

Explanatory Memorandum on the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity

Title of Agreement

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity

Command Paper No: 8856

Subject matter

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization ("the Nagoya Protocol") is an international treaty negotiated under the Convention on Biological Diversity ("CBD"). It was adopted by the CBD on 29 October 2010 in Nagoya, Japan. The CBD is the main international forum devoted to the conservation of the Earth's biological diversity.

The Nagoya Protocol aims to promote the conservation and sustainable use of biodiversity by ensuring that benefits derived from research on genetic resources are fairly shared with the owners of those resources. A genetic resource is defined as any actually or potentially useful material that contains functional units of hereditary (genetic code from either DNA or RNA). Utilisation of genetic resources is the attempt, through research and development, to extract any useful traits from such resources, often with the intention of commercialising those useful traits.

Parties to the Nagoya Protocol must take measures to provide that all users of genetic resources and associated traditional knowledge in their jurisdiction access those resources in accordance with the relevant, applicable legislation or regulatory requirements of the country providing those resources, where such legislation or requirements exist. When required, users will have to set out in a contract how they will share any benefits that arise from research on genetic resources with the countries and communities from which the resources were accessed.

The Protocol is a mixed agreement. It was signed by the UK on 23rd June 2011 and was also signed on behalf of the European Union, which is implementing those elements of the Protocol falling within EU competence through an EU Regulation.

Ministerial responsibility

The Secretary of State for Environment, Food and Rural Affairs has primary responsibility for this treaty as it is a Protocol to the Convention on Biological Diversity, a multilateral environmental agreement (MEA).

The Secretary of State for Foreign and Commonwealth Affairs has overall responsibility for the conclusion and implementation of treaty obligations and responsibility for their application in Overseas Territories. The Secretaries of State for Scotland, Wales, and Northern Ireland also have a policy interest.

Policy Considerations:

General

A total of 23 EU Member States signed the Protocol, in addition to the EU. The Protocol is being implemented in the EU through an EU Regulation, which is directly applicable in the UK and will be enforced in the UK by statutory instrument.

This Regulation will be directly applicable in the UK, and will require users to exercise due diligence that they only utilise genetic resources or traditional knowledge associated to genetic resources that have been accessed in accordance with the relevant requirements of the provider country, and seek and keep related information. Users will also be required to make a declaration confirming that they have been duly diligent at the final stage of development of any product that emerges from the research. These declarations will be made to the UK's Competent National Authority, which will be nominated in a statutory instrument that also sets penalties and offences for non-compliance with the Regulation. The statutory instrument also extends the due diligence obligation set down in the EU Regulation to a small proportion of users of traditional knowledge associated to genetic resources not covered by the Regulation for competence reasons. This statutory instrument will be laid in June.

The Protocol has implications both for countries rich in biodiversity that provide genetic resources to users overseas, and to countries where such users reside. The UK is predominantly a user of genetic resources in that businesses in the UK utilise genetic resources from overseas to develop commercial products. Additionally, UK research organisations and collections access genetic resources for research purposes. Research carried out for Defra estimated the gross value added of the main sectors using genetic resources at £0.4bn to £1.2bn per year, supporting up to 25,000 jobs. Ratifying the Nagoya Protocol will secure and improve UK access to genetic resources and traditional knowledge from outside the UK. This value chain could be put in jeopardy if the UK has not ratified the Nagoya Protocol when it comes into force, as from this point users in countries that have done so will begin to take advantage of streamlined access to resources in provider countries

Implementing an international agreement that is a priority for developing countries will also bolster the UK's good reputation in the international environmental community, as well as that of UK businesses and researchers, who currently benefit from this reputation. The wider objective of the Nagoya Protocol is to encourage the conservation of biodiversity by incentivising its sustainable use. The Protocol encourages users and owners of genetic resources to direct some of the benefits generated through research on those resources towards conservation activity, and such funding would support the UK's international conservation objectives. More broadly, the effective function of the Protocol will signal the value of biodiversity to developing countries and incentivise the conservation of those resources. Ratification by the UK will be a strong signal of our intentions to support international efforts to protect the environment and to work with biodiversity-rich countries in this process.

When the Nagoya Protocol was negotiated Parties recognised that many users are already accessing genetic resources in a manner that is consistent with the Convention's Access and Benefit Sharing objective. Such users in the UK will not face additional burdens from the ratification of the Protocol, aside from the need to demonstrate their compliance with the new obligations. Other users will need to take appropriate measures to ensure that genetic resources and traditional knowledge they utilise have been accessed legally and on terms that include provision for benefit sharing where that is required in the law of the providing country, from the date that the Protocol enters into force. Ongoing uses of genetic resources that commenced before the Protocol enters into force, or new uses of material that was accessed before that date, will not be affected by the Protocol. As the EU Regulation implementing the Protocol will be directly applicable, UK users will be obliged to meet its requirements even if the UK does not ratify the Protocol. Were such a situation to arise, UK users would face the burdens outlined here but with no corresponding benefits.

Financial

The UK will face an annual subscription cost as a Party to the Nagoya Protocol. The precise cost of this subscription is not yet known as it will be negotiated at the first Meeting of the Parties to the Protocol, expected to be held this October. However, the annual cost is likely to be similar to the subscription for the CBD's other Protocol, the Cartagena Protocol on Biosafety. This implies a cost of around \$350,000 per annum.

Reservation and Declarations

None. In accordance with its Article 34, no reservations may be made to the Nagoya Protocol.

Implementation

The Nagoya Protocol is a mixed agreement that was signed by both the EU and its Member States. An EU Regulation implementing the Protocol (the "Regulation 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") has been concluded by the Council and the European Parliament, and will be published in the Official Journal in May.

The One-in Two-out Rule is not applicable as the UK implementing legislation is required by virtue of both the EU Regulation and the Nagoya Protocol, which is binding in international law.

Consultations

During the negotiation of the Protocol in the 2 years preceding the 10th CBD Conference of Parties in 2010 the Government consulted widely with UK organisations and individuals that it was likely to affect. These ranged from commercial users of genetic resources including pharmaceutical and biotechnology firms, to non-commercial collections. Industry representatives and civil society were also involved in the negotiations. This input guided the UK position and set the red lines for the negotiation of the Protocol. The process was mirrored in other Member States, at an EU level and more recently continued with the negotiation of the EU Regulation, with stakeholder input sought over the Council's and European Parliament's position.

A consultation on the UK's proposals for implementing the EU Regulation and the Nagoya Protocol was held in spring 2014.



Lord de Mauley

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