#### STATUTORY RULES OF NORTHERN IRELAND

### 1997 No. 534

# EUROPEAN COMMUNITIES ENVIRONMENTAL PROTECTION

The Genetically Modified Organisms (Deliberate Release and Risk Assessment) (Amendment) Regulations (Northern Ireland) 1997

Made - - - - 11th December 1997
Coming into operation 30th January 1998

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 by Articles 5(7), 8(1), (4) and (7) of the Genetically Modified Organisms (Northern Ireland) Order 1991(3) and of all other powers enabling it in that behalf, hereby makes the following Regulations:

#### Citation, commencement and interpretation

- 1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release and Risk Assessment) (Amendment) Regulations (Northern Ireland) 1997 and shall come into operation on 30th January 1998.
- (2) The Interpretation Act (Northern Ireland) 1954(4) shall apply to these Regulations as it applies to a Measure of the Northern Ireland Assembly.

### Amendment of the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 1994

**2.**—(1) The Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 1994(**5**) shall be amended as provided by paragraphs (2) and (3).

<sup>(1)</sup> S.I.1991/755

<sup>(2) 1972</sup> c. 68

<sup>(3)</sup> S.I. 1991/1714 (N.I. 19). See Article 2(2) for the definition of "the Department"; see Articles 5(10) and 8(11) for the definition of "prescribed" in those Articles

<sup>(4) 1954</sup> c. 33 (N.I.)

<sup>(5)</sup> S.R. 1994 No. 144; regulation 10 was amended by S.R. 1995 No. 413, regulation 6(2)

- (2) In paragraph (1) of regulation 10 (consent to market products containing genetically modified organisms) there shall be added at the end the following sub-paragraph—
  - (c) the marketing of a novel food or novel food ingredient within the scope of Regulation (EC) No. 258/97 of the European Parliament and of the Council."(6).
  - (3) For Schedule 2 there shall be substituted the Schedule set out in the Schedule.

## Amendment of the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations (Northern Ireland) 1996

**3.** In the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations (Northern Ireland) 1996(7) in paragraph (2) of regulation 4 (exemptions from requirement to carry out risk assessments) there shall be added at the end the following sub-paragraph—

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(e) are or are contained in a novel food or novel food ingredient which is authorised for marketing in accordance with the provisions of Regulation (EC) No. 258/97 of the European Parliament and of the Council.".

Sealed with the Official Seal of the Department of the Environment on

L.S.

11th December 1997.

R. W. Rogers
Assistant Secretary

<sup>(6)</sup> O.J. No. L43, 14.2.97, p. 1. A Regulation of the European Parliament and of the Council concerning novel foods and novel food ingredients. The Regulation provides for specific environmental risk assessment of novel foods or novel food ingredients which contain or consist of genetically modified organisms

<sup>(7)</sup> S.R. 1996 No. 442

#### **SCHEDULE**

Regulation 2(3)

#### "SCHEDULE 2

Regulation 11

### INFORMATION TO BE CONTAINED IN AN APPLICATION FOR CONSENT TO MARKET GENETICALLY MODIFIED ORGANISMS

#### Part I

#### General Information

- 1. The name of the product and the name of the genetically modified organisms in the product.
- 2. The name and address in the Community of the manufacturer or distributor of the product.
- 3. The specificity of the product and the exact conditions of use including, where appropriate, the type of environment and/or the geographical areas within the Community for which the product is suited.
- 4. The type of expected use of the product and the description of the persons who are expected to use the product.
- 4a. Information relating to the introduced genetic modification which could be of relevance to the establishment of a possible register of modifications introduced into organisms (species). This may include nucleotide sequences or any other type of information which is relevant for inclusion in such a register.
- 4b. Information regarding proposed labelling which must include, in a label or an accompanying document, an indication that the product contains, or consists of, genetically modified organisms. In the case of products to be placed on the market in mixtures with non-genetically modified organisms, it is sufficient to indicate the possibility that genetically modified organisms may be present.

#### Part II

#### Additional Relevant Information

- 5. The measures to be taken in the event of the escape of the organisms in the product or misuse of the product.
  - 6. Specific instructions or recommendations for storage and handling of the product.
- 7. The estimated level and amount of production within the Community and the estimated level and amount of imports of the product into the Community.
- 8. Information regarding the proposed packaging for the product and its appropriateness so as to avoid the escape of genetically modified organisms during storage or at a later stage.
- 9. Information regarding proposed labelling including the proposals for stating, in full or summarised form, the information prescribed in paragraphs 1 to 3, 5 and 6."

#### **EXPLANATORY NOTE**

(This note is not part of the Regulations.)

These Regulations implement as respects Northern Ireland Commission Directive 97/35/EC (O.J. No. L169, 27.6.97, p. 72) adapting to technical progress for the second time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms, by amending the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 1994 (S.R. 1994 No. 144) (the 1994 Regulations).

Regulation 2(3) substitutes the Schedule for Schedule 2 to the 1994 Regulations.

In addition these Regulations amend the 1994 Regulations to take account of Regulation (EC) No. 258/97 (O.J. No. L43, 14.2.97, p. 1) concerning novel foods and novel food ingredients (the Novel Foods Regulation), with regard to the cases and circumstances in which a marketing consent is required under the 1994 Regulations.

These Regulations also amend the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations (Northern Ireland) 1996 (S.R. 1996 No. 442) to take account of the Novel Foods Regulation with regard to exemptions from the requirement to carry out risk assessments.

Copies of the Directive and Regulation and extracts from the Official Journal of the European Communities may be obtained from The Stationery Office, 16 Arthur Street, Belfast BT1 4GD.