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STATUTORY RULES OF NORTHERN IRELAND

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**2015 No. 339**

**The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015**

**PART 1**

**Interpretation and General**

**Application**

**3.—(1)** These Regulations (except regulation 18) shall not apply to the genetic modification of organisms solely by any of the techniques referred to in Part 3 of Schedule 2 nor to any organisms so modified.

**(2)** These Regulations shall not apply to any activity in which—

**(a)** genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used, where such organisms are, or are contained in, a product marketed in accordance with—

**(i)** the consent of any of the following granted under section 111(1) of the Environmental Protection Act 1990<sup>(1)</sup>—

**(aa)** the Secretary of State;

**(bb)** the Scottish Ministers, as regards Scotland;

**(cc)** the Welsh Ministers, as regards Wales;

**(ii)** a consent granted by the Department of the Environment under Article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991<sup>(2)</sup>, or

**(iii)** a written consent given by the competent authority of an EEA State in accordance with Article 15(3), 17(6), or 18(2) of Directive (EC) No 2001/18 of the European Parliament and the Council on the deliberate release into the environment of genetically modified organisms<sup>(3)</sup>,

and, in each case, that activity is conducted in accordance with any conditions or limitations attached to that consent;

**(b)** genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used, where such organisms are, or are contained in—

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<sup>(1)</sup> 1990 c 43. The functions of the Secretary of State under section 111(1) are exercisable in relation to Scotland by the Scottish Ministers, by virtue of section 53 of the Scotland Act 1998 (c.46). The functions of the Secretary of State under section 111(1) are exercisable in relation to Wales by the Welsh Ministers. Those functions were originally conferred on the National Assembly for Wales under S.I. 1999/672, which was an Order in Council made under section 22 of the Government of Wales Act 1998 (c.38). Functions which had been conferred on the Assembly under an Order in Council under section 22 were transferred to the Welsh Ministers by virtue of paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c.32).

<sup>(2)</sup> S.I. 1991/1714 (N.I. 19)

<sup>(3)</sup> OJ No L 106, 17.04.2001, p1. Under Article 4.4 member States must designate a competent authority responsible for complying with the requirements of the Directive.

- (i) a medicinal product for human or veterinary use marketed in accordance with Regulation (EC) No 726/2004 of the European Parliament and the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>(4)</sup>; [<sup>F1</sup>or]
- (ii) food or feed authorised in accordance with the provisions of Regulation (EC) No 1829/2003 of the European Parliament and the Council on genetically modified food and feed<sup>(5)</sup><sup>F2</sup>...
- <sup>F3</sup>(iii) . . . . .  
[<sup>F4</sup>; or
- (iv) a medicinal product for human use marketed in accordance with the Human Medicines Regulations 2012;]
- (c) genetically modified organisms are released or marketed in cases or circumstances in which—
- (i) the consent of any of the following is required under section 111(1) of the Environmental Protection Act 1990—
- (aa) the Secretary of State;
- (bb) the Scottish Ministers, as regards Scotland;
- (cc) the Welsh Ministers, as regards Wales; or
- (ii) the consent of the Department of the Environment is required under Article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991.
- (3) Regulations 7, 9 to 17, 18(2) and (4), 19, 20 and 23 to 25 shall not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.
- (4) Regulation 5 shall apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air, except that, in making the assessment required by regulation 5(1), the person undertaking that assessment shall not be required to include the steps set out in paragraph 3(i) to (k) of Part 2 of Schedule 3.
- (5) In this regulation, “product” means a product consisting of, or containing, a genetically modified organism or a combination of genetically modified organisms.

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#### Textual Amendments

- F1** Word in reg. 3(2)(b)(i) inserted (31.12.2020) by The Health and Safety (Amendments and Revocation) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/330), regs. 1(2), **10(2)(a)**
- F2** Words in reg. 3(2)(b)(ii) omitted (31.12.2020) by virtue of The Health and Safety (Amendments and Revocation) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/330), regs. 1(2), **10(2)(b)**
- F3** Reg. 3(2)(b)(iii) omitted (31.12.2020) by virtue of The Health and Safety (Amendments and Revocation) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/330), regs. 1(2), **10(2)(c)**
- F4** Reg. 3(2)(b)(iv) and word inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 8 para. 14**; 2020 c. 1, Sch. 5 para. 1(1)

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- (4) OJ No L 136, 30.4.2004, p. 1 as amended by Regulation (EC) No 1901/2006 (OJ No L378 27.12.2006 p. 1), Regulation (EC) No 1394/2007 (OJ No L 324, 10.12.2007, p. 121), Regulation (EC) No 219/2009 (OJ No L87 31.3.2009, p. 109), Regulation (EC) No 470/2009 (OJ No L 152, 16.6.2009, p. 11), Regulation (EU) No 1235/2010 (OJ No L348, 31.12.2010, p 1) (which was corrected by Corrigendum, OJ No L 201, 27.7.2012, p 138) and Regulation (EU) No 1027/2012 (OJ No L 316, 14.11.2012, p38).
- (5) OJ No L268 18.10.2003, p 1 as amended by Regulation (EC) No 1981/2006 (OJ No L368, 23.12.2006 p 99) and Regulation (EC) No 298/2008 (OJ No L 97 9.4.2008, p 64).

**Commencement Information**

**II** [Reg. 3](#) in operation at 23.10.2015, see [reg. 1](#)

**Changes to legislation:**

There are currently no known outstanding effects for the The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015, Section 3.