#### STATUTORY INSTRUMENTS

### 2010 No. 2840

## **HEALTH AND SAFETY**

# The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010

Made 25th November 2010 Laid before Parliament 30th November 2010 Coming into force 21st December 2010

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972(1) in relation to the control and regulation of genetically modified organisms(2).

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972 and by sections 15(1) and (2) and 82(3)(a) of, and paragraphs 1(1)(b) and (c) and (3), 6(1) and 13(1) of Schedule 3 to, the Health and Safety at Work etc. Act 1974(3) ("the 1974 Act").

The Regulations give effect without modifications to proposals submitted to the Secretary of State by the Health and Safety Executive under section 11(3) of the 1974 Act.

Before submitting those proposals to the Secretary of State, the Health and Safety Executive consulted the bodies that appeared to it to be appropriate as required by section 50(3) of the 1974 Act.

#### Citation and commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010 and come into force on 21st December 2010.

### Interpretation

2. In these Regulations, "the 2000 Regulations" means the Genetically Modified Organisms (Contained Use) Regulations 2000(4).

#### Amendment of the 2000 Regulations

**3.**—(1) The 2000 Regulations are amended as follows.

<sup>(1) 1972</sup> c.68.

S.I. 1991/755

<sup>1974</sup> c.37. Sections 15(1) and 50(3) were amended by the Employment Protection Act 1975 (c.71), Schedule 15, paragraphs 6 and 16 respectively. Section 15(1) was further amended by S.I. 2002/794. Section 50(3) was further amended by the Health Protection Agency Act 2004 (c.17), Schedule 3, paragraph 5(1) and (3) and by S.I. 2008/960, which also substituted section 11.

<sup>(4)</sup> S.I. 2000/2831, amended by S.I. 2005/2466; there are other amending instruments but none is relevant.

- (2) In paragraph 1 of Schedule 3—
  - (a) at the end of sub-paragraph (c) omit the word "and";
  - (b) at the end of sub-paragraph (d) for "." substitute "; and"; and
  - (c) after sub-paragraph (d) insert—
    - "(e) the disposal of waste and effluents.".
- (3) In paragraph 3 of Schedule 3, after sub-paragraph (b) insert the following new sub-paragraph
  - "(ba) recognition that, in general, only activities involving genetically modified microorganisms 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 cause 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 Table 1a in Schedule 8, after Containment Measure number 9 insert—

"9A	Biohazard sign on door	not required	required	required	required"
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Signed by authority of the Secretary of State for Work and Pensions.

C Grayling
Minister of State,
Department for Work and Pensions

25th November 2010

#### **EXPLANATORY NOTE**

(This note is not part of the Regulations)

These Regulations amend the Genetically Modified Organisms (Contained Use) Regulations 2000 (S.I. 2000/2831), as previously amended by S.I. 2001/2626, S.I. 2002/63, S.I. 2002/2443, S.I. 2005/2466, S.I. 2005/2759 and S.I. 2008/960 ("the 2000 Regulations"). The 2000 Regulations aim to control risks arising from activities involving the contained use of genetically modified organisms and micro-organisms, and implemented in Great Britain Council Directive 90/219/EEC of 23 April 1990 (OJ No L 117, 8.5.1990, p1) ("the 1990 Directive"), as amended by Commission Directive 94/51/EC (OJ No L 297, 18.11.1994, p29), Council Directive 98/81/EC (OJ No L 330, 5.12.1998, p13), Council Decision 2001/204/EC (OJ No L 73, 15.3.2001, p32), Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ No L 284, 31.10.2003, p1) and Commission Decision 2005/174/EC of 28 February 2005 (OJ No L 59, 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 (OJ No L 125, 21.5.2009, p75).

Regulation 6(1) of the 2000 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 2000 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.

Regulation 6(2) of the 2000 Regulations requires a person carrying out the risk assessment to include the steps set out in Part II of Schedule 3 to the 2000 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).

Table 1a in Schedule 8 to the 2000 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.

A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Health and Safety Executive's website (www.hse.gov.uk/ria/index.htm).

A copy of the transposition note relating to the implementation of the 1990 and 2009 Directives is available at www.hse.gov.uk/aboutus/europe/transposition/index.htm. Both of these documents are also annexed to the Explanatory Memorandum, which is available alongside the instrument on the OPSI website (www.opsi.gov.uk).