The Nagoya Protocol – A Practical Overview

The Nagoya Protocol aims to regulate the access to genetic resources and to ensure the fair and equitable sharing of benefits arising from their utilisation. Compliance with the protocol is important, especially since some countries, including Denmark and the United Kingdom, have the power to impose fines and – in the case of wilful non-compliance – a custodial sentence.

By Thomas Bjørn and David Hobson

"The Nagoya Protocol was adopted under the Convention on Biological Diversity (CBD) and the EU Nagoya Regulation (Regulation Nr. 511/2014) came into force on 12 October 2014. The enforcement regime will be fully implemented through national legislation in member states with effect from 12 October 2015".

The protocol and the regulation makes it an offence to use traditional knowledge or conduct commercial or non-commercial research and development on non-human genetic resources or derivatives thereof if they have not been accessed in accordance with the protocol.

In other words, it will be the responsibility of any natural or legal person (including any researcher) who uses genetic resources and the associated traditional knowledge (i.e. a user) to ensure that consent for access and terms for the sharing of arising benefits have been agreed before any research and development is carried out on such resources (e.g. microorganisms) and derivatives thereof (e.g. proteins expressed by a particular genetic resource).

Such "prior informed consent" (PIC) for access and "mutually agreed terms" (MAT) for benefits sharing must be negotiated with the relevant governmental body of a provider country, i.e. the country from which the genetic resource or derivative thereof originates.

ABOUT THE AUTHORS

THOMAS BJØRN works as a solicitor with Royds LLP in London. His areas of expertise include the protection and commercialisation of intellectual property, regulatory affairs and the sale of goods and services to the NHS. Royds LLP is a London City based law firm providing legal services to the international business community. The firm specialises in commercial law and has a strong focus on intellectual property and the life science industries.

DAVID HOBSON is a part-qualified patent attorney at Mathys & Squire, which is one of Europe's most established and renowned specialist IP firms, with specialist attorneys in a wide range of technical fields including biotechnology, phamacology, eletronics, engineering and more. David Hobson has experence of drafting and prosecuting UK, European and foreign patent applications for at wide range of technologies pertaining to the field of biotechnology.

The benefits shared may be either commercial or non-commercial and can include the sharing of data or intellectual property rights.

How Will the Nagoya Protocol Affect Users?

This means that users have a duty to carry out due diligence on any genetic resources that come into their possession, to ensure that they have been accessed in accordance with the Nagoya Protocol, and genetic resources should in the future be accompanied by documentation certifying this.

For 20 years after finishing research and development on a genetic resource, the user must, in addition, keep the internationally recognised certificate of compliance (IRCC) or information/documents concerning:

- the date and place of access.
- a description of the genetic resource.
- the direct source of the genetic resource and subsequent users.
- access and benefit sharing (ABS) agreements, access permits, mutually agreed terms including benefit-sharing, and any rights or obligations related to ABS.

Where it is unclear whether a genetic resource has been accessed in accordance with the protocol, research and development on the resource must cease.

How Can Researchers Comply with the Protocol?

Article 14 of the protocol establishes the so-called 'Access and Benefit-Sharing Clearing House' which serves as a platform for exchanging information related to access and benefit sharing. It serves as a key tool for compliance with the protocol by giving access to information provided by relevant parties and by issuing the internationally recognised certificate of compliance.

The clearing-house mechanism is summarised below:

1. A user wishing to use a genetic resource from provider-country A contacts the clearing house for information on obtaining PIC and MAT,
2. The user contacts the relevant government department in country A and obtains permission for either non-commercial or commercial use,
3. Country A issues a national permit to the user and a copy is sent to the clearing house,
4. The clearing house issues an internationally recognised

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certificate of compliance (IRCC) which is proof that the resource has been accessed in accordance with the Nagoya Protocol. The IRCC is an important document that will need to be presented when a compliance monitoring checkpoint is triggered, to indicate that access to the genetic resource complies with the Nagoya Protocol,

5. The user communicates details back to the clearing house which in turn contacts provider-country A to report on the research and development progress on the genetic resources. If necessary, country A can use this as an opportunity to negotiate new terms (e.g. pertaining to a commercialisation agreement).

A Requirement for EU-Led Guidance

Compliance with the Nagoya Protocol, whilst burdensome, will be possible for simple scenarios where a genetic resource exists in situ in one provider country.

More problematic are situations where the origin of a genetic resource is uncertain. For example, if a user wants to perform research and development on wheat, how does the user identify the provider country?

If a user creates a variant protein or microorganism, what is the country of origin? The country from which it was first isolated or the country in which the variant was produced? If the same user wants to perform further research and development on the protein or microorganism does PIC and MAT need to be negotiated? The Nagoya Protocol and its implementation will have far-reaching consequences for research and development in the life sciences industry, and the EU has promised that guidance documents will be forthcoming in the third quarter of 2015.

However, the extent and format of such guidance has yet to be disclosed, and it remains to be seen whether it will address the numerous difficult questions arising as a result of this legislation.

HOW TO BE PREPARED

Detailed below are some practical and proactive tips to aid with compliance for businesses, academic institutes, and users:

I **ensure that all genetic resources or derivatives thereof that were accessed before 12 October 2014 are clearly recorded as such, since the protocol is not retroactive and its provisions do not apply to genetic resources accessed prior to this date,**

II **ensure all new genetic resources are properly categorised and be cautious of the origin of such material,**

III **employers should ensure employees are aware of the protocol and that legal possession of a genetic resource does not automatically mean that research and development can be performed on the resource, and**

VI **employers may wish to be involved in setting up "best practices" in their country of operation. Once best practices have been established there will be an assumption that, by following these procedures, the due diligence requirements of the protocol have been complied with.**