1995 No. 413

EUROPEAN COMMUNITIES

ENVIRONMENTAL PROTECTION

The Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations (Northern Ireland) 1995

Made	*1st November 1995*
Coming into operation . .	*8th December 1995*

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 8(1), (4), (5) and (7) and 19(1) and (4) of the Genetically Modified Organisms (Northern Ireland) Order 1991(**c**), 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 (Deliberate Release) (Amendment) Regulations (Northern Ireland) 1995 and shall come into operation on 8th December 1995.

Interpretation

2.—(1) In these regulations "the 1994 Regulations" means the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 1994(**d**).

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

*Implementation of Commission Directive 94/15/EC(**f**)*

3.—(1) In regulation 2 of the 1994 regulations (interpretation), there shall be inserted after the definition of "heritable genetic material" the following definition—

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

(**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* Articles 8(11) and 19(4) for the definition of "prescribed" in those Articles
(**d**) S.R. 1994 No. 144
(**e**) 1954 c. 33 (N.I.)
(**f**) O.J. No. L103, 22.04.94, p. 20

(2) For sub-paragraph (*a*) of paragraph (1) of regulation 6 of the 1994 Regulations (information to be contained in an application for consent to release), there shall be substituted the following sub-paragraph—

"(*a*) the information prescribed in—

(i) Schedule 1, where the application is for consent to release any genetically modified higher plant; or

(ii) Schedule 1A, in any other case,

to the extent that such information is appropriate to the proposed release;".

(3) In paragraph (2) of regulation 6 of the 1994 Regulations, after "Schedule 1" there shall be inserted "and Schedule 1A".

(4) Paragraphs (3) and (4) of regulation 6 of the 1994 Regulations shall be deleted.

(5) For sub-paragraph (*a*) of paragraph (1) of regulation 11 of the 1994 Regulations (information to be contained in an application for consent to market), there shall be substituted the following sub-paragraph—

"(*a*) the information prescribed in—

(i) Schedule 1, where the application is for consent to market any genetically modified higher plant; or

(ii) Schedule 1A, in any other case,

to the extent that such information is appropriate to the nature and scale of the release which may result from the marketing,"

(6) In paragraph (2) of regulation 11 of the 1994 Regulations, after "Schedule 1" there shall be inserted "and Schedule 1A".

(7) Paragraphs (3) and (4) of regulation 11 of the 1994 Regulations shall be deleted.

(8) For Schedule 1 to the 1994 Regulations there shall be substituted the Schedules set out in the Schedule to these Regulations.

Amendment of the provisions relating to applications for consent to release

4.—(1) In regulation 2 of the 1994 Regulations (interpretation) there shall be inserted—

(*a*) the following definition—

" "application for a consent to release" shall include any notification made under the First Simplified Procedure (crop plants) Decision and cognate expressions shall be construed accordingly;";

(*b*) after the definition of "the Deliberate Release Directive" the following definition—

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

(2) In paragraph (2) of regulation 5 of the 1994 Regulations (consent to release organisms), after the words "the Department, and" there shall be

(a) O.J. No. L292, 12.11.94, p. 31

inserted the words, "unless made under and in accordance with the provisions set out in the First Simplified Procedure (crop plants) Decision,".

(3) In sub-paragraph (*a*) of paragraph (1) of regulation 6 of the 1994 Regulations after the words "appropriate to the proposed release" there shall be inserted the words "or application".

(4) In paragraph (1) of regulation 8 of the 1994 Regulations (advertisement of application for consent to release), for the words "Subject to paragraph (2)", there shall be substituted the words "Subject to paragraphs (1A) and (2)".

(5) After paragraph (1) of regulation 8 of the 1994 Regulations there shall be inserted the following new paragraph—

> "(1A) A notice published under paragraph (1) need not contain the information referred to in sub-paragraphs (*c*) and (*d*) insofar as the First Simplified Procedure (crop plants) Decision does not require that information to be submitted with the application and that information is not submitted with the application".

(6) In paragraph (3) of regulation 8 of the 1994 Regulations, after the words "the information prescribed in paragraph (1)(*a*) to (*d*)" there shall be inserted the words "save insofar as paragraph (1A) permits such information to be excluded from the notice referred to in paragraph (1)".

Amendment of the requirements for advertising applications for consent to release

5.—(1) In paragraph (1) of regulation 8 of the 1994 Regulations (advertisement of application for consent to release) for the words "not less than 14 days and not more than 28 days after the date of acknowledgement of receipt of that application is sent to him by the Department", there shall be substituted the words "not more than 10 days after he sends that application to the Department,".

(2) In paragraph (3) of regulation 8 of the 1994 Regulations—

(*a*) for the words "not less than 14 days and not more than 28 days after the date of acknowledgement of receipt of that application is sent to him by the Department,", there shall be substituted the words "not more than 10 days after he sends that application to the Department,";

(*b*) in sub-paragraph (*a*), for the words "the site of the proposed release," there shall be substituted the words "any site of a proposed release specified in the application for a consent to release,";

(*c*) sub-paragraphs (*b*), (*c*) and (*d*) shall be deleted.

Amendment of the cases and circumstances in which a marketing consent is required

6.—(1) In regulation 2 of the 1994 Regulations (interpretation), there shall be inserted immediately after the definition of "the Commission" the following definition—

" "the Contained Use Directive" means Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms(**a**);".

(2) In paragraph (1) of regulation 10 of the 1994 Regulations (consent to market products containing genetically modified organisms)—

(*a*) between the words "cases other than" and "the marketing of a product" there shall be inserted "(*a*)";

(*b*) after the words "the Deliberate Release Directive" there shall be inserted the following—

"; (*b*) the marketing of a product containing genetically modified micro-organisms within the meaning of Article 2 of the Contained Use Directive, the conditions of sale for which specify that it is to be used only in conditions of contained use in accordance with the Contained Use Directive; (*c*) the marketing of a medicinal product for human or veterinary use within the meaning of Council Regulation (EEC) No. 2309/93(**b**); (*d*) the marketing of an additive within the meaning of regulation 2(1) of the Feeding Stuffs Regulations (Northern Ireland) 1992(**c**) incorporated in or for incorporation in any feeding stuff within the meaning of that regulation.".

Amendment of provisions relating to keeping of the register

7.—(1) At the end of sub-paragraph (3)(*c*) of regulation 17 of the 1994 Regulations (information to be included in register) there shall be added the words "to the extent that this information is contained in the application for consent".

(2) At the end of sub-paragraph (3)(*e*) of regulation 17 of the 1994 Regulations (information to be included in register) there shall be added the words "to the extent that this information is contained in the application for consent".

(3) In paragraph (2) of regulation 18 of the 1994 Regulations (keeping of the register) for the words "14 days" there shall be substituted the words "12 days".

Sealed with the Official Seal of the Department of the Environment on 1st November 1995.

(L.S.) *John Crother*

Assistant Secretary

(a) O.J. No. L117, 08.05.90, p. 1

(b) O.J. No. L214, 24/08/93, p. 1. A Council Regulation laying down community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products. The Regulation provides for the specific risk assessment of medicinal products containing or consisting of genetically modified organisms

(c) S.R. 1992 No. 270, as amended by S.R. 1993 No. 349, S.R. 1994 No. 123 and S.R. 1994 No. 502. These Regulations implement Council Directive 70/524/EEC concerning additives in feeding stuffs (O.J. No. L270, 14.12.70, p. 1), as amended from time to time, in particular by Council Directive 93/114/EC (O.J. No. L334, 31.12.93, p. 24) which provides for the specific risk assessment of additives containing genetically modified organisms

SCHEDULE Regulation 3

"SCHEDULE 1 Regulations 6 and 11

Applications for Consent to Release or Market Genetically Modified Higher Plants

PART I

GENERAL INFORMATION

1. The name and address of the applicant and the name, qualifications and experience of the scientist and of every other person who will be responsible for planning and carrying out the release of the organisms and for the supervision, monitoring and safety of the release.

2. The title of the project.

PART II

INFORMATION RELATING TO THE PARENTAL OR RECIPIENT PLANT

3. The full name of the plant:

(*a*) family name,

(*b*) genus,

(*c*) species,

(*d*) subspecies,

(*e*) cultivar/breeding line,

(*f*) common name.

4. Information concerning—

(*a*) the reproduction of the plant:

(i) the mode or modes of reproduction,

(ii) any specific factors affecting reproduction,

(iii) generation time; and

(*b*) the sexual compatibility of the plant with other cultivated or wild plant species.

5. Information concerning the survivability of the plant:

(*a*) its ability to form structures for survival or dormancy,

(*b*) any specific factors affecting survivability.

6. Information concerning the dissemination of the plant:

(*a*) the means and extent of dissemination; and

(*b*) any specific factors affecting dissemination.

7. The geographical distribution of the plant.