
STATUTORY INSTRUMENTS

2019 No. 88

**EXITING THE EUROPEAN UNION, ENGLAND
ENVIRONMENTAL PROTECTION, ENGLAND**

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

<i>Sift requirements satisfied</i>	<i>27th November 2018</i>
<i>Made - - - -</i>	<i>17th January 2019</i>
<i>Laid before Parliament</i>	<i>23rd January 2019</i>
<i>Coming into force in accordance with regulation 1(2)</i>	

The Secretary of State makes these Regulations in exercise of the powers conferred by—

- (a) in relation to Part 1, the powers mentioned in paragraphs (b) to (c);
- (b) in relation to Part 2, section 2(2) of the European Communities Act 1972 ^{M1};
- (c) in relation to Parts 3 and 4, section 8(1) of, and paragraph 21(b) of Schedule 7 to, the European Union (Withdrawal) Act 2018 ^{M2}.

The Secretary of State is a Minister designated for the purposes of that subsection in relation to the control and regulation of genetically modified organisms ^{M3}.

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.

Marginal Citations

M1 1972 c. 68; section 2(2) was amended by the [Legislative and Regulatory Reform Act 2006 \(c. 51\)](#), [section 27\(1\)\(a\)](#) and the [European Union \(Amendment\) Act 2008 \(c. 7\)](#), the Schedule, Part 1. It is prospectively repealed by the [European Union \(Withdrawal\) Act 2018 \(c. 16\)](#), [section 1](#) from exit day (see [section 20](#) of that Act). The function of the former Minister of Agriculture, Fisheries and Food of making regulations under section 2(2) was transferred to the Secretary of State by [S.I. 2002/794](#). Under section 57(1) of the [Scotland Act 1998 \(c. 46\)](#), despite the transfer to Scottish Ministers of functions in relation to implementing obligations under EU law in relation to devolved matters, the Secretary of State retains power to exercise such functions as regards Scotland. Under paragraph 5 of Schedule 3 to the [Government of Wales Act 2006 \(c. 32\)](#), despite the transfer to the Welsh Ministers of functions in relation to implementing obligations under EU law in relation to devolved matters, the Secretary of State retains power to exercise such functions as regards Wales.

M2 2018 c. 16.

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019. (See end of Document for details)

M3 [S.I. 1991/755](#).

PART 1

Introduction

Citation and commencement

1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019.

(2) They come into force—

- (a) as regards this Part and Part 2, 21 days after the date on which these Regulations are laid;
- (b) as regards the remainder, on exit day.

Commencement Information

I1 Reg. 1 in force at 13.2.2019, see [reg. 1\(2\)\(a\)](#)

PART 2

Amendments made to out of date references

The Genetically Modified Organisms (Deliberate Release) Regulations 2002

2.—(1) The Genetically Modified Organisms (Deliberate Release) Regulations 2002 ^{M4} are amended as follows.

(2) In regulation 15—

- (a) in paragraph (e), in the second place it occurs, for “or” substitute “ and ”;
- (b) omit paragraph (f).

(3) Omit regulations 17 and 17A.

(4) In Schedule 3, paragraph 1 for the words “and any specific identification,” substitute “ the unique identifier assigned in accordance with Regulation 65/2004, and any other ”.

Commencement Information

I2 Reg. 2 in force at 13.2.2019, see [reg. 1\(2\)\(a\)](#)

Marginal Citations

M4 [S.I. 2002/2443](#), amended by [S.I. 2004/2411](#), 2005/2759, 2009/1892, 2011/1043, 2018/575.

PART 3

Amendments to subordinate legislation relating to withdrawal from the European Union

The Genetically Modified Organisms (Deliberate Release) Regulations 2002

3.—(1) The Genetically Modified Organisms (Deliberate Release) Regulations 2002 are amended as follows.

(2) In regulation 2—

(a) for the definition of “approved product” substitute—

““approved product” means a product—

(a) permitted to be marketed in England by—

(i) a consent granted by the Secretary of State under section 111(1) of the Act, or

(ii) 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(2) 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^{M5} as it applied immediately before exit day;”;

(e) in the definition of “the First Simplified Procedure (crop plants) Decision”, insert at the end “ as it applies immediately 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](#) ”.

(5) In regulation 15—

(a) the existing text becomes paragraph (1);

(b) in new paragraph (1), after sub-paragraph (a) insert—

“(aa) a pre-exit approved product is marketed during the relevant period for a use 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 2014^{M6},”;

(d) for sub-paragraph (e) substitute—

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- “(e) a genetically modified organism is marketed which is contained in a medicinal product authorised under the Human Medicines Regulations 2012 ^{M7} or the Veterinary Medicines Regulations 2013 ^{M8}”;
- (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”, insert “ , as read with the guidance notes set out in Commission Decision [2002/811/EC](#), ”;
- (c) in sub-paragraph (j), for the words from “established by the Commission” to the end substitute “ set out in the Annex to Commission 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) must be provided in the format set out in the Annex to Commission Decision [2003/701/EC](#).”.
- (9) In regulation 23—
- ^{F1}(a)
- (b) omit paragraph (2);
- (c) in paragraph (3), for “paragraphs (1) and (2)” substitute “ paragraph (1) ”;
- ^{F2}(d)
- (10) In regulation 24—
- ^{F3}(a)
- (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 Lists of Varieties) Regulations 2001 ^{M9} ”.
- (c) in paragraph (6), for the words from “an official national register” to the end substitute “ the National Register in accordance with regulations 6 and 7 of the Forest Reproductive Material (Great Britain) Regulations 2002 ^{M10} ”.
- (11) In regulation 25, omit paragraphs (1)(d) and (2).
- (12) In regulation 26—
- (a) for paragraph (1) substitute—

- “(1) The Secretary of State must not grant an application for the renewal of a consent under section 111(1) of the Act to market genetically modified organisms as it relates to the protection of human health without the agreement of the Health and Safety Executive.”;
- (b) for paragraph (2) substitute—
- “(2) The Secretary of State 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.”.
- (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 Secretary of State may only vary or revoke a consent to market genetically modified organisms under section 111(10) of the Act without the agreement of the holder of the consent where new information has become available which the Secretary of State considers would affect the assessment of the risk of damage being caused to the environment by the release.

(2) The Secretary of State must not revoke or vary a consent to market genetically modified organisms under section 111(10) of the Act as it relates to the protection of human health without the agreement of the Health and Safety Executive.”.

- (15) In regulation 32—
- (a) in paragraph (1), for “an approved” substitute “marketing a pre-exit approved”;
- (b) omit paragraphs (3) to (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 concerned not being confidential, in relation to an application for a consent under section 111(1) of the Act 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 Secretary of State;
- (f) the information included in the application as specified at paragraphs 3 and 7 of Schedule 3;

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- (g) information about stored samples of the 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”;
- ^{F4}(c)
- (d) in paragraph 8, omit “established in the European Union”;
- (e) in paragraph 14, for “the European Union” substitute “ England ”.
- (19) In Schedule 4, in paragraph 6, omit the words from “, and whether the views” to the end.

Textual Amendments

- F1** Reg. 3(9)(a) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Food and Farming \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/759), regs. 1(a), **11**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** Reg. 3(9)(d) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Food and Farming \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/759), regs. 1(a), **11**; 2020 c. 1, Sch. 5 para. 1(1)
- F3** Reg. 3(10)(a) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Food and Farming \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/759), regs. 1(a), **11**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Reg. 3(18)(c) omitted (29.9.2019) by virtue of [The Genetically Modified Organisms \(Deliberate Release\) \(Amendment\) \(England\) Regulations 2019](#) (S.I. 2019/1252), regs. 1(1), **9**

Commencement Information

- I3** Reg. 3 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see [reg. 1\(2\)\(b\)](#)

Marginal Citations

- M5** 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).
- M6** [S.I. 2014/1663](#).
- M7** [S.I. 2012/1916](#), amended by [S.I. 2013/235](#), 1855, 2593, 2014/323, 324, 490, 1878, 2015/178, 259, 354, 903, 1503, 1862, 1879, 2016/186, 190, 696, 2017/715, 1322, 2018/199, 378.
- M8** S.L 2013/2033, amended by [S.I. 2014/599](#), 2018/761.
- M9** [S.I. 2001/3510](#), amended by [S.I. 2004/2949](#), 2011/464, 2018/942; there are other amending instruments but none is relevant.
- M10** [S.I. 2002/3026](#), to which there are amendments not relevant to these Regulations.

The Genetically Modified Organisms (Transboundary Movements) (England) Regulations 2004

4. In the Schedule to the Genetically Modified Organisms (Transboundary Movements) (England) Regulations 2004^{M11}—

- (a) in Part 1, in the text in the second column in the row “Article 10(3)”, for the words from “without authorisation” to the end substitute “ which are not permitted to be marketed in [^{F5}Great Britain], or without authorisation to the import having been expressly agreed by the competent authority of the importing country. ”;
- (b) in Part 2, in the text in the second column in the row “Article 6”, in the second subparagraph, omit “and to the Commission”.

Textual Amendments

F5 Words in reg. 4(a) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), regs. 1(4), 3

Commencement Information

I4 Reg. 4 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1\(2\)\(b\)](#)

Marginal Citations

M11 [S.I. 2004/2692](#), amended by [S.I. 2008/2598](#), 2011/1043.

Department for Environment, Food and Rural
Affairs

George Eustice
Minister of State

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EXPLANATORY NOTE

(This note is not part of the Regulations)

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. They are also made in part using other powers to amend legislation that is deficient, where the deficiency does not arise from the withdrawal of the United Kingdom from the European Union.

Part 2 makes amendments to provisions in secondary legislation on genetically modified organisms that are out of date, specifically relating to exemptions from the need for consent for deliberate release or marketing, and the meaning of unique identifiers.

The remainder of the Regulations make amendments to legislation in the field of environmental protection and, in particular, amend legislation relating to the deliberate release, marketing and transboundary movements of genetically modified organisms.

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

Status:

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Changes to legislation:

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