, pens or tanks but not isolators</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required where and to extent the risk assessment shows it is required</td>
</tr>
<tr>
<td>9</td>
<td>Animals kept in isolators</td>
<td>not required</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required</td>
</tr>
</tbody>
</table>

**NOTES**

1. In the Table above, "animal unit" means a building, or separate area within a building, containing an animal facility and other areas including changing rooms, showers, autoclaves and food storage areas.

2. In the Table above and in Note 1 above, "animal facility" means a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures on animals.
3. In the Table above, "isolators" means transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

### Table 2: Containment Measures for Contained Use of Micro-organisms in Premises other than those referred to in Tables 1a, 1b and 1c

<table>
<thead>
<tr>
<th>Containment Measures</th>
<th>Containment Levels</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viable micro-organisms must be contained in a system which separates the process from the workplace and wider environment (closed system)</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required</td>
<td>required</td>
<td>required</td>
<td></td>
</tr>
<tr>
<td>Closed systems located within a controlled area</td>
<td>not required</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required</td>
<td>required</td>
<td></td>
</tr>
<tr>
<td>Control of exhaust gases from the closed system</td>
<td>not required</td>
<td>required so as to minimise release</td>
<td>required so as to prevent release</td>
<td>required so as to prevent release</td>
<td></td>
</tr>
<tr>
<td>Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required so as to minimise release</td>
<td>required so as to prevent release</td>
<td>required so as to prevent release</td>
<td></td>
</tr>
<tr>
<td>Inactivation of bulk culture fluids before removal from the closed system</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required by validated means</td>
<td>required by validated means</td>
<td>required by validated means</td>
<td></td>
</tr>
<tr>
<td>Seals must be designed so as to minimise or prevent release</td>
<td>not required</td>
<td>required so as to minimise release</td>
<td>required so as to prevent release</td>
<td>required so as to prevent release</td>
<td></td>
</tr>
<tr>
<td>The controlled area designed to contain spillage of the entire contents of the closed system</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required</td>
<td>required</td>
<td></td>
</tr>
<tr>
<td>The controlled area sealable to permit fumigation</td>
<td>not required</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required</td>
<td></td>
</tr>
<tr>
<td>Biohazard signs posted</td>
<td>not required</td>
<td>required</td>
<td>required</td>
<td>required</td>
<td></td>
</tr>
<tr>
<td><strong>Equipment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entry via airlock</td>
<td>not required</td>
<td>not required</td>
<td>required where</td>
<td>required</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Surfaces resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents and easy to clean</td>
<td>required for any bench</td>
<td>required for any bench</td>
<td>required for floor and any bench</td>
<td>required</td>
</tr>
<tr>
<td>12</td>
<td>Specific measures to adequately ventilate the controlled areas in order to minimise air contamination</td>
<td>required where and to extent the risk assessment shows they are required</td>
<td>required where and to extent the risk assessment shows they are required</td>
<td>required where and to extent the risk assessment shows they are required</td>
<td>required</td>
</tr>
<tr>
<td>13</td>
<td>The controlled area maintained at an air pressure negative to the immediate surroundings</td>
<td>not required</td>
<td>not required</td>
<td>required where and to extent the risk assessment shows it is required</td>
<td>required</td>
</tr>
<tr>
<td>14</td>
<td>Extract and input air from the controlled area must be HEPA filtered</td>
<td>not required</td>
<td>not required</td>
<td>required for extract air, optional for input air</td>
<td>required for input and extract air</td>
</tr>
</tbody>
</table>

**System of work**

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>Access restricted to authorised personnel only</td>
<td>not required</td>
<td>required</td>
</tr>
<tr>
<td>17</td>
<td>Personnel must shower before leaving the controlled area</td>
<td>not required</td>
<td>not required</td>
</tr>
<tr>
<td>18</td>
<td>Personnel must wear protective clothing</td>
<td>work clothing required</td>
<td>work clothing required</td>
</tr>
<tr>
<td>19</td>
<td>Written procedures and records of staff training</td>
<td>not required</td>
<td>required where and to the extent the risk assessment shows it to be required</td>
</tr>
</tbody>
</table>

**Waste**

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>Inactivation of GMMs in effluent from hand-washing sinks and showers or similar effluents</td>
<td>not required</td>
<td>not required</td>
</tr>
<tr>
<td>21</td>
<td>Inactivation of GMMs in contaminated material and waste including those in process effluent</td>
<td>required by validated means where and to the extent the risk</td>
<td>required by validated means</td>
</tr>
<tr>
<td>before final discharge</td>
<td>assessment shows it to be required</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
ANNEX B – Supplementary [draft] guidance on the inactivation of waste at Class 1

1. Genetic modification activities will generate contaminated waste. GMO(CU) 2014 require such waste containing genetically modified microorganisms (GMMs) to be inactivated by a validated means at Class 2, 3 and 4. For Class 1 activities, this requirement is determined by the outcome of a risk assessment. Only where the risk assessment concludes that the following criteria are met, would it be appropriate to conclude that some degree of inactivation by a validated means is not necessary:

- The GMMs do not have the potential to cause harm to human health or the environment;
- The GMMs must be biologically contained (e.g. possess disabling mutations or restrictive nutrient requirements that cannot be met outside of the laboratory);
- The GMMs cannot survive for a prolonged period (i.e. greater than several hours) in the environment;
- The GMMs do not have the capacity to replicate; and
- The GMMs do not have capacity to transfer genetic material to other microorganisms (e.g. mobilisable plasmid).

2. Where inactivation is required by the risk assessment at Class 1, the means by which this is achieved is the responsibility of the user. For the purposes of the regulations, any of the following methods i.e. disinfection, off-site treatment (e.g. rotaclave, incinerator) or autoclave may be considered to be validated means and comply with the regulations. This is provided appropriate steps are taken to confirm the efficacy of the method, the appropriate control measures are put in place for the safe transport and storage of the waste material and the process is completed in a safe manner.
ANNEX C – Supplementary [draft] guidance on the establishment of a Genetic Modification Safety Committee

1. GMO(CU) 2014 require the provision of expert advice on risk assessments. It is appropriate for such advice on Class 1 risk assessments to be provided by a competent individual (e.g. Biological Safety Officer/Advisor). For other activities including Class 2 and above, the advice must be provided by a committee. The individual or committee providing the advice on risk assessment should:

- Have sufficient knowledge and experience to understand the risks to both human health and the environment arising from the proposed genetic modification (GM) activity;
- understand the extent to which those risks are uncertain;
- be able to judge the adequacy of the risk assessment made under regulation 6 or 7;
- where appropriate and necessary, test emerging conclusions by discussion with relevant experts either within or outside their institution;

2. It is likely that institutions which already have an established genetic modification safety committee (GMSC) will continue to use the committee for all GM activities. Where a committee is used, there are no hard and fast rules governing its make-up. It should ideally be constituted to represent both management and employees with its members also being representative of all people having access to the genetic modification facilities or who might otherwise be exposed to such work. It is important to include members who will not benefit directly from the decisions of the committee (e.g. technical staff) and to ensure the discussion is that of the group rather than a particular individual. It is acceptable for the committee to consider other health and safety matters and not specifically genetic modification activities (e.g. biological safety committee), provided the committee has the appropriate expertise.

3. Where there is no established committee, it is possible for this advice to be provided by a shared committee or another institution’s GMSC provided there are written agreements in place confirming the arrangements for provision of this advice. It is not a requirement that every corporate body or institution sets one up a committee to advise on all risk assessments undertaken at the centre. It is possible for GMSCs to advise more than one centre – especially where notified premises are on split sites.

4. There may be instances where within a single institution there are several, separately notified, GM premises. In such cases, it may be appropriate for a single committee to cover all premises. Alternatively, where there are multiple GM centres working at a single premises, it may be appropriate for a single committee to cover all activities at the premises. Where activities are to be transferred between different premises or employers the risk assessment should be reviewed before work commences to ensure that the risk assessment takes account of the new local circumstances.
Title:
IA No:
Lead department or agency: Health and Safety Executive (HSE)
Other departments or agencies: DEFRA, Scottish Government, Welsh Government

Impact Assessment (IA)
Date: 13 September 2013
Stage: Preliminary
Source of intervention: Domestic
Type of measure: Secondary legislation
Contact for enquiries: Mike Paton
HSE, Redgrave Court 5S.2, Merton Road, Bootle L20 7HS   Tel: 0151 951 3058
michael.paton@hse.gsi.gov.uk

Summary: Intervention and Options

<table>
<thead>
<tr>
<th>Cost of Preferred (or more likely) Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Net Present Value</td>
</tr>
<tr>
<td>Business Net Present Value</td>
</tr>
<tr>
<td>Net cost to business per year (EANCB on 2009 prices)</td>
</tr>
<tr>
<td>In scope of One-In, Two-Out?</td>
</tr>
<tr>
<td>Measure qualifies as</td>
</tr>
</tbody>
</table>

| Not quantified | Not quantified | Not quantified | Yes | TBC |

What is the problem under consideration? Why is government intervention necessary?
The consolidation of the GMO regulations is one of the recommendations of the Lofstedt review of health and safety, published on the 28 November 2011. The Lofstedt review recommended that a consolidation of GMO legislation should: ensure the regulations reflect current industry practices; limit the extent to which UK health and safety legislation has enhanced EU Directives (gold-plated); and simplify the regulations (for example by reducing any duplication). The Government emphasised that the consolidation process should not reduce the protections provided by the existing legislation.

What are the policy objectives and the intended effects?
1. To consolidate the Genetically Modified Organisms (Contained Use) Regulations 2000 and its three amending regulations from 2002, 2005 and 2010 (4 into 1).
2. To ensure that the consolidation process does not in any way reduce the protections provided by the existing legislation.
3. To ensure changes made represent a more risk based and proportionate approach and reflect experience of applying these regulations since 2000.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)
Option 1 is to do nothing
Option 2 and the preferred option is to consolidate, modernise, and, where practicable, simplify the GMO (CU) Regulations 2000 and its three amending sets of legislation.
Option 3 is to consolidate all four sets of regulations to achieve a single set of regulations without making any changes.
The reasons for pursuing options 2 and 3 are provided in paragraphs 13 – 23 of the evidence base.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: TBC

Does implementation go beyond minimum EU requirements?
Yes
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.
Microl < 20 Small Medium Large
Yes Yes Yes Yes
What is the CO₂ equivalent change in greenhouse gas emissions?
(Million tonnes CO₂ equivalent)
Traded: NA Non-traded: NA

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: __________________________ Date: __________________________
### Policy Option 1

**Description:**
Do Nothing

### FULL ECONOMIC ASSESSMENT

<table>
<thead>
<tr>
<th>Price Base Year</th>
<th>PV Base Year</th>
<th>Time Period Years</th>
<th>Net Benefit (Present Value (PV)) (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Low: NA High: NA Best Estimate: 0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COSTS (£m)</th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Cost (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>High</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Best Estimate</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Description and scale of key monetised costs by ‘main affected groups’**
The 'do nothing' option is the baseline case and there are therefore no monetised costs associated with it.

**Other key non-monetised costs by ‘main affected groups’**
There is a reputational risk to HSE for failing to implement Government recommendations.

<table>
<thead>
<tr>
<th>BENEFITS (£m)</th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Benefit (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>High</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Best Estimate</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Description and scale of key monetised benefits by ‘main affected groups’**
The 'do nothing' option is the baseline case and there are therefore no monetised benefits associated with it.

**Other key non-monetised benefits by ‘main affected groups’**
The 'do nothing' option is the baseline case and there are therefore no non-monetised benefits associated with it.

**Key assumptions/sensitivities/risks**
NA

**Discount rate (%)**
NA

### BUSINESS ASSESSMENT (Option 1)

<table>
<thead>
<tr>
<th>Direct impact on business (Equivalent Annual) £m:</th>
<th>In scope of OITO?</th>
<th>Measure qualifies as</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs: NA</td>
<td>No</td>
<td>NA</td>
</tr>
<tr>
<td>Benefits: NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net: NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Summary: Analysis & Evidence  Policy Option 2

Description: To consolidate, modernise, and, where practicable, simplify the Genetically Modified Organisms (Contained Use) Regulations 2000 with its three amending sets of legislation

FULL ECONOMIC ASSESSMENT

<table>
<thead>
<tr>
<th>Price Base Year 2013</th>
<th>PV Base Year 2013</th>
<th>Time Period Years</th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Cost (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>10</td>
<td>Low: NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High: NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Best Estimate: NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

COSTS (£m)

- Description and scale of key monetised costs by ‘main affected groups’
  - The costs to business estimated at this stage accrue from familiarisation of the new regulations by the Biological Safety Officer, dissemination of that information and reviewing and revising risk assessments. These are estimated at a best estimate present value over ten years of around £192 thousand. As further costs remain to be estimated, we have not included estimates in the summary boxes at this time.

- Other key non-monetised costs by ‘main affected groups’
  - A one-off cost will be incurred by HSE to update its guidance on GMO. Although this is not expected to be substantial, further evidence will be gathered during consultation to estimate this cost.

BENEFITS (£m)

- Description and scale of key monetised benefits by ‘main affected groups’
  - It is estimated that the consolidation of the regulations will deliver benefits in terms of reducing the time it takes for dutyholders, particularly those new to the industry, to identify and understand their requirements under the GMO(CU) 2014 regulations. These savings are estimated to have a best estimate present value over ten years of around £33 thousand. Additional savings to Government estimated so far amount to a present value of around £5 thousand from no longer maintaining a hard copy public register of licence holders. As so many further cost savings remain to be estimated, we have not included figures in the summary boxes at this time.

- Other key non-monetised benefits by ‘main affected groups’
  - Several cost savings to business remain to be estimated, many of which are expected to be substantial. These include expected savings from using HEPA air filters less often, using cheaper approved methods for inactivating waste at the lowest risk premises and making less use of Genetic Modification Safety Committees. Further smaller savings to business related to simplification of the notification process and no longer being required to incinerate animal carcasses under some circumstances also remain to be estimated. HSE is preparing to proactively engage with industry during the consultation period to ascertain further information on likely industry responses to the proposed changes. This will allow HSE to estimate the probable cost savings impact for the final stage impact assessment.

Key assumptions/sensitivities/risks

- Familiarisation costs are based on assumptions around number of Biological Safety Officers and the time in which it will take to become familiar with the new regulations.
- HSE expects that some GM centres, particularly those operating at the lowest containment level, may retain their current control measures following implementation of the proposed measures, thereby resulting in over compliance and a reduction in the potential scale of cost savings available under the proposed measures.
- HSE will gather more information from stakeholders during consultation on this matter to account for any probable effects in the final stage impact assessment.

BUSINESS ASSESSMENT (Option 2)

- Direct impact on business (Equivalent Annual) £m:
  - Costs: NA
  - Benefits: NA
  - Net: NA

- In scope of OITO? Yes
- Measure qualifies as TBC
### FULL ECONOMIC ASSESSMENT

<table>
<thead>
<tr>
<th>Price Base Year</th>
<th>PV Base Year</th>
<th>Time Period Years</th>
<th>Net Benefit (Present Value (PV)) (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>2013</td>
<td>10</td>
<td>Low: £0.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High: £0.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Best Estimate: £0.0</td>
</tr>
</tbody>
</table>

#### COSTS (£m)

<table>
<thead>
<tr>
<th></th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Cost (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>£0.02</td>
<td>NA</td>
<td>£0.02</td>
</tr>
<tr>
<td>High</td>
<td>£0.02</td>
<td>NA</td>
<td>£0.02</td>
</tr>
<tr>
<td>Best Estimate</td>
<td>£0.02</td>
<td>NA</td>
<td>£0.02</td>
</tr>
</tbody>
</table>

**Description and scale of key monetised costs by ‘main affected groups’**

The costs to business accrue from familiarisation with the simplified regulations by the Biological Safety Officer. These are one-off costs estimated at around £16 thousand.

**Other key non-monetised costs by ‘main affected groups’**

No other costs are expected.

#### BENEFITS (£m)

<table>
<thead>
<tr>
<th></th>
<th>Total Transition (Constant Price)</th>
<th>Average Annual (excl. Transition) (Constant Price)</th>
<th>Total Benefit (Present Value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>NA</td>
<td>£0.004</td>
<td>£0.03</td>
</tr>
<tr>
<td>High</td>
<td>NA</td>
<td>£0.007</td>
<td>£0.04</td>
</tr>
<tr>
<td>Best Estimate</td>
<td>NA</td>
<td>£0.005</td>
<td>£0.03</td>
</tr>
</tbody>
</table>

**Description and scale of key monetised benefits by ‘main affected groups’**

It is estimated that the consolidation of the regulations will deliver benefits in terms of reducing the time it takes for dutyholders, particularly those new to the industry, to identify and understand their requirements under the GMO(CU) 2014 regulations. The improvements to layout and language should also have time savings. This is estimated to have a present value saving over ten years of around £33 thousand.

**Other key non-monetised benefits by ‘main affected groups’**

As the regulations will be simplified, there may be a reduction in the barriers to entry for genetic modification work, which may increase competition.

#### Key assumptions/sensitivities/risks

Discount rate (%) 3.5

Familiarisation costs are based on assumptions around number of Biological Safety Officers and the time in which it will take to become familiar with the new regulations.

Compliance rates are assumed to stay the same. Any unnecessary increases in compliance may lead to a reduction in cost savings or increase in costs.

Where gaps in data remain, efforts will be made in consultation to address this.

### BUSINESS ASSESSMENT (Option 3)

<table>
<thead>
<tr>
<th>Direct impact on business (Equivalent Annual) £m:</th>
<th>In scope of OITO?</th>
<th>Measure qualifies as</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs: 0.0</td>
<td>Yes</td>
<td>Break even</td>
</tr>
<tr>
<td>Benefits: 0.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net: 0.0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Evidence Base

Background and rationale for intervention

1. The Genetically Modified Organisms (Contained Use) Regulations 2000 (as amended) are concerned with the protection of the environment and prevention of harm to human health from activities using genetically modified microorganisms (GMMs) in ‘contained use’ facilities. They implement the relevant requirements of European Directive 2009/41/EC on the contained use of genetically modified organisms and other EU requirements concerning access to environmental information. Directive 2009/41/EC is itself a consolidation (recast) of the previous three Directives covering this issue.

2. Genetic modification (GM) in relation to an organism means altering the genetic material (either DNA or RNA) in that organism in a way that does not occur naturally by mating and/or recombination. Typically, this involves the removal of the genetic material, its manipulation outside the cell and reinsertion into the same or another organism. The aim is often to introduce a new or altered characteristic to the target organism.

3. Contained use activities (for the purposes of these regulations) cover any activity involving Genetically Modified Organisms (GMOs), encompassing microorganisms and larger organisms (e.g. animals, plants, insects) under the containment conditions laid down by the regulations. Barriers are required to be in place to limit contact between GMOs and humans and the environment, with the intention to provide a high level of safety for humans and the environment. For GMMs, these barriers can be provided by physical, biological or chemical means, or a combination of these. This includes the destruction and disposal of GMMs. For both GMMs and larger GMOs, these barriers are described in the extensive guidance\(^1\) from the Scientific Advisory Committee on Genetic Modification (SACGM).

4. The regulations set out the way in which GMMs are to be risk assessed and classified, and specifies waste management and containment requirements. The GMM activity classifications are:

   - **Class 1** – Activities of no or negligible risk, for which containment level 1 is appropriate to protect human health and the environment.
   - **Class 2** – Activities of low risk, for which containment level 2 is appropriate to protect human health and the environment.
   - **Class 3** – Activities of moderate risk, for which containment level 3 is appropriate to protect human health and the environment.
   - **Class 4** – Activities of high risk, for which containment level 4 is appropriate to protect human health and the environment.

5. Since 2000 (when the regulations first came into force), there have been three sets of amending regulations. The regulations are supported by a HSE guide ‘A guide to the Genetically Modified Organisms (Contained Use) Regulations 2000’, (L29) HSE Books.

\(^1\) The SACGM Compendium of guidance – This is guidance prepared, in consultation with HSE, by the Scientific Advisory Committee for Genetic Modification, which meets the Government principles for scientific advisory committees.

http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/
6. The consolidation of the GMO regulations is one of the recommendations of the Löfstedt review of health and safety [insert link], published on the 28 November 2011. The Löfstedt review of health and safety legislation recommended that a consolidation of GMO legislation should:

- ensure the regulations reflect current industry practices;
- limit the extent to which UK health and safety legislation has enhanced EU Directives (gold-plated); and
- simplify the regulations (for example by reducing any duplication)

7. At the same time, the Government has emphasised that the consolidation process should not reduce the protections provided by the existing legislation. Instead, the opportunity has been taken to make a number of changes to make the regulations more risk based and proportionate and reflect experience of applying these regulations since 2000. The opportunity is also being taken to remove potential hurdles that may impede the longer term goal of producing a single regulatory framework for human and animal pathogens and GMOs.

8. The majority of GMO contained use work is being undertaken at Class 1, deemed to be nil or negligible risk, with very few employers undertaking work at Class 4 (e.g. work with ebola virus, foot and mouth disease virus), deemed to present a serious risk to human health or the environment.

9. The GMO regulations cover the whole of Great Britain. HSE is the joint Competent Authority for the regulation of contained use of GMOs with Defra (in England and Wales) and with the Scottish Government (in Scotland). Northern Ireland has equivalent regulations. For administrative purposes, HSE acts as a single point of contact for users. This consultation relates to regulations that will apply in England, Scotland and Wales.

10. HSE has worked closely with other governemnt departments and key stakeholders in the lead up to the public consultation stage to gather information on areas where the existing legislation could be simplified and would benefit from changes to improve clarity, proportionality and remove unnecessary requirements on low risk activities. Stakeholders will be updated throughout the project to ensure they are familiar with any proposed changes in advance of the new regulations coming into force.

Policy objective

11. The policy objective is to implement the recommendation made in Professor Löfstedt’s report, specifically to:

- Consolidate the four existing sets of GMO(CU) legislation into one. These are:
  i. Genetically Modified Organisms (Contained Use) Regulations 2000
  ii. Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002
  iii. Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005
  iv. Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010
- Ensure effective transposition of the relevant EU legislation remains, whilst also ensuring that any unnecessary gold plating is removed;
- Reflect experience since 2000, to make the regulations more risk based and proportionate, and maintaining the level of protection from risks to human health and harm to the environment;
- Be mindful of progressing towards implementing the key principles of the regulatory framework covering work with human and animal pathogens and GMOs in contained use facilities; and
- Ensure changes reflect the most up-to-date knowledge about safe working practices for activities involving genetically modified organisms.

12. HSE proposes to introduce the new consolidated regulations by 1st October 2014.

Options Considered

Option 1: Do nothing (Baseline)

13. Under the baseline option the current situation would continue and therefore there are no costs and benefits.

14. The Löfstedt recommendations have been accepted by Government and HSE is now implementing these recommendations as they relate to the GMO (CU) Regulations.

15. The ‘do nothing’ option is not therefore a viable option available to HSE, however, it remains the baseline against which the other options for implementing Löfstedt’s recommendations are compared.

Option 2: Modernisation and consolidation.

16. The preferred option is to consolidate, modernise, and, where practicable, simplify the Genetically Modified Organisms (Contained Use) Regulations 2000 and its three amending sets of legislation.

17. The GMO(CU) 2014 regulations will aid clarity reflect experience since 2000, to make the regulations more risk based and proportionate whilst maintaining adequate levels of protection from risks to human health and harm to the environment.

18. This will satisfy the Löfstedt recommendation to consolidate, whilst ensuring any unnecessary burdens on dutyholders are removed.

19. For the health and safety elements of the regulations, these changes are permitted under Section 15 HSWA and for the environmental elements, under Section 80 HSWA.

Option 3: Consolidation only

20. To consolidate all four sets of regulations to achieve a single set of regulations without any changes to the requirements.

21. A purely legal redraft would benefit the dutyholder as they would have one single piece of legislation for GMO (CU) Regulations 2014. There would be initial costs associated with familiarisation of the new regulations and ongoing savings.

22. This option was ruled out for failing to meet the criteria set out in the Löfstedt recommendation. However, Option 3 is an opportunity to address simplification of the regulations if the further changes proposed under Option 2 proves unfeasible in the time available.
Other options considered

23. As part of the very early consideration of options, the possibility of introducing a new set of regulations that copied out Directive 2009/41/EC was ruled out for a number of reasons. They included reduced level of protection for human health and the environment, increasing burdens on dutyholders and further misalignment with other related health, safety and environmental regimes such as the Control of Substances Hazardous to Health Regulations (COSHH) 2002 (as amended) and the Specified Animal Pathogens Orders (SAPO 2008, 2009) in England, Scotland and Wales.

Summary of current provisions

24. The current GMO regulations already closely follow the European Directive on which they are based. Similarly previous consultation exercises have been supportive of the current GMO regulations. However, the existing legislation can be simplified and would benefit from changes to improve clarity, proportionality and remove unnecessary requirements on low risk activities.

25. The current provisions in the GMO regulations can be broadly grouped into the following areas:

- Risk assessment and classification of work
- Notification and provision of information
- Containment and control measures to be applied.

26. It is also hoped that the consolidation will provide for greater consistency in standards between GMOs and wild-type micro-organisms. Work with non-modified human pathogens is covered by the Control of Substances Hazardous to Health Regulations (COSHH) 2002 (as amended) and underpinned by the Biological Agents Directive 2000/54/EC. Work with specified animal pathogens is covered by the relevant Specified Animal Pathogen Orders (SAPO 2008, 2009) in England, Scotland and Wales.

27. These GMO regulations are solely concerned with the contained use of GMOs and do not cover the deliberate release into the environment of GMOs (e.g. field trials with genetically modified plants). The latter is covered by the Genetically Modified Organisms (Deliberate Release) Regulations 2002.

Summary of proposed changes

28. The following table contains a summary of the proposed changes to the current regulations and should be cross-referenced with the consultation document (CD263). Descriptions also appear in this impact assessment alongside the calculation of costs and cost savings from paragraph 39 to 101.
Table 1: Summary of proposed amendments

29. The tables referred to in this summary and throughout the impact assessment relate to the containment tables in Schedule 8 of the GMO (CU) Regulations 2000 (as amended).

<table>
<thead>
<tr>
<th>Change</th>
<th>Reference in current regulations</th>
<th>Subject of regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-1</td>
<td>Table 1a (measure 15)</td>
<td>Specified disinfection procedures in place</td>
</tr>
<tr>
<td>A-2</td>
<td>Table 1c (measure 6)</td>
<td>Incinerator for disposal of animal carcasses containing GMMs</td>
</tr>
<tr>
<td>A-3</td>
<td>Table 2 (measure 16)</td>
<td>Decontamination and washing facilities provided for personnel</td>
</tr>
<tr>
<td>B-1</td>
<td>Table 1a (measure 5)</td>
<td>Negative pressure relative to surroundings at CL2 and CL3</td>
</tr>
<tr>
<td>B-2</td>
<td>Table 1a (measure 6)</td>
<td>HEPA filtration at CL3</td>
</tr>
<tr>
<td>B-3</td>
<td>Table 1a (measure 7)</td>
<td>Microbiological safety cabinet at CL4</td>
</tr>
<tr>
<td>B-4</td>
<td>Table 1a (measure 17)</td>
<td>Inactivation of waste at CL1 - laboratories</td>
</tr>
<tr>
<td>B-5</td>
<td>Table 1a (measure 19)</td>
<td>Observation window at CL3</td>
</tr>
<tr>
<td>B-6</td>
<td>Table 1c (measure 9)</td>
<td>Use of isolators at CL1</td>
</tr>
<tr>
<td>B-7</td>
<td>Table 2 (measure 2)</td>
<td>Controlled areas purpose built at CL4</td>
</tr>
<tr>
<td>B-8</td>
<td>Table 2 (measure 9)</td>
<td>Biohazard signs at CL1</td>
</tr>
<tr>
<td>B-9</td>
<td>Table 2 (measure 19)</td>
<td>Written procedures and training records</td>
</tr>
<tr>
<td>B-10</td>
<td>Table 2 (measure 21)</td>
<td>Inactivation of waste at CL1 – other facilities</td>
</tr>
<tr>
<td>C-1</td>
<td>Regulations 10(3), 11(5), Schedules 5 &amp; 6</td>
<td>Emergency plans</td>
</tr>
<tr>
<td>C-2</td>
<td>Regulation 24(7), (8)</td>
<td>Information required for a Class 2 notification</td>
</tr>
<tr>
<td>C-3</td>
<td>Regulation 24(7), (8)</td>
<td>Register of notifications</td>
</tr>
<tr>
<td>D-1</td>
<td>Regulation 16</td>
<td>Requirement to establish a genetic modification safety committee</td>
</tr>
<tr>
<td>E-1</td>
<td>Restructure</td>
<td>Separating the duties on the Competent Authority and the users</td>
</tr>
<tr>
<td>E-2</td>
<td>Change of term used</td>
<td>Contained use</td>
</tr>
<tr>
<td>E-3</td>
<td>Change of term used</td>
<td>User</td>
</tr>
<tr>
<td>E-4</td>
<td>Replace term used</td>
<td>Larger GMOs (LGMOs)</td>
</tr>
<tr>
<td>E-5</td>
<td>Schedule 6</td>
<td>Notification requirements</td>
</tr>
<tr>
<td>E-6</td>
<td>Regulation 29 &amp; Schedule 11</td>
<td>Right of appeal and procedure</td>
</tr>
</tbody>
</table>

Organisations affected

30. The GMO or biotechnology contained use ‘sector’ cuts across academic and commercial research, health, chemicals and agriculture and is predominantly carried out in laboratories, plus some larger scale research and development and production facilities (mostly pharmaceutical). Some of the research activities carried on in the University sector may be funded by charitable societies, especially in medical research. This is an area in which the UK currently excels and has significant growth potential, attracting substantial research council
funding (e.g. Biological and Bioscience Research Council announced £20 million of investment in six synthetic biology research projects).

31. There are in the region of 600 premises in the UK carrying out contained use of microorganisms. The majority of work is being undertaken at Class 1, deemed to be nil or negligible risk and only 6 employers are undertaking work at Class 4, deemed to present a serious risk to human health or the environment. Approximately 30% of the premises undertake contained use work with GM animals and/or plants (larger GMOs) but it is likely that they will also be carrying out work with GMMs and therefore have been included in the cost calculations.

Table 2: Breakdown of employers and premises by class of activity (at 1 August 2013)

<table>
<thead>
<tr>
<th>Containment Level</th>
<th>Number of GM Centres</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>CL1</td>
<td>342</td>
<td>57%</td>
</tr>
<tr>
<td>CL2</td>
<td>179</td>
<td>30%</td>
</tr>
<tr>
<td>CL3</td>
<td>71</td>
<td>12%</td>
</tr>
<tr>
<td>CL4</td>
<td>6</td>
<td>1%</td>
</tr>
<tr>
<td>Total</td>
<td>598</td>
<td>100%</td>
</tr>
</tbody>
</table>

32. The proposed changes will have no detriment to health, safety or environmental protection. Many of these measures relate to Class 1 activities which by definition are nil or negligible risk.

33. Between May 2009 and April 2013 there have been, on average, an additional 24 GM centres notified each year. This figure does not account for the number of GM centres that close each year hence the net figures will be lower. We will seek to determine a net figure for the final impact assessment. The following analysis will assume that this will continue over the ten years of the appraisal and that new entrants will fall within Containment Levels 1 to 4 in the same proportions as the current GM centres shown in Table 1; that is, 57% will be CL1, 30% at CL2 etc. Table 3 shows the projected number of GM centres over the ten year appraisal period.

---

Table 3: Projection of number of GM centres by activity over ten years

<table>
<thead>
<tr>
<th></th>
<th>CL1</th>
<th>CL2</th>
<th>CL3</th>
<th>CL4</th>
<th>Total</th>
</tr>
</thead>
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<tr>
<td>Year 0</td>
<td>342</td>
<td>179</td>
<td>71</td>
<td>6</td>
<td>598</td>
</tr>
<tr>
<td>Year 1</td>
<td>356</td>
<td>186</td>
<td>74</td>
<td>6</td>
<td>622</td>
</tr>
<tr>
<td>Year 2</td>
<td>369</td>
<td>193</td>
<td>77</td>
<td>6</td>
<td>646</td>
</tr>
<tr>
<td>Year 3</td>
<td>383</td>
<td>201</td>
<td>80</td>
<td>7</td>
<td>670</td>
</tr>
<tr>
<td>Year 4</td>
<td>397</td>
<td>208</td>
<td>82</td>
<td>7</td>
<td>694</td>
</tr>
<tr>
<td>Year 5</td>
<td>411</td>
<td>215</td>
<td>85</td>
<td>7</td>
<td>718</td>
</tr>
<tr>
<td>Year 6</td>
<td>424</td>
<td>222</td>
<td>88</td>
<td>7</td>
<td>742</td>
</tr>
<tr>
<td>Year 7</td>
<td>438</td>
<td>229</td>
<td>91</td>
<td>8</td>
<td>766</td>
</tr>
<tr>
<td>Year 8</td>
<td>452</td>
<td>236</td>
<td>94</td>
<td>8</td>
<td>790</td>
</tr>
<tr>
<td>Year 9</td>
<td>466</td>
<td>244</td>
<td>97</td>
<td>8</td>
<td>814</td>
</tr>
</tbody>
</table>

Note: totals may not sum due to rounding

34. Notification fees recovered from GMO(CU) requirements totalled around £154 thousand (averaged over the last 2 years 2011/12-2012/13).

Assumptions

35. It is assumed that GM centres working at the higher containment levels will also carry out work at the lower containment levels, i.e. a GM centre working at CL4 will also carry out work at CL1-3, CL3 GM centres will carry out work at CL1-2 etc.

36. We can assume that any action required to understand or implement changes outlined in this impact assessment will be carried out by either a ‘Science and Technology Professional’ or a ‘Higher Education Teaching Professional’ and estimates are taken from the Annual Survey of Hours and Earnings (ASHE 2012 provisional figures).

37. Costs and benefits are assessed over 10 years as there is no reason to depart from the general advice in the Better Regulation Executive’s Impact Assessment toolkit to use this time frame.

38. The discount rate is 3.5%, in line with the HM Treasury Green Book.

Option 1 – Costs and benefits

39. Option 1 is the baseline or ‘do nothing’ option. As such, the status quo remains and there are no additional costs or benefits.

Option 2 – Costs and benefits

Containment measures to be removed (Changes A-1 to A-3 in consultation document)

40. A-1: Specified disinfection procedures to be in place. This measure (Table 1a, measure 15) requires users to ensure there are specified disinfection procedures in case of spillage of GMMs at CL2-4 and where the risk assessment deems it necessary at CL1.

41. This measure duplicates principle (m) in the general principles of good microbiological and occupational safety and hygiene in Schedule 7 of the regulations. Removing this measure from the table will simplify Table 1a by reducing the overall number of containment measures but the requirement to
have specified disinfection procedures will remain at all containment levels hence there will be no reduction in the level of protection for human health and the environment.

42. HSE does not envisage there to be any costs or cost savings to this change as nothing in practice will alter.

43. **A-2: Incinerator for the disposal of animal carcasses.** This measure (containment measure 6, Table 1c) requires users to dispose of animal carcasses by incineration. The incinerator should be accessible at CL1-3 and on site at CL4. The requirement to inactivate animal carcases will remain (within the term contaminated material and waste), however, the prescriptive requirement for an incinerator will be removed, enabling greater flexibility in choosing the most appropriate inactivation method to be used. The proposed change will not therefore lower the level of protection for human health and the environment.

44. The regulations require inactivation of GMMs in contaminated material and waste. The Directive makes no separate provision for animal carcasses as this is encompassed within the term contaminated material and waste. Consequently, the regulations are overly prescriptive in requiring an incinerator to dispose of animal carcasses. There are alternative modern technologies available (e.g. autoclaves, tissue digesters, rotoclaves) that provide effective means of inactivation and are more environmentally friendly. Specifically, the requirement to have an incinerator on site at CL4 may preclude the development of new facilities in certain geographical areas (due to environmental permissions) or within certain institutions (where cost would be prohibitive). Removing this measure from the table will simplify Table 1c by reducing the overall number of containment measures. For human pathogens, the requirement for an incinerator specified in COSHH will still apply. The intention would be to amend in the Biological Agents Directive, when the opportunity arises.

45. Whether users would move to an alternative technology will be determined by a number of factors, such as size of carcasses for disposal, commitments to the costs of an incinerator and cash flow issues (trade off between initial set up costs versus annual savings). It is not possible to predict how many sites may respond to this, but in principal, this proposal is beneficial for industry. The full extent of the benefit achieved depends on how quickly and how many sites change to different methods of disposal compared to incineration, which cannot be quantified as it will depend on business decisions.

46. **HSE analysts will undertake to gather more information from stakeholders during the consultation period on this issue.**

47. **A-3: Decontamination and washing facilities provided for personnel.** This measure (containment measure 16, Table 2) requires users to have decontamination and washing facilities in place to ensure GMMs are not transferred outside the laboratory.

48. This measure duplicates principle (h) in the general principles of good microbiological and occupational safety and hygiene in Schedule 7 of the regulations. Removing this measure from the table will simplify Table 2 by reducing the overall number of containment measures but the requirement to have decontamination and washing facilities will remain at all containment levels hence there will be no reduction in the level of protection for human health and the environment.

49. HSE does not envisage there to be any costs or cost savings to this change as nothing in practice will alter.
**Containment measures to be changed (Changes B-1 to B-10 in consultation document)**

50. **B-1: Negative pressure relative to surroundings at CL2 and CL3.** This measure (containment measure 5, Table 1a) requires users to operate negative pressure at CL3 and where a risk assessment shows that this is required at CL2. Following the proposed change, this measure will not be required at CL2 and only required where transmission does not occur via an airborne route at CL3.

51. The requirement for negative pressure relative to the pressure of the immediate surroundings refers to the need for inward airflow into the laboratory, providing protection to those outside who may be exposed to a biological agent. The current requirement at CL2 goes beyond the standard in the Directive. There are very few situations where this measure is required at CL2, which by definition covers low risk activities. It is difficult to envisage activities which require this measure that would not also require other CL3 associated measures (e.g. HEPA filter of extract; room sealability). In short, it is more appropriate for work that requires this measure to be undertaken at CL3 rather than CL2. This proposed change will ensure the most appropriate protection for human health and the environment is applied. The proposed change has the benefit of creating a greater distinction between containment levels and provides consistency in the requirement for measure 13 in Table 2 of the regulations.

52. HSE estimates that the change to this measure will remove a cost from business. This will overlap with the proposed change under B-2: HEPA filtration at CL3, as the two usually form one system, and so is discussed in paragraph 53-56.

53. **B-2: HEPA filtration at CL3.** This measure (containment measure 6, Table 1a) requires users to operate a HEPA filter at CL3 for extract air. Following the proposed change, this will no longer be required where transmission does not occur via an airborne route.

54. This measure is required to ensure that air is filtered before leaving (and at CL4, entering) the laboratory. The current requirement at CL3 goes beyond the standard in the Directive, which indicates that this measure is required except for activities where transmission does not occur via airborne route. This change means that the control measure is only required when it is needed to control airborne infection hence ensures the most appropriate protection for human health and the environment is applied.

55. Whether a GM centre requires this measure will be dependant on the activity they are undertaking and if there is a risk of airborne transmission. If the user decided this measure was not required at the time of notifying, they could apply for a derogation to dispense of this measure. The majority of notifications apply for derogation in this way and there is no additional cost to the notification fee for a class 3 activity. However, it is possible to dispense with a control measure following notification and this would require further notification to HSE at an additional cost. The Competent Authority receives, on average, 3 subsequent derogations per year at an additional fee of £706. However, a subsequent request to dispense with this measure has not been made to date.

56. HSE is currently unable to estimate the number of CL3 GM centres that are operating negative air pressure and HEPA filtration for work with non-airborne GMMs, nor the number that are applying for derogations (although this latter number is expected to be small). HSE can not predict how businesses will respond to the greater flexibility proposed under B-2 in terms of changes to the usage of negative air pressure and HEPA filters, particularly at sites carting out work at different Containment Levels or with different GMMs with different possible exposure routes (i.e. airborne and non-airborne). It is estimated that
potential cost savings could come in administrative costs if GM centres no longer need to apply for a derogation, or in running costs if negative air pressure and HEPA systems are used less. Additional information will be sought from stakeholders during the consultation period in order to provide as robust an estimate as possible for the final stage impact assessment.

57. **B-3: Microbiological safety cabinet at CL4.** This measure (containment measure 7, Table 1a) requires users to use a specific microbiological safety cabinet (MSC) (namely, a Class III MSC) for work with infective material. Following the proposed change in wording, it is anticipated that most sites currently using this approach will continue to do so as it offers operator protection proportionate to the level of risk presented.

58. At CL4, the current requirement in the regulation goes beyond the Directive (and the Biological Agents Directive) in prescribing a particular type of MSC (i.e. Class III MSC is a fully enclosed glove box). The proposed change is to revert more closely to the standard in the Directives. The selection of the most appropriate MSC to provide high levels of operator and environmental protection will be based upon risk assessment and the benchmark set out in industry guidance. This flexibility recognises that not all CL4 work (e.g. foot and mouth disease virus does not present a risk to the operator) requires a Class III MSC and also accommodates the use of alternative containment approaches for human pathogens (e.g. positive pressure suited systems), where a Class III MSC is not practicable. When combined with other MSC types (e.g. Class I MSC – open fronted cabinet), the suited systems can offer an equal level of protection hence will not lower protection of human health or the environment.

59. The cost saving of this change is expected to be limited, given that there are currently only six GM centres operating at CL4 and only projected to be eight by the end of the appraisal period. It is also difficult to predict how CL4 operators will respond to the change, and the business factors that will weigh upon their decision whether to replace their existing safety cabinets or carry on as usual. HSE considers that rather than lead to quantifiable cost savings, the proposals under B-3 will allow for greater flexibility in choosing between control measures and allow UK business to compete more easily with EU businesses (and worldwide) where this measure is already not as prescriptive.

60. **B-4: Inactivation of waste at CL1 - laboratories.** This measure (containment measure 17, Table 1a) requires the user to inactivate all GMMs in contaminated waste by a validated method at CL1. Following the proposed change, GM centres will be required to inactivate GMMs in contaminated waste where a risk assessment shows this is required.

61. The Directive emphasises the need to assess the routes of disposal and means of inactivation for material contaminated with GMMs. This measure goes beyond the standard specified in the Directive for CL1. The proposed change will revert to the standard in the Directive and make the requirement for inactivation of waste at CL1 to be determined by the risk assessment. This change would permit flexibility on the means and method by which inactivation is undertaken and remove the perceived mandatory use of an autoclave (a high-pressure steam steriliser) for this purpose. The proposed change in this containment measure is supplemented by guidance to explain under what circumstances (i.e. where the GMM is biologically contained and therefore cannot survive, replicate, spread or transfer genetic material) it is permissible to dispose of waste without inactivation (see Annex B of the consultation document) thereby ensuring the protection of human health and the environment.
62. HSE estimates that currently CL1 waste is autoclaved, except where GM centres assess that an alternative inactivation method is appropriate and apply for a derogation. Following the proposed change, HSE expects that businesses will continue to assess the risk of their waste at CL1 and decide that it is either appropriate to autoclave it, inactivate it by alternative means or, where the GMM is either biologically contained or incapable of survival outside of the laboratory, dispose of it untreated. Alternatives to autoclaving would no longer require the derogation.

63. HSE believes from information from industry that running an autoclave to inactivate CL1 waste can cost up to around £14 thousand per annum for larger GM centres (i.e. those inactivating approximately 500kg of waste per week). The majority of GM centres will generate a percentage of Class 1 waste so there will be savings to be made across the sector and on an ongoing basis. As such, HSE estimates that this measure has the potential to yield substantial savings to industry over the ten-year appraisal period.

64. However, at this stage it is difficult to accurately predict the number of GM centres that currently autoclave their waste and would simply continue to do so or reassess their practices and introduce alternative methods. In particular, GM centres performing work at multiple containment levels may not choose to operate two different processes for inactivating waste.

65. Further information of current practices and likely changes to practice will be sought from industry during consultation in order to provide a more robust estimate for this potential saving in the final stage impact assessment.

66. **B-5: Observation window at CL3.** This measure (containment measure 19, Table 1a) requires GM centres to have a window built into their CL3 laboratories so that workers can be observed from the outside. Following the proposed change, this window would only be required where a risk assessment showed it is required.

67. This measure provides a means of viewing the occupants of the laboratory. At CL3, this goes beyond the standard in the Directive. The proposed change will revert to the Directive so that the observational window requirement would be determined by risk assessment. This would bring the requirements in line with the Biological Agents Directive, where an observation window is only recommended at CL3 (i.e. not an absolute requirement). The current measure is often at odds with other regulatory requirements (e.g. security measures) and so the proposed change will allow equally effective alternatives (e.g. personal alarms, buddy systems, management procedures) that do not lower the level of protection for human health and the environment or security of the laboratory.

68. The removal of this requirement at CL3 will allow greater flexibility in the design of laboratories and may have some security advantages where solid doors and walls replace ones with windows in. However, costs may be encountered if alternative methods are used but this will be the choice of the user. Overall, HSE considers that the change is most relevant to new build laboratories but it is unlikely that any changes will be made to existing laboratories and therefore do not envisage any savings.

69. **B-6: Use of isolators at CL1.** This measure (containment measure 9, Table 1c) requires GM centres to keep animals in isolators at CL1 where a risk assessment shows this is required. Following the proposed changes, this would not be required.

70. Isolators are intended to contain infected animals and afford a level of protection to users. It is not apparent in what situation this containment measure would be
required at CL1, where risk to human health is nil or negligible. This is an entirely domestic requirement not in the Directive containment tables, which reflects current working practices and clarifies the need for an enclosure or appropriate & distinct containment for animals. However, the proposed change is limited to CL1, where isolators will not be required. This change reflects the HEPA requirements for isolators (Measure 5 Table 1c) and provides a greater distinction between CL1 and CL2. In short, it is more appropriate for work that requires this measure to be undertaken at CL2 rather than CL1. This proposed change will ensure the most appropriate protection for human health and the environment is applied.

71. There are two possible outcomes to this change. The first would be if a risk assessment shows that an isolator is necessary to protect human health or the environment, the likelihood is that the level of activity is not class 1, which by definition is nil or negligible risk. It is most likely that the activity would be a minimum of class 2, which is low risk. This could result in the user having to notify the class 2 activity but we do not believe there will be any examples of this. The other option is that the risk assessment shows the isolator is necessary to protect the animal and therefore not protecting human health or the environment and the user may choose to select this control measure on that basis. There will be no costs associated with this proposal, as the purposes of the containment measure are outside the scope of the GMO regulations.

72. **B-7: Controlled areas purpose built at CL4.** This measure (containment measure 2, Table 2) requires controlled areas for CL4 work to be purpose built. Following the proposed change, such areas will be permitted to be refurbished at existing facilities.

73. This measure relates to specifically building a controlled area to house a closed system at CL4 (rather than, for example, using an existing controlled area). This goes beyond the standard in the Directive. The proposed change will retain the need for a controlled area but remove the requirement for this area to be purpose built. Although this change will create an inconsistency between the GMO regulations and COSHH in the UK, there are currently no CL4 facilities of this type working with human pathogens and only one working with a specified animal pathogen. The intention would be to amend in the Biological Agents Directive, when the opportunity arises.

74. Changing this requirement may allow existing facilities to be refurbished or alternative approaches to be applied. This could facilitate expansion in CL4 work and could be beneficial to the industry. The choice to build from scratch or refurbish could be based on risk and a cost effectiveness analysis. While it is not possible to assign a monetary value to this measure, or indeed estimate what value this could bring to the economy and to the future of research, it is clear that this could be beneficial to the UK and enable manufacturing at the highest containment level. Before commencing work, the commissioning process would ensure the appropriate level of protection for human health and the environment is achieved.

75. **B-8: Biohazard signs at CL1.** This measure (containment measure 9, Table 2) requires GM centres operating at CL1 to post biohazard signs where a risk assessment shows this is required. Following the proposed change, this will not be required.

76. The intention of the biohazard sign is to inform those entering the facility of relevant hazards that may be present. At CL1, the current requirement goes beyond the standard in the Directive. The proposed change is to remove the need for a biohazard sign at CL1. As work at this level is defined as of
nil/negligible risk, the biohazard sign is not necessary. This change will therefore not affect the protection of human health or the environment.

77. We do not envisage there to be any cost or cost savings to this change as those operating at CL1 in a large-scale facility are unlikely to have identified a biohazard sign was required as part of their risk assessment. If this is not the case and they have posted biohazard signs, they are unlikely to remove the sign. There could be a small saving related to not having to replace those signs when they become faded and worn. However, this is expected to be so infrequent and the signs so inexpensive as to be immaterial.

78. **B-9: Written procedures and training records.** Presently, GM centres at CL2 are not required to retain written record of staff training. Following the proposed changes, they will be required to do so where a risk assessment shows this is required.

79. The requirement for written procedures and training records (containment measure 19, Table 2) arises in the Directive from the principles of good microbiological practice. The containment table is used in addition to the general principle to clarify this requirement. Currently at CL2, this measure is not required, however this is inconsistent with the similar requirement in Table 1a (measure 21). By amending the requirement, to be risk based, this will remove inconsistencies in the containment tables and will not increase regulatory requirements unless the risk assessment indicates this is necessary. In this way, the change requires the most appropriate protection for human health and the environment to be applied.

80. We do not expect there to be any costs or cost savings to this change as those operating at CL2 who do not provide written procedures and make a record of staff training are unlikely to now require them. It is also expected that those who do keep a written record will continue to do so for reasons of staff development and knowledge management. This measure simply aligns requirements in the different tables (1a and 2).

81. **B-10: Inactivation of waste at CL1 – other facilities.** This measure requires users to inactivate all GMMs in contaminated waste by a validated method at CL1. Following the proposed change, they will only be required to do so where a risk assessment shows this is required. This proposal is very similar to that under B-4 in paragraph 60 to 65, above. However, this proposed change refers to facilities other than laboratories, such as manufacturers.

82. The Directive emphasises the need to assess the routes of disposal of and means of inactivation for material contaminated with GMMs. The current requirement at CL1 goes beyond the standard specified in the Directive. The proposed change will revert to the standard in the Directive and make the requirement for inactivation of waste at CL1 determined by the risk assessment. The proposed change in this containment measure is supplemented by guidance to explain under what circumstances (i.e. where the GMM is biologically contained and therefore cannot survive, replicate, spread or transfer genetic material) it is permissible to dispose of waste without inactivation (see Annex B of the consultation document) thereby ensuring the protection of human health and the environment.

83. As discussed in paragraph 64 under B-4, above, HSE is currently unable to estimate this potential cost saving as further information is needed regarding current inactivation practice and how that may change. It should be noted that HSE expects the cost of inactivation per GM centre under B-10 to be greater than that under B-4, as B-10 is expected to affect large-scale pharmaceutical manufacturers rather than laboratories. However, the total cost will probably be
smaller as there are only around 37 such manufacturers. Further information will be gathered in consultation to estimate this cost for the final stage impact assessment.

**Changes to the notification requirements and register (Changes C-1 to C-3 in the consultation document)**

84. **C-1: Emergency plans.** The requirement for an emergency plan is based upon the risk assessment determining that a foreseeable accident is liable to result in either the health of people outside the premises being seriously affected or a risk of serious damage to the environment. Currently the regulations place a duty on the Competent Authority to ensure an emergency plan is in place but is not explicitly risk based. Consequently, the amendments will clarify and make it explicit that the emergency plan should only be confirmed where the risk assessment identifies a need for one.

85. We do not envisage there to be any costs or cost savings to this change as users will still need to assess whether an emergency plan is required and put one in place, if the risk assessment shows it is necessary.

86. **C-2: Information required for a Class 2 notification.** The current information required for a notification of a Class 2 activity requires the user to provide a risk assessment for the proposed activity. This goes beyond the information requirements within the Directive, which stipulates the provision of a summary of the assessment. The Defra led Smarter Environmental Regulation Review has identified this as an area where the Competent Authority requirement for information could be reduced.

87. The user has to undertake the risk assessment as a requirement of the regulations anyway and feedback from stakeholders during pre-consultation suggests that producing a summary of the risk assessment may create an additional burden. There are two possible outcomes to this change. The first is that each user will spend an additional 30 minutes to one hour summarising the risk assessment. There are, on average, 120 Class 2 activity notifications submitted to the Competent Authority each year. The second outcome is that either the user would submit the full risk assessment anyway or that summaries are already produced, such as for senior management or training purposes. HSE will seek further information from stakeholders in consultation to try and estimate any possible cost burden for the final stage impact assessment.

88. **C-3: Register of notifications.** The notifications made under the GMO regulations are maintained on a public register, which is held in HSE offices (in Bootle and Edinburgh) as a paper copy register and as an electronic document on the HSE website. The proposal is to withdraw the paper copy register and retain only an online electronic version.

89. This change will not affect the accessibility by the public who may wish to inspect the register. The proposal will remove the administration costs involved in maintaining a paper copy in two locations.

**Cost Savings to Government**

90. The Competent Authority receive, on average, 160 notifications per year and it takes one Band 6 employee approximately 10 minutes to make a copy of the notification to place on the public register in Bootle. In addition, it is estimated that a further three hours are spent by a Band 6 Administrator maintaining the regional copy in Edinburgh.

91. This gives around 30 hours per year. The full economic cost to HSE of a Band 6 Administrator is around £18.37 per hour, giving a total average annual cost
saving to HSE of **around £550 per annum** and in present value terms, **just under £5 thousand over ten years.**

**Change to the requirement for a Genetic Modification Safety Committee (GMSC) (Change D-1 in the consultation document)**

92. **D-1: Requirement to establish a Genetic Modification Safety Committee.**

Users are required to establish a GMSC, which is required to provide advice on risk assessments made under the GMO regulations. The Directive is less prescriptive in that as part of the general principles, it requires that a biological safety committee or subcommittees should be established 'if required'. The proposed change will permit advice on risk assessments for Class 1 activities to be obtained elsewhere (e.g. biological safety advisor, other organisations) and by a committee whose remit is not solely focused on GM activities but has the appropriate expertise (e.g. biological safety committee). It is envisaged that collectively this will ensure adequate oversight is maintained but reduce the time spent by the committee discussing activities of nil or negligible risk. This change is supplemented by additional explanation in the guide to the regulations (See Annex C of the consultation document).

93. From information collected as part of the pre-consultation, we can estimate that on average, a GMSC meets between 1-3 times per annum for an average of 2 hours per meeting. The make-up of the GMSC will be dependant on the containment level(s) at which the GM centre is operating and the volume of activities undertaken. The constitution of the GMSC is left to the judgement of the GM centre but on average, we estimate it will comprise between 5-10 participants of different disciplines, all likely to be academic. Some GM centres will have more than one GMSC. There are a number of possible outcomes to this change:

94. The GM centre may maintain their GMSC on the basis that it is beneficial to their operations and/or because the committee also consider risk assessments of Class 2 and above;

95. The GM centre may maintain their GMSC but reduce the remit of the committee by not requiring Class 1 risk assessments to be considered and use alternative means for considering these assessments using a fast track approach, such as email etc;

96. The GM centre may discontinue their GMSC as they only operate at CL1 and seek advice on their risk assessments elsewhere; or

97. The GM centre may merge the GMSC with a broader biological safety committee.

98. Any organisation may also do a combination of the options listed above.

99. **The costs of this change are yet to be calculated as HSE does not currently have sufficient information from stakeholders to estimate which of the above courses is most likely to be taken by GM centres. HSE will be seeking direct engagement with GM centres during consultation to try to estimate this for the final stage impact assessment.**

**Restructuring and tidy up (Changes E-1 to E-6 of the consultation document)**

100. Collectively, these make changes to the language and layout of the regulations. These changes have no impact on the legal duties under the regulations but should assist users with compliance.

101. As part of this restructure, the opportunity has been taken to divide the regulations into ‘Parts’ to help differentiate between duties on the user and the
Competent Authority. This format clearly directs the user to the relevant requirements and is expected to improve understanding of what is required and aid compliance with the regulations.

Cost Savings to Business

102. We estimate based on knowledge of the sector that, on average, 40% of GM centres will currently be spending one hour referring to the regulations per annum. Taking account of the expected growth in the sector shown in Table 2, this means that in Year 0, around 239 GM centres are expected to refer each year, rising to about 326 in Year 9. Expert opinion within HSE anticipates that the revised format will reduce the time spent by 30%, saving each GM centre around 18 minutes per annum.

103. Assuming this is done by a Biological Safety Officer (BSO) at a full economic cost of about £26.81 per hour, this gives an average annual saving of just over £2 thousand, or around £19 thousand in present values over ten years.

104. However, this change should not to be considered in isolation, as any simplification to the structure of the regulations will also have an impact on the guide to the regulations (see paragraphs 104-106) and improved understanding.

105. In addition, new entrants to the sector will encounter savings as they establish their operations and make efforts to identify their duties for the first time. There are approximately 24 new entrants to the GM sector per annum. We estimate that it takes a BSO or equivalent, approximately 1 to 3 days to become familiar and understand their requirements under the GMO regulations. Note that new entrants are also included in the savings due to ongoing referrals in paragraphs 102 to 104, above. This is not considered double-counting, however, since HSE estimates that new entrants will need to refer to the guidance throughout the year subsequent to their initial reading of them. We can presume the same saving of 30% will be made for each new entrant using the new simplified structure of the regulations.

106. Assuming eight hours per working day, this gives a time saving per GM centre of between just under 2.5 hours and just over 7 hours, with a best estimate of just under 5 hours. Costed at £26.81 per hour, this gives an average annual saving of between just under £2 thousand and just under £5 thousand, with a best estimate of about £3 thousand. The present value over ten years is between around £7 thousand and £21 thousand, with a best estimate of about £14 thousand.

107. Therefore, the total average annual cost saving, including both savings from established centres referring to simplified guidance and from new entrants more easily understanding their duties, is between about £4 thousand and £7 thousand, with a best estimate of just over £5 thousand.

108. The total present value over ten years is estimated to be between about £26 thousand and £40 thousand, with a best estimate of about £33 thousand.

Guide to the Regulations

109. The subject matter of the regulations is highly technical. The guide to the current regulations has an amalgamation of regulatory and technical guidance, which makes the document dense, long and difficult for the user to navigate. Consequently, the intention is to provide a slim-line guide to the regulations restricted to explaining the regulatory requirements and moving the technical content to the Scientific Advisory Committee for Genetic Modification (SACGM) compendium of guidance.
110. In response to the feedback during pre-consultation with practitioners, the guide to the regulations will include expanded sections on how to notify groups of (rather than single) genetic modification activities (referred to in the regulations as ‘Connected Programmes of Work’) and when to notify ‘Significant Changes to Notifications’. Stakeholders will be invited to be involved in the drafting of the guide via the HSE online community established for the consolidation.

111. It is expected that the redrafting of guidance will impose a cost on HSE beyond the ‘business as usual’ costs of regulatory update. These costs have not been estimated at this stage, but will be calculated for the final stage impact assessment.

**Familiarisation costs**

112. There will be one-off costs to industry of familiarisation with their new requirements under the GMO (CU) 2014.

**Cost to Business**

113. It is assumed that 100% of GM centres need to read and understand the new requirements and decide if and how the changes impact their operations. This will take on average between 1 to 3 hours depending on the containment level at which they are operating at and the number of changes to the regulations which impact on any given level(s). It will be carried out by a BSO at a cost of £26.81 per hour.

114. There are currently around 598 GM centres and the total time required for familiarisation will be in the region of 600 to 1,800 hours, with a best estimate of about 1,200. This gives a total one-off cost in Year 0 of between about £16 thousand and £48 thousand, with a best estimate of about £32 thousand.

115. In addition, it is expected that the BSO will need to disseminate relevant information to colleagues. Based on the length and complexity of the changes, HSE estimates that this will take the form of a 30 minute presentation to between 5 and 15 colleagues, with a best estimate of around 10. Assuming that the workers’ time has a value equal to the BSO, this gives a one-off cost of between about £48 thousand and £128 thousand, with a best estimate of about £88 thousand.

116. This gives a **total one-off cost** of familiarisation of between £64 thousand and £176 thousand, with a **best estimate of about £120 thousand**.

**Reviewing risk assessments**

117. Following familiarisation, GM centres will need to account for changes to practice in their risk assessments. The costs of reviewing risk assessments will also be in terms of the time taken to complete this task.

**Cost to Business**

118. It is assumed that it will take each of the 598 GM centres between 1-2 hours to revise each risk assessment and that there will be on average three risk assessments per GM centre. This is assumed to be carried out by a BSO. The total one-off costs associated with reviewing risk assessments are therefore expected to be between about £48 thousand and £96 thousand, with a **best estimate of about £72 thousand**.

**Summary of Costs and Cost Savings of Option 2**

119. The costs and cost savings of Option 2 that have been estimated at this stage are as follows.
Table 4: Estimated monetised costs and cost savings of Option 2 (£thousands)$^3$

<table>
<thead>
<tr>
<th>Costs</th>
<th>Minimum</th>
<th>Best Estimate</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs to Business</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Familiarisation</td>
<td>£64</td>
<td>£120</td>
<td>£176</td>
</tr>
<tr>
<td>Reviewing risk assessments</td>
<td>£48</td>
<td>£72</td>
<td>£96</td>
</tr>
<tr>
<td><strong>Total Costs</strong></td>
<td><strong>£112</strong></td>
<td><strong>£192</strong></td>
<td><strong>£272</strong></td>
</tr>
<tr>
<td>Cost Savings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost Savings to Business</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-1 - E-5: Restructuring</td>
<td>£26</td>
<td>£33</td>
<td>£40</td>
</tr>
<tr>
<td><strong>Total Cost Savings to Business</strong></td>
<td><strong>£26</strong></td>
<td><strong>£33</strong></td>
<td><strong>£40</strong></td>
</tr>
<tr>
<td>Cost Savings to Government</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C-3: Notifications register</td>
<td>£5</td>
<td>£5</td>
<td>£5</td>
</tr>
<tr>
<td><strong>Total Cost Savings to Government</strong></td>
<td><strong>£5</strong></td>
<td><strong>£5</strong></td>
<td><strong>£5</strong></td>
</tr>
<tr>
<td><strong>Total Cost Savings</strong></td>
<td><strong>£31</strong></td>
<td><strong>£38</strong></td>
<td><strong>£45</strong></td>
</tr>
</tbody>
</table>

Note: totals may not sum due to rounding

120. The total estimated costs are estimated to be between about £112 thousand and £272 thousand, all of which falls on business. The best estimate is about £192 thousand.

121. Total cost savings estimated at this stage are between about £31 thousand and £45 thousand, with a best estimate of about £38 thousand. Most of this falls to business. However, some of the largest expected cost savings are yet to be estimated, as shown in Table 5.

122. In addition, the following potential cost and cost savings have not yet been estimated, but efforts will be made during consultation to gather further information to do so for the final stage impact assessment.

$^3$ Please note that the calculation of the net position of Option 2 has been omitted to prevent giving a misleading impression of the full impact before all the costs and cost savings have been estimated. A full net calculation will be made for the final stage impact assessment.
Table 5: Summary of proposed changes not yet monetised

<table>
<thead>
<tr>
<th>Proposed Chance</th>
<th>Expected to be cost or saving?</th>
<th>Expected to be substantial?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-2: Incinerator for the disposal of animal carcasses</td>
<td>This is expected to be an ongoing saving to business</td>
<td>This is expected to be a small saving as it only affects CL4s, of which there are currently only six</td>
</tr>
<tr>
<td>B-1 : Negative pressure at CL2 and CL3; &amp; B-2: HEPA filtration at CL3</td>
<td>This is expected to be an ongoing saving to business</td>
<td>This may be a substantial saving as the running costs of negative pressure and HEPA systems are expected to be sizeable</td>
</tr>
<tr>
<td>B-4: Inactivation of waste at CL1 - laboratories</td>
<td>This is expected to be an ongoing saving to business</td>
<td>This may be a substantial saving as it is expected to affect most if not all GM centres</td>
</tr>
<tr>
<td>B-10: Inactivation of waste at CL1 – other facilities</td>
<td>This is expected to be an ongoing saving to business</td>
<td>This my be a substantial saving, although not as great as that under B-4 as fewer GM centres will be affected</td>
</tr>
<tr>
<td>C-2: Information required for a Class 2 notification</td>
<td>This is expected either to be an ongoing saving or have no impact on business</td>
<td>This is expected to be a small or nil saving</td>
</tr>
<tr>
<td>D-1: Requirement to establish a GMSC</td>
<td>This is expected to be an ongoing saving to business</td>
<td>This may be a substantial saving as it has potential to affect many CL1s</td>
</tr>
<tr>
<td>Updating guidance</td>
<td>This is expected to be a one-off cost to Government</td>
<td>This is expected to be a small cost</td>
</tr>
</tbody>
</table>

**Option 3 – Costs and benefits**

*Restructuring and tidy up (Changes E-1 to E-6 of the consultation document)*

123. Under Option 3 it is proposed to consolidate and simplify the GMO regulations, but without the further changes described under A, B, C and D. As such, it is estimated that the only potential cost saving will relate to the time saved referring to the guidance, as described in Option 2 above.

**Cost Savings to Business**

124. As described in paragraphs 102-103, above, the total annual average cost saving is expected to be between about £4 thousand and £7 thousand, with a best estimate of just over £5 thousand.

125. The total present value over ten years is estimated to be between about £26 thousand and £40 thousand, with a best estimate of about £33 thousand.
Familiarisation costs

126. There will be a one-off cost to business from familiarising with the consolidated regulations under Option 3. However, as there will not have been any change to their duties under Option 3, it is not expected that as much time will be spent familiarising as under Option 2. In addition, it is not expected that any time will be spent revising risk assessments.

Cost to Business

127. It is estimated that at each GM centre, a BSO will spend around 1 hour familiarising with the consolidation and restructuring under Option 3. Unlike under Option 2, there is not expected to be a presentation to co-workers.

128. Costed at the BSO hourly cost of £26.81, across the 598 GM centres this is estimated to give a one-off cost of around £16 thousand.

Summary of Costs and Cost Savings of Option 3

129. Total costs and cost savings of Option 3 are summarised in Table 6.

<table>
<thead>
<tr>
<th>Table 6: Estimate Costs and Cost Savings of Option 34</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Costs</strong></td>
</tr>
<tr>
<td><strong>Minimum</strong></td>
</tr>
<tr>
<td>Costs to Business</td>
</tr>
<tr>
<td>Familiarisation</td>
</tr>
<tr>
<td><strong>Total Costs</strong></td>
</tr>
<tr>
<td>Cost Savings</td>
</tr>
<tr>
<td>Cost Savings to Business</td>
</tr>
<tr>
<td>E-1 - E-5: Restructuring</td>
</tr>
<tr>
<td><strong>Total Cost Savings</strong></td>
</tr>
</tbody>
</table>

Note: totals may not sum due to rounding

130. Total cost estimates are estimated to be around £16 thousand and fall wholly on business. Cost savings are estimated to be between about £26 thousand and £40 thousand with a best estimate if about £33 thousand. These, too, accrue to business.

Non-monetised costs and benefits

131. There are wider non-monetised benefits under Option 2 of ensuring that the UK remains one of the best places in Europe to carry out research with genetically modified organisms. This area of research provides some of the scientific building blocks for key growth areas such as biotechnology and synthetic biology. The UK is currently carrying out some of the world-leading research in this area,

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4 Please note that the calculation of the net position of Option 2 has been omitted to prevent giving a misleading impression of the full impact before all the costs and cost savings have been estimated. A full net calculation will be made for the final stage impact assessment.
including work in collaboration with wider international ventures. The proposed changes should ensure that the regulatory approach for protecting human health and the environment reflects current industry practice, is robust, proportionate to risk and it is clear what needs to be done to comply.

132. It is not expected that there will be any health and safety implications of the proposed changes, under either Option 2 or 3. The consolidation is not intended to rewrite the substance of the regulations. Instead, the opportunity has been taken to make a number of changes that allow the regulations to be more risk based and proportionate and reflect experience of applying these regulations since 2000. The proposed changes will remove regulatory burden with no detriment to health, safety or environmental protection. Many of those changes relate to Class 1 activities which by definition are of nil or negligible risk.

Rationale and evidence that justify the level of analysis used in the IA (proportionality approach)

133. Notification data has been provided to the most accurate level possible and some cost estimates and assumptions have been tested during informal consultation. Areas requiring further evidence and estimate have been highlighted and HSE has a strategy in place to gather further information during consultation stage. Consequently, the level of analysis in this IA, based on HSE best estimates and information gathered from industry about the potential impacts of the changes, is considered to be appropriate for this consultation stage IA.

Risks and assumptions

134. Feedback from larger organisations has suggested that there may be over-compliance at CL1 after the proposed changes, because these dutyholders may choose to retain current working practices and standards rather than implement the changes proposed at CL1. Although this would not result in any additional cost to the dutyholder, it does not have the desired effect of reducing the regulatory burden at this lower risk work. However, it is anticipated from the feedback that the smaller biotech companies will benefit from these changes.

135. It must be noted, therefore, some cost savings will not be realised where GM centres choose to continue operating as before. HSE cannot currently estimate what proportion of GM centres will over-comply at CL1 or how this will be affected by, for example, the size of the GM centre or whether it is also carrying out work at other containment levels. As part of consultation stage evidence gathering, HSE will attempt to estimate the likely scale of this effect in order to adjust estimated cost savings for the final stage impact assessment. This will be taken into account in the estimation of the costs and cost savings outlined in Table 5.

Direct costs and benefits to business calculations (following OITO methodology)

136. This section will be completed following the full estimation of costs and cost savings.

Wider impacts

Statutory equality duties

137. None has been identified.
Economic impacts / Competition:

138. It is expected that where the proposed changes under Options 2 and 3 lead to a simplifying of the regulatory regime, this will make it easier for new entrants to comply and may encourage additional sector growth, as well as allowing existing GM centres to move into other areas of work.

139. Where the proposals under Option 3 allow for greater flexibility in the types of equipment or premises that may be used, this may reduce the capital costs for both operation within and entry to the sector. However, the full scale of these impacts will not be able to be fully assessed until further information is gathered during consultation regarding the effects of proposed changes on business costs and cost savings.

Small and Micro-businesses

140. The changes proposed under the GMO consolidation will impact on small and micro-businesses as they make up the largest proportion of organisations carrying out work at Containment Levels 1 and 2 (approximately 44%). Another factor is the number of activities being undertaken at each centre. For small or micro-businesses this will be limited to small numbers, whilst for larger organisations (e.g. a major University) this can consist of several hundred activities. It is estimated that the number of small and micro-businesses involved in work at Containment Level 1 will grow as the biotechnology industry develops.

141. Under the current regulations, there are already fewer regulatory requirements on those doing Class 1 activities than there are for Class 2 to 4 activities as proportionate to the risk (for example, those carrying out activities at Class 1 are not required to notify those activities to the Competent Authority). Where changes to the regulations have been possible, it is with the proviso that they should reduce regulatory impact on the dutyholder but without reducing the level of protection to human health or the environment. This has been possible, particularly for the lower risk work, based on knowledge and experience as the regulations have matured. Consequently, this will result in a further reduction in regulatory requirements on the smaller businesses doing Class 1 activities. It does not mean they are exempt from health and safety legislation, but their level of regulation will be proportionate to the level of risk arising from their work.

142. In accordance with the Better Regulation Framework guidance, it is not necessary to carry out a small and micro-business assessment for the purposes of this impact assessment as the regulations implement Directive 2009/41/EC.

Environmental impacts

143. None has been identified. No containment standards will be affected by the proposed changes under Option 2 or 3.

Health and Well Being

144. None has been identified. No containment standards will be affected by the proposed changes under Option 2 or 3.
Human Rights
145. Human rights – the proposed changes do not affect people’s human rights.

Justice System
146. None has been identified.

Rural Proofing
147. None has been identified

Sustainable Development
148. None has been identified.

Social impacts
149. None has been identified.

Summary and preferred option with description of implementation plan.
150. The preferred option is Option 2, which meets the requirements of the Löfstedt recommendation to consolidate, modernise, and simplify the Genetically Modified Organisms (Contained Use) Regulations 2000 and its three amending sets of legislation, whilst ensuring that the proposed changes do not reduce the level of protection to the environment or increase risks to human health.

151. The costs and benefits of the changes are not great as the sector concerned is small. The most significant costs arise from the need for those working with biological agents to familiarise themselves with the changes. The cost savings arise from the changes which reduce regulatory requirements at CL1 work, particularly for small businesses, and reduced time spent identifying duties within the regulations. There are expected to be further cost savings from reduced running costs for some control systems, but these have yet to be estimated at this stage.
ANNEX E – Consultation Question Set

Q1(a) Should containment measure 15 (disinfection procedures) of Table 1a be removed as suggested?

Y/N

Q1(b) Should containment measure 6 (incinerator) of Table 1c be removed as suggested?

Y/N

Q1(c) Should containment measure 16 (decontamination facilities) of Table 2 be removed as suggested?

Y/N

Q1(d) Please provide some comments to support your answers including any costs or benefits that these changes may cause.

Q2(a) Should containment measure 5 (inward airflow) of Table 1a be amended as suggested at CL2?

Y/N

Q2(b) Should containment measure 5 (inward airflow) of Table 1a be amended as suggested at CL3?

Y/N

Q2(c) Please provide some comments to support your answers including any costs or benefits that these changes may cause.

Q3(a) Should containment measure 6 (HEPA filtration) of Table 1a be amended as suggested at CL3?

Y/N

Q3(b) Please provide some comments to support your answer including any costs or benefits that this change may cause.

Q4(a) Should containment measure 7 (microbiological safety cabinet) of Table 1a be amended as suggested at CL4?

Y/N
Q4(b) Please provide some comments to support your answer including any costs or benefits that this change may cause.

Q5(a) Should containment measure 17 (waste inactivation) of Table 1a be amended as suggested at CL1?
Y/N

Q5(b) Does the related guidance in Annex B clarify the requirements for inactivation of waste at CL1?
Y/N

Q5(c) Please provide some comments to support your answers including any costs or benefits that this change may cause.

Q6(a) Should containment measure 19 (observation window) of Table 1a be amended as suggested at CL3?
Y/N

Q6(b) Please provide some comments to support your answer including any costs or benefits that this change may cause.

Q7(a) Should containment measure 9 (isolators) of Table 1c be amended as suggested at CL1?
Y/N

Q7(b) Please provide some comments to support your answer including any costs or benefits that this change may cause?

Q8(a) Should containment measure 2 (controlled area) of Table 2 be amended as suggested at CL4?
Y/N

Q8(b) Please provide some comments to support your answer including any costs or benefits that this change may cause.
Q9(a) Should containment measure 9 (biohazard sign) of Table 2 be amended as suggested at CL1?

Y/N

Q9(b) Please provide some comments to support your answer including any costs or benefits that this change may cause.

Q10(a) Should containment measure 19 (records of training) of Table 2 be amended as suggested at CL2?

Y/N

Q10(b) Please provide some comments to support your answer including any costs or benefits that this change may cause.

Q11(a) Should containment measure 21 (waste inactivation) of Table 2 be amended as suggested at CL1?

Y/N

Q11(b) Please provide some comments to support your answer including any costs or benefits that this change may cause.

Q12(a) Should the emergency plan provisions be amended as suggested?

Y/N

Q12(b) Would you prefer to a) submit a full risk assessment for Class 2 activities; or b) would you prefer to submit a summary of the assessment for Class 2 activities?

a) or b)

Q12(c) Do you have any objections to remove the hardcopy register of notifications and move to an electronic version (only)?

Y/N

Q12(d) Please provide some comments to support your answers including any costs or benefits that these changes may cause.

Q13(a) Should the source of advice on risk assessments be amended as suggested for Class 1 risk assessments?
Y/N

Q13(b)  Provided the committee has appropriate expertise, do you agree with multi-functional committees providing advice on GM risk assessments?

Y/N

Q13(c)  Does the related guidance in Annex C clarify the requirements for the Genetic Modification Safety Committee?

Y/N

Q13(d)  Please provide some comments to support your answers including any costs or benefits that these changes may cause.

Q14(a)  Do you agree or disagree with the proposed changes to the structure and language of the regulations? If you disagree, please state which change you disagree with and why?

Q14(b)  Should the term genetically modified organisms other than micro-organisms be amended as suggested? Are there alternatives that would be more appropriate?

Q15(a)  Are you content that the savings and transitional arrangements are adequate to cover the changes arising from the new regulations?

Y/N

Q15(b)  Please provide some comments to support your answer including whether you will be required to re-classify your work or notify under the transitional arrangements?

Q16(a)  Does the application of GMO contained use regulations to synthetic biology present any practical problems?

Q16(b)  Considering future applications (or products) of synthetic biology outside those of the traditional contained use sector, do you have views on any better-fit regulatory models suitable for the effective and responsible regulation of synthetic biology?
Q17(a) Do you have any views on any aspect of the preliminary impact assessment?

Q17(b) Are there any costs or benefits related to the proposed changes which have not been included in the impact assessment?

Q18(a) Do you have any objections to replacing the hardcopy of the guide to the regulations (L29) with an electronic online version (only)?

Y/N

Q18(b) Please provide some comments to support your answer including any costs or benefits that this change may cause.
Consultation on Proposal to Consolidate the Genetically Modified Organisms (Contained Use) Regulations 2000 and the three amending Regulations of 2002, 2005 and 2010

The full text of this and other Consultative Documents can be viewed and downloaded from the Health and Safety Executive website on the internet: www.hse.gov.uk/consult/index.htm