

**2005 No. 2466**

**HEALTH AND SAFETY**

**The Genetically Modified Organisms (Contained Use)  
(Amendment) Regulations 2005**

<i>Made</i>	- - - -	<i>4th September 2005</i>
<i>Laid before Parliament</i>		<i>9th September 2005</i>
<i>Coming into force</i>		
	<i>for the purpose of regulation 2(12) to 2(16)</i>	<i>1st January 2006</i>
	<i>for all other purposes</i>	<i>1st October 2005</i>

The Secretary of State, being the Minister designated(a) under section 2(2) of the European Communities Act 1972(b) in relation to the control and regulation of genetically modified organisms and in the exercise of the powers conferred upon him by the said section 2(2)(c) and sections 15(1) and (2) and 43(2), (4), (5) and (6) and 82(3)(a) of, and paragraphs 1(1)(b) and (c), (2), 11 and 15(1) of Schedule 3 to, the Health and Safety at Work etc. Act 1974(d) (“the 1974 Act”) and of all powers enabling him in that behalf and for the purpose of giving effect without modifications to proposals submitted to him by the Health and Safety Commission under section 11(2)(d) of the 1974 Act after the carrying out by the said Commission of consultations in accordance with section 50(3) of that Act, hereby makes the following Regulations:

**Citation and commencement**

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005 and for the purpose of regulation 2(12) to (16) shall come into force on 1st January 2006 and for all other purposes on 1st October 2005.

**Amendment of the Genetically Modified Organisms (Contained Use) Regulations 2000**

2.—(1) The Genetically Modified Organisms (Contained Use) Regulations 2000(e) shall be amended as follows.

(2) In regulation 2(1)—

(a) after the definition of “organism”, insert—

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(a) S.I. 1991/755.  
(b) 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).  
(c) As regards Scotland, see also section 57(1) of the Scotland Act 1998 (c.46), which provides that, despite the transfer to the Scottish Ministers by virtue of that Act of functions in relation to observing and implementing obligations under community law, any function of a Minister of the Crown in relation to any matter shall continue to be exercisable by him as regards Scotland for the purposes specified in section 2(2) of the European Communities Act 1972.  
(d) 1974 c.37; sections 11(2), 15(1) and 50 were amended by section 116 of, and paragraphs 4, 6 and 16 respectively of Schedule 15 to the Employment Protection Act 1975 (c.71).  
(e) S.I. 2000/2831, as amended by S.I. 2002/63.

“transboundary movement” has the meaning assigned to it by Article 3 of Regulation 1946/2003/EC of the European Parliament and of the Council on transboundary movements of genetically modified organisms<sup>(a)</sup>”.

(3) In regulation 3—

- (a) in (3)(a)(i)(aa), after the word “Ministers,” add “or, as regards Wales, by the National Assembly for Wales,”;
- (b) after (3)(a)(i)(aa), insert as a new (3)(a)(i)(bb), “a consent granted by the Northern Ireland Department of the Environment under article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991<sup>(b)</sup>, or”;
- (c) renumber the existing (3)(a)(i)(bb) as (3)(a)(i)(cc) and after “Article 13(4) of Council Directive 90/220/EEC” insert “or Article 15(3), 17(6), or 18(2) of Directive 2001/18/EC of the European Parliament and Council on the deliberate release into the environment of genetically modified organisms<sup>(c)</sup>”;
- (d) for (3)(a)(iii) substitute, “food or feed authorised in accordance with the provisions of Regulation 1829/2003/EC of the European Parliament and of the Council on genetically modified food and feed<sup>(d)</sup>”;
- (e) insert as (3)(a)(iv), “food products notified to the Commission in accordance with the provisions of Article 8.1, or feed products notified to the Commission in accordance with the provisions of Article 20.1, of Regulation 1829/2003/EC”;
- (f) in (3)(b),
  - (i) after the word “Ministers,” add “or, as regards Wales, by the National Assembly for Wales,”;
  - (ii) after “1990”, add “or the consent of the Northern Ireland Department of the Environment is required under article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991”.

(4) In regulation 13(1)—

- (a) in subparagraph (a) for the words “in both England and Scotland”, substitute “on the border of England and Scotland”; and
- (b) in subparagraph (b), for the words “both England and Scotland”, substitute “premises situated on the border of England and Scotland.”.

(5) In regulation 15—

- (a) in paragraph (2)(g), for the words “, provided that a notification has been submitted by him in accordance with”, substitute “and without prejudice to”;
- (b) in paragraph (3), for the words “subject to paragraphs (4) and (5)”, substitute “Without prejudice to regulation 11 and subject to paragraph (5)”;
- (c) omit paragraph (4); and
- (d) in paragraph (5)—
  - (i) for the words “Paragraph (4)”, substitute “Regulation 11”, and
  - (ii) after the words “regulation 11(1)(b) and”, insert “, but for this paragraph,”.

(6) In regulation 18(2), after “necessary”, insert “or practicable”.

(7) Omit regulations 22, 23 and 23A.

(8) In regulation 24—

- (a) in paragraph (3) for the words “regulation 22(2) (b) or shall be withheld under regulations 22(8)” substitute “ the provisions of the Environmental Information Regulations 2004<sup>(a)</sup> or the Environmental Information (Scotland) Regulations 2004<sup>(b)</sup>.”;

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(a) OJ L 287/1 5.11.2003.

(b) S.I. 1991/1714 (N.I.19).

(c) O.J. No. L106, 17.04.01, p.1 as supplemented by Commission Decision 2002/623/EC (O.J. L200, 30.07.02, p.22).

(d) OJ No. L268, 18.10.2003, p1.

(b) for paragraph (4) substitute—  
“(4) Information shall be entered in the register within 14 days of its receipt by the competent authority.”;

(c) omit paragraphs (5) and (9).

(9) In regulation 29—

(a) omit paragraph (3);

(b) for paragraph (8)(b)(ii), substitute the following—

“(ii) an appeal under paragraph (2)(a) or (b) against a request or instruction relating to—

(aa) the undertaking or proposed undertaking of an activity involving genetic modification in premises situate, or

(bb) premises which are the subject of a notification under regulation 9(1) and are situate,

wholly in Scotland or on the border between England and Scotland, as the case may be.”.

(10) Omit Regulation 30.

(11) In paragraph 2 of Schedule 6—

(a) omit the word “and” at the end of sub-paragraph (n)(vi);

(b) for sub-paragraph (o), substitute—

“(o) a copy of the assessment referred to in regulation 6(1); and

(p) whether the genetically modified organism is likely to be subject to transboundary movement.”.

(12) In Schedule 8, in Table 1a for point 17, substitute—

	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>
Inactivation of GMMs in contaminated material and waste	required by validated means	required by validated means	required by validated means, with waste inactivated within the laboratory suite	required by validated means, with waste inactivated within the laboratory”.

(13) In Schedule 8, in Table 1b point 3 (control of contaminated run-off water), for containment level 2, for the word “prevent” substitute “minimise”.

(14) In Schedule 8, in Table 1b point 6 (procedures for transfer of living material), for containment level 2, for the word “prevent” substitute “minimise”.

(15) In Schedule 8, in Table 1c for point 8, substitute—

	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>Additional</i>	
8	Animals kept in appropriate containment facilities, such as cages, pens or tanks but not isolators	required where and to the extent the risk assessment shows it is required	required where and to the extent the risk assessment shows it is required	required where and to the extent the risk assessment shows it is required	required where and to the extent the risk assessment shows it is required	Additional”.

(a) S.I. 2004/3391.

(b) S.I. 2004/520.

(16) In Schedule 8, in Table 1c, after point 8, insert—

		<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>Additional</i>
9	Animals kept in isolators	required where and to the extent the risk assessment shows it is required	required where and to the extent the risk assessment shows it is required	required	required	Additional”.

(17) In Schedule 11, paragraph 9(4), after “a solicitor” add “or any other person”.

(18) Omit paragraph 9(6) of Schedule 11.

### **Amendment of the Health and Safety (Fees) Regulations 2005**

**3.**—(1) Regulation 14 of the Health and Safety (Fees) Regulations 2005(**a**) shall be amended as follows.

(2) at the beginning of paragraph (1) insert “Subject to paragraph (1A) below”;

(3) after paragraph (1) insert—

“(1A) No Fee shall be payable by a notifier to the competent authority for a notification of an activity involving genetic modification in class 3 under regulation 11(1), or an application for the written agreement of that authority under regulation 18(2), of the 2000 Regulations in circumstances where—

(a) the notifier is of the view, and makes a statement in writing to the effect, that the containment measure for the activity in question has changed as a result of an amendment to any of the containment measures that has been effected by the Genetically Modified Organisms (Contained Use)(Amendment) Regulations 2005; and

(b) the application was submitted to the authority no later than 30 November 2005.”.

### **Revocation**

**4.** Regulation 5 of the Genetically Modified Organisms (Contained Use)(Amendment) Regulations 2002(**b**) is hereby revoked.

Signed by authority of the Secretary of State for Work and Pensions

4th September 2005

*Philip Hunt*  
Parliamentary Under-Secretary of State  
Department for Work and Pensions

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(a) S.I. 2005/676.  
(b) S.I. 2002/63.

## EXPLANATORY NOTE

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

1. These Regulations amend the Genetically Modified Organisms (Contained Use) Regulations 2000 (S.I. 2000/2831) (“the 2000 Regulations”), as amended by the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002 (S.I. 2002/63). The principal amendments are as follows.

2. Paragraph 7 of regulation 2 revokes regulations 22, 23 and 23A and paragraph 8 amends regulation 24. Paragraph 9(a) removes appeal provisions relating to regulations 22 and 23. Regulation 4 revokes the provision in the Genetically Modified Organisms (Contained Use) Regulations 2002, which inserted regulation 23A into the Genetically Modified Organisms (Contained Use) Regulations 2000. These amendments implement the provisions of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information (O.J. No. L41, 14.2.2003, p.26) and repealing Council Directive 90/313/EEC of 7 June 1990 on the freedom of access to information on the environment (O.J. No. L158, 23.6.1990, p. 56). The existing provisions in the 2000 Regulations implemented the provisions of Article 19 of Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms (O.J. No. L117, 8.5.1990, p. 1) as amended by Commission Directive 94/51/EC of 7 November 1994 (O.J. L297, 18.11.94, p. 29) and Council Directive 98/81/EC of 26 October 1998 (O.J. No. L330, 5.12.98, p. 13). These provisions have been superseded by Directive 2003/4/EC which is implemented by the Environmental Information Regulations 2004 (S.I. 2004/3391) and the Environmental Information (Scotland) Regulations 2004 (S.S.I. 2004/520).

3. Paragraph 10 of regulation 2 removes regulation 30 so that the Regulations are no longer extended outside Great Britain.

4. Paragraph 11 of regulation 2 requires additional information for notifications. This is necessary in order to fully comply with the requirements of Regulation 1946/2003/EC of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (O.J. No. L287, 5.11.2003, p. 1).

5. Paragraphs 12 to 16 of regulation 2 amend the containment levels for specified containment measures.

6. The remaining paragraphs of regulation 2 make changes to correct errors, including provisions for representation at appeals, provisions in respect of Wales and provisions for notifications and appeals relating to premises and activities that are situated partly in Scotland.

7. The Regulations also amend the Health and Safety (Fees) Regulations 2005 (S.I. 2005/676). Under regulation 3, no fee shall be charged in respect of notifications under regulation 11(1) or applications under regulation 18(2) of the 2000 Regulations that have arisen as a result of the changes to containment measures in regulation 2.

8. A copy of the regulatory impact assessment prepared in respect of these Regulations may be obtained from the Health and Safety Executive, Rose Court, 2 Southwark Bridge, London SE1 9HS. A copy has been placed in the library of each House of Parliament.





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