EXPLANATORY MEMORANDUM TO

THE GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS 2014

2014 No. 1663

1. This explanatory memorandum has been prepared by the Health and Safety Executive (HSE) on behalf of the Department for Work and Pensions (DWP) and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

This instrument ("the 2014 Regulations") is intended to protect persons and the environment from contained use of genetically modified micro-organisms and to protect persons from contained use of larger genetically modified organisms (e.g. animals, plants, insects). The instrument consolidates and revokes the Genetically Modified Organisms (Contained Use) Regulations 2000 (SI 2000/2831) ("the 2000 Regulations"), the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002 (SI 2002/63), the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005 (SI 2005/2466) and the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010 (SI 2010/2840).

3. Matters of special interest to the Joint Committee on Statutory Instruments

None

4. Legislative Context

4.1 The 2014 Regulations implement Commission Directive 2009/41/EC of 6th May 2009 on the contained use of genetically modified micro-organisms ("the 2009 Directive"), with a view to protecting persons and the environment from the contained use of genetically modified micro-organisms. As in the 2000 Regulations, the 2014 Regulations also include domestic provisions to protect persons from the contained use of larger genetically modified organisms (e.g. animals, plants, insects), which removes the need for additional regulations. 'Contained use' means work in, for example, research, laboratories and commercial bioscience facilities, where the intention is to provide barriers to minimise contact with people and the environment. It does not concern the deliberate release of genetically modified plants or animals into the environment or to the use of genetically modified products in food and medicines.

4.2 The primary purpose of the 2014 Regulations is deregulatory in consolidating the 2000 Regulations (and amending regulations in 2002, 2005 and 2010) into a single set of regulations, and the opportunity has been taken to make the regulations more risk based and proportionate. The changes will assist users to comply with the regulations. This has involved aligning the requirements of the regulations more closely to Directive 2009/41/EC, with consequent removal of gold plating, whilst maintaining the necessary level of protection for persons and the environment. The Transposition Note is at Appendix 1.

4.3 The Regulations are made under powers conferred by the Health and Safety at Work etc. Act 1974 and the European Communities Act 1972.

4. 4 The scrutiny history of European Directive 2009/41/EC on the contained use of genetically modified micro-organisms and the implementing Genetically Modified Organisms (Contained Use) Regulations 2014 is at Appendix 2.

5. Territorial Extent and Application

5.1 This instrument applies to Great Britain. Northern Ireland will introduce equivalent legislation (The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015).

6. European Convention on Human Rights

6.1 As the instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background - What is being done and why

7.1 In 2011, Professor Löfstedt's report 'Reclaiming Health and Safety for All': An independent review of health and safety legislation' recommended that the Genetically Modified Organisms (Contained Use) Regulations 2000 and the three subsequent amendments should be consolidated as part of a general process of consolidating health and safety legislation. This was on the basis that the consolidation process should not reduce the health and safety protection afforded by the current regulations. The Government accepted this recommendation, and committed to delivering the revised regulations by the end of 2014.

7.2 The 2014 regulations retain the key provisions of the 2000 Regulations:

- An assessment of the risks to human health and the environment (or human health for larger GMOs) must be carried out before any contained use involving genetic modification of micro-organisms can commence and competent advice on that assessment must be sought;
- Before commencing a contained use with genetically modified organisms, notification to the competent authority is required in respect of the first use of a premises as well as low, moderate and high risk activities;
- The competent authority must examine notifications for compliance with the regulations and where content, issue consent for moderate and high risk activities;
- A person who undertakes contained use must observe safety principles and apply containment and control measures which are appropriate to that activity to afford protection to human health and the environment;
- Where accidents happen, the competent authority must be informed;
- The competent authority must maintain a register of the notifications, which should be made available for public inspection;
- The Regulations contain provisions relating to keeping certain information confident on grounds of national security;
- Provision of a range of powers to the competent authority to administer and enforce the regulations;
- Provision of a right of appeal for any person who is aggrieved by certain decisions of the competent authority.

7.3 The 2014 Regulations, remove areas of gold plating in the 2000 Regulations, where this is commensurate with the risks. The Regulations therefore are closely aligned with Directive 2009/41/EC and the requirements are risk based and proportionate. The

2014 Regulations incorporate changes to the provisions related to containment measures, notification and administrative arrangements. In addition, the language and layout of the regulations has been modernised and simplified. A summary of the changes is provided in Appendix 3.

7.4. **Consolidation**

The 2014 Regulations will revoke and replace the 2000 Regulations and the three amending sets of regulations from 2002, 2005 and 2010, with a single set of Regulations.

8. Consultation outcome

8.1 HSE carried out a public consultation exercise on the proposed 2014 Regulations. The consultation was preceded by extensive stakeholder engagement to inform the draft regulations and enabled the consultation to run for 8 weeks between 28 October to 20 December 2013. The consultation document and response form were made available on the HSE website http://www.hse.gov.uk/consult/condocs/cd263.htm

8.2 More than 4700 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 or via subscription to the HSE Biological Agents eBulletin.

8.3 HSE received a total of 42 responses to the consultation. The responses were received largely from stakeholders involved in genetic modification work or with health and safety responsibility for these activities. The proposals were positively received and supported by the majority of respondents (an average of 83% of responses supported the amendments to the containment measures). Where respondents disagreed, the points raised included matters for clarification and interaction with other legislation. These have been addressed in the guidance supporting the regulations. Respondents were most appreciative of the increased flexibility, the reflection of current working practices, which supports their application of the regulations and welcomed the changes where risk based selection had replaced prescriptive measures.

8.4 Since completion of the consultation, HSE has presented the findings from the consultation and proposed way forward, to key stakeholders in academia and industry (two separate meetings of regional biosafety officers in Cardiff (15 participants) and London (30 participants)) as well as a cross-Government/industry governance subgroup on synthetic biology. Participants in these meetings did not foresee any practical implementation issues and were content with the proposed consolidation.

8.5 The Secretary of State has policy responsibility for the control and regulation of genetically modified organisms. The Secretary of State and HSE act jointly as competent authority for the 2014 Regulations in England/Wales, and Scottish Ministers and HSE in Scotland. The competent authority have been consulted and are supportive of the 2014 Regulations.

9. Guidance

9.1 The feedback from consultation indicates several areas where guidance could be clarified and HSE has in conjunction with representatives from industry, revised the 'Guide to the Regulations' (L29). This will be published on the HSE website (http://www.hse.gov.uk/pubns/books/l29.htm) prior to the 2014 Regulations coming into force on 1 October 2014. The Regulations are also supported with technical

guidance on risk assessment and containment/control measures produced by the Scientific Advisory Committee on Genetic Modification (Contained Use). This guidance will also be updated and published on the HSE website as soon as available.

10. Impact

10.1 The 2014 Regulations are likely to provide a net cost saving to businesses of £110,000 per annum over a 10 year appraisal period. The impact on public sector organisations operating under the 2014 Regulations has been accounted for in this figure.

10.2 The final impact assessment for the 2014 Regulations will be published alongside the Explanatory Memorandum on www.legislation.gov.uk.

11 Regulating small business

11.1 The legislation applies to small businesses. Small businesses cannot be exempted as they are not exempt from the Directive.

11.2 Small businesses make up the largest proportion of organisations carrying out the lowest risk contained use of genetically modified micro-organisms (~44%). The 2014 Regulations do not introduce any new duties on business and make the regulatory requirements more risk based and proportionate, therefore having a positive impact on small businesses.

12 Monitoring & review

12.1 The regulations will be monitored by publishing the three yearly summary report required by the directive, for informing the European Commission on its implementation. The consolidation process is considered to have comprehensively reviewed the regulations. Given the extent of the monitoring arrangements for the 2014 Regulations, a further review clause is not deemed necessary.

13. Contact

13.1 Michael Paton at the Health and Safety Executive (Tel: 0151 951 3058 or email: michael.paton@hse.gsi.gov.uk) can answer any queries regarding the instrument.

Appendix 1 – Transposition Note

TRANSPOSITION NOTE FOR THE IMPLEMENTATION OF COMMISSION DIRECTIVE 2009/41/EC OF 6 MAY 2009 ON THE CONTAINED USE OF GENETICALLY MODIFIED MICRO-ORGANISMS.

These Regulations are called the **Genetically Modified Organisms (Contained Use) Regulations 2014**.

Article	**Purpose**	**Implementation**	**Responsibility**
Article 1	Subject matter of the Directive.	While no specific transposition of this Article is necessary, the Regulations cover its subject matter.	
Article 2(a)	Definition of "micro-organism"	Regulation 2(1)	
Article 2(b)	Definition of "genetically modified micro-organism"	Regulation 2(1) and Parts 1 and 2 of Schedule 2	
Article 2(c)	Definition of "contained use"	Regulation 2(1)	
Article 2(d)	Definition of "accident"	Regulation 2(1)	
Article 2(e)	Definition of "user"	Regulation 2(1)	
Article 2(f)	Definition of "notification"	No need to transpose (definition used for purposes of Directive)	
Article 3.1(a)	Scope – techniques excluded from scope	Regulation 3(1) and Part 3 of Schedule 2	Secretary of State.
Article 3.1(b)	Scope - excluded GMMs -	Regulation 26	
Article 3(2)	Scope – excluded activities	Regulation 3(3) and (4)	
Article 3(3)	Scope – excluded; contained use in scope of other EU legislation	Regulation 3(2)	
Article 4.1	Requires measures to be taken to avoid adverse effects which might arise from the contained use of GMMs.	Regulation 18(1)	As above

Article	Purpose	Implementation	Responsibility
Article 4.2	Requires the user to carry out a risk assessment.	Regulation 5 and Schedule 3	As above
Article 4.3	Risk assessment to result in a final classification	Regulation 5(2), Schedule 1 and Part 2 of Schedule 3.	As above
Article 4.4	Where there is doubt, the more stringent protective measures shall be applied unless agreed otherwise with competent authority	Regulation 19(2) and paragraph 4 of Schedule 3,	As above
Article 4.5	Risk assessment must take into account the disposal of waste and effluents and safety measures to be put into effect	Regulations 18(1) and 19(1) and Paragraph 1(e) of Schedule 3,	As above
Article 4.6	Requirements as to the record of the risk assessment	Regulation 7(2), paragraph (h)(i) of Schedule 5 and paragraph (n) of Schedule 6	As above
Article 5.1	Requirements to apply the general principles and appropriate protective measures	Regulations 18 and 19 and Schedules 7 and 8	As above
Article 5.2	Requirements to periodically review the protective measures	Regulations 7(1) and 19(3)	As above
Article 6	Requirements for use of premises for the first time	Regulation 9(1) and (2) and Schedule 5	As above
Article 7	Requirements for Class 1 contained use	Regulations 9(1) and 7(2)	As above
Article 8.1	Requirements for first and subsequent Class 2 contained uses	Regulations 10(1) and (2) and Schedule 6	As above
Article 8.2	Requirements for Class 2 or higher contained use where previous consent has been given	Regulations 10(5) - (7)	As above
Article	Provision to proceed with Class 2 contained use	Regulation 10(4)	As above

Article	Purpose	Implementation	Responsibility
8.3	where previous consent has not been given		
Article 9.1	Requirements for first and subsequent Class 3 & 4 contained uses	Regulation 11(1) & (2) and Schedule 6	As above
Article 9.2	Provisions controlling the start of Class 3 & 4 contained uses	Regulation 11(1), (4), and (5)	As above
Article 10.1	Member states to designate a competent authority to implement the measures in the Directive.	Regulation 2(1)	As above
Article 10.2	Required the competent authority to examine the accuracy and correctness of the notification	Regulation 23	As above
Article 10.3	Provisions relating to what the competent authority may require from the user.	Regulations 16, 24(1), 25	As above
Article 10.4	Exemptions when calculating time periods for when Class 2-4 contained uses may start.	Regulation 24(5)	As above
Article 11.1	Requires the user to notify the competent authority of any new information or modifications likely to have significant consequences in terms of risk posed.	Regulation 15	As above
Article 11.2	Further to Article 11.1, the competent authority may require the user to modify, suspend or terminate the contained use.	Regulation 25	As above
Article	Where appropriate, the	No transposition is	As above

Article	Purpose	Implementation	Responsibility
12	Member State may provide that the public is consulted.	necessary.	
Article 13.1	Requirement that an emergency plan is drawn up and made available to others.	Regulations 11(6), 21(1), (3) and (4) and 23(f)	As above
Article 13.2	Member states responsibilities to disseminate information to other member states.	No transposition is necessary	As above
Article 14.1	Requires the user to immediately inform the competent authority of any accident.	Regulation 22	As above
Article 14.2	Provisions relating to the information received on the accident.	Regulation 27	As above
Article 15(1)	Requires the Member State to inform other Member States and the Commission about any accident.	No transposition is necessary but see Regulation 27 for certain duties imposed on competent authority	As above
Article 15(2)	Duties imposed on Commission	No transposition is necessary	
Article 16	Requires the competent authority to ensure users comply with the Directive	Sections 16 – 26 and 33 – 42 of the Health and Safety at Work etc. Act 1974 together with regulation 30.	As above
Article 17	Requires the Member State to send reports to the Commission	No transposition is necessary	As above
Article 18	Provisions relating to confidential information in notifications.	Regulation 28(4) and (5). Common law duty of confidence.	As above
Article 19	Provisions for amendments to non-essential elements of the Directive	No transposition is necessary.	As above

Article	Purpose	Implementation	Responsibility
Article 20	Committees to assist the Commission	No transposition is necessary.	As above
Article 21	Repeals	No transposition is necessary.	As above
Article 22	Entry into force.	No transposition is necessary.	As above
Annex 1	Techniques of genetic modification that are within scope of the Directive and others that are not.	Schedule 2, Parts 1 and 2	As above
Annex 2, Part A	Techniques which are excluded from the Directive.	Schedule 2, Part 3	As above
Annex 2, Parts B and C	The criteria for establishing the safety of genetically modified micro-organisms for human health and the environment.	No transposition is necessary.	As above
Annex 3	The elements of and the procedure for the risk assessment.	Schedule 3	As above
Annex 4	Containment and other protective measures.	Regulations 8 and 18(2) Schedules 7 and 8	As above
Annex 5	Information required for notifications.	Schedules 5 and 6	As above

Appendix 2 - Scrutiny History

1. **Directive 90/219/EEC** was the subject of Commission proposals 8378/89, COM (89)409 and COM(88)160: Proposal and Modified Proposal for a Council Directive on the contained use of genetically modified micro-organisms. No scrutiny history is available for the proposal contained in COM(88)160. The modified proposal published as 8378/96, COM(89)409 was the subject of a Government explanatory memorandum submitted to parliament dated 26 June 1989.

2. Lords EU Scrutiny Committee: the modified proposal was cleared at the Chairman's sift on 3 July 1989 (Sift 647). Commons EU Scrutiny Committee: The modified proposal was cleared on 5 June 1989, Report 28, 88/89.

3. **Directive 98/81/EC** was the subject of a proposal from the Commission in document 5791/06, COM(95)640; Proposal for a Council Directive amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms. The Government submitted an explanatory memorandum to parliament dated 7 May 1996.

4. Lord EU Scrutiny Committee: Sifted the proposal to Sub-Committee C on 13 May 1996 (Sift 888) where it was cleared by the Sub-Committee on 11 June 1996. Commons EU Scrutiny Committee cleared the proposal on 15 May 1996, Report 19, 95/96.

5. Directive 2009/41/EC was the subject of Commission proposal 15782/07, COM(2007)736: Proposal for a Directive of the European Parliament and Council on the contained use of genetically modified organisms (recast). The government submitted an explanatory memorandum to parliament dated 18 December 2007.

6. Lords EU Scrutiny Committee: the proposal was cleared at the Chairman's sift on 15 January 2008. Commons EU Scrutiny Committee: The proposal was cleared on 9 January 2008, Report 7, 07/08.

Appendix 3 – Summary of changes in the 2014 Regulations

Summary of the change in the 2014 Regulations	
Changes to containment measures in Schedule 8	
Table 1a	Removal of duplicated requirement for disinfection procedures
Table 1a	Removal of requirement for inward airflow at containment level (CL) 2
Table 1a	Amendment of requirement for inward airflow where non-airborne transmission at CL3
Table 1a	Amendment of requirement for HEPA filtration where non-airborne transmission at CL3
Table 1a	Amendment of microbiological safety cabinet (MSC) requirement at CL4 – selection of most appropriate MSC based on the risk assessment
Table 1a	Amendment of requirement for waste inactivation at CL1
Table 1a	Amendment of requirement for an observation window at CL3
Table 1a	Amendment of requirement for training records at CL2
Table 1c	Removal of requirement for an incinerator for animal carcasses
Table 1c	Removal of the requirement for isolators at CL1
Table 2	Removal of duplicated requirement for decontamination facilities
Table 2	Removal of requirement for the controlled area to be purpose built at CL4
Table 2	Removal of requirement for biohazard sign at CL1
Table 2	Amendment of requirement for waste inactivation at CL1
Changes to administrative arrangements	
All	Amendments to the language/layout of the regulations
Regulation 2	Replacement of the term ‘genetically modified organisms other than micro-organism’ with the term ‘larger genetically modified organisms’
Regulation 8	Amendment to the requirements for a genetic modification safety committee – advice on Class 1 risk assessments can be provided by individuals with appropriate expertise
Regulation 21	Amendment of the requirement for an emergency plan – requirement risk based
Regulation 26	Removal of the requirement for a hardcopy of the public register of notifications – provision of an on-line version only
Regulation 31	Replacement and simplification of the appeals procedure with on-line guidance
Regulation 33	Amendment of the savings and transitional arrangements