SCOTTISH STATUTORY INSTRUMENTS

2019 No. 57

EXITING THE EUROPEAN UNION ENVIRONMENTAL PROTECTION

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

Made - - - - 19th February 2019
Laid before the Scottish Parliament - - - - 20th February 2019

Coming into force in accordance with regulation 1(2)

The Scottish Ministers make the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**1**), paragraph 1(1) and (3) of schedule 2 and paragraph 21 of schedule 7 of the European Union (Withdrawal) Act 2018(**2**), and all other powers enabling them to do so.

PART 1

Introduction

Citation, commencement, extent and interpretation

1.—(1) These Regulations may be cited as the Genetically Modified Organisms (EU Exit) (Scotland) (Amendment) Regulations 2019.

(2) They come into force—

(a) as regards this Part and Part 2, on 28 March 2019, and

(b) as regards the remainder, on exit day.

(3) These Regulations extend to Scotland only.

(**1**) 1972 c.68. Section 2(2) was amended by the Scotland Act 1998 (c.46) ("the 1998 Act"), schedule 8, paragraph 15(3) (which was amended by section 27(4) of the Legislative and Regulatory Reform Act 2006 (c.51) ("the 2006 Act")). Section 2(2) was also amended by section 27(1)(a) of the 2006 Act and by the European Union (Amendment) Act 2008 (c.7), schedule, Part 1. The functions conferred upon the Minister of the Crown under section 2(2), insofar as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act.

(**2**) 2018 c.16.

(4) In these Regulations, "the 2002 Regulations" means the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002(**3**).

PART 2

Amendments to subordinate legislation made in exercise of powers conferred by section 2(2) of the European Communities Act 1972

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

2.—(1) The 2002 Regulations are amended in accordance with paragraphs (2) to (15).

(2) In regulation 2 (interpretation), in paragraph (1), in the definition of "Food Standards Scotland", for "Food Standards Act 1999" substitute "Food (Scotland) Act 2015(**4**)".

(3) In regulation 9 (exempt activities)—

(a) after "approved product" insert ", which is permitted to be marketed for a use in pursuance of its consent,",

(b) for "conditions and limitations" substitute "limitations, conditions and restrictions" and

(c) for "the use" substitute "that use".

(4) In regulation 11 (information to be contained in application for consent to release), in paragraph (1)(b), for "any Member" substitute "a member".

(5) In regulation 15 (exempt activities), in paragraph (1)—

(a) for "sections 108(7) and" substitute "section",

(b) omit—

(i) "section 108(1)(a) of the Act (to carry out a risk assessment) and of", and

(ii) ", respectively",

(c) for "they relate" substitute "it relates", and

(d) in sub-paragraph (a)—

(i) for "and conditions" substitute ", conditions and restrictions", and

(ii) for "the use of that" substitute "that use of the".

(6) In regulation 24 (decisions on applications for consents to market)—

(a) in paragraph (4), after "(6)" insert "and regulation 26",

(b) in paragraph (7), for the words from "a genetically" to "corresponding", substitute "genetically modified organisms granted by the Scottish Ministers under section 111(1) of the Act must include such limitations and conditions as they consider appropriate to restrict or prohibit the cultivation of the genetically modified organisms in all or any part of Scotland corresponding", and

(c) in paragraph (9), for the words from "following" to the end, substitute "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".

(7) In regulation 25 (duties on receiving applications for renewal of consent to market)—

(a) in paragraph (1)(c)—

(**3**) S.S.I. 2002/541, as amended by S.S.I. 2004/439, S.I. 2005/2759, S.I. 2011/1043, S.S.I. 2015/100 and the Genetically Modified Organisms (Deliberate Release etc.) (Miscellaneous Amendments) (Scotland) Regulations 2019.

(**4**) 2015 asp 3; to which there are amendments which are not relevant to these Regulations.

(i) in head (i), for "Schedule 4" substitute "schedule 5", and

(ii) in head (ii), after "report" insert "prepared in accordance with schedule 5", and

(8) In regulation 26 (decisions on applications for renewals of consents to market)—

(a) in paragraph (4), for "under the conditions specified in the existing consent" substitute "in accordance with the limitations and conditions included the existing marketing consent",

(b) in paragraph (5), for the words from "a genetically" to "corresponding", substitute "genetically modified organisms granted by the Scottish Ministers under section 111(1) of the Act must include such limitations and conditions as they consider appropriate to restrict or prohibit the cultivation of the genetically modified organisms in all or any part of Scotland corresponding", and

(c) in paragraph (6), for the words from "following" to "Scotland", substitute "where any such consent includes a limitation or condition referred to in paragraph (5), vary the consent to remove or modify the limitation or condition".

(9) In regulation 26A (demand for the adjustment of the geographical scope of consent or authorisation), in paragraph (1), for the words from "the geographical" to "Scotland", substitute "any resulting consent or authorisation is adjusted to ensure that genetically modified organisms are prohibited from cultivation in all or such part of Scotland as may be specified in the demand".

(10) In regulation 26B (request for reintegration following exclusion from geographical scope), for paragraph (1) substitute—

"**26B.**—(1) Where a consent or authorisation referred to in sub-paragraphs (a) to (d) of regulation 26A(3) restricts or prohibits the cultivation of genetically modified organisms in all or any part of Scotland following a demand under regulation 26A(1), the Scottish Ministers may request that the consent or authorisation is adjusted to remove or modify, insofar as they consider appropriate, any such restriction or prohibition.".

(11) In regulation 29A (restrictions on cultivation)—

(a) in paragraph (1)(a)—

(i) for "given", where it first occurs, substitute "granted", and

(ii) for "given under" substitute "granted under that section in accordance with",

(b) in paragraph (3)—

(i) in sub-paragraph (a), for the words from "a condition" to the end, substitute "such limitations and conditions in the consent or renewed consent as they consider appropriate to restrict or prohibit the cultivation of genetically modified organisms in all or any part of Scotland", and

(ii) in sub-paragraph (b), for "a", in the second place it occurs, substitute "the",

(c) in paragraph (6), after "food or" insert "genetically modified",

(d) in paragraph (7), after "restrict" insert "or, as the case may be, prohibit",

(e) in paragraph (11), for "condition or suspension notice" substitute "limitation or condition referred to in paragraph (3)(a), or a suspension notice issued under paragraph (3)(b), (c) or (d),", and

(f) in paragraph (12)(a)—

(i) after "communicate the" insert "limitation,", and

(ii) after "notice" insert ", as the case may be,".

(12) In regulation 29B (removal of restrictions under regulation 29A), in paragraph (1)—

(a) in sub-paragraph (a)—

(i) after "vary a" insert "limitation or",

(ii) after "consent" insert "or renewed consent",

(iii) for "the limit on geographical scope in respect of the cultivation of a genetically modified organism" substitute "or modify a restriction or prohibition on the cultivation of genetically modified organisms in all or any part of Scotland", and

(b) in sub-paragraph (b), after "consent" insert "or renewed consent".

(13) In regulation 30A (stop notices), in paragraph (1)—

(a) in sub-paragraph (a)—

(i) in head (i)—

(aa) for "granted by the Scottish Ministers" substitute "required", and

(bb) at the end, after the comma, omit "or",

(ii) at the end of head (ii), after "subject," insert "or", and

(iii) after head (ii) insert—

"(iii) exempt from any such requirement for consent, including by virtue of not being in accordance with any limitation or condition to which the exemption is subject,",

(b) in sub-paragraph (b)—

(i) for "limit included on the geographical scope of" substitute "limitation or condition included in", and

(ii) for "under", in both places it occurs, substitute "pursuant to",

(c) in sub-paragraph (c), for "condition in a consent to limit its geographical scope under" substitute "limitation or condition included in a consent or a renewed consent pursuant to", and

(d) in sub-paragraph (d), for "or (c)" substitute ", (c) or (d)".

(14) In regulation 32B (offences and penalties), in paragraph (1)—

(a) in sub-paragraph (d)—

(i) for "limit included on the geographical scope of" substitute "limitation or condition included in", and

(ii) for "under", in both places it occurs, substitute "pursuant to", and

(b) in sub-paragraph (e), for "condition in a consent to limit its geographical scope under" substitute "limitation or condition included in a consent or a renewed consent pursuant to".

(15) In regulation 34 (information to be included in the register)—

(a) in paragraph (3)(h)—

(i) for "an application for release of" substitute "the applied for consent to release or, as the case may be, market", and

(ii) for "rejected" substitute "refused", and

(b) in paragraph (7), for "Member" substitute "member".

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)(**5**)—

(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)(**6**), after "its consent" insert "or authorisation".

(5) In regulation 11(1) (information to be contained in application for consent to release)(**7**)—

(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".

(**5**) Regulation 2(1) is amended by Part 2 of these Regulations.
(**6**) Regulations 9 is amended by Part 2 of these Regulations.
(**7**) Regulation 11(1) is amended by Part 2 of these Regulations.

(6) In regulation 15 (exempt activities)(**8**)—

(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(**9**)",

(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(**10**), or

(ii) the Veterinary Medicines Regulations 2013(**11**).", 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

(**8**) Regulation 15(1) is amended by Part 2 of these Regulations.
(**9**) S.I. 2014/1663, as amended by S.I. 2015/1637 and S.I. 2018/1370.
(**10**) S.I. 2012/1916.
(**11**) S.I. 2013/2033.

(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)(**12**), 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(**13**).

(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(**14**).

(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.

(**12**) Regulation 24(4) and (7) is amended by Part 2 of these Regulations.
(**13**) 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.
(**14**) S.I. 2002/3026, as amended by S.I. 2006/2530, S.I. 2013/755 and S.I 2014/1833.

(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)(**15**)—

(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)(**16**)—

(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**) Regulation 25(1) is amended by Part 2 of these Regulations.
(**16**) Regulation 26(5) is amended by Part 2 of these Regulations.

(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)(**17**)—

(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)(**18**)—

(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".

(**17**) Regulation 29A(1), (3), (6), (7), (11) and (12) is amended by Part 2 of these Regulations.
(**18**) Regulation 29B(1) is amended by Part 2 of these Regulations.

(19) In regulation 30A (stop notices)(**19**), 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)(**20**)—

(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.",

(**19**) Regulation 30A(1) is amended by Part 2 of these Regulations.
(**20**) Regulation 34(3) and (7) is amended by Part 2 of these Regulations.

(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.

The Genetically Modified Organisms (Transboundary Movements) (Scotland) Regulations 2005

4. In schedule 1 (specified community provisions) of the Genetically Modified Organisms (Transboundary Movements) (Scotland) Regulations 2005(**21**)—

(a) in Part 1, in the text in the second column of the row relating to Article 10(3)—

(i) for "it is authorised within the European Union" substitute "its use is permitted in the United Kingdom",

(ii) for "a third" substitute "the importing", and

(iii) omit "as required" to the end, and

(b) in Part 2, in the text in the second column of the row relating to Article 6, omit "and to the Commission".

St Andrew's House,
Edinburgh
19th February 2019

MAIRI GOUGEON
Authorised to sign by the Scottish Ministers

(**21**) S.S.I. 2005/316, as amended by S.I. 2011/1043.

SCHEDULE 1 Regulation 3(24)

NEW SCHEDULE 1 TO BE INSERTED

"SCHEDULE 1 Regulation 6(1) and schedule 2

PRINCIPLES FOR ENVIRONMENTAL RISK ASSESSMENT

Introduction

1.—(1) This schedule describes in general terms the objective to be achieved, the elements to be considered and the general principles and methodology to be followed to perform the environmental risk assessment.

(2) In this schedule—

"cumulative long-term effects" means the accumulated effects of consents on human health and the environment, including among other things flora and fauna, soil fertility, soil degradation of organic material, the feed/food chain, biological diversity, animal health and resistance problems in relation to antibiotics,

"delayed effects" means the effects on human health or the environment which may not be observed during the period of the release of the genetically modified organism, but become apparent as a direct or indirect effect either at a later stage or after termination of the release,

"direct effects" means the primary effects on human health or the environment which are a result of the genetically modified organism itself and which do not occur through a causal chain of events,

"immediate effects" means the effects on human health or the environment which are observed during the period of the release of the genetically modified organism. Immediate effects may be direct or indirect, and

"indirect effects" means the effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management (observations of indirect effects are likely to be delayed).

(3) A general principle for environmental risk assessment is that an analysis of the cumulative long-term effects relevant to the release and the placing on the market of genetically modified organisms is to be carried out.

PART A

OBJECTIVE

2. The objective of an environmental risk assessment is, on a case by case basis, to identify and evaluate potential adverse effects of the genetically modified organism, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of genetically modified organisms may have. The environmental risk assessment should be conducted with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used.

PART B

GENERAL PRINCIPLES

3. In accordance with the precautionary principle, the following general principles should be followed when performing the environmental risk assessment—

(a) identified characteristics of the genetically modified organism and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations,

(b) the environmental risk assessment should be carried out in a scientifically sound and transparent manner based on available scientific and technical data,

(c) the environmental risk assessment should be carried out on a case by case basis, meaning that the required information may vary depending on the type of the genetically modified organisms concerned, their intended use and the potential receiving environment, taking into account, among other things, genetically modified organisms already in the environment, and

(d) if new information on the genetically modified organism and its effects on human health or the environment becomes available, the environmental risk assessment may need to be readdressed in order to—

(i) determine whether the risk has changed, and

(ii) determine whether there is a need for amending the risk management accordingly.

PART C

METHODOLOGY

CHAPTER C.1

GENERAL AND SPECIFIC CONSIDERATION FOR THE ENVIRONMENTAL RISK ASSESSMENT

Step 1: Intended and unintended changes

4.—(1) As part of the identification and evaluation of the potential adverse effects referred to in Part A of this schedule, the environmental risk assessment must identify the intended and unintended changes resulting from the genetic modification and must evaluate their potential to cause adverse effects on human health and on the environment.

(2) Intended changes resulting from the genetic modification are changes that are designed to occur and which fulfil the original objectives of the genetic modification.

(3) Unintended changes resulting from the genetic modification are consistent changes which go beyond the intended change(s) resulting from the genetic modification.

(4) Intended and unintended changes can have either direct or indirect, and either immediate or delayed effects on human health and on the environment.

Step 2: Long-term adverse effects and cumulative long-term adverse effects in the environmental risk assessment of applications to which Part 3 of these Regulations applies

5.—(1) Long-term effects of a genetically modified organism are effects resulting either from a delayed response by organisms or their progeny to long-term or chronic exposure to a genetically modified organism or from an extensive use of a genetically modified organism in time and space.

(2) The identification and evaluation of the potential long-term adverse effects of a genetically modified organism on human health and on the environment must take into account the following—

(a) the long-term interactions of the genetically modified organism and the receiving environment,

(b) the characteristics of the genetically modified organism which become important on a long- term basis, and

(c) data obtained from repeated deliberate releases or placings on the market of the genetically modified organism over a long period.

(3) The identification and evaluation of the potential cumulative long-term adverse effects referred to in the introduction of this schedule must also take into account the genetically modified organisms deliberately released or placed on the market in the past.

Step 3: Quality of the data

6.—(1) In order to carry out an environmental risk assessment for an application to which Part 3 of these Regulations applies, the applicant must collate already available data from scientific literature or from other sources, including monitoring reports, and must generate the necessary data by performing, where possible, appropriate studies. Where applicable, the applicant must justify in the environmental risk assessment why generating data by studies is not possible.

(2) The environmental risk assessment for applications to which Part 2 of these Regulations applies must be based at least on already available data from scientific literature or from other sources and may be supplemented by additional data generated by the applicant.

(3) Where data generated outside the United Kingdom is provided in the environmental risk assessment, its relevance to receiving environment(s) in the United Kingdom must be justified.

(4) Data provided in the environmental risk assessment for applications to which Part 3 of these Regulations applies, must comply with the following requirements—

(a) where toxicological studies carried out to assess risk to human or animal health are provided in the environmental risk assessment, the applicant must provide evidence to demonstrate that they were conducted in facilities which comply with—

(i) if carried out in the United Kingdom, retained EU law relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances,

(ii) if carried out in a member State of the EU, EU law relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances, or

(iii) if carried out elsewhere, the 'OECD Principles on Good Laboratory Practice',

(b) where studies other than toxicological studies are provided in the environmental risk assessment, they must—

(i) comply with the principles of Good Laboratory Practice laid down in retained EU law, where relevant, or

(ii) be conducted by organisations accredited under the relevant ISO standard, or

(iii) in the absence of a relevant ISO standard, be conducted in accordance with internationally recognised standards,

(c) information on the results obtained from the studies referred to in sub-paragraphs (a) and (b) and on the study protocols used must be reliable and comprehensive and must include the raw data in an electronic format suitable for carrying out statistical or other analysis,

(d) the applicant must specify, where possible, the size of effect that each study performed intends to detect and justify it,

(e) the selection of sites for field studies must be based on relevant receiving environments in view of the potential exposure and impact that would be observed where the genetically modified organism may be released. The selection must be justified in the environmental risk assessment, and

(f) the non-genetically modified comparator must be appropriate for the relevant receiving environment(s) and must have a genetic background comparable to the genetically modified organism. The choice of the comparator must be justified in the environmental risk assessment.

Step 4: Stacked transformation events in applications to which Part 3 of these Regulations applies

7. The following must apply to the environmental risk assessment of a genetically modified organism containing stacked transformation events in applications to which Part 3 of these Regulations applies—

(a) the applicant must provide an environmental risk assessment for each single transformation event in the genetically modified organism or refer to already submitted applications (or equivalent notifications) for those single transformation events,

(b) the applicant must provide an assessment of the following aspects—

(i) the stability of the transformation events,

(ii) the expression of the transformation events, and

(iii) the potential additive, synergistic or antagonistic effects resulting from the combination of the transformation events, and

(c) where the progeny of the genetically modified organism can contain various sub-combinations of the stacked transformation events, the applicant must provide a scientific rationale justifying that there is no need to provide experimental data for the concerned sub-combinations, independently of their origin, or, in the absence of such scientific rationale, must provide the relevant experimental data.

CHAPTER C.2

CHARACTERISTICS OF THE GENETICALLY MODIFIED ORGANISM AND OF THE RELEASES

8.—(1) The environmental risk assessment must take into account the relevant technical and scientific details regarding characteristics of—

(a) the recipient or parental organism(s),

(b) the genetic modification(s), be it insertion or deletion of genetic material, and relevant information on the vector and the donor,

(c) the genetically modified organism,

(d) the intended release or use including its scale,

(e) the potential receiving environment(s) into which the genetically modified organism will be released and into which the transgene may spread, and

(f) the interaction(s) between these characteristics.

(2) Relevant information from previous releases of the same or similar genetically modified organisms and organisms with similar traits and their biotic and abiotic interaction with similar receiving environments, including information resulting from the monitoring of such organisms, must be considered in the environmental risk assessment, subject to regulations 11(2) and 16(3).

CHAPTER C.3

STEPS IN THE ENVIRONMENTAL RISK ASSESSMENT

9. The environmental risk assessment must be conducted for each relevant area of risk referred to in Chapters D.1 and D.2 of Part D of this schedule in accordance with the following six steps.

Step 1: Problem formulation including hazard identification

10.—(1) The problem formulation must—

(a) identify any changes in the characteristics of the organism, linked to the genetic modification, by comparing the characteristics of the genetically modified organism with those of the chosen non-genetically modified comparator under corresponding conditions of release or use,

(b) identify potential adverse effects on human health or the environment which are linked to the changes that have been identified under sub-paragraph (1)(a),

(c) identify relevant assessment end-points,

(d) identify and describe the exposure pathways or other mechanisms through which adverse effects may occur,

(e) formulate testable hypotheses, and define relevant measurement end-points, to allow, where possible, a quantitative evaluation of the potential adverse effect(s), and

(f) consider possible uncertainties, including knowledge gaps and methodological limitations.

(2) For the purposes of sub-paragraph (1)(b)—

(a) potential adverse effects must not be discounted on the basis that they are unlikely to occur,

(b) potential adverse effects will vary from case to case, and may include—

(i) effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations leading to a potential decline in biodiversity,

(ii) altered susceptibility to pathogens facilitating the dissemination of infectious diseases or creating new reservoirs or vectors,

(iii) compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine,

(iv) effects on biogeochemistry (biogeochemical cycles), including carbon and nitrogen recycling through changes in soil decomposition of organic material,

(v) disease affecting humans, including allergenic or toxic reactions, and

(vi) disease affecting animals and plants, including toxic, and, in the case of animals, allergenic reactions, where appropriate, and

(c) where potential long-term adverse effects of a genetically modified organism are identified, they must be assessed in the form of desk based studies using, where possible, one or more of the following—

(i) evidence from previous experiences,

(ii) available data sets or literature, or

(iii) mathematical modelling.

(3) For the purposes of sub-paragraph (1)(c), the potential adverse effects that could impact the identified assessment end-points must be considered in the next steps of the risk assessment.

(4) For the purposes of sub-paragraph (1)(d), adverse effects may occur directly or indirectly through exposure pathways or other mechanisms which may include—

(a) the spread of the genetically modified organism(s) in the environment,

(b) the transfer of the inserted genetic material to the same organism or other organisms, whether genetically modified or not,

(c) phenotypic and genetic instability,

(d) interactions with other organisms, and

(e) changes in management, including, where applicable, in agricultural practices.

Step 2: Hazard characterisation

11.—(1) The magnitude of each potential adverse effect must be evaluated. This evaluation must assume that such an adverse effect will occur. The environmental risk assessment must consider that the magnitude is likely to be influenced by the receiving environment(s) into which the genetically modified organism is intended to be released and by the scale and conditions of the release.

(2) Where possible, the evaluation must be expressed in quantitative terms.

(3) Where the evaluation is expressed in qualitative terms, a categorical description ('high', 'moderate', 'low' or 'negligible') must be used and an explanation of the scale of effect represented by each category must be provided.

Step 3: Exposure characterisation

12.—(1) The likelihood or probability of each identified potential adverse effect occurring must be evaluated to provide, where possible, a quantitative assessment of the exposure as a relative measure of probability, or otherwise a qualitative assessment of the exposure. The characteristics of the receiving environment(s) and the scope of the application must be taken into consideration.

(2) Where the evaluation is expressed in qualitative terms, a categorical description ('high', 'moderate', 'low' or 'negligible') of the exposure must be used and an explanation of the scale of effect represented by each category must be provided.

Step 4: Risk characterisation

13.—(1) The risk must be characterised by combining, for each potential adverse effect, the magnitude with the likelihood of that adverse effect occurring to provide a quantitative or semi quantitative estimation of the risk.

(2) Where a quantitative or semi quantitative estimation is not possible, a qualitative estimation of the risk must be provided. In that case, a categorical description ('high', 'moderate', 'low' or 'negligible') of the risk must be used and an explanation of the scale of effect represented by each category must be provided.

(3) Where relevant, the uncertainty for each identified risk must be described and, where possible, expressed in quantitative terms.

Step 5: Risk management strategies

14.—(1) Where risks are identified that require, on the basis of their characterisation, measures to manage them, a risk management strategy must be proposed for each risk.

(2) The risk management strategies must be described in terms of reducing the hazard or the exposure, or both, and must be proportionate to the intended reduction of the risk, the scale and conditions of the release and the levels of uncertainty identified in the environmental risk assessment

(3) The consequent reduction in overall risk must be quantified where possible.

Step 6: Overall risk evaluation and conclusions

15.—(1) A qualitative and, where possible, quantitative evaluation of the overall risk of the genetically modified organism must be made taking into account the results of the risk characterisation, the proposed risk management strategies and the associated levels of uncertainty.

(2) The overall risk evaluation must include, where applicable, the risk management strategies proposed for each identified risk.

(3) The overall risk evaluation and conclusions must also propose specific requirements for the monitoring plan of the genetically modified organism and, where appropriate, the monitoring of the efficacy of the proposed risk management measures.

(4) For applications to which Part 3 of these Regulations applies, the overall risk evaluation must also include an explanation of the assumptions made during the environmental risk assessment and of the nature and magnitude of uncertainties associated with the risks, and a justification of the risk management measures proposed.

PART D

CONCLUSIONS ON THE SPECIFIC AREAS OF RISK OF THE ENVIRONMENTAL RISK ASSESSMENT

16. Conclusions on the potential environmental impact in relevant receiving environments from the release or the placing on the market of genetically modified organisms must be drawn for each relevant area of risk listed in Chapter D.1 for genetically modified organisms other than higher plants or, as the case may be, Chapter D.2 for genetically modified higher plants, on the basis of an environmental risk assessment carried out in accordance with the principles outlined in Part B of this schedule and following the methodology described in Part C of this schedule, and on the basis of the information required pursuant to schedules 2 and 3.

CHAPTER D.1

GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS

Areas of risk

17.—(1) Likelihood of the genetically modified organism becoming persistent and invasive in natural habitats under the conditions of the proposed release(s).

(2) Any selective advantage or disadvantage conferred to the genetically modified organism and the likelihood of this becoming realised under the conditions of the proposed release(s).

(3) Potential for gene transfer to other species under conditions of the proposed release of the genetically modified organism and any selective advantage or disadvantage conferred to those species.

(4) Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the genetically modified organism and target organisms (if applicable).

(5) Potential immediate and/or delayed environmental impact of the direct and indirect interactions between the genetically modified organism with non-target organisms, including impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

(6) Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the genetically modified organism and persons working with, coming into contact with or in the vicinity of the genetically modified organism release(s).

(7) Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the genetically modified organism and any product derived from it, if it is intended to be used as animal feed.

(8) Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the genetically modified organism and target and non-target organisms in the vicinity of the genetically modified organism release(s).

(9) Possible immediate and/or delayed, direct and indirect environmental impacts of the specific techniques used for the management of the genetically modified organism where these are different from those used for non-genetically modified organisms.

CHAPTER D.2

GENETICALLY MODIFIED HIGHER PLANTS

Areas of risk

18.—(1) Persistence and invasiveness of the genetically modified higher plants, including plant to plant gene transfer.

(2) Plant to micro-organisms gene transfer.

(3) Interactions of the genetically modified higher plants with target organisms.

(4) Interactions of the genetically modified higher plants with non-target organisms.

(5) Impacts of the specific cultivation, management and harvesting techniques.

(6) Effects on biogeochemical processes.

(7) Effects on human and animal health."

SCHEDULE 2 Regulation 3(29)

NEW SCHEDULE 5A TO BE INSERTED

"SCHEDULE 5A Regulation 16(2)(g) and schedule 4

MONITORING PLAN

Introduction

1. This schedule describes in general terms the objective to be achieved and the general principles to be followed in the design of the monitoring plan referred to in regulations 16(2)(g) and 28(f).

PART A

OBJECTIVE

2. The objective of a monitoring plan is to—

(a) confirm that any assumption regarding the occurrence and impact of potential adverse effects of the genetically modified organism or its use in the environmental risk assessment are correct, and

(b) identify the occurrence of adverse effects of the genetically modified organism or its use on human health or the environment which were not anticipated in the environmental risk assessment.

PART B

GENERAL PRINCIPLES

3.—(1) Monitoring takes place after the consent to the placing of a genetically modified organism on the market.

(2) The interpretation of the data collected by monitoring should be considered in the light of other existing environmental conditions and activities. Where changes in the environment are observed, further assessment should be considered to establish whether they are a consequence of the genetically modified organism or its use, as such changes may be the result of environmental factors other than the placing of the genetically modified organism on the market.

(3) Experience and data gained through the monitoring of experimental releases of genetically modified organisms may assist in designing the post marketing monitoring regime required for the placing on the market of genetically modified organisms as or in products.

PART C

DESIGN OF THE MONITORING PLAN

4. The design of the monitoring plan should—

(a) be detailed on a case by case basis taking into account the environmental risk assessment,

(b) take into account the characteristics of the genetically modified organism, the characteristics and scale of its intended use and the range of relevant environmental conditions where the genetically modified organism is expected to be released,

(c) incorporate general surveillance for unanticipated adverse effects and, if necessary, (case-)specific monitoring focusing on adverse effects identified in the environmental risk assessment—

(i) whereas case-specific monitoring should be carried out for a sufficient time period to detect immediate and direct as well as, where appropriate, delayed or indirect effects which have been identified in the environmental risk assessment, and

(ii) whereas surveillance could, if appropriate, make use of already established routine surveillance practices such as the monitoring of agricultural cultivars, plant protection, or veterinary and medical products. An explanation as to how relevant information collected through established routine surveillance practices will be made available to the consent-holder should be provided,

(d) facilitate the observation, in a systematic manner, of the release of a genetically modified organism in the receiving environment and the interpretation of these observations with respect to safety to human health or the environment,

(e) identify who (applicant, users) will carry out the various tasks the monitoring plan requires and who is responsible for ensuring that the monitoring plan is set into place and carried out appropriately, and ensure that there is a route by which the consent holder and the Scottish Ministers will be informed on any observed adverse effects on human health and the environment (time points and intervals for reports on the results of the monitoring must be indicated), and

(f) give consideration to the mechanisms for identifying and confirming any observed adverse effects on human health and environment and enable the consent holder or the Scottish Ministers, where appropriate, to take the measures necessary to protect human health and the environment."

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are mainly made in exercise of the powers conferred by paragraph 1(1) and (3) of schedule 2, and paragraph 21 of schedule 7, of the European Union (Withdrawal) Act 2018 in order to address, on exit day, failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union. But Part 2 also makes some changes to related subordinate legislation, before exit day, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972. More specifically—

Part 2 amends the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 to clarify and adjust some provisions before exit day.

Part 3 amends the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 and the Genetically Modified Organisms (Transboundary Movements) (Scotland) Regulations 2002 to address deficiencies arising from the withdrawal of the UK from the EU.

No business and regulatory impact assessment has been prepared for these Regulations as no impact upon business, charities or voluntary bodies is foreseen.