

The Negotiating History of the Nagoya Protocol on ABS: Perspective from Japan

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【Abstract】 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 was intensely negotiated during the tenth meeting of the Conference of Parties to the Convention on Biological Diversity (COP10). The agreement of so-called “Nagoya Protocol on Access and Benefit-Sharing” is an important milestone for international environmental law and the Convention on Biological Diversity. This paper reviews the history of the negotiations of the Nagoya Protocol and considers the balance between the sovereign rights of states over their natural resources and the public benefits of the products derived from these resources. Current discussions on benefit-sharing of genetic resources and intellectual property rights under the CBD and other relevant international fora are examined as part of this discussion.

【KEYWORD】 Convention on Biological Diversity Genetic Resources Access and Benefit-Sharing
Intellectual Property Rights

【Date of receipt】 2011.3.22 **【Date of approval】** 2012.4.13

1. Initial Negotiations

Ten years after the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro, the negotiation of an international regime on access and benefit-sharing (ABS) was launched at the World Summit on Sustainable Development in September 2002. From then, it took almost ten years for the negotiation of an international regime on ABS to be agreed, a significant milestone for the Convention on Biological Diversity (CBD). During those years, access and benefit-sharing of genetic resources rose to be an intensively discussed topic, with discussions covering a range of issues relating to biotechnology, international politics, and intellectual property rights, in-

cluding traditional knowledge.

Prior to the CBD, there was no international mechanism to share the benefits arising from developing new products or patent with the provider of such resources, even cases utilizing genetic resources or traditional knowledge of local communities. Developing countries considered this was not equitable treatment and initiated to argue for the fair and equitable sharing of benefits and claimed to change the rules of intellectual properties, especially those related to traditional knowledge. Intellectual property rights can be directly affected by the drafting of ABS contracts, a necessary element under the objectives of the CBD, and can be an incentive for the utilizing Party to obtain prior informed consent¹. In particular, biodiversity-rich developing countries were concerned about the limita-

tions—even under existing frameworks of the CBD—to their rights in the fair and equitable sharing of benefits arising from the development of products relating to their resources and traditional knowledge.

In 2002, at the sixth Conference of the Parties to the CBD (COP 6), a voluntary guideline was agreed based on a draft submitted by the Swiss government. This was named “Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (hereafter called the Bonn Guidelines).” The purpose of the Bonn Guidelines was to support Parties and stakeholders in the drafting of ABS contracts, especially in relation to obtaining prior informed consent (PIC)². Many developing countries and some NGOs demanded a legally binding instrument, which obliges state Parties to implement fair and equitable sharing of the benefits arising out of the use of genetic resources, but a voluntary set of guidelines was all that was feasible at the time. However, the adoption of the Bonn Guidelines served as a platform for further advancements for the establishment of an International Regime on ABS. In particular, the practical nature of the Bonn Guidelines made it instrumental in further discussions towards the development of the Nagoya Protocol; in fact, all main characteristics remained in the Nagoya Protocol—with a few changes, such as to set checkpoints. Furthermore, Parties could not agree on whether there should be obligations to disclose the country of origin when applying for patents. In the Bonn Guidelines, the agreed texts stated that individual countries should take measures to *encourage* the disclosure of the country of origin for both the genetic resources and traditional knowledge.

To further their cause, developing countries—being dissatisfied with the results particularly related to the disclosure of country of origin³—formed an alliance to establish an international binding regime to effectively protect the fair and equitable sharing of the benefit arising from the utilization of genetic resources at the Johannesburg summit, which was held later in 2002.

It was the origin of a framework that is commonly referred to as the International Regime on ABS. As requested by the Johannesburg Plan of Implementation, Parties were instructed to negotiate an international regime to promote and safeguard the fair and equitable sharing of the benefits arising out of the utilization of genetic resources within the existing frameworks of the CBD⁴. A direct result of these negotiations is that Parties decided to re-consider this issue under a Working Group on ABS at the seventh meeting of the Conference of the Parties (COP 7) to the CBD in 2004. The Working Group, dubbed “Ad-Hoc” because it was not permanently established, but set with a specific mandate and time-frame for providing the decision (text) to the Conference of the Parties for adoption. Following COP 7, at COP 8 in 2006, Parties agreed to complete its work at the earliest possible time, preferably before the tenth meeting of the Conference of the Parties (COP 10).

The negotiation of an international regime on ABS began at the third meeting of the Working Group on ABS (known as WG-ABS 3) in 2005. In the beginning, the key point of the discussion was whether or not to make a legally binding document, that is, a Protocol under the CBD. However, due to the wide gap between developing and developed countries, which included issues such as intellectual property rights, Parties could not reach consensus on building an international regime. From then, there had been a fierce confrontation between the two sides, extending beyond the period of discussion. Developing countries wanted to create a stricter framework for users of genetic resources with the mandatory provision on sharing benefits to the provider of such resources and restrictions on application of patent and so on. On the other hand developed countries wanted to avoid such restrictions because restrictions discourage the development of industries and academic research, resulting in decreased cases of benefits sharing arising out of utilization of such resources. The slow progress resulted in no substantive advancements being made on formulat-

ing an international regime on ABS until COP 9 in Bonn, in 2008. In Bonn, Parties finally identified the elements of an international regime on ABS, including: objective, scope, fair and equitable benefit-sharing, access to genetic resources, compliance, traditional knowledge associated with genetic resources, capacity, and nature of the document and decided to hold the Working Group on ABS three times prior to the COP10.

Through negotiations of the Working Group (WG-ABS), Parties have developed the text of an international regime on ABS. However, the negotiations were a reiteration of progress and retrogress. At the first negotiation session, which was the seventh meeting of the Ad Hoc Open-ended Working Group on ABS (WG-ABS 7) in Paris, Parties developed a draft text with numerous square brackets which means a lack of agreement, and it was to be narrowed down or agreed upon at a later stage.

At the end of the second session of the WG-ABS 8 in Montreal there were still over 3,000 brackets as numerous issues and items were under intense debate. At this moment, there was only one negotiating session left before the COP 10, in October 2010. Furthermore, the group was required to circulate the text of the Protocol to the Parties six months before the COP as it required by Article 28, paragraph 3 of the Convention. Majority of participants considered that it was substantially impossible to adopt any type of text, far from the Protocol on ABS, at the COP 10 due to time limitations and deadlock discussions.

2. The accelerated negotiations on the ABS Protocol

At the ninth meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing (WG-ABS 9) in Cali, Colombia, in March 2010, the Co-Chairs of the Working Group summarized a large amount of draft decisions that still included over 3,000 brackets in an attempt to break the deadlock. The

Co-Chairs developed the Co-Chairs Proposal consists of 31 articles as draft texts of ABS Protocol and distributed them to each Party to the Convention. In the beginning of the WG-ABS 9, Parties agreed to negotiate with the Co-Chairs Proposal, which should expectantly have resulted in significant progress in the discussion. However, the negotiation still walked an extremely hard road as a result of two reasons: first, the Co-Chairs Proposal was rather ambiguous; second, the arguments—based on the various issues of the bracketed items—were insufficiently understood by all Parties. As a result, there was intense confrontation between developed and developing countries regarding numerous issues, including benefit sharing, access to genetic resources, compliance, and disclosure of origin. Moreover, predominantly, in discussions of contact groups in the WG-ABS 9, Party demands escalated, taking a hard-line stance and strenuously insisted on reflecting their own country's claims. Therefore, the discussion was suspended and Parties could not enter into substantial negotiation using the Co-Chairs Proposal.

To finalize the negotiating text, Parties decided to resume the meeting of the Working Group at the end of June. The resumed ninth meeting of the Working Group (resumed WG-ABS9) was held in Montreal, Canada, in July 2010.

At the resumed WG-ABS9, the Co-Chairs proposed to convene an Interregional Negotiating Group (ING) which consists of no more than five representatives from each of the United Nations regional groups (Africa, Asia, Central and Eastern European Group (CEE), the Group of Latin America and Caribbean Countries (GRULAC), and the Western European and Others Group (WEOG)) and two representatives each from indigenous and local communities, civil society, industry and public research groups, as well as the representatives of the President of the Conference of the Parties and the incoming President of the Conference of the Parties, namely German and Japan.

At the ING meeting, representatives considered the

articles of the draft Protocol on ABS one by one from the first article. In addition to each consideration, they established contact groups to intensely discuss the contentious key issues ensuring various views were included. Groups reached agreement behind closed doors late into the midnight every day.

At the resumed WG-ABS 9 there seemed to be significant progress compared with previous negotiations. However, there were still sharply divided opinions between developed and developing countries regarding derivatives, retroactive application, benefit-sharing, and compliance. As a result, there were still many brackets left. To facilitate their work, Parties decided to resume the ING meeting as far as possible until the COP 10 in order to reach an agreement.

In mid-September of 2010, Parties met in Montreal, Canada again and intensively discussed pending issues. At the meeting, Parties focused on the key contentious issues of both developed and developing countries, which had been written down in the draft texts of opinions, and tried to integrate the various draft texts. Due to the result of their extended hours of negotiations, they successfully reached a consensus on almost all draft texts. Nevertheless, the negotiations reached no agreement by the deadline due to the sharply divided opinions on issues such as derivatives, scope (including retroactive application), and compliance (including disclosure of origin and check-

points). The divided opinions at the meeting are summarized in the table below :

In response, Parties agreed to hold the ING meeting again just before the COP 10 from 13 to 16 October, to coordinate views on continuingly contentious issues. From 13 to 15 October, the venue of the ING meeting was moved to Nagoya and fierce negotiations took place back-to-back with the fifth meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 5). At the ING meeting, as preparatory negotiations for the COP 10, Party discussions narrowed down the contentious issues as follows : derivatives, pathogen, compliance, and institutional arrangements. At earlier stages, the process of narrowing the issues met difficulties with a few Parties rejecting suggested text by Co-Chairs that their views were not properly reflected or preempted. Repeated ING meetings facilitated the narrowing process. Groups were formed for these individual contentious issues (this process continued during the COP 10 period). If certain differences were not solved then the term were accommodated under the key issues often with brackets. In addition, time limitation helped Parties to focus under limited number of issues. There were issues with slow progress. The issue related to “institutional arrangements” scarcely progressed and the procedures of the

Table 1 Issues with divided opinions on ABS prior to the COP10

Issues	Opinions in favor of Users of Genetic Resources (mainly from Developed Countries)	Opinion in favor of Providers of Genetic Resource (mainly from Developing Countries)
Retroactive application	Retroactive application is against the principle of international law (such as Article 28 of Vienna Convention on the Law of Treaties).	It should be applied prior to the Nagoya Protocol and even prior to the Convention.
Scope/ Derivatives	The scope should be decided by the individual MAT.	The Nagoya Protocol should include derivatives and products.
Disclosure of origin	The judgment of intellectual property rights and ABS are two different issues. Issues related to disclosure of origin for patents are beyond the mandate of the CBD.	To prevent biopiracy, misappropriation and other illegal activities, disclosure of origins are necessary measures when applying for patents.
Checkpoints	Procedures should be left to national regulations.	A list of checkpoints are necessary (such as agencies related to trades, patent, research grants).

Protocol were unclear.

On 16 October, just before the COP 10, the resumed WG-ABS 9 was convened and Parties decided to adopt the draft Protocol including pending issues as a final report and submitted it for the consideration of Parties at the COP 10.

In addition to the Working Group and the ING, the Government of Japan sent delegations to Africa, Europe and Latin America and established formal and informal negotiating channels prior to the COP 10. In addition to bilateral discussions, informal discussions were conducted at the Bureau meetings of the CBD and meetings facilitated by the Secretariat. These channels have been instrumental in exchanging information.

3. Negotiations on the draft Protocol on ABS at the COP10

At the COP10, from 18 to 29 October, Parties continued negotiations on the draft Protocol on ABS day and night throughout the week. Parties established an open-ended Informal Consultation Group (ICG) to finalize the draft Protocol, which consisted of five representatives from each region in the previous style of the Interregional Negotiating Group (ING), to facilitate negotiations on the draft Protocol. With a streamlined number of representatives, the ICG focused to discuss the following issues ;

1. Derivatives : Under this issue, Parties discussed whether or not to specify the subject of benefit sharing. The definition of the term derivative is defined in Article 2 of the Protocol as “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.”
2. Scope : Parties considered the scope of applications and whether they should be retroactive applied.

3. Special consideration : Parties considered whether or not to make exceptions to the rules for the following cases, noncommercial use of genetic resources (such as academic research) and emergencies, including public hygiene.
4. Traditional knowledge : Parties considered whether or not to specify in the Protocol that traditional knowledge was individually or specifically owned, due to the diverse domestic situations in each country.
5. Compliance : Parties considered whether or not it should be obligatory to : disclose the origin of resources and information at the application of intellectually property rights, especially patent application ; set checkpoints to monitor the usage of genetic resources ; and list the organizations of each checkpoint concretely.

However, these issues were so cross-cuttingly related to the entire Protocol that there was little progress even if Parties continued separate negotiations on them. In fact, there was little progress on these issues in discussions after the first week of COP 10. In the days and nights of the following weekend and week, Parties divided into contact groups and worked hard to coordinate views and reported this progress to the Plenary in order to whittle the final agreement down to an acceptable text. Then in the Plenary on 26 October, Mr. Ryu Matsumoto, Minister of the Environment of Japan as well as the President of the COP 10, proposed that if there was no agreement on the draft Protocol by 24 o'clock on 28 October, he mentioned that he would present a Draft President's text on the Nagoya Protocol.

At the final stage of the negotiations with three days left, Mr. Matsumoto as the Chairman of the COP10 felt that he was under pressure because neither the overall strategic plan and goal of the Convention after 2010 (so-called post-2010) nor the ABS regime were not agreed⁵. There were two major options explored ; one was to suggest a resumed meeting and roadmap and the other was to present Draft President's

text. The latter was an option with higher risk and higher returns and Mr. Matsumoto chose to present the Draft President's text. Mr. Matsumoto communicated with the Secretariat to the Convention and asked for an initial text. The text was then drafted by two legal experts from the Secretariat in close consultation with the Japanese government, particularly with Director from the Ministry of Foreign Affairs of Japan (MOFA). The language of the text was carefully chosen based on previous discussions and disagreements by legal experts to avoid further intense debates. The experts informally consulted a range of expertise, including officers in international organizations. Then the text was discussed with other Ministers and participants of the high-level segments. The process was open to all delegates because the Mr. Matsumoto as a Chairman wanted to avoid the failure of the COP 15 of the UNFCCC (United Nations Framework Convention on Climate Change). The Draft President's text at the COP 15 was criticized for being created behind closed doors with limited number of participants and inputs. Comments were received from African groups, India and other delegations commented on the text but the text remained almost unchanged.

Parallel to the Draft President's text, the ICG continued their negotiations but was still no agreement on the draft Protocol at midnight on 28 October, a night before the final day of the meeting. The time was deadline to propose the alternative way, the Draft President's text. Mr. Matsumoto, as a Chairman, thus proposed the draft text on Nagoya Protocol in the morning on Friday 29 October, on the final day. With the Draft President's text, Mr. Matsumoto continuously persuaded representatives of each region in informal negotiations to adopt it. In persuading Parties, including developing countries, Japan committed a multilateral fund with a concrete figure, which later became the global multilateral benefit-sharing mechanism. For developed countries, issues related to retroactive application or the listing of checkpoints were removed and the applicability of derivatives was not

made explicit. The Draft President's text was a full of compromising language so that it was acceptable to both sides. As a consequence, the text included procedures still to be clarified and negotiated when the Protocol is ratified and comes into force.

In the afternoon on the last day of the COP 10, in an informal meeting consisting of representatives of each region, the chair declared the acceptance of the Draft President's text on the Nagoya Protocol with the condition that minor amendments can be put forth by developing countries. (For example, a word "genetic" was replaced by "biological" by the request of the Brazil.) At last, Parties had come to an agreement before dawn on 30 October. Although some still opposed it, the Draft President's text was adopted by consensus under the agreed upon title of the Nagoya Protocol on Access and Benefit-Sharing.

4. Development of key issues of the Nagoya Protocol on ABS

The key issues of the Nagoya Protocol are derivatives, scope, benefit-sharing, access, and compliance. There are brief comments on main discussion points below ;

(1) Derivatives

The Nagoya Protocol defined in Article 2 of the Protocol that the term "derivatives" as "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." Accordingly, as the definition can be interpreted to refer to a natural compound made from organisms, then a compound synthesized artificially is not subject to the derivatives part of the Protocol. As an example, shikimic acid extracted from star anise, which is the raw material of Tamiflu, a medicine for flu treatment, is a "derivative," while a compound synthesized artificially with reference to shikimic acid is not a "derivative" and will not be regarded as an object of

the Protocol. Provided that the utilization of genetic resources includes an “application of biotechnology” in Article 2 of the Protocol, it is possible to interpret that the benefits arising out of the utilization of derivatives as an object of the Protocol. The other key term “biotechnology” is defined in Article 2 of the Convention and means “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.” However, the scope of biotechnology is not explicit in the Nagoya Protocol. In case of the Cartagena Protocol, the scope of biotechnology is clearer, with limitation to “modern” biotechnology in the definition of “living modified organism”—defined as “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology” in the Article 3 of the Cartagena Protocol.

(2) Scope

With regard to the applicable scope of the Protocol, the discussion has focused on retroactive application of the Protocol and it was a key component for developing countries. The African group insisted on this as moral obligations that developed countries, in particular European countries, should compensate for genetic resources which deprived in colonial era. They tried to apply benefit-sharing obligation prior to the Convention on Biological Diversity came into effect, namely in 1993. However, the language of retroactive application was removed from the text, as no previous examples were found in past environmental treaties. In the text of the Chair’s proposal that was adopted, the reference to retroactive application was not referred to. Instead, a fund was proposed as a compromise—in line with the African group’s proposal—that will be implemented at a future date, but that potentially included benefit sharing derived from the utilization of genetic resources in past cases. The beneficiaries of the funds, which include capacity building and other measures, will most probably be countries where genetic resources were accessed and obtained prior to

the Convention. In sum, it was agreed that a mechanism called a “global multilateral benefit-sharing mechanism” in Article 10 of the Protocol will be considered for promoting benefit sharing arising from the utilization of genetic resources of unknown origin.

(3) Benefit-Sharing

In accordance with Article 5 of the Protocol, benefit-sharing is defined as follows: “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.” Building on this, the objects of benefit-sharing are described in Article 2 of the Protocol as the “research and development on the genetic and/or biochemical composition of genetic resources” and in Article 5 as the “benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization.” As such, the actual conditions of benefit-sharing shall be operated on a case-by-case basis. Furthermore, in regards to the procedure of sharing—a contract between those concerned—it should be set under mutually agreed terms, or MAT⁶.

(4) Access

With regard to Access, this is mainly advocated by developed countries because currently there are considerable amount of ambiguity for the ABS legislation or regulation of developing countries. Consequently, it disturbs access to genetic resources which each Party shall endeavor to facilitate access to genetic resources and not to impose restrictions that actually run counter to the objectives of the Convention. As a result of a compromise between both sides, Article 6 of the Nagoya Protocol determined that “access to genetic resources for their utilization shall be subject to the prior informed consent (PIC) of the Party providing such resources” but on the other hand the Protocol obliges that Party requiring PIC shall take the neces-

sary legislative, administrative or policy measures in order to “provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements.”

(5) Compliance

In accordance with Article 15 of the Protocol, each Party is obliged to 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 (PIC) and that mutually agreed terms (MAT) have been established.” Consequently, in accordance with Article 17, the Protocol obliges each Party to take measures to designate checkpoints to monitor the utilization of genetic resources whether a user of genetic resources acquires PIC and establishes MAT with the provider in their countries. At the beginning of the process of negotiations, there was a proposal to list concrete bodies as checkpoints, such as an entities publishing research results relating to the utilization of genetic resources, authorities providing regulatory or marketing approval of products and intellectual property examination or patent and plant variety offices.

Developing countries insisted on listing those Intellectual Property Rights (IPR) authorities in the Protocol as a checkpoint of monitoring the use of genetic resources. They also demanded those IPR application related to use of genetic resources without PIC and MAT shall not be approved. This is called “disclosure requirement.” However, those specific listing and requirements were removed by the proposal made by the COP10 President in the end. The reason why developing countries insisted on limiting IPR is that they were frustrated with the discussion at the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO).

Since 2001, the WIPO and the WTO discussed similar issues at their fora. For example, the WIPO has been discussing the intellectual property aspects of ac-

cess to genetic resources and equitable benefit-sharing arrangements and disclosure requirements in patent applications. The WIPO has established Inter-Governmental Committee (IGC) and is continuously discussing those issues from their perspectives. Under the WTO, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Council is looking at the relationship between the TRIPS Agreement and the CBD. It is conducted in the context of a review of Article 27.3(b) of the TRIPS which deals with patentability or non-patentability of plant and animal inventions, and the protection of plant varieties. Among those fora, developing countries considers that they were always forced to compromise and little chance to reflect their opinions. This is mainly a result of power politics in the economic fora. But in the environmental fora, it is much easier to make one voice of developing countries with criticizing developed countries based on various international principles, such as common but differentiated responsibilities referred in the Rio Declaration adopted in 1992.

The majority of the developed countries argue that the issues related to intellectual property should be regulated with domestic laws and individual contracts rather than disclosure requirements in patent applications regarding origins of genetic resources and traditional knowledge. The United States expressed concern that ABS regime, particularly new disclosure requirements may be inconsistent with, or may conflict with WIPO-administered treaties and WTO-administered TRIPS Agreement⁷. The disclosure requirements in patent applications are criticized from practical point of views that the process and cost will not be realistic in implementing such process⁸.

5. Other international Processes

There are several other relevant international fora on the ABS and intellectual property rights. The characteristics of the relevant international processes are listed in the table.

Table 2 Overview of International Fora on Access and Benefit-Sharing of Genetic Resources and Intellectual Property Rights

Convention and Institution	Purposes	Issues
Convention on Biological Diversity (CBD)	<ul style="list-style-type: none"> - Conservation of biological diversity - Sustainable use of its components - Fair and equitable sharing of the benefits arising out of the utilization of genetic resources 	(See Nagoya Protocol on ABS)
Nagoya Protocol on ABS* <not entered into force>	<ul style="list-style-type: none"> - Fair and equitable sharing of the benefits arising out of the utilization of genetic resources - Contributing to the conservation of biological diversity and the sustainable use of its components 	<ul style="list-style-type: none"> - Benefit-sharing of derivatives of genetic resources - User country measures (Checkpoint, disclosure requirement etc) - Compliance mechanism of the Protocol (TBC)
WTO - TRIPS Agreement	<ul style="list-style-type: none"> - Ensure adequate standards of intellectually property rights protection 	<ul style="list-style-type: none"> - Creating a multilateral register for wines and spirits - extending the higher level of protection beyond wines and spirits (“GI extension”) -Review of Article 27.3(b) (Relationship between the TRIPS and the CBD, and the Protection of Traditional Knowledge)
FAO - International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR-FA)	<ul style="list-style-type: none"> - Sustainable agriculture and food security - Conservation and sustainable use of plant genetic resources for food and agriculture - Fair and equitable sharing of the benefits arising out of use of plant genetic resources - Ensure harmonization with the CBD 	<ul style="list-style-type: none"> - Operation and management of Multi-lateral System (MLS) for ABS (currently 64 major crops) - Cooperation with Convention on Biological Diversity and other organizations
WIPO - Intergovernmental Committee (IGC) and Intersessional Working Group (IWG)	<ul style="list-style-type: none"> - Reaching agreement on a text of an international legal instrument (or instruments) which will ensure the effective protection of traditional knowledge (TK), traditional cultural expressions (TCEs)/ folklore and genetic resources 	<ul style="list-style-type: none"> - Disclosure requirements in patent applications that relate to genetic resources and associated TK - Intellectual property aspects of ABS - Defensive protection of genetic resources
WHO - Pandemic Influenza Preparedness (PIP) Framework	<ul style="list-style-type: none"> - Sharing of H5N1 and other influenza viruses with human pandemic potential - Access to vaccines and sharing of other benefits 	<ul style="list-style-type: none"> - Definition of “PIP biological materials” - Balance between intellectually property rights and public health

(as of 2012 February) Revised from Kohsaka and Honda (2009)⁹

The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR-FA) is in cooperation with the CBD and languages of the goals are similar with focus on conservation, sustainable use and benefit sharing.

There are several differences in their characteristics as well. The access to genetic resource is multi-lateral system (MLS) in the ITPGR-FA and bilateral in CBD. The scope of MLS is listed crops (35 food crops and 29 forages) in the Appendix I of the ITPGR-FA while CBD is generally on genetic resources. The procedure for the access is standardized as Standard Material Transfer Agreement at the ITPGR-FA while these are negotiated or agreed bilaterally as Mutually

Agreed Terms at the CBD. Having said this, because the ITPGR-FA is at operational stage with benefit sharing and these will have implications on levels and ratio at the bilateral negotiations under the CBD.

6. Entry into force

In accordance with Article 33 of the Protocol, the Nagoya Protocol “shall be open for signature by Parties to the Convention at the United Nations Headquarters in New York, from 2 February 2011 to 1 February 2012” and Article 34.1 says that “The Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, accep-

tance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.”

As many developing countries supported a Protocol on ABS for many years, the Nagoya Protocol is supposed to enter into force at an early stage. Japan as the host country of the COP 10—in a position of both user and provider country of genetic resources—should meet the expectations of the Nagoya Protocol’s early entry into force and continue to make efforts to take part in its decision making process. In line with this, the Government of Japan signed the Protocol in May 2011—one of the first developed country to do so. In June 2011, 12 European Union member states joined, enhancing the number of Signatories.

There are challenges both domestically and internationally for Japan. First, Japan needs to set up its national regulations and institutions domestically. Second, Japan need to strategically collaborate with the developing countries for capacity buildings and setting international momentum for the Nagoya Protocol to enter into force. The Parties have committed that “by 2015, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization is in force and operational, consistent with national legislation” under the post-2010 Target¹⁰.

Domestically, Japan will need to decide which governmental body it will be designated to function as the checkpoints domestically, which will include options to establish a new body or to designate an existing body. As was the case for the Cartagena Protocol on Biosafety, Ministry of Environment in collaboration with other relevant agencies is preparing the domestic setups. A new organizational unit, Biodiversity Promotion Office (*Suishin Shitsu* in Japanese) is set up within the Ministry of Environment in order to promote the domestic process of the ABS. The process has just started and future visions are undecided and currently under discussion.

Internationally, Japan committed to promote capacity

building activities for developing countries and other relevant bodies. Obviously, the decision to sign and ratify the Protocol is left to individual governments. Based on this principle, there are rooms for international collaboration, if certain countries request supports. Such efforts, for example, include the Japan Biodiversity Funds and new funds to the Global Environment Facility (GEF). Recently the GEF council approved to establish the “Nagoya Protocol Implementation Fund” to help developing countries build their capacity to engage in both the ratification and implementation of the Protocol. The Government of Japan pledged its pioneer contribution of 1 billion Yen (about US\$ 12.5 million).

7. Concluding remarks

The decision by the Japanese government to propose the Draft President’s text was sudden and risky but a successful option for an agreement. It was successful partially because schedule for extension nor resumed negotiations were not provided. By the pressure of having no further negotiations schedule, delegations shared the sense of urgency to agree or to compromise. The agreement could not be met at the ICG but it was instrumental in having all the options and disagreements on the table. The Draft President’s text reflected the discussions and defined certain concepts, such as in the case for the term derivative, but left strategic rooms for individual contracts.

The Nagoya Protocol does not require any drastic changes in national legislation on IPR or existing practices of using genetic resources at this stage. The Nagoya Protocol is international treaty so it only binds State Parties, not private entities directly. Nonetheless users of genetic resources need to obey the laws of the country in which they accessed the genetic resources. However, there are some general pitfalls remain unsolved in the Nagoya Protocol through its negotiations. Access to genetic resources for non-commercial researches, such as academic explorations,

are not exempted but in principle need to obtain PIC and MAT from the provider of genetic resources. Furthermore, this PIC and MAT rules of the Nagoya Protocol shall apply in case of the situation of imminent emergencies that threaten or damage human, animal or plant health, such as pandemic influenza. During the negotiation, developing countries insisted on deleting any consideration to the non-commercial research purpose access to genetic resources and emergency situations, but Japan and some developed countries has strongly opposed to remove it. Then, the draft President's text has taken this consideration and finally it has been approved by consensus at the end of the COP10.

Since the COP10, the future vision of the Japanese government is undecided. An office is set up for the process but the domestic discussions have just started. In addition to private entities, awareness raising and consultations with the academic institutions and universities will be one of the major tasks. It needs to be made clear that scientific activities are no exceptions for Japanese scientists as well.

Internationally, it remains to be seen what kind of projects will be implemented with the Nagoya Protocol Implementation Fund under the GEF. Based on past bilateral collaborative relationships, Japanese government can potentially contribute to technological transfer and capacity buildings upon requests by other countries. In doing so, it will be useful to analyze past-bilateral collaborations in the field (except for those subjected to Confidentiality Agreement).

Nearly a year has passed since the COP10 in 2010. In the meantime, various related meetings have been held under the CBD and the number of Signatories of the Nagoya Protocol is steadily rising and the number is above 60 (To date, Gabon ratified the Protocol on 11 November 2011). As the number suggests, many

countries are preparing to ratify or accept the Nagoya Protocol and it will be sooner or later come into force. It is time to consider how best to promote access to genetic resources and traditional knowledge and contribute the implementation of the Nagoya Protocol in the future.

ACKNOWLEDGEMENT

The author would like to thank Mr. Yusuke Honda, who participated in several WGs on ABS and the COP10, for his comments on an early draft of this paper. Any error or omissions remains entirely the author's responsibility.

NOTE, REFERENCE

- 1 Report of the Panel of Experts on Access and Benefit Sharing. UNEP/CBD/5/8 (November, 2 1999) para 145-155.
- 2 "Prior informed consent" means that permission from the competent national authority or authorities of the provider country is to be obtained prior to accessing genetic resources, in accordance with national legislation. See also the CBD website.
- 3 Chambers, W. Bradnee, 2003, "WSSD and an International Regime on Access and Benefit Sharing: Is a Protocol the Appropriate Legal Instrument?," RECIEL, Vol. 12, Iss. 3, pp. 310-320.
- 4 Plan of Implementation of the World Summit on Sustainable Development, para. 44(o), 2002.
- 5 Matsumoto, Ryu (2011) "The Backstage of Environmental Diplomacy: Truth revealed by the Minister" (*Kankyo Gaikou no Butaiura* [in Japanese]) Nikkei BP.
- 6 "Mutually agreed terms" is an agreement reached between the provider of genetic resources and a user with respect to the conditions of access to genetic resources in the provider country and the benefits to be shared between both parties, which may arise from the commercial or other uses of these resources. See also the CBD website.
- 7 WIPO (2005) Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications—Second Draft, WIPO/IP/GR/05/3 (12 May 2005), para. 109
- 8 Kato, Hiroshi (2008) "Harmonization of Intellectual Property Rights System and Convention on Biological Diversity" (*Seibutsutayouseijouyaku to Chizai no Chowa* [in Japanese]) In Sumikura (ed.) "Policy of Intellectual Property Rights and Management" (*Chitekizaisanseisaku to management* [in Japanese]) Hakutosya, 190-194.
- 9 Kohsaka, Ryo and Honda, Yusuke (2009) "Interlinkages between Benefit-Sharing of Genetic Resources and Intellectual Property Rights under the Convention on Biological Diversity," Journal of Intellectual Property Association of Japan, Vol. 5 No. 4, pp. 3-13.
- 10 CBD COP10 decision X/2 Strategic Goal D Target 16. UNEP/CBD/COP/DEC/X/2