After six years of negotiation, 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 (hereinafter ‘Nagoya Protocol’ ‘Protocol’) was adopted on 29 October 2010, at the 10th Conference of the Parties to the Convention on Biological Diversity held in Nagoya, Japan. The Protocol entered into force on 12 October 2014. The objective of the Protocol is ‘the fair and equitable sharing of the benefits arising from the utilization of genetic resources, ... thereby contributing to the conservation of biological diversity and the sustainable use of its components’ (Article 1). As of 30 June 2017, 99 countries and the EU have become Parties to the Protocol.

After six and half years of deliberation for ratification, Japan deposited its instrument of acceptance on 22 May 2017 after being approved by the Diet and the Nagoya Protocol shall enter into force for Japan on 20 August pursuant to its Article 33.2. The Explanatory Note presented by the Ministry of Foreign Affairs to the Diet for its approval of the conclusion of the Nagoya Protocol explains that ‘any new legislative measures are not required for implementing the Nagoya Protocol’ (Ministry of Foreign Affairs, 2017, p. 10). On 18 May 2017, six ministries jointly issued the Guideline for Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS Guideline) as measure to implement the Protocol, which shall be effective on the day of entry into force of

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* Ph.D Student, Graduate School of Environmental Studies, Nagoya University, Aichi. Research fields are international environmental law, in specific the aspects of implementation of environmental treaties in biodiversity regime and climate regime.  
E-mail: morinaka.yuki@c.mbox.nagoya-u.ac.jp

** Professor of international law, Graduate School of Environmental Studies, Nagoya University, Aichi.  
E-mail: takamura.yukari@g.mbox.nagoya-u.ac.jp
the Nagoya Protocol for Japan.

This article provides an overview of the ABS Guideline as measure to implement the Nagoya Protocol after briefly introducing the Protocol itself. It then presents some evaluation on the ABS Guideline. The evaluation provided here is of preliminary nature; more accurate and comprehensive evaluation should be made through looking into the actual application of and practices around the ABS Guideline.

(1) Main Obligations of Parties under the Nagoya Protocol

The Nagoya Protocol applies to genetic resources and traditional knowledge associated with genetic resources within the scope of Article 15 of the Convention on Biological Diversity (CBD), and benefits arising from their utilization (Article 3 of the Nagoya Protocol). The CBD defines in its Article 2 that ‘Genetic resources’ means genetic material of actual or potential value.

The Nagoya Protocol imposes obligations on both parties providing and using genetic resources. Parties may be both providers and users of genetic resources.

For the Parties providing genetic resources, Article 5.1 requires that benefits arising from the utilization of genetic resources shall be shared in a fair and equitable way with the party providing genetic resources. Such sharing shall be upon mutually agreed terms (MAT). Article 5.3 requires each Party to take measures, as appropriate, to implement Article 5.1.

Article 6 provides for access to genetic resources. Article 6.1 requires that access to genetic resources is subject to prior informed consent (PIC) by the Party providing such genetic resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the CBD, unless otherwise determined. Article 6.3 obliges each Party requiring PIC to take the necessary legislative, administrative or policy measures, as appropriate, pursuant to Article 6.1. Such measures include measures to create legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements, measures to provide information on how to apply for PIC and to establish clear rules and procedures for requiring and establishing MAT, as well as measures to provide for issuance of a permit or its equivalent as evidence of the decision to grant PIC and of the establishment of MAT and to notify the Access and Benefit sharing Clearing-House (ABS Clearing-House).

Article 7 regulates access to traditional knowledge associated with genetic resources. In accordance with domestic law, each Party shall take measures, as appropriate, with the
view to ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the PIC and involvement of these indigenous and local communities, and that MAT have been established.

Parties providing genetic resources are thus required to take measures to clarify the scope and content of PIC, and the condition of MAT in taking domestic ABS measures.

For the Parties using genetic resources, Article 15.1 requires each Party to ‘take appropriate, effective and proportionate 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 15.2 requires Parties to ‘take appropriate, effective and proportionate measures to address situations of non-compliance with the measures’ adopted in accordance with Article 15.1.

Article 16 is formulated in a way parallel to Article 15, with difference that it addresses traditional knowledge associated with genetic resources. Articles 15 and 16 allows Parties discretions in their implementation (Greilber, 2012), for instance, in their choice of measures. Furthermore, Parties are required to take measures and that these measures are ‘appropriate, effective and proportionate’.

Article 17 (1) requires each Party to take measures, as appropriate, to monitor and enhance transparency about the utilization of genetic resources in order to support compliance.

The Nagoya Protocol thus requires that access to genetic resources is subject to prior informed consent (PIC) by the Party providing such genetic resources and that benefits arising from the utilization of genetic resources shall be shared in a fair and equitable way with the party providing genetic resources upon MAT. The Party providing genetic resources is obliged to take measures as appropriate for this purpose. Each Party is obliged to take appropriate, effective and proportionate measures to ensure that genetic resources utilized within its jurisdiction have been accessed in accordance with PIC and MAT as required by the Party providing such resources, and it is obliged to take appropriate, effective and proportionate measures to address situations of non-compliance with such measures. The Protocol will thus create legal certainty and transparency for both providers and users of genetic resources and thereby enhance the third pillar of the objectives of the CBD, that is the fair and equitable sharing of the benefits arising out of the utilization of
genetic resources (Secretariat of the Convention on Biological Diversity, 2011).

(2) Deliberation on Measures to Implement the Nagoya Protocol in Japan

i. Japan’s procedure for ratification of a treaty

There exist four steps for Japan’s ratification of an international treaty (Matsuda, 2011). As the first step, the Cabinet Legislation Bureau examines draft of the treaty that are to be brought before the Cabinet for its decision of ratification and, if any, draft bill to implement the treaty (Cabinet Legislation Bureau, 2017). The Cabinet Legislation Bureau checks out draft of the treaty whether Japanese text of the treaty is appropriate and consistent with the existing domestic laws and whether expected domestic measures can ensure full implementation of the treaty under the domestic law. The Cabinet then decides to seek approval by the Diet for conclusion of the treaty and forward to the Diet a bill to seek approval for its conclusion. Where the Diet provides approval, the Cabinet decides to conclude the treaty by depositing its instrument of ratification to the depository, which means official expression of its consent to be bound by the treaty.

Implementation is defined as ‘all relevant laws, regulations, policies, and other measures and initiatives, that contracting parties adopt and/or take to meet their obligations under a multilateral environmental agreement and its amendments if any’ (UNEP, 2006). The measures of implementation are thus full of variety, some are legally binding and others non-legally binding. When a State concludes an international treaty, State takes measures necessary to implement the treaty in order to avoid possible non-compliance with it. State has discretion about the choice of measures of implementation, except that the treaty stipulates specific type of measures. In case of Japan, ‘ensuring full transposition of a treaty into domestic law before concluding a treaty’ is a principle adopted in the administrative practices (Takamura, 2013). The government (mainly relevant ministries) vigilantly examines the text of a treaty to identify whether any new legislation and/or modification of any existing legislation would be necessary or not in light of the text for full transposition of the treaty. Much discretion is left to the government in terms of choice of measures. However, legislative measures are required under some circumstances. For instance, if the government imposes an obligation on persons, natural or legal, and/or it limits their rights in order to implement a treaty, the government is required to take legislative measures to do it. The same is true for the case in which the government imposes any punishment on non-compliant persons. Since the Constitution of Japan in its Article 31 stipulates *nulla poena*
sine lege (no punishment without law), introduction of any punishment requires a legal basis.

ii. Deliberation on measures to implement the Nagoya Protocol

Deliberation started with establishment of an informal gathering (Kondankai) organized by the Ministry of the Environment in November 2011. This informal gathering was transformed to the ‘Consultative Committee on the domestic measures to implement the Nagoya Protocol’ in September 2012. Since then, the Committee met 16 times and it issued a final report in March 2014 (Consultative Committee, 2014). The Committee is mainly composed of experts of relevant field and representatives of industry. The deliberation by the Committee covered a broad range of issues, such as scope of ‘genetic resources’ for the Nagoya Protocol to be applied (derivatives, genetic resources contained in commodity, information on genetic resources, and others), measures to be taken by countries providing genetic resources, and measures to be taken by countries using these resources including measures to ensure compliance with domestic legislation/regulatory requirement of the other party.

The final report consists of a compilation of discussions and recommendations from members. It seems that while indicating ambiguity in the scope of application and of Parties’ obligation, the report reflects general ideas that, Japanese industry and researchers have so far complied with requirements under the Nagoya Protocol in treating genetic resources, based on ‘Guidelines on Access to Genetic Resources for Users in Japan’ made by Japan Bio-industry Association (JBA) and Ministry of Economy, Trade and Industry (MIT) (JBA and MIT 2012) so that introduction of additional (more stringent) measures would not be necessary.

After coordination among relevant ministries, the draft of ‘Guideline for Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS Guideline)’ was elaborated based on the final report of the Committee as Japanese domestic measures to implement the Nagoya Protocol, which was made publicly available for seeking public comments from 20 January to 18 February 2017 (Ministry of the Environment website). The proposal to seek approval for conclusion of the Nagoya Protocol was sent to the Diet on 24 February 2017. After its deliberation, the Diet approved the conclusion of the Protocol on 10 May 2017. Then, after the Cabinet’s decision to conclude the Protocol on 19 May 2017, Japan deposited its instrument of acceptance to the depositary on 22 May 2017.
(3) The ABS Guideline to Implement the Nagoya Protocol

i. Structure and Elements of the ABS Guideline

The ABS Guideline as measure to implement the Nagoya Protocol was issued on 18 May 2017 in the form of joint notice by six ministers, that is the Ministry of Finance, Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labor and Welfare, Ministry of Agriculture, Forestry and Fisheries, Ministry of Economy, Trade and Industry as well as Ministry of the Environment. The ABS Guideline is considered as non-legally binding: a notice providing for rules delegated from specific legislation and regulation could have a binding force, but the ABS Guideline is not the case. The Guideline will become operational on 20 August 2017 when the Nagoya Protocol will enter into force for Japan.

The structure and elements of the ABS Guideline is below.

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Elements</th>
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| I. General rules | - Objective  
- Definition  
- Scope of application |
| II. Measures to promote compliance with legislation of the Parties providing genetic resources | - Reporting on lawful acquisition of genetic resources  
- Reporting on lawful acquisition of traditional knowledge associated with genetic resources  
- Encouragement of reporting  
- Cooperation relating to complaints about non-compliance with legislation of the Parties providing genetic resources  
- Request for submitting relevant information on the use of genetic resources |
| III. Measures to encourage ABS | - Duty to make efforts to conclude a contract for fair and equitable benefit sharing  
- Duty to make effort to include sharing information in MAT |
| IV. Measures on access to genetic resources located in Japan | - Not require PIC for access to genetic resources located in Japan |
| V. Issuance of documents | - Coordination and other measures for issuing documents confirming that genetic resources is of Japanese origin |
ii. Objective and Scope of the Guideline

The objective of the ABS Guideline is to ensure appropriate and smooth implementation of the Nagoya Protocol by taking the domestic ABS measures, thereby to contribute to conservation and sustainable use of biodiversity (1 of Chapter I).

The ABS Guideline explicitly excludes genetic resources and traditional knowledge associated with these resources to which the Protocol is not applicable. It provides a list of matters to be excluded from its scope of application, such as information on genetic resources other than traditional knowledge associated with these resources, genetic resources of human being, genetic resources and traditional knowledge acquired before the date when the Nagoya Protocol enters into force for Japan, genetic resources contained in commodity, and utilization of genetic resources to which the International Treaty on Plant Genetic Resources for Food and Agriculture is applicable (3 of Chapter I).

iii. Measures to Promote Compliance with legislation of the Parties providing genetic resources

Regarding the measures to promote compliance with legislation of the Parties providing genetic resources (Chapter II), a person acquiring genetic resources will submit a report containing a unique identifier of the Internationally Recognized Certificate of Compliance (Certificate) with a copy of the Certificate as evidence of its lawful acquisition of genetic resources to the Minister of the Environment, in case the Certificate was made available to the ABS Clearing-House. In principle, the reporting will be made within 6 months after the Certificate to which Article 17.2 of the Protocol refers is made available to the ABS Clearing-House (1.1 of Chapter II). An importer acquiring genetic resources from a person outside Japan or other acquirer acquiring genetic resources from a person in Japan (who may be called as secondary acquirer) may similarly report on its lawful acquisition (1.3 of Chapter II). This reporting system on its lawful acquisition is to implement Article 15.1 of the Protocol. A person acquiring traditional knowledge associated with genetic resources...
will similarly report on its lawful acquisition to the Minister of the Environment (2 of Chapter Ⅱ).

In cases of non-compliance with the reporting, the Minister of the Environment will request a non-compliant person to report. The competent ministers will give necessary guidance and advice to such person where necessary (3 of Chapter Ⅱ). This measure is to ensure implementation of Article 15.2 of the Protocol.

The Minister of the Environment will put these reports on the web site of the Ministry. The Minister will also provide them to the ABS Clearing-House if a person reporting its lawful acquisition desires.

In addition, the Minister of the Environment requests a person having acquired genetic resources and declared to acquire them for its own use to submit information on its utilization of genetic resources about 5 years after its first reporting. In the case of non-compliance with such a request, the Minister of the Environment will request the non-compliant person to do so. (5 of Chapter Ⅱ) The competent ministers will give guidance and advice to the non-compliant person as appropriate. A person utilizing genetic resources and wishing to make its lawful utilization public may report information certifying its lawful acquisition and relevant information on the utilization of genetic resources. This monitoring system on its lawful utilization and measure to non-compliance with the request is to implement Article 17.1 of the Protocol.

In cases where the other Party to the Nagoya Protocol submits a complaint about non-compliance with legislation of the Parties providing genetic resources, the Minister of the Environment will seek information to an alleged acquirer, importer, or user of genetic resources about its acquisition, import and utilization if the Minister find it necessary, to the extent that the case is within the scope of Parties’ obligation to cooperate under the Nagoya Protocol (4.1 of Chapter Ⅱ). Then, the Minister will, where necessary, provide submitted information to the alleging party through its national focal point (4.2 of Chapter Ⅱ). This is to ensure Article 15.3 of the Protocol.

iv. Measure to Encourage ABS

As regards the measures to encourage ABS (Chapter Ⅲ), a provider or a user of genetic resources located in Japan will make efforts to conclude a contract that allows benefit sharing from the utilization of genetic resources to be fair and equitable, if he/she wishes. Similarly, a user of genetic resources in the Parties providing genetic resources will make efforts to do so, if he/she is required. Moreover, a provider or a user of genetic resources
located in Japan, or a user of genetic resources in the Parties providing genetic resources will make efforts so that benefits arising from the utilization of these resources will go to conservation and sustainable use of genetic resources. They will also make efforts to include clauses on duty to report implementation of MAT provided for in the contract and other clauses for information sharing. Business associations and other associations relevant to the utilization of genetic resources, according to their circumstances, will make efforts to develop and update model contractual clauses, and to promote the use of such model clauses. Furthermore, such associations, according to their circumstances, will make efforts to develop and update code of conducts, guidelines and best practices or standards as well as to promote the use of them.

v. Measure to Promote ABS

Regarding access to genetic recourses located in Japan, PIC is not required for any person to have access to genetic resources in Japan (Chapter IV). It seems that it might reflect concerns on the part of industry and academics using genetic resources about possible additional burden for their use in case where PIC would be required for access to genetic resources located in Japan. However, supplementary provision of the Guideline provides for a possibility of introducing legislative measures on this matter in future.

(4) Preliminary Evaluation of the Japan’s Implementing Measure

One of the questions arising from Japanese measures to implement the Nagoya Protocol is whether the non-legally binding ABS Guideline could ensure fully implementation of the Protocol.

As it is mentioned above, Article 15.1 requires each Party to take appropriate, effective and proportionate measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with PIC and that MAT have been established, as required by the domestic ABS legislation or regulatory requirements of the other Party. The reporting requirement on the part of an acquirer or importer under the ABS Guideline could promote implementation of Article 15.1. However, since there’s no system to capture the overall situation of ABS and thus to detect cases of non-compliance, there has been some question as to whether the Japanese measures to implement would be ‘appropriate’ ‘effective’ under Article 15.1. It should also be noted that the Guideline would provide for only week measures in response to non-compliance with the reporting requirement: under the Guideline, it would be only possible for the Minister of the
Environment to request once again the non-compliant to report it and to providing guidance and advice to the non-compliant eventually. With that, there has been some question again as to whether the Japanese measures to address situations of non-compliance would be ‘appropriate’ ‘effective’ under Article 15.2.

Due to ambiguity in the text of the Protocol, different interpretation might emerge among Parties, for instance, in terms of ‘effective’ ness of the measures to implement the Protocol under Article 15.1 and to the measures to address non-compliance under Article 15.2; however, it should be noted that number of the Contracting Parties, especially Parties using genetic resources, has so far introduced legally binding measures to ensure their implementation of Articles 15.1 and 15.2 of the Protocol.

Another feature of Japan’s measures to implement the Nagoya Protocol is that no PIC procedure has been introduced for access to genetic resources located in Japan. Japan is often considered as country only using genetic resources, but as the report issued by the Consultative Committee indicates, Japan may also be the one providing genetic resources, especially rich in genetic resources located in the maritime area under its jurisdiction. As supplementary provisions in the Guideline indicate, option of introducing appropriate measures for management of genetic resources located within Japan’s jurisdiction should be considered from such perspective, which could allow Japan to better protect genetic resources and to ensure fair benefit sharing arising from their utilization within its jurisdiction.

Note

2) For instance, Articles 27, 28 and 29 of 1958 Convention on High Sea stipulate that ‘Every State shall take the necessary legislative measures’ so that the Contracting Party is obliged to take the legislative measures.

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