

2019 No. 190

**EXITING THE EUROPEAN UNION, NORTHERN
IRELAND**

**ENVIRONMENTAL PROTECTION, NORTHERN
IRELAND**

**The Genetically Modified Organisms (Amendment) (Northern
Ireland) (EU Exit) Regulations 2019**

Sift requirements satisfied 16th January 2019

Made - - - - 31st January 2019

Laid before Parliament 7th February 2019

Coming into force in accordance with regulation 1

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(a).

The requirements of paragraph 3(2) of Schedule 7 to the European Union (Withdrawal) Act 2018 (relating to the appropriate parliamentary procedure for these Regulations) have been satisfied.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Amendment) (Northern Ireland) (EU Exit) Regulations 2019 and shall come into force on exit day.

(2) These Regulations extend to Northern Ireland only.

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

2.—(1) The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations (Northern Ireland) 1996(b) are amended as follows.

(2) In regulation 4(2)—

(a) in sub-paragraph (c), for the words from “for human or veterinary use” to the end substitute “which is authorised for marketing under the Human Medicines Regulations 2012(c) or the Veterinary Medicines Regulations 2013(d);”;

(a) 2018 c.16.

(b) S.R. 1996 No. 442, as amended by S.R. 1997 No. 534

(c) S.I. 2012 No. 1916

(d) S.I. 2013 No. 2033

- (b) for sub-paragraph (e) substitute—
 - “(e) consist of, or are included in, a product which has marketing consent immediately before exit day under Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms(a) or Directive 2001/18/EC on the deliberate into the environment of genetically modified organisms(b)—
 - (i) which is imported or acquired in accordance with the conditions and limitations on the use of the product specified in the consent, and
 - (ii) in the case of a consent for genetically modified carnations (*Dianthus caryophyllus*), where the product is imported or acquired within 10 years of the date on which the consent was issued;”.
- (c) after sub-paragraph (e) insert—
 - “(f) are genetically modified organisms which are approved for food or feed use in the United Kingdom.”.

The Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003

3.—(1) The Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003(c) are amended as follows.

- (2) In regulation 2(1)—
 - (a) in the definition of “approved product” substitute—
 - ““approved product” means a product—
 - (a) permitted to be marketed in Northern Ireland by—
 - (i) a consent granted under Article 8(1) of the Order; or
 - (ii) a consent granted under Section 111(1) of the Environmental Protection Act 1990(d); or
 - (iii) an authorisation under the Food and Feed Regulation; or
 - (b) which, immediately before exit day, was permitted to be marketed by a consent granted in accordance with Article 15(3) 17(6) or 18 of the Deliberate Release Directive or Article 13(2) or (4) of the 1990 Directive (a “pre-exit approved product”);”;
 - (b) omit the definition of “the Commission”;
 - (c) omit the definition of “the Contained Use Directive”;
 - (d) for the definition of “the Deliberate Release Directive” substitute—
 - ““the Deliberate Release Directive” means Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms as it applies immediately before exit day(e);”;
 - (e) in the definition of “the First Simplified Procedure (crop plants) Decision” insert at the end “as it applies immediately before exit before exit day”.
 - (3) In regulation 9, omit the words from “the release is” to “or in which”.
 - (4) In regulation 11(1)(d)—
 - (a) omit the words from “, in the format” to “Directive,”;
 - (b) at the end, insert “, in the relevant format set out in the Annex to Council Decision 2002/813/EC”.

(a) OJ No L 117, 8.5.1990, p. 15, as last amended by Commission Directive 97/35/EC (OJ No L 169, 27.6.1997, p. 72).
 (b) OJ No L 106, 17.4.2001, p. 1, as last amended by Commission Directive (EU) 2018/350 (OJ No L 67, 9.3.2018, p. 30)
 (c) S.R. 2003 No. 167, as amended by S.R. 2005 No. 272
 (d) 1990 c.43
 (e) OJ No. L106, 17.4.2001, p 1, as last amended by Commission Directive (EU) 2018/350 (OJ No L 67, 9.3.2018, p. 30)

- (5) In regulation 15—
- (a) the existing text becomes paragraph (1);
 - (b) in the new paragraph (1), after sub-paragraph (a) insert—
 - “(aa) a pre-exit approved product is marketed during the relevant period for which it had approval before exit day and in accordance with the limitations and conditions to which the use of that product was subject before exit day.”;
 - (c) for sub-paragraphs (b) and (c) substitute—
 - “(b) genetically modified organisms are made available for activities regulated under the Genetically Modified Organisms (Contained Use) Regulations Northern Ireland 2015(a);”;
 - (d) for sub-paragraph (e) substitute—
 - “(e) a genetically modified organism is marketed which is contained in a medicinal product authorised under the Human Medicines Regulations 2012 or the Veterinary Medicines Regulations 2013.”;
 - (e) omit sub paragraph (g);
 - (f) after new paragraph (1) insert—
 - “(2) For the purposes of paragraph (1), “the relevant period”, in relation to a pre-exit approved product, means the period beginning with exit day and ending on the day on which the consent concerned ceases to be valid.”.
- (6) In regulation 16(2)—
- (a) in sub paragraph (b)—
 - (i) for “European Union” substitute “United Kingdom”;
 - (ii) omit the words from “or to another competent authority” to the end;
 - (b) in sub paragraph (g), after “Directive” add “, as read with the guidance notes set out in Commission Decision 2002/812/EC.”;
 - (c) in sub paragraph (j), for the words from “established by the Commission” to the end substitute “set out in the Annex to Council Decision 2002/812/EC”.
- (7) In regulation 20—
- (a) omit sub paragraph (c);
 - (b) in sub-paragraph (f), omit the words from “and any comments made” to the end.
- (8) In regulation 21—
- (a) in paragraph (3), omit “and to the Commission”;
 - (b) for paragraph (6) substitute—
 - “(6) Information submitted in accordance with paragraph (5) shall be provided in the format set out in the Annex to Commission Decision 2003/701/EC.”.
- (9) In regulation 23—
- (a) in paragraph (1)—
 - (i) for sub-paragraph (b) substitute—
 - “(b) invite any person, by means of a request placed on the register, to make representations to the Department relating to a risk of damage being caused to the environment by the marketing before the end of a period to be specified, which shall not be less than 60 days from the date the application was received by the Department.”;
 - (ii) for sub-paragraph (e) substitute—

- “(e) take into account any representations relating to risks of damage being caused to the environment by the marketing made to the Department before the end of the period specified in accordance with paragraph (b);”;
- (b) omit paragraph (2);
- (c) in paragraph (3), “for paragraphs (1) and (2)” substitute “paragraph (1)”;
- (d) omit paragraph (4).
- (10) In regulation 24,
- (a) for paragraphs (1) to (4) substitute—
- “(1) The Department must not grant consent to market genetically modified organisms under Article 8(1) of the Order as it relates to the protection of human health without the agreement of the Health and Safety Executive Northern Ireland.
- (2) The Department must not grant or refuse consent to market genetically modified organisms before the end of the period specified for representations in accordance with regulations 23 (b) and (e) and, if any representations referred to in regulation 20(e) are received within that period, before it has considered those representations.
- (3) The Department must communicate the decision on an application for a consent to market genetically modified organisms to the applicant before the end of a period of 90 days beginning with the day on which the application was received, and shall include in any refusal of consent the reasons for that refusal.
- (4) The period prescribed in paragraph (3) must not include—
- (a) any period beginning with the day on which the Department gives notice in writing under Article 8 (6) of the Order that further information in respect of the application is required and ending on the day on which that information is received by the Department, or
- (b) any period of time during which the Department is considering representations submitted by any persons in accordance with regulation 23 (b), provided that this consideration shall not prolong the 90 day period referred to in paragraph (3) by more than 30 days.”.
- (b) in paragraph (5)—
- (i) omit “under the relevant EU provisions”;
- (ii) for the words from “an official national catalogue” to the end substitute “a National List in accordance with regulation 3 of the Seeds (National List of Varieties) Regulations 2001(a)”.
- (c) in paragraph (6), for the words “an official national catalogue” to the end substitute “ the National Register in accordance with regulations 6 and 7 of the Forest Reproductive Material Regulations (Northern Ireland) 2002(b)”.
- (11) In regulation 25 omit paragraphs (1) (d) and (2).
- (12) In regulation 26—
- (a) for paragraph (1) substitute—
- “(1) The Department must not grant an application for the renewal of consent under Article 8(1) of the Order to market genetically modified organisms as it relates to the protection of human health without agreement of the Health and Safety Executive Northern Ireland.”;
- (b) For paragraph (2) substitute—
- “(2) The Department must communicate a decision on an application to renew a consent to market genetically modified organisms to the applicant as soon as possible and must include in any refusal of a consent the reasons for that decision.”.

(a) S.I. 2001 No. 3510

(b) S.I. 2002 No. 404

(13) In regulation 28(f), for the words from “the reports of” to “Member States” substitute “monitoring reports in the relevant format set out in the Annexes to Commission Decision 2009/770/EC”.

(14) For regulation 31 substitute—

“Variation or revocation of a consent to market

31.—(1) The Department may only vary or revoke a consent to market genetically modified organisms under Article 8(10) of the Order without the agreement of the holder of the consent where new information has become available which the Department considers would affect the assessment of the risk of damage being caused to the environment by the release.

(2) The Department must not revoke or vary a consent to market genetically modified organisms under Article 8(10) of the Order as it relates to the protection of human health without the agreement of the Health and Safety Executive Northern Ireland.”

(15) In regulation 32—

- (a) in paragraph (1), for “an approved” substitute “marketing a pre-exit approved”;
- (b) omit paragraphs (3), (4) and (5).

(16) In regulation 34—

- (a) in paragraph (3)—
 - (i) in sub-paragraph (h), after “release of” insert”, or to market.”;
 - (ii) after sub-paragraph (h) insert—
 - “(i) the summary of the information contained in the application required by regulation 11(1)(d) or, as the case may be, of the application required by regulation 16(2)(j).”;

(b) after paragraph (3) insert—

“(3A) Subject to paragraph (4) and to the information not being confidential, in relation to an application for a consent under Article 8(1) of the Order to market genetically modified organisms—

- (a) the name and address of the person who is responsible for the marketing, whether manufacturer, importer or distributor,
 - (b) the proposed commercial name of the product,
 - (c) the names of the genetically modified organisms in the product, including the scientific and common names of, where appropriate, the parental, recipient and donor organisms,
 - (d) the unique identifiers of the genetically modified organisms in the product,
 - (e) an application reference code assigned by the Department
 - (f) the information included in the application as specified at paragraphs 3 and 7 of Schedule 3,
 - (g) information about stored samples of genetically modified organisms, including the type of material, its genetic characterisation and stability, the amount of repository material and the conditions of appropriate storage and shelf-life.”;
- (c) in paragraph (7), after “granted” insert “before exit day”;
- (d) in paragraph (9), for “by the” substitute “before exit day by the European”.

(17) In regulation 35, omit paragraphs (8) and (10).

(18) In Schedule 3—

- (a) in paragraph 2, omit “ in the European Union”;
- (b) in paragraph 5, omit “within the European Union”;
- (c) in paragraph 7, in the first sentence, omit the words from “for the purposes” to modifications in organisms.”;

- (d) in paragraph 8, omit “established in the European Union”; and
 - (e) in paragraph 14, for “the European Union” substitute “Northern Ireland”.
- (19) In Schedule 4, paragraph 6, omit the words from “, and whether the views” to the end.

The Genetically Modified Organisms (Transboundary Movements) Regulations (Northern Ireland) 2005

4.—(1) The Genetically Modified Organisms (Transboundary Movements) Regulations (Northern Ireland) 2005(a) are amended as follows;

(2) In the Schedule—

(a) in part I, in the text in the second column allied to Article 10(3) substitute—

“Exporting genetically modified organisms subject to transboundary movements for direct use as food or feed or for processing which are not permitted to be marketed in the United Kingdom, or without authorisation to the import having been expressly agreed by the competent authority of the importing country.”;

(b) in part II, in the text in the second column allied to Article 6, in paragraph 2 omit the words “and to the Commission”.

31st January 2019

George Eustice
Parliamentary Under Secretary of State
Department for Environment, Food and Rural Affairs

EXPLANATORY NOTE

(This note is not part of the Order)

These Regulations are made in exercise of the powers conferred by section 8(1) of, and paragraph 21(b) of Schedule 7 to, the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(b), (c), and (g) arising from the withdrawal of the United Kingdom from the European Union.

These Regulations make amendments to subordinate legislation in the field of the deliberate release, marketing and transboundary movements of genetically modified organisms in relation to Northern Ireland.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.

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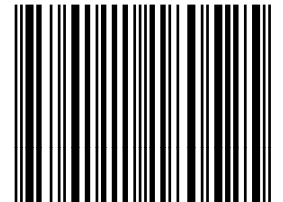
(a) S.R. 2005 No. 209

£6.90

UK201902051028 02/2019 19585

<http://www.legislation.gov.uk/id/uksi/2019/190>

ISBN 978-0-11-118052-5



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