

**EXPLANATORY MEMORANDUM TO**  
**THE NAGOYA PROTOCOL (COMPLIANCE) (AMENDMENT) (EU EXIT)**  
**REGULATIONS 2018**

**2018 NO. XXX**

**1. Introduction**

- 1.1 This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before Parliament by Act.
- 1.2 This memorandum contains information for the Sifting Committees.

**2. Purpose of the instrument**

- 2.1 The purpose of the Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018 is to ensure that regulations in the UK which implement the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation, will continue to be operable after the UK leaves the EU.

*Explanations*

What did any relevant EU law do before exit day?

- 2.2 The Nagoya Protocol is an international agreement (to which both the EU and the UK are parties) which puts in place measures to ensure that where genetic resources are used in research and development (R&D) programmes, benefits are returned to the country or community that the genetic resource came from. Benefits can either be monetary or non-monetary, such as knowledge sharing or capacity building. The Protocol also covers ‘traditional knowledge associated with genetic resources’, which can be understood as the knowledge of indigenous people about how genetic resources are used.
- 2.3 The Nagoya Protocol was implemented within the UK as a member state of the European Union by means of two European Union regulations which are directly applicable in the UK:
- Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 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;
  - Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 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.
- 2.4 Monitoring and compliance requirements under those European Union regulations were implemented in the UK by a statutory instrument:
- The Nagoya Protocol (Compliance) Regulations 2015 (S.I. 2015/821).
- 2.5 Together, these regulations laid down compliance measures for users of genetic resources who conduct R&D in the Union, as well as the role of the Commission and member states, such as the establishment of national focal points and competent national authorities.

Why is it being changed?

- 2.6 The regulations referred to in paragraphs 2.3 and 2.4 contain a number of references to and responsibilities of the Commission, the European Union and its member states which, after the UK exits from the European Union, will no longer operate effectively.

What will it now do?

- 2.7 This instrument clarifies the responsibilities of the Secretary of State and the competent national authority. It also removes unnecessary requirements such as reporting to the Commission.

### **3. Matters of special interest to Parliament**

*Matters of special interest to the Sifting Committees*

- 3.1 This instrument is being laid in draft for sifting by the Sifting Committees pursuant to the European Union (Withdrawal) Act 2018.

*Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)*

- 3.2 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

### **4. Extent and Territorial Application**

- 4.1 The territorial extent of this instrument is the United Kingdom.  
4.2 The territorial application of this instrument is the United Kingdom.

### **5. European Convention on Human Rights**

- 5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation no statement is required.

### **6. Legislative Context**

- 6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation no statement is required.

### **7. Policy background**

*What is being done and why?*

- 7.1 The UK is a party to the Nagoya Protocol in its own right and will continue to be bound by the obligations of the Protocol after the UK leaves the European Union. To ensure continued compliance with the Protocol, we will convert the two European regulations into a UK-specific regime under the powers set out in the European Union (Withdrawal) Act 2018, to ensure that it remains operable outside the EU legal framework.
- 7.2 Without the corrections set out in this instrument, the converted regulations would contain deficiencies and be largely inoperable. In addition, this instrument will amend the domestic legislation which implements a monitoring and compliance regime in the UK.

- 7.3 The changes proposed are to:
- clarify that the current responsibilities of the European Commission with regards to best practices and registered collections will in future lie with the Secretary of State;
  - amend references to the Union, Member States and the Commission as appropriate to UK references;
  - delete clauses which will no longer be appropriate, such as obligations to inform the Commission or other Member States.
- 7.4 Additionally there are further substantive corrections which are not included in this instrument but will instead will be contained within a separate instrument to be made under affirmative procedure. These corrections will transfer powers from the European Commission to the Secretary of State, to:
- make regulations for the monitoring of user compliance;
  - recognise best practices; and
  - establish a register of collections.
- 7.5 This instrument applies to the Nagoya Protocol which is a transferred matter for Northern Ireland under the Northern Ireland Act 1998. The UK Government remains committed to restoring devolution in Northern Ireland. This is particularly important in the context of EU Exit where we want devolved Ministers to take the necessary actions to prepare Northern Ireland for exit. We have been considering how to ensure a functioning statute book across the UK including in Northern Ireland for exit day absent a Northern Ireland Executive. With exit day less than six months away, and in the continued absence of a Northern Ireland Executive, the window to prepare Northern Ireland's statute book for exit is narrowing. UK Government Ministers have therefore decided that in the interest of legal certainty in Northern Ireland, the UK Government will take through the necessary secondary legislation at Westminster for Northern Ireland, in close consultation with the Northern Ireland departments. This is one such instrument.

## **8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union**

- 8.1 This instrument is being made using the power in section 8 of the European Union (Withdrawal) Act 2018 in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

## **9. Consolidation**

- 9.1 The Department does not intend to consolidate the relevant legislation at this time.

## **10. Consultation outcome**

- 10.1 No consultation exercise was conducted as this instrument merely corrects deficiencies arising from the exit of the UK from the European Union and does not change the policy.

10.2 The current European Union and domestic regulations apply uniformly across the UK, on the basis that they concern both devolved and reserved matters (such as agri-food and medicines respectively). The devolved administrations have been consulted during development of the instrument and are content with the instrument. It has been agreed that the Secretary of State will be empowered to make regulations with regard to the Nagoya Protocol for the United Kingdom with the consent and involvement of the Devolved Administrations.

## **11. Guidance**

11.1 None

## **12. Impact**

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 The impact on the public sector is minimal. There will be no change to monitoring and enforcement requirements.

12.3 An Impact Assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.

## **13. Regulating small business**

13.1 The legislation applies to activities that are undertaken by small businesses. No, or no significant, impact on small businesses is foreseen as a result of this instrument.

## **14. Monitoring & review**

14.1 As this instrument is made under the European Union (Withdrawal) Act 2018, no review clause is required.

## **15. Contact**

15.1 Sally Cunningham at the Department for Environment, Food and Rural Affairs (email: [sally.cunningham@defra.gsi.gov.uk](mailto:sally.cunningham@defra.gsi.gov.uk)) can answer any queries regarding the instrument.

15.2 Emma Williams, Deputy Director for International Environment Strategy at the Department for Environment, Food and Rural Affairs (email: [emma.williams@defra.gsi.gov.uk](mailto:emma.williams@defra.gsi.gov.uk)) can confirm that this Explanatory Memorandum meets the required standard.

15.3 The Parliamentary Under Secretary of State for the Environment, Thérèse Coffey MP at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.

# Annex

## Statements under the European Union (Withdrawal) Act 2018

### Part 1

#### Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them.  State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.

Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9, and 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	Set out the ‘good reasons’ for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Schedule 7.	Statement of the reasons for the Minister’s opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before exit day, and explaining the instrument’s effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority’s response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

## **Part 2**

### **Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act**

#### **1. Sifting statement(s)**

- 1.1 The Parliamentary Under Secretary of State for the Environment, Thérèse Coffey, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:
- 1.2 “In my view the Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018 should be subject to annulment in pursuance of a resolution of either House of Parliament (i.e. the negative procedure)”. This is the case because: this instrument does not fall into the category of regulations identified in schedule 7 Part 1 paragraph 1(2) as requiring approval in draft by resolution of both Houses of Parliament. This instrument makes minor and technical amendments to the existing legislation described above to ensure retained EU law and preserved UK law is operable after Exit. No substantive policy changes are brought in by this instrument.

#### **2. Appropriateness statement**

- 2.1 The Parliamentary Under Secretary of State for the Environment, Thérèse Coffey, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:
- 2.2 “In my view the Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018 does no more than is appropriate”.
- 2.3 This is the case because: this instrument corrects deficiencies as necessary to ensure that regulations ensuring UK compliance with the Nagoya Protocol are maintained in the UK after we leave the EU.

#### **3. Good reasons**

- 3.1 The Parliamentary Under Secretary of State for the Environment, Thérèse Coffey, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:
- 3.2 “In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action”.
- 3.3 These are: this instrument corrects deficiencies as necessary to ensure that the regulations covering access to and utilisation of genetic resources in accordance with the Nagoya Protocol are maintained in the UK after we leave the EU.

#### **4. Equalities**

- 4.1 The Parliamentary Under Secretary of State for the Environment, Thérèse Coffey, has made the following statement: “The instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts.”

- 4.2 The Parliamentary Under Secretary of State for the Environment, Thérèse Coffey, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018: “In relation to the instrument, I, Thérèse Coffey have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010.”
- 4.3 The amendments made by the instrument do not raise any issues relevant to the public sector equality duty under section 149(1) Equality Act 2010 because they are minor and technical and do not alter the operation of the underlying schemes or impose any new liabilities or obligations on any relevant persons.

## **5. Explanations**

- 5.1 The explanations statement has been made in section 2 of the main body of this explanatory memorandum.

## **6. Criminal offences**

- 6.1 No new criminal offences are created by the instrument.

## **7. Legislative sub-delegation**

- 7.1 No sub-delegated powers are created by the instrument.

## **8. Urgency**

- 8.1 We are not invoking the need for urgency to avoid a draft affirmative procedure as the instrument is suitable for a negative procedure.