EXPLANATORY MEMORANDUM TO

The Genetically Modified Organisms (Contained Use) (Amendment) Regulations (Northern Ireland) 2010

S.R. 2010 No. 343

1. Introduction

1.1. This Explanatory Memorandum has been prepared by the Department of Enterprise, Trade and Investment to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2. The Statutory Rule is made under section 2(2) of the European Communities Act 1972 and by Articles 2(5), 17(1) to (5), 40(2) and (4) and 55(2) of, and paragraphs 1(1), (2), (3), (4) and (5), 3(1), 4, 5(1), 7(2), 8, 10, 12(1) and (3), 13, 14(1), 15 and 19 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978 and is subject to the negative resolution procedure.

2. Purpose

2.1. The Genetically Modified Organisms (Contained Use) (Amendment) Regulations (Northern Ireland) 2010 ('the 2010 Regulations') make minor changes to the existing Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001 (S.R. 2001 No.295) ("the 2001 Regulations") in order to make explicit certain requirements set out in European Directive 2009/41/EC which covers the contained use of genetically modified organisms (GMOs).

3. Legislative Background

3.1. The 2001 Regulations implement the requirements of European Directive 90/219/EC on the contained use of genetically modified micro-organisms (GMMs). The requirements are now contained in Directive 2009/41/EC, which superseded the 1990 Directive.

3.2. The European Commission is of the view that the UK has not implemented three aspects of the Directive. The UK has given the Commission an assurance that the minor changes to national legislation, needed to make these aspects of the Directive clear, would be made by October 2010. The 2010 Regulations make those changes in Northern Ireland. The amendments are minor and do the minimum necessary to implement the requirements of the Directive.

3.3. The Directive applies to activities involving GMMs such as bacteria and viruses. This instrument relates only to the contained use of such organisms, as defined in the 2001 Regulations (such as work in laboratories) and not, for example, to releases of GMOs into the environment or to the use of genetically modified products in food.

4. Policy Background

What is being done and why

4.1. Genetic modification in relation to an organism means altering the genetic material (either deoxyribonucleic acid (DNA) or ribonucleic acid (RNA)) in that organism in a way that does not occur naturally by mating and/or recombination. Typically, this involves the removal of DNA, its manipulation outside the cell and reinsertion into the same or another organism.

4.2. Contained use activities (for the purposes of the 2001 Regulations) cover any activity involving GMOs (which includes genetically modified micro-organisms (GMMs)) under the containment conditions laid down by the Regulations. This means that barriers are required to be in place to limit contact between GMMs and humans and the environment. These barriers can be provided by physical, biological or chemical means, or a combination of these. The intention is to provide a high level of safety for humans and the environment. 'Contained use' includes the destruction and disposal of GMMs.

4.3. The Directive sets out the way in which GMMs are to be risk assessed and classified, and specifies waste management and containment requirements. The Directive sets out activity classifications levels for this work as follows:

- 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.

4.4. The key requirement of the 2001Regulations is for any person working with GMOs to assess the risks of all activities and to make sure that any necessary controls are put in place. The Regulations provide a framework for making these judgments, and place clear legal obligations on people who work with GMOs. They:

- Require risk assessment of activities involving GMMs and activities involving organisms other than micro-organisms.
- Introduce a classification system based on the risk of the activity independent of the purpose of the activity. The classification is based on the four levels of containment shown above.
- Require notification of all premises to the Health and Safety Executive for Northern Ireland (HSENI) before they are used for genetic modification activities for the first time.
- Require notification of individual activities of Class 2 (low risk) to Class 4 (high risk) to be notified to the Competent Authority (which HSENI administers). Consents are issued for all Class 3 (medium risk) and Class 4

(high risk) activities. Class 1 (no or negligible risk) activities are non-notifiable, although they are open to scrutiny by HSENI's specialist inspectors who enforce the Regulations.

- Require the maintenance of a public register of genetic modification premises and certain activities.

4.5. The 2010 Regulations amend these requirements as follows:

4.5.1. Article 4(5) of the Directive requires risk assessments to take account especially of the disposal of waste and effluents and, where appropriate, to implement the safety measures needed to protect human health and the environment.

4.5.2. Regulation 6(1) of the 2001 Regulations already states that "no person shall undertake any activity involving genetic modification of micro-organisms unless… he has ensured that a suitable and sufficient assessment of the risks to human health and the environment has been carried out." Part 1 of Schedule 3 to the 2001 Regulations sets out matters to be taken into account when carrying out a risk assessment.

4.5.3. The 2010 Regulations therefore amend paragraph 1 of Schedule 3, Part 1 to add the disposal of waste and effluents to the list of specific matters that must be taken into account when carrying out a risk assessment.

<u>Characteristics of GMMs appropriate to include as Class 1 micro-organisms</u>

4.5.4. Annex III, Part B.4 of the Directive sets out the characteristics that would generally be expected of GMMs for any activity involving them to be appropriate to include in Class 1 (activities of no or negligible risk). Part II of Schedule 3 to the 2001 Regulations sets out the steps to be included when carrying out an assessment. The 2010 Regulations amend paragraph 3 of Schedule 3 so as to include the characteristics set out in the Directive. Guidance on these requirements is provided in the UK in technical guidance in the Compendium of Guidance produced by the Scientific Advisory Committee on Genetic Modification.

<u>Requirement to place biohazard signs on doors</u>

4.5.5. The Directive sets out the containment and other protective measures that should be in place to prevent exposure to GMMs as a result of laboratory activities. These include the placing of biohazard signs on doors where containment level 2, 3 and 4 activities are being undertaken. The 2010 Regulations contain an explicit requirement on duty holders to display a biohazard sign on doors where the work involves GMMs of containment levels 2, 3 and 4.

5. Consultation

5.1. A full consultation exercise was carried out on the proposed Genetically Modified Organisms (Contained Use) (Amendment) Regulations (Northern Ireland) 2010 which ran from 30 April 2010 until 23 July 2010. There were approximately 600 consultees, including individuals and

bodies representative of section 75 of the Northern Ireland Act 1998 and other organisations with an interest in equality and related issues (including each member of the Northern Ireland Assembly). In total there were six responses, with no adverse comments in relation to the proposed 2010 Regulations.

6. Equality Impact

6.1. The Statutory Rule has 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.

7. Regulatory Impact

7.1. Since the measures provided for in the Regulations were already largely incorporated into existing guidance, any additional costs to duty holders are likely to arise from the provision of additional biohazard signage, together with some minor familiarisation costs; in total estimated to range between £1,364 and £4,513 for the 8 GMO centres located in NI.

8. Financial Implications

8.1. An impact assessment prepared for the GB Regulations estimated that the costs associated with the provision of additional biohazard signage at the 570 GMO centres in GB, together with the costs of familiarisation with the amendments to the Regulations, should range between £90,000 and £320,000. There are 8 GMO centres in NI. Based on the GB estimate the costs associated with implementing the Regulations should range between £1,364 and £4,513.

8.2. Implementation of the measures will avoid any costs associated with further infraction proceedings by the European Commission.

9. Section 24 of the Northern Ireland Act 1998

9.1. The Department has considered the matter of Convention rights and is satisfied that there are no matters of concern.

10. EU Implications

10.1. Directive 98/81/EC was adopted on 26 October 1998. Member States had to implement its provisions by Year 2000. The Directive amended 90/219/EEC on the Contained Use of Genetically Modified Micro-organisms. In 2009 the European legislation on contained use was recast in the interests of clarity, due to the various enactments that had been made. Directive 2009/41/EC, repealing Directive 90/219/EEC, was published on 21 May 2009. The Directive was implemented in Northern Ireland by the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001.

10.2. The 2010 Regulations are essential to correct deficiencies in the 2001 Regulations and to give full implementation to the Directive. Failure to do so would result in the risk of proceedings in the European Courts and potentially heavy fines for the UK.

10.3. As the Regulations are limited to correction of deficiencies in the 2001 Regulations to give full implementation to the Directive a Transposition

Note is not required. Instead, once the required measures are in place, HSE (GB) will issue a letter to the Commission explaining what has been done in GB, NI and Gibraltar to address the under-implementation issues.

11. Parity or Replicatory Measure

11.1. In Great Britain the corresponding Statutory Instrument will be the proposed Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010. The Statutory Instrument has not yet been made.

12. Additional Information

12.1. Not applicable.

Department of Enterprise, Trade and Investment

6 October 2010

ANNEX

PART I

GREAT BRITAIN IMPACT ASSESSMENT

(Prepared by the Health and Safety Executive)

The draft Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010

("the draft GB Regulations")

1. The following pages contain a copy of the Impact Assessment, prepared by the Great Britain Health and Safety Executive, in respect of the draft GB Regulations.

2. The overall assessment shows that the impact on business associated with the provision of additional biohazard signage at 570 GMO centres in GB, together with the costs of familiarisation with the amendments to the Regulations, should range between £90,000 and £320,000.

3. There is no impact on charities, social enterprise or voluntary bodies.

Title:	Impact Assessment (IA)
The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010	**IA No:**
Lead department or agency: Health and Safety Executive	**Date:** 10/06/2010
Other departments or agencies: DEFRA, Scottish Executive	**Stage:** Final
	Source intervention: EU
	Type of measure: Secondary Legislation
	Contact for enquiries: Craig Bell Tel: 0151 951 3325 Email craig.bell@hse.gsi.gov.uk

Summary: Intervention and Options

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

Changes to the Genetically Modified Organisms (Contained Use) Regulations 2000, as amended are required in order to fully implement the requirements of Directive 98/81/EC (now 2009/41/EC) on the contained use of genetically modified micro-organisms. The European Commission has notified the United Kingdom that it considers that three specific aspects of the Directive have not been fully transposed into national law. It has been agreed with the Commission that the relevant legislation in Great Britain will be amended by October 2010.

What are the policy objectives and the intended effects?

Amend the existing regulations to implement the following aspects of the Directive:

- Article 4(5). which requires risk assessment to take account of disposal of waste and effluents and, where appropriate, to implement necessary safety measures.
- Annex III, Part B.4, which sets out necessary characteristics of the GMM to be included in Class 1 (negligible or no risk).
- Annex IV, Table 1A, Provision 10, which sets out biohazard notification requirements (display of biohazard signs on doors.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

It has been accepted that the UK will amend the legislation in Great Britain, Northern Ireland and Gibraltar to fully transpose the Directive. It was intended that the required changes would be brought about in GB through the introduction of the proposed Single Regulatory Framework for human and animal pathogens. However that proposal is under review and will not now be implemented on its original intended date of 1 October 2010. As a result, it is necessary to amend the Genetically Modified Organisms (Contained Use) Regulations 2000. In order to satisfy the European Commission that the Directive has been fully implemented there are no alternatives to amending the legislation.

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	It will not be reviewed.
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Not applicable

Summary: Analysis and Evidence Policy Option 1

Description: Do nothing

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value		
2010	2010	10	**Low: Nil**	**High: Nil**	**Best Estimate: Nil**

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

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

Option 1 is the baseline case and so does not have any costs associated with it. There will be a cost of infraction proceedings, and avoiding these costs is considered to be a benefit of Option 2.

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

Not applicable

BENEFITS (£m)	**Total Transition** (Constant Price)Years		**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low		1	Nil	**Nil**
High	Nil		Nil	**Nil**
Best Estimate	Nil		Nil	**Nil**

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

Not applicable

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

Not applicable

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

Not applicable

Impact on admin burden (AB) (£m):			**Impact on policy cost savings**	**In scope**
New AB: Nil	**AB savings:** Nil	**Net:**	**Policy cost savings:**	No

Summary: Analysis and Evidence Policy Option 2

Description: To amend the Regulations in Great Britain, Northern Ireland and Gibraltar to fully implement the requirements of Directive 98/81/EC on the Contained Use of Genetically Modified Micro-organisms.

Price Base Year 2010	PV Base Year 2010	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -0.09	High: 0.03	Best Estimate: -0.2

COSTS (£m)	Total Transition (Constant Price)Years		Average Annual (excl. Transition) (Constant	Total Cost (Present Value)
Low	0.09	1	N/A	**0.09**
High	0.3		N/A	**0.3**
Best Estimate	0.2		N/A	**0.2**

Description and scale of key monetised costs by 'main affected groups' The estimated costs to industry relate to the amendments resulting from Annex IV, Table 1A, Provision 10, which requires biohazard signs to be specifically displayed on doors as opposed to the current 'where appropriate' requirement, of between £40,000 and £220,000. The amendments resulting from Article 5(5) and Annex III, Part B.4 are not anticipated to require industry to do anything additional in practice. There are also one off familiarisation costs for duty holders to understand the amendments to the Regulations estimated to be between £50,000 and £100,000.

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

Not applicable

BENEFITS (£m)	Total Transition (Constant Price)Years		Average Annual (excl. Transition) (Constant	Total Benefit (Present Value)
Low		1		
High				
Best Estimate	Not quantified		Not quantified	**Not Quantified**

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

Not applicable

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

The amendments to the regulations will enable GB to respond to the requirements of the Directive and thus avoid exposing GB to further infraction proceedings. It is possible that any additional signs that are displayed as a result of the requirements of Annex IV, Table 1a, Provision 10 might result in a small improvement in health and safety outcomes, but there is no reasonable basis on which to quantify this effect.

Key assumptions/sensitivities/risks **Discount** 3.5%

There are 570 notified genetic modification centres. There are approximately 4,000 laboratories using GMMs

Dutyholders will already be including waste disposal as part of their assessments.

The number of additional signs required per lab might range between 1 and 3, at a financial cost of between £4 and £15 each depending on size/material chosen.

The time taken to order and display the additional signs might range between 30 and 40 minutes

There will be between 1 and 2 people per laboratory required to familiarise themselves with the amendments and this will take around 30 minutes per duty holder.

Impact on admin burden (AB) (£m):	Impact on policy cost	In scope

New AB: Nil	**AB savings:** Nil	**Net:** Nil	**Policy cost savings: Nil**	No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			Great Britain		
From what date will the policy be implemented?			01/10/2010		
Which organisation(s) will enforce the policy?			Health and Safety Executive		
What is the total annual cost (£m) of enforcement for			Nil		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU			No		
What is the CO_2 equivalent change in greenhouse gas emissions?			**Traded:** Nil	**Non-traded:**	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** Nil	**Benefits:** Nil	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro** Nil	**< 20** Nil	**Small** Nil	**Mediu m**	**Lar ge**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Does your policy option/proposal have an impact on…	**Impact**	**Page ref within IA**
Statutory equality duties[1]? Equality and Human Rights Commission: General guidance	No	13
Economic impacts		
Competition? Competition Impact Assessment	No	14
Small firms? Small Firms Impact Test	No	14
Environmental impacts		
Greenhouse gas assessment?	No	14
Wider environmental issues?	Yes	14
Social impacts		
Health and well-being? Health: Health Impact Assessment	Yes	14
Human rights? Ministry of Justice: Human Rights	No	14
Justice?	No	14
Rural proofing? Commission for Rural Communities	No	15
Sustainability? Defra: Think sustainable	No	15

[1] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

References

No.	Legislation or publication
1	The Genetically Modified Organisms (Contained Use) Regulations 2000 (as amended) S.I 2000/2831
2	Consultative Document – Proposals for the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010
3	A guide to the Genetically Modified Organisms (Contained Use) Regulations 2000 (L29, HSE Books)
4	Scientific Advisory Committee on Genetic Modification (SAGCM) Compendium of Guidance

Evidence Base

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs	0.2	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Annual recurring	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Total annual costs	0.2	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Transition benefits	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Annual recurring	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Total annual	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil

* For non-monetised benefits please see summary pages and main evidence base section

Evidence Base

Issue and rationale for intervention

The amendment is required in order to fully transpose Directive 2009/41/EC (the Directive) on the Contained Use of Genetically Modified Micro-organisms (GMMs). Failure to incorporate into national law the three aspects identified by the European Commission would leave the UK open to court proceedings and consequent financial penalties for failure to fully implement the Directive. The Commission's opinion concerned the transposition of Directive 98/81/EC. This Directive and other European provisions amending Directive 90/219/EEC on GMMs have since been replaced by the consolidating Directive 2009/41/EC. The 2009 Directive now contains the provisions to which the Commission's opinion relates

Objective

The policy objective is to amend the Genetically Modified Organisms (Contained Use) Regulations 2000 in order to fully implement the following aspects of the Directive:

- **Article 4(5)** - which requires risk assessments especially to take account of the disposal of waste and effluents, and, where appropriate, to implement necessary safety measures.

- **Annex III, Part B.4** - which sets out the characteristics generally required of a GMM for it to be appropriately included in class 1 (negligible risk).

- **Annex IV, Table 1A, Column 10** - which sets out the requirement that for laboratory activities a biohazard sign be placed on the door.

Background

Directive 90/219/EEC required Member States to regulate the contained use of genetically modified micro-organisms in order to minimise their potential negative effects on human health and the environment. Directive 98/81/EC (the Directive) changed the way that GMMs were risk assessed and classified, as well as laying out specific waste management and containment requirements. The Directive was implemented in GB by the Genetically Modified Organisms (Contained Use) Regulations 2000. Regulations were supported in GB by a guide to the Regulations, as well as extensive guidance from the Scientific Advisory Committee on Genetic Modification.

The European Commission has notified the United Kingdom that it considers that three specific aspects of the 1998 Directive have not been fully transposed into domestic law. An assurance was given to the Commission that these issues would be addressed by October 2010.

In order to avoid further action by the European Commission it is now necessary to amend the existing Genetically Modified Organisms (Contained Use) Regulations 2000 to bring about the changes required to fully implement the Directive. These being:

- A requirement to take into account the question of the disposal of waste and effluents when carrying out a risk assessment (Article 4(5) of the Directive refers). It is proposed to amend Schedule 3 Part 1 to the 2000 Regulations so as to include this requirement. Existing guidance (e.g. the Scientific Advisory Committee on Genetic Modification (SACGM) Compendium of Guidance) already explicitly states that waste management should be considered as part of a risk assessment.

- Specification of the characteristics of a GMM which would be considered appropriate for inclusion in class 1 (no or negligible risk) (Annex III, Part B.4 of the Directive refers). It is proposed to amend Schedule 3 Part 2, paragraph 3 of the 2000 Regulations to set out the relevant characteristics.

- A requirement in respect of the display of a biohazard sign on doors (Annex IV, Table 1A, Provision 10 of the Directive refers). Dutyholders already have an obligation to post biohazard signs “where appropriate” but it is proposed to amend Table 1A in Schedule 8 to the 2000 Regulations in order to set out the relevant requirements.

The amendments are minor. Consideration is currently being given to how best to implement the recommendations of the Callaghan Review into the regulation of work involving human and animal pathogens, including GMOs. This could provide an opportunity to replace or consolidate this instrument and the 2000 Regulations at a later date.

Northern Ireland and Gibraltar are making their own legislative changes in order to ensure that all of the UK complies with the Directive.

Options

Option 1: Do nothing

To do nothing would leave the UK open to further action for failure to implement the EC Directive.

Option 2: Introduce amending Regulations to address the deficiencies in respect of Article 4 (5), Annex III, Part B.4 and Annex IV, Table 1A, Provision 10 of the Directive.

This option would address the concerns of the European Commission and thus avoid further infraction proceedings.

Benefits

Option1: do nothing. - There are no perceived benefits associated with this option.

Option 2: introduce amending Regulations - The amendment will enable us to comply with the requirements of the Directive and thus avoid exposing the UK to further infraction proceedings.

It is possible that there might be some health and safety benefit from specifying the bio hazard signs must be included on doors, but given the current requirements to use such signs 'as appropriate' this effect is not expected to be significant.

Costs

Option 1: do nothing – There are no costs to business associated with this option.

Option 2: introduce amending Regulations – HSE understands that there are 570 notified GM centres in England, Scotland and Wales. For the purposes of this assessment it is estimated that there are 4,000 laboratories. However, it is difficult to estimate the number of laboratories undertaking Class 1 activities (those involving no or negligible risk) so this figure may be higher. The cost impact on these GM centres will be as follows:

- **Article 4(5)** - which requires risk assessments especially to take account of the disposal of waste and effluents, and, where appropriate, to implement necessary safety measures.

Existing guidance (e.g. the Scientific Advisory Committee on Genetic Modification Compendium of Guidance) already explicitly states that waste management should be considered as part of a risk assessment. The form (CU2) used for "Notification of intention to conduct individual contained use activities" also asks for a description of the waste management measures.

Thus, in practice the HSE would expect that all GM risk assessments (estimated to be up to 27,000 in GB) will already take account of the disposal of waste and effluents and so the additional costs to industry as a result of this amendment will be negligible.

Consultation with stakeholders confirmed the assumption that there will not be any costs associated with this amendment. One consultee raised the concern that this

amendment may lead to an unspoken expectation of a disproportionate response to waste handling. HSE intends to make it expressly clear in guidance on its website that the steps taken by duty holders in relation to waste management should be proportional.

- **Annex III, Part B.4** - which sets out the characteristics generally required of a GMM for it to be appropriately included in class 1 (negligible risk).

The classification is based on the full risk assessment procedure outlined in Annex III of the Directive. The requirement is supported at a national level in the UK with HSE guidance (L29) and also in technical guidance in the Scientific Advisory Committee on Genetic Modification Compendium of Guidance which accompanies the Regulations.

In practice therefore, it is not anticipated that duty holders will have to amend their classification of GMMs as a result of the proposed amendment. The amendment is required in order to ensure consistency between the EC Directive and the GB Regulations. Respondents to the Consultation agreed that there is unlikely to be an impact on the industry as a result of this change.

- **Annex IV, Table 1A, Provision 10** - which sets out the requirement that for laboratory activities a biohazard sign be placed on doors.

The amendment is anticipated to result in certain laboratories needing to increase the number of signs that are displayed to ensure that they are present on doors compared to the current requirement of where is deemed to be appropriate.

For those laboratories that need to put up additional signs, there will be financial costs in terms of purchasing the signs and also an opportunity cost in terms of the time taken to arrange for this to be done.

For the purposes of this assessment it has been assumed that each of the 4,000 laboratories will be required to purchase between 1 and 3 new signs (in practice however many laboratories will already have biohazard signs on doors). This range should allow for small sites who don't have to purchase any additional signs, and those which are much larger and have several doors on which a sign has to be displayed.

Financial Cost: The cost of a biohazard sign depends on the style chosen. From a review of current prices on the internet, prices range from between £4 to £15 depending on how big the sign is and the material it is made from.

Assuming 4,000 laboratories purchase between 1 and 3 signs at this range of prices, the total one off cost to industry ranges between £16,000 and £180,000.

Opportunity Cost: It is assumed that there is very little difference between the time it takes to order 1 sign and the time it takes to order 3 signs. It is estimated that for a laboratory that orders just 1 sign the total time taken to order the sign, take delivery and display it might be 30 minutes. For a laboratory requiring up to 3 signs, there may be a small amount of additional time required for displaying the extra signs, and so the total time is assumed to take 40 minutes.

It is also assumed that the employee undertaking this task is likely to be a laboratory technician on a gross hourly wage rate of £12 (according to the Annual Survey of Hours and Earnings 2009). The true economic cost of employing the technician is assumed to be 30% greater i.e. £15.60, to reflect the overheads associated with employing a person.

Based on these assumptions, the opportunity cost to industry of the time required to order and display the additional signs is estimated to be a one off cost of between £24,000 and £40,000.

The total one off cost to industry as a result of amending Annex IV, Table 1a, Column 10 is estimated to be between £40,000 and £220,000.

Respondents to the Consultation did not raise any concerns with the total estimated cost of this amendment.

- **Familiarisation** – it is expected that there will be between 1 and 2 people per laboratory who are required to familiarise themselves with the amendments to the GMO Contained use Regulations. Given that these changes are not thought to be complex or require significant changes to what happens in practice, it is estimated that this will not take more than 30 minutes per person. It is assumed that the true economic cost of employing each duty holder is £25.16[2] per hour, and so the total one off cost to industry of familiarisation is estimated to be between £50,000 and £100,000.

Respondents to the consultation did not raise any concerns with the assumptions used in this estimated cost.

HSE is the enforcing authority for the Genetically Modified Organisms (Contained Use) Regulations 2000. In view of the modest scope of the proposed measures, it is not envisaged that any additional burdens will be placed on the enforcing authority as a consequence of these amendments.

Summary of costs and benefits

Since the proposed measures are already largely reflected in existing guidance, additional costs to the industry are only expected to arise from the provision of additional bio-hazard signage and familiarisation, estimated to be between £90,000 and £320,000. The views of duty holders and others from Consultation are that these costs are reasonable.

The amendments will enable GB to comply with the requirements of the Directive and so avoiding further infraction proceedings. It is not possible to quantify the health and safety benefit from specifying that bio hazard signs must be displayed on doors, but given the current requirement to use such signs 'as appropriate' this is not expected to be significant.

Risks and assumptions

The main assumptions used in this impact assessment are detailed in the summary boxes on page 8. Consultation with duty holders and others has confirmed that these assumptions are reasonable.

[2] According to the Annual Survey of Hours and Earnings 2009, the average gross hourly wage rate of a Biological Scientist is £19.35. This is inflated by 30% to reflect the true economic cost of employment, i.e. the overheads and tax and NI contributions.

Admin burdens and policy costs savings

It has been calculated that the increase in policy costs on industry will be between £40,000 and £220,000, being the one off costs of purchasing and displaying the additional bio hazard posters. It is not expected that there will be additional administrative burdens on industry.

Wider Impacts

Statutory Equality Duties:

No impact expected.

Competition:

The Office for Fair Trading's advice on competition provides four filter questions:

Does the policy:

- Directly limit the number or range of suppliers – No. All laboratories / GM sites will be subject to the same requirements in the UK and also in the EU. The total cost of the amendments is not expected to be more than £60 per laboratory and so will not limit the number / range of suppliers.
- Indirectly limit the number of range of suppliers – No, it is not expected that the number of suppliers will be indirectly limited.
- Limit the ability of suppliers to compete –No, it is not expected that the channels available to suppliers will be reduced or reduce the geographic area in which they can operate.
- Reduce suppliers' incentives to compete rigorously – No, it is not expected that it will encourage or enable the exchange of information on prices, costs, sales, or outputs between suppliers.

Impact on Small Businesses, Charities and Voluntary Organisations

As above, the total cost per laboratory of amending the Genetically Modified Organisms (Contained Use) Regulations is not significant. Additionally, the total cost is proportional to the number of additional signs required per laboratory, with small firms likely to require fewer additional signs.

Environmental impacts

Greenhouse gas assessment: The proposed amendments to the Genetically Modified Organisms (Contained Use) Regulations are not anticipated to have any effect on greenhouse gas emissions.

Wider environmental issues: It is not anticipated that the amendments will have a significant impact on environmental outcomes. The requirement to have signs on all doors might have the effect of increasing awareness of hazards and reduce the risk of a loss in containment, but this effect is expected to be small and is not possible to quantify.

Social impacts

Health and Wellbeing: As above, the amendments are not expected to have a significant impact on health and well being, but the amendments to the signage requirement could in some way reduce the risk of a loss of containment and therefore reduce the risk of ill health.

Human Rights: No impact expected

Justice: No impact expected

Rural proofing: No impact expected

Sustainability: No impact expected

Summary and preferred option

The proposed amendments will enable GB to comply with the requirements of the Directive.

It is recommended that the Genetically Modified Organisms (Contained Use) Regulations 2000 be amended following a public consultation on the proposed amendment which was undertaken in April/May 2010.

Statement by Chief Economist, Health and Safety Executive

As HSE Chief Economist I confirm that the attached Impact Assessment (IA), prepared by HSE Specialised Industries Division in collaboration with the Economic Analysis Unit, makes appropriate use of evidence in analysing the costs and benefits of the alternative options.

The proposal to amend the Genetically Modified Organisms (Contained Use) Regulations 2000 is designed to implement three aspects of the European Directive 2009/41/EC which had not been fully transposed into UK law: taking account of disposal of waste and effluents when carrying out a risk assessment; setting out characteristics of organisms classified as of negligible risk (class 1); and displaying biohazard signs on doors of laboratories (as opposed to 'where appropriate' as required at present).

The IA considers two options: doing nothing; and introducing amending Regulations to make the three changes. Option 1 has no costs or benefits. Option 2 would only impose costs in relation to the third change, displaying signs on doors, since the other two aspects are covered by existing guidance. The estimated costs to business are small: one-off costs of up to £220,000 for purchasing and displaying signs on doors plus up to £100,000 in familiarisation time. Option 2 would bring benefits but these are not quantifiable: avoidance of the risk of infraction proceedings from the European Commission, plus some possible improvement in health and safety standards.

Given the limited scale of the costs and benefits, I am satisfied that the evidence has been analysed in a proportionate way and that the IA's preferred option is supported.

PART II

NORTHERN IRELAND COSTS AND BENEFITS

The Genetically Modified Organisms (Contained Use) (Amendment) Regulations (Northern Ireland) 2010

Costs

1. The impact assessment prepared for the GB Regulations estimated that the costs, which are those associated with the provision of additional biohazard signage at 570 GMO centres in GB together with the costs of familiarisation with the amendments to the Regulations, should range between £90,000 and £320,000.

2. There are 8 GMO centres in NI. Based on the GB estimate the costs associated with implementing the Regulations should range between £1,364 and £4,513.

Benefits

3. Implementation of the proposed measures will avoid any costs associated with further infraction proceedings by the European Commission.

4. It is possible that there might be some health and safety benefit from specifying that biohazard signs must be included on doors, but given the current requirements to use such signs “as appropriate” this effect is not expected to be significant.

Summary

5. Overall it is considered that there will be no significant impact on NI business.