Guidelines on Access to Genetic Resources For Users in Japan

Second Edition

Japan Bioindustry Association (JBA)
Ministry of Economy, Trade and Industry, Japan (METI)

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About the Second Edition

Seven years have passed since the first edition of the “Guidelines on Access to Genetic Resources for Users in Japan” was issued by the Ministry of Economy, Trade and Industry (METI) and Japan Bioindustry Association (JBA) in March, 2005.

In October, 2010, 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” (the “Nagoya Protocol”) was adopted at the Tenth Conference of the Parties to the Convention on Biological Diversity held in Nagoya, Japan.

The Nagoya Protocol is characterized by new features including compliance measures within user countries that are proportionate to the measures taken by countries providing genetic resources, and the establishment of the Access and Benefit-sharing (ABS) Clearing-House. Furthermore, under the Protocol, "traditional knowledge associated with genetic resources" that is held by indigenous and local communities is to be accessed in a manner similar to the manner of accessing genetic resources, in accordance with the domestic law of the providing country.

Under these circumstances, METI and JBA decided to update the first edition of the Guidelines to make them reflect key principles of the Nagoya Protocol in addition to those of the Convention on Biological Diversity and the Bonn Guidelines, replacing that first edition with this new revised edition. We also decided to update frequently asked Q&As under “Practical Problems and Suggested Solutions” to make them more user-friendly.

The fundamental ABS principles and procedures derived from the Convention on Biological Diversity (e.g. that States have sovereign rights over their genetic resources and that the authority to determine access to genetic resources rests with the national governments and is subject to their national legislation), which were fully reflected in the first edition of the Guidelines are unchanged after the adoption of the Nagoya Protocol.

We hope that the second edition of the Guidelines on Access to Genetic Resources for Users in Japan will be useful to those who access and use genetic resources and traditional knowledge associated with genetic resources in foreign nations, including, in the transitional period before the Nagoya Protocol enters into force.

March 12, 2012
Research Institute of Biological Resources
Japan Bioindustry Association (JBA)

Contents

Acronyms

ABS	Access and Benefit-Sharing
CBD	Convention on Biological Diversity
COP	Conference of the Parties to the CBD
IR	International Regime
ITPGR	International Treaty on Plant Genetic Resources for Food and Agriculture
JBA	Japan Bioindustry Association
MAT	Mutually Agreed Terms
METI	Ministry of Economy, Trade and Industry
MTA	Material Transfer Agreement
NGO	Non-Governmental Organization
PIC	Prior Informed Consent
UPOV	Union internationale pour la protection des obtentions végétales (International Union for the Protection of New Varieties of Plants)

Chapter I General Information

1. Background and Aims

(1) Background

1) The Convention on Biological Diversity (CBD),[1] adopted on May 22, 1992, entered into force on December 29, 1993. The CBD, while recognizing the sovereign rights of States over their natural resources, states that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. Access shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party. Benefits arising from the utilization of the genetic resources shall be shared in a fair and equitable way and upon mutually agreed terms.

   The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (the "Bonn Guidelines")[2] were adopted at the Sixth Meeting of the Conference of the Parties to the CBD (COP6) in April 2002. The Bonn Guidelines are voluntary and intended to serve as a reference when developing and drafting legislative, administrative, or policy measures and/or contracts and other arrangements on ABS as described in Article 15 of the CBD.

2) However, following adoption of the Bonn Guidelines, some countries asserted that, given that those Guidelines were not legally binding, they were insufficient as a mechanism for the sharing of the benefits arising from the utilization of genetic resources with the countries providing those resources.

   As a result, a resolution to start new negotiations regarding an "international regime (IR) on ABS" was adopted at the World Summit on Sustainable Development in 2002. Then, following a decision at the Seventh Meeting of the Conference of the Parties to the CBD (COP7) in 2004, negotiations concerning an IR began under the CBD.

3) At COP8 in 2006, the CBD Parties agreed "to continue IR negotiations in accordance with the COP7 decision, and to complete its work at the earliest possible time before COP10."

[1] See the website for the Biodiversity Center of Japan, Nature Conservation Bureau, Ministry of the Environment (http://www.biodic.go.jp/biolaw/jo_hon.html), for the official Japanese translation.

[2] See the website for the Japan Bioindustry Association (JBA) Research Institute of Biological Resources (http://www.mabs.jp/archives/bonn/index.html), for the Japanese translation by JBA (9/5/2002, with English.)

Nevertheless, discussion of IR did not proceed smoothly due to differences in views among countries, and an extremely difficult situation ensued.

Then, on the final day of the COP10 in October 2010 in Nagoya, Aichi Prefecture, Japan, the IR negotiation saw a dramatic development: a political settlement, leading to the adoption of 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" (the "Nagoya Protocol.")[3]

4) Countries are currently in the process of preparing to develop their various domestic measures on ABS to implement the Nagoya Protocol. Therefore, it is reasonable to expect that the legal certainty, clarity, and transparency of ABS procedures worldwide will remain insufficient for some time for those corporations and researchers that utilize genetic resources or traditional knowledge associated with genetic resources in or from other countries.

5) On the other hand, there are expectations that research and development in biotechnology will produce significant achievements in the 21st century. Bioindustry is an important and attractive segment of industry that has the potential to solve some of the global-scale problems that humankind is facing. Japan's bioindustry is willing to develop businesses that utilize genetic resources positively and appropriately despite the above-mentioned conditions worldwide.

(2) Aims

1) It is important that corporations and researchers, as users of genetic resources and traditional knowledge associated with genetic resources (hereinafter collectively referred to as "genetic resources, etc.") understand actively the ABS principles of the CBD and the Nagoya Protocol, and that they access genetic resources, etc. accordingly, thereby building good relationships with providers based on mutual trust. Therefore, it is necessary for METI and JBA to promote policies that develop an enabling environment for streamlined access to genetic resources, etc. in a sustainable manner, through which both the providers and the users of genetic resources, etc. will enjoy fair and equitable benefit-sharing.

[3] See the website for the JBA Research Institute of Biological Resources, for the Japanese translation by JBA (1/31/2011) (http://www.mabs.jp/archives/nagoya/index.html).

2) Based on this thinking, we developed the first edition of Guidelines on Access to Genetic Resources for Users in Japan in 2005. In the preparation of those guidelines, we consulted experts in academia and industry, in Japan and in other countries.

Now, with the adoption of the Nagoya Protocol, we have updated the 2005 edition to incorporate important principles contained in the Protocol into the present second edition of **the Guidelines on Access to Genetic Resources for Users in Japan 2012** (hereinafter referred to as **"The Guidelines 2012."**)

3) The specific aims of The Guidelines 2012 are as follows:
   - To help both providers and users to enjoy benefits and build win-win relationships, through streamlined access to genetic resources according to the relevant legislation or regulatory requirements of the providing countries and by fair and equitable sharing of the benefits arising from these uses.
   - To minimize the risk to users of getting involved in problems when they seek to utilize genetic resources for commercial purposes; and to promote business flexibility in those activities.
   - To facilitate users' understanding by providing concrete explanations and examples about the relevant provisions and terminology of the CBD, the Nagoya Protocol, and the Bonn Guidelines.

4) The Guidelines 2012 are voluntary and should not be interpreted as making any change in the existing legal rights and obligations of providers and users of genetic resources.

2. Scope

1) The scope of The Guidelines 2012 is based on that of the Nagoya Protocol (Article 3). Namely, it applies to “genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources, and also to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge." (In addition, human genetic resources are excluded from the scope of The Guidelines 2012.)

Furthermore, there are countries that have already put in place domestic laws or regulatory requirements on the utilization of genetic resources, etc. In these cases, the scope of the domestic laws or regulatory requirements of those countries will of course prevail, regardless of the scope of The Guidelines 2012. Therefore, please ascertain the specific situation of the country where you wish to access genetic resources, etc.

2) Genetic resources covered by the International Treaty on Plant Genetic Resources for Food and Agriculture, adopted in 2001 by the Conference of the Food and Agriculture Organization of the United Nations, are exempt from The Guidelines 2012.

3) The Guidelines 2012 address all access to foreign genetic resources, whether in a foreign nation or in Japan. With regard to the laws, regulatory procedures, etc. related to Japanese genetic resources within Japan, please refer to the relevant national laws, etc. (e.g., the Plant Variety Protection and Seed Act, the Plant Protection Act, the Act on Domestic Animal Infectious Diseases Control, the Invasive Alien Species Act, the Law for the Conservation of Endangered Species of Wild Fauna and Flora, etc.)

3. Basic Concepts

(1) Treatment of Genetic Resources, etc. under the Laws of Providing Countries

1) According to the CBD, “recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with national governments and is subject to national legislation.” (Article 15, Paragraph 1 of the CBD.)

2) Consequently, when accessing genetic resources of a foreign country, the basic premise is for a user to conform to the domestic laws and administrative measures stipulated by that country.

To determine which laws and measures apply, please check by contacting that country’s National Focal Point for the CBD (see *infra* Chapter II, Part1 “National Focal Point and Competent National Authorities”) or by consulting a legal expert in that country in case you need information in greater depth.

(2) Handling of Genetic Resources, etc. by Contracts

In some countries, there are no laws or administrative measures governing access to genetic resources. In such cases, business will be conducted in accordance with a contract that you will develop with your counterpart. When negotiating a contract in such a situation, please bear in mind that the relevant provisions of the CBD and the Nagoya Protocol and rules recommended in the Bonn Guidelines have important implications as references.

(3) How to Use The Guidelines 2012

1) The Guidelines 2012 present and discuss relevant provisions of the CBD, the Nagoya Protocol and the Bonn Guidelines, and also touch on some of major points under discussion at international forums. The Questions and Answers shown below present types of problems that you may encounter in actual situations, and give suggested solutions to them for your reference.

2) If you are still unclear about key points or encounter problems in checking the regulatory system of a country, as part of your preparations for doing business or research there, please contact JBA or the METI. (See Chapter IV, *infra,* for the contact points.)

4. Use of Terms

(1) Genetic resources

"Genetic resources" means genetic material (any material of plant, animal, microbial or other origin containing functional units of heredity) of actual or potential value. (Article 2 of the CBD.)

(2) "Country of origin of genetic resources" and "country providing genetic resources"

1) "Country of origin of genetic resources" means the country which possesses those genetic resources in *in-situ* conditions[4]. (Article 2 of the CBD.)

2) "Country providing genetic resources" means the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country. (Article 2 of the CBD.)

(3) *In-situ* conditions

"In-situ conditions" means conditions where genetic resources exist within ecosystems and natural habitats, and in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties. (Article 2 of the CBD.)

(4) Utilization of genetic resources

"Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the CBD. (Article 2(c) of the Nagoya Protocol.)

(5) Biotechnology

"Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. (Article 2 of the CBD and Article 2(d) of the Nagoya Protocol.)

[4] It must be noted that the definition of "country of origin" in the CBD is not the same as that used in a biology text book.

(6) Derivative

"Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity. (Article 2(e) of the Nagoya Protocol.)

(7) Traditional knowledge associated with genetic resources

"Traditional knowledge" is not defined in the CBD and the Nagoya Protocol, but a relevant description is found in the Article 8(j)[5] of the CBD. Under the Nagoya Protocol, traditional knowledge associated with genetic resources is also subject to the ABS, and is to be treated in accordance with the domestic laws (Articles 7 and 12 of the Nagoya Protocol) or regulatory requirements (Article 16 of the Nagoya Protocol) of the providing countries.

(8) Benefits

For the purpose of The Guidelines 2012, "benefits" refer to the benefits that the provider and/or the user of genetic resources, etc. gain as a result of utilization of those resources. Benefits may include monetary and non-monetary benefits. (Annex to the Nagoya Protocol.)

(9) Prior informed consent (PIC)

When a user wishes to access genetic resources, etc. in a foreign country, the user is obliged to submit specific information to the government of the country providing such resources and to acquire its prior informed consent, if required by the law of that country. (Article 15, Paragraph 5 of the CBD; and Article 6, Paragraph 2 and Article 7 of the Nagoya Protocol.)

It may also be necessary, if required by the domestic law, to obtain similar prior informed consent from the relevant indigenous and local communities. (Article 6, Paragraph 2 and Article 7 of the Nagoya Protocol.)

(10) Mutually agreed terms (MAT)

Sharing of benefits arising from the access and utilization of genetic resources, etc. must be conducted on the basis of a mutual agreement between the provider and the user of such resources. Specific terms and conditions of such an agreement are to be negotiated

[5] CBD Article 8 ("In-situ Conservation"): "Each Contracting Party shall, as far as possible and as appropriate: … (j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices."

between the parties concerned in compliance with the law and administrative measures of the country providing such resources. (Article 15, Paragraphs 4 and 7 of the CBD; and Article 5, Paragraphs 1, 2, and 5 of the Nagoya Protocol.)

(11) ABS Clearing-House

An Access and Benefit-sharing Clearing-House is to be established as part of the clearing-house mechanism under Article 18, paragraph 3, of the CBD. It shall serve as a means for sharing of information related to access and benefit-sharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of the Nagoya Protocol. (Article 14, Paragraph 1 of the Nagoya Protocol.)

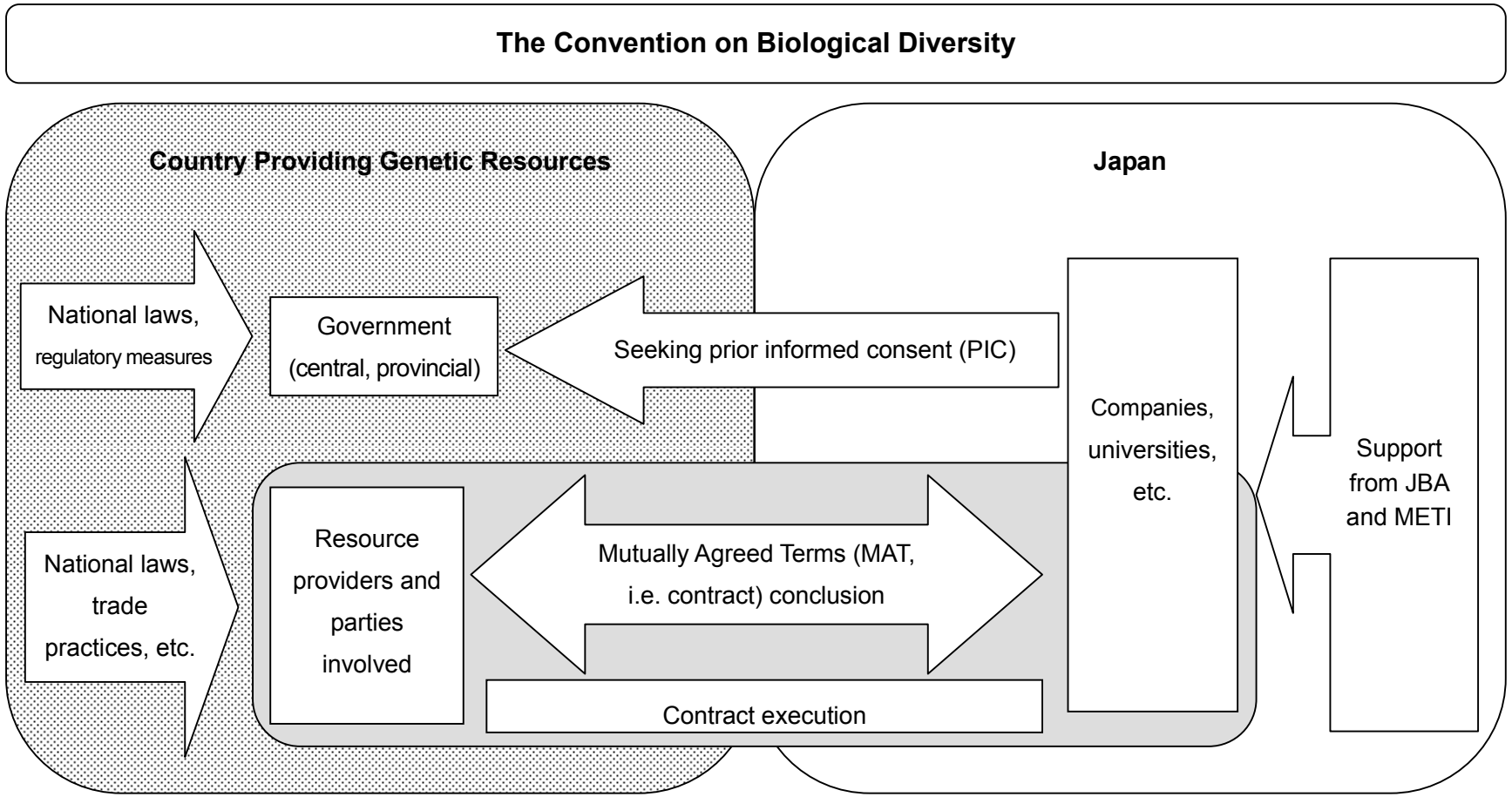
Information provided through the ABS Clearing-House shall include the following (Article 14, Paragraph 2 of the Nagoya Protocol):

(a) Legislative, administrative and policy measures on access and benefit-sharing;
(b) Information on the national focal point and competent national authority or authorities; and
(c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms.

Additional information, if available and as appropriate, may include the following (Article 14, Paragraph 3 of the Nagoya Protocol):

(a) Relevant competent authorities of indigenous and local communities, and information as so decided;
(b) Model contractual clauses;
(c) Methods and tools developed to monitor genetic resources; and
(d) Codes of conduct and best practices.

Access and Benefit-Sharing Framework



Chapter II Steps in the Access and Benefit-Sharing Process

1. National Focal Point and Competent National Authorities

Provisions Set Forth in the CBD and the Nagoya Protocol

[Article 15, Paragraph 1 of the CBD; Article 13, Paragraphs 1 and 2 of the Nagoya Protocol; Paragraphs 13 and 14 of the Bonn Guidelines]

[CBD]

Article 15, Paragraph 1

Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

[Nagoya Protocol]

Article 13. National Focal Points and Competent National Authorities

Article 13, Paragraph 1

Each Party shall designate a national focal point on access and benefit-sharing. The national focal point shall make information available as follows:

(a) For applicants seeking access to genetic resources, information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing;

(b) For applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit-sharing; and

(c) Information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.

The national focal point shall be responsible for liaison with the Secretariat.

Article 13, Paragraph 2

Each Party shall designate one or more competent national authorities on access and benefit-sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.

(1) Explanatory Notes

It is the principle of the CBD that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

Thus, when accessing genetic resources, etc., the domestic laws, administrative measures, etc. of the country providing the resources must first be checked. For that purpose, you can inquire through the national focal point and competent national authorities of the providing country.

Note that you need to exercise caution, when you obtain genetic resources from foreign sources via intermediaries, for example. (see *infra,* Chapter III, Part 2(3) “Practical Problems and Suggested Solutions,” Question 6.)

1) National Focal Point

Under the CBD, a Contracting Party designates a single national focal point and makes this information available through sources such as the ABS Clearing-House of the Secretariat to the CBD (http://www.biodiv.org/world/map.asp).[6]

Under the Nagoya Protocol, the national focal point is to provide information on competent national authorities, relevant indigenous and local communities, and relevant stakeholders through the ABS Clearing-House. (Article 13, paragraph 1(c) of the Nagoya Protocol.)

2) Competent National Authority

Article 13, Paragraph 2 "National Focal Points and Competent National Authorities" in the Nagoya Protocol describes "competent national authority" as follows:

"Each Party shall designate one or more competent national authorities on access and benefit-sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.”

Furthermore, the role of competent national authorities is described as follows in paragraph 14 of the Bonn Guidelines:

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[6] The comprehensive name for the CBD’s information disclosure systems is “clearing-house mechanism.” This mechanism provides information, such as documentation, to people all over the world. The comparable system in the Nagoya Protocol is called the “Access and Benefit-sharing Clearing-House” (see Article 14 of the Nagoya Protocol.)

"Competent national authorities, where they are established, may, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access and be responsible for advising on:

(a) The negotiating process;

(b) Requirements for obtaining prior informed consent and entering into mutually agreed terms;

(c) Monitoring and evaluation of access and benefit-sharing agreements;

(d) Implementation/enforcement of access and benefit-sharing agreements;

(e) Processing of applications and approval of agreements;

(f) The conservation and sustainable use of the genetic resources accessed;

(g) Mechanisms for the effective participation of different stakeholders, as appropriate for the different steps in the process of access and benefit-sharing, in particular, indigenous and local communities; and

(h) Mechanisms for the effective participation of indigenous and local communities while promoting the objective of having decisions and processes available in a language understandable to relevant indigenous and local communities."

See "Lists of National Focal Points" on the website of the Secretariat to the CBD (http://www.cbd.int/information/nfp.shtml) for information regarding competent national authorities.

(2) National Focal Point in Different Countries

The national focal points and competent national authorities of Contracting Parties to the CBD are available on the CBD Secretariat website, as mentioned above. It should be noted that, in some countries, the entities with actual responsibility for granting access may be different from the national focal points or competent national authorities designated on the CBD Secretariat website.

(3) Practical Problems and Suggested Solutions

Question 1: What should I do if there is no information given in the CBD Secretariat website about the national focal point or competent national authority of a country?

Answer 1: You may be able to get the necessary information by consulting with JBA or METI. (Please refer to Chapter IV, *infra,* for the contact point at JBA or METI that handles such inquiries.)

At paragraph 3(a) of Article 6 "Access to Genetic Resources," the Nagoya Protocol stipulates that a Party requiring prior informed consent must "provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements." Furthermore, paragraph 2(a) of Article 14 "The Access and Benefit-sharing Clearing-House and Information Sharing" obligates each Party to make available to the ABS Clearing-House information related to "legislative, administrative and policy measures on access and benefit-sharing."
Accordingly, this type of problem will be resolved as the Nagoya Protocol enters into force and the CBD Secretariat's ABS Clearing-House becomes operationally advanced.

Question 2: What should I do when I do not get a prompt reply after contacting the national focal point, or when, with only a preliminary reply given by the national focal point, I find myself being referred to a variety of different departments within that country's government without meaningful progress?

Answer 2: While you should keep trying to get in touch with the most appropriate entity of that government by all available communication means, you may consult with JBA or METI which may have useful information. (Please refer to Chapter IV, *infra,* for the contact point at JBA or METI that handles such inquiries.)

Question 3: Is there a way to check which countries have an ABS national law and which do not?

Answer 3: You can check using the "ABS Measures Search Page" on the CBD Secretariat's website (https://www.cbd.int/abs/measures/), but the listing may not be comprehensive.

2. Obtaining Prior Informed Consent (PIC)

Provisions Set Forth in the CBD and the Nagoya Protocol

[Article 15, Paragraphs 1, 2, 3 and 5 of the CBD; Articles 6, 7, 13, 14 and 17 of the Nagoya Protocol; Paragraphs 26, 27, 28, 33, 34, 36, 38, 39 and 40 of the Bonn Guidelines]

[CBD]

Article 15, Paragraph 1

Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

Article 15, Paragraph 2

Each Contracting Party shall endeavor to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.

Article 15, Paragraph 3

For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.

Article 15, Paragraph 5

Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

[Nagoya Protocol]

Article 6, Access to Genetic Resources

1. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.

2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.

3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:

(a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;
(b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;
(c) Provide information on how to apply for prior informed consent;
(d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;
(e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;
(f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and
(g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, inter alia:
    (i) A dispute settlement clause;
    (ii) Terms on benefit-sharing, including in relation to intellectual property rights;
    (iii) Terms on subsequent third-party use, if any; and
    (iv) Terms on changes of intent, where applicable.

Article 7, Traditional Knowledge Associated with Genetic Resources

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

(1) Explanatory Notes

In ordinary contracts, it is sufficient that the parties directly involved agree on the content of the contract; under the CBD and the Nagoya Protocol, however, when accessing genetic resources, etc., prior informed consent is to be obtained through the competent authorities in compliance with the domestic laws or regulatory requirements of that country.

1) Obtaining Prior Informed Consent (PIC)

When accessing genetic resources, etc., you are required to go through the procedure for submitting specified information and to obtain permission in accordance with the domestic laws or regulatory requirements of the country providing genetic resources, etc.[7]

Note that, depending on the country or region, it may also be necessary to obtain prior informed consent from other stakeholders, such as indigenous and local communities of the country providing genetic resources, etc., in accordance with the domestic laws or regulatory requirements of the country.

2) Points to Note

You need to study the procedure for obtaining PIC in the country or region where you wish to access genetic resources, etc. In doing so, you should find answers to the following questions:

i) Entity issuing PIC

- At what level of government should PIC be obtained, e.g., from the central government or provincial government?
- Is prior informed consent or approval required from indigenous and local communities concerned with the genetic resources, etc., in accordance with domestic laws or administrative measures?
- In accordance with domestic laws or administrative measures, are there any procedures of customary law, community protocol, and/or other structures that are unique to the community?

[7] As a practical matter, it is necessary, of course, to first obtain informal consent for access from your counterpart (the party who has the rights regarding the genetic resources, etc., with whom the contract is to be negotiated.)

ii) Procedure for obtaining PIC

- What are the requirements of the domestic laws or administrative measures for obtaining PIC?
- Specific procedures:
  (a) Where should inquiries be addressed and applications submitted?
  (b) Is there a specified application format and, if so, what items of information (such as purpose, duration, targeted genetic resources, and fees) are then required?
  (c) Are there any other conditions?
- For what use is the PIC granted? What kind of procedure is required for change in use, or transferring genetic resources to a third party?
- Is the PIC to be issued as a written document?
- How many days will it take for PIC to be issued, after filing of application?
- Will the permit be made available to the ABS Clearing-House of the CBD Secretariat as an internationally recognized certificate of compliance?

(2) National / Domestic Laws

Concerning national / domestic laws of countries, refer to the following websites:

- CBD Secretariat website:
  "ABS Measures Search Page" (http://www.cbd.int/abs/measures/)
- JBA website:
  Access to Biological Resources and Benefit Sharing under the Convention on Biological Diversity (CBD): A Corporate Guide
  "CBD-related Information by Country" (http://www.mabs.jp/countries/index.html)

(3) Practical Problems and Suggested Solutions

Question 4: Are activities for academic purposes subject to the CBD?

Answer 4: Accessing genetic resources, etc. for academic purposes is not excluded from the scope of the CBD and the Nagoya Protocol. Therefore, academic activities are considered subject to the CBD and the Nagoya Protocol, unless otherwise determined by the countries providing the genetic resources, etc.

Question 5: Does one need to seek PIC for genetic resources, etc. that were obtained before the CBD entered into force (December 29, 1993)?

Answer 5: It is generally accepted that there is no obligation under the CBD to obtain PIC for genetic resources that had been accessed before the CBD entered into force. Furthermore, if a country providing genetic resources ratified the CBD after December 29, 1993, there is also no obligation under the CBD to obtain PIC from that country prior to the date when the CBD entered into force in that country, unless otherwise determined by the domestic laws or administrative measures of the providing country.

Question 6: How can a user verify that PIC has been obtained when a commercial intermediary provides genetic resources, etc. to the user?

Answer 6: We recommend that you use one or more of the following steps to verify whether the commercial intermediary has obtained the genetic resources according to the procedure in compliance with the domestic laws or administrative measures of the country providing the genetic resources and whether the intermediary has been authorized by that country to transfer those genetic resources, etc. to a third party user:

a) obtain from the intermediary a copy of the documentation to confirm that PIC was granted;
b) obtain a letter of confirmation from the intermediary stating that the intermediary obtained PIC; and/or
c) include a clause in the contract explicitly stating that the intermediary warrants that it has obtained the genetic resources, etc. in compliance with the domestic laws or administrative measures of the country providing the genetic resources.

In order to manage risk, it is further recommended that you independently verify compliance with the procedure required by the particular providing country for PIC under its domestic laws and/or administrative measures.

Note that commercial intermediaries may range from agents for accessing genetic resources to general retailers.

When the ABS Clearing-House becomes fully operational after the Nagoya Protocol enters into force, you are supposed to be able to confirm whether or not the commercial intermediary has properly obtained PIC, by checking the section of the "internationally recognized certificates of compliance" (Article 17, Paragraph 3 of the Nagoya Protocol) of that country on the ABS Clearing-House.

Question 7: Is it necessary to obtain PIC when acquiring genetic resources from *ex-situ* collections (such as microbial culture collections)?

Answer 7: *Ex-situ* collections are also subject to the CBD. If the law of a country, where a culture collection, a botanical garden, or other type of BRC[8] is located, requires PIC, then, you must obtain PIC. Furthermore, if the *ex situ* collection obtains a genetic resource from a foreign country and provides this resource to a user in another country, then the *ex-situ* collection is considered as a type of intermediary. Therefore, our suggestion, given under Question 6 above, would apply.

Question 8: What should I do to access a plant species if that species is found *in situ* within the territory of more than one country?

Answer 8: In the CBD, a "country of origin of genetic resources" is a "country which possesses those genetic resources in *in-situ* conditions." According to this definition, if a genetic resource has been moved to country A from country B before the CBD came into force and exists in *in-situ* conditions, then country A is also a country of origin.

When there are several countries of origin in that sense, you can choose a single country from among them and access the genetic resource there, in compliance with the law of that country.

However, there are some points to be noted when there is a regional agreement among the countries of origin. For example, there are plants common to Bolivia, Colombia, Ecuador, and other countries along the Andes, and these countries have concluded a regional pact (the Andean Pact). The principles of such a regional pact must also be noted.

Question 9: Is it necessary to obtain a separate governmental PIC of a country even when I have the approval of the owner of, for example the property on which the genetic resource is located?

Answer 9: Prior approval of the owner and a governmental PIC are two different things. In a case where the domestic law of that country stipulates that a governmental PIC is required, you must obtain a separate governmental PIC even when the owner of the genetic resource has given you prior approval.

[8] Biological Resource Center

Question 10: In Country A, at a public market, I bought an endemic species of a plant for ornamental purposes. After returning to my country, I used it by chance for my research, and I discovered a component specific to that endemic species that has potential for commercialization. Is it necessary for me to obtain PIC from Country A if I wish to develop a commercial product using this component?

Answer 10: As in some cases, the law of Country A may require you to obtain PIC even when you use the plant purchased at a public market in Country A as a genetic resource for commercialization. If that is the case, you must follow the procedure in accordance with the law of Country A. On the other hand, there may be other cases where the country does not have such a law in place. In such cases, there is no legal obligation for you to obtain PIC, but “change of use” issue could arise; commercialization of the genetic resource of that country without notifying the government could be criticized as improper by citizens, non-governmental organizations and others in that country, which could result in damage to your corporate image[9].

Question 11: What do I need to do in order to bring seeds or crops that are indigenous to a foreign country that were purchased at a local market or were kindly provided to me by a local farmer, to my country to be used as a genetic resource?

Answer 11: In order to bring such seeds, which were purchased at a local market or received as a gift, back to your country, you need to obtain PIC for accessing and transferring those genetic resources in accordance with that country's domestic laws or administrative measures, if the country has such a system in place.

Note that if the country is a member of the International Convention for the Protection of New Varieties of Plants (UPOV), registered species in general distribution can be used in breeding as far as plant breeders' rights are concerned; however, we recommend that you verify beforehand how that country handles the relation between the CBD and the UPOV and whether there is any regulation about taking seeds out of the country, etc.

(Genetic resources covered by ITPGR are excluded from the scope of The Guidelines 2012.)

[9] UNEP/CBD/WG-ABS/4/INF/6 (22 December 2005)

Question 12: I have applied to the relevant authorities of the providing country for PIC, in compliance with that country's law, but even after a number of months passed I still have not been informed whether or not my application was approved. What should I do?

Answer 12: First, you need to make an inquiry or request to the authorities in the providing country, preferably using the services of local legal professionals. If there is still no progress, you may consult with JBA or METI which may have useful information. (Please refer to Chapter IV, *infra,* for the contact point at JBA or METI that handles such inquiries.)

Question 13: I hear that there is no ABS law in Japan. So what should I keep in mind, in the event that I should wish to provide Japanese genetic resources to a foreign country?

Answer 13: Even though there is no specific law related to ABS, there are laws and regulations that can be partially or indirectly related, such as laws and regulations in the field of agriculture, forestry, and fisheries; intellectual property rights; various types of zoning; import and export laws and regulations; commercial law concerning various rights; and criminal laws. Therefore, you need to take these laws and regulations into consideration.
Also as mentioned below, it is important to set mutually agreed terms (MAT) and to secure a reasonable sharing of benefits.

3. Establishing Mutually Agreed Terms

Provisions Set Forth in the CBD and the Nagoya Protocol

[Article 1, and Article 15, Paragraphs 2, 4 and 7 of the CBD; Article 5, Paragraphs 1, 2 and 5, Article 6, Article 13, Paragraphs 1 and 2, Article 14, Article 18, Paragraph 1, Article 19, Paragraph 1 of the Nagoya Protocol; Paragraphs 41, 42, 43, 45 and 49 of the Bonn Guidelines]

[CBD]

Article 1

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, [The rest of the Article is here omitted.]

Article 15, Paragraph 2

Each Contracting Party shall endeavor to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.

Article 15, Paragraph 4

Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

Article 15, Paragraph 7

Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19…with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

[Nagoya Protocol]

Article 5, Fair and Equitable Benefit-sharing

Article 5, Paragraph 1

In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such

resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.

Article 5, Paragraph 2

Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.

Article 5, Paragraph 5

Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

Article 6, Access to Genetic Resources

1. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.

2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.

3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:
   (a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;
   (b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;

(c) Provide information on how to apply for prior informed consent;

(d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;

(e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;

(f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and

(g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia*:

(i) A dispute settlement clause;

(ii) Terms on benefit-sharing, including in relation to intellectual property rights;

(iii) Terms on subsequent third-party use, if any; and

(iv) Terms on changes of intent, where applicable.

Article 13, National Focal Points and Competent National Authorities

Article 13, Paragraph 1

Each Party shall designate a national focal point on access and benefit-sharing. The national focal point shall make information available as follows:

(a) For applicants seeking access to genetic resources, information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing;

(b) For applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit-sharing; and

(c) Information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.

The national focal point shall be responsible for liaison with the Secretariat.

Article 13, Paragraph 2

Each Party shall designate one or more competent national authorities on access and benefit-sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be

responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.

Article 14, Access and Benefit-sharing Clearing-House and Information-Sharing

1. An Access and Benefit-sharing Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention. It shall serve as a means for sharing of information related to access and benefit-sharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol.

2. Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-sharing Clearing-House any information required by this Protocol, as well as information required pursuant to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol. The information shall include:
   (a) Legislative, administrative and policy measures on access and benefit-sharing;
   (b) Information on the national focal point and competent national authority or authorities; and
   (c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms.

3. Additional information, if available and as appropriate, may include:
   (a) Relevant competent authorities of indigenous and local communities, and information as so decided;
   (b) Model contractual clauses;
   (c) Methods and tools developed to monitor genetic resources; and
   (d) Codes of conduct and best practices.

4. The modalities of the operation of the Access and Benefit-sharing Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article 18, Compliance with Mutually Agreed Terms

Article 18, Paragraph 1

In the implementation of Article 6, paragraph 3 (g) (i) and Article 7, each Party shall

encourage providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including:

(a) The jurisdiction to which they will subject any dispute resolution processes;
(b) The applicable law; and/or
(c) Options for alternative dispute resolution, such as mediation or arbitration.

Article 19, Model Contractual Clauses

Article 19, Paragraph 1

Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms.

A. Mutually Agreed Terms (MAT)

(1) Explanatory Notes

1) As in the case of other ordinary transactions, access to genetic resources, etc. and benefit-sharing should take place in accordance with MAT. This is explicitly stated in Article 15, Paragraphs 4 and 7 of the CBD and Article 5 of the Nagoya Protocol.

2) Accordingly, the parties first negotiate MAT. Paragraph 44 of the Bonn Guidelines provides an "indicative list of typical mutually agreed terms."

3) When negotiating MAT with your counterpart, you need to study their country's domestic laws and administrative measures regarding access to genetic resources, etc. It is also advisable for you to investigate their trade laws and business customs. Careful investigation may be necessary about their country's traditional knowledge associated with genetic resources, because there is often a high level of uncertainty about it.

4) Furthermore, some providing countries will have set clear rules and procedures for requiring and establishing MAT based on Article 6, Paragraph 3(g) of the Nagoya Protocol. Therefore, you will need to pay attention to those rules and procedures.

5) Handling of the transfer of genetic resources, etc. involves the use of another type of document, the "Material Transfer Agreement (MTA)."
   In the cases involving the transfer of genetic resources, etc., an MTA will need to be concluded between the provider and the user of the genetic resources, etc.

The MTA is intended as a contract to establish the terms and conditions for the transfer of materials, such as the following:

- The type and quantity of material to be transferred;
- The timing of the transfer;
- The intended use of the transferred material (to be specified as necessary, including, e.g., for non-commercial use, or for commercial use); and
- Whether or not the material can be transferred to a third party and, if yes, the procedure for doing so.

In some countries, domestic laws and/or administrative measures may stipulate content requirements for the material transfer agreement. Accordingly, you need to carefully investigate the domestic laws and/or administrative measures of the country providing the genetic resources, etc.

In addition, refer to the Suggested Elements for Material Transfer Agreements described in Appendix I of the Bonn Guidelines which lists elements that should be specifically agreed upon in the MTA.

6) If there are any concerns or problems, you may consult with JBA or METI which may have useful information. (Please refer to Chapter IV, *infra,* for the contact point at JBA or METI that handles such inquiries.)

(2) Practical Problems and Suggested Solutions

Question 14: What type of issues should I keep in mind for the MAT?

Answer 14: Refer to the Bonn Guidelines for examples in “Indicative list of typical mutually agreed terms," in Paragraph 44, or for those in Appendix I, "Suggested Elements for Material Transfer Agreements." Also refer to Article 6, Paragraph 3(g) of the Nagoya Protocol for items to be included in mutually agreed terms. Note that Article 19 of the Nagoya Protocol calls upon each Contracting Party to the Protocol to encourage, as appropriate, the development, update and use of model contractual clauses.

Question 15: Our MAT negotiation has been consuming a lot of time. What should I do?

Answer 15: It is not uncommon for negotiations on contract terms to take a long time. Judge for yourself whether to continue or terminate the negotiation.

If there are any concerns or problems, you may consult with JBA or METI which may have useful information. (Please refer to Chapter IV, *infra,* for the contact point at JBA or METI that handles such inquiries.)

Question 16: We are interested in conducting a research and development project using traditional knowledge associated with genetic resources. How do we identify the stakeholders concerning that kind of knowledge?

Answer 16: "Traditional knowledge" is not defined under the CBD or the Nagoya Protocol; although the Nagoya Protocol includes provisions related to access and benefit-sharing with regard to traditional knowledge associated with genetic resources (see, for example, Articles 5, 6, 12, and 16 of the Nagoya Protocol). Users must abide by the domestic laws and/or administrative measures of the country providing the resources. Accordingly, you need to study the domestic laws, administrative measures, customary laws and other procedures of the relevant indigenous and local communities of that country.

In practice, however, there may be cases where it is not easy to clearly identify the entity responsible for prior informed consent or approval and for negotiation of MAT, because traditional knowledge is held collectively by indigenous or local communities and because several different communities often hold the same traditional knowledge. We recommend that you closely consult with the competent national authority of the country under consideration.

If there are any concerns or problems, you may consult with JBA or METI which may have useful information. (Please refer to Chapter IV, *infra,* for the contact point at JBA or METI that handles such inquiries.)

Question 17: Does a user have to accept the MAT proposed by the provider of genetic resources?

Answer 17: If you find that all the provisions of the MAT proposed by the provider are identical to those stipulated by the domestic laws and/or administrative measures of the country providing the resources, then, you must comply with the proposed MAT.

On the other hand, your counterpart in the negotiation may propose his/her own terms and conditions which are not based on the domestic laws and/or administrative measures of his/her government. In such cases, you are not obligated to agree to these parts of the terms and conditions.

It is important for you to verify which part of the proposed terms and conditions are based on the domestic laws and/or administrative measures of the country. You should conduct your negotiation on the basis of this clarification.

B. Sharing the Benefits of Utilization

(1) Explanatory Notes

When you utilize genetic resources, etc. of another country, you should share benefits fairly and equitably based on MAT, in compliance with the domestic laws or administrative measures of the providing country. If there is no such law or measure in place in the providing country, you should negotiate a MAT with the individual or entity that is providing the genetic resources, bearing in mind the principles of the CBD and the Nagoya Protocol.
In the negotiation, It is important that both you and the provider discuss and understand what each other needs to achieve, and make a “win-win” agreement.

1) Benefit-Sharing

i) Meaning of “benefit”

The term “benefit,” as used in the phrase “benefits arising out of the utilization of genetic resources, etc.,” does not necessarily refer to net monetary profit that remains after expenses have been deducted from the revenue generated from the product that has used the genetic resources, etc.; rather, the word is used in a broader sense to mean “what the provider and/or the user of genetic resources obtain” as a result of using those resources.

ii) Methods for benefit-sharing

As shown below, "benefits arising from the utilization of genetic resources" can be divided into two major categories: "monetary benefits" and "non-monetary benefits."

(a) Monetary benefits: These include, for example, fees for obtained samples, milestone payments, and royalties.
(b) Non-monetary benefits: These include, for example, training of staff of the providing country in joint research or technology transfer, and sharing the results of research.

Refer to the Annex in the Nagoya Protocol for examples of "Monetary and Non-monetary Benefits."

2) Points to Note

i) Domestic laws or administrative measures of the providing country:

Note in MAT negotiations that, under some countries' domestic ABS law or administrative measures, a specific rule is stated for sharing benefits arising from the utilization of genetic resources, etc. Also pay attention to the trade laws and business customs in the providing country.

ii) Points to bear in mind in negotiations:

- Common understanding regarding benefit-sharing:

In negotiations, it is important for both sides to have a common understanding of what "benefits to be shared" means. In the case of monetary benefit-sharing, for example, it may be that you assume that the benefit is the amount remaining after R&D costs and other expenses are deducted from product sales, while your counterpart may have a different understanding. You should explain and make sure that both sides have a common understanding.

If your counterpart is not experienced in R&D processes, you need to explain about the steps involved in research, development and commercialization, indicating that it usually take a considerable length of time before monetary benefit can be generated from the utilization of genetic resources.

Furthermore, it is important that you explain to your counterpart that benefit-sharing patterns vary, depending on the business sector involved (e.g., food, cosmetics, pharmaceuticals, etc.), because profit margins vary considerably from one sector to another.

- Sharing of benefits in proportion to the degree of contribution:

Although some providers are not aware of it, "fair and equitable sharing of benefits" does not mean that benefits will be shared on a fifty-fifty basis. It is important for the negotiating parties to agree on the principle they will apply in order to share benefits in proportion to the degree of each party's contribution to the overall achievement.

If there are any concerns or problems, you may consult with JBA or METI which may have useful information. (Please refer to Chapter IV, *infra,* for the contact point at JBA or METI that handles such inquiries.)

(2) Practical Problems and Suggested Solutions

Question 18: How should I handle derivatives obtained from the utilization of genetic resources?

Answer 18: On the basis of mutually agreed terms, derivatives can be made subject to benefit-sharing. It is important that the provider and the user negotiate to confirm the specific definition of “derivative” that will apply within the framework of their contract and how it will be treated thereunder.

Note that, in some cases, the definition of “derivatives” and their treatment are stipulated in the domestic laws and/or administrative measures of the country providing genetic resources. Therefore, you should check them before starting negotiation.

4. Compliance

Provisions Set Forth in the Nagoya Protocol and the Bonn Guidelines

[Article 15, Paragraphs 1, 2 and 3, Article 16, Paragraphs 1, 2 and 3, Article 17, Paragraphs 1, 2 and 3 of the Nagoya Protocol; Paragraph 16 of the Bonn Guidelines]

[Nagoya Protocol]

Article 15, Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing

Article 15, Paragraph 1

Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.

Article 15, Paragraph 2

Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

Article 15, Paragraph 3

Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

Article 16, Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing for Traditional Knowledge Associated with Genetic Resources

Article 16, Paragraph 1

Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.

Article 16, Paragraph 2

Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

Article 16, Paragraph 3

Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

Article 17, Monitoring the Utilization of Genetic Resources

Article 17, Paragraph 1

To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:

(a) The designation of one or more checkpoints, as follows:

(i) Designated checkpoints would collect or receive, as appropriate, relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate;

[The rest of Article 17, Paragraph 1, omitted.]

Article 17, Paragraph 2

A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

Article 17, Paragraph 3

An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent.

[The Article 17, Paragraph 4, omitted.]

(1) Explanatory Notes

The Nagoya Protocol contains compliance provisions in Article 15 "Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing"; Article 16 "Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing for Traditional Knowledge Associated with Genetic Resources"; and, Article 17 "Monitoring the Utilization of Genetic Resources" provides measures to support compliance. The Nagoya Protocol assumes that every country is both a user and a provider of genetic resources.

1) Measures in the User Country

Each Contracting Party is obligated to take measures to provide that the genetic resources utilized within its jurisdiction have been accessed in compliance with the ABS legislation or regulatory requirements of the other Party (Article 15 of the Nagoya Protocol). Each Contracting Party is obligated to designate at least one checkpoint to monitor the utilization of genetic resources. (Article 17 of the Nagoya Protocol.)

2) Measures in the Providing Country

The obligations of Articles 15, 16 and 17 of the Nagoya Protocol are balanced by the obligation of the country providing the resources to implement the provisions in the Article 6 "Access to Genetic Resources." For example, in Article 6, Paragraph 3, each Party requiring PIC is obligated to take the necessary measures to provide for legal certainty, clarity and transparency of their domestic access and benefit sharing legislation or regulatory requirements. Furthermore, there is an obligation for the providing Party to make available to the ABS Clearing-House the information concerning its ABS measures (see Article 6.3(e) and Article 14 of the Nagoya Protocol).

3) Certificate of Compliance

To implement Article 17 "Monitoring the Utilization of Genetic Resources," the internationally recognized certificate of compliance" system shall serve as evidence (Article 17, Paragraph 3), for which the ABS Clearing-House will play a critical role as an information source. Effective operation of the ABS Clearing-House will be the key for the implementation of the Nagoya Protocol in general, and the Articles 6, 15, 16 and 17 in particular.

As outlined above, the Nagoya Protocol is characterized by imposing obligations on both the country providing genetic resources and the country using genetic resources [10]. Each country is allowed to exercise considerable discretion in implementing of the Nagoya Protocol. It remains to be seen at this point of time what kind of domestic ABS legislation and regulatory requirements will emerge and what kind of impact they will have on countries.

Particularly in the months before the Nagoya Protocol enters into force, we strongly recommend that the users of genetic resources conduct ABS activities according to **the Guidelines on Access to Genetic Resources for Users in Japan 2012** which have been developed on the basis of the CBD, the Bonn Guidelines and the Nagoya Protocol.

[10] Background leading to the adoption of this principle in the Nagoya Protocol: In the Bonn Guidelines, there is a section (Paragraph 16) entitled "Responsibilities" regarding access and benefit-sharing pursuant to Article 15 of the Convention on Biological Diversity. The Bonn Guidelines recommend principles such as the following as "responsibilities" of the Contracting Parties: “1. Recognize that Parties may be both users and providers of genetic resources. 2. Review national policy, and administrative and legislative measures to ensure they are fully complying with Article 15 of the Convention. 3. Contracting Parties with users of genetic resources under their jurisdiction should take appropriate legal, administrative, or policy measures, as appropriate, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted.

5. Dispute Resolution

Provisions Set Forth in the Nagoya Protocol and the Bonn Guidelines

[Article 6, Paragraph 3 (g) and Article 18 of the Nagoya Protocol; Paragraph 59 of the Bonn Guidelines]

[Nagoya Protocol]

Article 6, Access to Genetic Resources

Article 6, Paragraph 3

Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:

[Sub-paragraphs (a) to (f) are omitted.]

(g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia*:

(i) A dispute settlement clause;

(ii) Terms on benefit-sharing, including in relation to intellectual property rights;

(iii) Terms on subsequent third-party use, if any; and

(iv) Terms on changes of intent, where applicable.

Article 18, Compliance with Mutually Agreed Terms

1. In the implementation of Article 6, paragraph 3 (g) (i) and Article 7, each Party shall encourage providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including:
   (a) The jurisdiction to which they will subject any dispute resolution processes;
   (b) The applicable law; and/or
   (c) Options for alternative dispute resolution, such as mediation or arbitration.

2. Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.

3. Each Party shall take effective measures, as appropriate, regarding:
   (a) Access to justice; and
   (b) The utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.

4. The effectiveness of this article shall be reviewed by the Conference of the Parties serving as the meeting of the Parties to this Protocol in accordance with Article 31 of this Protocol.

(1) Explanatory Notes

An unexpected situation can sometimes arise in a joint research or business project conducted with a research institution or corporation in a country with different customs and culture, even if you have enjoyed a good relationship with your collaborators at the outset. Therefore, it is prudent to establish a risk management system in case of disputes. Particularly, you need to outline the following points in the contract after thorough discussion with your counterpart for the purpose of mitigating risk:

1) Determination of Jurisdiction

The contract should clarify in which country the legal action may be taken in the event that a dispute arises.

2) Determination of Applicable Law

The contract should clearly define which country's law is to be applied for judgment with regard to the interpretation of wordings in the contract and its validity.

There can be a number of ways of resolving disputes. The following examples represent major methods:

a) Direct negotiation between the parties involved:
   Resolution of disputes through mutual consultation between the parties involved would minimize the time and cost burden and is the most desirable solution.

b) Mediation, conciliation and arbitration:
   If a dispute should arise that the parties cannot resolve through direct negotiation, the next step would be to seek the involvement of a neutral third party. This step can be broadly classified as follows: i) the third party recommends a compromise between the parties after listening to their conflicting claims (mediation); ii) the third party presents the parties with a settlement plan (conciliation); and iii) the third party issues a judgment with which the parties are bound to comply (arbitration). (Please consult appropriate professionals with regard to the specific procedures.)

c) Litigation:

Dispute resolution through litigation may also be considered. Therefore, you need to clearly stipulate the jurisdiction and governing law when concluding a contract.

(2) Practical Problems and Suggested Solutions

Question 19: What are the advantages of resolving disputes through mediation, conciliation, or arbitration?

Answer 19: These resolution methods can reduce time and cost burdens, when compared to litigation. In addition, when different stakeholders make diverse claims based on the respective cultures and customs of the countries, the diverse claims may be reconciled.

Chapter III Other Issues

1. In-House Management Systems for Corporations and Other Organizations

(1) Explanatory Notes

To cope with the international situation surrounding the CBD and the Nagoya Protocol, it is increasingly important for corporations, universities, research institutes, and other relevant organizations, on their own initiative, to each put in place an appropriate in-house system. This is also an important element for maintaining and further developing good relations with providers and countries providing genetic resources.

It is particularly relevant for these in-house systems to strengthen their organizational management, through actions such as those set out below:

1) Disseminate information about the ABS principles of the CBD and the Nagoya Protocol throughout the organization;
2) Upgrade the in-house structure addressing access to and utilization of genetic resources, etc.; and
3) Upgrade the preservation and recording system for the genetic resources, etc. that have been either acquired from or provided to a source or entity outside of Japan.

When preparing such systems within your organization, you may consult with the JBA and METI, as necessary. They may be able to provide you with useful information.

Chapter IV　Roles of the JBA and the Ministry of Economy, Trade and Industry

(1) On behalf of **the Ministry of Economy, Trade and Industry (METI)**, **Japan Bioindustry Association (JBA)** has been implementing CBD-ABS for two decades. As a result, the JBA has accumulated many diverse experiences, and developed an extensive network with diverse countries. With this background, JBA has been offering advice, as requested, to corporations, universities, research institutes, individuals, etc. concerning ABS matters.

(2) METI can also be consulted not only for general questions about CBD-ABS but also for problems difficult for corporations to resolve on their own. The earlier you consult, the better, when you feel that there is a problem.

(3) Finally, we recommend that you conduct business or research activities according to **The Guidelines 2012**. If you do so, it will be much easier for JBA or METI to provide you with appropriate support.

Below are the contact information on JBA and METI:

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Reference Materials

I. The Convention on Biological Diversity
(The text of the Convention) http://www.cbd.int/convention/text/
(The official Japanese translation) http://www.biodic.go.jp/biolaw/jo_hon.html

2. The Nagoya Protocol
(English with Japanese translation by JBA,)
http://www.mabs.jp/archives/nagoya/index.html

3. The Bonn Guidelines
(The English text) http://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf
(Japanese translation by JBA) http://www.mabs.jp/cbd_kanren/guideline/index.html

4. Information sources for National Laws of Different Countries relating to Access to Genetic Resources and Benefit-Sharing
(1) CBD Secretariat website:
"ABS Measures Search Page" (http://www.cbd.int/abs/measures/)
(2) JBA website:
"Access to Biological Resources and Benefit Sharing based on the Convention on Biological Diversity (CBD): A Corporate Guide - CBD-related Information by Country" (http://www.mabs.jp/countries/index.html)

5. Examples of Agreements and Contracts relating to Access to Genetic Resources and Benefit-Sharing
"Standard Forms and Agreements, the National Cancer Institute, the National Institutes of Health, the United States"
(http://ttc.nci.nih.gov/forms/)

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