

Meeting of Member States and International Depositary Authorities under the Budapest Treaty

Geneva, November 13 to 14, 2023

**BACKGROUND DOCUMENT: THE NAGOYA PROTOCOL AND THE BUDAPEST
TREATY**

Document prepared by the International Bureau

BACKGROUND INFORMATION ON THE NAGOYA PROTOCOL

1. 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 (Nagoya Protocol) regulates the access and benefit sharing of genetic resources, and traditional knowledge associated with genetic resources, covered by the Convention on Biological Diversity (CBD). It creates a framework for accessing genetic resources in compliance with the access rules of the Parties and for using the genetic resources in conformity with the rules applied by the Parties regarding the fair and equitable benefit sharing.¹ It entered into force on October 12, 2014. 141 Parties have ratified or acceded to the Nagoya Protocol.

2. The terms defined in Article 2 of the CBD shall apply to the Nagoya Protocol.² Accordingly, for the purposes of the Protocol, the term “genetic resources” means “a genetic material of actual or potential value”. Likewise, the term “genetic material” means “any material of plant, animal, microbial or other origin containing functional units of heredity”, in accordance with Article 2 of the CBD.

¹ The text of the Nagoya Protocol is available at <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>.

² See Article 2 of the Nagoya Protocol.

3. It follows from Article 3 of the Nagoya Protocol that it applies to genetic resources within the scope of Article 15 of the CBD (Access to Genetic Resources) and the benefits arising from the utilization of genetic resources and associated traditional knowledge. The term “utilization of genetic resources” is defined in Article 2 of the Protocol as conducting research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.

4. The Nagoya Protocol also contains provisions that require the Parties to take measures to provide that genetic resources utilized within their jurisdiction have been accessed in accordance with prior informed consent of the Party providing such resources and that mutually agreed terms on benefit sharing have been established, as required by the domestic legislation or regulatory requirements of the other Party.³ The Parties to the Nagoya Protocol shall also take measures to monitor the utilization of genetic resources, as appropriate,⁴ and to the extent appropriate, the interests of indigenous and local communities shall be taken into consideration on both access and benefit sharing.

5. It should also be noted that each Party to the Nagoya Protocol may determine the measures to be taken to implement the provisions of the Nagoya Protocol, in accordance with the Protocol. Thus, implementation of the provisions depends on each Party. The measures taken for utilization of genetic resources in accordance with the rules of access and benefit-sharing may be different from one Party to another Party.

RELATIONSHIP BETWEEN THE CBD/NAGOYA PROTOCOL AND OTHER INTERNATIONAL AGREEMENTS

6. With respect to the relationship between the CBD and other international conventions, Article 22, paragraph 1 of the CBD states that:

“1. The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.”

7. Similarly, Article 4 of the Nagoya Protocol also regulates its relationship with international agreements and instruments, as follows:

“1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.

2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

³ See Article 15.1 of the Nagoya Protocol.

⁴ See Article 17.1 of the Nagoya Protocol.

4. This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.”

THE BUDAPEST TREATY AND THE INTERNATIONAL DEPOSITARY AUTHORITIES (IDAS)

8. The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (BT) provides the framework in which international deposits of microorganisms are recognized by the Contracting Parties for the purposes of their patent procedure, i.e., to fulfill the sufficiency of disclosure requirement under their patent laws. The BT thus lays down the procedure that must be followed by depositors and IDAs. It also regulates the required duration of storage of deposited microorganisms and the mechanisms for the furnishing of samples. The BT entered into force on August 19, 1980.⁵

9. In the framework of the BT, the deposit of a microorganism by a depositor is the act of transmitting a microorganism to the IDA, while accepting the storage and handling of the microorganism by the IDA in accordance with the requirements laid down in the BT. The tasks of the IDAs are to accept deposits, examine their viability and store them, and furnish samples of deposited microorganisms under the conditions and in conformity with the procedure, as prescribed in the BT.⁶

10. To request an original deposit with an IDA, a depositor must submit a written statement. Rule 6.1(a) of the Regulations under the BT specifies the information that the depositor must contain in the statement and supply to the IDA. In addition, Rule 6.3(a) lists the additional requirements that the IDA may require for acceptance of the microorganism so that it will be able to properly handle the deposited material. The latter, permissible requirements under Rule 6.3(a) are of technical and administrative nature: for example, the IDA may require a depositor to submit a specific number of batches of the material, to complete a specific form or to conclude an agreement with the IDA defining the liabilities of the two parties.

11. According to Rule 6.4(b) of the Regulations under the BT, the IDA shall accept the deposit of the microorganism when it complies with the requirements provided in Rules 6.1(a) and 6.3(a). Information that relates to the Nagoya Protocol, such as information related to prior informed consent or the establishment of mutually agreed terms, is not included in either Rule 6.1(a) or Rule 6.3(a).

12. At the same time, even if non-submission of an additional information that might be necessary for, for example, the implementation of the Nagoya Protocol cannot be a reason for the IDAs to refuse the request for deposit, the IDAs may optionally ask depositors to submit additional information on a voluntary basis. Model BP/1 Form,⁷ entitled “Statement in the Case of an Original Deposit pursuant to Rule 6.1”, contains Box VIII (Additional Data), which allows depositors to submit additional information, if they so wish.⁸

⁵ The text of the Budapest Treaty is available at: <https://www.wipo.int/wipolex/en/treaties/textdetails/12244>.

⁶ See Article 6.2 of the BT.

⁷ Fourteen forms, numbered BP/1 to BP/14, have been drawn up by the International Bureau on the basis of the discussions held by the Assembly of the Budapest Union and the Interim Advisory Committee for the preparation of the entry into force of the Budapest Treaty. Certain Forms, including BP/1, are model forms and their use is not mandatory.

⁸ The footnote to Box VIII states that the depositor should mark the Box with a cross if additional information is given on an attached sheet, such as the source of the microorganism, the name(s) and address(es) of any other depositary institution(s) with which the microorganism has been deposited, or the criterion used when

[Footnote continued on next page]

13. On a related matter, after the mandatory storage period of the deposited microorganisms under the BT, there is a possibility that these microorganisms would be made available to the public.⁹ Depending on the national implementation of the Nagoya Protocol, however, if information regarding, for example, prior informed consent or the establishment of mutually agreed terms does not accompany these former BT deposits, third parties might be reluctant to access and use such microorganisms due to legal uncertainty around the compliance with the national access and benefit sharing legislation, even if they are placed in an open collection.

14. With respect to furnishing of samples by the IDAs, Rule 11 of the Regulations under the BT stipulates three situations where the IDAs shall furnish samples of the deposited microorganisms. These are: (i) furnishing of samples to interested Industrial Property Offices (Rule 11.1); (ii) furnishing of samples to, or with authorization of, the depositor (Rule 11.2); and (iii) furnishing of samples to a “certified party” (Rule 11.3(a)) or a “requesting party” (Rule 11.3(b)).

15. Whether a party requesting a certification of the Industrial Property Office under Rule 11.3(a) has indeed the right to a sample of the deposited microorganism is determined by the Office in accordance with the law applicable to that Office. A number of the Contracting Parties to the BT have prescribed in their laws certain conditions for receiving a sample of deposited microorganisms or certain restrictions to the usage of samples by certified parties.¹⁰ Accordingly, access to a sample and possible usage of the sample by a third party recipient not authorized by the depositor are largely determined by the applicable national/regional patent law.

16. While the above paragraphs illustrated a potential area of an intersection between the Nagoya Protocol and the Budapest Treaty, i.e., handling of information relating to prior informed consent and/or access and benefit sharing in relation to depositing microorganisms or furnishing a sample of a deposited material under the Budapest Treaty, the synergy between the Nagoya Protocol and the Budapest Treaty has not been explored by the Member States and IDAs. Since the national implementation of the Nagoya Protocol varies, the potential intersection issues may be different throughout the Budapest membership. Nevertheless, the International Bureau invites Member States and IDAs to share information on their national implementation of the Nagoya Protocol and any legal or practical relevance of such implementation to the operation of the Budapest system as a whole and to the work of the IDAs in accepting and furnishing microorganisms under the Budapest system.

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drafting the proposed taxonomic designation. The footnote also states that the supplying of such additional information is optional.

⁹ See document WIPO/IDAS/GE/23/2 for the handling of deposited microorganisms after the mandatory storage period under the Budapest Treaty.

¹⁰ See document WIPO/IDAS/GE/23/3 for more information about furnishing of samples by the IDAs.