STATUTORY RULES OF NORTHERN IRELAND

2001 No. 295

HEALTH AND SAFETY

Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001

Made - - - -	*6th August 2001*
Coming into operation	*25th September 2001*

The Department of Enterprise, Trade and Investment(**1**), being a Department designated(**2**) for the purpose of section 2(2) of the European Communities Act 1972(**3**) in relation to the control and regulation of genetically modified organisms, in the exercise of the powers conferred on it by the said section 2(2) and, being the Department concerned(**4**), in exercise of the powers conferred by Articles 2(5), 17(1), (2), (3), (4) and (5)(**5**), 40(2) and (4) and 55(2) of, and paragraphs 1(1), (2), (4) and (5), 3(1), 4, 5(1), 7(2), 8, 10, 12(1) and (3), 13, 14(1), 15 and 19 of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978(**6**) and of every other power enabling it in that behalf, and for the purpose of giving effect without modifications to proposals submitted to it by the Health and Safety Executive for Northern Ireland under Article 13(1A) of that Order(**7**) after the carrying out by the said Executive of consultations in accordance with Article 46(3) of that Order(**8**), hereby makes the following Regulations:

Part I

Interpretation and General

Citation and commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001 and shall come into operation on 25th September 2001.

(**1**) Formerly the Department of Economic Development; *see* S.I. 1999/283 (N.I. 1), Article 3(5)
(**2**) S.I. 1991/755
(**3**) 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)
(**4**) *See* Article 2(2) of S.I. 1978/1039 (N.I. 9)
(**5**) Article 17 must 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), Article 3(1). Article 47A was inserted by Article 3, and Article 2 was amended by Articles 4 and 8, of S.I. 1997/1774 (N.I. 16)
(**7**) Article 13(1) was amended 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(*c*)

Interpretation

2.—(1) In these Regulations—

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

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

"activity involving genetic modification" means a contained use;

"class", in relation to an activity involving genetic modification of micro-organisms, means one of the four classes described 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;

"EEA State" means a State, other than the United Kingdom, which is a Contracting Party to the Agreement on the European Economic Area signed at Oporto on 2nd May 1992, as adjusted by the Protocol signed at Brussels on 17th March 1993(**9**) and adopted as respects the United Kingdom by the European Economic Area Act 1993(**10**);

"emergency plan" means a plan required by virtue of regulation 20;

"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 I of Schedule 2; and

(b) the techniques listed in Part II of Schedule 2 are not considered to result in genetic modification,

and "genetically modified" shall be construed accordingly;

"the Great Britain competent authority" means the joint competent authority defined in regulation 2(1) of the Genetically Modified Organisms (Contained Use) Regulations 2000(**11**);

"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 a person who has submitted a notification to the competent authority pursuant to regulation 9(1), 10(1), 11(1) or 12(1);

"organism" means a biological entity capable of replication or of transferring genetic material and includes a micro-organism, but does not include a human or a human embryo;

"territorial waters" means United Kingdom territorial waters adjacent to Northern Ireland and "within territorial waters" includes on, over and under them; and

(**9**) Cm 2073 and 2183
(**10**) 1993 c. 51
(**11**) S.I. 2000/2831

"working day" means any day other than a Saturday, a Sunday, Christmas Day or Good Friday, or a bank holiday within the meaning given by the Banking and Financial Dealings Act 1971(**12**).

(2) In these Regulations—

(a) in relation to an activity involving genetic modification, any reference to an appropriate containment level is a reference to the containment level assigned to that activity in accordance with paragraphs 3(*h*) and 4 of Part II of Schedule 3; and

(b) any reference to an activity involving genetic modification in a numbered class is a reference to an activity involving genetic modification of micro-organisms which has been classified as belonging to the class of that number in accordance with paragraph 3(*i*) and (*j*) of Part II of Schedule 3.

(3) The provisions in—

(a) Part II of Schedule 8 shall be applied in accordance with Part I of that Schedule; and

(b) Tables 1a, 1b and 1c in Part II of Schedule 8 shall be applied in accordance with the notes set out at the end of the Table in question.

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

Application

3.—(1) These Regulations shall have effect with a view to—

(a) protecting persons against risks to their health, whether immediate or delayed, arising from activities involving genetic modification of organisms; and

(b) protecting the environment against harm from activities involving genetic modification of micro-organisms.

(2) These Regulations (except regulation 17) shall not apply to the genetic modification of organisms solely by any of the techniques referred to in Part III of Schedule 2 nor to any organisms so modified.

(3) 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—

(i) a product marketed in pursuance of either—

(aa) a consent granted by the Department of the Environment under Article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991(**14**), or

(bb) a written consent given by the competent authority of an EEA State in accordance with Article 13(4) of Council Directive 90/220/EEC(**15**) on the deliberate release into the environment of genetically modified organisms,

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

(ii) a medicinal product for human or veterinary use marketed in accordance with Council Regulation (EEC) No. 2309/93(**16**), or

(**12**) 1971 c. 80
(**13**) 1954 c. 33 (N.I.)
(**14**) S.I. 1991/1714 (N.I. 19)
(**15**) O.J. No. L117, 8.5.90, p. 15, as amended by Commission Directive 94/15/EC (O.J. No. L103, 22.4.94, p. 20) and Commission Directive 97/35/EC (O.J. No. L169, 27.6.97, p. 72)
(**16**) O.J. No. L124, 24.8.93, p. 1, as amended by Commission Regulation (EC) 649/98 (OJ No. L88, 24.3.98, p. 7)

(iii) a novel food or novel food ingredient marketed in accordance with the provisions of Regulation (EC) No. 258/97 of the European Parliament and of the Council(**17**); or

(b) genetically modified organisms are released or marketed in cases or circumstances in which the consent of the Department of the Environment is required under Article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991.

(4) Regulations 8 to 15, 17(2) and (3), 18 and 19 shall not apply to the transport of genetically modified organisms by road, rail, inland waterway, sea or air.

(5) Regulation 6 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 6(1), the person undertaking that assessment shall not be required to include the steps set out in paragraph 3(*h*) to (*j*) of Part II of Schedule 3.

(6) In this regulation, "product" means a product consisting of or containing a genetically modified organism or a combination of genetically modified organisms.

Meaning of "work" and "at work"

4. For the purpose of these Regulations and Parts I and II of the 1978 Order, the meaning of "work" shall be extended to include any activity involving genetic modification and the meaning of "at work" shall be extended accordingly.

Modification of the Health and Safety at Work (Northern Ireland) Order 1978

5.—(1) Articles 4(1), (2) and (3) and 8 of the 1978 Order shall be modified in relation to an activity involving genetic modification so as to have effect as if the reference to an employer therein includes a reference to an educational establishment providing a course of study, and the reference to an employee therein includes a reference to a student of that educational establishment and that student shall be treated as the employee of that educational establishment, to the extent that the activity involving genetic modification is under the control of that educational establishment

(2) Section 5(2) of the 1978 Order shall be modified in relation to an activity involving genetic modification so as to have effect as if the reference in that section to a self-employed person is a reference to any person (except a student) who is not an employer or an employee and the reference in that section to his undertaking includes a reference to such an activity.

(3) In this regulation—

(a) "educational establishment" means a university, college, school or similar educational or technical institute; and

(b) "student" means any person studying at an educational establishment.

Part II

Risk assessment and notification of activities involving Genetic Modification

Risk assessment of activities involving genetically modified micro-organisms

6.—(1) A person shall not undertake any activity involving genetic modification of micro-organisms unless, before commencing that activity, he has ensured that a suitable and sufficient assessment of the risks created thereby to human health and the environment has been carried out.

(**17**) O.J. No. L43, 14.2.97, p. 1 (to be read with Corrigenda published in O.J. No. L173, 1.7.97, p. 12 and O.J. No. L187, 20.7.99, p. 74)

(2) The person carrying out an assessment required by paragraph (1) shall take into account the matters set out in Part I of, and include the steps set out in Part II of, Schedule 3.

Risk assessment of activities involving genetically modified organisms other than micro-organisms

7.—(1) A person shall not undertake any activity involving genetic modification of organisms other than micro-organisms unless, before commencing that activity, he has ensured that a suitable and sufficient assessment of the risks created thereby to human health has been carried out.

(2) The person carrying out an assessment required by paragraph (1) shall take into account the matters set out in Part I of, and include the steps set out in Part II of, Schedule 4.

Review and recording of risk assessments

8.—(1) Where—

(a) there is reason to suspect that an assessment is no longer valid; or

(b) there has been a significant change in the activity involving genetic modification to which an assessment relates,

the person undertaking the activity involving genetic modification to which the assessment relates shall ensure that the assessment is reviewed forthwith.

(2) The person undertaking an activity involving genetic modification—

(a) shall keep a record of the assessment relating to that activity, and any review of that assessment, for at least 10 years from the date of the cessation of that activity; and

(b) shall make such record available to the competent authority when requested to do so.

(3) In this regulation, "assessment" means an assessment carried out for the purposes of regulation 6 or regulation 7.

Notification of the intention to use premises for the first time for activities involving genetic modification

9.—(1) A person shall not use premises for the first time for the purpose of undertaking an activity involving genetic modification, unless—

(a) he has submitted to the competent authority a notification informing it of his intention to do so and containing the information specified in Schedule 5; and

(b) he has received an acknowledgement from the Executive of receipt of that notification.

(2) Within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1), the Executive shall send to the notifier an acknowledgement of receipt.

Notification of class 2 activities involving genetic modification of micro-organisms

10.—(1) Subject to the following paragraphs, a person shall not undertake an activity involving genetic modification of micro-organisms in class 2 unless he has submitted a notification to the competent authority informing it of his intention to do so and containing the information specified in Part I of Schedule 6.

(2) Within 10 working days of the competent authority receiving a notification submitted in accordance with paragraph (1), the Executive shall send to the notifier an acknowledgement of receipt.

(3) The competent authority shall ensure that any emergency plan has been prepared.