

**EXPLANATORY MEMORANDUM TO**  
**THE NAGOYA PROTOCOL (COMPLIANCE) REGULATIONS 2015**

**2015 No. 821**

1. This explanatory memorandum has been prepared by Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

- 2. Purpose of the instrument**

- 2.1 This statutory instrument put in place the measures needed for the UK to implement the EU Regulation and those elements of the Nagoya Protocol, which is a legally binding international agreement, which are not covered by the EU Regulation. The Nagoya Protocol puts in place measures to ensure that where genetic resources are used to create a product, some of the benefits are returned to the country or community that the genetic resource came from. Benefits can either be money or can be ‘in kind’, 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.

- 3. Matters of special interest to the Joint Committee on Statutory Instruments**

- 3.1 None.

- 4. Legislative Context**

- 4.1 The Nagoya Protocol (Compliance) Regulations 2015 (“the Regulations”):

- (1) enforces 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 Utilization in the Union (“the EU Regulation”).
    - (2) implements, within the UK, those elements of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (“the Protocol”) that relate to traditional knowledge which are not covered by the EU Regulation. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization is an international treaty under the Convention on Biological Diversity and was signed by the UK on 23 June 2011.

4.2 The Regulations also designates the Secretary of State as the competent authority for the EU Regulation; establish offences and set penalties for the administration and enforcement of the EU Regulation.

## **5. Territorial Extent and Application**

5.1 This instrument applies to all of the United Kingdom.

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

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

## **7. Policy background**

7.1 The Convention on Biological Diversity is the main international forum devoted to the conservation of the Earth's biological diversity. The third aim of the Convention on Biological Diversity is to ensure that the owners or guardians of genetic resources receive a fair share of any benefits that arise from research carried out on those resources.

7.2 The Convention on Biological Diversity recognises the sovereign rights of countries to govern access to genetic resources and the sharing of their benefits, if they choose to do so. The Nagoya Protocol was adopted in 2010 to implement these aims. The Nagoya Protocol requires member countries to take measures to provide that users of genetic resources and traditional knowledge associated with genetic resources comply with national access legislation, where it exists, so benefits can be shared. This generally means ensuring users of genetic resources have prior informed consent to access the resources and negotiate mutually agreed terms (a contract) that set out how benefits will be shared. These obligations apply to both genetic resources and traditional knowledge associated with genetic resources.

7.3 The desired outcome of the EU Regulation is that the owners or guardians of genetic resources, or traditional knowledge associated with genetic resources, gain benefits from use of those resources. The EU Regulation implements certain articles of the Nagoya Protocol governing compliance measures for users. It does so by requiring users to exercise due diligence to: access genetic resources in accordance with the requirements of the country where access takes place; seek and keep related information; and declare that they have been duly diligent at the final stage of development of any product that emerges from the research. The Regulation requires Member States to designate competent authorities to enforce its provisions, adopting a risk-based approach.

- 7.4 The EU Regulation defines traditional knowledge by referencing its description in the contract agreed between the user and provider applying to the utilisation of genetic resources ('mutually agreed terms'). The Protocol distinguishes between mutually agreed terms applying to the utilisation of genetic resources and mutually agreed terms applying to the utilisation of traditional knowledge. The utilisation of traditional knowledge without the linked use of genetic resources is not covered by the EU Regulation. To avoid uncertainty for users, the UK Regulations address this gap by applying the same regime to the utilisation of traditional knowledge when this is covered in a separate agreement.
- 7.5 In addition to putting in place enforcement measures within the UK to implement the EU Regulation, these Regulations will enable the UK to ratify the Nagoya Protocol, which in turn will ensure continued access for UK users to the genetic resources they use for research and development. The Regulations make provision for civil sanctions for obligations related to due diligence, failure to keep the information required under the EU Regulation and for obstruction of an officer. Criminal offences are included for failure to comply with those civil sanctions.
- 7.6 The National Measurement Office (NMO), an Executive Agency of the Department for Business, Innovation and Skills, has been designated as the enforcement body. The NMO was selected for the role because of its experience in enforcing similar EU legislation that takes a due diligence approach.

## **8. Consultation outcome**

- 8.1 The public consultation ran from 17 March 2014 to 22 April 2014, a period of five weeks. The relatively short consultation period was considered appropriate due to the extensive stakeholder engagement (both bilateral and sector specific stakeholder meetings were held) during the negotiation of the Protocol and the EU Regulation and in development of the consultation on the UK Regulations. Stakeholders were contacted directly when the consultation opened and further stakeholder meetings were held during the consultation period.
- 8.2 The consultation sought views on six main elements of the proposed approach to implementing the Regulations: the designation of the National Measurement Office (NMO) as the enforcement agency; how to implement those parts of the Nagoya Protocol that are not covered by the EU Regulation; the proposals for the due diligence process; the proposed declarations process for users to declare they have exercised due diligence; the proposed enforcement regime; and the availability of guidance.
- 8.3 Defra received 27 responses from businesses, trade organisations, non-governmental organisations, and individuals. Responses were broadly supportive of the approaches proposed. In particular there was widespread support for the appointment of the NMO as the enforcement agency due to their solid reputation and collaborative approach. A number of respondents did not consider it

appropriate for criminal sanctions to be used as a first recourse, although many felt that some form of criminal sanction was necessary.

- 8.4 As a result of the consultation, the policy was changed to give primacy to civil sanctions, ensuring that only civil sanctions are available in the first instance for non-compliance with obligations related to due diligence and with criminal sanctions only applying to a failure to comply with either a stop notice or compliance notice (both civil sanctions) for due diligence obligations.

## **9. Guidance**

- 9.1 The enforcement agency will create guidance on the details of the sanctions regime set out in the Regulations. The EU will also create guidance on the EU Regulation and the supporting Implementing Acts; this is likely to focus on scope, utilisation for the research community and a set of sectorial guidance documents. If necessary, Defra will consider creating further UK level guidance.

## **10. Impact**

- 10.1. A full impact assessment of the EU Regulation was carried out at an EU level.
- 10.2 A Regulatory Triage Assessment (RTA) was prepared to assess the impacts of the new measures on stakeholders. The RTA showed that there are minimal costs associated with the measures and, given the low costs, further efforts to monetise other impacts would be disproportionate. Based on the information provided in the RTA, the Regulatory Policy Committee confirmed that the proposal qualified for the fast track as a low-cost regulatory proposal.
- 10.3 The impact on the public sector is the cost to Government in funding the National Measurement Office to enforce the Regulations through: provision of support to businesses to achieve compliance, regular and spot-check inspections, evidence gathering and legal action.

## **11. Regulating small business**

- 11.1 The legislation applies to small business.
- 11.2 There are no exemptions for small businesses. It is not possible to exempt small businesses from the enforcement regime as there is no such exemption in the EU legislation in respect of the due diligence regime.
- 11.2 Measures were, however, included in the EU Regulation that will minimise the impact of the requirements on small businesses; for instance through the creation of best practice, registered collections and model contractual clauses.

## **12. Monitoring & review**

- 12.1 The Regulations include a sunset clause. This requires the Secretary of State to review them and assess the extent to which their objectives have been met, the extent to which they remain appropriate and the extent to which they could be achieved in a less burdensome way. A first report setting out the conclusions must be published within five years of these Regulations coming into force and further reports must be published subsequently at intervals not exceeding five years.
- 12.2 Evaluation and monitoring of the EU Regulation will also be undertaken at EU level, to which the UK will provide input.

## **13. Contact**

For any queries regarding this instrument please contact Julian Jackson at the Department for Environment, Food and Rural Affairs. Tel: 0207 238 6813 or email: [julian.jackson@defra.gsi.gov.uk](mailto:julian.jackson@defra.gsi.gov.uk)