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STATUTORY INSTRUMENTS

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**2019 No. 90**

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

PART 4

Amendments to retained direct EU legislation

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.