NAGOYA PROTOCOL – NOTIFICATION TO THE SCOTTISH PARLIAMENT

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

1. Name of the instrument and summary of proposal

The Nagoya Protocol (Compliance) (EU Exit) Regulations 2018 ("the Regulations") address minor and technical deficiencies arising from the withdrawal of Scotland as part of the United Kingdom from the European Union, based on a presumed "no deal" scenario.

The Regulations deal with retained directly applicable EU legislation (Regulation (EU) No 511/2014 of the European Parliament and of the Council – "the EU Regulation" - and Commission Implementing Regulation (EU) No 2015/1866) and UK legislation (The Nagoya Protocol (Compliance) Regulations 2015 – S.I. 2015/821).

The Regulations relate to a mixture of reserved and devolved matters. The precise boundary between reserved and devolved issues in this area has not been established in practical terms to date, as so far there have been no transactions involving Scotland that fall within the scope of the Protocol and only a single transaction in the rest of the UK.

2. Explanation of law that the proposals amend

The Secretary of State is the agreed single competent authority within the UK as regards implementation of, and compliance with, the Nagoya Protocol. The information in this section 2 of this notification is based on the relevant UK Government guidance.

The Nagoya Protocol entered into force in October 2014. It provides a framework for the effective implementation of one of the three objectives of the Convention on Biological Diversity (CBD): being the fair and equitable sharing of benefits arising out of the utilisation of genetic resources. It recognises that benefits derived by users of genetic resources should be shared with those who provide them, with the ultimate objective being the conservation and sustainable use of biodiversity.

Users of genetic resources – those conducting research and development – are required to exercise due diligence to demonstrate that genetic resources and / or associated traditional knowledge (aTK) are accessed and utilised in accordance with applicable legislation of the providing country.

The regulations in force in the UK are:

- The Nagoya Protocol (Compliance) Regulations 2015
- Regulation (EU) No. 511/2014 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 Utilisation in the Union
- Implementing Regulation (EU) 2015/1866 laying down the detailed rules for the implementation of Regulation (EU) 511/2014 as regards the register of collections, monitoring user compliance and best practices

The legislation is implemented and enforced in the UK by the Office for Product Safety and Standards (Safety & Standards).

Scope of the regulations relating to Nagoya Protocol

The regulations apply when research and development is conducted on genetic resources and/or aTK. A genetic resource is any plant, animal, microbial or material of other origin which contains functional units of heredity and is of actual or potential value. Human genetic resources are not covered by the Nagoya Protocol.

A variety of sectors conduct activities that are in scope of the regulations in the UK, which apply to both commercial and non-commercial research. Those sectors include:

- animal breeding
- bio-control
- biotechnology
- collections
- cosmetic and personal care
- food and feed
- pharmaceutical
- plant breeding
- research institutions

The regulations in the UK apply to any company, organisation or individual conducting research and development on genetic resources and / or aTK (the user) where:

- the genetic material and / or aTK was accessed on or after 12 October 2014, and
- was from a country that is party to the Nagoya Protocol and has access and benefit sharing (ABS) legislation

3. Summary of the proposals

Part 1 of The Nagoya Protocol (Compliance) (EU Exit) Regulations 2018 amends subordinate legislation and Part 2 amends directly applicable European Union legislation. The Regulations transfer certain functions from the Commission such as responsibilities with regards to best practices and registered collections, and preparation of a report every five years on the application of the Regulation, to the Secretary of State. They also make a number of technical amendments to ensure continued effective operation of existing domestic law and retained EU law.

These changes are consistent with the agreed position of the Secretary of State as the single competent authority within the UK for compliance with the Nagoya Protocol. The Scottish Ministers are content that the amendments to the proposed Regulations are appropriate and respect the devolution settlement. In practical terms, Nagoya Protocol compliance issues have, to date, had no impact in Scotland, as no transactions under the Protocol have taken place so far involving a Scottish dimension. Should the Protocol become more significant for trade or research in Scotland, Defra and the Scottish Ministers recognise that increased involvement of the Scottish Ministers and the Scottish Parliament in this area of regulation could be called for.

4. Why are these changes necessary?

These changes are necessary to allow the continuation of the effective functioning of this legislation.

5. Scottish Government categorisation of significance of proposals

Category A. The provisions are making small, minor technical changes to preserve the functioning of the legislation.

6. Impact on devolved areas

These changes relate to subject matter that involves a mix of reserved and devolved matters. Under the Scotland Act 1998, observing and implementing international obligations and obligations under EU law are generally devolved. Relevant reservations and exceptions under the Scotland Act 1998 relating to potential transactions within the scope of the Nagoya Protocol are-

C7. Consumer protection

Section C7.

- Regulation of—
  (a) the sale and supply of goods and services to consumers,
  (b) …..cont.

C8. Product standards, safety and liability

Section C8.

- Technical standards and requirements in relation to products in pursuance of an obligation under EU law.
- The national accreditation body and the accreditation of bodies which certify or assess conformity to technical standards in relation to products or environmental management systems.
- Product safety and liability.
- Product labelling.

Exceptions

- The provision of consumer advocacy and advice by, or by agreement with, a public body or the holder of a public office.
- Food, agricultural and horticultural produce, fish and fish products, seeds, animal feeding stuffs, fertilisers and pesticides (including anything treated as if it were a pesticide by virtue of section 16(16) of the Food and Environment Protection Act 1985).
- In relation to food safety, materials which come into contact with food.

Interpretation

> *"Food"* has the same meaning as it has in Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (as at 7th December 2004).

Application of the above reservations and exceptions indicates, for example, that regulation of a transaction involving use of relevant genetic materials in relation to food and feed may be amenable to being regulated within devolved competence whereas regulation of a transaction relating to pharmaceuticals would more likely relate to reserved matters.

7. Stakeholder engagement/consultation

We have written to our stakeholders setting out the general approach we are taking to correcting deficiencies in environmental legislation and we are in regular contact with all our stakeholders regarding the move towards leaving the EU. However, these measures are aimed solely at preserving the functioning of the law as it stands at present and, therefore, we have not undertaken any engagement, or any formal consultation, about these specific amendments.

No specific consultations on this issue have been carried out with Scottish stakeholders. The list of potential stakeholders is very wide and the proposed measures will not bring about any change in the requirements placed upon users of genetic resources.

8. Any other impact assessments?

On the basis that these amendments do not result in any policy changes, no impact assessment has been prepared.

9. Summary of reasons for Scottish Ministers' proposing to consent to UK Ministers legislation

The primary reason for proposing to consent to UK Ministers' legislation is the agreed position of the Secretary of State as the single competent authority for Nagoya Protocol compliance within the UK and the importance of the effective continued operation of the relevant law. In practical terms, the number of transactions falling within the scope of the Protocol is very small (one transaction only in the UK thus far). The legislation is enforced in the UK by the Office for Product Safety and Standards (Safety & Standards).

It is therefore considered that the proper and most efficient way of proceeding at this stage is to consent to UK-wide legislation. Defra has agreed to operate a co-decision making procedure with devolved administrations, and also recognises that devolved administrations may have the competence to make their own regulations in this area. Scottish Ministers take the view that if this Protocol becomes more significant to

Scottish research and trade sectors in the future, it may be appropriate to consider some specific Scottish arrangements.

10. Have Scottish Ministers had regard to the guiding principles on animal welfare and the environment?

The proposed changes are minor technical changes and adhere fully to the existing environmental principles. There are no changes relevant to animal welfare.

11. Are there governance issues in relation to this proposal, and how will these be regulated and monitored post-withdrawal?

The sole governance issue arising from these proposed changes is the matter of reporting requirements, as reporting to the Commission will no longer be required. It is proposed that this is replaced by a new duty of the Secretary of State to produce a report every five years. The co-decision making procedure (see section 9) will apply to deciding on the format and approach to reporting.

More widely, later this year, Scottish Ministers will consult on the governance gaps that will be created once the UK leaves the EU, with a view to bringing proposals back to the Scottish Parliament on environmental governance arrangements once the future relationship is clear.

12. Intended UK laying date

This instrument is subject to the negative procedure and will be laid for sifting at Westminster on 15 November. Defra have agreed that no EU Exit SIs will be made (for negative procedure SIs), or laid in draft (for affirmative SIs), until after they have been through the consent process agreed with the Scottish Parliament.

13. Does the Scottish Parliament have 28 days to scrutinise Scottish Ministers' proposal to consent?

Yes

14. Information about any time dependency associated with the proposal

There is no time dependency associated with the proposals.

15. Any significant financial implications

There are no financial implications associated with the proposals.

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