

2019 No. (W.)

**EXITING THE EUROPEAN
UNION, WALES**

**ENVIRONMENTAL
PROTECTION, WALES**

**The Genetically Modified
Organisms (Deliberate Release and
Transboundary Movement)
(Miscellaneous Amendments)
(Wales) (EU Exit) Regulations 2019**

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 2(2) of the European Communities Act 1972 (c. 68) and paragraph 1(1) of Schedule 2 and paragraph 21 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 retained EU law arising from the withdrawal of the United Kingdom from the European Union.

These Regulations make amendments to subordinate legislation, which applies in relation to Wales, relating to the control and regulation of the deliberate release, placing on the market and transboundary movements of genetically modified organisms.

Part 2 of these Regulations corrects certain out of date references in Welsh subordinate legislation, with effect prior to exit day, in reliance on powers of the Welsh Ministers under section 2(2) of the European Communities Act 1972.

Part 3 of these Regulations makes various amendments to Welsh subordinate legislation in order to correct failures of retained EU law to operate effectively and other deficiencies arising from withdrawal from the European Union.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry out a Regulatory Impact Assessment as to the likely costs and benefits of complying with these Regulations.

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(Wales) (EU Exit) Regulations 2019**

Sift requirements satisfied ***

Made ***

Laid before the National Assembly for Wales

*Coming into force in accordance with
regulation 1(2) and (3)*

The Welsh Ministers are 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 the deliberate release, placing on the market and transboundary movements of genetically modified organisms.

The Welsh Ministers make the following Regulations in exercise of the powers conferred by—

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- (1) S.I. 2003/2901. By virtue of paragraphs 28(1) and 30 of Schedule 11 to the Government of Wales Act 2006 (c. 32), S.I. 2003/2901 has effect as if made under section 59(1) of that Act.
- (2) 1972 c. 68. Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c. 51) and section 3 of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c. 7).

- (a) in relation to Part 1, the provisions referred to in paragraphs (b) and (c);
- (b) in relation to Part 2, section 2(2) of the European Communities Act 1972;
- (c) in relation to Part 3, paragraph 1(1) of Schedule 2 and paragraph 21(1) of Schedule 7 to, the European Union (Withdrawal) Act 2018⁽¹⁾.

The requirements of paragraph 4(2) of Schedule 7 to the European Union (Withdrawal) Act 2018 relating to the appropriate National Assembly for Wales scrutiny procedure for these Regulations have been satisfied.

PART 1

Introduction

Title, commencement and application

1.—(1) The title of these Regulations is the Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019.

(2) Parts 1 and 2 of these Regulations come into force 21 days after the day on which these Regulations are laid.

(3) Part 3 of these Regulations comes into force on exit day.

(4) These Regulations apply in relation to Wales.

PART 2

Amendments to out of date references

Amendments to the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002

2.—(1) The Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002⁽²⁾ are amended as follows.

(2) In regulation 16 omit paragraph (f).

(3) Omit regulations 18 and 18A.

(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”.

(1) 2018 c.16.

(2) S.I. 2002/3188 (W.304), amended by S.I. 2005/1913 (W.156), 2011/1043, 2013/755 (W.90), 2018/1216 (W.249).

PART 3

Amendments to subordinate legislation relating to withdrawal from the European Union

Amendments to the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002

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

(2) In regulation 2(1)—

(a) for the definition of “approved product” (*“cynnyrch wedi'i gymeradwyo”*) substitute—

““approved product” (*“cynnyrch wedi'i gymeradwyo”*) means a product permitted to be marketed in Wales by—

(a) a consent granted by the Welsh Ministers under section 111(1) of the Act, or

(b) an authorisation under the Food and Feed Regulation;”;

(b) omit the definition of “the Commission” (*“y Comisiwn”*);

(c) omit the definition of “the Contained Use Directive” (*“y Gyfarwydddeb Defnydd Amgaeedig”*);

(d) for the definition of the “Deliberate Release Directive” substitute—

“the Deliberate Release Directive” (*“y Gyfarwydddeb Defnydd Amgaeedig”*) means Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms⁽¹⁾ 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”;

(f) in the appropriate place insert—

““pre-exit approved product” (*“cynnyrch wedi'i gymeradwyo cyn y diwrnod ymadael”*) means a product which immediately before exit day was permitted to be marketed by a consent granted in accordance with Article 15(3), 17(6) or

(1) 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).

18(2) of the Deliberate Release Directive or Article 13(2) or (4) of the 1990 Directive;”.

(3) In regulation 10, omit the words from “release is” to “or in which”.

(4) In regulation 12(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 16—

- (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 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(1);”;

(d) in sub-paragraph (d) at the end insert “or”;

(e) 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(2) or the Veterinary Medicines Regulations 2013(3).”;

(f) omit sub-paragraph (g);

(g) after new paragraph (1) insert—

“(2) For the purposes of paragraph (1)(aa), “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 17(2)—

(a) in sub-paragraph (b)—

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- (1) S.I. 2014/1663
 - (2) S.I. 201/1916, amended by S.I. 2013/235, 2013/1855, 2013/2593, 2014/323, 2014/324, 2014/490, 2014/1878, 2015/178, 2015/259, 2015/354, 2015/903, 2015/1503, 2015/1862, 2015/1879, 2016/186, 2016/190, 2016/696, 2017/715, 2017/1322, 2018/199, 2018/378.
 - (3) S.I. 2013/2033, amended by S.I. 2014/599, 2018/761.

- (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 21—
- (a) omit sub-paragraph (c);
 - (b) in sub-paragraph (f) omit the words from “and any comments made” to the end.
- (8) In regulation 22—
- (a) in paragraph (3) omit “and shall ensure that its decision is communicated 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 24—
- (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 Welsh Ministers relating to any risks of damage being caused to the environment by the marketing, before the end of a period to be specified which is not less than 60 days from the date the application was received by the Welsh Ministers;”;
 - (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 Welsh Ministers 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 25—
- (a) for paragraphs (1) to (4) substitute—

“(1) The Welsh Ministers must not grant an application for consent to market genetically modified organisms under section 111(1) of the Act as it relates to the protection of human health without the agreement of the Health and Safety Executive.

(2) The Welsh Ministers must not grant or refuse an application for consent to market genetically modified organisms before the end of the period specified for representations in accordance with regulation 24(1)(b) and (e) above and, if any representations referred to in regulation 24(1)(e) are received within that period, before the Welsh Ministers have considered those representations.

(3) The Welsh Ministers must communicate a 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 must include in the communication of any refusal to grant a consent, the reason for that refusal.

(4) The period referred to in paragraph (3) does not include—

- (a) any period beginning with the day on which the Welsh Ministers give notice in writing under section 111(6) of the Act that further information in respect of the application is required and ending on the day on which that information is received by the Welsh Ministers, or
- (b) any period during which the Welsh Ministers are considering representations submitted by any persons in accordance with regulation 24(1)(b), provided that such consideration does 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 Lists of Varieties) Regulations 2001⁽¹⁾”;
- (c) in paragraph (6), for the words from “an official national register” to the end substitute

(1) S.I. 2001/3510, amended by S.I. 2004/2949, 2011/464, 2018/942: there are other amendments but none is relevant.

“the National Register in accordance with regulations 6 and 7 of the Forest Reproductive Material (Great Britain) Regulations 2002⁽¹⁾”.

(11) In regulation 26 omit paragraphs (1)(d) and (2).

(12) In regulation 27—

(a) for paragraph (1) substitute—

“(1) The Welsh Ministers 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 Welsh Ministers 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 29(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 32 substitute—

“32 Variation or revocation of a consent to market

(1) The Welsh Ministers 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 Welsh Ministers consider would affect the assessment of the risk of damage being caused to the environment by the release.

(2) The Welsh Ministers 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 33—

(a) in paragraph (1), for “an approved” substitute “marketing a pre-exit approved”;

(b) omit paragraphs (3) to (5).

(1) S.I. 2002/3026, to which there are amendments not relevant to these Regulations.

- (16) In regulation 35—
- (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 12(1)(d) or, as the case may be, of the application required by regulation 17(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 Welsh Ministers;
 - (f) the information included in the application as specified at paragraphs 3 and 7 of Schedule 3;
 - (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 36 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”;
- (e) in paragraph 14, for “the European Union” substitute “Wales”.

(19) In Schedule 4 in paragraph 6, omit the words from “, and whether the views” to the end.

**The Genetically Modified Organisms
(Transboundary Movements) (Wales) Regulations
2005**

4.—(1) The Genetically Modified Organisms (Transboundary Movements) (Wales) Regulations 2005⁽¹⁾ are amended as follows.

(2) In the Schedule—

- (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 the United Kingdom, 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”.

Name

Minister for Environment, Energy and Rural Affairs,
one of the Welsh Ministers

Date

(1) S.I. 2005/1912 (W. 155)