Title: **The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010** **Lead department or agency:** Health and Safety Executive **Other departments or agencies:** DEFRA, Scottish Executive	Impact Assessment (IA) **IA No: HSE 0052** **Date:** 10/06/2010 **Stage:** Final **Source intervention: EU** **Type of measure:** Secondary Legislation **Contact for enquiries:** Anna Bliss Tel: 0151 951 3581 Email anna.bliss@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 has been delayed 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

Ministerial sign-off

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

Signed by the responsible Minister: …… Date: ……

Summary: Analysis and Evidence Policy Option 1

Description: Do nothing

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

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

Not applicable

Discount rate (%) 3.5%

Impact on admin burden (AB) (£m):			Impact on policy cost savings	In scope
New AB: Nil	**AB savings:** Nil	**Net:** Nil	**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)	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 people working with GMMs 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)	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 rate (%)** 3.5%

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

People working with GMMs 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 person.

Impact on admin burden (AB) (£m):			Impact on policy cost savings	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 these			Nil		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions?			**Traded:** Nil	**Non-traded:** Nil	
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	**Medium** Nil	**Large** Nil
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	9
Economic impacts		
Competition? Competition Impact Assessment	No	10
Small firms? Small Firms Impact Test	No	10
Environmental impacts		
Greenhouse gas assessment? http://www.defra.gov.uk/environment/index.htm	No	10
Wider environmental issues? Guidance has been created on the Defra site	Yes	10
Social impacts		
Health and well-being? Health: Health Impact Assessment	Yes	10
Human rights? Ministry of Justice: Human Rights	No	10
Justice?	No	10
Rural proofing? Commission for Rural Communities	No	11
Sustainability? Defra: Think sustainable	No	11

[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 benefits	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 5(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 (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). People who work with GMMs are already required 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 GMMs. 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 5(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 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 any people working with GMMs will have to amend their existing classification 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 GMM 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 person 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.

[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.

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 expressed by consultees including those currently working with GMMs were 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 3. Responses to HSE's public consultation confirmed that these assumptions are reasonable.

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.

Annex 1 Post Implementation Review (PIR) Plan

Basis of the review: Not applicable
Review objective: Not applicable
Review approach and rationale: Not applicable
Baseline: Not applicable
Success criteria: Not applicable
Monitoring information arrangements: Not applicable
Reasons for not planning a PIR: It is not currently planned for amending regulations to be reviewed as the changes are minor.