Annex 2 – Outcome of public consultation on the consolidated Genetically Modified Organisms (Contained Use) Regulations

Summary report – Responses to HSE's consultation (CD263) on the proposed consolidation of the Genetically Modified Organisms (Contained Use) Regulations

Summary

- HSE received 42 consultation responses
- The academic sector provided 60% (25)[1] of responses including all the major universities and research institutes
- Health and safety professionals provided 53% (22) of responses
- An average of 83% of responses supported the amendments to the containment tables;
- An average of 88% of responses supported changes to the layout and language
- Each proposal was supported with positive responses ranging between 66% (25) & 97% (37)
- The proposals which received least support related to changes which presented differences in containment measure requirements between the consolidated regulations and Control of Substances Hazardous to Health (COSHH) Regulations 2002 (as amended)
- HSE will ensure that supporting guidance addresses any differences between the requirements of the consolidated regulations and the requirements of COSHH
- Given the overall support and positive response to the consultation, HSE will implement all of the proposed changes

Introduction

1. This is a summary report of HSE's statutory consultation on the proposal to consolidate the Genetically Modified Organisms (Contained Use) Regulations 2000 (S.I. 2000 No. 2831) and the three amending Regulations of 2002, 2005 and 2010, in response to the Löfstedt recommendation[2] on sector consolidation. The report is designed to be read in conjunction with the consultation document (CD263). The consolidation will make the regulations more risk based and proportionate, where possible, removing unnecessary burdens on the dutyholder and align more closely with the European Directive on contained use of genetically modified organisms (2009/41/EC). The changes will maintain the level of protection offered by the regulations.

2. The consultation document was divided into two parts and stakeholders were asked to comment on both:

[1] Percentages (based on the number of responses for a specific question) and actual number of responses in parenthesis are provided.

[2] Professor Ragnar E Löfstedt (2011), Reclaiming health and safety for all: An independent review of health and safety legislation, DWP, CM8219

- **Part 1 Control measures** - changes to the provisions within the containment tables, notifications and administrative arrangements. There are four containment tables: Table 1a – applies to laboratories; Table 1b – applies to plant growth facilities; Table 1c – applies to animal units; and Table 2 – applies to other premises (e.g. large scale).

- **Part 2 Restructure and technical tidy-up** - Changes to the language and layout of the consolidated regulations.

Consultation on proposals

3. CD263 was published on the HSE website and the consultation ran for 8 weeks between 28 October and 20 December 2013. Respondents were able to provide their response by a variety of means including online questionnaire, downloading a word template (returned by email or post), or providing more general comments via email.

4. More than 700 stakeholders across the biotech community (GM centres, academia, research, healthcare, advisory committees, non-government organisations, government, trade unions) were alerted to the consultation by direct email and a further 4000+ individuals via subscription to the HSE Biological Agents eBulletin. The Synthetic Biology Leadership Council and the synthetic biology special interest group (which currently has 750+ members) and the Secretariat for the Society for General Microbiology were also alerted to the consultation. Members of the HSE GMO consolidation team have also attended a number of stakeholder meetings to discuss the consultation in more detail (e.g. Northern Biological Safety Officers, University Department, Advisory Committee).

5. HSE received a total of 42 responses to the consultation from a wide cross-section of stakeholders. This exceeded HSE expectations based on responses to previous GMO consultations. 852 copies of the consultative document have been downloaded from the HSE website. A numerical analysis of the responses to the consultation is provided in Tables 1 to 3.

Summary of responses

6. Consultees were asked to consider a series of questions on the proposed changes to the regulations and to support their answer with some further explanation. Not all respondents answered every question and only half of respondents provided supportive text with their answer. Where no comment was made, it was not possible to determine why the respondent disagreed with the proposed change.

7. 53% (22) of the responses were received from health and safety professionals (e.g. Biological Safety Officers) and 24% (10) from employees, involved in GMO work and therefore in a good position to respond to the proposals. No responses were received from members of the public or self-employed. One response came from an organisation with self-employed members.

Table 1 - Sectorial breakdown of responses:

Capacity	Percentage
Academic	60% (25)
Charity	5% (2)
Consultancy	2% (1)
Industry	10% (4)
National government	2%(1)
Non-departmental public body	5% (2)
Non-government organisation	7% (3)
Membership organisation	7% (3)
Trade union	2% (1)
TOTAL	**100% (42)**

Table 2 – Type of respondents:

Capacity	Percentage
An employer	7% (3)
An employee	24% (10)
Health and safety professional	53% (22)
Trades union official	2% (1)
Non-government organisation	5% (2)
Membership organisation	7% (3)
Unknown	2% (1)
TOTAL	**100% (42)**

Table 3 - Analysis of responses to each question

Proposed change to GMO(CU) regulations	Agree with proposal	Disagree with proposal	Unsure/ Partly or possibly	Did not answer
Q1(a) – removal of duplicated requirement for disinfection procedures from Table 1a	66% (25)	34% (13)		(4)
Q1(b) – removal of requirement for an incinerator for animal carcasses	84% (32)	13% (5)	3% (1)	(4)
Q1(c) – removal of duplicated requirement for decontamination & wash facilities from Table 2	76% (28)	24% (9)		(5)
Q2(a) – removal of requirement for inward airflow at containment level (CL) 2	84% (31)	16% (6)		(5)
Q2(b) amendment of requirement for inward airflow for non-airborne transmission at CL3	74% (26)	26% (9)		(7)

Proposed change to GMO(CU) regulations	Agree with proposal	Disagree with proposal	Unsure/ Partly or possibly	Did not answer
Q3(a) amendment of requirement for HEPA filtration for non-airborne transmission at CL3	67% (24)	33% (12)		(6)
Q4(a) removal of specification of a Class 3 microbiological safety cabinet at CL4	89% (31)	11% (4)		(7)
Q5(a) amendment of requirement for waste inactivation to being risk based at CL1 in Table 1a	87% (34)	13% (5)		(3)
Q5(b) adequacy of the supporting guidance on waste inactivation at CL1 (Annex B)	79% (31)	18% (7)	3% (1)	(3)
Q6(a) amendment of requirement for an observation window to being risk based at CL3	70% (26)	30% (11)		(5)
Q7(a) removal of the requirement for isolators at CL1	90% (34)	10% (4)		(4)
Q8(a) removal of requirement for the controlled area to be purpose built at CL4 in Table 2	90% (29)	10% (3)		(10)
Q9(a) removal of requirement for biohazard sign at CL1 in Table 2	89% (33)	11% (4)		(5)
Q10(a) recording of training to be risk based at CL2 in Table 2	92% (33)	8% (3)		(6)
Q11(a) amendment of requirement for waste inactivation to being risk based at CL1 in Table 2	89% (33)	11% (4)		(5)
Q12(a) amendment of the requirement for an emergency plan to being risk based	97% (36)	3% (1)		(5)
Q12(b) requirement for full risk assessment for Class 2 contained use to be retained	79% (30)	21% (8)		(4)
Q12(c) removal of the hardcopy of the public register of notifications (on-line version only)	97% (37)	3% (1)		(4)
Q13(a) amendment to the requirements in relation to obtaining advise on Class 1 risk assessments	87% (34)	13% (5)		(3)
Q13(b) clarification on the remit of the genetic modification safety committee (i.e. multi-functional committee)	95% (36)	5% (2)		(4)

Proposed change to GMO(CU) regulations	Agree with proposal	Disagree with proposal	Unsure/ Partly or possibly	Did not answer
Q13(c) - adequacy of the supporting guidance on the genetic modification safety committee (Annex C)	94% (36)	3% (1)	3% (1)	(4)
Q14(a) amendments to the language/layout of the regulations	89% (34)	8% (3)	3% (1)	(4)
Q14(b) introduction of the term larger genetically modified organisms (LGMOs)	76% (29)	21% (8)	3% (1)	(4)
15(a) adequacy of the savings and transitional arrangements	92% (34)	5% (2)	3% (1)	(5)
Q16(a) Do the consolidated regulations adequately cover synthetic biology	70% (21)	13% (4)	17% (5)	(12)
Q18(a) - removal of the hardcopy of the Guide to the Regulations (L29) (electronic version only)	92% (35)	8% (3)		(4)

Part 1 Control measures

Q1a) and Q1c) Containment measure 15, Table 1a (A-1: disinfection procedures) and containment measure 16, Table 2 (A-3: decontamination facilities)

8. 66% (25) of the respondents were in favour of removing disinfection procedures from Table 1a and 76% (28) were in favour of removing decontamination and washing facilities from Table 2. Respondents agreed that these measures duplicate the requirements already stated in Schedule 7 (general principles). Respondents not supportive of the changes (34% (13) and 24% (9) respectively) preferred having all the necessary requirements presented in one place to act as a quick reference guide, particularly since there is no cost benefit in removing them. Respondents expressed concern that the measures may be overlooked or not given the same diligence as those listed in the tables.

9. ***HSE's response*** – Schedule 7 sets out the general principles of good microbiological practice and good occupational safety and hygiene. Some of the principles are absolute requirements, whilst others are couched in terms of 'where appropriate or necessary' or 'as required'. In the latter case, further explanation of the principle is provided in the containment table, to indicate where the requirement may differ at the various containment levels (CL). This is not the case for the requirements to have disinfection procedures (A-1) or decontamination/washing facilities (A-3), which are absolute requirements for any activity, regardless of the containment levels. Whilst HSE recognises the value of inclusion in the containment table for some measures, in this instance, this is unnecessary and inconsistent between containment tables.

To ensure these absolute requirements are not overlooked, the *Guide to the Regulations* (L29) will be amended to emphasise the importance of implementing and adhering to the general principles in Schedule 7. HSE proposes to implement the change.

Q1b) Containment measure 6, Table 1c (A-2: incinerator)

10. 84% (32) of respondents were in favour of the proposal to remove the requirement to dispose of animal carcasses using an incinerator from Table 1c. Respondents agreed the measure is overly prescriptive and costly and welcomed the flexibility to choose more environmentally friendly and cost effective alternatives. Respondents not supportive of the proposal (13% (5)), cited differences with the requirements of the COSHH regulations, which requires this measure when working with human pathogens at CL4. One respondent expressed concern that the change reduced the level of protection to the environment (e.g. increase risk of release of organisms or spread of antibiotic resistance genes into the environment).

11. ***HSE's response*** – HSE does not believe removing this measure increases the risks to the environment because the overarching requirement to protect the environment from contaminated materials (including carcasses) through inactivation by a validated means has not changed. The proposal permits the user to choose an alternative yet equally effective method to do so (based on their risk assessment).

12. HSE acknowledges that when working with a hazard group (HG) 4 human pathogen, COSHH requires this measure on site to inactivate animal carcases. Consequently, those users undertaking work of this nature with genetically modified HG4 human pathogens would have to meet the higher standard required by COSHH. Currently this applies to two users in the UK, which already have incinerators on site. When the opportunity arises, HSE will look to amend the COSHH regulations accordingly. HSE proposes to implement the change.

Q2a) containment measure 5 at CL2, Table 1a (B-1: inward airflow)

13. 84% (31) of respondents were in favour of removing the requirement for inward airflow at CL2, as this requirement was considered disproportionate to the risk from activities at CL2. One respondent explained that the change would facilitate clinical trials with genetically modified micro-organisms (GMMs) to be undertaken at CL2. Respondents welcomed the potential reduced operational costs and greater versatility. 16% (6) of respondents did not support the proposal and raised several concerns: potential for release of GMMs in event of a spillage involving large volumes; inconsistency with guidance on CL2 work with human pathogens; and the added value this measure gives in relation to containing nucleic acids.

14. ***HSE's response*** – This proposal brings the GMO regulations in line with the requirements of the COSHH regulations, where this measure is not required at CL2 for human pathogens. This measure is aimed at protecting

those outside rather than inside the laboratory from exposure to GMMs. Where large volumes of GMMs are used and the risk assessment concludes that inward airflow is required either to protect those outside the laboratory or the environment, it is considered more appropriate for this work to be done at CL3. It is accepted that some people may choose to operate a mechanical ventilation system at CL2 (not based on risk). In such circumstances, it is appropriate for this to have an inward airflow, and this will be reflected in guidance. HSE proposes to implement the change.

Q2b) and Q3a) Containment measure 5, Table 1a (B-1: inward airflow) and containment measure 6, Table 1a (B-2: HEPA filtration) both at CL3

15. The proposal to change the measures for inward airflow and HEPA filtration of extract air at CL3, to required except for activities where transmission does not occur via airborne transmission, was supported by 74% (26) and 67% (24) of respondents respectively. Respondents agreed the current provisions were disproportionate to the risk (i.e. where there was no risk of airborne infection) and were in favour of the flexibility and potential cost savings provided. Respondents not supportive of the changes (26% (9) and 33% (12) respectively) were largely concerned with differences in the requirements of COSHH, where these measures are required at CL3 for human pathogens. Other respondents raised concerns that infectious aerosols can be generated from agents that do not have a natural airborne route of transmission (e.g. where concentrations are very high or through genetic modification resulting in gain of function). In practice, a number of respondents indicated that despite the proposal, they would continue to operate the laboratory at negative pressure for all organisms rather than have to re-optimise settings.

16. ***HSE's response*** – These control measures are intended to prevent the dispersal of airborne micro-organisms beyond the confines of the laboratory. The regulations require the users to undertake a risk assessment for all GM activities in which the user would consider the initial hazard classification of the micro-organism, the type of genetic modification being undertaken (including gain of function, altered tropism or routes of transmission) and the nature of the activity (e.g. scale of work). The proposal will ensure that the airborne route of transmission is explicitly considered in the risk assessment (e.g. the agent's viability in aerosols, stability, persistence and inhalation by someone in the vicinity etc.) and that application of these control measures are proportionate rather than the previous blanket requirement for inward airflow/HEPA filtration at CL3. For most circumstances, these control measures would be required at CL3 and it is only where the risk assessment concludes that there is no risk of airborne transmission (hence the risks to human health or the environment do not warrant inward airflow and/or HEPA filters for extract air) could these measures be dispensed with. The changes are intended to make the containment measures more risk based, proportionate and meaningful and will align with the contained use directive.

17. HSE acknowledges that inward airflow and HEPA filtration (for extract air) are required at CL3, in the containment tables of Schedule 3 of COSHH.

However, the requirements can be adjusted through reference to the Approved List Classification, which provides guidelines on circumstances where these measures may not be required. More specifically, the classification identifies biological agents (e.g. blood-borne viruses) that are not normally infectious via the airborne route hence for which these measures may not be required subject to local assessment. The proposed changes are intended to be consistent with the approach set out in the COSHH regulations and Approved Classification. It is recognised that there are inconsistencies in the related guidance on contained use of biological agents and HSE is in the process of revising this guidance. Where there is a mixture of activities, i.e. where airborne and non-airborne biological agents are being used at the same time, then a HEPA filter and inward airflow would be required at CL3. HSE proposes to implement the change.

Q4a) Containment measure 7 at CL4, Table 1a (B-3: microbiological safety cabinet)

18. 89% (31) of respondents agreed the current measure is over-prescriptive. Respondents supported the flexibility of being able to choose the most appropriate microbiological safety cabinet (MSC). The 11% (4) of respondents not supportive questioned whether this was consistent with the COSHH hierarchy of control and some suggested it may lead to an increase in the risk of GMMs escaping into the environment.

19. ***HSE's response*** – The proposed change allows the selection of the most appropriate and suitable MSC for the type of activity being undertaken (based on risk assessment) and aligns this requirement with the contained use directive. In some circumstances, a closed fronted MSC may be required. However, where the risk to the operator is less or where a closed fronted MSC is not practical, the proposal provides more flexibility including supplementing the MSC with personal protective equipment (PPE) (e.g. suited system). The proposal maintains the requirement for an MSC hence is in line with the general principles in the regulations and COSHH hierarchy (i.e. applying engineering control measures at source and supplementing with PPE where appropriate). HSE proposes to implement the change.

Q5a), Q5b) and Q11a) Containment measure 17, Table 1a and containment measure 21, Table 2 (B-4, B-10 & Annex B: waste inactivation) both at CL1

20. Waste management is a key feature of the risk assessment for contained use work. The proposed change is intended to make inactivation of waste at CL1 (activities of no or negligible risk) risk based. 87% (34) and 89% (33) of respondents welcomed the flexibility in choosing the method to inactivate contaminated waste at CL1 based on risk assessment, rather than the perceived mandatory use of an autoclave. Respondents agreed that Class 1 GMMs pose no or negligible risk to human health or the environment. Respondents not supportive of the proposals (13% (5) and 11% (4) respectively) raised concern over an increased risk of escape and spread of GMMs into the environment and the need for stricter environmental

monitoring and enforcement. Overall, 79% (31) of respondents were content with the guidance in Annex B and felt it adequately clarified those situations when inactivation by validated means would not be necessary. 18% (7) of respondents suggested minor clarifications to the guidance (e.g. partial degree of inactivation, ability to replicate) and inclusion of clinical waste streams.

21. ***HSE's response*** – The changes are proposed to offer greater flexibility in the means of inactivation. Only where the risk assessment concludes that there is no risk to human health or the environment would inactivation not be required. The criteria provided in the related guidance will assist users with the risk assessment and in determining the appropriate method for inactivation. The guidance will be amended to reflect the proposed drafting changes and clarifications. Monitoring requirements are focused on the containment and control measures. Given the level of risk (nil or negligible) associated with Class 1 activities, environmental monitoring is not deemed necessary. HSE proposes to implement the changes.

Q6a) Containment measure 19 at CL3, Table 1a (B-5:observation window)

22. 70% (26) of respondents were in favour of changing the requirement for an observation window or alternative from required to risk based at CL3. This brings it in line with both European directives on the contained use of GMMs and Biological Agents. 30% (11) of respondents disagreed with the change citing inconsistency with COSHH regulations, where this measure is required at CL3; and concerns over lone working.

23. ***HSE's response*** – The intended purpose of the observation window is to check on the situation inside the laboratory, to ensure it is safe before entering; and to evaluate the most appropriate means of dealing with any spillage without having to enter the laboratory. This is particularly important for human pathogens, which present a risk of airborne exposure, and would require appropriate protective measures (e.g. RPE) to be taken before entry. For other types of work, this check before entry is less important. Consequently, the risk based approach accommodates both situations and permits identification of the most appropriate measures for the circumstances. Where laboratories are working with human pathogens, the risk assessment would conclude the need for an observation window (or alternative) to meet the requirement of COSHH. HSE proposes to implement the change.

Q7a) Containment measure 9 at CL1, Table 1c (B-6: isolators)

24. 90% (34) of respondents supported removing the requirement that animals should be kept in isolators at CL1. Respondents agreed that this was disproportionate and burdensome. 10% (4) of respondents were not supportive, saying that the current risk based approach was adequate or the change increased the risk spread of novel infections.

25. ***HSE's response*** – For an activity to be considered Class 1, there should be no risk to the user or the environment. Consequently, where a containment measure such as an isolator is required (on these grounds), then the work should be done at CL2 or above, which afford greater safeguards. The current requirement is therefore disproportionate for an activity of nil or negligible risk and, therefore, unnecessarily burdensome on the user. The proposed change will ensure that work that poses a risk to human health or the environment is undertaken at higher containment rather than in an isolator at CL1. As such, there is no increase in risk of the spread of infection. HSE proposes to implement the change.

Q8a) Containment measure 2 at CL4, Table 2 (B-7: controlled area)

26. The proposal is intended to align this requirement with the directive and remove the prescription for purpose built controlled area. 90% (29) of respondents were supportive of the proposal to change this measure at CL4. Respondents agreed that the change offers flexibility and cost savings. 10% (3) of respondents did not support the change because of the inconsistency with COSHH or a perceived increase in risk due to a lack of evidence on the proposed change.

27. ***HSE's response*** – The proposal does not change the requirement to house the activity in a controlled area, but rather removes the requirement for the area to be purpose built (i.e. it is permissible to use existing or a refurbished controlled area). It is acknowledged that when working with a HG4 human pathogen, COSHH prescribes the controlled area to be purpose built. When the opportunity arises, HSE will look to amend the COSHH regulations accordingly. However, those users undertaking work of this nature with genetically modified HG4 human pathogens would have to meet the higher standard required by COSHH. Currently there are no users in the UK working with human HG4 pathogens in this type of facility (to which Table 2 applies). HSE proposes to implement the change.

Q9a) Containment measure 9 at CL1, Table 2 (B-8: biohazard sign)

28. 89% (33) of respondents agreed that a biohazard sign is not needed at CL1 where there is no or negligible risk and is consistent with the similar requirement in Table 1a. Respondents commented that it can cause confusion and undue concern among emergency services and other personnel at CL1. 11% (4) of respondents were not supportive of the change believing it to be helpful in deterring non-laboratory staff from entering laboratory areas.

29. ***HSE's response*** – The biohazard sign does distinguish areas where biohazardous material is being used from other areas. The sign does not provide any distinction between the different containment levels. At CL1, the Directive does not require this measure because the activity should not present any harm to human health or the environment. The proposed change is proportionate to the risk and aligns the requirements in the containment tables. HSE proposes to implement the change.

Q10a) Containment measure 19 at CL2, Table 2 (B-9: records of training)

30. 92% (33) of respondents supported the proposal and welcomed the consistency with the similar requirement in Table 1a. 8% (3) of respondents were not supportive based on the view that the proposed change did not go far enough (i.e. training records should be required for everyone for inspection by regulators, for litigation purposes and for the professionalism of the organisation).

31. ***HSE's response*** – The requirement to keep training records and have written procedures needs to be proportionate to the risk. There is an overarching general requirement to provide information, instruction and training and this proposal introduces recording of this on a risk basis. HSE proposes to implement the change.

Q12a) Emergency plan provisions (C-1)

32. 97% (36) of respondents supported the proposal to make the requirement to have an emergency plan risk based. One person disagreed explaining their concern at weakening the emergency procedures.

33. ***HSE's response*** – The regulations require an emergency plan only where persons off site are liable to be seriously affected by an accident or there is potential for serious environmental harm. The plan provides details of the means of dealing with the accident and informing the emergency services. At Class 2, the activity is low risk and should not present a level of off-site risk that warrants an emergency plan. HSE proposes to implement the change.

Q12b) Preference for full or summary risk assessment for Class 2 activities (C-2)

34. 79% (30) of respondents preferred to submit a full risk assessment for Class 2 activities since they deemed producing a summary would require extra work. 21% (8) of respondents preferred to submit a summary, on grounds of commercial sensitivity of some of the information in the full assessment.

35. ***HSE's response*** – The regulations have a separate mechanism (in the notification procedure) for dealing with claiming confidentiality with regards to information published on the public register. Users are required to undertake a risk assessment for all GM activities. Provision of a summary places an additional burden on users that is not considered necessary. HSE proposes to keep the current requirement.

Q12c) and Q18a) Public register of notifications and Guide to the Regulations (L29) –electronic on-line versions (only) (C-3)

36. 97% (37) of respondents had no objection to withdrawing the paper copy of the public register. One person did not agree but the basis for this was

unclear from their comments. 92% (35) of respondents supported an electronic on-line version of the guide to the regulations. 8% (3) of respondents did not support this change, explaining that the hardcopy of the guide was useful for quick reference; or suggested this would lead to increased costs for users having to repeatedly print off versions or parts thereof.

37. ***HSE's response*** – An electronic version of the guidance is more accessible for users and is cheaper, quicker and easier to update and distribute to stakeholders. Paper copies can be printed from the HSE website as required. HSE proposes to implement the changes.

Q13a), Q13b) and Q13c) Requirement for Genetic Modification Safety Committee (GMSC) (D-1 and Annex C)

38. 87% (34) of respondents supported allowing expert advice, on risk assessments at Class 1, to be provided either by a suitably experienced person or by a committee. Respondents felt this increased flexibility and reduced burden, with greatest support from smaller organisations with limited resources. 13% (5) of respondents were not supportive, believing that it was not sufficient to give an individual full responsibility for advising and authorising Class 1 projects, due to insufficient competence for the range of activities and concern about their impartiality in the decision making process. 95% (36) of respondents supported the concept of multi-functional committees and 94% (36) were content that the guidance (Annex C) explained the GMSC sufficiently.

39. ***HSE's response*** – The proposal provides flexibility in provision of advice on risk assessments (i.e. it can be from an individual or committee, in-house or external). The key element of the change is that the person responsible for the work must ensure that the advice is from a **competent** individual or committee. The guidance in Annex C will be amended to reflect the respondents' comments and incorporated into the *Guide to the Regulations*. HSE proposes to implement the changes relating to the GMSC.

Q14a) Changes to the structure and language of the regulations (E1-E6)

40. 89% (34) of respondents supported the changes to the language and layout of the regulations. Those not supportive or partially supportive, raised the following points: definition of 'contained use' was incomplete; and questioned where information on the appeal process will be located.

41. ***HSE's response*** – The proposed changes should make the revised regulations clearer and more concise. The definition of contained use in the consultation document is expanded upon in the regulations and the appeal procedure will be published on the HSE website. HSE proposes to implement the changes.

Q14b) Genetically modified organisms other than micro-organisms (E-5)

42. 76% (29) of respondents supported using the term 'larger GMOs' (LGMOs) as an alternative to 'genetically modified organisms other than micro-organisms', providing it was adequately defined. 21% (8) of respondents were not supportive, feeling LGMO was not scientific or precise enough or could be confusing. There was some confusion amongst respondents in their understanding of the terms GMO and GMMs.

43. ***HSE's response*** – GMOs is the all encompassing term for any organism that is genetically modified. LGMOs are a subset of GMOs and clearly defined in Regulation 2, as anything other than micro-organisms. GMMs include animal and plant cells as well as micro-organisms. Given that the definition of LGMO is based on the current term (GMOs other than micro-organisms) it is not anticipated that there should be any confusion. HSE proposes to implement the change.

Q15a) Views on the savings and transitional arrangements

44. 92% (34) of respondents are content with the savings and transitional arrangements. They were satisfied that the proposed changes would have minimal or no impact on their work. Two respondents were not content with the arrangements and only one supported their answer with a comment, which was a wider comment on the adequacy of the regulations rather than the savings and transitional arrangements.

45. ***HSE's response*** – Overall the savings and transitional arrangements appear adequate; hence HSE intends to implement these accordingly.

Q16a) and Q16b) Views on the application to synthetic biology

46. 70% (21) of respondents did not foresee any practical problems by applying the GMO regulations to synthetic biology. 17% (5) were unsure. Of the total respondents, 12 did not answer these questions. A further 13% (4) of respondents highlighted several issues that may apply in future:

- given the potential of synthetic biology to create novel organisms with no natural comparators, there may be significant challenges to risk assessment;
- as synthetic biology applications develop, there may be use of increasingly diverse facilities and scaling up in quantities, which may require different containment approaches (e.g. move from the laboratory to bioreactors);
- concerns relating to the potential for over regulation of synthetic biology technologies that are more targeted and lower risk than existing GM technologies.

47. There were no suggestions for a better-fit regulatory model for synthetic biology, although a common point raised was the need to update definitions and associated guidance once the applications and products of synthetic biology become more advanced. It was also highlighted that many of the

potential future applications will fall under deliberate release rather than contained use regulations.

48. ***HSE's response*** – Overall the current activities involved in synthetic biology fall comfortably within the limits of the contained use regulations. However, it is acknowledged that future applications may challenge existing definitions and associated existing guidance. In the longer term, HSE will work with relevant parties (including the Synthetic Biology Leadership Council and Governance Subgroup) to ensure the contained use regulations remain fit for purpose.

49. More specifically, the risk based classification system (and application of containment/control measures proportionate to the risk) applies equally to synthetic biology and conventional genetic modification. Consequently, the regulations should not increase the regulatory burden on synthetic biology activities. HSE obtains independent scientific advice from the Scientific Advisory Committee for Genetic Modification (SACGM). The membership of the committee is such as to enable the most up to date technical advice, which will assist with the risk assessment process for novel organisms. The containment requirements within the regulations apply to a variety of types of facility including large-scale manufacturing. This is supplemented by technical guidance in the SACGM Compendium of Guidance. This will be updated accordingly to take account of technological advances and varying applications. The Guide to the Regulation (L29) is currently being revised and will be amended to take account of the comments.

Q17a) Views on the preliminary impact assessment

50. Only 30% (12) of respondents provided any comment on the preliminary impact assessment, whilst the remaining 70% (28) reported no views or did not answer the question. Of those who provided comments, the majority were largely positive stating that the changes provided benefits although more in terms of flexibility rather than cost savings. Overall the impact is expected to be modest n terms of cost savings. Several respondents indicated that they would maintain the status quo despite the changes to legislation (i.e. continue to apply measures which are no longer required). Most recognised there would be unavoidable familiarisation costs. One concern was that the impact assessment does not estimate the costs of any increased risk of adverse impacts (e.g. release from containment).

51. ***HSE's response*** – HSE recognises that it is difficult to monetise many of the proposed changes because the impact is dependent on the outcome of the risk assessment for each activity, whilst behavioural changes are dependent on the specific circumstances of the institution or management arrangements within a department. Consequently, the key benefits are likely to be increased flexibility in the application of control measures in a risk based and proportionate manner. Where possible, relevant costs and savings will be monetised. The proposed changes are intended to maintain the level of protection to human health and the environment, hence should not result in

an increased risk of adverse incidents. Based on this premise, the impact assessment has not provided costs resulting from a release.

Other matters raised

52. The revision of the regulations is based on a need to consolidate the regulations with three sets of amending regulations as recommended by the Löfstedt review. The consultation focused on the changes necessary to achieve this purpose and make the regulations more risk based and proportionate. A number of wider comments were received that did not relate to the proposed changes to the regulations. These are captured in Annex 1 and grouped into three categories: matters related to the consolidation (not covered in the questions); wider legislative or guidance matters; and matters in the existing legislation not addressed by the consolidation. Responses to these points have also been provided.

Conclusions

53. The consultation was preceded by a concerted stakeholder engagement to develop the proposed changes to the regulations. The consultation was brought to the attention of >5000 stakeholders, from which ~800 stakeholders downloaded the consultation document and 42 stakeholders responded. The responses were received largely from stakeholders involved in genetic modification work or with health and safety responsibility for these activities. No responses were received from wider interested parties (e.g. members of the public). Overall, HSE is content that the consultation was sufficient and responses well informed.

54. The proposals were positively received and supported by the majority of respondents. The majority of points raised will be addressed in the updated *Guide to the Regulations* (L29) and associated (*Compendium of Guidance*) or related (*Biological Agents: managing the risks*) guidance. This includes the points raised in relation to differences between the GMO regulations and COSHH regulations. Consequently, HSE intends to proceed with implementation of all of the proposed changes identified in the consultation document.

55. A number of additional points were raised in relation to the existing regulations or genetic modification activities that are not within scope of the consolidation. These more general or wider issues will be considered separately and will be used to inform future policy development in this area where appropriate.

56. HSE wishes to express thanks to all those who have taken the time to provide a response.

Annex 1 – Other matters raised in relation to the existing regulations that did not relate to the proposed changes

A number of points were raised in relation to the current arrangements set out in the regulations:

1) Consolidation issues not covered in the question set

a) Further explanation of self cloning definition
b) Clarification on the definition of genetic modification, where the resulting GMM is identical to something produced by non-GM methods
c) "Biological containment" is not included in directive 2009/41/EC and is open to misinterpretation
d) Requirement for an autoclave should be amended to be more risk based

HSE Response to points a)-c): *The Guide to the Regulations (L29) is being reviewed and will be amended to provide further clarification on the points raised above.*

HSE Response to points d): *The requirement for an autoclave and its location is specified in the European Directive. The contained use regulations are the same as those in the Directive. Consequently, it is not possible to reduce the requirements as this would under-implement the Directive.*

2) Wider legislative or guidance related issues

e) Greater consistency between the different regulatory regimes for biological agents (e.g. single regulatory framework)
f) Reference to the Canadian Biosafety guidelines for human and animal pathogens in context of single regulatory framework
g) Update of the SACGM Compendium of Guidance required (more current examples)
h) Greater consideration of horizontal gene transfer in risk assessment

HSE Response to points e) & f): *The consolidation of the GMO(CU) regulations is part of a wider programme to move the regulatory approach closer to the objective of a single regulatory framework. This wider programme is set out in the HSE Board Paper of April 2013 and is exploring legislative and non-legislative changes in parallel.*

HSE Response to points g) & h): *The SACGM compendium will be updated to take account of the consolidated regulations (this is unlikely to be completed until 2015). The opportunity will be taken to look at the risk assessment sections and update according to the comments provided in the consolidation.*

3) Matters not addressed in the consolidation of the existing regulations

i) The provisions in the GMO(CU) regulations in relation to LGMOs were not consulted upon and do not consider the risks to the environment in the risk assessment or possess a meaningful mechanism to set containment levels for non-GMMs (e.g. animals, plants)

j) Stricter measures for environmental monitoring and enforcement of containment requirements for GMMs under contained use
k) Lack of public information and consultation on risk assessment – insufficient to meet the requirements of Aarhus convention

HSE response to i): *The GMO(CU) regulations place requirements on users to assess the risks to human health in respect of LGMOs. This requirement has not been changed as part of the consolidation. However, the Environmental Protection Act (EPA) 1990 and associated regulations, require users to assess the risks to the environment and implement containment measures. The Guide to the Regulations includes reference to this requirement. In addition, HSE works together with Defra and the Devolved Governments to ensure that risks to the environment from contained uses with LGMOs are assessed and managed appropriately. The SACGM Compendium of Guidance (Parts 4 and 5) provides advice on environmental risk assessment and sets out specific containment measures that are suitable for LGMOs.*

HSE response to j): *For facilities operating in this area, the inspection and investigation is undertaken by specialist microbiologists who have a thorough understanding of the risks involved with this work. Monitoring arrangements are focused on the containment and control measures, to ensure they prevent release into the environment. HSE takes enforcement action in line with its enforcement policy statement and enforcement management model.*

HSE response to k): *HSE maintains a public register of GM activities notified under the GMO(CU) regulations. Risk assessments are available upon request under the conditions of the Environmental Information Regulations. There are provisions within the notification arrangements to provide comments on notified activities. HSE will continue to look at the systems in place to see if there are improvements that can be made within the resources available. The SACGM hold open meetings, which are advertised on the HSE website and open to all.*

Annex 2 - Glossary

BSO – biological safety officer
CD – consultative document
CL – containment level
COSHH – Control of Substances Hazardous to Health Regulations 2002 (as amended)
Defra – Department for Environment, Food and Rural Affairs
GM – genetic modification
GMSC – genetic modification safety committee
GMO – genetically modified organism
GMO(CU) – Genetically Modified Organisms (Contained Use) Regulations 2000 (as amended)
GMM – genetically modified micro-organism
HEPA – high efficiency particulate air filter
HG – hazard group
HSE – Health and Safety Executive
LGMO – larger genetically modified organism
MSC - microbiological safety cabinet
PPE - personal protective equipment
RPE - respiratory protective equipment
SACGM - Scientific Advisory Committee for Genetic Modification