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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 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 “[<sup>F1</sup>the Community]” to “third country,” substitute “[<sup>F2</sup>Great Britain]”;
- (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—

[<sup>F3</sup>“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 means “marketed” within the meaning given in section 107(11) of the Environmental Protection Act 1990.”];

(d) after paragraph 12, insert—

“13. “Competent authority” means—

- (a) in England, the Secretary of State;
- (b) in Wales, the Welsh Ministers;
- (c) in Scotland, the Scottish Ministers;

<sup>F4</sup>(d) .....

- (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.”.

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| <b>F1</b> | Words in reg. 4(3)(a) substituted (31.12.2020 immediately before IP completion day) by <a href="#">The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421)</a> , reg. 1(4), <a href="#">Sch. para. 2(a)(i)</a>    |
| <b>F2</b> | Words in reg. 4(3)(a) substituted (31.12.2020 immediately before IP completion day) by <a href="#">The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421)</a> , reg. 1(4), <a href="#">Sch. para. 2(a)(ii)</a>   |
| <b>F3</b> | Words in reg. 4(3)(c) substituted (31.12.2020 immediately before IP completion day) by <a href="#">The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421)</a> , reg. 1(4), <a href="#">Sch. para. 2(b)</a>       |
| <b>F4</b> | Words in reg. 4(3)(d) omitted (31.12.2020 immediately before IP completion day) by virtue of <a href="#">The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421)</a> , reg. 1(4), <a href="#">Sch. para. 2(c)</a> |

**Commencement Information**

- II** Reg. 4 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1(2)(b)

**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—
- [<sup>F5</sup>(a) in paragraph 10, for subparagraph (a) substitute—
- “(a) the permanent or temporary leaving of Great Britain of GMOs which originated—

- (i) in Great Britain, or
  - (ii) in a third country but have entered, and are in free circulation in, Great Britain;”];
- [<sup>F6</sup>(b) in paragraph 11, for the words from “outside the” to the end substitute “outside Great Britain by an exporter”];
- [<sup>F7</sup>(c) in paragraph 12, for “the customs territory of the Community”, in both places it occurs, substitute “Great Britain”];
- (d) in paragraph 14, omit “, excluding intentional movements between Parties within the Community”;
- [<sup>F8</sup>(da) for paragraph 15 substitute—
  - “15. “Party” means—
  - (a) Great Britain,
  - (b) Northern Ireland, or
  - (c) any other country or regional economic integration organisation being a Party to the Protocol;”];
- [<sup>F9</sup>(e) in paragraph 19, after ““competent authority”” insert “, other than in the expression “relevant GB competent authority”];
- [<sup>F10</sup>(ea) after paragraph 19, insert—
  - “19A. “relevant GB competent authority”—
  - (a) in relation to performing the administrative functions required by the Protocol in England, means the Secretary of State;
  - (b) in relation to performing the administrative functions required by the Protocol in Wales, means the Welsh Ministers;
  - (c) in relation to performing the administrative functions required by the Protocol in Scotland, means the Scottish Ministers.”];
- [<sup>F11</sup>(f) in paragraph 20, after “Party” insert “(other than Great Britain)”];
- (fa) after paragraph 20, insert—
  - “20A. “GB focal point” means the Secretary of State, who has been designated as Great Britain’s entity to be responsible on its behalf for liaising with the Secretariat;”];
- (g) after paragraph 21, insert—
  - “22. “constituent nation” means England, Wales [<sup>F12</sup>or Scotland], as the case may be;
  - 23. “relevant [<sup>F13</sup>GMO] authority” means [<sup>F14</sup>a relevant GB competent authority], 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.
  - [<sup>F15</sup>24. “third country” means a country other than Great Britain.”].
- (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 [<sup>F16</sup>the relevant GB competent] authority for [<sup>F17</sup>each] constituent nation in which the exporter is based ”;

- (b) in paragraph 5, for “Commission and the Member States” substitute “ [F18GB focal] point ”.
- (5) In Article 6—
  - (a) in the heading, for “Party of export” substitute “ [F19relevant GB competent] authority ”;
  - (b) in the first paragraph, for the words “of the Member State” to the end substitute “ for [F20each] constituent nation in which the exporter is based ”;
  - (c) in the second paragraph—
    - (i) for “Commission” substitute “ [F21relevant GB competent authority for each] 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 “ [F22GB focal] point ”;
      - [F23(bb) for “the Community or use within a Member State” substitute “Great Britain”];
    - (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,
      - F24(d) .....

where the GMO is not intended for direct use as food or feed or for processing in a [F25third country] without a subsequent decision.”;
  - (b) in paragraph 3, for the words from “Commission” to “them” substitute “ [F26GB focal] point must process requests submitted ”;
  - (c) in paragraph 4, for the words from “Commission” to “paragraph 1” substitute “ [F27GB focal] point ”.
- [F28(7) In Article 10(3), in the second sentence, for the words from “it is authorised” to the end substitute “its use is permitted in Great Britain or the competent authority of the importing country has expressly agreed to the import”.]
- (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 [F29relevant GB 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 [<sup>F30</sup>GB focal] point becomes aware of an occurrence within [<sup>F31</sup>Great Britain]”;
    - (bb) for “that Member State” substitute “ the [<sup>F32</sup>GB 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 “ [<sup>F33</sup>GB 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 [<sup>F34</sup>relevant GMO 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;

<sup>F35</sup> ... ,”;

[<sup>F36</sup>(iv) in point (f), for “the Community’s” substitute “Great Britain’s”];

- (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;

<sup>F37</sup>(iv) . . . . .

- (i) any application of procedures, agreements or regulations instead of the procedures of the Protocol for intentional movements within or imports into [<sup>F38</sup>Great Britain] 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 “ [<sup>F39</sup>relevant GB competent] authorities ”;
- (b) in paragraph 4, for “Member States and the Commission” substitute “ [<sup>F40</sup>relevant GB 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 [<sup>F41</sup>GB 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 [<sup>F42</sup>relevant GB competent] authorities.”.

(13) Omit Article 18.

(14) In Article 19—

- (a) omit paragraph 1;
- (b) in paragraph 2—
  - (i) for “Commission” substitute “ [<sup>F43</sup>GB focal] point ”;
  - (ii) for the words from “basis of” to “Member States” substitute “ implementation of the Protocol in [<sup>F44</sup>Great Britain] ”.

(15) After Article 20, omit the words from “This Regulation” to “Member States.”.

(16) In Annex 1—

[<sup>F45</sup>(a) in point (c), for “the State of export” substitute “Great Britain”];

(b) in point (m)—

- [<sup>F46</sup>(i) for “the State of export”, in the first place it occurs, substitute “Great Britain”];
- (ii) omit “in the State of export”, in both places it occurs.

[<sup>F47</sup>(17) In Annex 3, in point (b), for “the originating Party” substitute “Great Britain”.]

<p><b>F5</b> Reg. 5(3)(a) substituted (31.12.2020 immediately before IP completion day) by <a href="#">The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421)</a>, reg. 1(4), <b>Sch. para. 3(2)(a)</b></p>
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- F6** Reg. 5(3)(b) substituted (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(2)(b)**
- F7** Reg. 5(3)(c) substituted (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(2)(c)**
- F8** Reg. 5(3)(da) inserted (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(2)(d)**
- F9** Reg. 5(3)(e) substituted (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(2)(e)**
- F10** Reg. 5(3)(ea) inserted (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(2)(f)**
- F11** Reg. 5(3)(f)(fa) substituted for reg. 5(3)(f) (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(2)(g)**
- F12** Words in reg. 5(3)(g) substituted (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(2)(h)(i)**
- F13** Word in reg. 5(3)(g) inserted (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(2)(h)(ii)(aa)**
- F14** Words in reg. 5(3)(g) substituted (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(2)(h)(ii)(bb)**
- F15** Words in reg. 5(3)(g) inserted (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(2)(h)(iii)**
- F16** Words in reg. 5(4)(a) substituted (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(3)(a)(i)**
- F17** Word in reg. 5(4)(a) substituted (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(3)(a)(ii)**
- F18** Words in reg. 5(4)(b) substituted (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(3)(b)**
- F19** Words in reg. 5(5)(a) substituted (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(4)(a)**
- F20** Word in reg. 5(5)(b) substituted (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(4)(b)**
- F21** Words in reg. 5(5)(c)(i) substituted (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(4)(c)**
- F22** Words in reg. 5(6)(a)(i)(aa) substituted (31.12.2020 immediately before IP completion day) by The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1421), reg. 1(4), **Sch. para. 3(5)(a)(i)**

- F23** Reg. 5(6)(a)(i)(bb) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(5)(a)(ii)**
- F24** Words in reg. 5(6)(a)(ii) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(5)(a)(iii)(aa)**
- F25** Words in reg. 5(6)(a)(ii) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(5)(a)(iii)(bb)**
- F26** Words in reg. 5(6)(b) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(5)(b)**
- F27** Words in reg. 5(6)(c) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(5)(b)**
- F28** Reg. 5(7) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(6)**
- F29** Words in reg. 5(9)(a) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(7)(a)**
- F30** Words in reg. 5(9)(b)(i)(aa) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(7)(b)(ii)**
- F31** Words in reg. 5(9)(b)(i)(aa) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(7)(b)(i)**
- F32** Words in reg. 5(9)(b)(i)(bb) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(7)(b)(ii)**
- F33** Words in reg. 5(10)(a)(i)(aa) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(8)(a)**
- F34** Words in reg. 5(10)(a)(iii) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(8)(b)(i)**
- F35** Words in reg. 5(10)(a)(iii) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(8)(b)(ii)**
- F36** Reg. 5(10)(a)(iv) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(8)(c)**
- F37** Reg. 5(10)(a)(v) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(8)(d)(i)**
- F38** Words in reg. 5(10)(a)(v) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(8)(d)(ii)**
- F39** Words in reg. 5(11)(a) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(9)(a)**
- F40** Words in reg. 5(11)(b) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(9)(b)**



- F41** Words in reg. 5(12)(c) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(10)(a)**
- F42** Words in reg. 5(12)(c) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(10)(b)**
- F43** Words in reg. 5(14)(b)(i) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(11)(a)**
- F44** Words in reg. 5(14)(b)(ii) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(11)(b)**
- F45** Reg. 5(16)(a) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(12)(a)**
- F46** Reg. 5(16)(b)(i) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(12)(b)**
- F47** Reg. 5(17) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 3(13)**

**Commencement Information**

- I2** Reg. 5 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1(2)(b)

**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 [<sup>F48</sup>or ] —

- (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,

<sup>F49</sup>(d) .....

and applications for placing on the market under such legislation.

[<sup>F50</sup>2. This Regulation does not apply to medicinal products for human and veterinary use authorised under—

- (a) Regulation (EC) No 726/2004 of the European Parliament and of the Council,
- (b) the Human Medicines Regulations 2012, or
- (c) the Veterinary Medicines Regulations 2013,

or applications for authorisation under such legislation.”].

(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 [<sup>F51</sup>Great Britain] ”.

**F48** Word in reg. 6(2) substituted (31.12.2020 immediately before IP completion day) by [The Food and Farming \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/759\)](#), regs. 1(a), **12(3)**; 2020 c. 1, Sch. 5 para. 1(1)

**F49** Words in reg. 6(2) omitted (31.12.2020 immediately before IP completion day) by virtue of [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 4(2)(a)**

**F50** Words in reg. 6(2) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 4(2)(b)**

**F51** Words in reg. 6(7)(b) substituted (31.12.2020 immediately before IP completion day) by [The Genetically Modified Organisms \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1421\)](#), reg. 1(4), **Sch. para. 4(3)**

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#### Commencement Information

**I3** Reg. 6 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1(2)(b)

**Changes to legislation:**

There are currently no known outstanding effects for the The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019, CHAPTER 1.