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STATUTORY RULES OF NORTHERN IRELAND

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**1996 No. 442**

**ENVIRONMENTAL PROTECTION**

**The Genetically Modified Organisms (Risk Assessment)  
(Records and Exemptions) Regulations (Northern Ireland) 1996**

<i>Made</i>	- - - -	<i>23rd September</i>
		<i>1996</i>
<i>Coming into operation</i>		<i>31st October 1996</i>

The Department of the Environment, in exercise of the powers conferred on it by Article 5(5) and (7) of the Genetically Modified Organisms (Northern Ireland) Order 1991(1), and of all other powers enabling it in that behalf, hereby makes the following regulations:—

**Citation and commencement**

1. These regulations may be cited as the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations (Northern Ireland) 1996 and shall come into operation on 31st October 1996.

**Interpretation**

2.—(1) In these regulations—

“the Contained Use Regulations” means the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 1994(2);

“the Order” means the Genetically Modified Organisms (Northern Ireland) Order 1991.

(2) Expressions used in these Regulations and in the Contained Use Regulations shall have the same meaning in these Regulations as in the Contained Use Regulations.

**Duty to keep records of risk assessments**

3. The period for which a person who carries out an assessment under Article 5(1)(a) of the Order (Risk assessment and notification requirements) shall keep a record of that assessment shall be ten years.

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

(2) S.R. 1994 No. 143; Relevant amending regulations are S.R. 1996 No. 250

### **Exemptions from requirement to carry out risk assessments**

4.—(1) A person who imports or acquires genetically modified organisms shall be exempt from the requirements of Article 5(1)(a) of the Order in so far as they relate to the protection of human health.

(2) A person who imports or acquires genetically modified organisms shall be exempt from the requirements of Article 5(1)(a) of the Order where the organisms to be imported or acquired—

- (a) are genetically modified micro-organisms;
- (b) are organisms, other than micro-organisms, which are modified by means of:—
  - (i) the application of the techniques which, by virtue of Part II of Schedule 1 to the Contained Use Regulations, are not considered to result in genetic modification; or
  - (ii) the application of the techniques to which, by virtue of regulation 3(3) of and Part III of Schedule 1 to the Contained Use Regulations, those Regulations do not apply;
- (c) are or are contained in a medicinal product for human or veterinary use which is the subject of a market authorisation under Council Regulation (EEC) No. 2309/93(3);
- (d) consist of, or are included in, an approved product as defined in the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 1994(4) which is imported or acquired in accordance with the conditions and limitations to which the use of the product is subject.

### **Revocation**

5. The Genetically Modified Organisms (Contained Use) (No. 2) Regulations (Northern Ireland) 1994(5) are hereby revoked.

Sealed with the Official Seal of the Department of the Environment on 23rd September 1996.

*R. W. Rogers*  
Assistant Secretary

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

(4) S.R. 1994 No. 144; Relevant amending regulations are S.R. 1995 No. 413

(5) S.R. 1994 No. 145

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## EXPLANATORY NOTE

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

These Regulations make provision in relation to Article 5(1)(a) of the Genetically Modified Organisms (Northern Ireland) Order 1991 (“the Order”) which restricts the import and acquisition, release and marketing of genetically modified organisms (“GMOs”).

They revoke and replace, with certain drafting changes, the Genetically Modified Organisms (Contained Use) (No. 2) Regulations (Northern Ireland) 1994 (S.R. [1994 No. 145](#)) and take account of amendments made to the Genetically Modified Organisms (Contained Use) Regulations 1994 (S.R. [1994 No. 143](#)) (“the 1994 Contained Use Regulations”) by the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1996 (S.R. [1996 No. 250](#)).

Regulation 3 prescribes the period for which records must be kept of risk assessments required to be carried out under Article 5(1)(a) of the Order before importing or acquiring GMOs.

Regulation 4 exempts persons who import or acquire GMOs from the requirements of Article 5(1)(a) of the Order where the GMOs to be imported or acquired:—

- (a) are genetically modified micro-organisms;
- (b) are organisms, other than micro-organisms, which are modified by means of:—
  - (i) the application of the techniques which, by virtue of Part II of Schedule 1 to the Contained Use Regulations, are not considered to result in genetic modification; or
  - (ii) the application of the techniques to which, by virtue of regulation 3(3) of and Part III of Schedule 1 to the Contained Use Regulations, those Regulations do not apply;
- (c) are or are contained in a medicinal product for human or veterinary use which is the subject of a market authorisation under Council Regulation ([EEC](#)) No. 2309/93;
- (d) consist of, or are included in, an approved product as defined in the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 1994 which is imported or acquired in accordance with the conditions and limitations to which the use of the product is subject.