Health and Safety Executive

CD263 – Consultation on Proposals to Consolidate the Genetically Modified Organisms (Contained Use) Regulations 2000 and the three amending Regulations of 2002, 2005 and 2010

Reply Form

Completing this Questionnaire

You can move between questions by pressing the 'Tab' / 'Shift-Tab' or 'Page Up' / 'Page Down' keys or by clicking on the grey boxes with a mouse. Please type your replies within the rectangular grey boxes, or click on the square grey boxes to select an answer (e.g. 'Yes' or 'No').

Respondent's details:

Name:	Helen Wallace
Email:	helen.wallace@genewatch.org
Town / City:	Buxton
Telephone:	01298 24300
Job Title:	Director
Postcode:	SK17 7BB
Street address:	60 Lightwood Rd
Organisation:	GeneWatch UK
Fax:	

Size of organisation:

Choose one option:

Not applicable	☐	1 to 9 employees	☒
10 to 49 employees	☐	50 to 249 employees	☐
250 to 1000 employees	☐	1000+ employees	☐
Self-employed	☐		

#

Type of organisation:

Choose one option:

Academic	☐	Charity	☐
Consultancy	☐	Industry	☐
Local government	☐	Member of the public	☐
National government	☐	Non-departmental public body	☐
Non-governmental organisation	☒	Pressure group	☐
Trade association	☐	Trade union	☐

If you chose 'Other' please specify: ☐

Is your response being made in your capacity as:

Choose one option:

An employer	☐	An employee	☐
Health and safety professional	☐	Trade union official	☐
Training provider	☐		

Other – please specify:

NGO

Confidentiality

Please indicate below if you do not wish details of your comments to be available to the public. (NB if you do not put a cross in the box they will be made available to the public. This takes precedence over any automatic notes on e-mails that indicate that the contents are confidential.) ☐

Questions

Q1(a) Should containment measure 15 (disinfection procedures) of Table 1a be removed as suggested?

Yes	☐
No	☒

Q1(b) Should containment measure 6 (incinerator) of Table 1c be removed as suggested?

No

Q1(c) Should containment measure 16 (decontamination facilities) of Table 2 be removed as suggested?

Yes	☐
No	☒

Q1(d) Please provide some comments to support your answers including any costs or benefits that these changes may cause

No justification for these changes has been provided because no information on the consequences for health or the environment has been supplied (see comments under "other"). No evidence has been provided of an undue burden on users, nor have the costs of weakening the regulations been considered.

Failure to incinerate animal carcasses containing GMMs carries an increased risk of spreading GM bacteria, viruses or antibiotic resistance genes into the environment.

Q2(a) Should containment measure 5 (inward airflow) of Table 1a be amended as suggested at CL2

Yes	☐
No	☒

Q2(b) Should containment measure 5 (inward airflow) of Table 1a be amended as suggested at CL3?

Yes	☐
No	☒

Q2(c) Please provide some comments to support your answers including any costs or benefits that these changes may cause

No justification for these changes has been provided because no information on the consequences for health or the environment has been supplied (see comments under "other"). No evidence has been provided of an undue burden on users, nor have the costs of weakening

the regulations been considered. These changes will increase the risk of escape of GMMs through airflow.

Q3(a) Should containment measure 6 (HEPA filtration) of Table 1a be amended as suggested at CL3?

Yes	☐
No	☒

Q3(b) Please provide some comments to support your answer including any costs or benefits that this change may cause

No justification for these changes has been provided because no information on the consequences for health or the environment has been supplied (see comments under "other"). No evidence has been provided of an undue burden on users, nor have the costs of weakening the regulations been considered. These changes increase the risk of escape of GMMs by air.

Q4(a) Should containment measure 7 (microbiological safety cabinet) of Table 1a be amended as suggested at CL4?

Yes	☐
No	☒

Q4(b) Please provide some comments to support your answer including any costs or benefits that this change may cause

No justification for these changes has been provided because no information on the

consequences for health or the environment has been supplied (see comments under "other"). No evidence has been provided of an undue burden on users, nor have the costs of weakening the regulations been considered. The propose changes increase the risk of escape of GMMs.

Q5(a) Should containment measure 17 (waste inactivation) of Table 1a be amended as suggested at CL1?

Yes	☐
No	☒

Q5(b) Does the related guidance in Annex B clarify the requirements for inactivation of waste at CL1?

Yes	☐
No	☒

Q5(c) Please provide some comments to support your answers including any costs or benefits that this change may cause

No justification for these changes has been provided because no information on the consequences for health or the environment has been supplied (see comments under "other"). No evidence has been provided of an undue burden on users, nor have the costs of weakening the regulations been considered. Failure to inactivate waste increases risk of escape and spread of GMMs, including e.g. antibiotic resistance genes.

Q6(a) Should containment measure 19 (observation window) of Table 1a be amended as suggested at CL3?

Yes	☐
No	☒

Q6(b) Please provide some comments to support your answers including any costs or benefits

that these changes may cause

No justification for these changes has been provided because no information on the consequences for health or the environment has been supplied (see comments under "other"). No evidence has been provided of an undue burden on users, nor have the costs of weakening the regulations been considered.

Q7(a) Should containment measure 9 (isolators) of Table 1c be amended as suggested at CL1?

Yes	☐
No	☒

Q7(b) Please provide some comments to support your answers including any costs or benefits that these changes may cause

No justification for these changes has been provided because no information on the consequences for health or the environment has been supplied (see comments under "other"). No evidence has been provided of an undue burden on users, nor have the costs of weakening the regulations been considered. Failure to isolate infected animals increases the risk of spread of novel infections.

Q8(a) Should containment measure 2 (controlled area) of Table 2 be amended as suggested at CL4?

Yes	☐
No	☒

Q8(b) Please provide some comments to support your answer including any costs or benefits that this change may cause

No justification for these changes has been provided because no information on the consequences for health or the environment has been supplied (see comments under "other"). No evidence has been provided of an undue burden on users, nor have the costs of weakening the regulations been considered.

There is no justification for creating an inconsistency with the Biological Agents Directive, and any consultation on amending the Directive should not be pre-judged here.

Q9(a) Should containment measure 9 (biohazard sign) of Table 2 be amended as suggested at CL1?

Yes	☐
No	☒

Q9(b) Please provide some comments to support your answer including any costs or benefits that this change may cause

No justification for these changes has been provided because no information on the consequences for health or the environment has been supplied (see comments under "other"). No evidence has been provided of an undue burden on users, nor have the costs of weakening the regulations been considered.

Biohazard signs are an important aspect of public information which help to restrict access by unauthorised and untrained personnel.

Q10(a) Should containment measure 19 (records of training) of Table 2 be amended as suggested at CL2?

Yes	☐
No	☒

Q10(b) Please provide some comments to support your answer including any costs or benefits that this change may cause

No justification for these changes has been provided because no information on the consequences for health or the environment has been supplied (see comments under "other"). No evidence has been provided of an undue burden on users, nor have the costs of weakening the regulations been considered.

Training is an important aspect of health and safety and there is no justification for not keeping records of training which will facilitate good management of a facility.

Q11(a) Should containment measure 21 (waste inactivation) of Table 2 be amended as suggested at CL1?

Yes	☐
No	☒

Q11(b) Please provide some comments to support your answer including any costs or benefits that this change may cause

No justification for these changes has been provided because no information on the consequences for health or the environment has been supplied (see comments under "other"). No evidence has been provided of an undue burden on users, nor have the costs of weakening the regulations been considered.

Failure to inactivate waste increases risks, including e.g. spread of antibiotic resistance genes.

Q12(a) Should the emergency plan provisions be amended as suggested?

Yes	☐
No	☒

Q12(b) Would you prefer to:

a) submit a full risk assessment for Class 2 activities	☒

b) submit a summary of the assessment for Class 2 activities	☐

Q12(c) Do you have any objections to remove the hardcopy register of notifications and move to an electronic version (only)?

Yes	☐
No	☒

Q12(d) Please provide some comments to support your answer including any costs or benefits that this change may cause

Q12(b) is extremely badly worded – is this consultation for operators only? The purpose of the Regulations is to protect health and the environment, not to ask operators what they "prefer". If the full RA has been done there is no reason why it is a burden to supply it. No justification has been provided for weakening the emergency procedures.

GeneWatch does not object to information being provided only in electronic form.

Q13(a) Should the source of advice on risk assessments be amended as suggested for Class 1 risk assessments?

Yes	☐
No	☒

Q13(b) Provided the committee has appropriate expertise, do you agree with multi-functional committees providing advice on GM risk assessments?

Yes	☐
No	☒

Q13(c) Does the related guidance in Annex C clarify the requirements for the Genetic Modification Safety Committee?

Yes	☐
No	☒

Q13(d) Please provide some comments to support your answer including any costs or benefits that this change may cause

It is widely accepted that GMO risk assessments require (i) a broad range of expertise, including detailed knowledge of GMOs; (ii) input from a panel which is independent and free of bias. Relying on a single individual (or a committee without relevant expertise) to make a recommendation risks biased outcomes, particularly when risk assessments are not made public, and also significantly increases the risk that potential for major adverse effects may be missed due to lack of expertise in a relevant area. Costs of potential errors have not been considered.

Q14(a) Do you agree or disagree with the proposed changes to the structure and language of the regulations?

Yes	☐
No	☒

Q14(b) Should the term genetically modified organisms other than micro-organisms be amended as suggested?

Yes	☐
No	☒

Q15(a) Are you content that the savings and transitional arrangements are adequate to cover the changes arising from the new regulations?

Yes	☐

No	☒

Q15(b) Please provide some comments to support your answer including whether you will be required to re-classify your work or notify under the transitional arrangements

The proposed changes fail to address the main problem with the Regulations, namely that they provide no meaningful mechanism to set containment levels for non-GMMs, because environmental risk assessments are not included. See comments under "other" below.

Q16(a) Does the application of GMO contained use regulations to synthetic biology present any practical problems?

Yes	☒
No	☐

Q16(b) Considering future applications (or products) of synthetic biology outside those of the traditional contained use sector, do you have views on any better-fit regulatory models suitable for the effective and responsible regulation of synthetic biology?

The general framework of the regulation may be adequate but more attention needs to be paid to the novelty of synthetic biology applications and therefore the increased difficulties in predicting risk. For both synbio micro-organisms and GMMs more broadly the issue of scale of production has not been properly considered here (it is listed as a factor that must be taken into account in 2009/41/EC). Increased scale of production e.g. in bioreactors could lead to substantial discharges into the environment, with potentially devastating environmental consequences if anything goes wrong, or routing degradation of the environment for example through the release of anti-biotic marker genes. See comments under "other".

Q17(a) Do you have any views on any aspect of the preliminary impact assessment?

The preliminary impact assessment is completely meaningless because it does not estimate costs of increased risk of adverse impacts (such as the £100m Purbright FMD incident in 2007). This is difficult to do in the context of the current consultation because no information has been provided on what current and future applications will be affected by the proposed weakening of the regulations. More details should have been provided on this and some examples considered e.g. a significant release of antibiotic marker genes, or escape of GMMs

modified for biofuels production from cellulose (see comments under 'other' below).

Q17(b) Are there any costs or benefits related to the proposed changes which have not been included in the impact assessment? Please give details

Yes, all costs associated with increased risks of escape or ongoing discharges and impacts on the environment or human and animal health have been omitted. This leads to a baised outcome which does not serve the stated purpose of the Regulation to protect human health and the environment.

Q18(a) Do you have any objections to replacing the hardcopy of the guide to the regulations (L29) with an electronic online version (only)?

Yes	☐
No	☒

Q18(b) Please provide some comments to support your answer including any costs or benefits that this change may cause

Printing this out may add to costs for users, but an online copy is adequate for NGOs and members of the public who may wish to read the regulations.

Other

Do you have any other comments on the proposals covered by this Consultative document? Please provide comments if you wish

There are three main problems with the way the Regulations have been drafted: 1.The removal of certain requirements for containment levels for genetically modified micro-organisms (GMMs) has not been justified by reference to the claimed aim of maintaining standards of protection for human health and the environment. There is no monitoring to ensure that these legal objectives are met, which will become an increasingly important issue as production is scaled up and more novel traits are introduced (e.g. through synbio). There is also an ongoing lack of public information and consultation on risk assessments, which will become more important as applications move out of the laboratory e.g. into bioreactors;

2. The extra provisions in the CU Regulations that cover GM plants and animals ("larger GMOs") are deeply flawed. Since containment levels for non-GMMs are not defined (and are not proposed to be defined in the new Regulations), and environmental risk assessments are not included, the Regulations and the consultation lack any clear meaning for "larger GMOs". This means it is unclear when uses of GM insects might be allowed in polytunnels, or GM fish in tanks, or GM birds in sheds (especially if production is for broodstock rather than for food);

3. "Biological containment" is not included in 2009/41/EC and is open to misinterpretation.

In more detail:

For GMMs, the consultation relies on a comparison between 2009/41/EC and the Contained Use Regulations to argue that the European legislation has been "gold plated". The draft 2014 Regulations use the term "required where and to the extent the risk assessment shows it is required" in a number of places instead of the term "optional" in 2009/41/EC, and in all cases replace requirements for stricter measures in the earlier Regulations. The April 2013 HSE paper on consolidation: http://www.hse.gov.uk/aboutus/meetings/hseboard/2013/240413/paprb1333.pdf states in para 10 that "In particular, we need to identify if the consequence of any proposed changes would be to lower the protection provided to human health or the environment". However, no such information has been provided. We would expect to see some indications in the consultation of the actual applications (current and projected) being undertaken under the CU legislation, their assigned classes and the potential consequences for human health and the environment of weakening these containment measures. Since the April 2013 paper also states (para 4) that there is a consensus amongst scientific institutions that the standards are broadly adequate it is particularly hard to understand the motivation for weakening them. The HSE paper also notes that it was estimated that the FMD outbreak in 2007 cost the UK economy £100million, so it is surprising that potentially significant costs of weakening the regulations have not been considered: a major contamination incident could be extremely expensive. This is particularly important as research institutes and companies consider scaling-up contained use production of an increased range of industrial chemicals or biologics using GMMs or synthetic biology production systems. Examples of potential issues of concern might include: 1. Environmental risks associated with large-scale production of GMM or synthetic microbes designed to digest cellulose in bioreactors to produce biofuels, which could pose significant risks to the environment (i.e. by digesting woody materials) if they escape (see: http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Genewatch_Report_August_2009.pdf) . This may be a particular concern for synthetic biology applications, due to the increased complexity and novelty of potential traits; 2. Large scale escape of antibiotic resistance marker genes into the environment, potentially representing a source of antibiotic resistance in humans. (Chen et al. (2012): http://www.ncbi.nlm.nih.gov/pubmed/23215020).

In GeneWatch's view, the consultation represents a missed opportunity to introduce stricter measures for environmental monitoring and enforcement of containment requirements for GMMs under contained use, and for greater transparency and consultation. Such measures will become increasingly important as new larger-scale applications are introduced and the risk of escapes (discharges) as well as accidents increases. Instead the consultation proposes reducing oversight, so that only one person can sign off on risk assessments, rather than a committee, and removing some existing requirements for containment. It is important to note that NO CONTAINMENT MEASURES AT ALL may be applied to some "contained use" applications under the proposals in Schedule 7, Part 2. This is particularly problematic for Table 2 (Premises other than labs, plant growth facilities and animal units) where even the type of premise is unspecified (garages, bioreactors?). Plans for discharges from chemical plants etc. are normally published for public consultation, and discharges from bioreactors should meet the same standards in terms of public consultation and access to justice. The UK must comply with the Aarhus Convention on such matters.

In relation to GMOs other than GMMs, the consultation fails to note that 2009/41/EC covers only GM micro-organisms (GMMs) not "larger GMOs" (such as GM plants and animals). In addition, there is no recognition in the Consultation that the Contained Use Regulations cover "larger GMOs" only in

respect of human health risks, not environmental risks (see e.g. Part 2 Section 7 of the new draft 2014 Regulations), and that therefore it is impossible to set meaningful containment levels for "larger GMOs" under this legislation because users' duty to protect the environment (Environmental Protection Act 1990, Part VI) requires a separate risk assessment process. In GeneWatch's view, this should also be consulted on, consistent with the provisions of the Aarhus Convention. Users will also have to comply with additional legislation where applicable, such as plant pest licences issued by FERA in England and Wales under the Plant Health (England) Order 2005 (applicable for example to Oxitec's GM agricultural pests): such legislation is also relevant to setting containment requirements. "Contained Use" is wrongly defined in the draft regulations as providing "a high level of protection for human health and the environment", in fact this definition only works for GMMs since environmental risks of "larger GMOs" are not included and relevant powers do not exist under the Health and Safety at Work Act 1974. Similarly, the Classes of Contained Use defined in Schedule 1 apply to GMMs only (since they also refer to protection of the environment, which is not covered for non-GMMs) and Schedule 8 (Containment Measures) (as stated) applies to GMMs only. The SACGM Compendium of Guidance section on GM animals (part 5: http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part5.pdf) is incorrect since it states (paras 34 and 35) that: "It is recommended that the minimum containment measures that are necessary to protect the environment be set at this stage", yet the CU Regulations do not provide sufficient information (i.e. no environmental risk assessment or information about other requirements such as FERA licence conditions) or powers to set containment levels which protect the environment for "larger GMOs" (only health risks are considered). This fundamental problem has not been addressed in the consultation. It therefore remains unclear under what circumstances uses of GM insects might be allowed in polytunnels, or of GM fish in tanks, or GM birds in sheds (especially if the latter applications are to produce broodstock rather than food products which are covered by 1829/2003/EC).

There is an increasing amount of experimental "contained use" work being conducted on GM animals (including GM insects, GM fish and GM mammals and birds) some of which are highly mobile and may potentially have devastating effects on the environment. However, these issues cannot be resolved under the CU Regulations: environmental risk assessments are required. Suitability of confinement methods is considered in detail as part of the recommended assessment under 2001/18/EC for GM animals in EFSA's Guidance: http://www.efsa.europa.eu/en/efsajournal/doc/3200.pdf and must be considered when any application is scaled up.

Containment levels based on health risks alone may miss serious potential environmental risks e.g. the risk of GM salmon wiping out wild salmon (e.g. Aikio S, Valosaari K-R, Kaitala V (2008) Mating preference in the invasion of growth enhanced fish. Oikos 117(3):406–414; Muir WM, Howard RD. Possible ecological risks of transgenic organism release when transgenes affect mating success: Sexual selection and the Trojan gene hypothesis. PNAS. 1999;96(24):13853–13856). No information has been made available to stakeholders about any "larger GMO" product (such as GM fish eggs) that may be produced in tanks but could harm threatened species (e.g. wild Atlantic Salmon) if they escape. The costs of such losses (including impacts on the aquaculture and fishing industries) if containment measures are weakened have not been included in the Preliminary Impact Assessment. For GM animals (such as experimental GM pigs and chickens) which are engineered to be resistant to animal diseases (such as bird flu), it is widely recognised that serious risks could be posed if the GM animal acts as a silent reservoir of disease, or if the virus evolves in response to the genetic modification to become more virulent (e.g. EFSA, 2013, page 21: "*Furthermore, GM animals with enhanced resistance may act as vectors, carriers or reservoirs of pests/pathogens or may change the nature of pests/pathogens (e.g. change their virulence or resistance)*": http://www.efsa.europa.eu/en/efsajournal/doc/3200.pdf). Yet the Regulations refer only to the risk of acting as a human disease reservoir (Schedule 4, Part1, para2(b)) due to the exclusion of consideration of environmental risks for "larger GMOs" within the CU Regulations. There could be major (and costly) adverse consequences (e.g. spread of bird flu) if containment levels are set based only on an assessment of risks to human health. For GM insects, establishment of pests (e.g. .*Aedes albopictus* mosquitoes, or agricultural pests) will need to be considered before setting containment rules. Thus the Regulation is totally inadequate to set containment levels for non-GMMs and this

should have been acknowledged in the consultation.

A further problem arises in relation to "biological containment", which is exacerbated by the lack of any physical containment requirements for some applications, as noted above. "Biological containment" is not included in 2009/41/EC, but is included in the CU Regulation definition of "biological containment". GeneWatch UK is concerned about misleading industry definitions of "biological containment" as a means to avoid a full environmental risk assessment (being attempted by Oxitec for GM insects: http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Regnbrief_fin2.pdf and Aquabounty for GM fish: http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/GeneWatch_FDAfish_Feb13_fin.pdf). Measures to limit reproductive capacity are not 100% effective and do not prevent contact with the environment. Further, sterility mechanisms may not prevent gene transfer e.g. of anti-biotic resistance occurring on a large scale from bioreactors, with potentially serious adverse impacts on the environment and human and animal health. It is widely recognised that any method of "biological containment" requires an environmental risk assessment to assess its consequences and efficacy (see e.g. EFSA, 2013, as cited above). Limiting reproductive capacity is not the same as preventing contact with the environment and cannot replace the need for physical containment measures. Further, even if such products were genuinely "sterile" they could still have devastating effects on ecosystems through population suppression effects (such as the "Trojan gene" effect for fish cited above) as in some cases the release of sterile or semi-sterile organisms can actually increase (not reduce) risks to wild species. Limited reproductive capacity can actually increase some risks in some circumstances through population suppression effects on the wild species. The definition of "contained use" in the Regulations is in any case incorrect because it cannot apply to "larger GMOs" where the regulations cover only health, not environmental, impacts.

GeneWatch UK does not agree that the starting point of the consultation should be that the CU regulations are too burdensome. There are legal obligations to protect human health and the environment as "contained use" production of GMOs increases in the future. Many more sites and traits may be involved, at a larger scale, and it is critically important that loopholes such as the lack of published risk assessments (including consultation) and lack of monitoring and enforcement are properly addressed.

Is there anything you particularly like or dislike about this consultation? Please provide comments.

The Government consultation guidelines (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/255180/Consultation-Principles-Oct-2013.pdf) state (inter alia):

> Policy makers should be able to demonstrate that they have considered who needs to be consulted and ensure that the consultation captures the full range of stakeholders affected; and
>
> Sufficient information should be made available to stakeholders to enable them to make informed comments.

The consultation has been prepared with extensive input from licence-holders but virtually no input from the many stakeholders who could be affected by escapes of GMMs or synbio organisms (especially if produced on a large scale e.g. in bioreactors), or of GM plants/seeds from glasshouses or polytunnels (e.g. plants genetically engineered to produce industrial chemicals, biofuels or drugs), or of GM fish, chickens, pigs or insects. This might include e.g. the fishing industry, farmers, the general public. Further, no information has been provided on any of these products i.e. on either existing or likely future activities, making it difficult to participate in the consultation in a meaningful

way, and the structure of the proposals is flawed as described above.

It should have been made clearer to consultees that the CU Regulations contain no provisions to protect the environment from discharges or escapes of “larger GMOs” as environmental risk assessment does not fall within the scope of the regulations. There is no definition of containment classes for non-GMMs (which in any case cannot be set on purely health-related grounds), making the existing Regulation essentially meaningless for non-GMMs (which are in any case not covered by the European contained use Regulation 2009/41/EC). In the case of GMMs, any proposals to weaken the regulations should have been justified with evidence regarding the likely impacts on human and animal health and the environment and the costs of the increased risks of adverse incidents should have been included in the impact assessment.

Please send your response by 20 December 2013 to:

GMO Consolidation Team
Health and Safety Executive
5S2 Redgrave Court
Merton Road
Bootle
Liverpool
L20 7HS
Email: gmoconsolidation@hse.gsi.gov.uk

Thank you for taking the time to complete this questionnaire