SCOTTISH STATUTORY INSTRUMENTS

2019 No. 57

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

PART 3

Amendments to subordinate legislation to address deficiencies arising from the withdrawal of the United Kingdom from the European Union

The Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002

3.—(1) The 2002 Regulations are amended in accordance with paragraphs (2) to (29), as read with schedules 1 and 2.

(2) In regulation 2(1) (interpretation) [M1]—

(a) for the definition of "approved product" substitute—

""approved product" means a product consisting of or including genetically modified organisms which—

(a) is permitted to be marketed in Scotland in pursuance of—

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

(ii) an authorisation under the Food and Feed Regulation, or

(b) is a pre-exit approved product,",

(b) omit the definition of "the Commission",

(c) omit the definition of "the Contained Use Directive", and

(d) after the definition of "monitoring plan" insert—

""pre-exit approved product" means a product consisting of or including genetically modified organisms which, immediately before exit day, was permitted to be marketed in Scotland in pursuance of a consent granted (other than by the Scottish Ministers under section 111(1) of the Act) in accordance with—

(a) Article 15(3), 17(6) or 18(2) of the Deliberate Release Directive, or

(b) Article 13(2) or (4) of the 1990 Directive,".

(3) In regulation 6(1)(b) (environmental risk assessment)—

(a) for "Annex II of the Deliberate Release Directive" substitute " schedule 1 ", and

(b) for "section D of that Annex" substitute " Part D of that schedule ".

(4) In regulation 9 (exempt activities) [M2], after "its consent" insert " or authorisation ".

(5) In regulation 11(1) (information to be contained in application for consent to release) [M3]—

(a) in sub-paragraph (b)—

(i) after "has made" insert " under section 111(1) of the Act (in relation to any part of the United Kingdom) or ", and

(ii) omit "(including the Scottish Ministers)", and

(b) in sub-paragraph (d)—

(i) omit the words from ", in the format" to "Directive,", and

(ii) after "application" insert " , in the relevant format set out in the Annex to Decision 2002/813/EC ".

(6) In regulation 15 (exempt activities) [M4]—

(a) in paragraph (1)—

(i) in sub-paragraph (a), after "approved product" insert " , which is permitted to be marketed in Scotland in pursuance of an authorisation under the Food and Feed Regulation, ",

(ii) after sub-paragraph (a) insert—

"(aa) a pre-exit approved product is marketed during the relevant period—

(i) for a use (other than cultivation in Scotland) for which it had marketing consent in accordance with the Deliberate Release Directive or the 1990 Directive immediately before exit day and for which it continues to have consent for that use in Scotland, and

(ii) in accordance with the limitations and conditions to which that use of the product was subject immediately before exit day, as may be modified by virtue of these Regulations or the Act,",

(iii) in sub-paragraph (b), for "the Contained Use Directive" substitute " the Genetically Modified Organisms (Contained Use) Regulations 2014 [M5] ",

(iv) omit sub-paragraph (c),

(v) at the end of sub-paragraph (d), after "Part II;" insert " and ",

(vi) for sub-paragraph (e) and the word "and" immediately following it, substitute—

"(e) a genetically modified organism is marketed which is, or is contained in, a medicinal product authorised under—

(i) the Human Medicines Regulations 2012 [M6], or

(ii) the Veterinary Medicines Regulations 2013 [M7].", and

(vii) omit sub-paragraph (g), and

(b) for paragraph (2) substitute—

"(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 with the day which immediately precedes the day on which the consent concerned ceases to be valid.".

(7) In regulation 16 (applications for consent to market)—

(a) in paragraph (2)—

(i) in sub-paragraph (b), for the words from "to any competent authority" to the end, substitute " under section 111(1) of the Act (in relation to any part of the United Kingdom) ",

(ii) in sub-paragraph (g), for "Annex VII of the Deliberate Release Directive" substitute " schedule 5A ", and

(iii) 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 ", and

(b) in paragraph (5)—

(i) for "by any competent authority of any Member State (including the Scottish Ministers) in accordance with Article 6(5) of" substitute " under section 111(1) of the Act or a consent under Part B of either ", and

(ii) omit "Article 6(2) of".

(8) In regulation 20 (duties in relation to applications for consent to release)—

(a) omit sub-paragraph (c), and

(b) for sub-paragraph (f) substitute—

"(f) take into account and give due weight to any representations made to them before the end of the period specified pursuant to paragraph (b) relating to risks of damage being caused to the environment by the release.".

(9) In regulation 21 (decisions on applications for consent to release)—

(a) in paragraph (2) omit—

(i) "and comments", and

(ii) the words from "and (f)" to "those comments",

(b) for paragraph (3) substitute—

"(3) The Scottish Ministers must communicate in writing their decision on an application for a consent to release 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 any refusal of consent the reason for the decision.", and

(c) for paragraph (6) substitute—

"(6) Information submitted in accordance with paragraph (5) must be provided in the format set out in the Annex to Decision 2003/701/EC.".

(10) For regulation 23 (duties in relation to applications for consent to market) substitute—

"**Duties of the Scottish Ministers in relation to applications for consent to market**

23.—(1) On receipt of an application for consent to market genetically modified organisms, the Scottish Ministers must—

(a) inform the applicant in writing of the date of receipt of the application,

(b) without delay 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, and

(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 5 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 5 which indicates that the genetically modified organisms should not be marketed.

(2) The period of 90 days referred to in paragraph (1)(c) must not include any period beginning with the day on which the Scottish 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 Scottish 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 Scottish 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 Scottish 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 register in accordance with regulation 35(7A)).".

(11) For regulation 24 (decisions on applications for consents to market) [M8], together with its heading, substitute—

"**Decisions by the Scottish Ministers on applications for consent to market**

24.—(1) The Scottish Ministers must not grant 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 Scottish Ministers invite representations under regulation 23(3) in relation to an application for consent to market genetically modified organisms, the Scottish Ministers—

(a) must not determine whether to grant or refuse consent to market the genetically modified organisms until after the period for making representations under regulation 23(3) has ended and they have considered any representations made in accordance with that regulation, and

(b) must, within a period of 105 days beginning with the day after the end of the period for making representations under regulation 23(3)—

(i) determine the application, and

(ii) notify the applicant in writing of the decision to grant or refuse consent to market the genetically modified organisms, and the reasons for the decision.

(3) The period of 105 days referred to in paragraph (2)(b) does not include any period beginning with the day on which the Scottish 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 Scottish Ministers.

(4) Subject to paragraphs (5) and (6) and regulation 26, a consent to market genetically modified organisms may be granted by the Scottish Ministers under section 111(1) of the Act for a maximum period of up to 10 years beginning with the day on which the consent is granted.

(5) In the case of a consent to market a genetically modified organism or any progeny of that genetically modified organism contained in a plant variety where that plant variety is intended only for the marketing of its seeds, the period of the first consent must end at the latest 10 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 [M9].

(6) In the case of a consent to market a genetically modified organism contained in forest reproductive material, the period of the first consent must end at the latest 10 years after 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 [M10].

(7) A consent to market genetically modified organisms granted by the Scottish Ministers under section 111(1) of the Act may include such limitations or conditions as they consider

appropriate to restrict or prohibit the cultivation of the genetically modified organisms in all or any part of Scotland.

(8) The Scottish Ministers may, where any such consent includes a limitation or condition referred to in paragraph (7), vary the consent to remove or modify the limitation or condition.

(9) The Scottish Ministers must inform the holder of the consent of any variation under paragraph (8).".

(12) In regulation 25 (duties on receiving applications for renewal of consent to market) [M11]—

(a) in paragraph (1)—

(i) at the end of sub-paragraph (b), after "information;" insert " and ",

(ii) at the end of sub-paragraph (c), for "; and" substitute " . ", and

(iii) omit sub-paragraph (d), and

(b) omit paragraph (2).

(13) In regulation 26 (decisions on applications for renewals of consents to market) [M12]—

(a) for paragraphs (1) and (2) substitute—

"(1) The Scottish Ministers must not grant a renewal of 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.

(2) The Scottish 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 consent the reasons for the decision.",

(b) for paragraph (5) substitute—

"(5) A renewed consent to market genetically modified organisms granted by the Scottish Ministers under section 111(1) of the Act may include such limitations or conditions as they consider appropriate to restrict or prohibit the cultivation of the genetically modified organisms in all or any part of Scotland.", and

(c) for paragraphs (7) and (8), substitute—

"(7) The Scottish Ministers must inform the holder of the renewed consent of any variation under paragraph (6).".

(14) For regulation 26A (demand for the adjustment of geographical scope), together with its heading, substitute—

"**Demand to adjust a food or feed authorisation to prohibit the cultivation of genetically modified organisms in all or part of Scotland**

26A.—(1) On receipt of a relevant application Food Standards Scotland must forward a copy of the application to the Scottish Ministers.

(2) The Scottish Ministers may, in respect of a relevant application, demand that any resulting authorisation is adjusted to ensure that genetically modified organisms are prohibited from cultivation in all or such part of Scotland as is specified in the demand.

(3) A demand under paragraph (2) must be communicated by the Scottish Ministers to the Food Standards Scotland before it determines the application.

(4) In this regulation, "relevant application" means an application for—

(a) an authorisation to place on the market genetically modified organisms under Article 5 or 17 of the Food and Feed Regulation, or

(b) renewal of an authorisation to place on the market genetically modified organisms under Article 11 or 23 of the Food and Feed Regulation.".

(15) For regulation 26B (request for reintegration following exclusion from geographical scope), together with its heading, substitute—

"**Request to adjust a food or feed authorisation to remove or modify a restriction or prohibition on the cultivation of genetically modified organisms in all or part of Scotland**

26B.—(1) Where an authorisation referred to in sub-paragraph (a) or (b) of regulation 26A(4) restricts or prohibits the cultivation of genetically modified organisms in all or any part of Scotland, the Scottish Ministers may request that the authorisation is adjusted to remove or modify, insofar as they consider appropriate, any such restriction or prohibition.

(2) A request under paragraph (1) is to be made by notifying Food Standards Scotland.".

(16) In regulation 28(f) (general provisions of consents to market), for the words from "the reports of" to "Member States", substitute " monitoring reports to the Scottish Ministers in the relevant format set out in the Annexes to Decision 2009/770/EC ".

(17) In regulation 29A (restrictions on cultivation) [M13]—

(a) in paragraph (1)—

(i) in sub-paragraph (b), for "an" substitute " a pre-exit ",

(ii) in sub-paragraph (c), for "," substitute " . ", and

(iii) omit the full-out (from "in respect" to "apply."),

(b) omit paragraph (2),

(c) in paragraph (3)(c), after "the" insert " pre-exit ",

(d) in paragraph (5)—

(i) for "15(a)" substitute " 15(aa) ",

(ii) before "approved" insert " pre-exit ",

(e) in paragraph (6), for "15(g)" substitute " 15(a) ",

(f) in paragraph (7)—

(i) in sub-paragraph (a)(v), omit ", without prejudice to any measures adopted in respect of Article 26a of the Deliberate Release Directive",

(ii) in sub-paragraph (b), after "with" insert " retained ", and

(iii) in sub-paragraph (e), for "the Deliberate Release Directive or the Food and Feed Regulation" substitute " retained EU law on the deliberate release into the environment of genetically modified organisms (including the Food and Feed Regulation) ",

(g) in paragraph (9), omit sub-paragraph (a),

(h) in paragraph (11), for "comments from the Commission or another member State" substitute " any comments they receive ", and

(i) in paragraph (12)(a), omit "the Commission, the other member States and".

(18) In regulation 29B (removal of restrictions under regulation 29A) [M14]—

(a) in paragraph (1)(c), for "an" substitute " a pre-exit ", and

(b) in paragraph (2), for "Commission and the other member States" substitute " consent or authorisation holder ".

(19) In regulation 30A (stop notices) [M15], in paragraph (1)(a)(i), omit "or otherwise granted under the Deliberate Release Directive", and

(20) For regulation 31 (new information on risks of damage from marketing genetically modified organisms) including the heading, substitute—

"**Variation or revocation of consents to market**

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

(2) The Scottish 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.".

(21) In regulation 32 (safeguard)—

(a) in paragraph (1), for "or by a consent granted in respect of an approved product" substitute " , by an authorisation under the Food and Feed Regulation, or by a consent granted in respect of a pre-exit approved product, ", and

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

(22) In regulation 34 (information to be included in the register) [M16]—

(a) in paragraph (3)—

(i) at the end of sub-paragraph (g), after "emergency;" omit "and",

(ii) at the end of sub-paragraph (h), after "not be granted" insert " , and ", and

(iii) after sub-paragraph (h), insert the following sub-paragraph—

"(i) the summary of the application required by regulation 11(1)(d) or regulation 16(2)(j), as the case may be.",

(b) after paragraph (3) insert—

"(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 for the genetically modified organisms in the product,

(e) an application reference code assigned by the Scottish Ministers,

(f) the information included in the application as specified at paragraphs 3 and 7 of schedule 4, and

(g) information on 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)—

(i) after "granted" insert " before exit day ",

(ii) for "another" substitute " a ", and

(iii) after "State" insert " or, at the time it was granted, the United Kingdom ".

(d) after paragraph (7), insert—

"(7A) A copy of any assessment report referred to in regulation 23(1)(c) or regulation 25(1)(c).", and

(e) in paragraph (9), for "by the" substitute " before exit day by the European ".

(23) In regulation 35 (keeping the register)—

(a) in paragraph (3), after "(a) to (g)" insert " and (i) ",

(b) after paragraph (3) insert—

"(3A) The information prescribed in regulation 34(3A) must be placed on the register within 12 days of receipt by the Scottish Ministers of the application for consent to market.",

(c) after paragraph (7), insert—

"(7A) The information prescribed in regulation 34(7A) must be placed on the register within 12 days of its production.", and

(d) omit paragraphs (9) and (11).

(24) Before schedule 2 (information to be included in application for consent to release or market genetically modified higher plants), insert schedule 1 (principles for environmental risk assessment) which is in schedule 1 (new schedule 1 to be inserted) of these Regulations.

(25) In schedule 2 (information to be included in application for consent to release or market genetically modified higher plants)—

(a) in paragraph 13, for "EU" substitute " United Kingdom ",

(b) in paragraph 14(b), for "Europe" substitute " the United Kingdom ",

(c) in paragraphs 42, 43 and 46, for "EU" substitute " United Kingdom ",

(d) in paragraph 53, for "Section D.2 of Annex II of the Deliberate Release Directive" substitute " in Chapter D.2 of Part D of schedule 1 ", and

(e) in paragraph 54(h)—

(i) in head (i), for "Section C.3 of Annex II of the Deliberate Release Directive" substitute " Chapter C.3 of Part C of schedule 1 ", and

(ii) in head (ii), for "point 5 of Section C.3 of Annex II of the Deliberate Release Directive" substitute " step 5 of the methodology described in that Chapter ".

(26) In schedule 3 (information to be included in applications for consent to release or market organisms other than genetically modified higher plants), in paragraph 12(a), for "existing Community rules" substitute " retained EU law ".

(27) In schedule 4 (information to be included in applications for consent to market genetically modified organisms)—

(a) in paragraph 1, for "competent authority" substitute " Scottish Ministers ",

(b) in paragraph 2, omit "in the European Union",

(c) in paragraph 5, omit "within the European Union",

(d) in paragraph 7, for "publicly accessible part of the register referred to in Article 31(2) of the Deliberate Release Directive" substitute " register ",

(e) in paragraph 8, omit "established in the European Union",

(f) in paragraph 11, for "Part C of Annex VII to the Deliberate Release Directive" substitute " Part C of schedule 5A ", and

(g) in paragraph 14, for "the European Union" substitute " Scotland and other parts of the United Kingdom ".

(28) In schedule 5 (information to be included in an assessment report), in paragraph 6, omit the words from ", or whether the views" to "regulation 6".

(29) After schedule 5, insert schedule 5A (monitoring plan) which is in schedule 2 (new schedule 5A to be inserted) of these Regulations.

Commencement Information

I1 Reg. 3 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)(b)

Marginal Citations

M1 Regulation 2(1) is amended by Part 2 of these Regulations.
M2 Regulations 9 is amended by Part 2 of these Regulations.
M3 Regulation 11(1) is amended by Part 2 of these Regulations.
M4 Regulation 15(1) is amended by Part 2 of these Regulations.
M5 S.I. 2014/1663, as amended by S.I. 2015/1637 and S.I. 2018/1370.
M6 S.I. 2012/1916.
M7 S.L 2013/2033.
M8 Regulation 24(4) and (7) is amended by Part 2 of these Regulations.
M9 S.I. 2001/3510, as amended by S.I. 2004/2949, **S.I**. 2007/1871, S.I. 2009/1273, **S.I**. 2010/1195, S.I. 2011/464, **S.I**. 2011/1043, S.S.I. 2015/395, **S.I**. 2018/942 and S.I. 2019/162.
M10 S.I. 2002/3026, as amended by S.I. 2006/2530, **S.I**. 2013/755 and S.I 2014/1833.
M11 Regulation 25(1) is amended by Part 2 of these Regulations.
M12 Regulation 26(5) is amended by Part 2 of these Regulations.
M13 Regulation 29A(1), (3), (6), (7), (11) and (12) is amended by Part 2 of these Regulations.
M14 Regulation 29B(1) is amended by Part 2 of these Regulations.
M15 Regulation 30A(1) is amended by Part 2 of these Regulations.
M16 Regulation 34(3) and (7) is amended by Part 2 of these Regulations.

Changes to legislation:
There are currently no known outstanding effects for the The Genetically Modified Organisms (EU Exit) (Scotland) (Amendment) Regulations 2019, Section 3.