

2018 No. 000

EXITING THE EUROPEAN UNION
ENVIRONMENTAL PROTECTION

**The Genetically Modified Organisms (Amendment) (EU Exit)
Regulations 2018**

<i>Sift requirements satisfied</i>	***
<i>Made</i> - - - -	***
<i>Laid before Parliament</i>	***
<i>Coming into force in accordance with regulation 1(2)</i>	

The Secretary of State makes these Regulations in exercise of the powers conferred by—

- (a) in relation to Part 1, the powers mentioned in paragraphs (b) to (c);
- (b) in relation to Part 2, section 2(2) of the European Communities Act 1972(a);
- (c) in relation to Parts 3 and 4, section 8(1) of, and paragraph 21(b) of Schedule 7 to, the European Union (Withdrawal) Act 2018(b).

The Secretary of State is a Minister designated for the purposes of that subsection in relation to the control and regulation of genetically modified organisms(c).

The requirements of paragraph 3(2) of Schedule 7 to the European Union (Withdrawal) Act 2018 (relating to the appropriate Parliamentary procedure for these Regulations) have been satisfied.

(a) 1972 c. 68; section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c. 51), section 27(1)(a) and the European Union (Amendment) Act 2008 (c. 7), the Schedule, Part 1. It is prospectively repealed by the European Union (Withdrawal) Act 2018 (c. 16), section 1 from exit day (see section 20 of that Act). The function of the former Minister of Agriculture, Fisheries and Food of making regulations under section 2(2) was transferred to the Secretary of State by S.I. 2002/794. Under section 57(1) of the Scotland Act 1998 (c. 46), despite the transfer to Scottish Ministers of functions in relation to implementing obligations under EU law in relation to devolved matters, the Secretary of State retains power to exercise such functions as regards Scotland. Under paragraph 5 of Schedule 3 to the Government of Wales Act 2006 (c. 32), despite the transfer to the Welsh Ministers of functions in relation to implementing obligations under EU law in relation to devolved matters, the Secretary of State retains power to exercise such functions as regards Wales.

(b) 2018 c. 16.

(c) S.I. 1991/755.

PART 1

Introduction

Citation and commencement

- 1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2018.
- (2) They come into force—
- (a) as regards this Part and Part 2, 21 days after the day on which these Regulations are laid;
 - (b) as regards the remainder, on exit day.

PART 2

Amendments to out of date references

The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996

2. In regulation 3(2) of the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996(a)—
- (a) for sub-paragraph (e) substitute—
 - “(e) consist of, or are included in, a product which is authorised for marketing under—
 - (i) in relation to England, the Genetically Modified Organisms (Deliberate Release) Regulations 2002(b);
 - (ii) in relation to Wales, the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002(c);
 - (iii) in relation to Scotland, the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002(d);”;
 - (b) after sub-paragraph (e) insert—
 - “(f) are genetically modified organisms which are approved for food or feed use in the United Kingdom.”.

PART 3

Amendments to subordinate legislation relating to withdrawal from the European Union

The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996

3. In regulation 3(2) of the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996—
- (a) in sub-paragraph (c), for the words from “for human or veterinary use” to the end substitute “which is authorised for marketing under the Human Medicines Regulations 2012(a) or the Veterinary Medicines Regulations 2013(b)”;

(a) S.I. 1996/1106, amended by S.I. 1997/1900, 2000/2831, 2005/2759, 2018/575.
(b) S.I. 2002/2443, amended by S.I. 2004/2411, 2005/2759, 2009/1892, 2011/1043, 2018/575.
(c) S.I. 2002/3188 (W. 304), amended by S.I. 2005/1913, 2759, 2011/1043, 2013/755.
(d) S.S.I. 2002/541, amended by S.S.I. 2004/439, S.I. 2005/2759, 2011/1043.

(b) for sub-paragraph (d) substitute—

“(d) consist of, or are included in, a product which has marketing consent immediately before exit day under Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms(c) or Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms(d)—

(i) which is imported or acquired in accordance with the conditions and limitations on the use of the product specified in the consent, and

(ii) in the case of a consent for genetically modified carnations (*Dianthus caryophyllus*), where the product is imported or acquired within 10 years of the date on which the consent was issued;”.

PART 4

Amendments to retained direct EU legislation

CHAPTER 1

EU Regulations

Regulation (EC) No 1830/2003 of the European Parliament and of the Council

4.—(1) 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 is amended as follows.

(2) In Article 2—

(a) in paragraph 1, in each place it occurs, for “Community legislation” substitute “retained EU law”;

(b) in paragraph 2, for the words from “for human” to the end substitute “authorised under the Human Medicines Regulations 2012 or the Veterinary Medicines Regulations 2013”.

(3) In Article 3—

(a) in paragraph 5, for the words from “Community” to “third country,” substitute “United Kingdom”;

(b) in paragraph 8, for “Article 6(4) of Directive 2000/13/EC” substitute “Article 2(2)(f) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council”;

(c) for paragraph 10 substitute—

“10. “Placing on the market” means placing on the market as defined in the specific legislation under which the relevant product is authorised; in other cases, it has the meaning given in the definition of “marketed”—

(a) in England, Wales and Scotland, in section 107(11) of the Environmental Protection Act 1990(e);

(b) in Northern Ireland, in article 4(11) of the Genetically Modified Organisms (Northern Ireland) Order 1991(f).”;

(d) after paragraph 12, insert—

(a) S.I. 2012/1916, amended by S.I. 2013/235, 1855, 2593, 2014/323, 324, 490, 1878, 2015/178, 259, 354, 903, 1503, 1862, 1879, 2016/186, 190, 696, 2017/715, 1322, 2018/199, 378.

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

(c) OJ No L 117, 8.5.1990, p. 15, as last amended by Commission Directive 97/35/EC (OJ No L 169, 27.6.1997, p. 72).

(d) OJ No L 106, 17.4.2001, p. 1, as last amended by Commission Directive (EU) 2018/350 (OJ No L 67, 9.3.2018, p. 30).

(e) 1990 (c. 43); section 107(11) was amended in England by S.I. 2002/2443, in Wales by S.I. 2002/3188 (W. 304), and in Scotland by S.S.I. 2002/541.

(f) S.R. 1991/1714 (N.I. 19).

“13. “Competent authority” means—

- (a) in England, the Secretary of State;
- (b) in Wales, the Welsh Ministers;
- (c) in Scotland, the Scottish Ministers;
- (d) in Northern Ireland, the Department of Agriculture, Environment and Rural Affairs.”.

(4) In Article 4—

- (a) in paragraph 1(b), omit “in accordance with Article 8”;
- (b) in paragraphs 5, 6 and 7, for “Community legislation” substitute “retained EU law”;
- (c) in paragraph 8, for “, 24 or 47” substitute “or 24”.

(5) In Article 5—

- (a) in paragraph 3, for “Community legislation” substitute “retained EU law”;
- (b) in paragraph 4, for “, 24 or 47” substitute “or 24”.

(6) In Article 6, for “Community” substitute “other”.

(7) Omit Article 7.

(8) In Article 9—

- (a) in paragraph 1, for “Member States” substitute “The competent authorities”;
- (b) omit paragraph 3.

(9) Omit Articles 11 and 12.

(10) After Article 13, omit the words from “This Regulation” to “Member States.”.

Regulation (EC) No 1946/2003 of the European Parliament and of the Council

5.—(1) Regulation (EC) No 1946/2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms is amended as follows.

(2) In Article 1, omit the following—

- (a) “and without prejudice to the provisions of Directive 2001/18/EC,”;
- (b) “common”;
- (c) “on behalf of the Community”.

(3) In Article 3—

- (a) in paragraph 10(a), for the words from “customs territory” to the end substitute “United Kingdom of GMOs”;
- (b) in paragraph 11, for “Community from a Party within the Community” substitute “United Kingdom by a United Kingdom exporter”;
- (c) in paragraph 12, for “customs territory of the Community”, in both places it occurs, substitute “United Kingdom”;
- (d) in paragraph 14, omit “, excluding intentional movements between Parties within the Community”;
- (e) for paragraph 19 substitute—

“19. “competent authority”, in relation to performing the administrative functions required by the Protocol, means—

- (a) in England, the Secretary of State;
- (b) in Wales, the Welsh Ministers;
- (c) in Scotland, the Scottish Ministers;
- (d) in Northern Ireland, the Department of Agriculture, Environment and Rural Affairs;”;

(f) for paragraph 20 substitute—

“20. “focal point” means the Secretary of State, who has been designated as the United Kingdom’s entity to be responsible on its behalf for liaising with the Secretariat;”;

(g) after paragraph 21, insert—

“22. “constituent nation” means England, Wales, Scotland or Northern Ireland, as the case may be;

23. “relevant authority” means any of the competent authorities, together with the Food Standards Agency, the Health and Safety Executive, the Medicines and Healthcare products Regulatory Agency or other agencies as the case may be and as appropriate in the circumstances.”.

(4) In Article 5—

(a) in paragraph 2, in the first sentence, for the words from “, to the Member State” to the end substitute “and to the competent authority for any constituent nation in which the exporter is based”;

(b) in paragraph 5, for “Commission and the Member States” substitute “focal point”.

(5) In Article 6—

(a) in the heading, for “Party of export” substitute “competent authority”;

(b) in the first paragraph, for the words “of the Member State” to the end substitute “for any constituent nation in which the exporter is based”;

(c) in the second paragraph—

(i) for “Commission” substitute “competent authority for any constituent nation in which the exporter is based”;

(ii) for “the Community rules” substitute “retained EU law”.

(6) In Article 9—

(a) in paragraph 1—

(i) in the first subparagraph—

(aa) for the words from “Commission on behalf of” to “made the decision” substitute “focal point”;

(bb) for “, Community or use within a Member State,” substitute “United Kingdom”;

(ii) for the second subparagraph substitute—

“This paragraph does not apply to decisions to grant a consent for the deliberate release of a GMO taken, pursuant to—

(a) in England, regulation 21 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002,

(b) in Scotland, regulation 21 of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002,

(c) in Wales, regulation 22 of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002,

(d) in Northern Ireland, regulation 21 of the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003(a),

where the GMO is not intended for direct use as food or feed or for processing in a country outside the United Kingdom without a subsequent decision.”;

(b) in paragraph 3, for the words from “Commission” to “them” substitute “focal point must process requests submitted”;

(a) S.R. 2003/167, amended by S.R. 2005/272.

- (c) in paragraph 4, for the words from “Commission” to “paragraph 1” substitute “focal point”.
- (7) In Article 10(3), in the second sentence, for “it is authorised within the Community” substitute “its use is permitted in the United Kingdom”.
- (8) In Article 12—
- (a) in paragraph 2, in the final sentence, for “Directive 2001/18/EC and, when applicable, future Community legislation” substitute “retained EU law”;
- (b) in paragraph 5, omit “Community”.
- (9) In Article 14—
- (a) in paragraph 1, for “Member States” substitute “The competent authorities”;
- (b) in paragraph 2—
- (i) in the words before point (a)—
- (aa) for the words from “a Member State” to “jurisdiction,” substitute “the focal point becomes aware of an occurrence within the United Kingdom”;
- (bb) for “that Member State” substitute “the focal point”;
- (ii) in point (a), omit “the Commission, all other Member States,”.
- (10) In Article 15—
- (a) in paragraph 1—
- (i) in the words before point (a)—
- (aa) for “Member States” substitute “focal point”;
- (bb) omit “and the Commission”;
- (ii) in point (c), for “Member State” substitute “United Kingdom”;
- (iii) for point (e) substitute—
- “(e) any final decision taken by a relevant authority on the use of GMOs, including decisions in accordance with Article 11 and Article 20(3)(d) of the Protocol, within 15 days of the adoption of that decision, where that decision is—
- (i) on contained use classified in risk class 3 or 4 of GMOs which are likely to be subject to transboundary movements;
- (ii) on the marketing or import of GMOs;
- (iii) to grant a consent for the deliberate release of a GMO—
- in England, pursuant to regulation 21 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002;
- in Wales, pursuant to regulation 22 of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002;
- in Scotland, pursuant to regulation 21 of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002;
- in Northern Ireland, pursuant to regulation 21 of the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003;”;
- (iv) in point (f), for “Community’s regulatory process” substitute “United Kingdom’s regulatory processes”;
- (v) for point (h) substitute—
- “(h) any decision to take emergency measures under Article 34 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed, or any decision to serve a prohibition notice—
- (i) in relation to England, pursuant to regulation 32 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002;

- (ii) in relation to Wales, pursuant to regulation 33 of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002;
 - (iii) in relation to Scotland, pursuant to regulation 32 of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002;
 - (iv) in relation to Northern Ireland, pursuant to regulation 32 of the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003;
 - (i) any application of procedures, agreements or regulations instead of the procedures of the Protocol for intentional movements within or imports into the United Kingdom of GMOs, in accordance with Article 14(3) and (4) of the Protocol;
 - (j) reports submitted pursuant to Article 19 of this Regulation, including those on implementation of the advanced informed agreement procedure, in accordance with Article 20(3)(e) of the Protocol.”;
- (b) omit paragraph 2.
- (11) In Article 16—
- (a) in paragraph 1, for “Commission and the Member States” substitute “competent authorities”;
 - (b) in paragraph 4, for “Member States and the Commission” substitute “competent authorities”.
- (12) In Article 17—
- (a) in the heading, for “points” substitute “point”;
 - (b) omit paragraphs 1 and 2;
 - (c) for paragraph 3 substitute—
- “3. The focal point must forthwith inform the Secretariat of any change in the designation of the focal point, and of any changes in the names, addresses or responsibilities of the competent authorities.”.
- (13) Omit Article 18.
- (14) In Article 19—
- (a) omit paragraph 1;
 - (b) in paragraph 2—
- (i) for “Commission” substitute “focal point”;
 - (ii) for the words from “basis of” to “Member States” substitute “implementation of the Protocol in the United Kingdom”.
- (15) After Article 20, omit the words from “This Regulation” to “Member States.”.
- (16) In Annex 1—
- (a) in point (c), for “State of export” substitute “United Kingdom”;
 - (b) in point (m)—
- (i) for “State of export”, in the first place it occurs, substitute “United Kingdom”;
 - (ii) omit “in the State of export”, in both places it occurs.
- (17) In Annex 3, in point (b), for “originating Party” substitute “United Kingdom”.

Commission Regulation (EC) No 65/2004

6.—(1) Commission Regulation (EC) No 65/2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms is amended as follows.

- (2) For Article 1 substitute—

“Article 1

1. This Regulation applies to genetically modified organisms, hereinafter ‘GMOs’, authorised for placing on the market in accordance with Regulation 1829/2003 of the European Parliament and of the Council and—

- (a) in England, the Genetically Modified Organisms (Deliberate Release) Regulations 2002,
- (b) in Wales, the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002,
- (c) in Scotland, the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002,
- (d) in Northern Ireland, the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003,

and applications for placing on the market under such legislation.

2. This Regulation does not apply to medicinal products authorised under the Human Medicines Regulations 2012 or the Veterinary Medicines Regulations 2013, or applications for authorisation under those Regulations.”.

(3) In Article 2(2), after “Biosafety clearing house” insert “established by the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the “Biosafety clearing house”)”.

(4) In Article 3—

(a) in point (b), for the words from “Commission” to “original application” substitute “Secretary of State”;

(b) for point (c) substitute—

“(c) for GMOs authorised under Regulation (EC) No 1829/2003, the unique identifier must be recorded in the register maintained in accordance with Article 28 of that Regulation.”.

(5) Omit Articles 4 to 6.

(6) After Article 7, omit the words from “This Regulation” to “Member States.”.

(7) In the Annex—

(a) in Section A, in paragraph 1, in the first subparagraph, omit “under Community legislation”;

(b) in section B, for “endorsed at Community level” substitute “implemented in the United Kingdom”.

CHAPTER 2

EU Decisions

Commission Decision 94/730/EC

7.—(1) 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 is amended as follows.

(2) For Article 1 substitute—

“Article 1

1. Applications for consent to release genetically modified plants for any other purpose than marketing may be made in accordance with the simplified procedures set out in the Annex.”.

(3) Omit Article 2.

(4) The Annex is amended in accordance with paragraphs (5) to (17).

- (5) In paragraph 1—
- (a) for “notification dossier” substitute “application”;
 - (b) omit “pursuant to Part B of Directive 90/220/EC”.
- (6) In paragraph 2, for “A notifier” substitute “An applicant”.
- (7) For paragraph 3 substitute—
- “The information required in the application is that specified in—
1. in the case of an application to release in England, Schedule 1 to the Genetically Modified Organisms (Deliberate Release) Regulations 2002;
 2. in the case of an application to release in Wales, Schedule 1 to the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002;
 3. in the case of an application to release in Scotland, Schedule 2 to the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002;
 4. in the case of an application to release in Northern Ireland, Schedule 1 to the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003.”.
- (8) In paragraph 4—
- (a) in the first sentence, for “notification” substitute “application”;
 - (b) omit the second sentence.
- (9) In paragraph 5—
- (a) for “notification”, in the first and second places it occurs, substitute “application”;
 - (b) omit the words from “, and the appropriate” to the end.
- (10) In paragraph 6—
- (a) for “A notifier” substitute “An applicant”;
 - (b) for “notification” substitute “application”.
- (11) In paragraph 6.1—
- (a) for “notification”, in both places it occurs, substitute “application”;
 - (b) for “initially notified plants” substitute “plants contained in the initial application”;
 - (c) for “initially notified recipient plant species” substitute “recipient plant species contained in the initial application”.
- (12) In paragraph 7, in the first sentence, for “notifier” substitute “applicant”.
- (13) Omit paragraph 7.1.
- (14) In paragraph 7.2, for “notifier” substitute “applicant”.
- (15) In paragraph 7.3—
- (a) for “notifier” substitute “consent holder”;
 - (b) for “notification” substitute “application”;
 - (c) for the words from “consent is granted” to the end substitute “new consent is applied for and granted that does not rely on the simplified procedures provided for in this Decision”.
- (16) In paragraph 8, omit the second sentence.
- (17) In paragraph 9—
- (a) in the first sentence, for “notifier” substitute “consent holder”;
 - (b) in the second sentence, for “a notification” substitute “an application”.

Council Decision 2002/812/EC

8.—(1) Council Decision 2002/812/EC establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products is amended as follows.

(2) For Article 1 substitute—

“Article 1

The information format set out in the Annex must be used to summarise applications for consent to market genetically modified organisms, pursuant to—

- (a) in relation to England, regulation 16(2)(j) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002;
- (b) in relation to Wales, regulation 17(2)(j) of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002;
- (c) in relation to Scotland, regulation 16(2)(j) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002;
- (d) in relation to Northern Ireland, regulation 16(2)(j) of the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003.”.

(3) Omit Article 2.

(4) The Annex is amended in accordance with paragraphs (5) to (7).

(5) In the Introduction, in the second paragraph, for “Directive 2001/18/EC” substitute “retained EU law”.

(6) In Part 1—

(a) in section A—

(i) in paragraph 1—

(aa) for the heading substitute “Name of the product to be notified”;

(bb) omit points (a), (b) and (d);

(ii) in paragraph 2, in each place it occurs, for “notifier” substitute “applicant”;

(iii) in paragraph 4, omit points (f) and (h);

(iv) omit paragraphs 5 to 7;

(v) in paragraph 12, for “notifier” substitute “applicant”;

(b) in section B—

(i) omit paragraphs 24 and 34;

(ii) in paragraph 41(e), at the end, insert “of Directive 2001/18/EC”;

(c) in section D—

(i) in the subheading, for the words “notified under” to the end substitute “for purposes other than marketing notified to a competent authority in the United Kingdom or to a member State”;

(ii) in paragraph 8, omit the words from “according to” to the end;

(iii) in the words after paragraph 8, for “Community” substitute “United Kingdom”.

(7) In Part 2—

(a) in section A—

(i) in paragraph 1—

(aa) for the heading substitute “Name of the product to be notified”;

(bb) omit points (a), (b) and (d);

(ii) in paragraph 3, omit points (e) and (i);

(iii) omit paragraphs 4 to 6;

- (b) in section B, in paragraph 13, for “Member State(s)” substitute “United Kingdom”;
- (c) in section C—
 - (i) in paragraph 32—
 - (aa) in the subheading, for the words from “notified under” to the end substitute “for purposes other than marketing notified to a competent authority in the United Kingdom or of a member State by the same applicant”;
 - (bb) in point (c), omit the words from “(submitted to” to the end;
 - (ii) in paragraph 33, in the subheading—
 - (aa) for “Community” substitute “United Kingdom”;
 - (bb) for “notifier” substitute “applicant”.

Council Decision 2002/813/EC

9.—(1) Council Decision 2002/813/EC establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market is amended as follows.

(2) For Article 1 substitute—

“Article 1

1. The Summary Notification Information Format set out in the Annex must be used for the purpose of summarising an application for consent to release genetically modified organisms, pursuant to—
 - (a) in relation to England, regulation 11(1)(d) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002;
 - (b) in relation to Wales, regulation 12(1)(d) of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002;
 - (c) in relation to Scotland, regulation 11(1)(d) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002;
 - (d) in relation to Northern Ireland, regulation 11(1)(d) of the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003.
 2. In this Decision, “constituent nation” means England, Wales, Scotland or Northern Ireland, as the case may be.”.
- (3) Omit Article 2.
- (4) The Annex is amended in accordance with paragraphs (5) to (7).
- (5) In the Introduction section—
- (a) omit the first paragraph;
 - (b) in the sixth and eighth paragraphs, for the words from “to the competent authority” to the end substitute “in the full application for consent to release”.
- (6) In Part 1—
- (a) in the heading, omit the words from “in accordance” to the end;
 - (b) in section A—
 - (i) omit paragraph 1(a);
 - (ii) in paragraph 4—
 - (aa) in the heading, for the words from “elsewhere in” to “Article 6(1))” substitute “in any other constituent nation of the United Kingdom to that for which the application has been made”;
 - (bb) in the second row of the table, for “insert the country code(s)” substitute “state the countries concerned”;

- (iii) in paragraph 5—
 - (aa) in the heading, for “Community” substitute “United Kingdom”;
 - (bb) for the second row of the table substitute—
 “If yes, state the countries concerned”;
 - (iv) in paragraph 6—
 - (aa) in the heading, for “Community” substitute “United Kingdom”;
 - (bb) for the second row of the table substitute—
 “If yes, state the countries concerned”;
 - (c) in section B—
 - (i) in paragraph 3—
 - (aa) in point (a), for “country where the notification is made” substitute “United Kingdom”;
 - (bb) in point (b), for “other EC countries” substitute “member States”;
 - (cc) in points (c) and (d), for “country where the notification is made” substitute “United Kingdom”;
 - (ii) in paragraph 6, omit “Community”;
 - (d) in section D, in paragraph 4, in the heading—
 - (i) omit “Community”;
 - (ii) for “Directive 90/679/EEC on” substitute “those relating to”;
 - (e) in section E, in paragraph 3(b), at the end, insert “of Directive 2001/18/EC”.
- (7) In Part 2—
- (a) in section A—
 - (i) in paragraph 3—
 - (aa) in the heading, for the words from “elsewhere, inside” to “Article 6(1)” substitute “in any other constituent nation of the United Kingdom to that for which the application has been made,”;
 - (bb) in the second row of the table, for “insert the country code(s)” substitute “state the countries concerned”;
 - (ii) in paragraph 4—
 - (aa) in the heading, for “, inside or outside the Community” substitute “in the United Kingdom”;
 - (bb) in the second row of the table, for “notification number” substitute “state the countries concerned”.

Commission Decision 2003/701/EC

10.—(1) Commission Decision 2003/701/EC establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market is amended as follows.

(2) For Article 1 substitute—

“Article 1

1. The results of a release of genetically modified higher plants (GMHP) undertaken pursuant to a consent granted—
 - (a) in relation to England, pursuant to regulation 21 of the Genetically Modified Organisms (Deliberate Release) Regulations 2002,

- (b) in relation to Wales, pursuant to regulation 22 of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002,
- (c) in relation to Scotland, pursuant to regulation 21 of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002,
- (d) in relation to Northern Ireland, pursuant to regulation 21 of the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003,

must be presented to the relevant competent authority by the consent holder using the format set out in the Annex to this Decision, hereinafter “the report format”.

2. In this Decision, “constituent nation” means England, Wales, Scotland or Northern Ireland, as the case may be.”.

- (3) In Article 2, for “notification” substitute “consent”.
- (4) In Article 3—
 - (a) in paragraph 1—
 - (i) for “notification” substitute “consent”;
 - (ii) for “notifier” substitute “consent holder”;
 - (b) in paragraph 2, omit paragraph 4.
- (5) In Article 4, for “notifier” substitute “consent holder”.
- (6) Omit Article 5.
- (7) In the Annex—
 - (a) in the first heading, omit “in accordance with Article 10 of Directive 2001/18/EC”;
 - (b) omit paragraphs 1.1 and 1.2;
 - (c) in paragraph 4.1—
 - (i) in the first sentence, for “under Community legislation(s)” substitute “in the United Kingdom”;
 - (ii) in the second sentence, for “country(ies) of notification” substitute “constituent nations of the United Kingdom in which the product is intended to be marketed”;
 - (d) in paragraph 6.1.7, in point (b), in the first sentence, for the words from “measures according” to “2001/18/EC)” substitute “emergency measures”;
 - (e) in paragraph 6.4.3, omit the footnote;
 - (f) in the words after paragraph 7, in the first sentence, omit “in accordance with Article 25 of Directive 2001/18/EC”.

Commission Decision 2009/770/EC

11.—(1) Commission Decision 2009/770/EC establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council is amended as follows.

- (2) For Article 1 substitute—

“Article 1

1. This Decision concerns the reporting of monitoring results in respect of genetically modified organisms authorised for marketing under Regulation (EC) No 1829/2003 of the European Parliament and of the Council, or any decision in respect of genetically modified organisms authorised for marketing pursuant to the following legislation—

- (a) the Genetically Modified Organisms (Deliberate Release) Regulations 2002;
- (b) the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002;

- (c) the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002;
- (d) the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003.

2. Holders of authorisations or consents to market genetically modified organisms must use the formats set out in the Annexes to this Decision to report the results of their required monitoring activities.”.

- (3) Omit Article 2.
- (4) Annex 1 is amended in accordance with paragraphs (5) to (9).
- (5) In the first subheading, omit the words from “in accordance” to the end.
- (6) Omit paragraphs 1.2 and 1.3.
- (7) Appendix 2 is amended in accordance with paragraphs (8) and (9).
- (8) In section B, omit the first two paragraphs.
- (9) In section C—
 - (a) omit section C.1;
 - (b) in section C.2—
 - (i) omit the heading;
 - (ii) in the paragraph before paragraph 1—
 - (aa) omit the second sentence;
 - (bb) in the third sentence, for “A non-confidential” substitute “Where confidential data does arise, it should be provided in a separate Annex, with a verifiable justification for confidentiality, and a non-confidential”;
 - (iii) in paragraph 1, in the first subparagraph, omit “within the EU,”;
 - (iv) in paragraph 3.1.1, in point (c), for “each Member State” substitute “the United Kingdom”;
 - (v) in paragraph 3.1.2, in point (b), for “Member States where the surveillance network is active” substitute “whether the surveillance network is active,”;
 - (vi) in paragraph 3.1.3, in the first subparagraph, for “Community” substitute “United Kingdom”.
- (10) Annex 2 is amended in accordance with paragraphs (11) to (14).
- (11) In the first subheading, omit the words from “in accordance” to the end.
- (12) Omit paragraphs 1.2 and 1.3.
- (13) In paragraph 3—
 - (a) for “Community”, in each place it occurs, substitute “United Kingdom”;
 - (b) omit paragraph 3.1.2;
 - (c) in paragraph 3.1.3, for “tables 3.1.1 and 3.1.2” substitute “table 3.1.1”;
 - (d) in paragraph 3.3.2, in the table—
 - (i) omit the first column;
 - (ii) in the heading of the second column, insert at the end “in the United Kingdom”.
- (14) Appendix 2 is amended in accordance with paragraphs (15) and (16).
- (15) In section B, omit the first two paragraphs.
- (16) In section C—
 - (a) omit subsection C.1;
 - (b) in subsection C.2—
 - (i) omit the heading;

- (ii) in the paragraph before paragraph 1—
 - (aa) omit the second sentence;
 - (bb) in the third sentence, for “A non-confidential” substitute “Where confidential data does arise, it should be provided in a separate Annex, with a verifiable justification for confidentiality, and a non-confidential”;
- (c) in paragraph 1—
 - (i) in the first subparagraph, omit “within the EU,”;
 - (ii) omit the second subparagraph;
- (d) in paragraph 3—
 - (i) for “Community”, in each place it occurs, substitute “United Kingdom”;
 - (ii) in paragraph 3.1.2—
 - (aa) omit the heading;
 - (bb) in the first sentence, for “Tables 3.1.1 and 3.1.2” substitute “Table 3.1.1”;
 - (cc) omit points (b) and (c);
 - (dd) in point (d), at the end, insert “into the United Kingdom”;
 - (iii) in paragraph 3.1.3—
 - (aa) in the heading, for “tables 3.1.1 and 3.1.2” substitute “table 3.1.1”;
 - (bb) for “years and”, in the first place it occurs, substitute “years,”;
 - (cc) for “change,” substitute “change and”;
 - (dd) omit the words from “as well as” to the end;
 - (iv) in paragraph 3.2.2, in point (b), for “Member States where the surveillance network is active” substitute “whether the surveillance network is active,”;
 - (v) in paragraph 3.3.2, in point (b), for “Member State/the Community” substitute “United Kingdom”.

Commission Implementing Decision (EU) 2016/321

12.—(1) Commission Implementing Decision (EU) 2016/321 adjusting the geographical scope of the authorisation for cultivation of genetically modified maize (*Zea mays* L.) MON 810 (MON-ØØ81Ø-6) is amended as follows.

(2) In Article 1, for the words from “the territories” to the end substitute “Wales, Scotland and Northern Ireland”.

(3) For Article 2 substitute—

“Article 2

The information set out in this Decision must be entered—

- (a) in Wales, in the register maintained under the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002;
 - (b) in Scotland, in the register maintained under the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002;
 - (c) in Northern Ireland, in the register maintained under the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003.”.
- (4) Omit Article 3.
- (5) Omit the Annex.

Name
Minister of State

Date Department for Environment, Food and Rural Affairs

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(b), (c) and (g)) arising from the withdrawal of the United Kingdom from the European Union. They are also made in part using other powers to amend legislation that is deficient, where the deficiency does not arise from the withdrawal of the United Kingdom from the European Union.

Part 2 makes amendments to provisions in secondary legislation on genetically modified organisms that are out of date, specifically relating to devolution issues in risk assessment and record-keeping.

The remainder of the Regulations make amendments to legislation in the field of environmental protection and, in particular, amend legislation relating to the risk assessment, deliberate release, transboundary movements, traceability and labelling, unique identifiers, and placing on the market of genetically modified organisms. Part 3 amends subordinate legislation and Part 4 amends retained direct EU legislation.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.

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