STATUTORY INSTRUMENTS

2019 No. 88

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

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(**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".

(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".

(**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).

(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(**2**);";

(d) 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**);";

(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—

(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 Secretary of State relating to any risks of

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

(**3**) 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.

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

damage being caused to the environment by the marketing before the end of a period to be specified which is not to be less than 60 days from the date the application was received by the Secretary of State;";

(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 Secretary of State 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 24—

(a) for paragraphs (1) to (4) substitute—

"(1) The Secretary of State 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 Secretary of State 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 23(1)(b) and (e) above and, if any representations referred to in regulation 23(1)(e) are received within that period, before the Secretary of State has considered those representations.

(3) The Secretary of State 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 reasons for that refusal.

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

(a) any period beginning with the day on which the Secretary of State gives 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 Secretary of State, or

(b) any period during which the Secretary of State is considering representations submitted by any persons in accordance with regulation 23(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 25, omit paragraphs (1)(d) and (2).

(12) In regulation 26—

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

(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—

"**31 Variation or revocation of a consent to market**

(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;

(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";

(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 "England".

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

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

4. In the Schedule to the Genetically Modified Organisms (Transboundary Movements) (England) Regulations 2004(**7**)—

(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 sub-paragraph, omit "and to the Commission".

(**7**) S.I. 2004/2692, amended by S.I. 2008/2598, 2011/1043.