

2006 No. 524

HEALTH AND SAFETY

**The Genetically Modified Organisms (Contained Use)
(Amendment) Regulations (Northern Ireland) 2006**

Made - - - - *18th December 2006*

Coming into operation

*for the purpose of regulation 3(12)
to 3(16)*

1st May 2007

for all other purposes

1st February 2007

The Department of Enterprise, Trade and Investment(a), being the Department concerned(b), makes the following Regulations in exercise of powers conferred on it by Articles 17(1) and (2) and 40(2), (4) and 55(2) of and paragraphs 1(1), (2), 10, 14(1) and 15 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978(c) (“the 1978 Order”). It is a Department designated for the purposes of section 2(2) of the European Communities Act 1972(d) in relation to the control and regulation of genetically modified organisms(e). The Regulations give effect without modifications to proposals submitted to it by the Health and Safety Executive for Northern Ireland under Article 13(1A)(f) of the 1978 Order after the Executive had carried out consultations in accordance with Article 46(3)(g) of the 1978 Order.

Citation and Commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) (Amendment) Regulations (Northern Ireland) 2006 and for the purpose of regulation 3(12) to 3(16) shall come into operation on 1st May 2007 and for all other purposes on 1st February 2007.

Interpretation

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

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

(a) Formerly the Department of Economic Development; see S.I. 1999 No. 283 (N.I. 1), Article 3(5)
(b) See Article 2(2) of S.I. 1978 No. 1039 (N.I. 9)
(c) S.I. 1978 No. 1039 (N.I. 9)
(d) 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)
(e) S.I. 1991/755
(f) Article 13(1) was substituted by S.I. 1998 No. 2795 (N.I. 18), Article 4
(g) Article 46(3) was amended by S.I. 1998 No. 2795 (N.I. 18), Article 6(1) and Schedule 1, paragraphs 8 and 18
(h) S.R. 2001 No. 295
(i) 1954 c. 33 (N.I.)

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

- 3.—(1) The 2001 Regulations shall be amended as follows.
- (2) In regulation 2(1)—
- (a) after the definition of “organism”, insert—
““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(a)”; and
 - (b) the definition of “territorial waters” shall be omitted.
- (3) In regulation 3—
- (a) In (3)(a)(i)(bb) after “Article 13(4) of Council Directive 90/220/EEC” insert “or Articles 15(3), 17(6), or 18(2) of Directive 2001/18/EC of the European Parliament and Council(b)”;
 - (b) 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(c)”;
 - (c) 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 Council Regulation 1829/2003/EC”.
- (4) In regulation 15—
- (a) in paragraph (4), for the words “Subject to paragraphs (5) and (6)”, substitute “Subject to paragraph (5)”;
 - (b) in paragraph (5) for the words “Subject to paragraph (6), where a change referred to in paragraph (3)(a)”, substitute “Where a change referred to in paragraph (4)(a)”; and
 - (c) omit paragraph (6).
- (5) In regulation 18(2), after “necessary”, insert “or practicable”.
- (6) Regulations 22 and 23 shall be omitted.
- (7) In regulation 24—
- (a) for paragraph 1 there shall be substituted the following paragraph, namely—“This regulation is subject to regulation 24A.”;
 - (b) in paragraph (2), for the words “register referred to in paragraph (1)”, there shall be substituted the words—
“competent authority shall maintain a register of every notification submitted under regulations 9 to 12 and the register”;
 - (c) in paragraph (3), there shall be omitted the words “referred to in paragraph (1)”, and for the words “regulation 22(2)(b) or shall be withheld under regulation 22(8)” substitute “the provisions of the Environmental Information Regulations 2004(d).”;
 - (d) for paragraph (4) substitute—
“(4) Information shall be entered in the register within 14 days of its receipt by the competent authority.”;
 - (e) omit paragraph (5); and
 - (f) after paragraph (8), there shall be added the following paragraph, namely—
“(9) In this regulation “the register” means the register maintained by the competent authority in accordance with paragraph (2)”.

(a) O.J. L 287/1 5.11.2003

(b) 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).

(c) O.J. No. L268, 18.10.2003, p1.

(d) S.I. 2004 No. 3391.

(8) After regulation 24 there shall be inserted the following regulation, namely—

““Information not to be included in the register

24A.—(1) No information shall be included in the register if and so long as, in the opinion of the Department of Enterprise, Trade and Investment, the inclusion in the register of that information, or information of that description, would be a breach of confidentiality.

(2) For the purpose of securing the exclusion from the register of information to which paragraph (1) applies, the Department of Enterprise, Trade and Investment may give to the competent authority directions—

(a) specifying information, or descriptions of information, to be excluded from the register; or

(b) specifying descriptions of information to be referred to the Department of Enterprise, Trade and Investment for its determination.

(3) No information referred to the Department of Enterprise, Trade and Investment pursuant to paragraph (2)(b) shall be included in the register until the Department of Enterprise, Trade and Investment determines that it should be so included.

(4) The competent authority shall notify the Department of Enterprise, Trade and Investment of any information it excludes from the register in accordance with directions given to it under paragraph (2).

(5) A person may give a written notice to the Department of Enterprise, Trade and Investment —

(a) specifying information which appears to that person to be information to which paragraph (1) may apply; and

(b) indicating its apparent nature.

(6) If a person gives a written notice pursuant to paragraph (5), at the same time he shall give written notice to the competent authority that he has done so.

(7) No information notified pursuant to paragraph (5) shall be included in the register until the Department of Enterprise, Trade and Investment has determined that it shall be so included.

(8) In this regulation, “the Register” means the register maintained by the competent authority in accordance with regulation 24(2).”.

(9) In regulation 29 omit paragraph (3).

(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”

(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) Omit Schedule 11.

Amendment of the Health and Safety (Fees) Regulations (Northern Ireland) 2005

4.—(1) Regulation 10 of the Health and Safety (Fees) Regulations (Northern Ireland) 2005(a) shall be amended as follows.

(2) At the beginning of paragraph (1) insert the following words “Subject to paragraph (1A)”;

(3) after paragraph (1) there shall be inserted the following paragraph—

“(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 2001 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 (Northern Ireland) 2006; and

(b) the application was submitted to the authority no later than 1st April 2007.”.

Sealed with the Official Seal of the Department of Enterprise, Trade and Investment, on 18th December 2006

(a) S.R. 2005 No. 523



Michael J Bohill
A senior officer of the Department of Enterprise, Trade and Investment

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”). The principal amendments are as follows.

2. Paragraph 6 of regulation 3 revokes regulations 22 and 23 and paragraph 7 amends regulation 24. These amendments implement the provisions of Council 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 2001 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 Council Directive 2003/4/EC which is implemented by the Environmental Information Regulations 2004 (S.I. 2004/3391).

3. Paragraph 8 of regulation 3, inserts a new regulation, regulation 24A, which makes provision for the exclusion from the register, maintained in accordance with regulation 24 of the 2001 regulations, of information where, in the opinion of the Department of Enterprise, Trade and Investment the inclusion of such information in the register would be a breach of confidentiality.

4. Paragraph 10 of regulation 3 removes regulation 30 so that the 2001 Regulations no longer apply to territorial waters.

5. Paragraph 11 of regulation 3 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).

6. Paragraphs 12 to 16 of regulation 3 amend the containment levels for specified containment measures.

7. Regulation 4 amends the Health and Safety (Fees) Regulations (Northern Ireland) 2005 (S.R. 2005 No. 523). Under this regulation no fee shall be charged in respect of notifications under regulation 11(1) or applications under regulation 18(2) of the 2001 Regulations that have arisen as a result of the changes to containment measures in regulation 3.

8. In Great Britain the corresponding Regulations are the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005 (S.I. 2005/2446). The Great Britain Health and Safety Executive has prepared a regulatory impact assessment in relation to those Regulations. A copy of that assessment together with a Northern Ireland supplement prepared by the Health and Safety Executive for Northern Ireland is held at the offices of that Executive at 83 Ladas Drive, Belfast, BT6 9FR from where a copy may be obtained on request.