WELSH STATUTORY INSTRUMENTS

2019 No. 379

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

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 Gyfarwyddeb Defnydd Amgaeëdig"*);

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

> "the Deliberate Release Directive" (*"y Gyfarwyddeb Defnydd Amgaeëdig"*) 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 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)—

(**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).

(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(**2**);";

(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(**3**) or the Veterinary Medicines Regulations 2013(**4**).";

(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)—

(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—

(**2**) S.I. 2014/1663

(**3**) 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.

(**4**) S.I. 2013/2033, amended by S.I. 2014/599, 2018/761.

"(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(**5**)";

(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(**6**)".

(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).

(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—

(**5**) S.I. 2001/3510, amended by S.I. 2004/2949, 2011/464, 2018/942: there are other amendments but none is relevant.
(**6**) S.I. 2002/3026, to which there are amendments not relevant to these Regulations.

"(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.