Title:
Consolidation of the Genetically Modified Organisms (Contained Use) Regulations 2000 and its three amending Regulations from 2002, 2005 and 2010.
IA No:

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

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Summary: Intervention and Options

RPC Opinion: Green

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	£-0.11m	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	**Medium** 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 Minister: ..... Date: 16/4/14

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

None

Discount rate (%)

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:** 0.1	**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 has 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[1], 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 consultation stage to gather information on areas where the existing legislation could be simplified and would benefit from changes to improve clarity, proportionality and remove unnecessary requirements on low risk activities. 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:

    - 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,

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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/

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

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[2]).

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%

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.

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

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. 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[3] 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[4] 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 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

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

[4] 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)

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 to have 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 to have 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 to have 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 -£0.11m 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.

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.