Draft Regulations laid before Parliament under paragraphs 1(3) and 8F(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2020 No.

EXITING THE EUROPEAN UNION

ENVIRONMENTAL PROTECTION

The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020

Made - - - - ***

Coming into force into force in accordance with regulation 1

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 8(1) and 8C of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**a**).

In accordance with paragraphs 1(3) and 8F(1) of Schedule 7 to that Act, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

Citation and commencement

1.—(1) These Regulations may be cited as the Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020.

(2) The following provisions of these Regulations come into force immediately before regulation 12 of the Food and Farming Regulations comes into force—

(a) this regulation;

(b) regulation 2;

(c) regulation 5.

(3) Regulation 7 comes into force on IP completion day.

(4) Otherwise these Regulations come into force immediately before IP completion day.

Interpretation

2. In these Regulations—

"the Food and Farming Regulations" means the Food and Farming (Amendment) (EU Exit) Regulations 2019(**b**);

(**a**) 2018 c. 16. Section 8 was amended by section 27 of the European Union (Withdrawal Agreement) Act 2020 (c. 1). Section 8C was inserted by section 21 of, and paragraphs 8A to 8G of Schedule 7 to the 2018 Act were inserted by Schedule 5, paragraph 51 to, that Act.

(**b**) S.I. 2019/759.

"the GMO Regulations" means the Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019(**a**).

Amendment of the Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019

3. In regulation 4 of the Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019(**b**), in paragraph (a), for "the United Kingdom" substitute "Great Britain".

Amendment of the GMO Regulations

4. The Schedule contains amendments to the GMO Regulations.

Amendment of the Food and Farming Regulations

5. In the Food and Farming Regulations—

(a) in regulation 1, in paragraph (a), for ", 12 and 13" substitute "and 12";

(b) omit regulation 10;

(c) in regulation 12, omit paragraph (2);

(d) omit regulation 13.

Amendment of the Environment, Food and Rural Affairs (Amendment) (EU Exit) Regulations 2019

6. In regulation 7 of the Environment, Food and Rural Affairs (Amendment) (EU Exit) Regulations 2019(**c**) (amendment of Regulation (EC) No 1830/2003)—

(a) in paragraph (2)—

(i) in the new paragraph 14 to be inserted by that paragraph—

(aa) omit point (d);

(bb) omit the second point (c);

(ii) in the new paragraph 15 to be inserted by that paragraph, in point (a), for ", Wales and Northern Ireland" substitute "and Wales";

(b) in paragraph (7), in the Article to be substituted by that paragraph, omit paragraphs 3 and 7.

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

7. In 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, omit Article 9a.

Name
Parliamentary Under Secretary of State
Date Department for Environment, Food and Rural Affairs

(**a**) S.I. 2019/90, relevant amending instrument is S.I. 2019/759.
(**b**) S.I.2019/88.
(**c**) S.I. 2019/778, amended by S.I. 2019/1342.

SCHEDULE

Regulation 4

Amendment of the GMO Regulations

General

1. The GMO Regulations are amended as follows.

Amendment of regulation 4 (amendment of Regulation (EC) No 1830/2003)

2. In regulation 4(3)—

(a) in sub-paragraph (a)—

(i) for "Community" substitute "the Community";

(ii) for "United Kingdom" substitute "Great Britain";

(b) in sub-paragraph (c), for the new paragraph 10 to be substituted by that sub-paragraph, 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 means "marketed" within the meaning given in section 107(11) of the Environmental Protection Act 1990(**a**).";

(c) in sub-paragraph (d), in the new paragraph 13 to be inserted by that sub-paragraph, omit point (d).

Amendment of regulation 5 (amendment of Regulation (EC) No 1946/2003)

3.—(1) Regulation 5 is amended as follows.

(2) In paragraph (3)—

(a) for sub-paragraph (a) substitute—

"(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;";";

(b) for sub-paragraph (b) substitute—

"(b) in paragraph 11, for the words from "outside the" to the end substitute "outside Great Britain by an exporter";";

(c) for sub-paragraph (c) substitute—

"(c) in paragraph 12, for "the customs territory of the Community", in both places it occurs, substitute "Great Britain";";

(d) after sub-paragraph (d), insert—

"(da) for paragraph 15 substitute—

"**15.** "Party" means—

(a) Great Britain,

(**a**) 1990 c. 43. Subsection (11) of section 107, as it applies in England, was substituted by regulation 4(6) of S.I. 2002/2443. Subsection (11) of section 107, as it applies in Wales, as substituted by regulation 5(2)(e) of S.I. 2002/3188 (W. 304). Subsection (11) of section 107, as it applies in Scotland, was substituted by regulation 4(6) of S.S.I. 2002/541. There are other amendments to section 107 but none is relevant.

(b) Northern Ireland, or

(c) any other country or regional economic integration organisation being a Party to the Protocol;";";

(e) for sub-paragraph (e) substitute—

"(e) in paragraph 19, after ""competent authority"" insert ", other than in the expression "relevant GB competent authority",";

(f) after sub-paragraph (e), insert—

"(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.";";

(g) for sub-paragraph (f) substitute—

"(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;" ;";

(h) in sub-paragraph (g)—

(i) in the new paragraph 22 to be inserted by that sub-paragraph, for ", Scotland or Northern Ireland" substitute "or Scotland";

(ii) in the new paragraph 23 to be inserted by that sub-paragraph—

(aa) after ""relevant" insert "GMO";

(bb) for "any of the competent authorities" substitute "a relevant GB competent authority";

(iii) after the new paragraph 23, insert—

"**24.** "third country" means a country other than Great Britain.".

(3) In paragraph (4)—

(a) in sub-paragraph (a)—

(i) for "the competent" substitute "the relevant GB competent";

(ii) for "any" substitute "each";

(b) in sub-paragraph (b), for "focal" substitute "GB focal".

(4) In paragraph (5)—

(a) in sub-paragraph (a) for "competent" substitute "relevant GB competent";

(b) in sub-paragraph (b) for "any" substitute "each";

(c) in sub-paragraph (c)(i) for "competent authority for any" substitute "relevant GB competent authority for each".

(5) In paragraph (6)—

(a) in sub-paragraph (a)—

(i) in paragraph (i)(aa) for "focal" substitute "GB focal";

(ii) in paragraph (i), for sub-paragraph (bb) substitute—

"(bb) for "the Community or use within a Member State" substitute "Great Britain";";

(iii) in paragraph (ii), in the subparagraph to be substituted by that paragraph—

(aa) omit point (d), and

(bb) in the words after point (d), for "country outside the United Kingdom" substitute "third country";

(b) in sub-paragraphs (b) and (c), for "focal" substitute "GB focal".

(6) For paragraph (7) substitute—

"(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".".

(7) In paragraph (9)—

(a) in sub-paragraph (a), for "competent" substitute "relevant GB competent";

(b) in sub-paragraph (b)(i)—

(i) in sub-paragraph (aa), for "the United Kingdom" substitute "Great Britain";

(ii) in sub-paragraphs (aa) and (bb), for "focal" substitute "GB focal".

(8) In paragraph (10)(a)—

(a) in paragraph (i)(aa), for "focal" substitute "GB focal";

(b) in paragraph (iii), in the point to be substituted by that paragraph—

(i) for "relevant authority" substitute "relevant GMO authority";

(ii) omit the words from "— in Northern Ireland" to "(Northern Ireland) 2003";

(c) for paragraph (iv) substitute—

"(iv) in point (f), for "the Community's" substitute "Great Britain's";";

(d) in paragraph (v), in the points to be substituted by that paragraph—

(i) in point (h), omit point (iv);

(ii) in point (i) for "the United Kingdom" substitute "Great Britain".

(9) In paragraph (11)—

(a) in sub-paragraph (a), for "competent" substitute "relevant GB competent";

(b) in sub-paragraph (b), for "competent" substitute "relevant GB competent".

(10) In paragraph (12)(c), in the new paragraph 3 to be inserted by that paragraph—

(a) for "focal" substitute "GB focal";

(b) for "competent" substitute "relevant GB competent".

(11) In paragraph (14)(b)—

(a) in paragraph (i), for "focal" substitute "GB focal";

(b) in paragraph (ii), for "the United Kingdom" substitute "Great Britain".

(12) In paragraph (16)—

(a) for sub-paragraph (a) substitute—

"(a) in point (c), for "the State of export" substitute "Great Britain";";

(b) in sub-paragraph (b), for paragraph (i) substitute—

"(i) for "the State of export", in the first place it occurs, substitute "Great Britain";
".

(13) For paragraph (17) substitute—

"(17) In Annex 3, in point (b), for "the originating Party" substitute "Great Britain".".

Amendment of regulation 6 (amendment of Commission Regulation (EC) No 65/2004)

4.—(1) Regulation 6 is amended as follows.

(2) In paragraph (2), in the new Article 1 to be substituted by that paragraph—

(a) in paragraph 1, omit point (d);

(b) for paragraph 2 substitute—

"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(**a**), or

(c) the Veterinary Medicines Regulations 2013(**b**),

or applications for authorisation under such legislation.".

(3) In paragraph (7)(b), for "the United Kingdom" substitute "Great Britain".

Amendment of regulation 8 (amendment of Council Decision 2002/812/EC)

5.—(1) Regulation 8 is amended as follows.

(2) In paragraph (2), in the Article 1 to be substituted by that paragraph, omit point (d).

(3) In paragraph (6)(c), for paragraph (iii) substitute—

"(iii) in the words after the first paragraph 8, for "the Community" substitute "Great Britain".".

(4) In paragraph (7)—

(a) for sub-paragraph (b) substitute—

"(b) in section B, in paragraph 13, for "the Member State(s)" substitute "Great Britain";
";

(b) in sub-paragraph (c)(ii), for sub-paragraph (aa) substitute—

"(aa) for "the Community" substitute "Great Britain";".

Amendment of regulation 11 (amendment of Commission Decision 2009/770/EC)

6.—(1) Regulation 11 is amended as follows.

(2) In paragraph (2), in the new Article 1 to be substituted by that paragraph, in paragraph 1, omit point (d).

(3) In paragraph (9)(b)—

(a) in paragraph (iv), for "the United Kingdom" substitute "Great Britain";

(b) for paragraph (vi) substitute—

"(i) in paragraph 3.1.3, in the first subparagraph, for "the Community" substitute "Great Britain".".

(4) In paragraph (13)—

(a) for sub-paragraph (a) substitute—

"(a) for "the Community", in each place it occurs, substitute "Great Britain";";

(b) in sub-paragraph (d)(ii), for "the United Kingdom" substitute "Great Britain".

(5) In paragraph (16)(d)—

(a) for paragraph (i) substitute—

(**a**) S.I. 2012/1916, to which there are amendments not relevant to these Regulations.
(**b**) S.I. 2013/2033, to which there are amendments not relevant to these Regulations.

"(i) for "the Community", in each place it occurs, substitute "Great Britain";";

(b) in paragraph (ii)(dd), for "the United Kingdom" substitute "Great Britain".

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by sections 8(1) and 8C of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018 (c. 16). They deal with matters arising out of, or related to, the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement (regulations 2 to 6), and make additional provision to address deficiencies in retained EU law (in particular under section 8(2)(a) of the 2018 Act) (regulation 7).

These 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.

A full impact assessment has not been produced for this instrument.

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