1994 No. 144

EUROPEAN COMMUNITIES

ENVIRONMENTAL PROTECTION

The Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 1994

Made . . . . . *12th April 1994*

Coming into operation . . *1st June 1994*

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SCHEDULES

1. Information to be contained in consent to release or market genetically modified organisms
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The Department of the Environment, being a Department designated(**a**) for the purposes of section 2(2) of the European Communities Act 1972(**b**), 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), 4(8), 8(1), (4), (5), (7) and (11), 19(1) and 20(7) of the Genetically Modified Organisms (Northern Ireland) Order 1991(**c**), and of all other powers enabling it in that behalf and being of the opinion that the techniques referred to in regulation 3(*c*) would produce organisms which should for the purposes of the said Order be treated as having been genetically modified, hereby makes the following regulations:

(**a**) S.I. 1991/755
(**b**) 1972 c. 68
(**c**) 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

PART I

GENERAL

Citation and commencement

1. These regulations may be cited as The Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 1994 and shall come into operation on 1st June 1994.

Interpretation

2.—(1) In these regulations—

"the Commission" means the Commission of the Communities;

"the Deliberate Release Directive" means Council Directive 90/220/EEC(**a**) on the deliberate release into the environment of genetically modified organisms;

"genetically modified organisms" includes a combination of genetically modified organisms;

"heritable genetic material" means genes or other genetic material, in any form, whether in cellular or sub-cellular entities, which are capable of being replicated or transferred by any means;

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

"product" means a product consisting of or including genetically modified organisms and "approved product" means a product marketed in pursuance of and in accordance with a consent or a consent given by another competent authority of a member State under Article 13(4) of the Deliberate Release Directive.

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

Artificial techniques of genetic modification

3. The following techniques are prescribed as artificial techniques for the purposes of Article 3(4) of the Order—

(*a*) the insertion by any method into a virus, bacterial plasmid or other vector system of a nucleic acid molecule, which has been produced by any method outside that virus, bacterial plasmid or other vector system, so as to produce a new combination of genetic material which is capable of being inserted into an organism in which that combination does not occur naturally and within which it will be heritable genetic material;

(*b*) the insertion into an organism, by micro-injection, macro-injection, micro-encapsulation or other direct means, of heritable genetic material prepared outside that organism;

(**a**) O.J. No. L117, 8.5.90, p. 15
(**b**) 1954 c. 33 (N.I.)

(*c*) the fusion (including protoplast fusion) or hybridisation, by any method that does not occur naturally, of 2 or more cells to form cells which have new combinations of heritable genetic material, and which (if derived solely from plant cells) cannot be produced by traditional breeding methods;

(*d*) where they involve the use of recombinant DNA molecules—

(i) *in vitro* fertilisation,

(ii) conjugation, transduction, transformation or any other natural process,

(iii) polyploidy induction.

Requirement to disregard capacity of certain organisms for causing harm, etc.

4.—(1) For the purposes of Articles 7(1), 9(5)(**a**) and (7)(*a*) and 14(1) of the Order there shall be disregarded—

(*a*) the capacity of genetically modified organisms of the description specified in paragraph (2) for causing harm of the description specified in paragraph (3), and

(*b*) harm, caused by genetically modified organisms of the description specified in paragraph (2), which is of the description specified in paragraph (3).

(2) The genetically modified organisms specified in this paragraph are genetically modified organisms which control—

(*a*) the number or activity (or both) of any organisms, or

(*b*) toxic wastes.

(3) The harm specified in this paragraph is harm caused to any organisms by genetically modified organisms which have been released or marketed in pursuance of and in accordance with—

(*a*) a consent, or

(*b*) a consent given by another competent authority of a member State under Article 13.4 of the Deliberate Release Directive.

PART II

RELEASE OF GENETICALLY MODIFIED ORGANISMS

Consent to release genetically modified organisms

5.—(1) Subject to paragraphs (3) and (4), the cases and circumstances prescribed under Article 8(1)(*a*) of the Order in relation to the release of any genetically modified organisms are any cases and circumstances other than the release of an approved product in accordance with the conditions and limitations to which the use of the product is subject.

(a) Article 9(5) is amended by regulation 9

(2) An application for consent to release genetically modified organisms must be made in writing to the Department, and must be made either—

(*a*) for one or more releases of one or more descriptions of genetically modified organisms on the same site for the same purpose within a limited period, or

(*b*) for one or more releases of one description of genetically modified organisms on one or more sites for the same purpose within a limited period.

(3) Paragraph (1) shall not apply to a person who—

(*a*) has, in accordance with regulation 5(1)(*a*) of the Genetic Manipulation Regulations (Northern Ireland) 1991(**a**), notified the Department of Economic Development of his intention to carry out an activity involving an intentional introduction into the environment, and

(*b*) carries out the activity in accordance with that notification before 29th August 1994.

(4) Paragraph (1) shall not apply to a person who releases a product which was marketed in the United Kingdom before 1st June 1994 and is not an approved product.

Information to be contained in application for consent to release

6.—(1) Subject to regulation 7 (exemptions from regulation 6), the following is the information which an application for a consent to release genetically modified organisms must contain—

(*a*) the information prescribed in Schedule 1, to the extent that such information is appropriate to the proposed release;

(*b*) information on data or results from any previous release of the same organisms, or of organisms of the same description, which has been carried out by the applicant, and information from any previous application for the release of the organisms, or of organisms of the same description, which the applicant has submitted to the Department under these regulations or to another competent authority of a member State under Article 5 of the Deliberate Release Directive;

(*c*) a statement evaluating the impacts and risks posed to human health and the environment by the release of the organisms;

(*d*) a statement whether the detailed description of the organisms and the details of the purpose for which the organisms will be released have been published, and the bibliographic reference for any information so published;

(*e*) a summary, in the format established by the Commission under Article 9.1 of the Deliberate Release Directive, of the information contained in the application.

(**a**) S.R. 1991 No. 238