Guidelines on Access to Genetic Resources For Users in Japan

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

Tokyo, Japan

Chronology of the implementation of the CBD leading to the "Guidelines on Access to Genetic Resources for Users in Japan":

- 2002 The Bonn Guidelines are adopted at COP6 in February.
  In September, Japanese translation of the Bonn Guidelines is completed.
- 2003 - 2004 The Bonn Guidelines are disseminated by a series of public seminars and international symposia in major cities in Japan.
  In parallel with promotional activities for the Bonn Guidelines, Ministry of Economy, Trade and Industry (METI) started developing user-specific guidelines in cooperation with Japan.Bioindustry Association (JBA)
- 2005 "Guidelines on Access to Genetic Resources for Users in Japan" are completed in March, and published by METI on April 1.
  Public seminars are organized in major cities throughout Japan to disseminate the new Guidelines.
- 2006 In February, this English translation of the Japan's Guidelines is completed for distribution

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I. General Information

1. Background and Aims

(1) Background

1) The Convention on Biological Diversity (CBD) entered into force on December 29, 1993. The CBD stipulates that, 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 and that access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources. Each Contracting Party shall take legislative, administrative or policy measures with the aim of sharing in a fair and equitable way benefits arising from the use of these genetic resources.
The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization were adopted at the Sixth Meeting of the Conference of the Parties to the CBD (COP6) which took place in April 2002. The Bonn Guidelines are voluntary and intended to serve as inputs when developing and drafting legislative, administrative, or policy measures and contracts and other arrangements on access and benefit-sharing.

2) However, some countries assert that, since the Bonn Guidelines are not legally binding, they are insufficient as a mechanism for appropriate sharing, with providing countries, of benefits arising from the use of genetic resources.
In response to this, discussions took place at international conferences such as the World Summit on Sustainable Development (WSSD) held in 2002, and the Seventh Meeting of the Conference of the Parties to the CBD (COP7) held in 2004, regarding the need for a legally binding international regime. However, as there are many issues to be considered, an agreement has yet to be reached and the outlook for the future remains uncertain.

3) Companies involved in the use of genetic resources find themselves in a situation in which it is increasingly difficult for them to conduct effective projects using genetic resources, due to the lack of transparency in the procedure for accessing such resources and to the impacts of restrictive regulations put in place in some countries.
The use of genetic resources often involves searching for unknown substances, to begin with, and conducting research on them. It needs to be noted that the chance is extremely slim for

researchers to identify something of ultimate commercial value. Development of a product takes a great deal of time and costs, and therefore this process generally entails a considerable amount of risk. Consequently, if a country puts in place too strict a regulation on access to and benefit-sharing of genetic resources, it deters companies from seeking access to such resources.

4) Research and development in biotechnology is expected to produce one of the greatest achievements in the 21st century, and the bioindustry has the potential to revolutionize both industrial structures and human lifestyles. Japanese companies seem willing to carry out projects that would properly use genetic resources, but they feel that it has been increasingly difficult to do so because of the above-mentioned trends.
This situation also means that providing countries would be unable to enjoy the benefits that could be generated from the use of their genetic resources, and, as a result, both providing countries and users could become losers.

(2) Aims

1) With this background in mind, the Government of Japan believes that it needs to promote measures that will enable both providers and users to enjoy benefits from the use of genetic resources in the following way:
First, users such as companies and researchers should be encouraged to understand sufficiently the principles of access to genetic resources and fair and equitable sharing of benefits as stipulated in the CBD and the Bonn Guidelines,
Second, users should be encouraged to access genetic resources accordingly and build good relationships with providers based on mutual trust, thereby creating an environment for smooth access and for benefit-sharing on a long-term basis.

2) Based on this thinking, we have developed **these Guidelines on Access to Genetic Resources** as practical guide for users (hereinafter referred to as **the Guidelines**). In preparing these Guidelines, we consulted experts in academia and industry in Japan, as well as our colleagues in other countries that are blessed with biological diversity.

The specific aims of the Guidelines are as follows:

- To help both providers and users to build win-win relationships through smooth access to genetic resources and fair and equitable sharing of benefits arising from the use of genetic resources.

- To minimize the risk of getting involved in problems, while ensuring business flexibility, when users seek to utilize genetic resources for commercial purposes. Therefore, the Guidelines try to provide concrete explanations about the relevant provisions and terminology of the CBD and the Bonn Guidelines in order to make it easier for users to understand them.

3) The Guidelines are intended to guide users of genetic resources on a voluntary basis. Nothing in these Guidelines should be interpreted as changing the existing legal rights and obligations of users and providers of genetic resources.

2. Scope

(1) The scope of the Guidelines is the same as that of the Bonn Guidelines. In other words, "all genetic resources and associated traditional knowledge, innovations and practices covered by the CBD and benefits arising from the commercial and other utilization of such resources" are covered by the Guidelines, with the exclusion of human genetic resources (see Paragraph 9 of the Bonn Guidelines). Furthermore, some countries have already put in place regulations on the use of genetic resources, traditional knowledge, etc. by means of national laws, administrative measures, etc. In these cases, the scope of the laws and administrative measures of those countries will of course prevail, regardless of the scope of these Guidelines. Therefore, please ascertain the specific situation in the country where you wish to access genetic resources.

(2) Genetic resources covered by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) formulated by the Food and Agriculture Organization of the United Nations (FAO) are exempt from these Guidelines.

(3) These Guidelines are intended to enhance users' awareness and thereby prevent problems from arising when accessing the genetic resources of foreign countries. With regard to the laws and regulatory procedures relating to genetic resources within Japan, please refer to the relevant national laws (e.g. the Seeds and Seedlings Law, the Plant Protection Law, the Domestic Animal Infectious Diseases Control Law, the Law on the Prevention of Harm to Ecosystems Arising From Organisms of Foreign Origin, the Species Preservation Law, etc.)

3. Basic Concepts

(1) Treatment of Genetic Resources Under the Laws of 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 the national governments and is subject to national legislation.

Consequently, when accessing genetic resources of a country, the basic premise is first and foremost to conform to the laws and administrative measures stipulated by that country.

2) When accessing genetic resources of a country, please check the laws and administrative measures of that country by contacting its National Focal Point for the CBD (see Chapter II Section 1 “National Focal Point and Competent National Authority(ies)” in the Guidelines), or by consulting a legal expert in that country in case you need information in greater depth.

3) These Guidelines give examples of relevant laws and administrative measures in several countries for your information (see Appendices).

(2) Handling of Contracts

In some countries, there are no laws or administrative measures specifically 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 you negotiate a contract in such a situation, please bear in mind that the elements indicated in the Bonn Guidelines and the relevant provisions of the CBD have important implications as references.

(3) How to Use The Guidelines

1) The Guidelines present relevant provisions of the CBD and refer to issues often discussed at international forums. Moreover, the Guidelines present types of problems that you may encounter and suggest solutions to them in the Q&A sections.

2) If you are still unclear about key points or encounter problems in checking the regulatory system of a country or doing business there, Japan Bioindustry Association (JBA) or the Ministry of Economy,

Trade and Industry (METI) may be able to help you (see Chapter IV for the contact points).

4. Use of Terms

(1) Genetic resources

"Genetic resources" means genetic material (material of plant, animal, microbial or other origin containing functional units of heredity) of actual or potential value[1]. (see Article 2 of the CBD)

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

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

3) "User of genetic resources" means the entity (individual or organization) obtaining genetic resources from the country of origin of genetic resources or from the country providing genetic resources, and using them.

(3) Benefit

"Benefit" refers to the benefits the provider and/or the user of genetic resources obtain as a result of using those resources.

(4) Net profit

"Net profit" refers to net monetary profit after expenses have been deducted from revenue.

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[1] Definition of "genetic resources" in the national laws of countries

1) The Philippine's *Regulating Access to Biological and Genetic Resources in the Philippines:* (A Manual on the Implementation of Executive Order No. 247) (1997)
"Genetic resources" means genetic material of actual or potential value.

2) *The ASEAN Framework Agreement on Access to Biological and Genetic Resources (Draft, 2000*)
"Biological and Genetic resources" include genetic materials, organisms and parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity

(5) Prior Informed Consent (PIC)

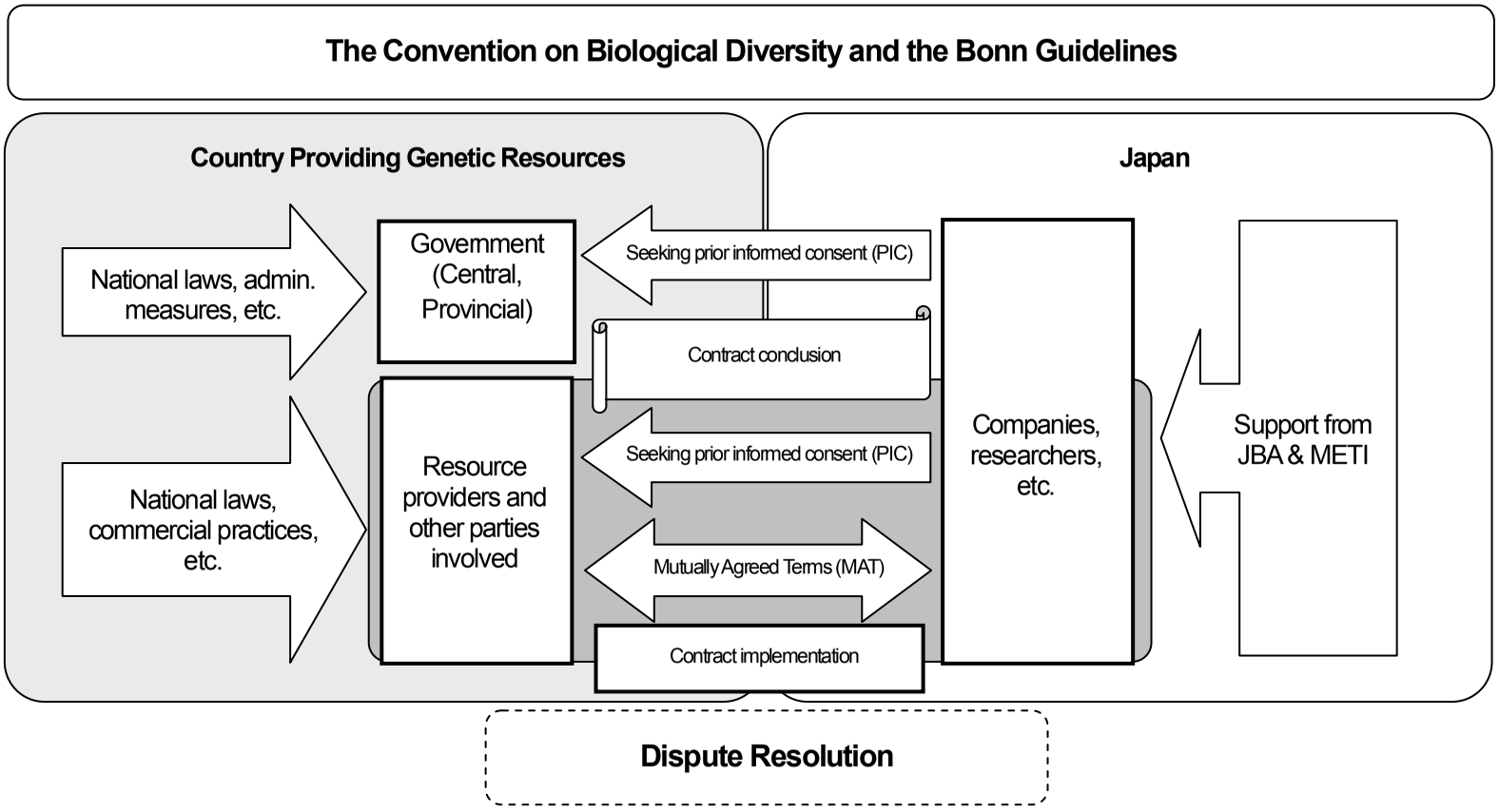
When a user wishes to access genetic resources in a foreign country, the user is obliged to submit required information to the government providing such resources, prior to the consent being granted, and subject to the laws and administrative measures of that country (see Article 15, Clause 5 of the CBD).

It may also be necessary in some cases to obtain similar prior informed consent from other stakeholders of the resources including those in the relevant indigenous and local communities (see Chapter II Section 2 Prior Informed Consent (PIC)).

(6) Mutually Agreed Terms (MAT)

Access to genetic resources and sharing of benefits arising from their use must be conducted on the basis of an agreement between the provider of the genetic resources and the user thereof. The terms and conditions need to be stipulated, usually in a contract between the parties concerned, subject to the laws and administrative measures of the country providing such resources (see Article 15, Clauses 4 & 7 of the CBD).

II. Steps in the Access and Benefit-Sharing Process



II. Steps in the Access and Benefit-Sharing Process

1. National Focal Point and Competent National Authority(ies)

Principles Set Forth in the CBD

[Basis: Article 15, Clause 1 of the CBD; Paragraphs 13 & 14 of the Bonn Guidelines]

[Key clause] Article 15, Clause 1 of the CBD
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.

(1) Explanatory Notes

1) Meaning

The principle in the CBD is that the authority to regulate access to genetic resources rests with the governments of the countries providing such resources. This authority is to be set out in national legislation. Accordingly, when accessing genetic resources, any user needs to check the laws and administrative measures of that country.

As the national focal point (see below) and the competent national authority(ies) (see below) are designated by that country, the user can request their assistance in making necessary inquiries.

2) National Focal Point

Most of the Contracting Parties have designated a single national focal point under the CBD and this information is available through such sources as the website of the Secretariat to the CBD (http://www.biodiv.org/world/map.asp)[2].

The national focal point is supposed to provide information, including on the competent national authority(ies), relevant indigenous and local communities and other stakeholders.

3) Competent National Authority(ies)

The competent national authority(ies) are those responsible for granting access to genetic

[2] In the CBD, this system for information dissemination is called the Clearing-House Mechanism

resources according to the applicable laws, administrative or policy measures of that country, and which may provide advice on the following points (these roles can be delegated to other entities as is deemed appropriate, and these entities are not necessarily governmental institutions):

(a) The negotiating process;
(b) PIC & MAT requirements;
(c) Monitoring and evaluation of access and benefit-sharing agreements;
(d) Implementation of access and benefit-sharing agreements;
(e) Processing of applications, and approval of agreements;
(f) Conservation and sustainable use of the genetic resources accessed;
(g) Mechanisms for the effective participation of different stakeholders, particularly indigenous and local communities, in the process of access and benefit-sharing.

Concerning information on the competent national authority(ies), please refer to the Clearing-House Mechanism of the Secretariat to the CBD (CHM-CBD) (http://www.biodiv.org/world/map.asp).

(2) Implementation in Different Countries

Details of the national focal points and competent national authority(ies) of Contracting Parties are available on the CHM-CBD.

It should be noted that, in some cases, the entities with actual responsibility may be different from the competent national authority(ies) designated on the CHM-CBD.

(3) Practical Problems and Suggested Solutions

Question 1: What should I do when I do not get a prompt reply after contacting the national focal point, or when I receive only a preliminary reply from the national focal point, but then I am kept being referred to different departments without meaningful progress?

Answer 1: It would be necessary for you to continue your efforts to establish a contact with the most appropriate entity of that government. However, if you still do not receive any response, you may consult JBA or METI which may have useful information. (Please refer to Chapter IV for the contact information on JBA and METI's division handling such inquiries.)

Question 2: What should I do if there is no information given in the CHM-CBD on the national focal point or the competent national authority(ies) of a country?

Answer 2: Please refer to the JBA's specialized website (http://www.mabs.jp/). If that turns out to be fruitless, you may consult JBA or METI which may have useful information. (Please refer to Chapter IV for the contact information on JBA or METI's division handling such inquiries.)

2. Prior Informed Consent (PIC)

Principles Set Forth in the CBD

[Basis: Article 15, Clauses 1, 2, 3 & 5 of the CBD; Paragraphs 26, 27, 28, 33, 34, 36, 38, 39 & 40 of the Bonn Guidelines]

[Key clause] Article 15, Clause 1 of the CBD 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. **[Key clause]** Article 15, Clause 2 of the CBD 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. **[Key clause]** Article 15, Clause 5 of the CBD Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

(1) Explanatory Notes

1) Meaning

In ordinary contracts, all you need is that the parties directly involved agree on the content of the contract. However, when accessing genetic resources in a foreign country, the CBD requires that, subject to its national legislation, prior informed consent be obtained from its government

(central and/or provincial) and possibly from other stakeholders, in addition to the parties directly involved in the contract.

More specifically, if it is so stipulated in the applicable laws and administrative measures of the government providing the genetic resources, specified items of information must be provided before consent is granted by the designated entities *(Prior Informed Consent, PIC)*. Furthermore, it is necessary to obtain PIC from stakeholders such as indigenous and local communities, if there is such a requirement in the laws and administrative measures of the government providing the genetic resources.

2) What to obtain from whom for PIC

For PIC, what should you obtain from whom? The following are likely cases:

i) From your direct counterpart

It is essential to obtain prior informed consent for access to genetic resources from your counterpart, through, e.g. concluding of a contract.

ii) From the government of the country providing genetic resources

In the case where the laws and administrative measures of the government providing genetic resources stipulate requirements for PIC, you must follow the procedures by, e.g. providing the specified information and applying for a permit.

iii) From other stakeholders

In some countries or regions, there may be stakeholders (e.g. indigenous and local communities), other than those stipulated in the laws and administrative measures, who maintain their customary rights over genetic resources and associated traditional knowledge. In such a situation, it will be necessary to obtain PIC in compliance with the customary rules of that country or region.

3) Points to Note

It is important that you study the need for and the procedures of obtaining PIC in the country or region where you wish to access genetic resources. You should bear in mind the following points when doing this:

i) Entity(ies) issuing PIC

- At what level of government should you obtain PIC in the country? (From the central government, provincial government, or both?)

- Are there any national laws or administrative measures which require you to obtain PIC from relevant indigenous and local communities having rights over genetic resources or associated traditional knowledge? Is there any customary law unique to that region which requires you to obtain PIC?

ii) Procedures for obtaining PIC

- What are the requirements that the laws and administrative measures stipulate for PIC?
- Steps in the process of obtaining PIC:
  (a) Identify the competent authority(ies) to which you should submit application for PIC or to which you make inquiries about PIC;
  (b) Identify the necessary format for application and specific items of information required (e.g. purpose, duration, specifics of the genetic resources to be accessed, fees, etc.); and
  (c) Any other requirements or conditions for obtaining PIC.
- Confirm whether PIC is granted only for the specified use of the genetic resources and whether you need to apply for a new PIC when a need arises for a change in use, including transfer of the resources to a third party.
- Confirm whether PIC is to be provided in a documented form, and within how many days you will be informed of the decision on PIC after the application is accepted.

(2) Examples of Laws in Different Countries

Please refer to the Appendices at the end of the Guidelines for examples of laws in different countries.

(3) Practical Problems and Suggested Solutions

Question 1: What should I do, if I do not find information on a country's entity responsible for PIC in the CBD's Clearing House Mechanism?

Answer 1: Please check if there is any related information in the JBA's '*Access to Biological Resources and Benefit Sharing'* website (in Japanese)(http://www.mabs.jp/). If that turns out to be fruitless, you may consult JBA or METI which may have useful information. (Please refer to Chapter IV for the contact information on JBA or METI's division handling such inquiries.)

Question 2: Is it necessary to obtain PIC once again for those genetic resources that have been obtained before the CBD entered into force (29 December 1993)?

Answer 2: It is generally accepted on the basis of the CBD that there is no obligation to obtain PIC with regard to the genetic resources that have been obtained before the CBD entered into force. Likewise, if a providing government ratified the CBD after 29 December 1993, there is no obligation to obtain PIC with regard to the genetic resources obtained from that country prior to the date when the CBD entered into force in that country. However, in the case where in the laws and administrative measures of the providing country regarding pre-CBD matters provide otherwise, it is necessary to comply with them.

Question 3: I made an application for PIC to the relevant authorities of the country, in which my business counterpart is based, in accordance with their laws. A number of months have passed since then, but I still have not been informed by the authorities whether or not permission has been granted. What should I do?

Answer 3: First of all, you need to make inquiries and requests with the national competent authority(ies) in that country. If there is still no progress after you have done so, you may be able to obtain useful information by consulting JBA or METI. (Please refer to Chapter IV for information on JBA or METI division handling such inquiries.)

Question 4: How can I verify that PIC has been obtained in a case where the genetic resources are provided indirectly to me via a commercial intermediary?

Answer 4: You need to check whether the commercial intermediary has obtained the genetic resources in compliance with the procedure stipulated by the laws and administrative measures of the country providing the genetic resources, and whether the intermediary has been authorized by that government to transfer those genetic resources to a third party user.

The ways of verifying these include obtaining a copy of the document from the intermediary that demonstrates that PIC was legitimately obtained for such purposes. If this proves difficult, the contract between you and the intermediary should include a clause stating explicitly that the intermediary warrants that it has obtained the genetic resources in compliance with the laws and administrative measures of the providing country. In order to avoid risk, we recommend that you, independently of the intermediary, check with the government providing the genetic resources what procedure is required for PIC under their national laws and administrative measures.

Question 5: Is it necessary to obtain PIC when acquiring genetic resources from culture collections (i.e., *ex situ* collections of microbial resources)?

Answer 5: Ex situ collections are subject to the CBD. If the law of the country where the culture collection or BRC[3] is situated requires PIC, then you must obtain PIC. Moreover, if the ex situ collection obtains a genetic resource from a third country and provides it to users, then the ex situ collection is considered to be a kind of intermediary. In that case, you need to follow the steps outlined in the Answer to Question 4 above.

A number of culture collections and BRCs have close relationships with governmental bodies. They often have prior agreements in place with governments of other countries concerning the transfer of genetic resources to third party users. If that is the case, the procedure for obtaining PIC from the providing country will be simplified, and you would be able to handle a situation more easily, in the event that someone asks you to show evidence of PIC.

Question 6: What should I do in the case that an intermediary (including culture collections and BRCs) insists that there is no need to worry about PIC, on the ground that the genetic resources have been obtained before the CBD entered into force?

Answer 6: The CBD is not retroactive, and therefore this case is generally not subject to the requirement for obtaining PIC. Nevertheless, depending on a country, there may be cases in which the country's laws and administrative measures impose obligations to obtain PIC for their genetic resources transferred before the CBD entered into force. Therefore, it is necessary to verify that there is indeed no need to obtain PIC regarding the pre-CBD genetic resources in question. Regarding the ways of verifying that, please refer to the Answer to Question 4 above.

Question 7: I bought an endemic species of plant in Country A for ornamental purposes. After returning to my home country, I happened to test it in my research and discovered that it contained a constituent peculiar to that species and that the constituent has potential for commercialization. If I wish to proceed to develop a commercial product, is it necessary for me to obtain PIC from Country A?

Answer 7: First, if you signed a contract when you bought it and if the contract includes a clause concerning the use of the genetic resource for purposes other than those stated, then, it is clear that

[3] Abbreviation for Biological Resource Center. National Institute of Technology and Evaluation (NITE) is a microbiological BRC in Japan.

you must comply with the terms, irrespective of the CBD.

Second, in some countries PIC is required under its domestic law, when you conduct R&D and commercialization using genetic resources obtained in that country. In such a case, you need to obtain PIC from that country, whether you signed a sales contract or whether you bought the genetic resource simply at a market in that country.

Third, there are countries that do not have national laws regulating such cases. In that case, there is no legally binding obligation to obtain PIC. But it is possible that your conduct might be criticized as improper by some people of that country if you successfully commercialize the product. Such a public outcry could be detrimental to your company's reputation. Therefore, even where there is no legal obligation, it would be wiser for you to consult the government of that country.

Please note that the aforementioned discussion is applicable not only to plants, but also to any other kind of genetic resources.

3. Mutually Agreed Terms (MAT)

Principles Set Forth in the CBD

[Basis: Articles1, 8(j) and 15, Clauses 2, 4 & 7 of the CBD; Paragraphs 41, 42, 43, 45 & 49 of the Bonn Guidelines]

[Key clause] Article 1 of the CBD
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 abbreviated).

[Key clause] Article 15, Clause 2 of the CBD
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.

[Key clause] Article 15, Clause 4 of the CBD
Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

[Key clause] Article 15, Clause 7 of the CBD
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.

[Key clause] Article 8, Clause (j) of the CBD
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.

A. Meaning of Mutually Agreed Terms (MAT)

(1) Explanatory Notes

1) As in the case of all other ordinary transactions, access to genetic resources and sharing of benefits should take place under the terms that both a provider and a user of genetic resources agree. This is explicitly stated in Article 15, Clause 4 of the CBD.

2) Therefore, the parties involved should negotiate the terms on which they can agree. It is not easy to judge what kind of agreement and which items of terms are considered most conforming to the CBD. An indicative list of typical mutually agreed terms are given in Paragraph 44 of the Bonn Guidelines (see Reference I in the Appendices of this document). In addition, please also see Reference III in the Appendices of this document, as examples of contracts (agreements) that have been published.

3) When conducting negotiation of mutually agreed terms with your counterpart, it is advisable to study not only the laws and administrative measures for access to genetic resources in the country of your counterpart, but also its laws and business practices relating to trade.

4) If you have any queries or problems, please consult JBA or METI, as they may have useful information.

(2) Practical Problems and Suggested Solutions

Question 1: Our negotiation of mutually agreed terms has been taking a long time. What should we do?

Answer 1: It is not uncommon that negotiations for the sharing of benefits take a long time. Please judge for yourself whether to continue or terminate the negotiation.
In the case of microbiological resources, some public institutions in Japan have concluded research agreements with governmental institutions in other countries, and opportunities are open for private companies to participate in projects with them.
If you have any queries or problems, please consult JBA or METI, as they may have useful information.

Question 2: What kind of items should I bear in mind with regard to mutually agreed terms?

Answer 2: Please refer to Paragraph 44 of the Bonn Guidelines. It provides an indicative list of typical mutually agreed terms (see Reference I in the Appendices of this document).

Question 3: I am interested in research and development using unique traditional knowledge. But I cannot identify the stakeholders for the traditional knowledge under consideration, so am unable to conclude a contract. What should I do?

Answer 3: Traditional knowledge is not defined in the CBD. It is generally the case that the definition of traditional knowledge unique to a country or region is not clear, and therefore, identifying the relevant stakeholders is not easy at all. It is necessary to consult the competent national authority(ies) of the country in question to handle your specific case.
In addition, you may consult JBA or METI, as they may have useful information.

B. Handling of Cases Involving the Transfer of Materials: Material Transfer Agreements (MTA)

(1) Explanatory Notes

1) In the case of agreement involving the transfer of genetic resources, the conclusion of a Material Transfer Agreement (MTA) between the provider and the user of the genetic resources is a general practice worldwide.
MTA is a contract that stipulates the terms for the transfer of genetic resources. Elements in MTA include the following:
- The kind and quantity of genetic resources to be transferred;
- The timing of the transfer;
- Permitted uses of the transferred genetic resources (research, commercialization, etc.); and
- Whether the genetic resources may be transferred to third parties and if so the conditions and procedures that should apply.

2) For suggested elements of MTAs, refer to Appendix I of the Bonn Guidelines (see Reference I in the Appendices of this document).

3) Since an MTA is a kind of contract based on mutually agreed terms, its content should be determined by the parties involved. But, in some countries, national laws and administrative

measures may contain specific stipulations concerning the content of MTA. Therefore, it is advisable to study sufficiently the laws and administrative measures of the country in question.

(2) Practical Problems and Suggested Solutions

Question 1: Is it impossible to have genetic resources transferred unless one complies with the MTA suggested by the providing side?

Answer 1: If the suggested MTA is stipulated by the laws and administrative measures of the providing country, it is of course necessary to comply with the content of the suggested MTA. Consequently, you need to clarify with the national competent authority(ies) of that country what kind of MTA content complies with that country's laws and administrative measures.

There may be other cases in which your counterpart in the contract negotiation requests you to comply with a standard MTA based on his/her own policy, but not based on the laws and administrative measures of that government. In this case, there is no obligation for you to agree, and therefore, while you pay a due respect to the standard MTA proposed by your counterpart, you should negotiate on your own judgment to determine the content of the contract.

C. Benefit-Sharing

(1) Explanatory Notes

1) Background

When drafting of the CBD was being negotiated, some delegates pointed out that, when some countries gained economic benefits using another country's genetic resources, they did not share any part of the benefits with the country that provided the resources; they insisted that their entitlement to the sharing of the benefits from such resources be explicitly recognized in the Convention. As a result, Article 1 of the CBD stipulates that, "The objectives of this Convention…are…the fair and equitable sharing of the benefits arising out of the utilization of genetic resources ". Moreover, specific provisions for this statement are set forth in Article 15 of the CBD (Access to Genetic Resources).

2) The Content of Benefit-Sharing

i) Meaning of benefits

The term benefits, as in "benefits arising out of the utilization of genetic resources", does not

refer specifically to net monetary profit that remains after expenses have been deducted from the revenue generated from the product that has used the genetic resources; rather, the word is used in a broader sense.

ii) Types of benefits to be shared and ways in which sharing can be done

The "benefits arising out of the utilization of genetic resources" can broadly be classified into two types: monetary benefits and non-monetary benefits. Non-monetary benefits such as technology, knowledge, research results and patents[4], are of value to both the provider and the user of the genetic resources, although they may not generate any money in the short-term. Benefit-sharing may be done in the following way:

a) Benefit-sharing by monetary means: This is a method of sharing benefits directly in a monetary form. An example would be a case in which a user pays a royalty as a certain percentage of the revenue (or net profit) earned from a product that uses the genetic resources, assuming the point of time at which the product's development costs will have been recouped.

b) Benefit-haring by non-monetary means: An example would be a case in which a company's technology is transferred to the providing country by including their researcher(s) in R&D activities, while sharing results of the joint activities.

(Please refer to Appendix II of the Bonn Guidelines, which sets forth examples of the sharing of both monetary and non-monetary benefits.)

When you use genetic resources, you should share benefits fairly and equitably according to the content of the agreement with the counterpart in compliance with the CBD. The mechanism of benefit-sharing should be determined by negotiation with the counterpart. For example, there may be cases in which the counterpart prefers non-monetary benefits, such as your technical assistance provided to their local staff, rather than monetary benefits. It is important to ascertain what the counterpart really wants and to negotiate an agreement to build a relationship in such a way that both parties can enjoy the benefits resulting from the resources (win-win relationship).

[4] As a method of benefit-sharing, handling of patent rights (e.g., who bears the cost burden of applying for and maintaining patents? and which side is responsible for what percentage of rights and obligations?) can be a subject of considerable discussion. Therefore, both sides need to study it closely beforehand for mutual agreement

3) Points to Note

i) Handling of laws and administrative measures of countries

In negotiations, appropriate attention should be paid with regard to the laws and administrative measures of the country in addition to its business practices and legal system, e.g., regarding trading, as there are some countries where methods for the sharing of benefits are regulated by the government.

ii) Points to remember in negotiations

- Mutual understanding of the benefits to be shared

  In negotiations, it is important to ensure that your counterpart and yourself understand exactly what benefits are to be shared, before you come to an agreement. For example, in sharing monetary benefits, you may take it as a matter of course that the benefit is the sum remaining after R&D costs and other expenses have been deducted from the sales revenue from the product. However, the assumption of your counterpart could be different from yours in a different country or situation.

  Moreover, in negotiations, it is essential for you to ensure that your counterpart accurately understands that the process of R&D and commercialization takes a considerable length of time before any benefit is actually generated and that a large amount of profit does not arise quickly.

  Furthermore, you need to explain that the process of developing commercial products that use genetic resources often begins with exploratory research followed by lengthy R&D steps. The probability that a product will ultimately be placed on the market is generally extremely low. Therefore, only in a limited number of cases, will it be possible to share the benefits arising from commercialization. (If you do not explain it sufficiently, your counterpart's expectations for benefit-sharing may become unrealistically high.)

- Approach to benefit-sharing (degree of contribution)

  The fair and equitable sharing of benefits does not mean sharing benefits on a fifty-to-fifty basis. For example, if the net profit from a product was ¥1 million, you do not necessarily have to pay 50% of it to your counterpart who provided the genetic resource. Consequently, it is vital for both you and your counterpart to reach an agreement on the percentages in which the benefits should be shared, after taking into consideration all relevant factors such as the degree of contribution made by each party to the successful development of the product.

If you have any queries, please consult JBA or METI. You may be able to obtain useful information from them. (Please refer to Chapter IV for information on the JBA and METI divisions handling such inquiries.)

(2) Practical Problems and Suggested Solutions

Question 1: How should I handle derivatives and products of genetic resources?

Answer 1: There has been no international consensus on the definitions of derivatives[5] and products of genetic resources. Therefore, it is important that the parties involved in your negotiation discuss and concretely stipulate the mutually agreed definitions and benefit-sharing method within the framework of your own contract.

In some countries, these matters are stipulated in their laws and administrative measures. You may also need to note business practices and other legal systems, e.g. trading, of the country that you are interested in. We recommend that you closely study these points before your negotiation takes place.

Question 2: I am interested in conducting research and development using traditional knowledge. How should I share the benefits and with whom?

Answer 2: Traditional knowledge[6] is not defined within the CBD and there has been no international

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[5] Definition of "derivatives" in different countries

i) The Philippines *An Act Providing for the Conservation and Protection of Wildlife Resources and Their Habitats, Appropriating Funds Therefor and For Other Purposes.* (Republic Act No.9147) (2001)
"By-products and derivatives" means any part, taken or substance extracted from wildlife, in raw or in processed form. This includes stuffed animals and herberium specimens.

ii) ASEAN *The ASEAN Framework Agreement on Access to Biological and Genetic Resources (Draft 2000*)
Derivatives: something extracted from biological and genetic resources such as blood, oils, resins, genes, seeds, spores, pollen and the like as well as the products derived from, patterned on, or incorporating manipulated compounds and/or genes.

iii) Organization of African Unity *The African Model Law (2001)*
Derivative is a product developed or extracted from a biological resource; a derivative may include plant products as plant varieties, oils, resins, gums, proteins etc

iv) Results of the Pilot Project for Botanic Gardens: *Principles on Access to Genetic Resources and Benefit-Sharing, Common Policy Guidelines for Botanical Gardens to Assist with Their Implementation and Explanatory Text (2000)*
"Derivatives" includes, but are not limited to any progeny, extracts and compounds obtained from genetic resources and analogues of those compounds.

[6] Definition of "traditional knowledge" in different countries.

i) Thailand *Law on Protecting and Promoting Traditional Knowledge of Thai Folk Medicine* (1999)
refer to http://www.mabs.jp/kunibetsu/thai/thai 0.3.html for Japanese translation.

ii) Malaysia *The Sarawak Biodiversity Regulations (2004)*
"ethnobiology" means the knowledge or information pertaining to the uses by the natives of the State of biological resources for medicinal, food, health or other purposes including the classification, indigenous nomenclature, conservation techniques and general sociological importance of such biological resources to them

iii) ASEAN *ASEAN Framework Agreement on Access to Biological and Genetic Resources (Draft, 2000*)
Traditional knowledge: knowledge, innovations and practices of indigenous and local communities relating to the use, properties, values and processes of any biological and genetic resource or any part thereof.

iv) Pacific Region *Model Law for the Protection of Traditional Knowledge and Expressions of Culture (2002)*
"Traditional knowledge" includes any knowledge that generally:

consensus on the handling of such knowledge. Therefore, we cannot offer generally applicable guidance to your question. As stated above, identifying the stakeholders is not easy. What you should do, therefore, is to consult the competent national authority(ies) of the country under consideration.
If you have further queries, please consult JBA or METI, as they may have useful information.

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a) is or has been created, acquired or inspired for traditional economic, spiritual, ritual, narrative, decorative or recreational purposes; and
b) is or has been transmitted from generation to generation; and
c) is regarded as pertaining to a particular traditional group, clan or community of people in [Enacting country]; and
d) is collectively originated and held.

"Traditional owners" of traditional knowledge or expressions of culture means:
a) the group, clan or community of people; or
b) the individual who is recognized by a group, clan or community of people as the individual;
in whom the custody or protection of the traditional knowledge or expressions of culture are entrusted in accordance with the customary law and practices of that group, clan or community.

III. Other Provisions

1. Dispute Resolution

Provisions Set Forth in the Bonn Guidelines

[Basis: Paragraph 59 of the Bonn Guidelines]

[Key clause] Paragraph 59 of the Bonn Guidelines
As most obligations arising under mutually agreed arrangements will be between providers and users, disputes arising in these arrangements should be solved in accordance with the relevant contractual arrangements on access and benefit-sharing and the applicable law and practices.

(1) Explanatory Notes

An unexpected situation can sometimes arise in a joint research or business conducted with a company or research institution in a country with a different culture and environment, even if you had a good relationship with your collaborators at the outset. Therefore, it is prudent to establish a risk management system. After thorough discussion with your counterpart, it will be helpful for both parties to outline in the contract about the following points 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

With regard to the interpretation of wordings in the contract and its validity, which country's law is to be applied for judgment is important. Therefore, the law applicable to the contract should be clearly defined in the contract.

3) Procedure for Dispute Resolution

There may be a number of steps as a means of international dispute resolution. These should be clarified in the contract.

There can be a number of ways for resolving disputes; the following are examples representing

main methods:

a) Direct negotiation between the parties involved

Resolving of dispute 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 and if the parties cannot resolve it 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)[7]. (Please consult appropriate professionals with regard to the specific procedures.)

c) Litigation

If both a) and b) mentioned above fail, resolving the dispute through litigation is the last resort. Therefore, at the time of concluding a contract, you need to define the jurisdiction, the law applicable to the contract, and the location of the court to which any lawsuit should be brought, in the case that litigation is pursued.

(2) Practical Problems and Suggested Solutions

Question 1: What are the advantages of resolving disputes through mediation, conciliation or arbitration?

Answer 1: Compared with litigation, these solutions would enable you to reduce your time and costs. Another advantage would be that, if different stakeholders make diverse claims based on their respective cultures and customs, you may be able to find a neutral person who is competent to handle the situation for reconciling the difference.

In some situations, you may ask the government or a government-associated entity of the country that your contract counterpart belongs to, for mediation, conciliation or arbitration.

You may encounter a case where dispute could be prolonged and a breakthrough could seem unlikely. Before the problem becomes too serious, you may consult JBA or METI. They may have useful information.

[7] The Japan Commercial Arbitration Association website (http://www.jcaa.or.jp/arbitration-j/kaiketsu/t-1.html)

Question 2: In the event that mediation, conciliation or arbitration becomes necessary, what kind of person would be appropriate as a neutral third party?

Answer 2: For example, a person with common sense, wisdom, knowledge and experience in the matter of genetic resources who may be from academia or the private sector, a legal expert from the counterpart country, or a person representing a relevant public institution.

2. In-House Management Systems for Companies and Other Relevant Organizations

Explanatory Notes

To cope with the international situation surrounding the CBD, it has become increasingly important for companies and other relevant organizations to put in place an appropriate in-house system for developing good relations with providing countries.
Recent trends within Japan and overseas[8] indicate the benefit of acting positively to the situation, for example, by strengthening your organizational management system with regard to access to and benefit-sharing of genetic resources.

Voluntary measures taken by some leading companies are given below as examples:

1) Dissemination of the key points of the CBD throughout the company;
2) Upgrading of the in-house system for access to and use of genetic resources; and
3) Upgrading of the storage and recording system for the genetic resources obtained

When you upgrade your organizational in-house system, you may consult JBA or METI which may have useful information.

8 Kerry ten Kate & Sarah A Laird, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit Sharing* (London: Earthscan Publications Ltd., 1999), pp.303-312
Mikihiko Watanabe & Satoshi Nimura (Eds.) *Access to Biological Resources* (Toyo Keizai Shinposha, 2002), p.260

IV. The Roles of JBA and METI

(1) Ministry of Economy, Trade and Industry (METI) can give advice to companies and other users of genetic resources about problems that they find it difficult to solve on their own, in addition to answering general questions about the CBD. We suggest that you consult us at as early a stage as possible before the problem becomes too serious.

(2) Japan Bioindustry Association (JBA) has been active in this field for many years. It has experience in diversified projects and situations, and has developed a network of contacts in different countries. On that basis, JBA can give advice to researchers as well as companies doing research or business relating to genetic resources.

(3) If you do business in a way that conforms to the Guidelines, it will be easier for us to provide you with appropriate support. Therefore, we recommend that you read the Guidelines thoroughly.

The contact points are as follows:

★ JBA Research Institute, Japan Bioindustry Association (JBA)
Tel: 03-5541-2731 Fax: 03-5541-2737 E-mail: abs.info@jba.or.jp

★ Bio-business Promotion Office, Bio-Industry Division, Manufacturing Industries Bureau, Ministry of Economy, Trade and Industry (METI)
Tel: 03-3501-8625 Fax: 03-3501-0197 E-mail: cbd-abs@meti.go.jp

Appendices

References

I. The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization
http://www.biodiv.org/doc/publications/cbd-bonn-gdls-en.pdf

II. Examples of Laws in Different Countries Concerning Access to Genetic Resources and Benefit-Sharing
(1) Laws of Sarawak, Chapter A106, State of Sarawak, Malaysia
Sarawak Biodiversity Centre (Amendment) Ordinance, 2003
The Sarawak Biodiversity Regulations, 2004
(2) Act No. 19 of 2004, State of Queensland, Australia
Biodiscovery Act 2004
http://www.legislation.qld.gov.au/LEGISLTN/ACTS/2004/04AC019.pdf.

III. Examples of Agreements and Contracts Concerning Access to Genetic Resources and Benefit-Sharing
(1) Memorandum of Understanding between NITE (Japan) and BPPT (Indonesia)
(http://www.bio.nite.go.jp/nbdc/asia_indonesia.html)
(2) Standard Forms and Agreements, National Institutes of Health, the United States
(http://ttb.nci.nih.gov/forms.html)

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