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STATUTORY RULES OF NORTHERN IRELAND

2015 No. 339

HEALTH AND SAFETY

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

Made - - - - 18th September 2015
Coming into operation 23rd October 2015

The Department of Enterprise, Trade and Investment ("the Department")(**1**), is designated for the purposes of section 2(2) of the European Communities Act 1972 ("the 1972 Act")(**2**) in relation to the control and regulation of genetically modified organisms(**3**).

The Department, being the Department concerned(**4**) makes the following Regulations in exercise of the powers conferred by section 2(2) of the 1972 Act and Articles 2(5), 17(1)to (5)(**5**), 40(2), 40(4), 54(1) and (2) and 55(2) of, and paragraphs 1(1), (2), (3), (4) and (5), 2, 3(1), 4, 5, 7(2), 8, 10, 12(1) and (3), 13, 14(1), 15, 16 and 19 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978(**6**)("the 1978 Order").

The Regulations give effect without modifications to proposals submitted to the Department by the Health and Safety Executive for Northern Ireland under Article 13(1A)(**7**) of the 1978 Order after the Executive had carried out consultations in accordance with Article 46(3)(**8**) of the 1978 Order.

PROSPECTIVE

(**1**) 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
(**2**) 1972 c.68
(**3**) S.I. 1991/755
(**4**) *See* Article 2(2) of S.I. 1978/1039 (N.I. 9)
(**5**) Article 17 shall be read with S.I. 1992/1728 (N.I.17), Articles 3(2) and 4(2)
(**6**) 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
(**7**) Article 13(1A) was substituted by S.I. 1998/2795 (N.I. 18), Article 4
(**8**) 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), section 11 and Schedule 3 paragraph 10

PART 1

Interpretation and General

Citation and commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015 and shall come into operation on 23rd October 2015.

Commencement Information

I1 Reg. 1 in operation at 23.10.2015, see **reg. 1**

Interpretation

2.—(1) In these Regulations—

"the 1978 Order" means the Health and Safety at Work (Northern Ireland) Order 1978;

"the 2001 Regulations" means the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001(**9**);

"accident" means an incident involving a significant and unintended release of genetically modified organisms in the course of a contained use which presents an immediate or delayed hazard to human health or to the environment;

"class" in relation to a contained use involving micro-organisms, means one of the four classes set out in Schedule 1;

"competent authority" means the Department of the Environment and the Executive, acting jointly;

"contained use" means an activity in which organisms are genetically modified or in which genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which physical, chemical or biological barriers, or any combination of such barriers, are used to limit their contact with, and to provide a high level of protection for, humans and the environment;

"emergency plan" means a plan required by regulation 21;

"emergency services" means the police, fire and ambulance services;

"the Executive" means the Health and Safety Executive for Northern Ireland;

"genetic modification" in relation to an organism means the altering of the genetic material in that organism in a way that does not occur naturally by mating or natural recombination (or both) and within the terms of this definition—

(a) genetic modification occurs at least through the use of the techniques listed in Part 1 of Schedule 2; and

(b) the techniques set out in Part 2 of Schedule 2 are not considered to result in genetic modification

and "genetically modified" is to be construed accordingly;

"larger GMO" means an organism which is genetically modified or is the subject of genetic modification which is not a micro-organism;

(**9**) S.R. 2001 No.295. The 2001 Regulations and all amending instruments are revoked by these Regulations (see regulation 36).

"micro-organism" means a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, and includes a virus, a viroid, and an animal or plant cell in culture;

"notifier" means, except in regulation 14, the person who submits or has submitted a notification to the competent authority under regulation 9(2), 10(2), 11(2), 12(2) or 33(3);

"organism" means a biological entity capable of replication or of transferring genetic material and includes a micro-organism, but does not include a human, human embryo or human admixed embryo and for the purpose of this definition—

(a) "human admixed embryo" has the same meaning as in the Human Fertilisation and Embryology Act 1990(**10**) by virtue of section 4A(6) and (11) of that Act; and

(b) "human embryo" has the same meaning as "embryo" in the Human Fertilisation and Embryology Act 1990 (apart from section 4A) by virtue of section 1(1) and (6) of that Act;

"person responsible for contained use" or "person responsible for the contained use" means —

(a) a person who has the authority to determine whether a particular contained use takes place; or

(b) a person who has control of the planning or conduct (or both) of that contained use,

and there may be more than one person responsible for the same contained use;

"premises" means both single buildings and a site made up of more than one building;

"risk assessment" means, in the context of contained use involving—

(a) genetically modified micro-organisms, an assessment carried out as required by regulation 5(1); or

(b) larger GMOs, an assessment carried out as required by regulation 6(1);

"transboundary movement" has the meaning assigned to it by Article 3 of Regulation (EC) No. 1946/2003 of the European Parliament and the Council on transboundary movements of genetically modified organisms(**11**);

"user" means a person who undertakes or proposes to undertake a contained use;

"working day" means any day other than a Saturday, a Sunday, Christmas Day or Good Friday, or a bank holiday specified in Schedule 1 to the Banking and Financial Dealings Act 1971(**12**).

(2) In these Regulations —

(a) a reference to an appropriate containment level is a reference to the containment level assigned to a contained use involving micro-organisms in accordance with paragraphs 3(i) and 4 of Part 2 of Schedule 3;

(b) any reference to a contained use in a numbered class is a reference to a contained use involving micro-organisms which has been classified as belonging to the class of that number in accordance with paragraph 3(j) and (k) of Part 2 of Schedule 3.

(3) The measures in —

(a) Part 2 of Schedule 8 are to be applied in accordance with Part 1 of that Schedule; and

(b) Tables 1a, 1b and 1c in Part 2 of Schedule 8 are to be applied in accordance with the notes set out at the end of the table in question.

(**10**) 1990 c.37. Sections 1(1) and (6) were substituted by section 1(2) and (5) of the Human Fertilisation and Embryology Act 2008 (c.22) and section 4A was inserted by section 4(2) of that Act.
(**11**) OJ No L 287 5.11.2003, p. 1.
(**12**) 1971 c.80

(4) The Interpretation Act (Northern Ireland) 1954(**13**) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

Commencement Information

I2 Reg. 2 in operation at 23.10.2015, see **reg. 1**

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(**14**)—

(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(**15**), 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(**16**),

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—

(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(**17**);

(**13**) 1954 c.33 (N.I.)

(**14**) 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).

(**15**) S.I. 1991/1714 (N.I. 19)

(**16**) 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.

(**17**) 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).

(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(**18**); or

(iii) 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 (EC) No 1829/2003 of the European Parliament and the Council;

(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.

Commencement Information

I3 Reg. 3 in operation at 23.10.2015, see **reg. 1**

Meaning of "work" and "at work" and modification of the 1978 Order

4.—(1) For the purpose of these Regulations and Part I of the 1978 Order, the meaning of "work" shall be extended to include any contained use and the meaning of "at work" shall be extended accordingly.

(2) Articles 4(1), (2) and (3) and 8 of the 1978 Order shall be modified in relation to contained use as follows—

(a) those Articles have effect as if a reference to —

(i) an employer includes a reference to an educational establishment providing a course of study; and

(ii) an employee includes a reference to a student undertaking contained use in that educational establishment to the extent that the contained use is under the control of that educational establishment.

(3) Article 5(2) of the 1978 Order shall be modified in relation to contained use so as to have effect as if the reference in that Article—

(**18**) 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).