

Draft Regulations laid before the National Assembly for Wales under paragraph 1(9) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of the National Assembly for Wales.

DRAFT WELSH STATUTORY
INSTRUMENTS

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) (No. 2)
Regulations 2019

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by 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 arising from the withdrawal of the United Kingdom from the European Union.

These Regulations revoke and remake with amendments Part 3 of the Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (S.I. 2019/379 (W. 94)) (“the 2019 Regulations”).

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 movement of genetically modified organisms.

Regulations 2 and 3 of these Regulations make 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.

Regulation 4 revokes various provisions including Part 3 of the 2019 Regulations.

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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Made ***

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

The Welsh Ministers make the following Regulations in exercise of the powers conferred by paragraph 1(1) of Schedule 2 and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(1).

In accordance with paragraph 1(9) of Schedule 7 to that Act, a draft of this instrument has been laid before and approved by a resolution of the National Assembly for Wales.

In accordance with paragraph 4 of Schedule 2 to that Act, the Welsh Ministers have consulted with the Secretary of State.

(1) 2018 c. 16.

Title and commencement

1.—(1) The title of these Regulations is the Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) (No. 2) Regulations 2019.

(2) Regulations 1 and 4 come into force immediately before exit day.

(3) Regulations 2 and 3 come into force on exit day.

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

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

(2) In regulation 2(1)—

- (a) omit the definition of “the Food and Feed Regulation” (“*y Rheoliad Bwyd a Bwyd Anifeiliaid*”);
- (b) for the definition of “approved product” (“*cynnyrch wedi’i gymeradwyo*”) substitute—
““approved product” (“*cynnyrch wedi’i gymeradwyo*”) means—
 - (a) a product permitted to be marketed in Wales by—
 - (i) a consent granted by the Welsh Ministers under section 111(1) of the Act,
 - (ii) an authorisation under Council Regulation (EC) No 1829/2003 on genetically modified food and feed, or
 - (b) a pre-exit approved product;”;
- (c) omit the definition of “the Commission” (“*y Comisiwn*”);
- (d) omit the definition of “the Contained Use Directive” (“*y Gyfarwyddeb Defnydd Amgaeëdig*”);
- (e) 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 in Wales by—
 - (a) a consent granted in accordance with Article 15(3), 17(6) or 18(2) of the

(1) S.I. 2002/3188 (W. 304), amended by S.I. 2005/1913 (W. 156) and S.I. 2018/1216 (W. 249).

- Deliberate Release Directive or Article 13(2) or (4) of the 1990 Directive, or
- (b) an authorisation under Council Regulation (EC) No 1829/2003 on genetically modified food and feed, and in respect of which the relevant consent or authorisation has not been withdrawn or otherwise become invalid;”.
- (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) for paragraph (b) substitute—
- “(b) genetically modified organisms are made available for activities regulated under the Genetically Modified Organisms (Contained Use) Regulations 2014(1);”;
- (b) omit paragraph (c);
- (c) in paragraph (d) for “,” substitute “; or”;
- (d) for paragraph (e) substitute—
- “(e) a genetically modified organism, which is contained in a medicinal product authorised under the Human Medicines Regulations 2012(2) or the Veterinary Medicines Regulations 2013(3), is marketed.”;
- (e) omit paragraph (g).
- (6) In regulation 17(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 Council Decision 2002/811/EC,”;

(1) S.I. 2014/1663.

(2) S.I. 2012/1916, 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 and 2018/378.

(3) S.I. 2013/2033, amended by S.I. 2014/599 and 2018/761.

- (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 21—
- (a) omit paragraph (c);
 - (b) in 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) For regulation 24 substitute—

“Duties of the Welsh Ministers in relation to applications for consent to market genetically modified organisms

24.—(1) Following the receipt of an application for consent to market genetically modified organisms under section 111(1) of the Act the Welsh Ministers must—

- (a) inform the applicant in writing of the date of receipt of the application;
- (b) examine the application for its conformity with the requirements of the Act and of these Regulations and, if necessary, request the applicant to supply additional information pursuant to section 111(6) of the Act;
- (c) before the end of a period of 90 days beginning with the day on which they received the application either—
 - (i) send to the applicant an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should be permitted to be marketed and under which conditions, or
 - (ii) refuse the application, stating reasons for their decision, supported by an assessment report prepared in accordance with Schedule 4 which indicates that the genetically modified organisms should not be marketed.

(2) The 90 day period prescribed in paragraph (1)(c) does not include 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.

(3) Where the assessment report referred to in paragraph (1)(c) indicates that the genetically modified organisms to which an application relates should be permitted to be marketed, the Welsh Ministers must invite any person, by means of a request placed on the register, to make representations on the assessment report, which must be received by the Welsh Ministers within a period of 30 days beginning with the day on which the request is placed on the register (which must not be earlier than the day on which the assessment report is placed on the registers under regulation 35(7A).”

(10) For regulation 25 substitute—

“Decisions by the Welsh Ministers on applications for consent to market genetically modified organisms

25.—(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) Where the Welsh Ministers invite representations on an assessment report relating to an application for consent to market genetically modified organisms—

- (a) the Welsh Ministers must not determine whether to grant or refuse the application before the period for making representations under regulation 24(3) has ended and the Welsh Ministers have considered any representations made in accordance with that regulation;
- (b) the Welsh Ministers must, within 105 days after the end of the period for making representations under regulation 24(3)—
 - (i) determine the application, and
 - (ii) notify the applicant in writing of the decision to grant or refuse the application, and the reasons for the decision.

(3) the period referred to in paragraph (2)(b) does not include 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.

(4) Subject to paragraphs (5) and (6), a consent to market genetically modified organisms may be given for a maximum period of ten years beginning with the day on which the Welsh Ministers grant a consent under section 111 of the Act.

(5) The period of the first consent to market—

- (a) a genetically modified organism, or
- (b) a progeny of that genetically modified organism contained in a plant variety where the plant variety is intended only for the marketing of its seeds,

must end at the latest ten years after the date of the first inclusion of the first plant variety containing the genetically modified organism on a National List in accordance with regulation 3 of the Seeds (National Lists of Varieties) Regulations 2001⁽¹⁾.

(6) For the purpose of granting consent to market a genetically modified organism contained in forest reproductive material, the period of the first consent shall end at the latest ten years after the specified date.

(7) In paragraph (6), “the specified date” means the date of the first inclusion of basic material containing the genetically modified organism on the National Register in accordance with regulations 6 and 7 of the Forest Reproductive Material (Great Britain) Regulations 2002⁽²⁾.”

(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, under section 111(1), of the Act an application for the renewal of a consent 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

(1) S.I. 2001/3510.
(2) S.I. 2002/3026.

to market genetically modified organisms to the applicant as soon as possible and must include in any refusal to renew 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—

“Variation or revocation of a consent to market

32.—(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, omit paragraphs (3) to (5).

(16) In regulation 35, for paragraphs (1) to (9) substitute—

“(1) The register must contain the particulars set out in paragraphs (2) to (10).

(2) In relation to a prohibition notice served by the Welsh Ministers under section 110 of the Act—

- (a) the name and address of the person on whom the notice is served;
- (b) the description of the genetically modified organisms in relation to which the notice is served;
- (c) the location at which the genetically modified organisms are proposed to be released;
- (d) the purpose for which the genetically modified organisms are proposed to be released or marketed;
- (e) the reason for the service of the notice;
- (f) any date specified in the notice as the date on which the prohibition is to take effect.

(3) Subject to paragraph (4), in relation to an application for a consent under section 111(1) of the Act—

- (a) the name and address of the applicant;
- (b) a general description of the genetically modified organisms in relation to which the application is being made;
- (c) the location at which the genetically modified organisms are proposed to be released, to the extent that this information is notified to the Welsh Ministers;
- (d) the purpose for which the genetically modified organisms are proposed to be released (including any future use to which they are intended to be put) or, in relation to a consent to market, the purpose for which they will be marketed;
- (e) the intended dates of the release;
- (f) the environment risk assessment;
- (g) the methods and plans for monitoring the genetically modified organisms and for responding to an emergency;
- (h) a summary of any advice the Welsh Ministers have received from the Advisory Committee on Releases to the Environment as to whether an application for release of, or to market, genetically modified organisms should be granted or rejected, and either—
 - (i) the conditions or limitations in accordance with which that Committee has advised that the consent should be granted, or
 - (ii) a summary of the reasons why that Committee has advised that the consent should not be granted;
- (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).

(3A) Subject to paragraph (4) and to the information 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.

(4) Where the Welsh Ministers are or become aware that information regarding the genetically modified organisms or the purpose for which they will be released or marketed has been published which is more detailed than that which would satisfy the requirements of paragraph (3), they must enter so much of that more detailed information on the register as they consider appropriate.

(5) In relation to consents granted under section 111(1) of the Act—

- (a) a copy of the consent, and a reference to the application in respect of which it was granted;
- (b) any information supplied to the Welsh Ministers in accordance with conditions imposed on the consent;
- (c) the fact that the consent has been varied or revoked, the contents of the notice by which the consent was varied or revoked, and a copy of the varied consent;
- (d) a summary of any advice the Welsh Ministers have received from the Advisory Committee on Releases to the Environment as to whether a consent to release genetically modified organisms should be varied or revoked.

(6) The following information concerning the risk of damage being caused to the environment by genetically modified organisms—

- (a) any information provided to the Welsh Ministers in accordance with section 111(6A) or 112(5)(b)(i) of the Act;
- (b) any information relating to an unforeseen event occurring in connection with a release of a genetically modified organism which might affect the risks there are of damage being caused to the environment notified to the Welsh Ministers in accordance with section 112(5)(b)(iii) of the Act.

(7) A copy of any consent to market genetically modified organisms granted before exit day by a competent authority of a Member State.

(7A) A copy of any assessment report produced in accordance with regulation 24(1)(c) or 26(1)(c).

(8) The location of any genetically modified organisms grown in Wales pursuant to a consent to market insofar as that information is supplied to the Welsh Ministers in accordance with the monitoring requirements imposed on the consent.

(9) Any decision adopted before exit day by the European Commission in accordance with Article 18 of the Deliberate Release Directive.”

(17) For regulation 36 substitute—

“Keeping the register

36.—(1) The information prescribed in regulation 35(2) shall be placed on the register within twelve days of the prohibition notice being served.

(2) The information prescribed in paragraphs (a) to (g) and (i) of regulation 35(3) shall be placed on the register within twelve days of the receipt by the Welsh Ministers of the application for consent to release or market.

(3) The information prescribed in regulation 35(3)(h) shall be placed on the register within twelve days of the consent being granted or refused.

(4) The information prescribed in regulation 35(3A) shall be placed on the register within twelve days of the receipt by the Welsh Ministers of the application for consent to market.

(5) The information prescribed in regulation 35(5)(a) shall be placed on the register within twelve days of the consent being granted.

(6) The information prescribed in regulation 35(5)(b) and (d) shall be placed on the register within twelve days of its receipt by the Welsh Ministers.

(7) The information prescribed in regulation 35(5)(c) shall be placed on the register within fourteen days of the consent being revoked or varied.

(8) The information prescribed in regulation 35(6) and (10) shall be placed on the register within fourteen days of its receipt by the Welsh Ministers.

(9) The information prescribed in regulation 35(7A) shall be placed on the register within twelve days of its production.

(10) The information prescribed in regulation 35(8) shall be placed on the register within fourteen days of its receipt by the Welsh Ministers.”

(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 8, omit “established in the European Union”;
- (d) 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.

Amendments to the Genetically Modified Organisms (Transboundary Movement) (Wales) Regulations 2005

3.—(1) The Genetically Modified Organisms (Transboundary Movement) (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”, omit “and to the Commission”.

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

Revocations

4.—(1) Regulation 4(2) of the Environment, Planning and Rural Affairs (Miscellaneous Amendments) (Wales) Regulations 2018⁽¹⁾ is revoked.

(2) Part 3 of the Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019⁽²⁾ is revoked.

(3) Regulation 17 of the Rural Affairs, Environment, Fisheries and Food (Miscellaneous Amendments and Revocations) (Wales) Regulations 2019⁽³⁾ is revoked.

Name

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

Date

(1) S.I. 2018/1216 (W. 249).
(2) S.I. 2019/379 (W. 94).
(3) S.I. 2019/463 (W. 111).