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STATUTORY RULES OF NORTHERN IRELAND

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**1996 No. 250**

**HEALTH AND SAFETY**

**Genetically Modified Organisms (Contained Use)  
(Amendment) Regulations (Northern Ireland) 1996**

*Made* - - - - *25th June 1996*  
*Coming into operation* *29th July 1996*

The Department of Economic Development, the Department of Agriculture and the Department of the Environment being Departments designated<sup>(1)</sup> for the purposes of section 2(2) of the European Communities Act 1972<sup>(2)</sup> in relation to the control and regulation of genetically modified organisms, acting jointly in the exercise of the powers conferred on them by the said section 2(2), the Department of Economic Development, acting as the Department concerned<sup>(3)</sup>, in exercise of the powers conferred by Articles 17(1), (2), (4) and (5) of, and paragraphs 1(1) and (5), 3(1), and 14(1) of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978<sup>(4)</sup> and those Departments, in exercise of every other power enabling them in that behalf, after consultation with the Health and Safety Agency for Northern Ireland and such other bodies as appeared to them to be appropriate, hereby make the following Regulations:—

**Citation and commencement**

1. These Regulations may be cited as the Genetically Modified Organisms (Contained Use) (Amendment) Regulations (Northern Ireland) 1996 and shall come into operation on 29th July 1996.

**Interpretation**

2.—(1) In these Regulations, “the principal Regulations” means the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 1994<sup>(5)</sup>.

(2) The Interpretation Act (Northern Ireland) 1954<sup>(6)</sup> shall apply to these Regulations as it applies to a Measure of the Northern Ireland Assembly.

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(1) S.I.1991/755

(2) 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)

(3) See Article 2(2) of S.I. 1978/1039 (N.I. 9)

(4) S.I. 1978/1039 (N.I. 9)

(5) S.R. 1994 No. 143, to which there are amendments not relevant to these Regulations

(6) 1954 c. 33 (N.I.)

**Amendments to the principal Regulations**

3.—(1) The principal Regulations shall be amended in accordance with Schedule 1 to these Regulations.

(2) The Schedule set out in Schedule 2 to these Regulations shall be substituted for Schedule 2 to the principal Regulations.

Sealed with the Official Seal of the Department of Economic Development on

L.S.

13th June 1996.

*Suzanna Cooper*  
Assistant Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on

L.S.

25th June 1996.

*Liam McKibben*  
Assistant Secretary

Sealed with the Official Seal of the Department of the Environment for Northern Ireland on

L.S.

17th June 1996.

*R. W. Rogers*  
Assistant Secretary

## SCHEDULE 1

Regulation 3(1)

### Amendments to the Principal Regulations

1. The principal Regulations shall be amended in accordance with the following paragraphs of this Schedule.

2. In regulation 2—

(a) in paragraph (1)—

(i) after the definition of “activity involving genetic modification” there shall be inserted the following definition—

““the Agreement” means 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 and adopted as respects the United Kingdom by the European Economic Area Act 1993(7);”,

(ii) after the definition of “the Department” there shall be inserted the following definition—

““the European Economic Area” means the Area referred to in the Agreement;”,

(iii) after the definition of “genetic modification safety committee” there shall be inserted the following definition—

““member State” means a State which is a Contracting Party to the Agreement;”, and

(iv) for the definition of “organism” there shall be substituted the following definition—

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

(b) for paragraph (2), there shall be substituted the following paragraph—

“(2) Genetically modified organisms shall be classified—

(a) in the case of micro-organisms—

(i) as Group I micro-organisms if they satisfy all of the criteria set out in Part I of Schedule 2, or

(ii) as Group II micro-organisms if they do not satisfy all of the said criteria; or

(b) in the case of genetically modified organisms other than micro-organisms, as satisfying the criteria set out in Part II of Schedule 2 if they so satisfy those criteria.”.

3. For sub-paragraph (a) of paragraph (2) of regulation 6 there shall be substituted the following sub-paragraph—

“(a) genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of, 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 for Northern Ireland under Article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991(8); or

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(7) 1993 c. 51

(8) S.I. 1991/1714 (N.I. 19)

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(bb) a written consent given by another competent authority of a member State in accordance with Article 13(4) of Council Directive [90/220/EEC](#)(9) on the deliberate release into the environment of genetically modified organisms; and

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

(ii) a medicinal product for human or veterinary use marketed in accordance with Council Regulation [\(EEC\) No. 2309/93](#)(10); or”

4. At the end of paragraph (2) of regulation 8 but before the full stop, there shall be inserted a comma followed by the words—

“except that a separate notification shall not be required—

(a) where a consent has already been given under paragraph (3) for activities involving Group II micro-organisms and the premises are to be used for activities involving Group I micro-organisms; or

(b) where simultaneous notification is being given of an intention to use premises for activities involving both Group I and Group II micro-organisms”.

5. In sub-paragraphs (2)(b) and (4)(b) of regulation 9 for the words “Part III” in each place where they occur there shall be substituted the words “Part II”.

6. In paragraph 3(e) of Schedule 1 for the words “fulfil the criteria of Part III” there shall be substituted the words “satisfy the criteria of Part II”.

## SCHEDULE 2

Regulation 3(2)

Schedule to be Substituted as Schedule 2 to the Principal Regulations

## “SCHEDULE 2

Regulation 2(2)

Criteria for the Classification of Genetically Modified Organisms

## Part I

### Criteria for the classification of genetically modified organisms into Group I

A genetically modified micro-organism is classified into Group I when all of the following criteria are satisfied:—

(1) The recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants.

(2) The nature of the vector and the insert is such that they do not endow the genetically modified micro-organism with a phenotype likely to cause disease to humans, animals or plants, or likely to cause adverse effects in the environment.

(3) The genetically modified micro-organism is unlikely to cause disease to humans, animals or plants and is unlikely to cause adverse effects in the environment.

(9) O.J. No. L117, 8.5.90, p. 15

(10) O.J. No. L214, 24.8.93, p. 1

## Part II

### Criteria for the classification of organisms other than micro-organisms

An organism which satisfies the criteria of this Part is a genetically modified organism—

- (a) which is not a micro-organism; and
- (b) which is as safe in the containment facility as any recipient or parental organism.”

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### EXPLANATORY NOTE

*(This note is not part of the Regulations.)*

These Regulations amend the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 1994 (“the principal Regulations”) in the following ways—

#### **Paragraph 2(a) of Schedule 1**

1. Council Directive [90/219/EEC](#) (O.J. No. L117, 8.5.90, p. 1), on the contained use of genetically modified micro-organisms, implemented by the principal Regulations, applies to the States of the European Economic Area by virtue of the Agreement on the European Economic Area. A definition of “member State”, which includes those States, is, therefore, inserted into regulation 2(1) of the principal Regulations. Definitions of “the European Economic Area” and “the Agreement” are also inserted into that regulation.

2. The definition of “organism” in regulation 2(1) of the principal Regulations is amended to exclude humans and human embryos, which are outside the scope of the above Directive.

#### **Paragraphs 2(b), 5 and 6 of Schedule 1; Schedule 2**

3. Regulation 2(2) of, and Schedule 2 to, the principal Regulations are replaced, to implement the new classification criteria for micro-organisms contained in Commission Directive [94/51/EC](#) (O.J. No. L297, 18.11.94, p. 29), which adapts to technical progress Council Directive [90/219/EEC](#). There are minor consequential amendments to regulation 9 of, and paragraph 3(e) of Schedule 1 to, the principal Regulations.

#### **Paragraph 3 of Schedule 1**

4. By Article 5 of Council Directive [90/219/EEC](#), genetically modified micro-organisms marketed in accordance with other Community legislation providing equivalent risk assessment to that required under the said Directive are excluded from the scope of that Directive as regards storage, transport, destruction and disposal. The exemptions contained in regulation 6(2)(a) of the principal Regulations are extended to exclude from the prohibitions in regulation 6(1) certain medicinal products marketed in accordance with Council Regulation ([EEC](#)) No. [2309/93](#) (O.J. No. L214, 24.8.93, p. 1).

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#### **Paragraph 4 of Schedule 1**

5. Regulation 8(2) of the principal Regulations is amended to provide that a separate notification is not required where a consent for Group II micro-organisms has already been granted and it is intended to use the premises for activities involving Group I organisms, or where simultaneous notification is being given for activities involving Group I and II organisms at the same premises.