STATUTORY INSTRUMENTS

2018 No. 1393

EXITING THE EUROPEAN UNION

ENVIRONMENTAL PROTECTION

The Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018

Sift requirements satisfied	*27th November 2018*
Made - - - -	*18th December 2018*
Laid before Parliament	*20th December 2018*
Coming into force in accordance with regulation 1	

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

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

PART 1

Introduction

Citation and commencement

1. These Regulations may be cited as the Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018 and come into force on exit day.

PART 2

Amendments to subordinate legislation

The Nagoya Protocol (Compliance) Regulations 2015

2.—(1) The Nagoya Protocol (Compliance) Regulations 2015(**b**) are amended as follows.

(2) In regulation 2(1), in the definition of "the EU Regulation", after "Union" insert "as it applies in the United Kingdom".

(**a**) 2018 c. 16.
(**b**) S.I. 2015/821, to which there are amendments not relevant to this instrument.

(3) In regulation 4, omit "of the member State".

(4) Omit regulation 6(a).

PART 3

Amendments to retained direct EU legislation

Regulation (EU) No 511/2014 of the European Parliament and of the Council

3.—(1) Regulation (EU) No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union is amended as follows.

(2) In Article 2—

(a) in paragraph 1, for "Union" substitute "United Kingdom";

(b) omit paragraph 3;

(c) for paragraph 5 substitute—

"5. Nothing in this Regulation obliges disclosure of information which the Secretary of State considers contrary to the essential interests of national security.".

(3) In Article 3—

(a) for paragraph 10 substitute—

"10. "associations of users" means an organisation that represents the interests of users in the United Kingdom and that is involved in developing and overseeing the best practices referred to in Article 8 of this Regulation;";

(b) after paragraph 11, insert—

"12. "serious cross-border threat to health" means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads or entails a significant risk of spreading across national borders, and which may necessitate international coordination in order to ensure a high level of human health protection.".

(4) In Article 4—

(a) in paragraph 7, for "Union" substitute "United Kingdom";

(b) in paragraph 8, in the first subparagraph omit the words from "as defined" to "Council".

(5) In Article 5—

(a) in paragraph 1—

(i) in both places it occurs, for "Commission" substitute "Secretary of State";

(ii) omit "within the Union";

(b) for paragraph 2 substitute—

"2. The Secretary of State must, upon request by a collection holder, consider the inclusion of that collection, or a part of it, in the register. After verifying that the collection, or a part of it, meets the criteria set out in paragraph 3, the Secretary of State must without delay include the information received in the register.";

(c) for paragraph 4 substitute—

"4. The Secretary of State must regularly verify that each collection or part of a collection included in the register meets the criteria set out in paragraph 3.

Where there is evidence, on the basis of information provided pursuant to paragraph 3, that a collection or a part of collection included in the register does not meet the criteria set out

in paragraph 3, the Secretary of State must, in dialogue with the collection holder concerned and without undue delay, identify remedial actions or measures.

Where the Secretary of State determines that a collection or a part of a collection no longer complies with paragraph 3, the Secretary of State must remove the collection or the part of the collection concerned from the register.".

(6) In Article 6—

(a) for paragraph 1, substitute—

"1. The Secretary of State must designate one or more competent authorities to be responsible for the application of this Regulation. The Secretary of State must publish from time to time any changes to the names or addresses of the competent authorities responsible for the application of this Regulation.";

(b) omit paragraph 2;

(c) in paragraph 3, for "Commission" substitute "Secretary of State";

(d) omit paragraph 4.

(7) In Article 7—

(a) in paragraph 1, for "Member States and the Commission" substitute "Secretary of State";

(b) in paragraph 3, omit "to the Commission";

(c) in paragraph 5, omit "Union or".

(8) In Article 8, in paragraphs 1 to 6, in each place it occurs, for "Commission" substitute "Secretary of State".

(9) In Article 9—

(a) in paragraph 2, for "Member States" substitute "The Secretary of State";

(b) in paragraph 6—

(i) in the first subparagraph, omit "Without prejudice to Article 11,";

(ii) in the second subparagraph, for "Member States" substitute "the Secretary of State".

(10) For Article 10(2) substitute—

"2. The information referred to in paragraph 1 must be made available—

(a) in England, Wales and Northern Ireland, in accordance with the Environmental Information Regulations 2004(**a**);"

(b) in Scotland, in accordance with the Environmental Information (Scotland) Regulations 2004(**b**).".

(11) Omit Article 11.

(12) In Article 12—

(a) in point (a), omit "and with the Commission";

(b) omit point (d).

(13) In Article 13—

(a) in the words before point (a), for "Commission and Member States" substitute "Secretary of State";

(b) in point (a), for "Union" substitute "United Kingdom".

(14) Omit Article 15.

(15) For Article 16 substitute—

(**a**) S.I. 2004/3391, which was amended by the Data Protection Act 2018 (c. 12); there is another amending instrument but it is not relevant.

(**b**) S.S.I. 2004/520, which was amended by the Data Protection Act 2018 (c. 12); there are other amending instruments but they are not relevant.

"*Article 16*

Reports and review

1. Unless an alternative interval for reports is determined, as referred to in Article 29 of the Nagoya Protocol, the Secretary of State must prepare a report on the application of this Regulation every five years beginning with the day after exit day.

2. Every 10 years after the first report the Secretary of State must, on the basis of reporting on, and experience with the application of, this Regulation, review the functioning and effectiveness of this Regulation in achieving the objectives of the Nagoya Protocol. In carrying out the review the Secretary of State must, in particular, consider the administrative consequences for public research institutions, micro, small or medium-sized enterprises and specific sectors. The Secretary of State must also consider the need to review the implementation of the provisions of this Regulation in light of developments in other relevant international organisations.

3. The Secretary of State must report to the Conference of the Parties to the Convention serving as the meeting of the Parties to the Nagoya Protocol on the measures taken by the United Kingdom to implement compliance measures in respect of the Nagoya Protocol.".

(16) After Article 17, omit the words from "This Regulation" to "Member States.".

Commission Implementing Regulation (EU) No 2015/1866

4.—(1) Commission Implementing Regulation (EU) No 2015/1866 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices is amended as follows.

(2) In Article 2—

(a) in the words before point (a), for "Commission" substitute "Secretary of State";

(b) omit point (a);

(c) in point (g), for the words from "institution" to "Member State" substitute "details of the competent authority".

(3) In Article 3—

(a) in the heading, omit "and notification to the Commission";

(b) omit paragraphs 2 and 4.

(4) In Article 5—

(a) in paragraph 1, omit from "of the Member State" the first time it occurs, until the end;

(b) in paragraph 2, for "national authorities" substitute "Secretary of State";

(c) in paragraph 3, omit the second and third sentences;

(d) omit paragraph 4.

(5) In Article 6—

(a) in paragraph 1, for the words from "competent authority" until the end of the first sentence substitute "relevant competent authority";

(b) in paragraphs 2 and 4, in each place it occurs, for "Union" substitute "United Kingdom".

(6) In Article 7, omit paragraphs 3 and 4.

(7) For Article 8 substitute—

"*Article 8*

Application for recognition of a best practice

1. An application submitted in accordance with Article 8(1) of Regulation (EU) No 511/2014 must be made to the Secretary of State by providing the information and supporting documentation specified in Annex 4 to this Regulation.

2. An interested party that does not represent users but is involved in the access, collection, transfer or commercialisation of genetic resources or in developing measures and policy related to genetic resources must provide with its application information, as specified in Annex 4 to this Regulation, on its legitimate interest in developing and overseeing a combination of procedures, tools or mechanisms, which, when effectively implemented by a user, enables that user to comply with the obligations provided for in Articles 4 and 7 of Regulation (EU) No 511/2014.

3. The Secretary of State must acknowledge receipt of an application within 20 working days from the date of receipt of the application. The Secretary of State must provide the applicant with an indicative time limit within which a decision on the application will be taken. The Secretary of State must inform the applicant if additional information or documentation is required in order to carry out the assessment of the application.

4. The applicant must submit to the Secretary of State any additional information and documentation requested without undue delay.

5. The Secretary of State must inform the applicant each time of any revision to the indicative time limit within which a decision on the application will be taken due to the necessity to obtain additional information or documents for the assessment of the application. The Secretary of State must inform the applicant in writing of the status of the assessment of the application at least every six months.".

(8) For Article 9 substitute—

"*Article 9*

Recognition and withdrawal of recognition as best practice

1. Where the Secretary of State decides to grant recognition as best practice under Article 8(2) of Regulation (EU) No 511/2014 or to withdraw the recognition of best practice under Article 8(5) of that Regulation, the Secretary of State must inform the association of users or the other interested parties of that decision without undue delay.

2. The Secretary of State must state reasons for the decision to grant recognition as best practice or to withdraw the recognition of best practice, and must publish that decision in the register established under Article 8(6) of Regulation (EU) No 511/2014.".

(9) For Article 10 substitute—

"*Article 10*

Information on subsequent changes to a recognised best practice

Where the Secretary of State is informed, pursuant to Article 8(3) of Regulation (EU) No 511/2014, of any changes or updates made to a recognised best practice, the Secretary of State must assess whether the changed or updated combination of procedures, tools or mechanisms still enables users to comply with their obligations provided for in Articles 4 and 7 of Regulation (EU) No 511/2014.".

(10) In Article 11—

(a) in each place it occurs, for "Commission" substitute "Secretary of State";

(b) omit paragraphs 3 and 4;

(c) in paragraph 5—

(i) insert “and assist” after “co-operate with”;

(ii) omit “and assist it in its actions”.

(11) In Article 12, for “Commission” substitute “Secretary of State”.

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

(13) In Annex 1, in Part B, point (d), omit the words from “, and about” until the end.

(14) In Annex 2, in Part B, omit paragraph 5.

(15) In Annex 3—

(a) in Part A, in each place it occurs (including in footnote 2), for “Union” substitute “United Kingdom”;

(b) in Part B—

(i) in paragraph 2, for “registration code” substitute “details”;

(ii) in paragraph 3—

(aa) after “511/2014” insert “, or other recognised best practice”;

(bb) for “registration number” substitute “identifying details of that best practice”;

(iii) for paragraphs 5 and 6 substitute—

“5. Any markets outside the United Kingdom on which the product has been placed:”.

(16) In Annex 4—

(a) in paragraph 3, point (a), for the words from “Member State” until the end substitute “competent authority”;

(b) omit paragraphs 8 and 9.

Thérèse Coffey
Parliamentary Under Secretary of State
Department for Environment, Food and Rural Affairs

18th December 2018

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) and (d)) arising from the withdrawal of the UK from the European Union. They are also made in exercise of the powers conferred by paragraph 21(b) of Schedule 7 to that Act, where it is considered necessary to restate or clarify provisions of retained EU law.

These Regulations make amendments to legislation in the field of environmental protection and, in particular, amend legislation relating to access to genetic resources and fair and equitable sharing of benefits. Part 2 amends subordinate legislation and Part 3 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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