Office for Product Safety & Standards

THE NAGOYA PROTOCOL ON ACCESS AND BENEFIT SHARING

THE UK COMPLIANCE MEASURES

What is the Nagoya Protocol?

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (The Nagoya Protocol) is a supplementary agreement to the Convention on Biological Diversity (CBD) that entered into force on 12 October 2014.

It provides a framework through which users of genetic resources and associated traditional knowledge (aTK) can share benefits with the provider countries, with the ultimate objective being the conservation and sustainable use of biodiversity.

Nagoya Protocol in the UK

The UK is a party to the Nagoya Protocol. Although the UK **does not have any access measures** under the Nagoya Protocol for its own genetic resources, there are compliance measures in force for 'in scope' genetic resources that must be followed. This leaflet provides a guide to understanding whether your work falls in scope of the UK compliance measures and what you need to do to comply.

Scope of Regulation

The UK Access and Benefit Sharing (ABS) Regulations apply to any user (company, organisation or individual) conducting research and development on the biochemical or genetic properties of genetic resources and/or aTK where:

- the genetic resources and/or aTK was/will be accessed on or after 12 October 2015;
- the genetic resources and/or aTK was/will be accessed from a country which is party to the Nagoya Protocol and has applicable ABS legislation; and
- the utilisation is/will be taking place within the UK.

Genetic resources = genetic material of actual or potential value.
Genetic material = any material of plant, animal, microbial or other origin containing functional units of heredity.

ABS Regulations in force in the UK

- Nagoya Protocol (Compliance) Regulations 2015 (S.I. 2015/821) as amended.
- Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018 (S.I. 2018/1393).
- Environment and Wildlife (Legislative Functions) (EU Exit) Regulations 2019 (S.I. 2019/473).
- Regulation (EU) No. 511/2014: compliance measure for users.
- Regulation (EU) 2015/1866: register of collections, monitoring user compliance and best practices.

UK ABS Compliance

In order to comply with these measures, you should ensure that the genetic resources being utilised have been accessed in line with the laws in the country that the genetic resources are originally from. The basic process for this is illustrated below:

Internationally Recognised Certificate of Compliance including content of Mutually Agreed Terms (MAT)

or

Date & place of access, Description of genetic resource & aTK, Source obtained & subsequent users.

If applicable: Rights & obligations / Access permits / MAT

1. Identify the genetic resource to utilise.

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2. Exercise due diligence. Identify if the country is a party to the Nagoya Protocol and if it has any applicable laws[1].

▼

3a. If the provider country is a party, and has applicable laws, follow their requirements and keep the above information for your records (for at least 20 years).

3b. If the provider country isn't a party or is a party but doesn't have any applicable laws, the genetic resource is out of scope of the UK compliance measures.

Follow any local laws if relevant and keep any evidence for due diligence.

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4. Access the genetic resource.

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5. Research starts, research funding may be received.

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6. A product may be developed or the result of the research sold/ transferred outside the UK.

▶

7. If research funding is received or point 6 applies, a Due Diligence Declaration must be submitted.

[1] Sites such as **https://absch.cbd.int/** or the local government site may be useful for this information.

Keywords

- **‘Users’** of genetic resources may constitute individuals, organisations or both who conduct research and development on genetic resources.
- **‘Utilisation’** is described as research and development into the genetic or biochemical properties of genetic resources and/or aTK.
- There are four key user **‘obligations’**. Users are required to a) exercise due diligence, b) seek, keep and transfer relevant documentation for a minimum of 20 years, and c) submit due diligence declarations at the stage of research funding and at the stage of final product development.

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See **www.gov.uk/guidance/abs** for more information.