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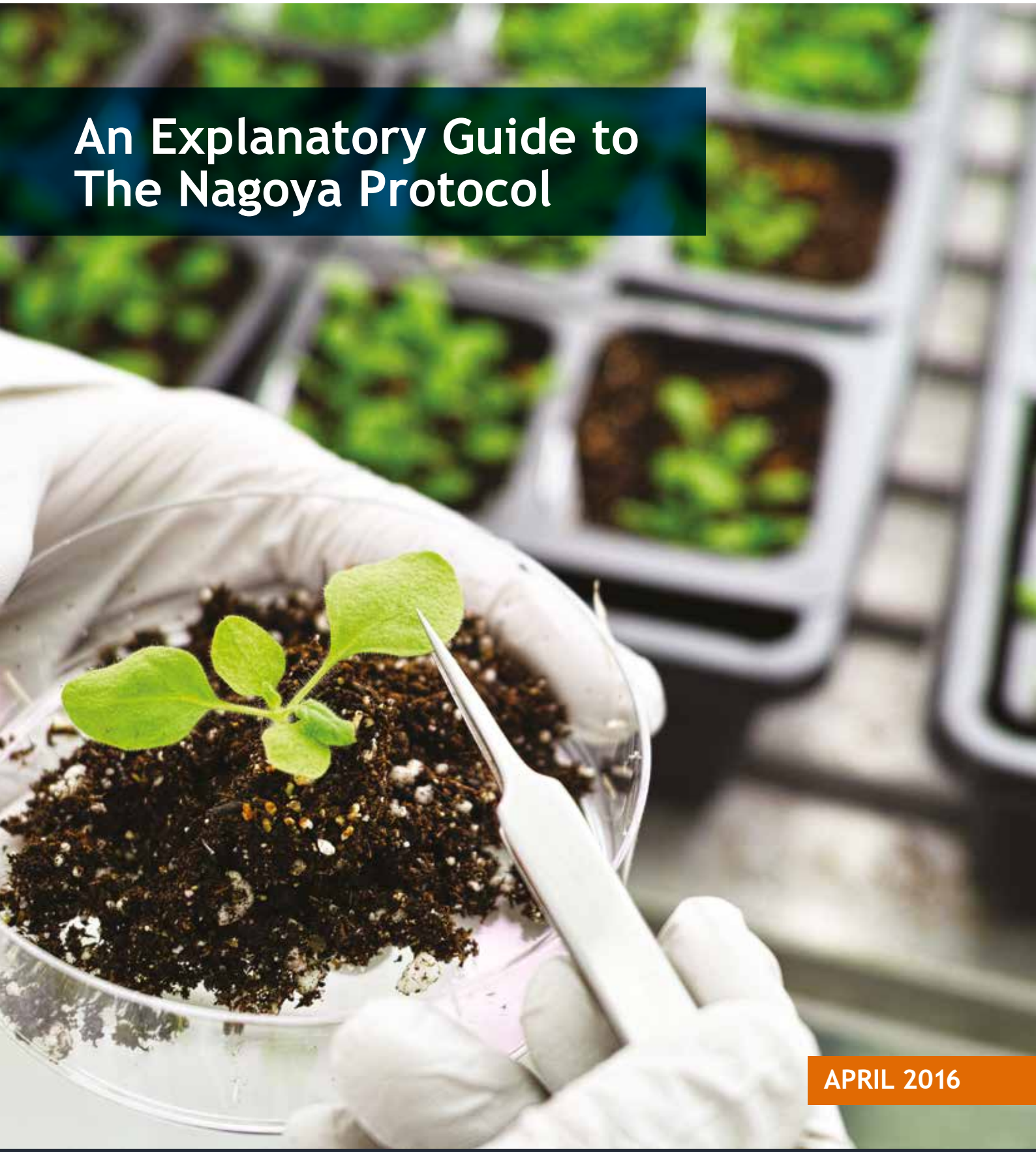
Convention on Biological Diversity

An Explanatory Guide to The Nagoya Protocol



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Executive Summary

This document provides a guide to the Nagoya Protocol with an explanation of the key points and objectives set out within the Protocol.

The Nagoya Protocol entered into force on 12 October 2014 and aims to implement the third objective of the Convention on Biological Diversity (CBD), namely the fair and equitable sharing of benefits arising out of the utilisation of genetic resources. In accordance with the Nagoya Protocol, parties are placed under an obligation to establish legislative, administrative and/or political measures regarding the access to genetic resources.

Ultimately, the Nagoya Protocol aims to prevent bio-piracy. Bio-piracy is the commercial or academic development of genetic resources by a country or organisation without obtaining prior consent from, or providing fair compensation to, the people or country where the genetic resource was first discovered.

Key points of the Protocol

- The Nagoya Protocol relates to the utilisation of genetic resources. A genetic resource is defined as any non-human genetic resource. 'Utilisation' refers to research and development on the genetic and/or biochemical composition of genetic resources. The Protocol, therefore, relates to both commercial and academic research.

- The Nagoya Protocol gives provider countries the rights to control access to genetic resources found within their jurisdiction. The aim of this is to re-establish a provider country's control over these resources. There are 2 categories of provider country:

    1. An originating country where the genetic resource exists in situ, i.e. a country in which the genetic resource exists in its natural habitat.

    2. An originating country where the genetic resource exists ex situ, i.e. a country in which the genetic resource exists outside of its natural habitat. A country falling within this category must have obtained the genetic resource from an originating country under the CBD.

- The burden is placed on the user, for example a researcher, to show that the genetic resource on which they are conducting research was legally obtained in accordance with the Nagoya Protocol. In order to do this, a user must:

    1. Obtain the prior informed consent of a providing country (i.e. the country where the genetic resource exists in situ) before access to a genetic resource is permitted

    2. Provide a fair and equitable share of the benefits which arise from utilisation of the genetic resources. Such sharing shall be upon mutually agreed terms. The benefits can be either commercial or non-commercial, including the sharing of data or a transfer of intellectual property rights.

If a user cannot show that a genetic resource has been accessed in accordance with the provisions of the Nagoya Protocol, all work utilising that genetic resource must be halted.

The effect of the Nagoya Protocol is to make it illegal to perform research and development on a genetic resource that has not been accessed in accordance with the Nagoya Protocol.

Who is party to the Nagoya Protocol?

1.	Albania	2013-01-29
2.	Belarus	2014-06-26
3.	Benin	2014-01-22
4.	Bhutan	2013-09-30
5.	Botswana	2013-02-21
6.	Burkina Faso	2014-01-10
7.	Burundi	2014-07-03
8.	Cambodia	2015-01-19
9.	Comoros	2013-05-28
10.	Congo	2015-05-14
11.	Côte d'Ivoire	2013-09-24
12.	Croatia	2015-09-02
13.	Cuba	2015-09-17
14.	Democratic Republic of the Congo	2015-02-04
15.	Denmark	2014-05-01
16.	Djibouti	2015-10-01
17.	Dominican Republic	2014-11-13
18.	Egypt	2013-10-28
19.	Ethiopia	2012-11-16
20.	European Union	2014-05-16
21.	Fiji	2012-10-24
22.	Gabon	2011-11-11
23.	Gambia (the)	2014-07-03
24.	Guatemala	2014-06-18
25.	Guinea	2014-10-07
26.	Guinea-Bissau	2013-09-24
27.	Guyana	2014-04-22
28.	Honduras	2013-08-12
29.	Hungary	2014-04-29
30.	India	2012-10-09
31.	Indonesia	2013-09-24
32.	Jordan	2012-01-10
33.	Kazakhstan	2015-06-17
34.	Kenya	2014-04-07
35.	Kyrgyzstan	2015-06-15
36.	Lao People's Democratic Republic	2012-09-26
37.	Lesotho	2014-11-12
38.	Liberia	2015-08-17
39.	Madagascar	2014-07-03
40.	Malawi	2014-08-26
41.	Marshall Islands	2014-10-10
42.	Mauritania	2015-08-18
43.	Mauritius	2012-12-17
44.	Mexico	2012-05-16
45.	Micronesia (Federated States of)	2013-01-30
46.	Mongolia	2013-05-21
47.	Mozambique	2014-07-07
48.	Myanmar	2014-01-08
49.	Namibia	2014-05-15
50.	Niger	2014-07-02
51.	Norway	2013-10-01
52.	Pakistan	2015-11-23
53.	Panama	2012-12-12
54.	Peru	2014-07-08
55.	Philippines	2015-09-29
56.	Rwanda	2012-03-20
57.	Samoa	2014-05-20
58.	Senegal	2016-03-03
59.	Seychelles	2012-04-20
60.	Slovakia	2015-12-29
61.	South Africa	2013-01-10
62.	Spain	2014-06-03
63.	Sudan	2014-07-07
64.	Switzerland	2014-07-11
65.	Syrian Arab Republic	2013-04-05
66.	Tajikistan	2013-09-04
67.	Togo	2016-02-10
68.	Uganda	2014-06-25
69.	United Arab Emirates	2014-09-12
70.	United Kingdom of Great Britain and Northern Ireland	2016-02-22
71.	Uruguay	2014-07-14
72.	Vanuatu	2014-07-01
73.	Viet Nam	2014-04-23

Since entering into force on 12 October 2014, 73 parties have ratified the Nagoya Protocol, including the European Union

Implementation of the Nagoya Protocol in the European Union (EU)

The Nagoya Protocol fully entered into force in the EU on 12 October 2014 under EU Reg. 511/2014. The rules for the implementation of Reg. 511/2014 regarding the registration of the collection of genetic resources, monitoring user compliance and best practices, entered into force on 9 November 2015 under EU Reg. 2015/1866.

The above EU Regulations are directly applicable to all EU member states. The regulations ensure a uniform application of the law across all states. The regulations apply to genetic resources over which EU member states exercise sovereign rights, and to 'traditional knowledge' associated with genetic resources falling within the scope of the Nagoya Protocol. For the regulations to apply, the genetic resources must be accessed by an EU member state after entry into force of the Nagoya Protocol for the EU.

Compliance with the Nagoya Protocol

Implementation of the Nagoya Protocol is to be co-ordinated by a newly formed international body known as the Access and Benefits Sharing (ABS) Clearing House.

The following steps are required to be taken in order to comply with the Nagoya Protocol:

1. A provider country informs the clearing house of its national provisions with regards to access and benefits sharing (ABS) information. The clearing house will keep this information up-to-date.

2. The clearing house acts as an intermediary. If a user wishes to access a genetic resource from a provider country, the user should contact the clearing house for details of how to agree mutually agreed terms with the provider country.

3. From the information provided by the clearing house, the user contacts the relevant government department in the provider country and obtains permission for either non-commercial or commercial use (details can be made confidential and, therefore, not open to inspection by third parties). If non-commercial use is initially agreed, terms can be re-negotiated at a later date if commercialisation appears likely.

4. The provider country issues to the user a national permit. Additionally, the provider country files the national permit at the clearing house.

5. An internationally recognised certificate of compliance (IRCC) is issued electronically by the clearing house. The IRCC acts as proof that the genetic resource has been accessed in accordance with the Nagoya Protocol.

6. Proof of compliance with the Nagoya Protocol must be issued when certain events are triggered. Such events include, receipt of research funding, commercialisation of a product and applying for market approval in the EU. Compliance can be proved by presenting the IRCC when required.

7. Details of the triggering event are communicated by the user to the clearing house which in turn contacts the provider country to report on the progress of the research and development of their genetic resources. This step gives the provider country an opportunity to negotiate new terms in light of the recent events, e.g. a commercialisation agreement if the initial agreement was only for non-commercial use.

Obligations of users

Users of genetic resources or traditional knowledge are obliged to exercise due diligence to ascertain that:

- any genetic resources and traditional knowledge utilised by the user has been accessed from a provider country party to the Nagoya Protocol in accordance with the applicable access and benefit-sharing legislation or requirements, and

- mutually agreed terms between the user and the provider country result in fair and equitable benefits to both parties, in accordance with applicable access and benefit-sharing legislation or requirements.

IRCC - Seek, keep and transfer procedure

The IRCC is issued for the purpose of the above obligations. A user is required to seek, keep and transfer to subsequent users the IRCC as evidence that the genetic resource it covers has been accessed in accordance with the Nagoya Protocol. The IRCC also shows that mutually agreed terms have been established between the user and a competent authority within the provider country. Further, any information relating to the content of the mutually agreed terms which is not contained in the IRCC must also be part of the 'seek, keep and transfer' procedure of the user.

If the relevant IRCC is not yet available, the user must seek, keep and transfer the following information and documents related to:

- date and place of access of the genetic resources or traditional knowledge;

- a description of the genetic resources or traditional knowledge utilised;

- the source from which the genetic resources or traditional knowledge were directly obtained;
- any subsequent users of the genetic resources or traditional knowledge;
- details regarding the presence or absence of rights and obligations pertaining to access and benefit-sharing, including any rights and obligations relating to subsequent applications and commercialisation;
- access permits, if applicable; and
- any information comprised in the mutually agreed terms and benefit-sharing agreements.

If the above information is found to be insufficient or there are legal uncertainties to the access and utilisation of the genetic resources, a user shall obtain an access permit (or equivalent) and establish mutually agreed terms with the provider country. If this is not achieved, utilisation must be discontinued by the user.

Further obligations

- Users must keep the information relevant to access and benefit-sharing for 20 years after the end of the period of utilisation.
- All recipients of research funding which involves the utilisation of genetic resources and traditional knowledge will be requested by the EU Member States to declare due diligence was exercised in accordance with the obligations of the users under EU Reg. 511/2014.
- At the final stage of development of a product developed via the utilisation of genetic resources or traditional knowledge, users must declare to the competent national authority that they have fulfilled the obligations of the users set by the EU regulations 511/2014 and 2015/1866. The declaration can take the form of presenting the IRCC to the competent national authority. If the IRCC is not available, the above-mentioned alternative information will suffice.

Register of collections

An internet-based register of collections is to be established within the EU in accordance with EU regulations. The register will comprise sets of collected samples of genetic resources and related information that is accumulated and stored. A user who obtains a genetic resource from a collection included in the register shall be deemed to have exercised due diligence in accordance with the relevant EU regulations.

Compliance checks

According to the EU regulations, the competent national authorities shall carry out effective, proportionate, and dissuasive checks to inspect whether users comply with the

obligations of the Nagoya Protocol. Compliance checks may include:

- Examination of the measures taken by a user to fulfil his obligations
- Examination of documentation and records which should demonstrate the users exercise of due diligence
- On-the-spot checks

If deficiencies are noted by the competent national authority, a notice of remedial action or a notice of measures to be implemented will be issued to the user.

Penalties for non-compliance

Each EU member state shall put forward effective, proportionate and dissuasive penalties which will be applicable to infringements of the obligations of users under the EU regulations which set out the Nagoya Protocol.

As the penalties are made at the discretion of each EU member state, violating the obligations of the user may have different consequences in different member states.

Penalties in the UK

Enforcement of the EU regulations relating to the Nagoya Protocol in the UK is the responsibility of the Department for Environment, Food and Rural Affairs (DEFRA). Compliance checks and monitoring will be handled by the National Measurements Office.

DEFRA have indicated that a fine of up to £250,000 and a maximum of two years in prison will be the appropriate penalties for severe cases of wilful non-compliance.

The effect of the Nagoya Protocol on patents

It is not yet known whether a violation of the aforementioned obligations will have consequences regarding the grant of a patent or the possible exploitation of a patent. Further, it is not yet known what the consequences, if any, will be.

However, it is predicted that competitors or other third parties will attempt to attack a patent if it is believed the patent owners have violated their obligations to the Nagoya Protocol. It is, therefore, of upmost importance that patentees and researchers exercise the required due diligence and take their obligations under the Nagoya Protocol (and relevant EU regulations) extremely seriously.

European Patents

The European Patent Convention (EPC) provides an autonomous legal system according to which European patents are granted. Currently, there are no plans to amend the EPC, or the respective rules, in response to the Nagoya Protocol. However, it is expected that the Nagoya Protocol and its corresponding EU regulations will at the minimum be taken into consideration with regard to the future grant of European patents.

Practical actions to be taken

1. **Ensure existing genetic resources are sufficiently documented as having been accessed before the date of entry into force of the Nagoya Protocol in the EU (i.e. before 14 October 2014).**
    - **The Nagoya Protocol will not have retroactive effect in the EU. Hence, genetic resources shown to be accessed before the Nagoya Protocol will not be required to comply with the EU regulations which set out the Protocol in the EU.**
2. **Take action to ensure administrative systems are in place to make certain any new genetic resources are documented in compliance with the Nagoya Protocol.**
3. **Carry out internal training to make employees aware of the Nagoya Protocol and the obligations of users of any genetic resources.**
    - **Ensure employees understand that legal possession of a genetic resource does not necessarily imply that person has the right to do any work on or with that resource.**
4. **Be aware of the origin of any genetic resources you might wish to use for the purposes of research and development.**

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If you would like further advice on the Nagoya Protocol, how it may impact your business, or advice on any other aspects of intellectual property, please do not hesitate to get in contact.

TO BOOK YOUR FREE CONSULTATION PLEASE CONTACT

Ben Appleton
ben.appleton@wilsongunn.com
0121 236 1038

MANCHESTER OFFICE
5th Floor
Blackfriars House
The Parsonage
Manchester M3 2JA
United Kingdom

manchester@wilsongunn.com
Tel: 0161 827 9400
Fax: 0161 832 4905

BIRMINGHAM OFFICE
Charles House
148/9 Great Charles Street
Birmingham
B3 3HT
United Kingdom

birmingham@wilsongunn.com
Tel: 0121 236 1038
Fax: 0121 233 2875

LONDON OFFICE
Central Court
25 Southampton Buildings
London
WC2A 1AL
United Kingdom

london@wilsongunn.com
Tel: 0203 178 2767
Fax: 0203 178 5823

CHESTERFIELD OFFICE
Tapton Park Innovation Centre
Brimington Road
Tapton
Chesterfield S41 0TZ
United Kingdom

chesterfield@wilsongunn.com
Tel: 01246 541 903
Fax: 01246 230 055