
STATUTORY INSTRUMENTS

1995 No. 304

**The Genetically Modified Organisms
(Deliberate Release) Regulations 1995**

Citation and commencement

1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) Regulations 1995 and shall come into force on 8th March 1995.

Interpretation

2. In these Regulations “the 1992 Regulations” means the Genetically Modified Organisms (Deliberate Release) Regulations 1992(1).

Implementation of Commission Directive 94/15/EC(2)

3.—(1) In regulation 2 of the 1992 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;”.

(2) For sub-paragraph (a) of paragraph (1) of regulation 6 of the 1992 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 to these Regulations, where the application is for consent to release any genetically modified higher plant; or
- (ii) Schedule 1A to these Regulations, 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 1992 Regulations, after “Schedule 1” there shall be added “and Schedule 1A”.

(4) Paragraphs (3) and (4) of regulation 6 of the 1992 Regulations shall be deleted.

(5) For sub-paragraph (a) of paragraph (1) of regulation 11 of the 1992 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 to these Regulations, where the application is for consent to market any genetically modified higher plant; or
- (ii) Schedule 1A to these Regulations, in any other case,

(1) 1992/3280, amended by the Genetically Modified Organisms (Deliberate Release) Regulations 1993, S.I.1993/152.
(2) OJ No. L103, 22.4.94, p.20.

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 1992 Regulations, after “Schedule 1” there shall be added “and Schedule 1A”.

(7) Paragraphs (3) and (4) of regulation 11 of the 1992 Regulations shall be deleted.

(8) For Schedule 1 to the 1992 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 1992 Regulations (interpretation) there shall be inserted—

(a) after the definition of “the Act” 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) before the definition of “the Deliberate Release Directive”, the following definition—

““controlled waters” in relation to England and Wales, has the meaning given by section 104 of the Water Resources Act 1991(3) and, in relation to Scotland, the meaning given by s. 30A of the Control of Pollution Act 1974(4).”

(c) after the definition of “the Deliberate Release Directive” the following definition—

““the First Simplified Procedure (crop plants) Decision” means Commission Decision 94/730/EC(5);”.

(2) In paragraph (2) of regulation 5 of the 1992 Regulations (Consent to release organisms), after the words “the Secretary of State, and” there shall be 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 1992 Regulations after the words “appropriate to the proposed release” there shall be added the words “or application”.

(4) In paragraph (1) of regulation 8 of the 1992 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 1992 Regulations there shall be inserted the following new paragraph—

“(1A) A notice published under paragraph (1) above need not contain the information referred to in sub-paragraphs (c) and (d) of that paragraph 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 1992 Regulations, after the words “the information prescribed in paragraph 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 1992 Regulations (Advertisement of application for consent to release) for the words “not less than fourteen days and not more than twenty-eight

(3) 1991 c. 57.

(4) 1974 c. 40; section 30A is inserted by paragraph (4) of Schedule 23 to the Water Act 1989 (c. 15).

(5) OJ No. L292, 12.11.94, p.31.

days after acknowledgement of receipt of that application is sent to him by the Secretary of State,” there shall be substituted the words “not more than ten days after he sends that application to the Secretary of State.”

(2) In paragraph (3) of regulation 8 of the 1992 Regulations—

- (a) for the words “not less than fourteen days and not more than twenty-eight days after acknowledgement of receipt of that application is sent to him by the Secretary of State”, there shall be substituted the words “not more than ten days after he sends that application to the Secretary of State,”;
- (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), (d), (e), and (g) shall be deleted; and
- (d) at the beginning of sub-paragraph (f) there shall be added the words “if the proposed release may have an impact on any controlled waters,”.

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

6.—(1) In regulation 2 of the 1992 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(6);”.

(2) In paragraph (1) of regulation 10 of the 1992 Regulations (Consent to market products)—

- (a) between the words “cases and circumstances other than” and “the marketing of a product” there shall be inserted “(a)”;
- (b) after the words “the Deliberate Release Directive” there shall be added 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](#)(7); (d) the marketing of an additive within the meaning of regulation 2(1) of the Feeding Stuffs Regulations 1991(8) incorporated in or for incorporation in any feeding stuff within the meaning of regulation 2(1) as aforesaid.”.

Amendment of provisions relating to keeping of the register

7.—(1) at the end of sub-paragraph (3)(c) of regulation 17 (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,”

(6) OJ No. L117, 8.5.90, p.1.

(7) OJ No. L214, 24.8.93, 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.

(8) S.I. 1991/2840, as amended by S.I. 1993/1442, S.I. 1994/499 and S.I. 1994/2510. These Regulations implement Council Directive [70/524/EEC](#) concerning additives in feedingstuffs (OJ No. L270, 14.12.70, p.1.), as amended from time to time, in particular by Council Directive [93/114/EC](#) (OJ No. L334, 31.12.93, p.24.) which provides for the specific risk assessment of additives containing genetically modified organisms.

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(2) at the end of sub-paragraph (3)(e) of regulation 17 (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 1992 Regulations (Keeping of the register) for the words “fourteen days” there shall be substituted the words “twelve days”.

8th February 1995 *John Selwyn Gummer*
Secretary of State for the Environment

9th February 1995 *Angela Browning*
Parliamentary Secretary, Ministry of Agriculture,
Fisheries and Food

7th February 1995 *John Redwood*
Secretary of State for Wales

9th February 1995 *Hector Munro*
Parliamentary Under Secretary of State, Scottish
Office