

**2010 No. 343**

**HEALTH AND SAFETY**

**The Genetically Modified Organisms (Contained Use)  
(Amendment) Regulations (Northern Ireland) 2010**

*Made* - - - - *6th October 2010*

*Coming into operation* - *29th October 2010*

The Department of Enterprise, Trade and Investment(**a**), being the Department concerned(**b**), makes the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**c**) and by Articles 2(5), 17(1) to (5), 40(2) and (4) and 55(2) of, and paragraphs 1(1), (2), (3), (4) and (5), 3(1), 4, 5(1), 7(2), 8, 10, 12(1) and (3), 13, 14(1), 15 and 19 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978(**d**) (“the 1978 Order”).

The Department was designated(**e**) for the purposes of section 2(2) in relation to the control and regulation of genetically modified organisms.

The Regulations give effect without modifications to proposals submitted to it by the Health and Safety Executive for Northern Ireland under Article 13(1A) of the 1978 Order(**f**) after the Executive had carried out consultations in accordance with Article 46(3)(**g**).

**Citation and commencement**

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) (Amendment) Regulations (Northern Ireland) 2010 and shall come into operation on 29th October 2010.

**Interpretation**

2.—(1) In these Regulations, “the 2001 Regulations” means the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001(**h**).

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- (a) Formerly the Department of Economic Development; *see* S.I. 1999/283 (N.I. 1), Article 3(5); that Department was formerly the Department of Manpower Services, *see* S.I. 1982/846 (N.I. 11), Article 3
- (b) *See* Article 2(2) of S.I. 1978/1039 (N.I. 9)
- (c) 1972 c. 68; the enabling powers conferred by section 2(2) were extended by virtue of section 1 of the European Economic Area Act 1993 (c. 51). Section 2(2) was further amended by section 27(1), and paragraphs 2 and 3 of Schedule 2 by section 27(2), of the Legislative and Regulatory Reform Act 2006 (c. 51)
- (d) S.I. 1978/1039 (N.I. 9): the general purposes of Part II referred to in Article 17(1) were extended by S.I. 1992/1728 (N.I. 17), Articles 3(1) and 4(1), Article 55(2) was amended by S.I. 1998/2795 (N.I. 18), Article 6(1) and Schedule 1, paragraph 19
- (e) Article 13(1) was substituted by S.I. 1998/2795 (N.I. 18), Article 4
- (f) Article 13(1)
- (g) Article 46(3) was amended by S.I. 1998/2795 (N.I. 18), Article 6(1), and Schedule 1, paragraphs 8 and 18 and the Health Protection Agency Act 2004 (c. 17), Schedule 3, paragraph 10
- (h) S.R. 2001 No. 295, revoked in part by S.R. 2003 No. 167 and S.R. 2003 No. 510; amended by S.R. 2006 No. 524

(2) The Interpretation Act (Northern Ireland) 1954(a) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

**Amendment of the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001**

3.—(1) The 2001 Regulations shall be amended as follows.

(2) In paragraph 1 of Schedule 3, Part I—

- (a) omit the word “and” at the end of sub-paragraph (c);
- (b) for “.” substitute “; and” at the end of sub-paragraph (d); and
- (c) after sub-paragraph (d) insert—  
“ (e) the disposal of waste and effluents.”.

(3) In paragraph 3 of Schedule 3, Part II, after sub-paragraph (b) insert the following new sub-paragraph—

- “(ba) recognition that, in general, only activities involving genetically modified micro-organisms which show the following characteristics are appropriate for inclusion in class 1 as described in Schedule 1—
  - (i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants,
  - (ii) the nature of the vector and the insert is such that they do not endow the genetically modified micro-organism with a phenotype likely to cause disease to humans, animals, or plants, or likely to have deleterious effects on the environment, and
  - (iii) the genetically modified micro-organism is unlikely to cause disease to humans, animals or plants and is unlikely to have deleterious effects on the environment;”.

(4) In Schedule 8, in Table 1a, after Containment Measure number 9, insert—

“9A	Biohazard sign on door	not required	required	required	required”
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Sealed with the Official Seal of the Department of Enterprise, Trade and Investment on 6th October 2010.



*C. Lewis*  
A senior officer of the  
Department of Enterprise, Trade and Investment

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(a) 1954 c. 33 (N.I.)

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

1. These Regulations amend the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001 (S.R. 2001 No. 295) (“the 2001 Regulations”), as revoked in part by S.R. 2003 No. 167 and S.R. 2003 No. 510 and amended by S.R. 2006 No. 524. The 2001 Regulations aim to control risks arising from activities involving the contained use of genetically modified organisms and micro-organisms, and implemented in Northern Ireland Council Directive 90/219/EEC of 23 April 1990 (O.J. No. L117, 8.5.1990, p1) (“the 1990 Directive”), as amended by Commission Directive 94/51/EC (O.J. No. L297, 18.11.1994, p29), Council Directive 98/81/EC (O.J. No. L330, 5.12.1998, p13), Council Decision 2001/204/EC (O.J. No. L73, 15.3.2001, p32), Regulation (EC) No. 1882/2003 of the European Parliament and of the Council (O.J. No. L284, 31.10.2003, p1) and Commission Decision 2005/174/EC of 28 February 2005 (O.J. No. L59, 5.3.2005, p20). The 1990 Directive as amended has been recast as Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 (O.J. No. L125, 21.5.2009, p75).

2. Regulation 6(1) of the 2001 Regulations requires a person, before undertaking any activity involving genetic modification of micro-organisms, to ensure that an assessment of the risks to human health and the environment has been carried out. Regulation 6(2) requires a person carrying out such an assessment to take into account the matters set out in Part I of Schedule 3 to the 2001 Regulations. Regulation 3(2) of these Regulations amends Part I of Schedule 3 to add the disposal of waste and effluents to the list of matters to be taken into account.

3. Regulation 6(2) of the 2001 Regulations requires a person carrying out the risk assessment to include the steps set out in Part II of Schedule 3 to the 2001 Regulations. Regulation 3(3) of these Regulations amends Part II of Schedule 3 to add to the list of steps to be included consideration of the characteristics of genetically modified micro-organisms set out in new sub-paragraph (ba).

4. Table 1a in Schedule 8 to the 2001 Regulations sets out, by reference to the relevant containment level, the containment measures which any person undertaking an activity involving genetic modification of micro-organisms in a laboratory must apply. Regulation 3(4) of these Regulations inserts an additional containment measure into Table 1a.

5. A copy of the impact assessment prepared for the Regulations is held at the offices of the Health and Safety Executive for Northern Ireland, 83 Ladas Drive, Belfast BT6 9FR from where a copy may be obtained on request.

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