

Report on HSE's consultation on proposals to amend the Genetically Modified Organisms (Contained Use) Regulations 2000 (CD231)

Background

1 Between March and May 2010 the Health and Safety Executive (HSE) consulted on proposals to amend the Genetically Modified Organisms (Contained Use) Regulations 2000 (S.I. 2000 No. 2831). The proposals addressed the views of the European Commission that aspects of the European Directive on the contained use of genetically modified organisms (GMOs) had not been fully implemented by the UK.

2 The Genetically Modified Organisms (Contained Use) Regulations 2000 implemented the requirements of European Directive 90/219/EC (as amended by Directive 98/81/EC) on the contained use of genetically modified organisms. These requirements are now consolidated into Directive 2009/41/EC.

3 In October 2007, the European Commission notified the UK of nine aspects of the Directive that it considered had not been fully implemented. The UK responded, defending its implementation, but, in November 2009, the Commission provided a reasoned opinion that it still considered that three aspects of the Directive had not been fully implemented. Legal advice was sought on the Commission's remaining concerns and, as a result, the UK gave an assurance that it would make the required legislative changes by October 2010.

4 To meet this assurance, HSE developed proposals to amend the existing legislation in Great Britain. Northern Ireland and Gibraltar developed their own proposals for making the required changes for the rest of the UK.

5 The proposals related only to the contained use of GMOs and not, for example, to releases of GMOs into the environment or the use of genetically modified (GM) products in food.

6 Genetic modification means altering the genetic material (either DNA or RNA) of an organism in way that does not occur naturally by mating and/or recombination. Typically, this involves the removal of DNA, its manipulation outside the cell and reinsertion into the same or another organism. The aim is often to introduce a new or altered characteristic to the target organism.

7 For the purposes of the Regulations 'contained use' covers any activity involving GMOs, which include genetically modified micro-organisms (GMMs), under the containment conditions laid down by the Regulations. Barriers are required to be in place to limit contact between GMMs and humans and the environment. These barriers can be provided by physical, biological or chemical means, or a combination of these. The intention is to provide a high level of safety for humans and the environment.

Consultation on proposals

8 Consultation on proposals for amending legislation (the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010) ran from 31 March to

31 May 2010 (CD 231). This was shorter than the normal twelve weeks but was considered necessary in order to meet the assurance on timescales given to the Commission.

9 The consultation was carried out electronically and the consultation document was made available on the HSE website along with an online response form. In order to allow duty holders the maximum opportunity to comment, the consultation document was also sent via e-mail to all organisations registered under the existing legislation. In addition, an e-mail alert was sent to other organisations with an interest in GM work.

10 DEFRA and the Scottish Executive, who are the Joint Competent Authorities for the existing legislation with HSE in England/Wales and Scotland respectively, were consulted on the proposals and were content.

Summary of responses

11 In all, seventeen organisations responded to the consultation. Six were universities, ten were companies engaged in work with, or research on, GMMs and one was a Government agency (these are listed at Annex 2). A more detailed analysis of the consultation responses is provided at Annex 1 but can be summarised as follows.

12 No objections to the proposals were received. Of the comments received, one suggested that clarification was needed for a term used in the regulations, and another suggested alternative wording for one of the proposed amendments. Three comments said that, in practice, there would be little or no additional impact or burden resulting from the changes.

13 Four comments were received on the Impact Assessment (IA) accompanying the proposals. Of these, three indicated that the impact of the changes would be minimal, and one that the IA and conclusions were appropriate. One response suggested that the IA offered sensible outcomes but there might be an unspoken expectation that more needed to be done on waste disposal than was the case.

14 The minor concerns raised during consultation can be addressed by clarifying the existing HSE guidelines in order to support the changes and explain what is expected of duty holders. Initially this can be done on the HSE website with changes to written guidance made the next time it is reviewed.

Recommendation

15 Because of the assurance given to the European Commission, and the results of the consultation exercise, it is recommended that the amendments to the existing legislation be made.

Craig Bell
Health and Safety Executive
August 2010

Analysis of responses for each question

Question 1 – Do you think that the proposed amendments to the regulations are clear?

1 The following responses were received for this question.

Numerical analysis

- Number of responses agreeing = 11
- Number of responses disagreeing = 2
- Number of responses that did not specifically answer this question = 4

Additional Comments

2 Five responses included additional comments. Of these, three considered that there would be little or no additional impact/burden/difficulty as a result of the proposals.

3 One comment suggested some alternative wording to the proposed amendments. These suggestions were passed on to our legal advisers. However the wording used reflected that in the Directive, so it was decided to keep the original wording to maintain compatibility.

4 One respondent considered that the term “parental micro-organism” to be misleading and needed stricter definition and clarification. Legal advice was that this could not be changed as this term originates in the Directive. However, if the proposed changes are made, HSE will clarify the definition in guidance (initially this will be online).

Question 2 – Do you agree with the assumptions and estimates used by HSE in the Impact Assessment and the conclusion reached on costs to duty holders?

5 The following responses were received for this question.

Numerical analysis

- Number of responses agreeing = 14
- Number of responses disagreeing = 1
- Number of responses that did not specifically answer this question = 2

Additional Comments

6 Five responses included additional comments. Of these, three comments indicated that there would be little or no additional impact or burden as a result of the proposals, and one that the impact assessment and conclusions were appropriate.

7 One respondent considered that the impact assessment offered sensible expected outcomes but that the proposed changes to specifically include waste management in the risk assessment could lead to additional unnecessary work. It is not intended that this should happen as the existing guidelines already cover the inclusion of waste management in the risk assessment. If the proposal changes are made, HSE will clarify this guidance to duty holders (initially this would be online).

Question 3 – Please provide any additional comments that you may have on the proposals

8 Four comments were received which are summarised below.

- It was unfortunate that the proposals to consolidate work with dangerous pathogens and GMs (known as the Single Regulatory Framework – SRF) could not be rolled out sooner. Assumption is that any changes resulting from this consultation will be carried forward into the SRF. A reply was sent thanking the contributor for the comments.
- The company in question only handled Class 1 GMOs and there were no additional signage requirements as a result. The risk assessment already covers the requirements regarding waste.
- Consultation clear, no major impacts. Most aspects already in place.
- Company's GMO safety committee believed these amendments to be relevant particularly the clarity given by the section on the waste generated in the use of GMOs.

9 The remaining 13 responses did not include any additional comments.

List of organisations who responded to consultation

Almac Group (UK) Ltd.
Biovital Research
Centre for Environment, Fisheries and Aquaculture Science (Cefas)
Croda Europe Ltd.
Eurofins Agrosience Services Ltd.
Evotec (UK) Ltd.
Moredun Research Institute
Novartis Vaccines and Diagnostics
Pfizer Ltd.
University College London
University College London, Royal Free Campus
University of Cambridge
University of Leicester
University of the West of Scotland
Wellcome Trust Sanger Institute

Two further participants asked for their responses to remain confidential.