Health and Safety Executive for Northern Ireland

Proposals for the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015

Consultative Document

June 2014

Proposals for the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015

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Summary of proposed changes

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

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

Introduction

2. This Consultative Document (CD) sets out proposals from the Health and Safety Executive for Northern Ireland (HSENI) to introduce a new set of regulations, provisionally titled 'The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015', which consolidates 'The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001' and its amending regulations made in 2006 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. HSENI is consulting stakeholders as required under article 46 of the Health and Safety at Work (Northern Ireland) Order 1978 (HSWO) 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. HSENI is the joint Competent Authority with the Department of the Environment for the regulation of contained use of GMOs.

Background

5. 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.

6. 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.

7. 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).

8. 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.

9. Since 2001, when the regulations first came into force, there have been two amending regulations, introduced in 2006 and 2010. A guide (L29[2]), published by the Health and Safety Executive for Great Britain (HSE) in respect of the equivalent Regulations in Great Britain can be read across in support of the NI Regulations.

Why are the Regulations being amended?

10. In Great Britain the consolidation of the equivalent regulations was one of the recommendations of the Löfstedt review of health and safety, commissioned by the UK Government and published on the 28 November 2011. The Löfstedt review recommended that a consolidation of the Great Britain GMO legislation should:

- ensure the regulations reflect current industry practices;

- limit the extent to which health and safety legislation has enhanced EU Directives (gold-plated); and

- simplify the regulations (for example by reducing any duplication).

11. As a result, HSE has been working towards consolidation of the Great Britain regulations. A consultation ran from 28 October 2014 to 20 December 2014 and the proposals were positively received by the majority of respondents. A similar consolidation of the Northern Ireland regulations is now proposed. The consolidation

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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.
http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/

[2] A guide to the Genetically Modified Organisms (Contained Use) Regulations 2000 (L29) HSE Books

is not intended to reduce the protections provided by the existing legislation. Instead, the opportunity has been taken to make a number of changes that make the Regulations more risk based and proportionate and reflect experience of applying the Regulations since 2001. The opportunity has 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.

12. The majority of GMO contained use work is being undertaken at Class 1, deemed to be of nil or negligible risk with no employers in Northern Ireland currently 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. 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.

13. HSENI proposes to introduce the new consolidated regulations by mid 2015. A draft of the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015 (GMO(CU) 2015) can be found at Annex 1. This incorporates the proposed structural and procedural changes explained in this consultation document. The annexed draft GMO(CU) 2015 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

14. 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.

15. 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

16. 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 (Northern Ireland) 2002 (as amended) (COSHH) and underpinned by the Biological Agents Directive 2000/54/EC. Work with specified animal pathogens is covered by the Specified Animal Pathogen Order (Northern Ireland 2008.

17. 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 Department of the Environment for

Northern Ireland regulates the latter as part of the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003.

Proposed Changes to the Regulations

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

19. **Part 1 Control measures** – These are changes to the provisions within the containment tables and include amendments involving notifications and administrative arrangements. Changes to the control measures are considered individually in Part 1.

20. **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. The revised GMO(CU) 2014 regulations (see Annex 1) 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 separates 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. Changes to the structure and layout of the regulations are described in Part 2.

PART 1: Control Measures

21. The proposed changes to the control measures reflect experience of applying the Regulations since 2001, 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.

22. 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

Change	Reference in current regulations	Containment measure
A-1	Table 1a (measure 15)	Specified disinfection procedures in place
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 carcases 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 the Table 2 by reducing the overall number of containment measures and will remove duplication from the regulations.		

23. 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 2001 , 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)

	Containment Measure	CL1	CL2	CL3	CL4
Current wording	Negative pressure relative to the pressure of the immediate surroundings	Not required	Required where and to extent the risk assessment shows it is required	Required	Required
Proposed wording	Negative pressure relative to the pressure of the immediate surroundings	Not required	**Not required**	**Required except for activities where transmission does not occur via airborne route**	Required

24. 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.

25. 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.

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

	Containment Measure	CL1	CL2	CL3	CL4
Current wording	Extract and input air from the laboratory shall be HEPA filtered	Not required	Not required	HEPA filters required for extract air	HEPA filters required for extract and input air
Proposed wording	Extract and input air from	Not required	Not required	**Required except for**	HEPA filters

	the laboratory shall be HEPA filtered			**activities where transmission does not occur via airborne route**	required for extract and input air

26. 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.

Table B-3: change to Table 1a (measure 7)

	Containment Measure	CL1	CL2	CL3	CL4
Current wording	Microbiological safety cabinet/ enclosure	Not required	Required where and to extent the risk assessment shows it is required	Required, and all procedures with infective materials required to be contained within a cabinet/ enclosure	Class III cabinet required
Proposed change	Microbiological safety cabinet/ enclosure	Not required	Required where and to extent the risk assessment shows it is required	Required, and all procedures with infective materials required to be contained within a cabinet / enclosure	**Required, and all procedures with infective materials required to be contained within a cabinet/ enclosure**

27. 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.

Table B-4: change to Table 1a (measure 17)

	Containment Measure	CL1	CL2	CL3	CL4
Current wording	Inactivation of GMMs in contaminated material and waste	Required by validated means	Required by validated means	Required by validated means, with waste inactivated within the laboratory suite	Required by validated means, with waste inactivated within the laboratory
Proposed wording	Inactivation of GMMs in contaminated material and waste	**Required by a validated means where and to the extent the risk assessment shows it is required**	Required by validated means	Required by validated means, with waste inactivated within the laboratory suite	Required by validated means, with waste inactivated within the laboratory

28. 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 2).

Table B-5: change to Table 1a (measure 19)

Reference	Containment Measure	CL1	CL2	CL3	CL4
Current wording	An observational window or alternative is	Required where and to extent the risk	Required where and to extent the risk	Required	Required

	to be present so that occupants can be seen	assessment shows it is required	assessment shows it is required		
Proposed wording	An observational window or alternative is to be present so that occupants can be seen	Required where and to extent the risk assessment shows it is required	Required where and to extent the risk assessment shows it is required	**Required where and to extent the risk assessment shows it is required**	Required

29. 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.

Table B-6: change to Table 1c (measure 8)

	Containment Measure	CL1	CL2	CL3	CL4
Current wording	Animals kept in isolators	Required where and to extent the risk assessment shows it is required	Required where and to extent the risk assessment shows it is required	Required	Required
Proposed change	Animals kept in isolators	**Not required**	Required where and to extent the risk assessment shows it is required	Required	Required

30. 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.

Table B-7: change to Table 2 (measure 2)

	Containment Measure	CL1	CL2	CL3	CL4
Current wording	Closed systems located within a controlled area	Not required	Required where and to extent the risk assessment shows they are required	Required	Required and required to be purpose built
Proposed wording	Closed systems located within a controlled area	Not required	Required where and to extent the risk assessment shows they are required	Required	**Required**

31. 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 Northern Ireland there are currently no CL4 facilities of this type working with human pathogens and only one in the UK working with a specified animal pathogen. The intention would be for the Biological Agents Directive to be amended when the opportunity arises.

Table B-8: change to Table 2 (measure 9)

Reference	Containment Measure	CL1	CL2	CL3	CL4
Current wording	Biohazard signs posted	Required where and to extent the risk assessment shows it is required	Required	Required	Required
Proposed change	Biohazard signs posted	**Not required**	Required	Required	Required

32. 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.

Table B-9: change to Table 2 (measure 18)

	Containment Measure	CL1	CL2	CL3	CL4
Current wording	Written procedures and records of staff training	Not required	Not required	Required	Required
Proposed wording	Written procedures and records of staff training discharge	Not required	**Required where and to extent the risk assessment shows it is required**	Required	Required

33. 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.

Table B-10: change to Table 2 (measure 20)

	Containment Measure	CL1	CL2	CL3	CL4
Current wording	Inactivation of GMMs in contaminated material and waste including those in process effluent before final discharge	Required by validated means	Required by validated means	Required by validated means	Required by validated means
Proposed wording	Inactivation of GMMs in contaminated material and waste including those in process effluent before final discharge	**Required by a validated means where and to extent the risk assessment shows it is required**	Required by validated means	Required by validated means	Required by validated means

34. 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 2).

Table C: changes to the notification requirements and register

change	Reference in current regulations	Requirement
C-1	Regulations 10(3) & Schedules 5 & 6	Information required in relation to an emergency plan
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.		

Table D: requirements for a genetic modification safety committee (GMSC)

D-1	Reference in current regulations	Genetic Modification Safety Committee (GMSC)
Current wording	Regulation 18	A person who carries out an assessment pursuant to regulation 6 or 7 shall establish a genetic modification safety committee to advise him in relation to that assessment
Proposed wording		(**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 risk 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.**
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.		

35. 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 3).

PART 2: Restructure and Tidy Up

36. One of the key objectives was to consolidate all of the 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

37. A copy of the proposed Regulations is at Annex 1.

38. Table E below describes the main changes made to the GMO(CU) 2015 regulations with a view to reducing, simplifying and clarifying the legislation.

Table E: changes to the regulations structure and terms

Reference	Change	Reasoning
E-1	Separating the duties on the competent authority and the users	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.
E-2	To replace the term "activity involving genetic modification" with "contained use"	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.
E-3	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."	Use of simple language
E-4	To replace the terms "GMOs other than micro-organisms" and "genetically modified animals and plants" with the term "larger GMOs (LGMOs)	Allows the use of one, shortened and simplified term instead of two interchanging terms
E-5	Streamlining of Schedule 6 for information required for notification of a Class 2, 3 or 4	The information requirements in this Schedule have not changed. Much of the information required

	contained use of micro-organisms, or contained use of larger GMOs	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.
E-6	To remove out of date references to the rights of appeal against the decision to include information on the register	This right of appeal was removed following the 2006 Amendment Regulations, but some references were unintentionally left in and need to be removed.

Additional Matters

Savings and Transitional Arrangements

43. The savings and transitional arrangements are set out in regulations 33 and 35 of the draft Regulations. These are intentionally brief as the changes introduced by the consolidation are limited and are unlikely to alter existing work 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 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.

Application to synthetic biology

44. 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.

45. 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[3]. 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 propose to make any changes with respect to the application of the GMO regulations to synthetic biology. However views would be welcome on any

[3] Katia Pauwels et al. (published online 2013) Event report: SynBio Workshop (Paris 2012) – Risk assessment challenges of Synthetic Biology; Journal of Consumer Protection and Food Safety and HSE research report RR944 on regulation of synthetic biology

difficulties this approach may present, particularly in terms of future applications and any longer term views on alternative regulatory approaches.

Guide to the Regulations

46. The subject matter of the regulations is highly technical. The guide to the current regulations, published by HSE, has an amalgamation of regulatory and technical guidance, which makes the document dense, long and difficult for the user to navigate. Consequently, HSE's 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.

47. In response to the feedback during informal consultation by HSE 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.

48. HSE's intention is also to replace the existing hard copy guide to the regulations (L29) with an on-line version only.

COSTS AND BENEFITS

49. An impact assessment produced by HSE in relation to the GB Regulations is attached at Annex 4. Costs to business will arise in terms of familiarisation with the new Regulations and the need to review risk assessments across some 598 GMO centres in Great Britain. Savings to industry will arise primarily from the revised provisions regarding waste disposal (see table A: A-2, page 8) and the circumstances in which a high-efficiency particulate absorption (HEPA) filter is required (see table B-2 and paragraph 30). It is also 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. Based on the GB impact assessment, savings of approximately £15,700 over the 10 year reference period have been calculated as attributable to the 8 GMO centres in Northern Ireland as a result of the revised and consolidated Regulations.

EQUALITY IMPACT

50. The proposals have been screened for any possible impact on equality of opportunity affecting the groups listed in section 75 of the Northern Ireland Act 1998 and no adverse or differential aspects were identified. A copy of the screening document is at Annex 5.

INVITATION TO COMMENT

51. HSENI would welcome your comments on the proposals in this CD. Comments are particularly welcome on the assumptions relating to costs and benefits relevant to Northern Ireland, and the conclusion that the proposals would have no adverse effect on any section 75 groups.

52. Comments, in whatever format you choose to use, should be sent to: -

Mr Andrew Patterson
Health and Safety Executive for Northern Ireland
83 Ladas Drive
Belfast BT6 9FR
(Tel: 028 9054 6814; Fax: 028 9054 5383:
Textphone: 028 9054 6896
E-mail: andrew.patterson@hseni.gov.uk)

*so as to arrive no*t later than **noon on 15 September 2014**.

53. HSENI tries to make its consultation procedures as thorough and open as possible. Responses to this consultation will be kept at the office of HSENI at the above address after the close of this consultation period, where they can be inspected by members of the public or be copied to them. HSENI can only refuse to disclose information in exceptional circumstances. Before you submit your response, please read the paragraphs below on the confidentiality given by you in response to this consultation.

54. The Environmental Information Regulations 2004 and the Freedom of Information Act 2000 give the public rights of access to information held by a public authority, namely, HSENI in this case. These rights of access to information include information provided in response to a consultation. HSENI cannot automatically consider as confidential information supplied to it in response to a consultation. However, it does have the responsibility to decide whether any information provided by you in response to this consultation, including information about your identity, should be made public or be treated as confidential.

55. This means that information provided by you in response to the consultation is unlikely to be treated as confidential, except in very particular circumstances.

List of Annexes

ANNEX 1 – Draft Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015

ANNEX 2 – Supplementary guidance on the inactivation of waste at Class 1

ANNEX 3 – Supplementary guidance on the establishment of a GMSC

ANNEX 4 – Regulatory Impact Assessment

ANNEX 5 – Equality impact screening document

ANNEX 6 – List of consultees

ANNEX 1

STATUTORY RULES OF NORTHERN IRELAND

2015 No. 000

HEALTH AND SAFETY

The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015

Made - - - -	***
Coming into operation -	***

The Department of Enterprise Trade and Investment ("the Department")([4]), is designated for the purposes of section 2(2) of the European Communities Act 1972 ("the 1972 Act")([5]) in relation to the control and regulation of genetically modified organisms([6]).

The Department, being the Department concerned([7]) makes the following Regulations in exercise of the powers conferred by section 2(2) of, and paragraph 1A of Schedule 2 to, the 1972 Act([8]) and Articles 17(1), (2), 3(b) and 5(b) ([9]) and 55(2) of, and paragraphs 1(1), (2) and (3), 3, 4, 5, 10, 12(1), 14(1), 15, 16 and 19 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978([10])("the 1978 Order").

The Regulations give effect without modifications to proposals submitted to the Department by the Health and Safety Executive for Northern Ireland under Article 13(1A)([11]) of the 1978 Order after the Executive had carried out consultations in accordance with Article 46(3)([12]) of the 1978 Order.

([4]) Formerly the Department of Economic Development; *see* S.I. 1999/283 (N.I. 1), Article 3(5); that Department was formerly the Department of Manpower Services; *see* S.I. 1982/846 (N.I.11), Article 3
([5]) 1972 c.68
([6]) S.I. 1991/755
([7]) *See* Article 2(2) of S.I. 1978/1039 (N.I. 9)
([8]) 1972 c.68; paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c. 51)
([9]) Article 17 shall be read with S.I. 1992/1728 (N.I.17), Articles 3(2) and 4(2)
([10]) S.I. 1978/1039 (N.I. 9); the general purposes of Part II referred to in Article 17(1) were extended by S.I. 1992/1728 (N.I. 17), Articles 3(1) and 4(1). Article 55(2) was amended by S.I. 1998/2795 (N.I. 18), Article 6(1) and Schedule 1, paragraph 19
([11]) Article 13(1A) was substituted by S.I. 1998/2795 (N.I. 18), Article 4
([12]) Article 46(3) was amended by S.I. 1998/2795 (N.I. 18), Article 6(1) and Schedule 1, paragraphs 8 and 18 and the Health Protection Agency Act 2004 (c.17), section 11 and Schedule 3 paragraph 10

PART 1

Interpretation and General

Citation and commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015 and shall come into operation on X XXX 2015.

Interpretation

2.—(1) In these Regulations—

"the 1978 Order" means the Health and Safety at Work (Northern Ireland) Order 1978;

"the 2001 Regulations" means the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001([13]);

"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 involving micro-organisms, means one of the four classes set out in Schedule 1;

"competent authority" means the Department of the Environment and the Executive, acting jointly;

"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([14]) signed at Oporto on 2nd May 1992, as adjusted by the Protocol signed at Brussels on 17th March 1993([15]) and adopted as respects the United Kingdom by the European Economic Area Act 1993([16]);

"emergency plan" means a plan required by virtue of regulation 21;

"emergency services" means the police, fire and ambulance services;

"the Executive" means the Health and Safety Executive for Northern Ireland;

"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 1 of Schedule 2; and

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([13]) S.R. 2001 No. 295. The 2001 Regulations and all amending instruments are revoked by these Regulations

([14]) OJ L 1, 3.1.1994 p. 3.

([15]) OJ L 1, 3.1.1994, p. 572 and as subsequently amended by EEA Council Decision No 1/95 of 10 March 1995,OJ L86, 20.4.1995 p 58; the Agreement on the participation of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic in the European Economic Area of 154 October 2003 OJ L 130, 29.4.2004 p 11; the Agreement on the participation of Bulgaria and Romania in the European Economic Area of 25 July 2007 OJ No l221, 25.8.2007 p 15 and the Agreement between the European Union, Iceland, Leichtenstein and Norway on an EEA Financial Mechanism for the period 2009 – 2014 (OJ L 291, 9.11.2010 p4)

([16]) 1993 c. 51, as amended by S.I. 2011/1043.

(b) the techniques set out in Part 2 of Schedule 2 are not considered to result in genetic modification,

and "genetically modified" is to be construed accordingly;

"human admixed embryo" has the meaning given in the Human Fertilisation and Embryology Act 1990([17]) by virtue of section 4A(6) and (11) of that Act;

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

"larger GMO" means an organism which is genetically modified or 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;

"notifier" means a person who submits or has submitted a notification to the competent authority under regulation 9(2), 10(2), 11(2), 12(2) or 33(2);

"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;

"person responsible for the contained use" means

(a) a person who has the authority to determine whether a particular contained use takes place or

(b) a person who has control of the planning or conduct (or both) of that contained use,

and there may be more than one person responsible for the same contained use;

"premises" includes both single buildings and sites made up of more than one building;

"transboundary movement" has the meaning assigned to it by Article 3 of Regulation 1946/2003/EC([18]) 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) a reference to an appropriate containment level is a reference to the containment level assigned to that activity in accordance with paragraphs 3(i) 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 involving micro-organisms which has been classified as belonging to the class of that number in accordance with paragraph 3(j) and (k) of Part 2 of Schedule 3.

(3) The measures 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.

(4) The Interpretation Act (Northern Ireland) 1954([19]) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

([17]) 1990 c. 37. Sections 1(1) and (6) were substituted by section 1(2) (3) and (5) of the Human Fertilisation and Embryology Act 2008 (c.22) and section 4A was inserted by section 4(2) of that Act.
([18]) OJ L 287 5.11.2003, p. 1.
([19]) 1954 c.33 (N.I.)

Application

3.—(1)

(2) These Regulations (except regulation 18) 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 Department of the Environment under Article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991([20]), or

(bb) a written consent given by the competent authority of an EEA State in accordance with Article 15(3), 17(6), or 18(2) of Directive 2001/18/EC([21]) of the European Parliament 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, or

(ii) a medicinal product for human or veterinary use marketed in accordance with Council Regulation (EEC) No 2309/93([22]) or Regulation (EC) No 726/2004([23]) 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([24]) 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 Department of the Environment is required under Article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991.

(4) Regulations 7, 9 to 17, 18(2) and (4), 19, 20and 23 to 25 do not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.

(5) Regulation 5 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 5(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) In this regulation, "product" means a product consisting of or containing a genetically modified organism or a combination of genetically modified organisms.

([20]) S.I. 1991/1714 (N.I. 19)
([21]) OJ L106, 17.04.2001, pp 1 – 37.
([22]) OJ L 214, 24.8.1993, p. 1
([23]) OJ L 136, 30.4.2004, p. 1 as amended by Regulation (EC) No 1901/2006 OJ L378 27.12.2006 p. 1, Regulation (EC) No 1394/2007 OJ L 324 10.12.2007 p. 121, Regulation (EC) No 219/2009 OJ L87 31.3.2009 p. 109, Regulation (EC) No 470/2009 OJ L 152, 16.6.2009, p. 11, and Regulation (EC) No 1235/2010 OJ L348 31.12.2010, p 1 which was corrected by Corrigendum OJ L 201, 27.7.2012 p 138.
([24]) OJ L268 18.10.2003, pp. 1 – 23 as amended by Regulation (EC) No 1981/2006 OJ L368 23.12.2006 pp. 99 - 109 and Regulation (EC) No 298/2008 OJ L 97 9.4.2008 pp. 64 – 66.

Meaning of "work" and "at work" and modification of the 1978 Order

4.—(1) For the purpose of these Regulations and Parts I and II of the 1978 Order, the meaning of "work" shall be extended to include any contained use and the meaning of "at work" shall be extended accordingly.

(2) Articles 4(1), (2) and (3) and 8 of the 1978 Order shall be modified in relation to a contained use as follows—

(a) those sections have effect as if a reference to —

(i) an employer in those articles includes a reference to an educational establishment providing a course of study,

(ii) an employee in those articles includes a reference to a student of that educational establishment to the extent that the contained use is under the control of that educational establishment.

(3) Article 5(2) of the 1978 Order shall be modified in relation to a contained use so as to have effect as if the reference in that section—

(a) to a self-employed person is a reference to any person (except a student) undertaking contained use who is not an employer or an employee ; and

(b) to that person's undertaking includes a reference to such an activity.

(4) 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

5.—(1) Before any contained use involving micro-organisms is commenced, a person responsible for the contained use shall ensure that a suitable and sufficient assessment of the risks created to human health and the environment by the contained use is carried out.

(2) The assessment required by paragraph (1) shall take into account the matters set out in Part 1, and include the steps set out in Part 2, of Schedule 3.

Risk assessment of contained use involving larger GMOs

6.—(1) Before any contained use involving larger GMOs is commenced a person responsible for the contained use must ensure that a suitable and sufficient assessment of the risks created to human health by the contained use is carried out.

(2) The assessment required by paragraph (1) shall take into account the matters set out in Part 1, and include the steps set out in Part 2, of Schedule 4.

Review and recording of risk assessments

7.—(1) A person responsible for the contained use shall ensure that the assessment is reviewed immediately 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.

(2) A person responsible for the contained use shall—

(a) keep a record of the assessment and any review of that assessment, for at least 10 years from the date the contained use 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 5 or 6.

Advice from a genetic modification safety committee

8.—(1) Subject to paragraph (2), a person responsible for contained use shall obtain advice on the assessment carried out under regulation 5 or 6 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 the contained use will be assigned to class 2 or above the advice must be obtained from a genetic modification safety committee.

Notification of premises to be used for contained use

9.—(1) A user shall not use premises for contained use, unless the premises have been notified to the competent authority in accordance with this regulation.

(2) Before premises are used for contained use for the first time, a person responsible for the contained use shall—

(a) submit a notification to the competent authority containing the information specified in Schedule 5; and

(b) have received an acknowledgement of receipt of the notification from the Executive.

(3) The Executive shall send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving a notification).

(4) A single notification may include more than one premises.

(5) The notifier shall nominate one address which is to be the principal address for the purposes of a notification under paragraph (4).

Notification of class 2 contained use involving micro-organisms

10.—(1) A user shall not undertake a class 2 contained use involving micro-organisms unless the provisions of this regulation have been complied with.

(2) A person responsible for the contained use must submit a notification to the competent authority containing the information specified in Schedule 6.

(3) The Executive shall send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving the notification.

(4) Where the premises in the notification have not been previously notified for class 2 or a higher class contained use, a user must not undertake the class 2 contained use unless—

(a) 45 days have elapsed since the acknowledgement of receipt was received and the competent authority has not informed the notifier that the class 2 contained use must not be undertaken; or

(b) the competent authority has agreed in writing that the class 2 contained use may begin within a shorter period.

(5) Where the premises in the notification have—

(a) previously been notified for class 2 contained use ; or

(b) already been granted consent for class 3 or class 4 contained use ,

a user may undertake the class 2contained use if the notifier has received the acknowledgement of receipt.

(6) Where a notifier submits a notification for a class 2 contained use which is to be undertaken for the second or subsequent time at the premises in the notification, the notifier may request that the competent authority provide a written agreement to the user undertaking that contained use.

(7) The competent authority shall decide whether to provide a written agreement requested under paragraph 6 within 45 days of the date on which the acknowledgement was sent to the notifier.

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

11.—(1) A user shall not undertake a class 3 or class 4 contained use involving micro-organisms unless written consent for that contained use has been granted by the competent authority.

(a)

(2) A person responsible for the contained use must submit a notification to the competent authority containing the information specified in Schedule 6.

(3) The Executive shall send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving the notification.

(4) Where the premises in the notification have not previously been notified for class 3 or class 4 contained use the competent authority shall inform the notifier in writing of its decision to grant or refuse consent for the class 3 or class 4 contained use within 90 days of the date on which the acknowledgement of receipt was sent to the notifier.

(5) Where the premises in the notification have previously been notified for class 3 or class 4 contained use and all relevant conditions of existing consents have been complied with, the competent authority shall inform the notifier in writing of its decision to grant or refuse consent for the class 3 or class 4 contained use within 45 days of the date on which the acknowledgement of receipt was sent to the notifier.

(6) Before granting consent, the competent authority shall ensure that an emergency plan has been prepared where the risk assessment shows an emergency plan is required.

(7) Before deciding whether to grant or refuse consent, the competent authority shall take into account any representations made to it by any person within 30 days of the date on which the acknowledgement of receipt was sent to the notifier.

(8) A consent granted under this regulation may be granted subject to conditions.

Notification of contained use involving larger GMOs

12.—(1) A user shall not undertake a contained use involving larger GMOs unless the provisions of this regulation have been complied with.

(a)

(2) A person responsible for the contained use must submit a notification to the competent authority containing the information specified in Schedule 6.

(3) The Executive shall send an acknowledgement of receipt to the notifier within 10 working days of the competent authority receiving the notification.

(4) A user must not undertake the contained use unless—

(a) 45 days have elapsed since the acknowledgement of receipt was received and the competent authority has not informed the notifier that the contained use must not be undertaken; or

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

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

Notifications of connected programmes of work

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

(a) one premises; or

(b) more than one premises.

(2) The competent authority may accept a single notification submitted under regulation 10(2), 11(2) or 12(2) in respect of a single contained use undertaken at more than one premises.

(3) In this regulation—

"connected programme of work" means a series of activities involving contained use which form a coherent and integrated programme.

Changes of circumstances relating to notifications

14.—(1) A person responsible for the contained use shall immediately send to the competent authority full details in writing of—

(a) any change in the information specified in paragraphs (a), (d) and (e) of Schedule 5 and provided by the notifier in accordance with regulation 9(2);

(b) any new building—

(i) added to the premises previously notified by the notifier in accordance with regulation 9(2), and

(ii) under the notifier's control;

(c) premises notified under regulation 9(2) that will no longer be used for contained use;

(d) any cessation for the time being of all contained use at premises notified under regulation 9(2);

(e) any cessation of a contained use notified in accordance with regulation 10(2),11(2) or 12(2);

(f) any recommencement of contained use at premises in respect of which the notifier had previously given details of a cessation under sub-paragraph (d) above;

(g) any use of additional premises in connection with a single contained use where a single notification for that contained use was submitted in accordance with regulation 13(3);

(h) any change in the information specified in paragraphs (b) or (c) of Schedule 5 and provided by the notifier in accordance with regulation 9(2);

(i) any change in the information specified in paragraphs (c) or (d) of Schedule 6 and provided by the notifier in accordance with regulation 10(2), 11(2) or 12(2).

(2) Where—

(a) a notifier has informed the competent authority of additional premises under paragraph (1)(g); and

(b) that information, 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 under regulation 9(2)

the provision of such information will be treated as notification of those premises for the purposes of regulation 9(2).

Duty to notify significant changes affecting risks

15.—(1) Where, after submitting a notification, a notifier—

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

(2) The notifier need not submit a further notification under regulation 10(2), 11(2) or 12(2) as long as the change or new information does not affect the class assigned to that contained use and, in such a case, the change or new information will be treated as a modification of the original notification.

Action of user and notifier on receipt of request for additional information

16.—(1) If additional information is requested by the Executive under regulation 24(1) a user shall not begin the contained use until the competent authority has given its approval in writing.

(2) Subject to paragraphs (3) and (4), if the contained use has commenced before the Executive requests additional information under regulation 24(1), a user may not continue that contained use until the competent authority has given its approval in writing.

(a)

(3) The Executive may give the notifier instructions concerning the cessation of the contained use and the notifier and any user undertaking that contained use must comply with any such instructions.

(4) Subject to any such instructions, the notifier or user may continue the contained use only to the extent necessary to store or destroy all genetically modified organisms resulting from the contained use.

Withdrawal of Notification

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

PART 3

Conduct of Contained Use

Principles of occupational and environmental safety

18.—(1) A user who undertakes a contained use involving micro-organisms shall 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) Themeasures to be taken in order to comply with the duty under paragraph (1) shall 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 involving larger GMOs shall ensure that risks to human health arising from that activity are reduced to the lowest level that is reasonably practicable.

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

Containment and control measures for contained use involving micro-organisms

19.—(1) A user who undertakes a contained use involving micro-organisms shall 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 containment measure required for the appropriate containment level where—

(a) the assessment, or any review of that assessment, shows that the containment measure is not necessary or practicable for a specific activity;

(b) the notifier of the contained use has provided justification in writing to the competent authority, and

(c) the notifier has received the written agreement of the competent authority that the containment measure need not be applied.

(3) A person responsible for a contained use involving micro-organisms shall review the containment measures applied to that contained use—

(a) at suitably regular intervals; and

(b) immediately if that person suspects that—

(i) the containment measures are no longer adequate,

(ii) the class assigned to the contained use involving micro-organisms identified in the assessment is no longer appropriate, or

(iii) in the light of new scientific or technical knowledge, the assessment is no longer valid.

Containment and control measures for contained use involving larger GMOs

20.—(1) A user who undertakes a contained use involving larger GMOs shall apply the containment measures selected in accordance with the assessment made under regulation 6(1).

(2) A person responsible for the contained use shall review those containment measures—

(a) at suitably regular intervals; and

(b) immediately if that person suspects that—

(i) the containment measures are no longer adequate, or

(ii) in the light of new scientific or technical knowledge, the assessment is no longer valid.

Emergency plans

21.—(1) Where an assessment carried out under regulation 5(1) shows that, as a result of any reasonably foreseeable accident—

(a) the health or safety of persons outside the premises in which the contained use is undertaken is liable to be seriously affected; or

(b) there is a risk of serious damage to the environment from the contained use,

a person responsible for the contained use shall ensure that, before the contained use commences, a suitable plan is prepared with a view to securing the health and safety of those persons or the protection of the environment, or both.

(2) Where an assessment carried out under regulation 6(1) shows that, as a result of any reasonably foreseeable accident, the health or safety of persons outside the premises in which the contained use is undertaken is liable to be seriously affected, a person responsible for the contained use shall ensure that, before the contained use commences, a suitable plan is prepared with a view to securing the health and safety of those persons.

(3) Every emergency plan shall—

(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) A person responsible for the contained use which is the subject of an emergency plan shall—

(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; and

(b) make information about the plan and any such revisions publicly available.

Information relating to accidents

22. If an accident occurs, a person responsible for the contained use shall immediately inform the competent authority of the accident and shall provide the following information—

(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, in the case of a genetically modified micro-organism, on the environment; and

(d) any measures taken in response to the accident.

PART 4

Duties and powers of the competent authority

Duties of the competent authority on receiving notifications

23. The competent authority shall examine a notification and accompanying documentation, submitted under regulation 9(2), 10(2), 11(2), or 12(2) for—

(a) conformity with the requirements of these Regulations;

(b) the accuracy and completeness of the information provided;

(c) the correctness of the assessment or summary of the assessment carried out under regulation 5(1) or 6(1);

(d) the adequacy of the waste management and emergency response measures;

(e) in the case of a notification submitted under regulation 10(2) or regulation 11(2) the correctness of the class assigned to the contained use involving micro-organisms; and

(f) the inclusion of an emergency plan where the assessment carried out under regulation 5(1) or 6(1) indicates that such a plan is necessary.

Requests for additional information

24.—(1) For the purpose of carrying out an examination of a notification in accordance with regulation 23, the Executive may, on behalf of the competent authority, request the notifier to provide such additional information relating to the notification as it may specify.

(2) If requested to do so by the Department of the Environment, the Executive shall request additional information under paragraph (1).

(3) A request for additional information shall be made in writing.

(4) The Executive shall send an acknowledgement of receipt to the notifier within 10 working days of receipt of all of the additional information.

(5) The period of time between the date when the Executive requests additional information and the date when the Executive receives all of that additional information will not be taken into account in calculating the period of days referred to in regulations 10(4), 10(7), 11 (4), 11(5) or 12(4).

(6) Where—

(a) contained use has not commenced at the premises to which the notification made under regulation 9(2) relates, or a contained use notified under regulation 10(2), 11(2), or 12(2) has not commenced;

(b) the Executive requests additional information; and

(c) the notifier does not provide all 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

25. The competent authority may at any time by notice in writing to a notifier—

(a) set a time limit for, or impose conditions with regard to, a particular contained use;

(b) require the notifier and any user to suspend, to terminate or not to commence a particular contained use;

(c) revoke or vary a consent granted to the notifier under regulation 11,

and the notifier and any user undertaking that contained use shall comply with that notice.

Exemption certificates

26.—(1) 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.

(2) An exemption may be granted subject to conditions and to a time limit and may be revoked by a certificate in writing at any time.

(3) The competent authority shall 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 relevant requirements imposed by or under any enactments,

it is satisfied about the matters referred to in paragraph (3).

(4) The matters about which the competent authority must be satisfied 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 involving a micro-organism, that the environment will not be prejudiced in consequence of the exemption.

Duties on receipt of information about accidents

27. Where the competent authority is informed of an accident in accordance with regulation 22, it shall—

(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 22(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.

Register of notifications

28.—(1) This regulation is subject to regulation 29.

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

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

(a) in relation to every notification submitted under regulations 9(2), 10(2), 11(2) or 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 Executive acknowledged receipt of the notification, and

(iii) where the competent authority receives details of a matter referred to in sub-paragraphs (a) to (g) of regulation 14(1) or in regulation 15(1), confirmation that such details have been received;

(b) in relation to each notification submitted under regulation 10(2),11(2) or 12(2), the date of any cessation of the contained use to which the notification relates;

(c) in relation to each notification submitted under regulation 9(2)—

(i) the information specified in paragraphs (d) to (g), (h)(ii) and (h)(iii) of Schedule 5, and

(ii) if the competent authority has been informed of an accident under regulation 22 in relation to the premises to which the notification relates, confirmation that the requirements of regulation 22 have been complied with;

(d) in relation to each notification submitted under regulation 10(2), 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(2)—

(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 consent for the contained use has been granted under regulation 11(4) or 11(5) ; and

(f) in relation to each notification submitted under regulation 12(2), the information specified in paragraphs (e) to (j) and (m)(i) of Schedule 6.

(4) The register shall not contain any information which the competent authority would refuse to disclose under the Environmental Information Regulations 2004.

(5) Information shall 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 14(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 14(1)(c) of a decision to cease to use such premises for the purposes of undertaking any contained use.

(7) A copy of the register shall be made available for inspection to members of the public by the Executive by such means as it considers appropriate which may include by publishing on its website.

Information not to be included in the register

29.—(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 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 his or her determination.

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

(4) The competent authority shall 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 specifying information which appears to that person to be information to which paragraph (1) may apply and stating why it should not be included in the register.

(6) If a person gives a written notice under paragraph (5), at the same time that person shall 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.

PART 5

Miscellaneous and General

Enforcement

30.—(1)This regulation applies to the extent that any part of these Regulations are not health and safety regulations within the meaning of Article 17 of the 1978 Order.

(2) The following provisions apply to the whole of these Regulations as if they were health and safety regulations for the purposes of that Act—

(a) Articles 18 to 28 (approved codes of practice and enforcement), Articles 31 to 39 (provisions as to offences) and Article 43 (civil liability) of the 1978 Order([25]); and

(b) the Health and Safety (Training for Employment) Regulations (Northern Ireland) 1994([26]).

(3) Every function of the Executive under any provision of the 1978 Order or under health and safety regulations, is exercisable in relation to these Regulations as if the whole of these Regulations were health and safety regulations for the purposes of that Order.

(4) Despite Article 31(1)(c) of the 1978 Order a failure to discharge a duty placed on the competent authority or the Executive by these Regulations shall not be an offence

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([25]) S.I.1978/1039 (N.I.9); Articles 18 to 20 and 31 were amended by, and Article 34A was inserted by, S.I. 1998/2795 (N.I..18), Article 6(1) and Schedule 1

([26]) S.R. 1994 No 1

(5) Despite regulation 4 of the Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1999([27]), the enforcing authority for these Regulations shall be the Executive.

Appeals

31.—(1) A person responsible for contained use who is aggrieved by any of the following may appeal to the Department of Enterprise, Trade and Investment—

(a) a decision by the competent authority——

(i) to refuse to provide a written agreement requested under regulation 10(6);

(ii) to refuse consent for a class 3 or class 4 contained use notified under regulation 11(2);

(iii) to refuse to provide written agreement under regulation 19(2)(c) that a particular containment measure need not be applied for a specific activity;

(iv) to refuse to grant an exemption certificate granted under regulation 26(1) or to revoke such a certificate; or

(v) to impose conditions or a time limit on an exemption certificate issued under regulation 26(1),

(b) an instruction to the user under regulation 16(3);

(c) a request to the user for additional information by the Executive under regulation 24(1); or

(d) a notice from the competent authority under regulation 25.

(2) Chapter I of the Schedule to the Deregulation (Model Appeal Provisions) Order (Northern Ireland) 1997([28]) shall apply to any appeal made under this regulation.

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

(a) a decision of the competent authority referred to in paragraph (1)(a);

(b) an instruction given under regulation 16(2);

(c) the operation of regulations 16(1) or 24(1) or (5); or

(d) a notice given under regulation 25.

Competent authority address

32. Anything required to be submitted or sent to the competent authority under these Regulations shall be sent to the Executive at the address published for this purpose on its website which may be, or include, an address for submission by electronic means.

Saving and transitional provisions

33.—(1) Subject to paragraph (2) the following continue to have effect and will be deemed to have been made , granted or imposed under these Regulations—

(a) a notification made under any of regulations 9 to 13 of the 2001 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 11 of the 2001 Regulations as if it were granted under regulation 11 of these Regulations;

([27]) S.R. 1999 No.90
([28]) S.R. 1997 No.269

(c) an agreement by the competent authority under regulation 18(2) of the 2001 Regulations that a specific containment measure need not be applied to a contained use, as if it were made under regulation 19(2) of these Regulations;

(d) a request for information made under regulation 14(2) of the 2001 Regulations, as if it were made under regulation 24(1) of these Regulations;

(e) a condition, limit of time or other requirement imposed by the competent authority under regulation 15(1) of the 2001 Regulations as if it were imposed under regulation 25 of these Regulations.

(2) Every record required to be kept under regulation 8(2) of the 2001 Regulations must be kept in the same manner and for the same period as specified in that regulation as if the requirement were imposed under regulation 7(2) of these Regulations.

(3) Where—

(a) a user was undertaking contained use before the relevant date in accordance with the 2001 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,

a person responsible for the contained use shall submit a notification to the competent authority containing the information required in Schedule 6 that is applicable to the new class of contained use.

(4) The notification shall be submitted to the competent authority within the specified period.

(5) The competent authority may exempt a notifier from some or all of the requirements of Schedule 6.

(6) Where a notification is submitted under paragraph (2) for a contained use that requires consent for class 3 or class 4 contained use, the competent authority shall inform the notifier of its decision whether or not to grant consent within 90 days of receipt of the notification.

(7) The provisions of regulations 23 to 29 of these Regulations apply to a notification submitted under paragraph (2) as if it were a notification under regulations 9 to 12 of the 2000 Regulations.

(8) 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 increase in the risks associated with the contained use;

(c) the competent authority does not require the notifier or user to suspend or terminate the contained use under regulation 25 of these Regulations;

(d) the competent authority has not refused consent for the contained use.

(9) In this regulation

"relevant date" means the date on which these Regulations come into operation;

"specified period" means the period of 90 days beginning with the relevant date.

Consequential Amendment

34.—(1) The Health and Safety (Fees) Regulations (Northern Ireland) 2012([29]) shall be amended as follows—

(a) In regulation 8—

(i) in the cross heading, for "2001" substitute "2014",

(ii) in paragraph (1), for "2001" substitute "2014",

(iii) omit paragraph (2) and substitute—

([29]) S.R. 2012/255

"No fee is to be returned to a notifier or applicant where the notifier withdraws a notification under regulation 18 of the 2014 Regulations or the competent authority returns a notification under regulation 25(5) of the 2014 Regulations.",

(iv) in paragraph (3) for "the 2001 Regulations" substitute "the 2014 Regulations".

(b) In Schedule 6—

(i) in the heading, for "2000" substitute "2014",

(ii) In column 1 of the table,

(aa) in paragraph (j), for "15(3)" substitute "17",

(bb) in paragraph (k) for 18(2) substitute "20(2)".

Revocations and saving

35.—(1) The following shall be revoked—

(a) the 2001 Regulations,

(b) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations (Northern Ireland) 2006([30]), and

(c) the Genetically Modified Organisms (Contained Use) (Amendment) Regulations (Northern Ireland) 2010([31]).

(2) Every record required to be kept under regulation 8(2) of the 2001 Regulations shall be kept in the same manner and for the same period as specified in that regulation as if these Regulations had not been made.

Sealed with the Official Seal of the Department of Enterprise, Trade and Investment on XX XXX 2015.

L.S.

J *Kerr*
A senior officer of the Department of Enterprise, Trade and Investment

SCHEDULE 1

Regulation 2(1)

Classes Of Contained Use

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

([30]) S.R. 2006/524
([31]) S.R. 2010/343

SCHEDULE 2

Regulation 2(1)

PART 1

Examples of techniques constituting genetic modification

1. Examples of the techniques which constitute genetic modification which are referred to in sub-paragraph (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 18) 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 re-combination; 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 5(2)

PART 1

Matters to be taken into account in carrying out an assessment for the purposes of regulation 5

1. The following matters must be taken into account in carrying out an assessment for the purposes of regulation 5—

(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 5

3. An assessment carried out for the purposes of regulation 5 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 Directive 2000/54/EU of 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 present 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 sub-paragraph (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 involving 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 involving micro-organisms to the appropriate containment level for the purposes of paragraph 3(i), the person carrying out the assessment for the purposes of regulation 5 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 sub-paragraph (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(i).

SCHEDULE 4

Regulation 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) 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 6

3. An assessment carried out for the purposes of regulation 6must 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(2), 14(1) and 28

Information required for a notification under regulation 9(2)

A notification required for the purposes of regulation 9(2) must contain the following information—

(g) the name, address and telephone number and any fax number and any e-mail address of the notifier;

(h) the name of the person with with specific responsibility for the supervision and safety of contained use;

(i) information on the training and qualifications of that person;

(j) details of the arrangements for obtaining advice on assessments in accordance with regulation 8, including details of any genetic modification safety committee if established;

(k) the address of the premises where the contained use is to be carried out and a general description of the premises, together with the principal address of premises notified under regulation 9(6);

(l) the nature of the work to be undertaken;

(m) the class of any contained use involving micro-organisms; and

(n) where the first activity to be carried out in those premises is a class 1 contained use—

(i) a summary of the assessment of that activity made for the purposes of regulation 5(1),

(ii) any advice received in relation to that assessment from a person or genetic modification safety committee in accordance with regulation 8,

(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; or

(o) 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(2)—

(i) a copy of the assessment made for the purposes of regulation 6(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.

SCHEDULE 6 Regulations 10(2), 11(2), 12(2), 14(1) and 26

Information required for a notification under regulations 10(2), 11(2) or 12(2)

A notification required for the purposes of regulations 10(2), 11(2) and 12(2) must contain the information below except where it is required only for a specified regulation—

(p) the name, address and telephone number and any fax number and any e-mail address of the notifier;

(q) any 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(2) relating to those premises;

(r) the name of the person with specific responsibility for supervision and safety of contained use;

(s) information on the training and qualifications of that person;

(t) the recipient or parental micro-organism to be used;

(u) the donor micro-organism to be used;

(v) where applicable, the host-vector system to be used;

(w) the source and intended function of the genetic material involved in the modification;

(x) the identity and characteristics of the genetically modified organism;

(y) the purpose of the contained use, including its expected results;

(z) for regulation 10(2) the approximate culture volumes to be used;

(aa) for regulation 11(2) the culture volumes to be used;

(bb) 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(2) justification for not applying any containment measure at containment level 2;

(iii) for regulation 11(2), for class 3 contained use, justification for not applying any containment measure at containment level 3;

(iv) for regulation 11(2), for class 4 contained use, justification for not applying any containment measure at containment level 4;

(cc) for regulations 10(2) and 11(2) a copy of the assessment carried out under regulation 5(1);

(dd) for regulations 10(2) and 11(2) the advice received in relation to that assessment from a genetic modification safety committee;

(ee) for regulation 12(2) a copy of the assessment carried out under regulation 6(1);

(ff) information in relation to any accident prevention and emergency plans including:

(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;

(iii) for regulation 11(2) 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;

(gg) for regulation 11(2) a description of the parts of the installation; and

(hh) for regulation 11(2) whether the genetically modified organism is likely to be subject to transboundary movement.

SCHEDULE 7

Regulation 18

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—

(ii) keeping workplace and environmental exposure to any genetically modified micro-organism to the lowest reasonably practicable level;

(jj) exercising engineering control measures at source and supplementing these with appropriate personal protective clothing and equipment where necessary;

(kk) testing adequately and maintaining control measures and equipment;

(ll) testing, where necessary, for the presence of viable process organisms outside the primary physical containment;

(mm) providing appropriate training of personnel;

(nn) establishing a genetic modification safety committee, if required;

(oo) formulating and implementing local codes of practice for the safety of personnel, as required;

(pp) displaying biohazard signs where appropriate;

(qq) providing washing and decontamination facilities for personnel;

(rr) keeping adequate records;

(ss) prohibiting in the work area eating, drinking, smoking, applying cosmetics or the storing of food for human consumption;

(tt) prohibiting mouth pipetting;

(uu) providing written standard operating procedures where appropriate to ensure safety;

(vv) having effective disinfectants and specified disinfection procedures available in case of spillage of genetically modified micro-organisms; and

(ww) providing safe storage for contaminated laboratory equipment and materials where appropriate.

SCHEDULE 8

Regulations 2(3) and 19(1)

Containment measures

PART 1

General

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 5.

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 relevant measure in Table 1a.

3. For the purposes of this Schedule—

(a) Table 1a describes containment measures applicable to contained use involving micro-organisms in laboratories;

(b) Table 1a, read with Table 1b, describes containment measures applicable to contained use involving micro-organisms in plant growth facilities;

(c) Table 1a, read with Table 1c, describes containment measures applicable to contained use involving micro-organisms in animal units;

(d) Table 2 describes containment measures applicable to contained use involving micro-organisms in premises other than those referred to in Tables 1a, 1b and 1c.

PART 2

Table 1a: Containment measures for contained Use involving micro-organisms in laboratories

Containment Measures	*Containment Levels*			
	1	*2*	*3*	*4*
1. Laboratory suite: isolation (**note 1**)	not required	not required	required	required
2. Laboratory: sealable for fumigation	not required	not required	required	required
Equipment				
3. Surfaces impervious to water, resistant to acids, alkalis, solvents, disinfectants and decontamination agents and easy to clean	required for bench	required for bench	required for bench and floor	required for bench, floor ceiling and walls
4. Entry to lab via airlock (**note 2**)	not required	not required	required where and to extent the risk assessment shows it is required	required
5. Negative pressure relative to the pressure of the immediate surroundings	not required	not required	required except for activities where transmission does not occur by the airborne route	required
6. Extract and input air from the laboratory must be HEPA filtered	not required	not required	HEPA filters required for extract air except for actitivities where transmission does not occur by the airborne route	HEPA filters required for input and extract air (**note 3**)
7. Microbiological safety cabinet/enclosure	not required	required where and to extent the risk assessment shows it is required	required, and all procedures with infective materials required to be contained within a cabinet/enclosure	required, and all procedures with infective materials required to be contained within a cabinet/ enclosure
8. Autoclave	required on site	required in the	required in the	double ended

		building	laboratory suite (**note 4**)	autoclave required in laboratory
System of work				
9. Access restricted to authorised personnel only	not required	required	required	required (via airlock key procedure)
10. Biohazard sign on door	not required	required	required	required
11.Specific measures to control aerosol dissemination	not required	required so as to minimise	required so as to prevent	required so as to prevent
12. Shower	not required	not required	required where and to extent the risk assessment shows it is required	required
13. Protective clothing	suitable protective clothing required	suitable protective clothing required	suitable protective clothing required; footwear required where and to extent the risk assessment shows it is required	complete change of clothing and footwear required before entry and exit
14. Gloves	not required	required where and to the extent the risk assessment shows they are required	required	required
15. Efficient control of disease vectors (e.g. rodents and insects) which could disseminate GMMs	required where and to extent the risk assessment shows it is required	required	required	required
Waste				
16. Inactivation of GMMs in effluent from hand-washing sinks and showers and similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
17. Inactivation of GMMs in contaminated material and waste	required by validated means where and to the extent the risk assessment shows it is required	required by validated means	required by validated means, with waste inactivated within the laboratory suite	required by validated means, with waste inactivated within the laboratory
Other measures				
18. Laboratory to contain its own equipment	not required	not required	required, so far as is reasonably practicable	required
19. An observation window or alternative is to be present so that occupants	required where and to extent the risk	required where and to extent the risk	required where and to extent the risk assessment	required

can be seen	assessment shows it is required	assessment shows it is required	shows it is required	
20. Safe storage of GMMs	required where and to extent the risk assessment shows it is required	required	required	secure storage required
21. Written records of staff training	not required	required where and to extent the risk assessment shows it is required	required	required

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 involving 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 involving micro-organisms in plant growth facilities (to be read with table 1a as indicated in paragraph 3)

Containment Measures	*Containment Levels*				*Additional/ modification*
	1	*2*	*3*	*4*	
Building					
1. Permanent structure (**note**)	required where and to extent the risk assessment shows it is required	required	required	required	Modification
Equipment					
2. Entry via a separate room with two interlocking doors	not required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required (via airlock key procedure)	Additional
3. Control of contaminated run-off water	required where and to extent the risk assessment shows it is	required so as to minimise run-off	required so as to prevent run-off	required so as to prevent run-off	Additional

	required				
System of work					
4. Effective control of disease vectors such as insects, rodents and arthropods which could disseminate GMMs	required	required	required	required	Additional
5. Effective control of pollen, seeds and other plant material which could disseminate GMMs	required where and to extent the risk assessment shows it is required	required so as to minimise dissemination	required so as to prevent dissemination	required so as to prevent dissemination	Additional
6. Procedures for transfer of living material between the plant growth facilities, protective structure and laboratory must control dissemination of GMMs	required so as to minimise dissemination	required so as to minimise dissemination	required so as to prevent dissemination	required so as to prevent dissemination	Additional

NOTES

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)

Containment Measures	*Containment Levels*				*Additional/ modification*
	1	*2*	*3*	*4*	
Facilities					
1. Isolation of animal unit (**note 1**)	required where and to extent the risk assessment shows it is required	required	required	required	Modification
2. Animal facilities (**note 2**) separated by lockable doors	required where and to extent the risk assessment shows it is required	required	required	required	Additional
3. Animal facilities (cages, etc.) designed to facilitate	required where and to extent the risk assessment	required where and to extent the risk assessment	required	required	Additional

decontamination (waterproof and easily washable material)	shows it is required	shows it is required			
4. Floor, walls and ceiling easily washable	required where and to extent the risk assessment shows it is required	required for floor	required for floor and walls	required for floor, walls and ceiling	Modification
5. Appropriate filters on isolators or isolated rooms (**note 3**)	not required	required where and to extent the risk assessment shows it is required	required	required	Additional
6. Appropriate barriers at the room exit, and at drains or ventilation duct work	required	required	required	required	Additional
7. Animals kept in appropriate containment facilities, such as cages, pens or tanks but not isolators	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	Additional
8. Animals kept in isolators	not required	required where and to extent the risk assessment shows it is required	required	required	Modification

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 involving micro-organisms in premises other than those referred to in tables 1a, 1b and 1c

Containment Measures	*Containment Levels*			
	1	*2*	*3*	*4*
General				
1. Viable micro-	required where	required	required	required

organisms must be contained in a system which separates the process from the workplace and wider environment (closed system)	and to extent the risk assessment shows it is required			
2. Closed systems located within a controlled area	not required	required where and to extent the risk assessment shows it is required	required	required
3. Control of exhaust gases from the closed system	not required	required so as to minimise release	required so as to prevent release	required so as to prevent release
4. Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	required where and to extent the risk assessment shows it is required	required so as to minimise release	required so as to prevent release	required so as to prevent release
5. Inactivation of bulk culture fluids before removal from the closed system	required where and to extent the risk assessment shows it is required	required by validated means	required by validated means	required by validated means
6. Seals must be designed so as to minimise or prevent release	not required	required so as to minimise release	required so as to prevent release	required so as to prevent release
7. The controlled area designed to contain spillage of the entire contents of the closed system	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required	required
8. The controlled area sealable to permit fumigation	not required	required where and to extent the risk assessment shows it is required	required where and to extent the risk assessment shows it is required	required
9. Biohazard signs posted	not required	required	required	required
Equipment				
10. Entry via airlock	not required	not required	required where and to extent the risk assessment shows it is required	required
11. Surfaces resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents and easy to clean	required for any bench	required for any bench	required for floor and any bench	required for any bench, floor, ceilings and walls
12. Specific measures to adequately ventilate the controlled areas in order to minimise air contamination	required where and to extent the risk assessment shows they are required	required where and to extent the risk assessment shows they are required	required where and to extent the risk assessment shows they are required	required

13. The controlled area maintained at an air pressure negative to the immediate surroundings	not required	not required	required where and to extent the risk assessment shows it is required	required
14. Extract and input air from the controlled area must be HEPA filtered	not required	not required	required for extract air, optional for input air	required for input and extract air
System of work				
15. Access restricted to authorised personnel only	not required	required	required	required
16. Personnel must shower before leaving the controlled area	not required	not required	required where and to extent the risk assessment shows it is required	required
17. Personnel must wear protective clothing	work clothing required	work clothing required	required	complete change required before exit and entry
18. Written procedures and records of staff training	not required	required where and to the extent the risk assessment shows it to be required	required	required
Waste				
19. Inactivation of GMMs in effluent from hand-washing sinks and showers or similar effluents	not required	not required	required where and to extent the risk assessment shows it is required	required
20. Inactivation of GMMs in contaminated material and waste including those in process effluent before final discharge	required by validated means where and to the extent the risk assessment shows it to be required	required by validated means	required by validated means	required by validated means

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations implement Directive 2009/41/EC (O.J. L 125 21.5.2009 p. 75) which lays down measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment. The Regulations also apply to the contained use of genetically modified organisms that are not micro-organisms known as "larger GMOs" but only in relation to risks to human health. The Regulations revoke and replace the Genetically Modified Organisms (Contained Use) Regulations 2001 (S.R. 2831/2000), and its amending instruments (S.I. 2002/63, S.I. 2005/2466, S.I. 2010/2840).

2.Contained use includes any activity or other action (for example storage) involving a genetically modified organism within a controlled environment where there are physical barriers and/or other controls in place to ensure that any genetically modified organism is not released into the environment. Certain techniques are or are not regarded as genetic modification and the

Regulations do not apply to genetically modified organisms in a number of circumstances including where there is a licence under other legislation. Some of the regulations are disapplied to genetically modified organisms when they are being transported (regulation 3 and Schedule 2).

3.The Regulations impose duties on people who are undertaking or proposing to undertake contained use (users) and persons responsible for contained use. These are people who either have the authority to determine whether contained use can take place, or people with control over the planning or conduct of the contained use.

4.The meaning of some terms within the Health and Safety at Work (Northern Ireland) Order 1978 are modified so that the Regulations apply to educational institutions as if they were workplaces and students as if they were employees of that university. They also apply to any person who is not an employee undertaking contained use (except a student) as if they were self-employed within the meaning of that Order (regulation 4).

5.Before contained can commence a person responsible for that contained use must ensure that an assessment of the risks created by the contained use to human health and the environment has been carried out. The person carrying out the risk assessment must assign a class (from 1 to 4 with 4 being the highest risk) to the contained use depending on the seriousness of the risks posed (regulation 5, Schedule 1 and Schedule 3). Similarly, contained use involving larger GMOs cannot commence until the person responsible has ensured that an assessment is carried out in relation to risks to human health (regulation 6 and Schedule 4) although there is no requirement to assign a class of use. There are specific requirements relating to the review, recording and keeping of risk assessments (regulation 7). A person responsible for contained use must obtain advice on the risk assessment either from an individual or (where the risk is assessed at class 2 or above) a genetic modification safety committee with relevant expertise (regulation 8).

6.Premises cannot be used for contained use unless they have been notified to the competent authority together with information specified (regulation 9 and Schedule 5) by a person responsible for the first contained use. One notification can include more than one premises.

7.Before class 2 contained use can commence, a person responsible for contained use must notify the competent authority of that contained use and provide information specified in Schedule 6 (regulation 10). A period of time must then elapse before contained use can begin, the period is dependent on whether contained use of that class or higher has taken place on those premises before.

8.Class 3 or 4 contained use cannot commence unless the competent authority has given consent for that contained use. A person responsible must submit a notification for that contained use and provide the information specified in Schedule 6. Consent must be notified within a specified period that is dependent on whether the notifier already has consent for contained use in that class (regulation 11).

9.Before contained use can commence involving a larger GMO (and the contained use will result in a more hazardous organism than its parent organism) a person responsible for that contained use must notify the competent authority of that contained use and provide the information specified in Schedule 6 (regulation 12).

10. In certain circumstances the competent authority may accept single notifications for contained use at more than one premises (regulation 13). There are various duties to notify the competent authority of changes of circumstances and changes that affect risks (regulations 14 and 15).

11. If the competent authority asks for further information about a notification, the contained use cannot begin or continue until the competent authority has agreed in writing except to store or destroy the genetically modified organisms (regulation 16). A notifier may withdraw their application as long as the contained use has not commenced (regulation 17).

12. Users are required to ensure that occupational and environmental safety principles are observed (Schedule 7) and that risks are kept to the lowest level reasonably practicable (regulation 18).

13.A user carrying out contained use involving genetically modified micro-organisms is required to apply the containment measures which are appropriate to that activity in accordance with the risk assessment. The containment measures are classified into different "containment levels" which largely correspond with the class assigned to the contained use, with level 4 being the highest level of containment. The measures are set out in Schedule 8 (regulation 19). A user carrying out contained use involving a larger GMO must apply the containment measures applicable in accordance with the risk assessment for that activity (regulation 20).

14. Where a risk assessment shows it is warranted, an emergency plan must be prepared before contained use can commence. In the case of genetically modified micro-organisms the plan must consider risks to human health and the protection of the environment, in the case of larger GMOs the plan only considers human health. (Regulation 21). If an accident occurs the person responsible for the contained use must notify the competent authority immediately and provide specified information (regulation 22).

15. The competent authority is placed under a duty to examine a notification submitted to it under regulations 9(2), 10(2), 11(2) and 12(2) (regulation 23) and the Executive may ask the notifier for additional information on behalf of the competent authority (regulation 24). The competent authority has power to impose time limits or conditions on contained use, to suspend, terminate or not commence contained use and to vary or revoke any consent previously granted under regulation 11 (regulation 25).

16. The competent authority must take certain steps if notified of an accident (regulation 26). The competent authority may grant an exemption from the requirements of the Regulations but only if it is satisfied that the health and safety of persons and the environment are not prejudiced by the granting of such an exemption (regulation 26).

17. The competent authority is to maintain a register of all notifications and copies of the register are to be made available for public inspection by the Executive by such means as are appropriate including by publication on its website. (regulation 28) Certain information may not be published if it would be contrary to the interests of national security (regulation 29).

18. Provision is made for the enforcement of the Regulations under the Health and Safety at Work (Northern Ireland) Order 1978 (regulation 30).

19. There is a right of appeal for any person who is aggrieved by certain decisions of the competent authority, a request for information or an instruction given to him by the Executive (regulation 31).

20. Anything that must be submitted to the competent authority under the regulations must be submitted to the Executive at the address they publish for the purpose, this could be an email or other form of electronic submission (regulation 32).

21. There are various transitional, saving and consequential provisions and various instruments are revoked (see paragraph 1 above) (regulations 33 to 35).

ANNEX 2 – 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 3 – 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 (eg 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.

ANNEX 4

Title: Consolidation of the Genetically Modified Organisms (Contained Use) Regulations 2000 and its three amending Regulations from 2002, 2005 and 2010. **IA No: HSE0086** **Lead department or agency:** Health and Safety Executive (HSE) **Other departments or agencies:** Defra, Scottish Government, Welsh Government	Impact Assessment (IA) **Date: 05/03/2014** **Stage: Validation** **Source of intervention: Domestic** **Type of measure: Secondary legislation** **Contact for enquiries:** Mike Paton: Michael.Paton@hse.gsi.gov.uk Kyran Donald: Kyran.Donald@hse.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: Awaiting Scrutiny

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, Two-Out?**	**Measure qualifies as**
£1.17m	£1.17m	£-0.13m	Yes	OUT

What is the problem under consideration? Why is government intervention necessary?

The consolidation of the Genetically Modified Organisms (Contained Use) Regulations 2000 and its three amending Regulations from 2002, 2005 and 2010 (GMO (CU) regulations) is one of the recommendations of the Löfstedt review of health and safety, published in 2011. The review recommended that a consolidation of the GMO (CU) regulations should: ensure the regulations reflect current industry practices; limit the extent to which UK health and safety legislation has enhanced (gold plated) EU directives; and simplify the regulations (for example by reducing any duplication). The Government's response emphasised that the consolidation process should not reduce the protections provided by the existing legislation.

What are the policy objectives and the intended effects?

To consolidate the Genetically Modified Organisms (Contained Use) Regulations 2000 and its three amending regulations from 2002, 2005 and 2010 (four into one) in line with the Better Regulation Executive guidelines without reducing the protections afforded by the existing legislation and 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 (preferred option) is to consolidate, modernise and where practical, simplify the GMO (CU) Regulations.

The reasons for preferring Option 2 are outlined in more detail in the main body of the document.

Will the policy be reviewed? It **will** be reviewed. **If applicable, set review date: 10/2019**

Does implementation go beyond minimum EU requirements?	No

Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Mediu m**Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**		**Non-traded:**

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 SELECT SIGNATORY: ..... Dat e: .....

Summary: Analysis & Evidence Policy Option 1

Description: Do nothing

FULL ECONOMIC ASSESSMENT

Price Base Year NA	PV Base Year NA	Time Period Years NA	Net Benefit (Present Value (PV)) (£m)		
			Low: NA	**High: NA**	**Best Estimate: NA**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	NA	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	NA		NA	**NA**

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 (and wider government) for failing to implement Löfstedt recommendations and deliver the Government response.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	NA	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	NA		NA	**NA**

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 **Discount rate (%)**

None

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: NA	**Benefits: NA**	**Net: NA**	No	NA

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

Price Base Year 2009	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 0.17	High: 2.64	Best Estimate: 1.17

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0.1		0.0	**0.1**
High	0.3	1	0.0	**0.3**
Best Estimate	0.2		0.0	**0.2**

Description and scale of key monetised costs by 'main affected groups'

There will be a one-off familiarisation cost to business for a biological safety officer (BSO) reading and understanding the changes and disseminating this information to colleagues, estimated at around £120k in the first year. There will also be a need for dutyholders to review their current risk assessments, estimated at approximately £73k. HSE will also rewrite the corresponding supporting guidance to make it simpler, at a cost of around £10k.

Other key non-monetised costs by 'main affected groups'

None expected

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0.0		0.1	**0.5**
High	0.0		0.3	**2.8**
Best Estimate	0.0		0.2	**1.4**

Description and scale of key monetised benefits by 'main affected groups'

Businesses will benefit from increased flexibility regarding disposal of waste. This could result in benefits of approximately £550k over the ten-year appraisal period. There may also be benefits from no longer having to run complex air filtering and room pressure systems. This is estimated as approximately £820k. There will also be some minor savings to HSE as a result of reduced administrative burden.

Other key non-monetised benefits by 'main affected groups'

There will be time savings resulting from simplified guidance, increased flexibility in obtaining competent advice on risk assessments and replacement of prescriptive with risk-based containment requirements however we are unable to quantify how much in a robust way. There is also a series of technical changes, which we have been unable to quantify the effects of, or it was deemed not proportionate to do so.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

There may be 'over-compliance' after the changes, as some businesses may continue to apply health and safety procedures based on the most hazardous organisms they work with, rather than changing practices based on the particular organism they are handling at any given time. Guidance will be provided to mitigate any over-compliance. The outcome will also be based on risk assessment and the choice taken based on greater flexibility and behavioural rather than compliance issues.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: **0.0**	Benefits: **0.2**	Net: **0.1**	Yes	OUT

Evidence Base (for summary sheets)

Background and rationale for intervention

1. The GMO (CU) regulations are concerned with the protection of the environment and prevention of harm to human health from activities involving genetically modified organisms (GMOs) in 'contained use' facilities. They implement the relevant requirements of European Directive 2009/41/EC on the contained use of genetically modified microorganisms (GMMs) and other EU requirements concerning access to environmental information. The regulations also include domestic provisions in relation to genetically modified animals and plants (larger GMOs). This was included in the GMO (CU) regulations in 2000, to avoid the need for separate regulations and increased regulatory burden associated with this. The provisions for larger GMOs have not been changed in the consolidated regulations. Since 2000 (when the regulations first came into force), there have been three sets of amending regulations. The regulations are supported by HSE publication '*A guide to the Genetically Modified Organisms (Contained Use) Regulations 2000*', (L29) HSE Books.
2. The GMO (CU) regulations cover the whole of Great Britain. HSE is the Competent Authority for the regulation of contained use of GMOs with Defra (in England and Wales) and with the Scottish Government (in Scotland) acting jointly. Northern Ireland has equivalent regulations. For administrative purposes, HSE acts as a single point of contact for users. This consultation relates to GMO (CU) regulations that will apply in England, Scotland and Wales.
3. 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.
4. Contained use activities (for the purposes of these regulations) cover any activity involving GMOs, encompassing microorganisms (e.g. bacteria, viruses, human or animal cells) and larger GMOs (e.g. animals, plants, insects) for which 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.
5. These barriers (containment measures) can be physical, chemical or biological and are selected based on the the outcome of a risk assessment. The control measures are grouped into four containment levels (CL), from 1 to 4, of increasing stringency and protection afforded i.e. CL1 being the lowest level and CL4 being the highest.
6. The risk assessment is used to identify the most appropriate containment measures (and therefore containment level) and assign the contained use in to one of four 'risk classes', which essentially equate to the containment level – CL1 is required for Class 1 contained use (no or negligible risk), CL2 for Class 2 contained use (low risk), CL3 for Class 3 contained use (moderate risk) and CL4 for Class 4 contained use (high risk).
7. Prior to Class 2, 3 or 4 activities commencing, the dutyholder must submit a notification, including an assessment of the hazardous properties of the GMMs and the proposed containment for the planned activity. Specialists at the Competent Authority review these notifications for technical content and compliance with the legislation placing an emphasis on the adequacy of the risk assessment and requesting additional information where necessary.

8. For Class 3 and 4 contained use the user may not proceed without the written consent of the Competent Authority.
9. The majority of contained use work is being undertaken at Class 1, deemed to be no or negligible risk, with very few employers undertaking work at Class 4 (which includes work with the ebola and foot and mouth disease viruses), deemed to present a serious risk to human health or the environment.
10. The consolidation of the GMO regulations is one of the recommendations of the Löfstedt review of health and safety[32], published on the 28 November 2011. The Löfstedt review recommended that a consolidation of GMO (CU) regulations 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)
11. 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.
12. HSE worked closely with other government departments and key stakeholders in the lead up to the public consutation 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. The significant majority of stakeholders have supported the proposed changes from their response to the public consultation. Stakeholder groups have also been updated following completion of the consultation, to ensure they are familiar with the proposed changes and have not raised any practical implementation issues. Stakeholders will be kept apprised of progress in advance of the new regulations coming into force. The consultation process was also used to check key assumptions in the impact assessment.

Summary of current provisions

13. The GMO (CU) regulations already closely follow the European Directive (2009/41/EC). Similarly, previous consultation exercises have been supportive of the current GMO (CU) regulations. However, there are areas where the requirements go beyond the directive, where the existing legislation can be simplified and would benefit from changes to improve clarity, proportionality and remove unnecessary requirements on low risk activities.
14. The current provisions in the GMO (CU) regulations can be broadly grouped into the following areas:

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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.
http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/

[32] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/66790/lofstedt-report.pdf

- Risk assessment and classification of work
- Notification and provision of information
- Application of containment and control measures.

15. It is also hoped that the consolidation will provide for greater consistency in standards between work involving GMOs and non-modified microorganisms. Work with non-modified microorganisms that present a risk to human health are 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 microorganisms that present a risk to specific animals is covered by the relevant Specified Animal Pathogen Orders (SAPO 2008, 2009) in England, Scotland and Wales.
16. The GMO (CU) 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 and is unaffected by this review.

Organisations affected

17. 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. the Biological and Bioscience Research Council announced £20million of investment in six synthetic biology research projects in 2012[33]).
18. There are in the region of 600 premises in GB carrying out contained use of microorganisms (Table 1). The majority of work is being undertaken at Class 1 and only 6 employers are undertaking work at Class 4. Approximately 30% of the premises undertake contained use work with 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 1: Breakdown of employers and premises by class of activity (at 1 August 2013)

Containment Level	Number of GM Centres	Percentage
CL1	342	57%
CL2	179	30%
CL3	71	12%
CL4	6	1%
Total	598	100%

[33] See BIS press release: http://news.bis.gov.uk/Press-Releases/Government-to-invest-20-million-in-synthetic-biology-682fa.aspx

Policy objective

19. 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 single set of regulations. 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 GMOs.

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

Options Considered

Option 1: Do nothing (Baseline)

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

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

23. The 'do nothing' option would therefore incur high reputational costs for HSE (and wider Government), however, it remains the baseline against which the other options for implementing Löfstedt's recommendations are compared.

Option 2: Modernisation and consolidation.

24. **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.**

25. The consolidated regulations (GMO (CU) 2014) will aid clarity and 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**.**

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

27. For the health and safety elements of the regulations, these changes are made under Section 15 of the Health and Safety At Work Act etc. 1974 (HSWA) and for the environmental elements, under Section 2(2) of the European Communities Act 1972.

Other options considered

28. The purpose of the consolidation is deregulatory, hence alternatives to regulation were not pursued as this would not achieve the intended purpose. As part of the consultation process, it was considered to consolidate all four sets of regulations to achieve a single set of regulations without any changes to the requirements. **This option was ruled out for failing to meet the criteria set out in the** Löfstedt recommendation.

29. 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, reduced clarity of requirements, increasing burdens on dutyholders and further misalignment with other related health, safety and environmental regimes such** COSHH and SAPO (2008, 2009).

General Assumptions

30. 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.

31. Between 2008 and 2013 there was, on average, a net increase of around 18 new GM centres notified to HSE each year. This was mostly made up of companies operating at CL1. It was found that any new GM centres operating at CL2-4 were offset by existing companies ceasing operations. The analysis will assume that this will continue over the ten years of the appraisal period and that the net number of new entrants in CL1-4 will follow the current trends in each of these activity levels. Table 2 shows the projected number of GM centres over the ten year appraisal period.

Table 2: Projection of number of GM centres by activity over ten years

	CL1	CL2	CL3	CL4	Total
Year 0	342	179	71	6	598
Year 1	360	179	71	6	616
Year 2	378	179	71	6	634
Year 3	395	179	72	6	652
Year 4	413	179	72	6	670
Year 5	431	179	72	6	688
Year 6	449	179	72	6	706
Year 7	467	179	72	6	724
Year 8	484	179	73	6	742
Year 9	502	179	73	6	760

Note: totals may not sum due to rounding

32. 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 guidance[34] to use this time frame.

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

34. Present value figures are given in terms of 2013 prices.

35. Equivalent Annual Net Cost to Business (EANCB) figures are given in terms of 2009 prices.

Costs and benefits

Option 1

36. 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

Changes to Control Measures

37. The consultation covered a number of proposals, which relate to changes to provisions in the containment tables[35] of the regulations. The proposals which are likely to have a monetary impact have been considered in paragraphs 38-53.

Removal of prescriptive requirement to dispose of animal carcases

38. Dutyholders are currently required to dispose of animal carcasses by incineration. The specific requirement for an incinerator is not in the EC directive (2009/41/EC). 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, as there are alternative modern technologies available (e.g. autoclaves, tissue digesters, rotaclaves) that provide effective means of inactivation and are more environmentally friendly. The current requirement to have an incinerator on site at CL4 may also preclude the development of new facilities in certain geographical areas (due to environmental permissions) or within certain institutions (where cost would be prohibitive).

39. Removing this requirement will provide greater flexibility in choosing the most appropriate inactivation method to be used. 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).

40. The proposed change will not lower the level of protection for human health and the environment. For human pathogens, the requirement for an incinerator specified in COSHH (mentioned in paragraph 15) will still apply. The intention would be to amend the Biological Agents Directive (2000/54/EC) and COSHH to align measures with the GMO(CU) regulations when the opportunity arises.

Requirement to allow increased flexibility for inactivation of CL1 waste

41. Dutyholders are required to inactivate all GMMs in contaminated waste by a validated method at CL1. The proposed change will revert to the standard in the Directive (2009/41/EC) and make the requirement for inactivation of waste at

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[34] http://www.bis.gov.uk/assets/biscore/better-regulation/docs/i/11-1111-impact-assessment-guidance.pdf

[35] There are four containment tables – Table 1a relates to laboratories; Table 1b relates to plant growth units; Table 1c relates to animal units and Table 2 relates to other premises (e.g. large scale manufacturing)

CL1 to be determined by the risk assessment. This change would permit flexibility on the method by which inactivation is undertaken and remove the perceived mandatory use of an autoclave (a high-pressure steam steriliser) for this purpose. This change will be supplemented by guidance to explain under what circumstances it is permissible to dispose of waste without inactivation, thereby ensuring the protection of human health and the environment.

42. 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 and incapable of survival outside of the laboratory, dispose of it untreated. Alternatives to autoclaving would no longer require specific derogation.

43. 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. However, 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.

44. Given the difficulty in predicting the response of dutyholders to the proposed changes, it is difficult to place a robust monetary estimate on potential savings. However, as a result of consultation, it was found that in 2013, approximately 270 tonnes of genetically modified waste material was processed by GM certified waste disposal companies, at an average cost of between £550/tonne and £850/tonne, with a best estimate of £700/tonne. It is estimated that disinfecting this waste on-site and then a waste disposal company processing this disinfected waste as domestic waste would cost between £200/tonne and £250/tonne, with a best estimate of £225/tonne. This gives total potential savings of between £350/tonne and £600/tonne, with a best estimate of around £475/tonne.

45. Based on responses from the consultation exercise, it is thought reasonable that half of the waste currently treated as GM waste might be disinfected and removed as normal domestic waste. This gives approximate annual savings of £64k, which equates to a total discounted saving of approximately £550k, across the ten year appraisal period.

46. Responses in the consultation were mixed as to whether industry would change their waste disposal practices or not, and there was no clear indication of what respondents' plans were. Owing to this uncertainty, sensitivity checks have been conducted for a 25% and a 75% take-up rate, combined with our lower and upper estimates for the cost savings from changing waste disposal practices, as it is assumed that a lower cost saving will result in a lower take-up rate These gave approximate savings of £200k and £1m over the ten year appraisal period.

47. The proposed changes will have no detriment to health, safety or environmental protection. These measures relate to Class 1 activities which by definition are no or negligible risk

Removal of the requirement for inward airflow at CL2 and introduction of a more risk based approach for inward airflow and HEPA filters at CL3 (where this is a risk of airborne transmission)

48. Dutyholders are currently required to operate the area containing the GMO at negative pressure relative to the surrounding areas at CL3, and where a risk

assessment shows that this is required at CL2. This creates an inward airflow into the laboratory, providing protection to those outside who may be exposed to the GMO. Following the proposed change, this measure will not be required at CL2 and will now only be required where transmission occurs via an airborne route at CL3. This aligns with the requirements of the directive (2009/41/EC). It is difficult to envisage activities which require this measure that would not also require other CL3 associated control measures (e.g. high-efficiency particulate absorption (HEPA) filter of extract; room sealability), and as such it is more appropriate for work that requires this measure to be undertaken at CL3 rather than CL2 anyway. This proposed change will ensure the most appropriate protection for human health and the environment is applied, it will create a greater distinction between containment levels and provide greater consistency within the regulations.

49. In addition to negative pressure requirements, users are also required to operate a high-efficiency particulate absorption (HEPA) filter at CL3 to extract air. These two control measures usually comprise one integrated system. HEPA filters ensure that air is filtered before exiting the laboratory. Following the proposed change, the requirement of a HEPA filter will only be required where transmission occurs via an airborne route. This ensures the most appropriate protection for human health and the environment is applied, and brings the legislation in line with the Directive (2009/41/EC).

50. Whether a GM centre requires these measures will be dependant on the activity they are undertaking and if there is a risk of airborne transmission. HSE can not predict precisely how businesses will respond to the greater flexibility proposed in terms of changes to the usage of negative air pressure and HEPA filters, particularly at sites carrying out work at different containment levels or with different GMMs with different possible exposure routes (i.e. airborne and non-airborne), however we estimate that there are currently 38 sites operating at CL3 working with non-airborne GMOs, and these have been identified as those sites where the greatest potential savings could be made.

51. It is estimated that potential cost savings could come from reduced running costs if negative air pressure and HEPA systems are used less. Responses to the consultation exercise suggested that the maintenance and running costs of a system are between £3k and £7k per year, with a best estimate of £5k per year. Based on consultation responses, we assume that half of the 38 CL3 sites working with non-airborne genetically modified material choose to stop using the systems, we estimate that this could deliver savings of around £95k per year, or £820k discounted over the ten-year appraisal period.

52. Owing to the uncertainty surrounding this, we also conducted sensitivity analysis, assuming a 25% and 75% take-up rate at the lower and upper bounds. Combined with our lower and upper estimates for the cost savings from not running a HEPA filter system, as it is assumed that a lower cost saving will result in a lower take-up rate, this gives lower and upper savings estimates of £250k and £1.7m respectively.

53. The proposed changes will have no detriment to health, safety or environmental protection.

Non-Monetised Costs and Benefits from changes to control measures

Removal of duplication in legislation

54. There will be removal of some duplication of requirements in the legislation. This will be purely a change to wording and have no material impact on industry

practices, and as such there are no direct costs or benefits associated with this, nor will there be any detriment to health, safety or environmental protection.

Removal of the requirement for a specific type of microbiological safety cabinet at CL4

55. Current regulations are prescriptive and require dutyholders to use a specific microbiological safety cabinet (MSC) (namely, a Class III MSC) for work with infective material. At CL4, this requirement goes beyond the Directive (and the Biological Agents Directive 2000/54/EC). The proposed change is to revert more closely to the standard in the Directives and allow users to select the most appropriate MSC based upon risk assessment and the benchmark set out in industry guidance. There are other control systems that can offer an equal level of protection and will not lower protection of human health or the environment, therefore this change will provide increased flexibility to dutyholders.

56. It is 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. 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. This, coupled with the fact that there are currently only six GM centres operating at CL4, means that expected cost savings are likely to be limited, and therefore it is disproportionate to quantify them. The proposals will, however, allow for greater flexibility in choosing between control measures and allow UK business to compete more easily on the worldwide market.

57. The proposed changes will have no detriment to health, safety or environmental protection, as a suitable MSC, or equivalent control measures, will still be required, this change merely removes the prescriptive element that a particular type must be used.

Introduction of a more risk based approach for the requirement to have an observation window at CL3

58. GM centres are required to have a window (or equivalent measures) built into their CL3 laboratories so that workers can be observed from the outside. 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. The proposed change will revert to the Directive (2009/41/EC) so that the observational window would only be required where it is determined necessary by risk assessment.

59. 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. Costs may be incurred 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 additional costs or savings.

60. A risk assessment may still deem that an observation window is a necessity, therefore there will be no reduction in health, safety or environmental protection, the change will merely remove the legal need for one where there is no health and safety benefit, and allow increased flexibility in the future.

Removal of the requirement for isolators at CL1

61. Based on a risk assessment, CL1 sites are required to keep animals in isolators (equipment that contains the animal infected with GMMs and prevents dispersion of aerosols – this is equivalent of an MSC in laboratories). Isolators are intended to contain infected animals and afford a level of protection to users. Given that risk to human health is nil or negligible at CL1, it is thought that this is unnecessary. The proposed change is to remove this requirement at CL1. This proposed change will ensure the most appropriate protection for human health and the environment is applied and reflects the HEPA requirements for isolators and provides a greater distinction between CL1 and CL2. A risk assessment may show that either the isolator is required to protect human health or the environment, in which case the activity should not be classed as CL1, or that the isolator is necessary to protect the animal and the user may choose to select this control measure on that basis. It is not anticipated that there will be any costs or benefits associated with this change. The proposed changes will have no detriment to health, safety or environmental protection. This measure relates to Class 1 activities which by definition are no or negligible risk

Removal of the requirement for a purpose built controlled area for CL4 large-scale work

62. Controlled areas for CL4 large-scale work are currently required to be purpose built. Following the proposed change, such areas will be permitted to be refurbished at existing facilities. Although this change will create an inconsistency between the GMO (CU) regulations and COSHH (as mentioned in paragraph 15), there are currently no CL4 facilities of this type working with human pathogens. The intention would be to amend this overly prescriptive measure in the Biological Agents Directive (2000/54/EC) and COSHH, when the opportunity arises. Changing this requirement may allow existing facilities to be refurbished or alternative approaches to be applied. This could reduce entry costs for CL4 work and facilitate expansion in CL4 activities and could be beneficial to the industry. It is not possible to assign a monetary value to this change, however 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. The proposed change will have no detriment on health, safety or environmental protection, as there is no reduction in the standards required, merely more flexibility in the location where those standards can be met.

Removal of the requirement for biohazard signs at CL1

63. GM centres operating at CL1 currently post biohazard signs, where a risk assessment shows this is required, to inform those entering the facility of relevant hazards that may be present. The proposed change is to remove the need for a biohazard sign at CL1, bringing the regulations in line with the Directive (2009/41/EC). 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. There will be no cost or cost savings related 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 negligible. The proposed changes will have no detriment to health, safety or environmental protection. This measure relates to Class 1 activities which by definition are no or negligible risk

Changes to duties on the dutyholder relating to administrative procedures

Changes to the way in which a Genetic Modification Safety Committee can operate

64. GM centres are required to establish a Genetic Modification Safety Committee (GMSC), which provides advice on risk assessments made under the GMO regulations. The proposed change will permit advice on risk assessments for Class 1 activities to be obtained elsewhere (e.g. biological safety officer, 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 no or negligible risk (Class 1), possibly reduce the number of committees within an institution and bring the legislation in line with the Directive (2009/41/EC), which stipulates that a GMSC need only be formed "if required".

65. 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, likely to be from a variety of academic disciplines. Some GM centres will also have more than one GMSC. After the proposed change, each dutyholder may decide to either keep their GMSC or not, depending on their individual circumstances.

66. Following consultation, it is clear that there will be a wide variety of different responses to the proposal to remove the need for GMSCs at CL1. Many respondents operate at higher containment levels and do not know what proportion of time is spent at meetings dealing with CL1 risk assessments, how much this would be reduced if the change was enacted, and a mixed response from purely CL1 sites as to whether they would continue using GMSCs or not. Owing to this uncertainty, no savings have been estimated for this proposed change, however the proposals will definitely not increase costs, and will provide increased flexibility to those dutyholders who wish to take advantage of potential cost savings.

67. The proposed changes will have no detriment to health, safety or environmental protection. This measure relates to Class 1 activities which by definition are nil or negligible risk

Improvements to structure of regulations and associated guidance

68. HSE is undertaking a rewrite of the guidance associated with the legislation as part of the consolidation. The aim is to make the guidance shorter and simpler to read and understand. It is thought that dutyholders currently spend a large amount of time referring to guidance as part of their ongoing work with genetically modified material, therefore, a simplified guidance will lead to a reduction in the amount of time that they spend doing this, allowing them to engage in more productive work. Specific areas highlighted by stakeholders (e.g. significant changes to notifications, connected programmes of work and specific definitions) have been targeted for improved clarity.

69. As part of the consultation, we found that there is currently a very wide range in the amount of time that people spend referring to guidance, from 1 day per year, to 1 day per week. As such, we are unable to come up with robust estimates for our baseline projections. Furthermore, we cannot predict what impact the rewritten guidance will have on the time that people spend reading it. This means

that we cannot monetise robustly the impact that rewriting the guidance will have, however we believe that it will represent a saving to dutyholders.

Familiarisation costs

70. There will be one-off costs to industry of familiarisation with their new requirements under the GMO (CU) 2014. 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, with a best estimate of 2 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).

71. We can assume that any action required to understand or implement changes outlined in this impact assessment will be carried out by a biological safety officer (BSO), whose time is assumed to be worth £27.21 per hour. This assumption is based on the cost of a 'Science and Technology Professional', taken from the Annual Survey of Hours and Earnings and upweighted by 30% to include non-wage costs.

72. There are currently 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 £49 thousand, with a best estimate of about £33 thousand.

73. In addition, it is expected that the BSO will need to disseminate relevant information to colleagues. To assist BSOs with this exercise, HSE will produce a presentation or web-based learning tool outlining the proposed changes. 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 £49 thousand and £130 thousand, with a best estimate of about £89 thousand.

74. This gives a total one-off cost of familiarisation of between £65 thousand and £179 thousand, with a best estimate of about £122 thousand.

75. Following familiarisation, GM centres will also need to consider whether the changes will alter their working practices and subsequently review their risk assessments. The costs of reviewing risk assessments will also be in terms of the time taken to complete this task.

76. It is assumed that it will take each of the 598 GM centres between 1 and 2 hours to revise each risk assessment, with a best estimate of 1 and ½ hours, and that this will be carried out by a BSO at a total hourly cost of £27.21. It is also assumed that there will be on average three risk assessments per GM centre. The total one-off costs associated with reviewing risk assessments are therefore expected to be between about £49 thousand and £98 thousand, with a best estimate of about £73 thousand. It is not envisaged that the risk assessment classification will change.

Non-Monetised Costs and Benefits

77. GM centres operating at CL2 are not required to retain written records of staff training. Following the proposed changes, they will be required to do so where a risk assessment shows this is required. The requirement for written procedures and training records arises in the Directive from the principles of good microbiological practice. Currently there are inconsistencies surrounding whether this is required or not. 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. We do not expect there to be any sizeable costs or benefits associated with this change as those who do not currently provide written procedures and make a record of staff training are unlikely to now be required to do so. It is also expected that those who do keep a written record will continue to do so, if only for reasons of staff development and knowledge management.

78. 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 GMOs. 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, 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 makes clear what needs to be done to comply.

Changes to duties on the Competent Authority

Provisions for emergency plans

79. An emergency plan is currently required to be prepared for sites working with GMOs where 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. The regulations place a duty on the Competent Authority to ensure an emergency plan is in place, but this is not explicitly risk based. Consequently, the amendments will clarify and make it explicit that an emergency plan should only be prepared where the risk assessment identifies a need for one. 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.

Register of notifications

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

Rewriting guidance

81. The current guide to the regulations (L29) is dense, long and includes specific technical guidance. 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. It is expected that this will

take 25 working days of HSE Policy time and a further 5 days of a microbiology specialist's time, at a full cost of £333.50 per day and £404.86 per day respectively. This gives a total one-off cost to HSE of just over £10k.

Summary of Costs and Cost Savings of Option 2

82. The costs that have been estimated for option 2, discounted over the ten-year appraisal period, are as follows (to two significant figures):

Table 3: Costs to industry and Government

	Low (£'000)	**Best (£'000)**	**High (£'000)**
Industry			
Familiarisation	65	120	180
Reviewing risk assessments	49	73	98
Competent Authority			
Rewriting Guidance	10	10	10
Total	**120**	**210**	**290**

Note: totals may not sum due to rounding

83. The benefits that have been estimated for option 2, discounted over the ten-year appraisal period, are as follows (to two significant figures):

Table 4: Savings to industry and Government

	Low (£'000)	**Best (£'000)**	**High (£'000)**
Industry			
Waste Disposal	200	550	1,000
HEPA Filters	250	820	1,700
Competent Authority			
Register of notifications	5	5	5
Total	**460**	**1,400**	**2,700**

Note: totals may not sum due to rounding

84. As the costs and benefits are expected to be independent of one another, rather than a higher cost implying a higher benefit, when calculating the net present value (NPV), we will subtract the low estimate of the cost from the high estimate of the benefit to give the high estimate for the net present value, and vice versa for the low estimate of NPV. This will show the appropriate range between the high and low estimates of the NPV. To ascertain our best estimate, we will simply subtract the best estimate of the costs from the best estimate of the benefits. Doing this gives us a total net present value of between £0.17m and £2.7m, with a best estimate of £1.2m.

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

85. Based on OITO methodology, the NPV to business will be £1.2m over the ten-year appraisal period. This equates to an equivalent annual net cost to business (EANCB) of -£0.13m per annum, and therefore represents an OUT.

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

86. Notification data has been provided to the most accurate level possible and cost estimates and assumptions have been tested at length during consultation and post-consultation. 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 final stage IA.

Risks and assumptions

87. 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.

88. 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. However, this will be offset by the fact that there are savings that we have been unable to monetise fully in this impact assessment.

Wider impacts

89. None has been identified.

Statutory equality duties

90. None has been identified.

Economic impacts / Competition:

91. It is expected that where the proposed changes under Option 2 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.

92. Where the proposals under Option 2 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, we are unable to accurately predict nor monetise any such impacts.

Small and Micro-businesses

93. The changes proposed under the GMO consolidation will impact on small and micro-businesses as they make up a large proportion of organisations carrying out work at CL1 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 CL1 will grow as the biotechnology industry develops.

94. 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.
95. 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 and qualify for the fast track.

Environmental impacts

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

Health and Well Being

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

Human Rights

98. Human rights – the proposed changed do not affect people's human rights.

Justice System

99. None has been identified.

Rural Proofing

100. None has been identified

Sustainable Development

101. None has been identified.

Social impacts

102. None has been identified.

Summary and preferred option with description of implementation plan.

103. 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.

104. 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 and some CL3 work, particularly for small businesses. There are expected to be further cost savings from reduced running costs for some control systems and reduced time spent identifying duties within the regulations, but these have not been estimated.

105. The regulations will come into effect on the 1 October 2014. In advance of this, the revised *Guide to the Regulations (L29)* will be published on the HSE website. HSE will also publicise the consolidated regulations via a number of means including HSE's Biological Agents eBulletin (>4000 subscribers), direct email to contacts at registered GM centres, updated HSE web pages (including details of how the regulations will change) and participation in stakeholder meetings (e.g. University of Cambridge annual biosafety seminar; regional biosafety officers network events). To coincide with the regulations coming into force, HSE will issue a press release and will launch the new regulations at the open meeting of the Scientific Advisory Committee for Genetic Modification and similar stakeholder events in Scotland and Wales. HSE will also develop a user-focused toolkit which will explain the main changes in the legislation, that can be used by biological safety officers to cascade information to users in their organisations.

106. The consolidation does not raise any enforcement or implementation issues. HSE will continue to enforce the regulations in line with the current enforcement policy statement and in accordance with the principles of good regulatory practice, with which this sector is already familiar.

ANNEX 5

DETI EQUALITY SCREENING FORM

Part 1. Policy scoping

The first stage of the screening process involves scoping the policy under consideration. The purpose of policy scoping is to help prepare the background and context and set out the aims and objectives for the policy, being screened. At this stage, scoping the policy will help identify potential constraints as well as opportunities and will help the policy maker work through the screening process on a step by step basis.

Public authorities should remember that the Section 75 statutory duties apply to internal policies (relating to people who work for the authority), as well as external policies (relating to those who are, or could be, served by the authority).

Information about the policy

Name of the policy

Proposal for the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015

Is this an existing, revised or a new policy?

Revised

What is it trying to achieve? (intended aims/outcomes)

The main aims and objectives of the regulations are to transpose Northern Ireland European Directive 2009/41/EC on contained use of Genetically Modified Organisms [GMOs]. The proposed regulations consolidate existing individual Northern Ireland GMO regulations into a single set of up-to-date, straightforward regulations in line with a similar consolidation of the equivalent Great Britain legislation as a result of the recommendations of the Lofstedt review of health and safety legislation.

Are there any Section 75 categories which might be expected to benefit from the intended policy?
If so, explain how.

The benefits from the policy will apply equally to S75 categories and to others affected by the policy.

Who initiated or wrote the policy?

European Directive 2009/41/EC provides for the policy changes to be made by Member States. HSENI is responsible for devising and delivering the proposals for the NI implementing legislation to DETI. If DETI accepts the proposals, it is responsible for enacting the legislation.

Who owns and who implements the policy?

HSENI

Implementation factors

Are there any factors which could contribute to/detract from the intended aim/outcome of the policy/decision?

If yes, are they

☐ financial

☐x legislative

☐ other, please specify

_____

Main stakeholders affected

Who are the internal and external stakeholders (actual or potential) that the policy will impact upon?

☐ staff

☐ service users

☐ other public sector organisations

☐ voluntary/community/trade unions

☐X other, please specify - The Regulations will apply to those working in the GMO contained use sector. There are eight centres in Northern Ireland where “contained use” activities are carried out. All eight centres are involved in scientific research covering a range of organisations including Hospital Trusts, Universities, Government departments and private companies.

Other policies with a bearing on this policy

• what are they?

The Löfstedt review of health and safety legislation ‘Reclaiming health and safety for all’. A UK Government independent review to make proposals for simplifying health and safety law.

- who owns them?

Department for Work & Pensions

Available evidence

Evidence to help inform the screening process may take many forms. Public authorities should ensure that their screening decision is informed by relevant data.

What evidence/information (both qualitative and quantitative) have you gathered to inform this policy? Specify details for each of the Section 75 categories.

Section 75 category	Details of evidence/information
Religious belief	Although there is no available data the policy changes apply equally beneficially to all Section 75 categories and others.
Political opinion	As above.
Racial group	As above.
Age	As above.
Marital status	As above.
Sexual orientation	As above.
Men and women generally	As above.
Disability	As above.
Dependants	As above.

Needs, experiences and priorities

Taking into account the information referred to above, what are the different needs, experiences and priorities of each of the following categories, in relation to the particular policy/decision? Specify details for each of the Section 75 categories

Section 75 category	Details of needs/experiences/priorities
Religious belief	Although there is no available data the policy changes apply equally beneficially to all Section 75 categories and others.
Political opinion	As above.
Racial group	As above.
Age	As above.
Marital status	As above.
Sexual orientation	As above.
Men and women generally	As above.
Disability	As above.
Dependants	As above.

Part 2. Screening questions

Introduction

In making a decision as to whether or not there is a need to carry out an equality impact assessment, the public authority should consider its answers to the questions 1-4 detailed below.

If the public authority's conclusion is **none** in respect of all of the Section 75 equality of opportunity and/or good relations categories, then the public authority may decide to screen the policy out. If a policy is 'screened out' as having no relevance to equality of opportunity or good relations, a public authority should give details of the reasons for the decision taken.

If the public authority's conclusion is **major** in respect of one or more of the Section 75 equality of opportunity and/or good relations categories, then consideration should be given to subjecting the policy to the equality impact assessment procedure.

If the public authority's conclusion is **minor** in respect of one or more of the Section 75 equality categories and/or good relations categories, then consideration should still be given to proceeding with an equality impact assessment, or to:

- measures to mitigate the adverse impact; or
- the introduction of an alternative policy to better promote equality of opportunity and/or good relations.

In favour of a 'major' impact

a) The policy is significant in terms of its strategic importance;
b) Potential equality impacts are unknown, because, for example, there is insufficient data upon which to make an assessment or because they are complex, and it would be appropriate to conduct an equality impact assessment in order to better assess them;
c) Potential equality and/or good relations impacts are likely to be adverse or are likely to be experienced disproportionately by groups of people including those who are marginalised or disadvantaged;
d) Further assessment offers a valuable way to examine the evidence and develop recommendations in respect of a policy

about which there are concerns amongst affected individuals and representative groups, for example in respect of multiple identities;
e) The policy is likely to be challenged by way of judicial review;
f) The policy is significant in terms of expenditure.

In favour of 'minor' impact

a) The policy is not unlawfully discriminatory and any residual potential impacts on people are judged to be negligible;
b) The policy, or certain proposals within it, are potentially unlawfully discriminatory, but this possibility can readily and easily be eliminated by making appropriate changes to the policy or by adopting appropriate mitigating measures;
c) Any asymmetrical equality impacts caused by the policy are intentional because they are specifically designed to promote equality of opportunity for particular groups of disadvantaged people;
d) By amending the policy there are better opportunities to better promote equality of opportunity and/or good relations.

In favour of none

a) The policy has no relevance to equality of opportunity or good relations.
b) The policy is purely technical in nature and will have no bearing in terms of its likely impact on equality of opportunity or good relations for people within the equality and good relations categories.

Taking into account the evidence presented above, consider and comment on the likely impact on equality of opportunity and good relations for those affected by this policy, in any way, for each of the equality and good relations categories, by applying the screening questions detailed below and indicate the level of impact on the group i.e. minor, major or none.

Screening questions

1 What is the likely impact on equality of opportunity for those affected by this policy, for each of the Section 75 equality categories? minor/major/none		
Section 75 Category	Details of policy impact	Level of impact? minor/major/none
Religious belief	Consolidation of existing Northern Ireland GMO legislation including changes to address areas where the regulations exceed the requirements of the EU Directive.	None. The policy has no bearing on equality of opportunity
Political opinion	As above	As above
Racial group	As above	As above
Age	As above	As above
Marital status	As above	As above
Sexual orientation	As above	As above
Men and women generally	As above	As above
Disability	As above	As above
Dependants	As above	As above

2 Are there opportunities to better promote equality of opportunity for people within the Section 75 equalities categories?		
Section 75 category	If **Yes**, provide details	If **No**, provide reasons
Religious belief		The policy will apply equally beneficially to all of the Section 75 Groups and to other groups and has no relevance to the promotion of equality of opportunity.
Political opinion		As above
Racial group		As above
Age		As above
Marital status		As above
Sexual orientation		As above
Men and women generally		As above
Disability		As above
Dependants		As above

3 To what extent is the policy likely to impact on good relations between people of different religious belief, political opinion or racial group?		
Section 75 category	Details of policy impact	Level of impact minor/major/none
Religious belief	Consolidation of existing Northern Ireland GMO legislation including changes to address areas where the regulations exceed the requirements of the EU Directive.	None. The policy has no bearing on good relations between the relevant people / groups.
Political opinion	As above	As above
Racial group	As above	As above

4 Are there opportunities to better promote good relations between people of different religious belief, political opinion or racial group?		
Good relations category	If **Yes**, provide details	If **No**, provide reasons
Religious belief		The policy will apply equally beneficially to all of the Section 75 Groups and to other groups and has no relevance to the promotion of good relations.
Political opinion		As above
Racial		As above

group		

Additional considerations

Multiple identity

Generally speaking, people can fall into more than one Section 75 category. Taking this into consideration, are there any potential impacts of the policy/decision on people with multiple identities? (*For example; disabled minority ethnic people; disabled women; young Protestant men; and young lesbians, gay and bisexual people).*

Provide details of data on the impact of the policy on people with multiple identities. Specify relevant Section 75 categories concerned.

Although there is no available data the policy will apply equally to all of the Section 75 Groups and adverse impact on people with multiple identities is not anticipated.

Part 3. Screening decision

If the decision is not to conduct an equality impact assessment, please provide details of the reasons.

The provisions of the proposed regulations will apply universally and would be expected to benefit, rather than adversely impact, all of the Section 75 groups equally and to the same extent as other groups.

If the decision is not to conduct an equality impact assessment the public authority should consider if the policy should be mitigated or an alternative policy be introduced.

The provisions of the proposed regulations will apply universally and would be expected to benefit, rather than adversely impact, all of the Section 75 groups equally. There are therefore no grounds for mitigation or alternative policies.

If the decision is to subject the policy to an equality impact assessment, please provide details of the reasons.

All public authorities' equality schemes must state the authority's arrangements for assessing and consulting on the likely impact of policies adopted or proposed to be adopted by the authority on the promotion of equality of opportunity. The Commission recommends screening and equality impact assessment as the tools to be utilised for such assessments. Further advice on equality impact assessment may be found in a separate Commission publication: Practical Guidance on Equality Impact Assessment.

Mitigation

When the public authority concludes that the likely impact is ‘minor’ and an equality impact assessment is not to be conducted, the public authority may consider mitigation to lessen the severity of any equality impact, or the introduction of an alternative policy to better promote equality of opportunity or good relations.

Can the policy/decision be amended or changed or an alternative policy introduced to better promote equality of opportunity and/or good relations?

If so, give the **reasons** to support your decision, together with the proposed changes/amendments or alternative policy.

Timetabling and prioritising

Factors to be considered in timetabling and prioritising policies for equality impact assessment.

If the policy has been **'screened in'** for equality impact assessment, then please answer the following questions to determine its priority for timetabling the equality impact assessment.

On a scale of 1-3, with 1 being the lowest priority and 3 being the highest, assess the policy in terms of its priority for equality impact assessment.

Priority criterion	**Rating (1-3)**
Effect on equality of opportunity and good relations	
Social need	
Effect on people's daily lives	
Relevance to a public authority's functions	

Note: The Total Rating Score should be used to prioritise the policy in rank order with other policies screened in for equality impact assessment. This list of priorities will assist the public authority in timetabling. Details of the Public Authority's Equality Impact Assessment Timetable should be included in the quarterly Screening Report.

Is the policy affected by timetables established by other relevant public authorities?

If yes, please provide details

Part 4. Monitoring

Public authorities should consider the guidance contained in the Commission's Monitoring Guidance for Use by Public Authorities (July 2007).

The Commission recommends that where the policy has been amended or an alternative policy introduced, the public authority should monitor more broadly than for adverse impact (See Benefits, P.9-10, paras 2.13 – 2.20 of the Monitoring Guidance).

Effective monitoring will help the public authority identify any future adverse impact arising from the policy which may lead the public authority to conduct an equality impact assessment, as well as help with future planning and policy development.

Part 5. Disability Duties

Under the Disability Discrimination Act 1995 (as amended by the Disability Discrimination (Northern Ireland) Order 2006), public authorities, when exercising their functions, are required to have due regard to the need:

- **to promote positive attitudes towards disabled people; and**

- **to encourage participation by disabled people in public life.**

5. Does this policy/legislation have any potential to contribute towards promoting positive attitudes towards disabled people or towards encouraging participation by disabled people in public life? If yes, please give brief details.

ANNEX 6

Name of Consultees

Action on Hearing Loss
Age NI
Age Sector Platform
Agency for the Legal Deposit Libraries
Agri-Food and Biosciences Institute
Airtricity
Alliance Party
Allpipe Engineering Ltd.
Almac Group Ltd
Amalgamated Engineering and Electrical Union
AMEY BPO
An Munia Tober
Archbishop of Armagh and Primate of all Ireland
Ards Business Centre Ltd.
Argyle Business Centre Ltd.
Armagh Business Centre Ltd.
Aspergers Network
Association of British Insurers
Association of Consulting Engineers (NI Branch)
Association of Independent Advice Centres
Association of Local Authorities of Northern Ireland
Association of Teachers and Lecturers
Association of University Teachers
Atlas Environmental NI
Attorney General (NI)
Autism Northern Ireland
Bakers, Food and Allied Workers Union
Ballymena Business Centre Ltd.
Banbridge Enterprise Centre
Bar Council
Barnardos
Belfast Centre for the Unemployed
Belfast City Centre Management
Belfast Education and Library Board
Belfast Harbour Commissioners
Belfast Health and Social Care Trust
Belfast Hebrew Congregation
Belfast Islamic Centre
Belfast Marine Engineering Employers' Association
Belfast Solicitors Association
Bishop of Down and Connor
Board of Deputies of British Jews
Borough Councils
British Chemical Distributors and Traders Association
British Clothing Industry Association (NI)
British Library – Legal Deposit Office

British Medical Association
British Oxygen Company
Bryson House
Budget Energy Ltd.
Buildhealth NI
Business in the Community
Calor Gas (NI) Ltd.
Cancer Focus Northern Ireland
Cara-Friend
Carers NI
Carrickfergus Enterprise Agency Ltd.
Catholic Bishops of Northern Ireland
Causeway Enterprise Agency Ltd.
Cedar Foundation
Central Services Agency
Chadwyck-Healey Ltd.
Chartered Institute of Environmental Health, NI
Chartered Institute of Marketing
Chemical Business Association
Chief Constable Police Service of Northern Ireland
Child Care Northern Ireland
Children in Northern Ireland
Children’s Law Centre
Chinese Chamber of Commerce
Chinese Welfare Association
Cinematograph Exhibitors' Association
City Councils
Civil Law Reform Division
Civil Service Occupational Health Service
Colloide Engineering Systems
Commission for Victims and Survivors
Commissioner for Children and Young People for NI
Commissioner for Older People for Northern Ireland
Committee on the Administration of Justice
Communication Access
Communication Workers' Union (CWU)
Community Foundation for Northern Ireland
Community Relations Council
Community Relations Training Learning Consortium
Community Union
Confederation of British Industry
CONNECT
Construction Employers' Federation
Construction Industry Training Board
Cookstown Enterprise Centre Ltd.
Coolkeeragh Power Ltd.
Co-Operation Ireland
Council for Catholic Maintained Schools
Countryside Services Ltd.
Courts and Tribunal Service

Craigavon Industrial Development Organisation Ltd.
Creggan Enterprises Ltd.
Deaf Association Northern Ireland
Democratic Unionist Party
Derry Well Woman
Desmond and Sons Ltd.
Disability Action
District Councils
Down's Syndrome Association
Driver and Vehicle Testing Agency
Driver Training Services
Du Pont (UK) Ltd.
Dungannon Enterprise Centre Ltd.
East Belfast Community Development Agency
East Belfast Enterprise Park Ltd.
East Belfast Partnership Board
Eastern Group Environmental Health Committee
Employers For Disability NI
Electric Ireland
Energia
Engineering Employers' Federation NI (EEF)
Engineering Training Council
Engineers' and Managers' Association (EMA)
Equality Coalition
Equality Commission
Equipment Hire Association of Northern Ireland Ltd
Equity
Executive Council of the Inn of Court of NI
Falls Community Council
Federation of Small Businesses
Federation of Petroleum Suppliers
Federation of the Retail Licensed Trade (NI)
Fermanagh Enterprise Ltd.
Fire Brigades Union
Firmus Energy
Food Standards Agency Northern Ireland
Forensic Science Agency of Northern Ireland
Fortress Pro-Tec Ltd
Foyle Meats
Foyle Women's Information Network
Fusion Antibodies
FPA NI (formerly Family Planning Association)
Freight Transport Association
General Consumer Council for Northern Ireland
Gingerbread Northern Ireland
Glass and Glazing Federation
GMB
Graphical Paper and Media Union
Gray & Adams (Ireland) Ltd
Greater Shankill Partnership

Green Party
Guide Dogs for the Blind Association
Harland and Wolff Heavy Industries Ltd.
Health and Safety Executive
Health and Social Care Board
Heating and Ventilating Contractors' Association
Heron Brothers Ltd.
HM Council of County Court Judges
HM Revenue and Customers
Home Retail Group
Inclusive Mobility and Transport Advisory Committee (IMTAC)
INCORE Conflict Resolutions Ltd.
Indian Community Centre
Independent Political Parties
Information Commissioner's Office
Institute of Acoustics
Institute of Directors
Institute of Directors (NI Division)
Institute of Professionals, Managers and Specialists (IPMS)
Institute of Quarrying
Invest NI
Irish Bank Officials Association
Irish National Teachers Organisation
James G McAlorum Ltd.
John Mackle (Moy) Ltd.
Joint Industry Board for the Electrical Engineering Industry
Judge McKibbin
Justice for Asbestos Victims
Kesh Development Association Charitable Trust
Labour Party
Labour Relations Agency
Lagan Group
Larne Development Forum
Law Centre (NI)
Law Society of Northern Ireland
Lilliput Services
Local Government Staff Commission for NI (LGSC)
Lord Chief Justice Office
Magherafelt Women's Group
Mallusk Enterprise Park
Maritime and Coastguard Agency
Mastic Asphalt Federation (NI)
McClay Library, QUB
Mr B McClintock
McGrigors, Solicitors
MENCAP
Methodist Church in Ireland
Mindwise
Ministry of Defence
MPs & MEPs (NI)

Mr George Condell
Mr Richard Steele
Musicians Union
National Association of Schoolmasters/Union of Women Teachers
National Association of Teachers in Further and Higher Education
National Collection of NI Publications
National Library of Ireland
National Union of Rail, Maritime and Transport Workers
Newry and Mourne Enterprise Agency
Newry and Mourne Senior Citizen's Consortium
Newry and Mourne Women
Newtownabbey Senior Citizen's Forum
NI21
NI-CO (Northern Ireland Public Sector Enterprises Ltd)
NIGEN
North Belfast Partnership
North City Business Centre Ltd.
North Down Development Organisation Ltd.
North Eastern Education and Library Board
North / South Ministerial Council
North West Community Network
North West Forum of People with Disabilities
North West Industrial Health and Safety Group
Northern Group
Northern Group Systems
Northern Health and Social Care Trust
Northern Ireland African Cultural Centre
Northern Ireland Agricultural Producers' Association
Northern Ireland Assembly Library
Northern Ireland Assembly Members
Northern Ireland Assembly – The Speaker
Northern Ireland Association for Mental Health
Northern Ireland Association for the Care and Resettlement of Offenders
Northern Ireland Audit Office
Northern Ireland Authority for Utility Regulation
Northern Ireland Association of Citizens Advice Bureaux
Northern Ireland Bakery Council
Northern Ireland Bankers' Association
Northern Ireland Centre for Competitiveness
Northern Ireland Chamber of Commerce
Northern Ireland Chamber of Trade
Northern Ireland Committee/Irish Congress of Trade Unions
Northern Ireland Commissioner for Children and Young People
Northern Ireland Conservative Association
Northern Ireland Council for Ethnic Minorities
Northern Ireland Council for Integrated Education
Northern Ireland Council for the Curriculum, Examinations and Assessment
Northern Ireland Council for Voluntary Action
Northern Ireland Court Service
Northern Ireland Dairy Association

Northern Ireland Economic Research Centre
Northern Ireland Environment Link
Northern Ireland Fire and Rescue Service
Northern Ireland Gay Rights Association
Northern Ireland Hotels Federation
Northern Ireland Housing Executive
Northern Ireland Human Rights Commission
Northern Ireland Judicial Appointments Commission
Northern Ireland Law Commission
Northern Ireland Local Government Association
Northern Ireland Master Plumbers' Association
Northern Ireland Occupational Health and Safety Group
Northern Ireland Oil Federation
Northern Ireland Polymers Association
Northern Ireland Prison Service
Northern Ireland Public Service Alliance (NIPSA)
Northern Ireland Quarry Owners' Association
Northern Ireland Railways
Northern Ireland Resident Magistrates' Association
Northern Ireland Safety Group
Northern Ireland Spinners Ltd.
Northern Ireland Statistics and Research Agency (NISRA)
Northern Ireland Textiles and Apparel Association Ltd
Northern Ireland Timber Trades' Association
Northern Ireland Tourist Board
Northern Ireland Women's European Platform
NSPCC, Northern Ireland Regional Office
NUS/USI
NW Community Network
Occupational Health Service
Office of Industrial Tribunals
Omagh Enterprise Co. Ltd.
Omagh Women’s Area Network
Ormeau Enterprises Ltd.
Participation the Practice of Rights Project
Pass International
PDA Consultant Engineers
Peter Scott Health and Safety
Pharmaceutical Society of Northern Ireland
Phoenix Natural Gas
POBAL
Police Federation for Northern Ireland
Police Service of Northern Ireland
Power NI (formerly NIE)
Premier Power Limited
Presbyterian Church in Ireland
PricewaterhouseCoopers
Prince's Trust
Progressive Unionist Party
Public Commerce Services Union (PCS)

Quarry Products Association NI
Queen's University
Questor Centre
Richards PLC
Roads Service
Roman Catholic Church
Roy Coulter Consulting Ltd.
Royal College of Midwives
Royal College of Nursing of the UK (NI Board)
Royal Institution of Chartered Surveyors in Northern Ireland
Royal National Institute for the Blind (NI)
Rural Community Network
Rural Development Council
Safety Advice Centre
Save the Children
SDLP
Seagate Technology (Ireland)
Senior Citizens Consortium Sperrin Lakeland
Sense NI
Services Industrial Professional Technical Union (SIPTU)
Shorts Bombardier PLC
Sinn Fein
Skyglaze Architectural Systems Ltd.
Social Security Agency
Society of Local Authority Chief Executives
Society of Occupational Medicine
South Belfast Partnership Board
South Eastern Education and Library Board
South Eastern Health and Social Care Trust
South West Fermanagh Development Organisation Ltd.
Southern Education and Library Board
Southern Group Environmental Health Committee
Southern Health and Social Care Trust
Spence Bryson Limited
SRT Donnelly and Co.
St John Ambulance NI
Strabane Industrial Properties Ltd.
Staff Commission for Education and Library Boards
Sypol Ltd.
Tennants Textile Colours Ltd.
Tesco Stores Ltd.
Thermomax Ltd.
Townsend Enterprise Park Ltd.
Traditional Unionist Voice
Trainfield Construction Ltd.
Training for Women Network Ltd.
Translink
Transport Salaried Staff Association
Transport Training Services Ltd.
Transtec Automotive (Campsie) Ltd.

UK Independence Party
UK National Committee of UN Women
Ulster Farmers' Union
Ulster Furniture Federation
Ulster Scots Community Network
Ulster Teachers' Union
Ulster Unionist Party
Union of Construction, Allied Trades and Technicians (UCATT)
Union of Shop, Distributive and Allied Workers (USDAW)
UNISON (Northern Ireland)
Unite the Union
University of Ulster at Coleraine
Volunteer Centre
Volunteer Now
Visual Access NI (Braille, Audio and DAISY)
Water Service
West Belfast Development Trust Ltd.
West Belfast Partnership Board
Western Education and Library Board
Western Group Environmental Service
Western Health and Social Care Trust
Westlink Enterprise Ltd.
William Keown Trust
Women's Forum NI
Women's Information NI
Women's Resource and Development Agency
Women's Support Network
Women’s Training, Enterprise and Childcare
Workers' Party
Workspace
Youth Action Northern Ireland Gender Equality Unit