STATUTORY RULES OF NORTHERN IRELAND

2003 No. 167

EUROPEAN COMMUNITIES ENVIRONMENTAL PROTECTION

The Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003

Made - - - -	*12th March 2003*
Coming into operation	*15th April 2003*

The Department of the Environment, being a Department designated(**1**) for the purposes of section 2(2) of the European Communities Act 1972(**2**) in relation to measures relating to the control and regulation of genetically modified organisms, in exercise of the powers conferred by that section and Articles 3(4) and (5), 8(1), (4), (5), (7) and (11), 19(1) and (4) and 20(7) of the Genetically Modified Organisms (Northern Ireland) Order 1991(**3**), having consulted the Food Standards Agency in accordance with Article 22(5) of that Order, and of all other powers enabling it in that behalf, hereby makes the following Regulations:

PART I

GENERAL

Citation and commencement

1. These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003 and shall come into operation on 15th April 2003.

Interpretation

2.—(1) In these regulations –

"the Advisory Committee on Releases to the Environment" means the Committee appointed by the Department under Article 22A of the Order;

(**1**) S.I.1991/755
(**2**) 1972 c. 68
(**3**) S.I. 1991/1714 (N.I. 19). *See* Article 2(2) for the definition of "the Department". *See* Article 8(11) for the definition of "prescribed" in that Article

"antibiotic resistance markers" means genes employed in the modification of an organism to make that organism express resistance to a particular antibiotic or antibiotics;

"application for consent to release" shall include any notification made under the First Simplified Procedure (crop plants) Decision;

"approved product" means a product permitted to be marketed by a consent granted under Article 8(1) of the Order or in accordance with Article 15(3), 17(6) or 18(2) of the Deliberate Release Directive or Article 13(2) or (4) of the 1990 Directive;

"the Commission" means the European Commission;

"the Contained Use Directive" means Council Directive 90/219/EEC(**4**) on the contained use of genetically modified micro-organisms as amended by Commission Directive 1994/51/EC and Directive 98/81/EC;

"the Deliberate Release Directive" means Council Directive 2001/18/EC(**5**) on the deliberate release into the environment of genetically modified organisms;

"electronic communication" means the same as in the Electronic Communications (Northern Ireland) Act 2001(**6**);

"environmental risk assessment" means the environmental risk assessment required to be contained in an application for consent to release or market genetically modified organisms by regulation 11(1)(c) and regulation 16(2)(c);

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

"the First Simplified Procedure (crop plants) Decision" means Commission Decision 94//730/EC(**7**);

"genetically modified organisms" means a genetically modified organism or a combination of genetically modified organisms;

"higher plant" means a plant belonging to the taxonomic group *Spermatophytae* (*Gymnospermae* or *Angiospermae*);

"monitoring plan" means the plan required by regulation 16(2)(g);

"the Order" means the Genetically Modified Organisms (Northern Ireland) Order 1991;

"the register" means the public register kept by the Department under Article 19 of the Order;

"the 1990 Directive" means Council Directive 1990/220/EEC(**8**) on the deliberate release into the environment of genetically modified organisms as amended by Commission Directive 1994/15/EC(**9**) and Commission Directive 1997/35/EC(**10**);

"the 1994 Regulations" means the Genetically Modified Organisms (Deliberate Release) Regulations (NI) 1994(**11**);

(2) The Interpretation Act (Northern Ireland) 1954(**12**) shall apply to these regulations as it applies to an Act of the Northern Ireland Assembly.

(**4**) O.J. No. L117, 8.5.1990, p. 1
(**5**) O.J. No. L106, 17.4.2001, p. 1
(**6**) 2001 c. 9
(**7**) O.J. No. L292, 12.11.1994, p. 31
(**8**) O.J. No. L1117, 8.5.1990, p. 15
(**9**) O.J. No. L103, 22.4.1994, p. 20
(**10**) O.J. No. L169, 27.6.1997, p. 72
(**11**) S.R. 1994 No. 144 as amended by the Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations (Northern Ireland) 1995 (S.R. 1995 No. 413), the Genetically Modified Organisms (Deliberate Release and Risk Assessment) (Amendment) Regulations (Northern Ireland) 1997 (S.R. 1997 No. 534) and the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2001 (S.R. 2001 No. 295)
(**12**) 1954 c. 33 (N.I.)

Purpose of the Order and meaning of expressions used

3.—(1) Article 3 of the Order (purpose of Order and meaning of "genetically modified organisms" and related expressions) is amended as follows.

(2) For paragraph (1) there shall be substituted –

"(1) This Order has effect for the purpose of ensuring that all appropriate measures are taken to avoid damage to the environment which may arise from the escape or release from human control of genetically modified organisms.".

(3) In paragraph (4) (definition of organism which is genetically modified) for sub-paragraph (a) (modification of prescribed artificial technique) there shall be substituted –

"(a) have been artificially modified, or".

(4) After paragraph (4) insert –

"(4A) Genes or other genetic material in an organism are "artificially modified" for the purposes of paragraph (4) if they are altered otherwise than by a process which occurs naturally in mating or natural recombination.

This paragraph is subject to paragraphs (4B) and (4C).

(4B) For the purposes of paragraph (4) –

(a) genes or other genetic material shall be taken to be artificially modified if they are altered using such techniques as may be prescribed for the purposes of this sub-paragraph;

(b) genes or other genetic material shall not be regarded as artificially modified by reason only of being altered by the use of such techniques as may be prescribed for the purposes of this sub-paragraph.

(4C) An organism shall be taken not to be a genetically modified organism for the purposes of this Order if it is an organism of a prescribed description.

(4D) In paragraphs (4B) and (4C) "prescribed" means prescribed by regulations made by the Department.".

(5) Paragraphs (5) and (6) are omitted.

Meaning of "damage to the environment" etc

4.—(1) Article 4 of the Order (meaning of "damage to the environment" etc) is amended as follows.

(2) For paragraph (2) (meaning of "environment") substitute –

"(2) The "environment" includes land, air and water and living organisms supported by any of those media.".

(3) In paragraph (3) (meaning of "damage to the environment") omit "to the living organisms supported by the environment".

(4) For paragraph (6) (meaning of "harm") substitute –

"(6) "Harm" means any adverse effects as regards the health of humans or the environment.".

(5) For paragraph (9) (meaning of organism being under a person's "control") substitute –

"(9) Organisms of any description are under the "control" of a person where he keeps them contained by measures designed to limit their contact with humans and the environment and to prevent or minimise the risk of harm.".

(6) For paragraph (11) (meaning of organism being "marketed") substitute –

"(11) Genetically modified organisms of any description are "marketed" by a person when products consisting of or including such organisms are placed on the market by being made available to other persons, whether or not for consideration.".

Techniques of genetic modification

5.—(1) Until the coming into operation of the first regulations under Article 3(4B)(a)(**13**) of the Order, genes or other genetic material shall be taken, for the purposes of paragraph (4) of that Article to be artificially modified if they are altered using any of the following techniques:

(a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

(b) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

(c) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

(2) Until the coming into operation of the first regulations under Article 3(4B)(b) of the Order, genes or other genetic material shall not be regarded, for the purposes of paragraph (4) of that Article, as artificially modified by reason only of being altered by the use of any of the following techniques: –

(a) in vitro fertilisation,

(b) natural processes such as conjugation, transduction and transformation,

(c) polyploidy induction.

provided that such techniques do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques or methods other than –

(i) mutagenesis;

(ii) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

(3) Until the coming into operation of the first regulations under Article 4(4C) of the Order, an organism shall be taken, for the purposes of the Order, not to be a genetically modified organism if it is yielded from the techniques or methods listed in paragraph (2)(i) or (ii) provided that those techniques or methods did not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those made by techniques or methods listed in that paragraph.

Environmental risk assessment

6.—(1) An environmental risk assessment contained in an application for consent to release or market genetically modified organisms shall –

(a) identify and evaluate the potential damage to the environment, whether direct or indirect, immediate or delayed, which may arise from the release or marketing of genetically modified organisms,

(b) be carried out in accordance with Annex II of the Deliberate Release Directive and contain the conclusions required in section D of that Annex,

(**13**) Article 3(4) is amended by regulation 3(3) and Article 3(4A) to 4(4D) is inserted by regulation 3(4)

(c) include any bibliographic reference and indications of the methods used where applicable.

(2) Where the genetically modified organisms contain antibiotic resistance markers, the environmental risk assessment shall include an examination of the particular risks of damage to the environment which may be posed by the deliberate release or marketing of those genetically modified organisms.

Communication with applicant for consent

7.—(1) Wherever an applicant for consent or renewal of a consent to which these Regulations apply or a holder of such consent is required under these Regulations to submit any document in writing, he is required to submit that document in both a paper and in a commonly used electronic form.

(2) Wherever these Regulations require any communication from the Department to the applicant for a consent or renewal of a consent to be in writing, "writing" shall include an electronic communication.

(3) Any documents required by these Regulations to be in writing which do not fall within the provisions of paragraph (1) or (2) must be in paper form.

PART II

RELEASING ORGANISMS FOR ANY OTHER PURPOSE THAN MARKETING

Requirement for consent to release

8. The cases and circumstances prescribed for the purposes of Article 8(1)(a) of the Order in relation to the release of any genetically modified organisms are all cases and circumstances in which genetically modified organisms are intended to be released.

Exempt activities

9. The cases and circumstances prescribed for the purposes of Article 8(7) of the Order in which persons are exempt from the requirements of Article 8(1)(a) of the Order, insofar as those requirements apply to the release of genetically modified organisms, are all cases and circumstances in which the release is in accordance with a consent to market genetically modified organisms under Article 8(1)(a) of the Order or in which an approved product is released in accordance with the conditions and limitations to which the use of the product is subject.

Applications for consent to release genetically modified organisms – general provisions

10.—(1) An application for a consent to release genetically modified organisms must be made in writing to the Department.

(2) Proposed releases of the same genetically modified organism or of a combination of genetically modified organisms on the same site or on different sites for the same purpose and within a defined period may be notified in a single application.

(3) Where an application for a consent to release genetically modified organisms is expressed to rely on the First Simplified Procedure (crop plants) Decision, in the event of any inconsistency in the requirements as to information to be provided under that Decision and the requirements as to information to be provided under these Regulations, the provisions of that Decision shall prevail.