
SCOTTISH STATUTORY INSTRUMENTS

2019 No. 86

**The Genetically Modified Organisms (Deliberate Release etc.)
(Miscellaneous Amendments) (Scotland) Regulations 2019**

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Deliberate Release etc.) (Miscellaneous Amendments) (Scotland) Regulations 2019 and come into force on 15 March 2019.

(2) These Regulations extend to Scotland only.

Amendment to the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002

2. The Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002(1) are amended in accordance with regulations 3 to 19.

3. In regulation 2(1) (interpretation)—

(a) in the definition of “approved product”, after “granted” insert “, by a person other than the Scottish Ministers,”,

(b) for the definition of “the Contained Use Directive”, substitute—

““the Contained Use Directive” means [Directive 2009/41/EC](#) of the European Parliament and of the Council on the contained use of genetically modified micro-organisms(2),”

(c) in the definition of “the Deliberate Release Directive”, for “as amended by” to the end substitute “, as last amended by Commission Directive (EU) 2018/350(3),”

(d) for the definition of “1990 Directive” substitute—

““1990 Directive” means Council [Directive 90/220/EEC](#) on the deliberate release into the environment of genetically modified organisms(4), as it had effect before it was repealed by [Directive 2001/18/EC](#) of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council [Directive 90/220/EEC](#)(5),”

(e) for the definition of “the First Simplified Procedure (crop plants) Decision” substitute—

““the First Simplified Procedure (crop plants) Decision” means Commission [Decision 94/730/EC](#) establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6(5) of Council [Directive 90/220/EEC](#)(6),”

(1) [S.S.I. 2002/541](#), as amended by [S.S.I. 2004/439](#), [S.I. 2005/2759](#), and [S.S.I. 2015/100](#).

(2) [OJ L 125](#), 21.5.2009, p.75.

(3) [OJ L 67](#), 9.3.2018, p.30.

(4) [OJ L 117](#), 8.5.1990, p.15, as amended by Commission [Directive 94/15/EC](#) ([OJ L 103](#), 22.4.1994, p.20) and Commission [Directive 97/35/EC](#) ([OJ L 169](#), 27.6.1997, p.72).

(5) [OJ L 106](#), 17.4.2001, p.1.

(6) [OJ L 292](#), 12.11.1994, p.31.

- (f) for the definition of “the Food and Feed Regulation” substitute—
 ““the Food and Feed Regulation” means Council Regulation (EC) No 1829/2003 on genetically modified food and feed(7),”, and
- (g) omit the definition of “Regulation 2309/93”.
4. For regulation 11(1)(a) (information to be contained in an application for consent to release), substitute—
- “(a) the information prescribed in Part 1 of schedule 2, where the application is for consent to release any genetically modified higher plant, or schedule 3 in any other case, to the extent that such information is—
- (i) appropriate to the nature and scale of the release or application, and
- (ii) in the case of schedule 2, relevant and necessary for the purposes of the environmental risk assessment referred to in sub-paragraph (c), in view particularly of the characteristics of the genetically modified organism and of the scale and conditions of the release or of its intended conditions of use;
- (aa) where the application is for consent to release a genetically modified higher plant, summaries and results of studies referred to in the application for consent to release, including an explanation of their relevance to the environmental risk assessment under sub-paragraph (c), where applicable.”
5. For regulation 12(4)(c) (advertisement of applications for consent to release) substitute—
- “(c) any person, or a genetic modification safety committee, from whom advice must be obtained under regulation 8 of the Genetically Modified Organisms (Contained Use) Regulations 2014(8).”
6. Omit regulation 13 (transitional provisions in respect of applications to release).
7. In regulation 15 (exempt activities)—
- (a) the existing text becomes paragraph (1),
- (b) in sub-paragraph (e), for the words from “Regulation (EC) No. 726/2004” to “Agency”, substitute “Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency(9)”,
- (c) at the end of sub-paragraph (e), after “marketed;” insert “and”,
- (d) omit—
- (i) sub-paragraph (f), and
- (ii) the word “and” immediately following that sub-paragraph, and
- (e) after paragraph (1) insert—
- “(2) In paragraph (1)(e), “Regulation 2309/93” means Council Regulation (EEC) No 2309/93 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products(10), as it had effect before it was

(7) OJ L 268, 18.10.2003, p.1, as last amended by Regulation (EC) No 298/2008 of the European Parliament and of the Council (OJ L 97, 9.4.2008, p.64).

(8) S.I. 2014/1663.

(9) OJ L 136, 30.4.2004, p.1, as last amended by Regulation (EU) No 1027/2012 of the European Parliament and of the Council (OJ L 316, 14.11.2012, p.38).

(10) OJ L 214, 24.8.1993, p.1, as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p.7), Council Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p.36), and Commission Regulation (EC) No 1647/2003 (OJ L 245, 29.9.2003, p.19).

repealed by Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency⁽¹¹⁾

8. For regulation 16(2)(a) (applications for consent to market), substitute—
- “(a) the information prescribed in Part 2 of schedule 2, where the application is for consent to market any genetically modified higher plant, or schedule 3 in any other case, to the extent that such information is—
 - (i) appropriate to the nature and scale of the release or application, and
 - (ii) in the case of schedule 2, relevant and necessary for the purposes of the environmental risk assessment referred to in sub-paragraph (c), in view especially of the characteristics of the genetically modified organism and of the scale and conditions of the release or of its intended conditions of use,
 - (aa) where the application is for consent to market a genetically modified higher plant, summaries and results of studies referred to in the application for consent to market, including an explanation of their relevance to the environmental risk assessment referred to in sub-paragraph (c), where applicable,
 - (ab) where the application is for consent to market a genetically modified higher plant, detailed information on the studies referred to in the application for consent to market, including—
 - (i) a description of the methods and materials used or the reference to standardised or internationally recognised methods, and
 - (ii) the name of the body or bodies responsible for carrying out the studies,”.
9. Omit—
- (a) regulation 17 (transitional provisions in respect of applications to market), and
 - (b) regulation 17A (transitional measures for adventitious and technically unavoidable presence of genetically modified material which has benefited from a favourable risk assessment).
10. In regulation 24 (decisions by the Scottish Ministers on applications for consent to market)—
- (a) in paragraph (1) for “In the cases of”, substitute “Subject to paragraph (8), in the cases of”,
 - (b) in paragraph (5)—
 - (i) after “agricultural plant species” insert “, as last amended by Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed⁽¹²⁾”, and
 - (ii) after “vegetable seed” insert “, as last amended by Commission Implementing Directive (EU) 2016/317 of 3 March 2016 amending Council Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/55/EC, 2002/56/EC and 2002/57/EC as regards the official label of seed packages⁽¹³⁾”,
 - (c) in paragraph (6) after “1999/105/EC” insert “on the marketing of forest reproductive material⁽¹⁴⁾”, and
 - (d) after paragraph (6) insert—

(11) OJ L 136, 30.4.2004, p.1.

(12) OJ L 268, 18.10.2003, p.1.

(13) OJ L 60, 5.3.2016, p.72.

(14) OJ L 11, 15.1.2000, p.17.

“(7) A consent to market a genetically modified organism received by the Scottish Ministers must include a limit on the geographical scope of the cultivation of the genetically modified organism corresponding to any demand made by—

- (a) the Scottish Ministers under regulation 26A(1), or
- (b) a member State under Article 26b(1) of the Deliberate Release Directive,

unless the applicant notifies the Scottish Ministers in writing of that applicant’s refusal to agree to the demand within 30 days of being notified of it by the Commission.

(8) Where a demand to limit the geographical scope of the cultivation of a genetically modified organism is made—

- (a) by the Scottish Ministers under regulation 26A(1), or
- (b) a member State under Article 26b(1) of the Deliberate Release Directive,

after the date of circulation of the assessment report by the Commission under Article 14(2) of the Deliberate Release Directive, the 60 and 105 day periods specified in paragraph (1)(a) and (b) are to be extended by a single period of 15 days.

(9) The Scottish Ministers may, following the inclusion of a limit under paragraph (7), vary the consent to reintegrate all or any part of Scotland.

(10) The Scottish Ministers must vary a consent in accordance with any request by a member State under Article 26b(5) of the Deliberate Release Directive to reintegrate all or part of its territory.

(11) The Scottish Ministers must inform—

- (a) the Commission of any refusal to agree to a demand notified to the Scottish Ministers under paragraph (7), and
- (b) the Commission, the member States and the holder of the consent of any variation under paragraph (9) or (10).”.

11. In regulation 26 (decisions by the Scottish Ministers on applications for renewals of consent to market), after paragraph (4) insert—

“(5) A renewed consent to market a genetically modified organism received by the Scottish Ministers must include a limit on the geographical scope for the cultivation of the genetically modified organism corresponding to any demand made by—

- (a) the Scottish Ministers under regulation 26A(1), or
- (b) a member State under Article 26b(1) of the Deliberate Release Directive,

unless the applicant notifies the Scottish Ministers of that applicant’s refusal to agree to the demand within 30 days of being notified of it by the Commission.

(6) The Scottish Ministers may, following the inclusion of a limit under paragraph (5), vary the renewed consent to reintegrate all or any part of Scotland.

(7) The Scottish Ministers must vary a renewed consent in accordance with any request by a member State under Article 26b(5) of the Deliberate Release Directive to reintegrate all or part of its territory.

(8) The Scottish Ministers must inform the Commission, the member States and the holder of the renewed consent of any variation under paragraph (6) or (7).”.

12. After regulation 26, insert—

“Demand for the adjustment of geographical scope of consent or authorisation in respect of cultivation of genetically modified organisms

26A.—(1) The Scottish Ministers may, in respect of any relevant application, demand that the geographical scope of any resulting consent or authorisation is adjusted to exclude all or any part of Scotland for the purposes of cultivating a genetically modified organism.

(2) A demand under paragraph (1) must be communicated by the Scottish Ministers to the Commission within 45 days at the latest of—

- (a) the date of circulation of the assessment report by the Commission under Article 14(2) of the Deliberate Release Directive, or
- (b) the date of receipt of the opinion of the European Food Safety Authority under Article 6(6), or Article 18(6) of the Food and Feed Regulation.

(3) In this regulation, “relevant application” means an application for any of the following—

- (a) consent to place on the market a genetically modified organism under—
 - (i) section 111(1) of the Act, or
 - (ii) otherwise under Part C of the Deliberate Release Directive,
- (b) renewal of consent to place on the market genetically modified organisms under—
 - (i) regulation 18, or
 - (ii) otherwise under Part C of the Deliberate Release Directive,
- (c) an authorisation to place on the market genetically modified organisms under Article 5 or 17 of the Food and Feed Regulation, or
- (d) renewal of authorisation to place on the market genetically modified organisms under Article 11 or 23 of the Food and Feed Regulation.

(4) A relevant application includes an application made to a competent authority other than the Scottish Ministers⁽¹⁵⁾ or Food Standards Scotland⁽¹⁶⁾.

Request for reintegration following exclusion from geographical scope

26B.—(1) The Scottish Ministers may request that all or any part of Scotland be reintegrated by being included in a consent (including a renewed consent) or authorisation from which it is excluded following a demand under regulation 26A(1).

(2) A request under paragraph (1) is made by notifying—

- (a) in the case of a consent under the Deliberate Release Directive, the competent authority which issued the consent, or

(15) Under Directive 2001/18 of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms (OJ L 106/17.4.2001), Part C, where an applicant intends to place a genetically modified organism on the market that person may notify the competent authority, as designated for the purposes of Article 4(4) of that Directive, of any member State. In addition, such a person may notify a competent authority in another part of the United Kingdom in accordance with the applicable legislation there.

(16) The Food and Feed Regulation (as defined in regulation 2(1) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 [S.S.I. 2002/541](#)) is implemented by the Genetically Modified Food (Scotland) Regulations 2004 ([S.S.I. 2004/432](#)) in relation to food and by the Genetically Modified Animal Feed (Scotland) Regulations 2004 ([S.S.I. 2004/433](#)) in relation to animal feed. Regulation 3 of [S.S.I. 2004/432](#) (as amended by [S.S.I. 2015/100](#)) designates Food Standards Scotland as the national competent authority in Scotland for the purposes of receiving applications for the authorisation of new genetically modified organisms in relation to food. Regulation 3 of [S.S.I. 2004/433](#) (as amended by [S.S.I. 2015/100](#)), designates Food Standards Scotland as the national competent authority in Scotland for receiving applications for the authorisation of new genetically modified organisms in relation to feed. Under the Food and Feed Regulation a person may make an application for authorisation to place on the market a genetically modified organism for food use or for food to the national competent authority of any member State (Article 5 refers). In addition, such a person may make such an application to the national competent authority in another part of the United Kingdom in accordance with the applicable legislation there.

- (b) in the case of an authorisation under the Food and Feed Regulation, the Commission.”.

13. After regulation 29, insert—

“Restrictions on cultivation

29A.—(1) This regulation applies to—

- (a) a consent given by the Scottish Ministers under section 111(1) of the Act (including a renewed consent given under regulation 26),
- (b) an approved product, or
- (c) an authorisation under the Food and Feed Regulation,

in respect of which the circumstances in paragraph (2) apply.

(2) The circumstances mentioned in paragraph (1) are—

- (a) the Scottish Ministers did not make a demand under regulation 26A(1), or
- (b) the applicant refused to agree with a demand made under regulation 26A(1) within a period of 30 days of being notified of it by the Commission.

(3) The Scottish Ministers may, in the circumstances prescribed in paragraph (7), do any of the following—

- (a) include a condition in the consent or renewed consent to limit its geographical scope as regards Scotland in respect of the cultivation of a genetically modified organism,
- (b) issue a suspension notice in respect of a consent or renewed consent,
- (c) issue a suspension notice in respect of the approved product, or
- (d) issue a suspension notice in respect of the authorisation under the Food and Feed Regulation.

(4) The effect of a suspension notice issued under paragraph (3)(b) is to suspend the operation of the consent in respect of the cultivation of a genetically modified organism for all or a specified geographical area of Scotland.

(5) The effect of a suspension notice issued under paragraph (3)(c) is to suspend, so far as it applies to the requirement in section 111(1)(a) of the Act for all or a specified geographical area of Scotland, the operation of the exemption in regulation 15(a) (exempt activities), in respect of the cultivation of a specified approved product.

(6) The effect of a suspension notice issued under paragraph (3)(d) is to suspend, so far as it applies to the requirement in section 111(1)(a) of the Act for all or a specified geographical area of Scotland, the operation of the exemption in regulation 15(g), in respect of the cultivation of genetically modified food or feed authorised under the Food and Feed Regulation.

(7) The prescribed circumstances are that the Scottish Ministers are of the view that it is necessary to restrict the cultivation of a genetically modified organism, or a group of genetically modified organisms, on the basis of compelling grounds that—

- (a) may include one or more of the following—
 - (i) environmental policy objectives,
 - (ii) town and country planning,
 - (iii) land use,
 - (iv) socio-economic impacts,

- (v) the avoidance of the presence of genetically modified organisms in other products, without prejudice to any measures adopted in respect of Article 26a of the Deliberate Release Directive,
 - (vi) agricultural policy objectives,
 - (vii) subject to paragraph (8), public policy,
 - (b) are in conformity with EU law,
 - (c) are proportional,
 - (d) are non-discriminatory, and
 - (e) do not conflict with the environmental risk assessment carried out pursuant to the Deliberate Release Directive or the Food and Feed Regulation.
- (8) Public policy can only be relied upon in combination with at least one other ground included in sub-paragraph (a)(i) to (vi) of paragraph (7).
- (9) Before taking any of the actions in paragraph (3), the Scottish Ministers must—
- (a) notify the Commission of—
 - (i) a draft of the condition or suspension notice, and
 - (ii) the applicable grounds under paragraph (7)(a),
 - (b) where they consider appropriate, in the case of a notice served under regulation 29A(3)(d), notify Food Standards Scotland, and
 - (c) make the reasons for the decision to take those actions available to the public.
- (10) A condition or suspension notice under paragraph (3) must not take effect until the expiry of the period of 75 days starting on the date of the notification under paragraph (9).
- (11) The Scottish Ministers may amend a condition or suspension notice to take account of comments from the Commission or another member State prior to its coming into force.
- (12) The Scottish Ministers must—
- (a) communicate the condition or suspension notice to the Commission, the other member States and the consent or authorisation holder without delay, and
 - (b) make details of the condition or suspension notice available to the public.

Removal of restrictions under regulation 29A

29B.—(1) The Scottish Ministers may, at any time, do any of the following in respect of measures adopted under regulation 29A—

- (a) vary a condition in a consent to remove the limit on geographical scope in respect of the cultivation of a genetically modified organism,
- (b) withdraw a suspension notice in respect of a consent,
- (c) withdraw a suspension notice in respect of an approved product,
- (d) withdraw a suspension notice in respect of an authorisation under the Food and Feed Regulation.

(2) The Scottish Ministers must notify the Commission and the other member States of any action taken under paragraph (1) without delay.”.

14. After regulation 30, insert—

“Stop notices

30A.—(1) The Scottish Ministers may serve a notice under this regulation (a “stop notice”) on any person they have reason to believe—

- (a) is releasing or marketing a genetically modified organism, or has released or marketed a genetically modified organism, and the release or marketing of that organism is not—
 - (i) pursuant to a consent granted by the Scottish Ministers under section 111(1) of the Act or otherwise granted under the Deliberate Release Directive, or
 - (ii) under and in accordance with any limitation or condition to which such a consent is subject,
- (b) is cultivating or has cultivated a genetically modified organism in contravention of a limit included on the geographical scope of a consent to market under regulation 24(7) or a renewed consent to market under regulation 26(5),
- (c) is cultivating or has cultivated a genetically modified organism in contravention of a condition in a consent to limit its geographical scope under regulation 29A(3) (a), or
- (d) is cultivating or has cultivated a genetically modified organism or approved product in contravention of a suspension notice issued under regulation 29A(3) (b) or (c).

(2) A stop notice served on a person may—

- (a) prohibit a person from carrying out any act,
- (b) require a person to cease carrying out any act,
- (c) require a person to carry out any act,

for the purposes of ensuring, in so far as is possible, that the release, cultivation, placing on the market or marketing of the genetically modified organism is terminated.

(3) The stop notice must—

- (a) state that the Scottish Ministers are, in relation to the person on whom it is served, of the belief mentioned in paragraph (1),
- (b) specify, for the purposes of paragraph (2), what act is to be prohibited, required or ceased and any applicable timescale, and
- (c) specify the date on which the stop notice takes effect (which may be the date of service).

(4) The Scottish Ministers must, where they consider appropriate, notify Food Standards Scotland before serving a stop notice.

(5) The Scottish Ministers may at any time vary or withdraw a stop notice served on any person by giving reasonable notice.”.

15. In regulation 32(1) (safeguard), after “consent granted” insert “by them under section 111(1) of the Act or by a consent granted”.

16. After regulation 32, insert—

“PART VIA

Inspection powers, offences and service of notices

Powers of inspectors

32A.—(1) For the purpose of enforcing these Regulations, an inspector may exercise any of the powers specified in this regulation.

(2) An inspector may, on producing if so required a duly authenticated document showing their authority, at all reasonable hours enter any land (excluding any premises used wholly or mainly as a private dwelling).

(3) If a sheriff, on sworn information in writing, is satisfied that there are reasonable grounds for entry into any premises by an inspector under this regulation and either that—

- (a) entry has been refused or a refusal is reasonably expected, and that person has given notice to the occupier of their intention to apply for an entry warrant, or
- (b) a request for entry, or the giving of such a notice, would frustrate the object of entry, or entry is urgently required, or the premises are unoccupied, or the occupier is temporarily absent and it would frustrate the object of entry to await the occupier’s return,

the sheriff, may, by signed warrant, valid for a period of no more than one month, authorise that person, together with any person who may accompany an inspector by virtue of paragraph (4)(a), to enter the premises, if need be by reasonable force.

(4) An inspector may—

- (a) take onto the land such other persons and such materials and equipment (including vehicles) as may be reasonably required for the purpose of assisting the inspector to exercise the power,
- (b) do anything else which is reasonably required for that purpose,
- (c) take samples of things on the land,
- (d) mark anything on the land for identification purposes,
- (e) in the case of anything on the land which appears to contain or have contained a genetically modified organism-
 - (i) cause it to be dismantled or subjected to any process or test, or
 - (ii) examine it,
- (f) take a photograph or any other digital record of anything on the land,
- (g) require access to, inspect and take copies of, or extracts from, any information on the land,
- (h) take away any information to enable it to be copied or kept as evidence,
- (i) require access to, inspect and check the operation of any computer and any associated apparatus or material and, for this purpose, require any person having charge of, or otherwise concerned with the operation of, any computer, apparatus or material to give the inspector such assistance as the inspector may reasonably require,
- (j) where information is kept by means of a computer, require it to be produced in a form in which it can be taken away.

(5) If an inspector causes damage in exercising the power, they must take reasonable steps to remedy the damage.

(6) If an inspector enters unoccupied land in exercising the power, the inspector must leave the land as effectively secured against unauthorised entry as the inspector found it.

(7) In this regulation, “inspector” means a person appointed by the Scottish Ministers.

(8) In this regulation, “sheriff” includes a summary sheriff.

Offences and penalties

32B.—(1) A person commits an offence if that person—

- (a) contravenes anything required of that person in a stop notice,
- (b) obstructs an inspector (or a person accompanying an inspector and acting under the inspector’s instructions) in exercise of the power conferred by regulation 32A,
- (c) supplies to an inspector (or a person accompanying an inspector and acting under the inspector’s instructions) any information knowing it to be false or misleading,
- (d) cultivates a genetically modified organism in contravention of a limit included on the geographical scope of a consent to market under regulation 24(7) or a renewed consent to market under regulation 26(5),
- (e) cultivates a genetically modified organism in contravention of a condition in a consent to limit its geographical scope under regulation 29A(3)(a), or
- (f) cultivates a genetically modified organism or approved product in contravention of a suspension notice issued under regulation 29A(3)(b),(c) or (d).

(2) It is a defence for a person charged with an offence under paragraph (1) to show that they took all reasonable precautions and exercised all due diligence to avoid committing that offence.

(3) A person who commits an offence under paragraph (1) is liable—

- (a) on summary conviction, to a fine not exceeding level 5 on the standard scale or to imprisonment for a term not exceeding three months, or to both, or
- (b) on conviction on indictment, to a fine or to imprisonment for a terms not exceeding 2 years or both.

Individual culpability for offending by an organisation

32C.—(1) Paragraph (2) applies where—

- (a) an offence under these regulations is committed by a relevant organisation, and
- (b) the commission of the offence involves the consent or connivance of, or is attributable to the neglect of—
 - (i) a responsible official of the organisation, or
 - (ii) an individual purporting to act in the capacity of a responsible official.

(2) The responsible official (or, as the case may be, the individual purporting to act in that capacity) as well as the organisation, commits the offence.

(3) “Relevant organisation” means—

- (a) a company,
- (b) a partnership (including a limited liability partnership),
- (c) another body or association.

(4) “Responsible official” means—

- (a) in the case of a company—

- (i) a director, secretary, manager or similar officer, or
- (i) where the affairs of the company are managed by its members, a member,
- (b) in the case of a limited liability partnership, a member,
- (c) in the case of a partnership other than a limited liability partnership, a partner,
- (d) in the case of another body or association, a person who is concerned in the management or control of its affairs.

Service of notices

32D.—(1) Any notice required to be given to any person by the Scottish Ministers by virtue of these Regulations may be given by—

- (a) delivering it to that person,
- (b) leaving it at that person’s proper address,
- (c) sending it by post or fax to that person’s proper address, or
- (d) sending it by email to that person’s last known email address.

(2) For the purposes of paragraph (1)(a), a notice is delivered to—

- (a) a body corporate where it is given to a relevant individual within that body,
- (b) a partnership where it is given to a partner or a person having control or management of the partnership, and
- (c) an unincorporated association where it is given to an officer or a member of the governing body of the association or any other person having management responsibilities in respect of the association.

(3) For the purposes of paragraph (1)(b) and (c) and section 7 of the Interpretation Act 1978(17) (service of documents by post) in its application to this regulation, “proper address” means—

- (a) in the case of a body corporate, the registered office (if it is in the United Kingdom) or the principal office of the body in the United Kingdom,
- (b) in the case of a partnership, the principal office of the partnership,
- (c) in the case of an unincorporated association, the principal office of the association,
- (d) in any other case, a person’s last known address.

(4) For the purposes of paragraph (1)(d), a notice is sent to an email address of—

- (a) a body corporate, where it is sent to an email address of—
 - (i) the body corporate, or
 - (ii) a relevant individual within that body,

where that address is supplied by that body for the conduct of the affairs of that body,

- (b) a partnership, where it is sent to an email address of—
 - (i) the partnership, or
 - (ii) a partner or person having control or management of that partnership,

where that address is supplied by that partnership for the conduct of the affairs of the partnership,

- (c) an unincorporated association, where it is sent to an email address of—

- (i) an officer or member of the governing body of the association, or
 - (ii) any other person having management responsibilities in respect of the association,
where that address is supplied by that association for the conduct of the affairs of that association, and
 - (d) a person other than a person mentioned in sub-paragraph (a), (b) or (c), where it is sent to an email address supplied by that person for the conduct of the affairs of that person.
- (5) In this regulation—
- (a) “partnership” includes a Scottish partnership, and
 - (b) “relevant individual” means—
 - (i) a director, manager, secretary or other similar officer of the body corporate, or
 - (ii) where the affairs of the body corporate are managed by its members, a member.”.

17. Omit schedule 1 (definition of Regulation 2309/93).

18. For schedule 2 (information to be included in applications for consent to release or market genetically modified higher plants) substitute—

“SCHEDULE 2

Regulations 11(1) and 16(2)

INFORMATION TO BE INCLUDED IN APPLICATIONS FOR CONSENT
TO RELEASE OR MARKET GENETICALLY MODIFIED HIGHER PLANTS

PART 1

INFORMATION TO BE INCLUDED IN APPLICATIONS
FOR CONSENT TO RELEASE FOR ANY OTHER
PURPOSE THAN FOR PLACING ON THE MARKET

A. General information

1. The name and address of the applicant, and the name, qualifications and experience of the scientist and of every other person who will be responsible for planning and carrying out the release of the organisms, and for the supervision, monitoring and safety of the release.
2. The title of the project.

B. Information relating to the release

3. The purpose of the release.
4. The foreseen date or dates and duration of the release.
5. The method by which the genetically modified plants will be released.
6. The method for preparing and managing the release site, prior to, during and after the release, including cultivation practices and harvesting methods.

7. The approximate number of genetically modified plants (or plants per square metre) to be released.

C. Information relating to the site of release

8. The location and size of the release site or sites.

9. A description of the release site ecosystem, including climate, flora and fauna.

10. The details of any sexually compatible wild relatives or cultivated plant species site or sites.

11. The proximity of the release site or sites to officially recognised biotopes or protected areas which may be affected.

D. Information relating to the recipient plant or, where appropriate, to the parental plants

12. The full name of the plant, that is—

- (a) family name,
- (b) genus,
- (c) species,
- (d) subspecies,
- (e) cultivar or breeding line, and
- (f) common name.

13. The geographical distribution and cultivation of the plant within the EU.

14. Information concerning—

- (a) the reproduction of the plant, that is—
 - (i) the mode or modes of reproduction,
 - (ii) any specific factors affecting reproduction,
 - (iii) the generation time, and
- (b) the sexual compatibility of the plant with other cultivated or wild plant species including the distribution in Europe of the compatible species.

15. Information concerning the survivability of the plant, that is—

- (a) its ability to form structures for survival or dormancy, and
- (b) any specific factors affecting survivability.

16. Information concerning the dissemination of the plant, that is—

- (a) the ways and extent of dissemination, and
- (b) any specific factors affecting dissemination.

17. Where the application relates to a plant species which is not normally grown in the UK a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

18. Information concerning any other potential interactions, relevant to the genetically modified organism, of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

E. Molecular characterisation

19. Information relating to the genetic modification, that is—
- (a) a description of the methods used for the genetic modification,
 - (b) the nature and source of the vector used, and
 - (c) the source of the nucleic acid or acids used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.
20. Information relating to the genetically modified higher plant, that is—
- (a) a general description of the trait or traits and characteristics which have been introduced or modified,
 - (b) information on the sequences actually inserted or deleted, namely—
 - (i) the size and copy number of all insert or inserts and methods used for its or their characterisation,
 - (ii) in case of deletion, size and function of the deleted region or regions,
 - (iii) the subcellular location or locations of the insert or inserts in the plant cells (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its/their determination,
 - (c) parts of the plant where the insert is expressed, and
 - (d) the genetic stability of the insert and phenotypic stability of the genetically modified higher plant.
21. Conclusions of the molecular characterisation

F. Information on specific areas of risk

22. Any change to the persistence or invasiveness of the genetically modified higher plant, and its ability to transfer genetic material to sexually compatible relatives and the adverse environmental effects thereof.
23. Any change to the ability of the genetically modified higher plant to transfer genetic material to microorganisms and the adverse environmental effects thereof.
24. Information on the mechanism of interaction between the genetically modified higher plant and target organisms (if applicable) and the adverse environmental effects thereof.
25. Information on the potential changes in the interactions of the genetically modified higher plant with non-target organisms resulting from the genetic modification and the adverse environmental effects thereof.
26. Information on the potential changes in agricultural practices and management of the genetically modified higher plant resulting from the genetic modification and the adverse environmental effects thereof.
27. Information on the potential interactions with the abiotic environment and the adverse environmental effects thereof.
28. Information on any toxic, allergenic or other harmful effects on human and animal health arising from the genetic modification.
29. Conclusions on the specific areas of risk.

G. Information on control, monitoring, post-release and waste treatment plans

30. Any measures taken, including—

- (a) spatial and temporal isolation from sexually compatible plant species, both wild and weedy relatives and crops, and
 - (b) any measures to minimise or prevent the dispersal of any reproductive part of the genetically modified higher plant.
- 31.** A description of methods for post-release treatment of the site.
- 32.** A description of post-release treatment methods for the genetically modified plant material including wastes.
- 33.** A description of monitoring plans and techniques.
- 34.** A description of any emergency plans.
- 35.** A description of the methods and procedures to,—
- (a) avoid or minimise the spread of the genetically modified higher plants beyond the site of release,
 - (b) protect the site from intrusion by unauthorised individuals, and
 - (c) prevent other organisms from entering the site or minimise such entries.
- H. Other**
- 36.** A description of detection and identification techniques for the genetically modified higher plant.
- 37.** Information about previous releases of the genetically modified higher plant, if applicable.

PART 2

INFORMATION TO BE INCLUDED IN APPLICATIONS FOR CONSENT TO PLACE ON MARKET

A. General information

- 38.** The name and address of the applicant, and the name, qualifications and experience of the scientist and of every other person who will be responsible for planning and carrying out the release of the organisms, and for the supervision, monitoring and safety of the release.
- 39.** The designation and specification of the genetically modified higher plant.
- 40.** The scope of the notification including—
- (a) cultivation
 - (b) any other use.

B. Information relating to the recipient plant or, where appropriate, to the parental plants

- 41.** The complete name of the plant, that is—
- (a) family name,
 - (b) genus,
 - (c) species,
 - (d) subspecies,

- (e) cultivar/breeding line, and
 - (f) common name.
42. The geographical distribution and cultivation of the plant within the EU.
43. The reproduction of the plant, that is—
- (a) the mode or modes of reproduction,
 - (b) any specific factors affecting reproduction,
 - (c) generation time, and
 - (d) the sexual compatibility of the plant with other cultivated or wild plant species including the distribution in the EU of the compatible species.
44. Information concerning the survivability of the plant, that is—
- (a) its ability to form structures for survival or dormancy, and
 - (b) any specific factors affecting survivability.
45. Information concerning the dissemination: of the plant, that is—
- (a) the ways and extent of dissemination, and
 - (b) any specific factors affecting dissemination.
46. Where a plant species is not normally grown in the EU, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.
47. Information concerning any other potential interactions, relevant to the genetically modified higher plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

C. Molecular Characterisation

48. Information relating to the genetic modification including—
- (a) a description of the methods used for the genetic modification,
 - (b) the nature and source of the vector used, and
 - (c) the source of the nucleic acid or acids used for transformation, size, and intended function of each constituent fragment of the region intended for insertion.
- 49.—(1) Information relating to the genetically modified plant, that is—
- (a) a description of the trait or traits and characteristics which have been introduced or modified,
 - (b) information on the sequences actually inserted or deleted namely—
 - (i) the size and copy number of all detectable inserts, both partial and complete, and methods used for its characterisation,
 - (ii) the organisation and sequence of the inserted genetic material at each insertion site in a standardised electronic format,
 - (iii) in case of deletion, the size and function of the deleted region or regions,
 - (iv) the subcellular location or locations of the insert or inserts (integrated in the nucleus, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its or their determination,
 - (v) in the case of modifications other than insertion or deletion, the function of the modified genetic material before and after the modification, as well as direct changes in expression of genes as a result of the modification,

- (vi) the sequence information in a standardised electronic format for both 5' and 3' flanking regions at each insertion site,
 - (vii) the bioinformatic analysis using up-to-date databases, to investigate possible interruptions of known genes,
 - (viii) all Open Reading Frames, ('ORFs') within the insert (either due to rearrangement or not) and those created as a result of the genetic modification at the junction sites with genomic DNA,
 - (ix) the bioinformatic analysis using up-to-date databases, to investigate possible similarities between the ORFs and known genes which may have adverse effects,
 - (x) the primary structure (amino acid sequence) and, if necessary, other structures, of the newly expressed protein, and
 - (xi) the bioinformatic analysis using up-to-date databases, to investigate possible sequence homologies and, if necessary, structural similarities between the newly expressed protein and known proteins or peptides which may have adverse effects.
- (2) An 'ORF' is defined as a nucleotide sequence that contains a string of codons that is uninterrupted by the presence of a stop codon in the same reading frame.

50. Information on the expression of the insert that is—

- (a) the method or methods used for expression analysis together with their performance characteristics,
- (b) any information on the developmental expression of the insert during the life cycle of the plant,
- (c) the parts of the plant where the insert or modified sequence is expressed,
- (d) the potential unintended expression of new ORFs identified under paragraph 49(b)(vii), which raise a safety concern,
- (e) the protein expression data, including the raw data, obtained from field studies and related to the conditions in which the crop is grown and,
- (f) the genetic stability of the insert and phenotypic stability of the genetically modified higher plant.

51. The conclusions of molecular characterisation.

D. Comparative analysis of agronomic and phenotypic characteristics and of composition of the genetically modified higher plant.

52. The comparative analysis of agronomic and phenotypic characteristics and of composition that is—

- (a) the choice of conventional counterpart and additional comparators,
- (b) the choice of sites for field studies,
- (c) the experimental design and statistical analysis of data from field trials for comparative analysis namely—
 - (i) a description of field studies design
 - (ii) a description of the relevant aspect of the receiving environments,
 - (iii) the statistical analysis,
- (d) the selection of plant material for analysis, if relevant,
- (e) the comparative analysis of agronomic and phenotypic characteristics,

- (f) the comparative analysis of composition, if relevant, and
- (g) the conclusions of the comparative analysis.

53. For each of the seven areas of risk referred to in Section D.2 of Annex II of the Deliberate Release Directive, a description of the pathway to harm explaining in a chain of cause and effect how the release of the genetically modified higher plant could lead to harm, taking into account both hazard and exposure.

54. The following information is required, except where it is not relevant in view of the intended uses of the genetically modified organism—

- (a) in respect of persistence and invasiveness including plant to plant gene transfer—
 - (i) an assessment of the potential for the genetically modified higher plant to become more persistent or invasive and the adverse environmental effects thereof,
 - (ii) an assessment of the potential for the genetically modified higher plant to transmit transgene or transgenes to sexually compatible relatives and the adverse environmental effects thereof, and
 - (iii) conclusions on the adverse environmental effect of persistence and invasiveness of the genetically modified higher plant including the adverse environmental effect of plant-to-plant gene transfer,
- (b) in respect of plant to micro-organism gene transfer—
 - (i) an assessment of the potential for transfer of newly inserted DNA from the genetically modified higher plant to microorganisms and the adverse effect or effects thereof, and
 - (ii) the conclusions on the adverse effect or effects of the transfer of newly inserted DNA from the genetically modified higher plant to microorganisms for human and animal health and the environment,
- (c) in respect of interactions of the genetically modified higher plant with target organisms, if relevant—
 - (i) an assessment of the potential for changes in the direct and indirect interactions between the genetically modified higher plant and target organisms and the adverse environmental effect or effects,
 - (ii) an assessment of the potential for evolution of resistance of the target organism to the expressed protein (based on the history of evolution of resistance to conventional pesticides or transgenic plants expressing similar traits) and any adverse environmental effect or effects thereof, and
 - (iii) the conclusions on adverse environmental effect or effects of interactions of the genetically modified higher plant with target organisms,
- (d) the interactions of the genetically modified higher plant with non-target organisms namely—
 - (i) an assessment of the potential for direct and indirect interactions of the genetically modified higher plant with non-target organisms, including protected species, and the adverse effect or effects thereof,
 - (ii) an assessment of the potential adverse effect or effects on relevant ecosystem services and on the species providing those services,
 - (iii) the conclusions on adverse environmental effect or effects of the interactions of the genetically modified higher plant with non-target organisms,
- (e) the impacts of the specific cultivation, management and harvesting techniques, namely—

- (i) for genetically modified higher plants for cultivation, an assessment of the changes in the specific cultivation, management and harvesting techniques used for the genetically modified higher plant and the adverse environmental effect or effects thereof, and
 - (ii) the conclusions on the adverse environmental effect or effects of the specific cultivation, management and harvesting techniques,
 - (f) the effects on biogeochemical processes, namely—
 - (i) an assessment of the changes in the biogeochemical processes within the area in which the genetically modified higher plant is to be grown and in the wider environment, and the adverse effects thereof, and
 - (ii) the conclusions on adverse effects on biogeochemical processes,
 - (g) the effects on human and animal health, namely—
 - (i) an assessment of the potential direct and indirect interactions between the genetically modified higher plant and persons working with or coming into contact with the genetically modified higher plants, including through pollen or dust from a processed genetically modified higher plant, and an assessment of the adverse effects of those interactions on human health,
 - (ii) for genetically modified higher plants not destined for human consumption, but where the recipient or parental organism or organisms may be considered for human consumption, an assessment of the likelihood of and possible adverse effects on human health due to accidental intake,
 - (iii) an assessment of the potential adverse effects on animal health due to accidental consumption of the genetically modified higher plant or of material from that plant by animals,
 - (iv) the conclusions on the effects on human and animal health, and
 - (h) an overall risk evaluation and conclusions, namely a summary of all the conclusions under each area of risk taking into account—
 - (i) the risk characterisation in accordance with steps 1 to 4 of the methodology described in Section C.3 of Annex II of the Deliberate Release Directive, and
 - (ii) the risk management strategies proposed in accordance with point 5 of Section C.3 of Annex II of the Deliberate Release Directive.
- 55.** A description of detection and identification techniques for the genetically modified higher plant.
- 56.** Information about previous releases of the genetically modified higher plant, if applicable.”.
- 19.** In schedule 4 (information to be included in applications for consent to market genetically modified organisms), in Part 1 (general information)—
- (a) for paragraph 1, substitute—
 - “**1.** The proposed commercial name of the product or products (which must be provided to the competent authority after consent has been granted) and name or names of the genetically modified organism or organisms in the product or products, and a proposal for a unique identifier of the genetically modified organism developed in accordance with [Commission Regulation \(EC\) No 65/2004](#) establishing a system

for the development and assignment of unique identifiers for genetically modified organisms(18).”, and

(b) for paragraph 7, substitute—

“7. Methods for the detection, identification and, where appropriate, quantification of the transformation event, samples of the genetically modified organism or organisms and their control samples, and information as to the place where the reference material can be accessed (identifying any such information that cannot be placed, for confidentiality reasons, in the publicly accessible part of the register referred to in Article 31(2) of the Deliberate Release Directive).”.

Amendments to the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996

20. The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996(19) are amended in accordance with regulations 21 and 22.

21. In regulation 1(3) (interpretation), in the definition of “the Contained Use Regulations”, for “the Genetically Modified Organisms (Contained Use) Regulations 2000” substitute “the Genetically Modified Organisms (Contained Use) Regulations 2014(20)”.

22. In regulation 3(2) (exemptions from the requirement to carry out risk assessments)—

(a) in sub-paragraph (b)(ii), for “regulation 3(2)” substitute “regulation 3(1)”, and

(b) for sub-paragraph (d) substitute—

“(d) consist of, or are included in, a product permitted to be marketed by a consent granted under section 111(1) of the Act, or otherwise in accordance with Council [Directive 90/220/EEC](#) on the deliberate release into the environment of genetically modified organisms(21) or [Directive 2001/18/EC](#) of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council [Directive 90/220/EEC](#)(22), and the product is imported or acquired in accordance with the conditions and limitations on the use of the product specified in the consent.”.

Amendments to the Genetically Modified Organisms (Traceability and Labelling) (Scotland) Regulations 2004

23. In regulation 2(1) (interpretation) of the Genetically Modified Organisms (Traceability and Labelling) (Scotland) Regulations 2004(23), for the definition of “the Council Regulation” substitute—

““the Council Regulation” means Regulation [\(EC\) No 1830/2003](#) of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending [Directive 2001/18/EC](#)(24).”.

(18) OJ L 10, 16.01.2004, p.5.

(19) [S.I. 1996/1106](#), amended by [S.I. 1997/1900](#), [S.I. 2000/2831](#), [S.I. 2005/2759](#), [S.I. 2018/575](#) (which extends to England and Wales, and applies in relation to England only)

(20) [S.I. 2014/1663](#), to which there are amendments not relevant to these Regulations.

(21) OJ L 117, 8.5.1990, p.15, as last amended by Commission [Directive 97/35/EC](#) (OJ L 169, 27.6.1997, p.72).

(22) OJ L 106, 17.4.2001, p.1, as last amended by Commission Directive (EU) 2018/350 (OJ L 67, 9.3.2018, p.30).

(23) [S.S.I. 2004/438](#), as amended by [S.I. 2011/2043](#).

(24) OJ L 268, 18.10.2003, p.24, as amended by Regulation [\(EC\) No 1137/2008](#) of the European Parliament and of the Council (OJ L 311, 21.11.2008, p.1).

Amendments to the Genetically Modified Organisms (Transboundary Movements) (Scotland) Regulations 2005

24. In the table in Part 1 of schedule 1 (specified Community provisions) of the Genetically Modified Organisms (Transboundary Movements) (Scotland) Regulations 2005⁽²⁵⁾, in the text in second column of the row which mentions Article 10(3), for “Article 12 of Regulation (EC) No 178/2002” substitute “Article 12 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁽²⁶⁾”.

St Andrew’s House,
Edinburgh
7th March 2019

MAIRI GOUGEON
Authorised to sign by the Scottish Ministers

⁽²⁵⁾ S.S.I. 2005/316, as amended by S.I. 2011/2043.

⁽²⁶⁾ OJ L 31, 1.2.2002, p.1, as last amended by Commission Regulation (EU) 2017/228 (OJ L 35, 10.2.2017, p.10).