

Concepts and Guidelines for Access to Genetic Resources and Benefit-sharing at the National Institute for Environmental Studies

【Background and Purpose】

At the 10th meeting of the Conference of Parties to the *Convention on Biological Diversity* (hereafter referred to as the "CBD"), 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* (hereafter referred to as the Nagoya Protocol) was adopted. Under the Nagoya Protocol, the necessary measures that each party to the CBD should follow to ensure access to genetic resources and the fair and equitable sharing of benefits arising from their utilization (i.e., access and benefit-sharing; hereafter referred to as "ABS") are specified. Following the adoption of the Nagoya Protocol, the Government of Japan issued *Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* (hereafter referred to as the Japanese ABS Guidelines) in 2017 to contribute to the conservation and sustainable use of biological diversity by ensuring appropriate and smooth implementation of the Nagoya Protocol.

Some of the environmental research activities conducted by the National Institute for Environmental Studies (hereafter referred to as "NIES") utilize genetic resources acquired in countries other than Japan; therefore, it is vital to establish relationships of mutual trust with providing countries. For this purpose, NIES adopted the *Basic Policy on Access to Genetic Resources and Benefit-sharing at the National Institute for Environmental Studies* (hereafter referred to as the "Basic Policy") in 2017 and clarified that it will comply with the CBD, Nagoya Protocol, and other related laws and regulations. In response to this, *Concepts and Guidelines for Access to Genetic Resources and Benefit-sharing at the National Institute for Environmental Studies* (hereafter referred to as the "Guidelines") was prepared to address the NIES's basic beliefs about ABS based on ethical considerations and to clarify processes required for acquisition and utilization of genetic resources. NIES staff are required to comply with the Nagoya Protocol and ABS Guidelines under the Basic Policy and to build relationships of mutual trust with providing countries and providers of genetic resources based on the Guidelines on utilization of genetic resources.

【Concepts】

1. NIES is keenly aware that States have sovereign rights over their own biological resources according to the provisions of the CBD and gives due consideration even when accessing a genetic resource belonging to a country that has not implemented a legal framework related to ABS.
2. For new utilization of a genetic resource currently in a third country that is not the country of its origin, NIES makes reasonable efforts towards best practices whenever appropriate and possible, recognizing that a consideration towards the sovereign right of the country of origin over its biological resources may be necessary.

3. Recognizing that biological and environmental sciences have been developed by utilizing genetic resources, and that these developments have further contributed to the conservation of nature and biological diversity as well as human well-being, NIES will endeavor to promote use of genetic resources under appropriate conditions.
4. NIES shall continue to improve its ABS approach and practices in a flexible manner by referring to public opinion and discussion with ABS stakeholders.

【Definition of Terms】

In this text, the definitions of the subsequent terms follow the definitions and usages used in the CBD and/or Nagoya protocol: biological resources, genetic resources, country providing genetic resources [providing countries], country of origin of genetic resources [country of origin], national focal point, prior informed consent [PIC], mutually agreed terms [MAT], and *in situ* and *ex situ*. In practice, however, the definitions of the legislation and regulatory requirements of the providing country and/or mutually agreed terms shall be followed.

"Staff" refers to executives, employees, and contract employees of NIES, as well as those who participate in the activities of NIES, such as visiting researchers, collaborative researchers, research students, research fellow of Japan Society for the Promotion of Science, on-site subcontractors, contract workers, and research associates.

【Guidelines】

1. Planning

When making research plans that include access to genetic resources, NIES gives due consideration to the conservation and sustainability of biological diversity, pays close attention to appropriate acquisition and utilization of and benefit-sharing arising from genetic resources, and adheres to the following approaches.

- The following points will be considered when developing a research plan:
 - a) The necessary procedures to access genetic resources in a providing country;
 - b) Identification of the stakeholders of genetic resources;
 - c) The period and purpose of the utilization of genetic resources and the conditions of benefit-sharing;
 - d) The impact of the research itself on the ecosystem and local communities;
 - e) Possible changes to the period, purpose, and/or users as the research progresses;
 - f) The conditions of perpetual preservation of voucher specimens and data as research results and the conditions for these to be studied by third parties;
 - g) The terms and conditions of use of biological resources not considered to be genetic resources;
 - h) The terms and conditions of use of modified genetic resources.
- When acquiring *in situ* genetic resources, collaborative research with a reliable counterpart in the providing country shall be considered to facilitate compliance and benefit-sharing within the providing country. It should be noted that it is mandatory in

some countries to establish a contract for collaborative research, although the contract of collaborative research itself is normally not considered as a permission or authorization from the providing country.

- When inviting researchers from other countries, NIES ensures that the invited researchers will not bring in genetic resources without permission from the providing country.
- If NIES staff participate in a research project conducted by another institute, and the project involves sampling, exporting, and utilizing genetic resources, the NIES staff will be responsible for confirming whether the ABS implementation of the project is sufficient and whether their participation in the project is permitted by reading the relevant documentation and then retaining a copy of the documentation.
- For every international transfer of genetic resources (i.e., exporting and importing), it is necessary to check regulations on plant and animal quarantine, national security and trade, and transportation safety (specified by the International Air Transport Association), as well as the ABS Guidelines, CBD, Nagoya Protocol, *Convention on International Trade in Endangered Species of Wild Fauna and Flora*, and the *International Treaty on Plant Genetic Resources for Food and Agriculture*.

2. Acquisition

When acquiring genetic resources, whether through *in situ* or *ex situ* conditions, NIES fulfills legal requirements by abiding by the relevant international agreements and legislation and regulatory requirements of the providing country. Noting that the providing country may not have implemented necessary legal frameworks, NIES will always respect the sovereign right of the providing country over its biological resources during acquisition.

i) Acquisition from countries where domestic ABS measures are implemented

- When acquiring genetic resources from countries in which domestic ABS measures are implemented, NIES follows all the measures relevant to the acquisition. It should be noted that the domestic ABS measures may include regulations that may not be within the scope of the Nagoya Protocol and that PIC and MAT may not cover all the necessary procedures.
- After acquiring a genetic resource, NIES submits a report to the Japanese Minister of the Environment, according to the conditions of the acquisition as designated in Chapter 2 of the Japanese ABS Guidelines.
- It should also be noted that the Minister of the Environment of Japan may urge NIES to explain the acquisition of genetic resources upon allegations made by the government of a providing country concerning a violation of its legislation (Article 15.3 of the Nagoya Protocol and Article 2.4 of the Japanese ABS Guidelines). Staff of NIES shall not publish the results of any studies obtained by using illegally acquired

genetic resources.

ii) Acquisition from countries in which domestic ABS measures are NOT clearly implemented

- When acquiring genetic resources from countries in which domestic ABS measures are not clearly implemented, conducting collaborative research with a reliable institute that can communicate properly with relevant agencies is considered essential.
- By consulting with the national focal point or relevant authorities of the providing country, NIES endeavors, as much as possible, to obtain PIC from the providing country and establish MAT with the provider of the genetic resources prior to the acquisition.

iii) Note on acquisition from *ex situ* conditions

- Irrespective of the implementation of domestic ABS measures of the providing country, NIES acquires *ex situ* genetic resources (e.g., genetic resources that are stored in museums, botanical gardens, and personal collections) only after signing a MAT with the provider to clarify the responsibilities of the provider and NIES.
- NIES asks the provider for an acquisition history of the genetic resources in writing if one is available. If the provider (i.e., institution, organization, or person) is unfamiliar with ABS, NIES pays special attention to the legal status (e.g., acquisition conditions) of the genetic resources and the credibility of the provider.
- If the collected *ex situ* genetic resources are revealed to have been acquired in a way that is not compliant with national legislation or against the will of the country of origin, NIES will immediately suspend acquisition and/or utilization of the genetic resources.

iv) Acquisition of commodities

- Commodities such as household and food items are generally assumed to not be used as the subject of research. However, when conducting research using a commodity as a genetic resource, NIES considers the overall aspects of the legislation of the country of origin, the location of acquisition, the purpose of the study, and if necessary, consults with the national focal point of the country of origin.

v) Acceptance to NIES's *ex situ* collection

- Recognizing the importance of *ex situ* collections as contributions to biology and the conservation of biological diversity, NIES understands its vital role as a reliable, fair, and neutral intermediary between countries of origin, depositors, and users.
- NIES pays special attention to the acquisition processes of genetic resources in order to promote appropriate utilization of genetic resources in its *ex situ* collections.
- When accepting genetic resources to NIES's *ex situ* collections, either through

deposition or donation, NIES, as far as possible, requires the provider to submit a written statement indicating that the genetic resources were acquired in accordance with applicable laws and that the provider has the proper right to provide the genetic resources to NIES. NIES confirms the provided statement to the extent possible, referring to the laws of the providing country, to ensure appropriate acceptance of genetic resources.

- NIES does not exchange genetic resources from its *ex situ* collections with other institutions without a written agreement.

3. Utilization

NIES utilizes genetic resources in accordance with the terms and conditions agreed upon by NIES and the provider at the time of acquisition.

- NIES complies with all national legislation and regulatory requirements of countries in which genetic resources are used. MAT is a contract and its conditions may extend beyond the scope of the Nagoya Protocol and contain clauses that remain in effect after the termination of use of the genetic resource.
- NIES outsources, for example, DNA sequencing analysis, in accordance with the terms and conditions to which NIES agreed at the time of acquisition.

4. Provisioning

NIES provides a genetic resource in accordance with the terms and conditions of the MAT agreed upon at the time of acquisition.

- NIES or its staff may provide genetic resources preserved by staff to a third party either as a loan or a donation, or to an *ex situ* collection such as those in museums and bioresource centers as a deposition or a donation. NIES may also distribute/exchange genetic resources in the NIES's *ex situ* collection to a third party.
- When providing genetic resources to a third party, NIES considers the following points by, for example, noting the terms and conditions agreed upon at the time of acquisition:
 - a) whether the provision to a third party, the purpose, the period, and the conditions of use are in accordance with the original terms and conditions;
 - b) whether there are interests belonging to NIES;
 - c) whether there are interests that NIES shall retain;
 - d) whether interests and/or regulations of the country of origin of the genetic resource are considered;
 - e) whether the provision is lawful in Japan;
 - f) whether the recipient is reliable enough to comply with the contract and relevant laws.
- Upon NIES's provisioning of genetic resources to a third party, the terms and conditions will be agreed upon by signing the MAT. NIES may also provide relevant

documents (e.g., a copy of documents prepared at the time of acquisition of the resource) as needed to facilitate smooth acquisition by the third party.

- NIES explains to the recipient that NIES may provide details of its provision of genetic resources (e.g., name of recipient and purpose) to investigative authorities upon lawful request.
- NIES may appropriately request benefit-sharing arising from the utilization of the genetic resources by the recipient. The shared benefit will be used for the conservation and understanding of biological diversity. The details of the procedures will be specified elsewhere.
- When providing genetic resources to a third party for commercial use, NIES will follow the process mentioned above. If the terms and conditions for commercial use of the genetic resources are unclear in the original agreement, NIES asks the third party to negotiate with the country of origin prior to the provisioning.

5. Benefit-sharing

Based on the MAT, NIES fairly and equitably shares benefits arising from the utilization of genetic resources with the providing country and other appropriate stakeholders.

- The Nagoya Protocol states that benefits can be shared by either non-monetary or monetary means. In principle, NIES carries out non-monetary benefit-sharing when the utilization of a genetic resource does not result in any monetary benefits. It carries out monetary benefit-sharing when the utilization does result in monetary benefits.

Examples of non-monetary benefit-sharing

- a) Provisioning of the biological information of the genetic resources, such as taxonomy and ecology.
- b) Provisioning of curated specimens.
- c) Co-authorship of publications.
- d) Hosting workshops and seminars.
- e) Long-term preservation of the genetic resources in NIES's *ex situ* collection.
- f) Cataloguing of biodiversity and access to the database.
- g) Sharing research results.
- h) Transfer of scientific knowledge, technology, and expertise.
- i) Capacity-building and training for scientific and institutional purposes.
- j) Collaborative research.

Examples of monetary benefit-sharing

- a) Up-front, milestone, or royalty payments.
- b) Joint ownership of relevant intellectual property rights.
- c) Payment for use of facilities and for employment of guides and researchers.

6. Management of genetic resources

NIES manages its genetic resources through the Access and Benefit-Sharing of Genetic Resources Committee.

- NIES staff shall consult with the Access and Benefit-Sharing of Genetic Resources Committee, established under the *Regulations on Access and Benefit-Sharing of Genetic Resources Committee*, prior to conducting research involving genetic resources.
- The Committee on Utilization of Genetic Resources performs an examination prior to the acquisition of genetic resources as needed and periodically assesses utilization and provision of genetic resources. The committee also collects and publicizes information on best practices from both within and outside of NIES to promote the appropriate handling of genetic resources.
- NIES retains and manages the records of consultations and processes between providing countries of genetic resources and recipients from NIES according to *Regulations on Records and Archives Management*.

7. Others

Traditional knowledge associated with genetic resources

When acquiring traditional knowledge associated with genetic resources, whether with or without actual acquisition of the associated genetic resources, NIES respects the rights of the indigenous and local communities and follows these Guidelines in the same manner as for the actual acquisition of genetic resources.

Revision of the Guidelines

These Guidelines shall be reviewed and revised as required according to the implementation status of acquisition, utilization, and benefit-sharing of genetic resources within NIES, as well as changes in scientific and social conditions.

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