
WELSH STATUTORY INSTRUMENTS

2019 No. 1492 (W. 271)

**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**

*Made - - - - 4 December 2019
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.

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(2) are amended as follows.

(2) In regulation 2(1)—

(1) 2018 c. 16.

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

- (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 Gyfarwydddeb Defnydd Amgaeedig*”);
- (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 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(3);”;
- (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(4) or the Veterinary Medicines Regulations 2013(5), is marketed.”;
- (e) omit paragraph (g).

(3) S.I. 2014/1663.

(4) 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.

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

- (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](#),”;
 - (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(6).

(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(7).”

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

(12) In regulation 27—

- (a) for paragraph (1) substitute—

(6) S.I. 2001/3510.

(7) S.I. 2002/3026.