
STATUTORY INSTRUMENTS

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 “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⁽¹⁾;
- (b) in Northern Ireland, in article 4(11) of the Genetically Modified Organisms (Northern Ireland) Order 1991⁽²⁾.”;

(d) after paragraph 12, insert—

“13. “Competent authority” means—

- (a) in England, the Secretary of State;

(1) 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.

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

- (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(3),
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”;
- (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”.