STATUTORY RULES OF NORTHERN IRELAND

2019 No. 223

ENVIRONMENTAL PROTECTION

The Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations (Northern Ireland) 2019

Made - - - - 12th December 2019

Coming into force - - 6th January 2020

The Department of Agriculture, Environment and Rural Affairs, 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, makes these Regulations in exercise of the powers conferred by that section, and by Article 8(4) of the Genetically Modified Organisms (Northern Ireland) Order 1991(**3**), having consulted the Food Standards Agency in accordance with Article 22(5) of that Order.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations (Northern Ireland) 2019 and come into operation on 6th January 2020.

(2) The Interpretation Act (Northern Ireland) 1954(**4**) applies to these Regulations as it applies to an Act of the Assembly.

Amendment of the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003

2. The Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003(**5**) are amended in accordance with regulations 3 to 8.

Amendment of regulation 2

3. In regulation 2 (interpretation), for the definition of "the Deliberate Release Directive" there shall be substituted the following definition—

(**1**) S.I.2008/301.
(**2**) 1972 c. 68. Section 2(2) is amended by section 27(1) of the Legislative and Regulatory Reform Act 2006 (c. 51) and by section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c. 7).
(**3**) S.I.1991/1714 (N.I.19).
(**4**) 1954 c. 33(N.I.).
(**5**) S.R.2003/167

""the Deliberate Release Directive" means Council Directive 2001/18/EC(**6**) on the deliberate release into the environment of genetically modified organisms as amended by the Food and Feed Regulation, Council Regulation (EC) No 1830/2003(**7**) and by Commission Directive (EU) 2018/350 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms(**8**);".

Amendment of regulation 11

4. In regulation 11 (information to be contained in applications for consent to release)—

(a) in paragraph (1)(a)—

(i) before "the information" insert "subject to paragraph (1A),",

(ii) in paragraph (ii) omit from "to the extent" to the end,

(b) after paragraph (1)(d) insert—

"(e) summaries and results of studies referred to in the application, including an explanation of their relevance to the environmental risk assessment, as appropriate.",

(c) after paragraph (1) insert—

"(1A) The information specified in paragraph (1)(a) is only required to be provided if it is necessary for the completion of an environmental risk assessment in the context of a specific application, and the level of detail to be provided may vary according to the nature and the scale of the proposed deliberate release.".

Amendment of regulation 16

5. In regulation 16 (applications for consent to market)—

(a) in paragraph (2)(a)—

(i) before "the information" insert "subject to paragraph (2A)",

(ii) in paragraph (i), for "Schedule 1" substitute "Schedule 1A",

(iii) in paragraph (ii) omit from "to the extent" to the end,

(b) in paragraph (2), after sub-paragraph (j) insert—

"(k) in respect of each subset of information required in this paragraph—

(i) summaries and results of studies referred to in the application, including an explanation of their relevance to the environmental risk assessment, as appropriate,

(ii) details of studies referred to in the application, including materials and methods used or reference to standardised or internationally recognised methods and the name of the body or bodies responsible for carrying out those studies.".

(c) after paragraph (2) insert—

"(2A) The information specified in paragraph (2)(a) is only required to be provided if it is necessary for the completion of an environmental risk assessment in the context of a specific application, and the level of detail to be provided may vary according

(**6**) O.J. No. L106, 17.04.2001, p.1.
(**7**) O.J. No. L268, 18.10.2003, p.24.
(**8**) O.J. No. L67, 9.3.2018, p.30.

to the nature and the scale of the proposed release resulting from the marketing of a genetically modified higher plant.".

Amendment of Schedule 1

6.—(1) Schedule 1 (information to be included in applications for consent to release or market genetically modified higher plants) is amended as follows.

(2) In the title, for the words following "consent to release" substitute "genetically modified higher plants for non-marketing purposes".

(3) For the shoulder note substitute "Regulation 11".

(4) In paragraph 7, at the end insert "in Europe".

(5) In paragraph 8, for "in the United Kingdom" substitute "in Europe".

(6) For paragraph 15 substitute "Information on parts of the plant where the insert is expressed".

(7) After paragraph 15 insert—

"**15A.** The genetic stability of the insert and phenotypic stability of the genetically modified plant.

15B. Conclusions on the molecular characterisation of the genetically modified plant.".

(8) Omit paragraphs 16 and 17.

(9) For paragraphs 18 to 23 substitute—

"PART IVA

Information on specific areas of risk

18. Information on—

(a) any change to the persistence or invasiveness of the genetically modified plant and its ability to transfer genetic material to sexually compatible relatives and the adverse environmental effects arising,

(b) any change in the ability of the genetically modified plant to transfer genetic material to microorganisms and the adverse environmental effects arising,

(c) the mechanism of interaction between the genetically modified plant and target organisms, if applicable, and the adverse environmental effects arising,

(d) potential changes in the interactions of the genetically modified plant with non-target organisms resulting from the genetic modification and the adverse environmental effects arising,

(e) potential changes in agricultural practices and management of the genetically modified plant resulting from the genetic modification, if applicable, and the adverse environmental effects arising,

(f) potential interactions with the abiotic environment and the adverse environmental effects arising,

(g) any toxic, allergenic or other harmful effects on human health arising from the genetic modification,

(h) conclusions on the specific areas of risk.".

(10) Under the heading to Part V omit "(Applications for consent to release only)".

(11) Under the heading to Part VI omit "(Applications for consent to release only)".

(12) Under the heading to Part VII omit "(Applications for consent to release only)".

(13) For paragraph 35 substitute—

"**35.**—(1) A description of any precautions to maintain spatial and, as the case may be, temporal separation of the genetically modified plant from sexually compatible plant species.

(2) In sub-paragraph (1) "plant species" means—

(a) wild and weedy relatives, or

(b) crops.".

Insertion of Schedule 1A

7. After Schedule 1 insert—

"SCHEDULE 1A Regulation 16

Information to be included in applications for consent to 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 designation and specification of the genetically modified plant, and the scope of the application, in particular whether the application is in respect of cultivation, for some other use (which must be specified), or both.

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 or 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, including the distribution in Europe of the compatible 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 (such as an estimation of how viable pollen or seeds decline with distance where applicable) of dissemination, and

(b) any specific factors affecting dissemination.

7. The geographical distribution of the plant in Europe.

8. Where the application relates to a plant species which is not normally grown in Europe, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

9. Any other potential interactions, relevant to the genetically modified organism, of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

PART III

Information Relating to the Genetic Modification

10. A description of the methods used for the genetic modification.

11. The nature and source of the vector used.

12. The size, intended function and name of the donor organism or organisms of each constituent fragment of the region intended for insertion.

PART IV

Information relating to the genetically modified plant

13. A description of the trait or traits and characteristics of the genetically modified plant which have been introduced or modified.

14.—(1) The following information on the sequences inserted or deleted—

(a) the size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced into the genetically modified plant or any carrier or foreign DNA remaining in the genetically modified plant,

(b) the size and function of the deleted region or regions, where appropriate,

(c) the copy number of the insert,

(d) the subcellular location of any insert in the plant cells (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form) and methods for its determination,

(d) the organisation and sequence of the genetic material at each insertion site in a standardised electronic format,