



**Convention on  
Biological Diversity**

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AD HOC OPEN-ENDED WORKING GROUP ON  
ACCESS AND BENEFIT-SHARING

Seventh meeting  
Paris, 2-8 April 2009

**COLLATION OF ANY OTHER VIEWS AND INFORMATION SUBMITTED BY PARTIES,  
GOVERNMENTS, INTERNATIONAL ORGANIZATIONS, INDIGENOUS AND LOCAL  
COMMUNITIES AND RELEVANT STAKEHOLDERS IN RESPECT OF THE MAIN  
COMPONENTS OF THE INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING  
LISTED IN DECISION IX/12, ANNEX I**

*Addendum*

1. The Executive Secretary is circulating herewith a submission from Japan as an addendum to the collation of views in respect of the main components of the international regime on access and benefit-sharing listed in decision IX/12, annex I.
2. The document is being reproduced in the form in which it was received by the Secretariat.

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\* Reposted on 25 March for technical reasons.

## SUBMISSION FROM JAPAN

### **Submission from the Government of Japan for the seventh ABS Ad-hoc Working Group**

Our position in the ABS negotiations has already been expressed in the previous meetings. Towards the seventh meeting of the Ad Hoc Open-ended Working Group on ABS, it is important that the participants enhance their understanding by making the best use of technical expertise provided at the past expert meetings. In particular, now that the last expert meeting on Compliance was held in Tokyo, we would like to contribute by presenting the following analyses so that the continuity of discussions in the forthcoming ABS Working Groups is ensured.

Regarding each option proposed at the meeting of the group of legal and technical experts on compliance, we would like to share our analysis from such perspectives as “Possible mechanisms”, “Implications”, “Challenges” and “Solutions to be discussed”.

It should be noted, however, that the analysis presented below neither changes our negotiating position nor predetermines our future position.

#### 1. Compliance with ABS domestic laws

##### (1) Internationally recognized certificate

###### <Possible mechanisms>

The international recognition of national certificate could be further facilitated if the format of certificate is standardized among countries or if such format contains common items for certification. National certificates here mean certificates issued by the governments of provider countries to confirm that the individual use of genetic resources is in compliance with their ABS domestic laws.

###### <Implications >

-From the viewpoint of providers, such a mechanism would facilitate the use of certificate in user countries as a reference for making judgement on whether the individual use of genetic resources complies with ABS domestic laws of provider countries, and thereby discourage users from using genetic resources which were accessed in violation of ABS domestic laws.

-From the viewpoint of users, it would enhance legal stability in each use of genetic resources, and make it less likely that they will be legally challenged when genetic resources are employed for actual application in user countries. In addition, if the certificates have effects of exempting end-users of liability for non-compliance with ABS domestic laws, they would be more inclined to require the original users to present the certificate when they receive or purchase genetic resources, thereby giving incentives to original users to comply with ABS domestic laws.

###### <Challenges>

International standardization of national certificate is destined to be limited, because the obligations of ABS domestic laws are varied among provider countries and the procedures for certification of compliance are accordingly different.

Given the fact that the procedures for certification are exclusively controlled by provider countries, the certificate cannot be sufficiently reliable in user countries unless it is ensured that certification is conducted in an objective and transparent manner.

<Solutions to be discussed>

-Certificate would be more reliable to users and user countries if the procedures for certification ensure objectivity and transparency. Another possible solution is to employ a third party certification which is conducted by some organizations other than the government of provider countries.

-A serial numbering would make it easier for authorities and users in user countries to check with provider countries whether individual use of genetic resources complies with ABS domestic laws. This would further improve reliability and transparency of certification system of provider countries. And if publicized, the certificate would be more useful to authorities and users in user countries and they would be more aware of the certificate.

(2) The designation of “checkpoints” in user countries

<Possible mechanisms>

In the case where a certificate system as mentioned above exists, the checkpoints could be designated in user countries to check if the uses of genetic resources comply with ABS domestic laws of provider countries. The authority in user countries could use such checkpoints, for example, in approving the production of new medicines and other products, or in providing subsidies for researchers.

<Implications >

-From providers’ viewpoint, it is expected that the checkpoint in the user countries could prevent the use of genetic resources that is not in compliance with ABS domestic laws of provider countries, and reduce the chance for users to benefit from such non-compliant use. It could lead to the further encouragement for users to comply with ABS domestic laws in provider countries, as users lose interests in using genetic resources without certificate of compliance.

-From the viewpoint of users who intend to receive or purchase genetic resources (end-users), the administrative check by authorities of user countries could help resolve the doubts that the genetic resources they are acquiring might not comply with ABS domestic law.

<Challenges >

-The authorities in user countries are only able to formally check if a particular use of genetic resources has already been certified by the government in provider countries, and not in a position to certify by themselves that it indeed complies with ABS domestic laws of provider countries. This is an inevitable consequence of the fact that authorities in user countries are not either involved in the process for certification or authorized to interpret ABS domestic laws of provider countries.

These can be sufficient reasons why it is difficult for the authorities of user countries, in the occasion of approving new medicines or other products, to differentiate certain uses of genetic resources, based on whether they are in compliance with ABS domestic laws or not.

-Given the fact that the governments of user countries could not either engage in the legislation process of ABS domestic laws in provider countries, or involve themselves in the process for certification, user countries are not able to give differentiated treatment to the non-compliant use. This is understandable

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more clearly when we consider the sovereign right of each provider country over access to genetic resources, which is clearly stipulated in the Article 15. 1 of the Convention on Biological Diversity.

<Solutions to be discussed>

The reliability of certificate issued by the government of provider countries could be enhanced, if the certification process is conducted in a transparent manner, especially by setting clear requirements and objective criteria for compliance certification.

It would also be helpful if authorities in user countries can serve as focal points for inquiring of the government of provider countries regarding the compliance or non-compliance of individual use of genetic resources, in response to request from users who would receive or purchase them.

(3) Several options for promoting information sharing regarding compliance with ABS domestic laws

<Possible mechanisms>

(a) Clearing-house mechanism

On the basis of the above-mentioned certificate system in provider countries, the Parties of CBD can share information on compliance of individual use of genetic resources if provider countries make notifications on certifications to the CBD clearing- house to be established for this purpose.

(b) Monitoring on compliance with ABS domestic laws

On the basis of the above-mentioned certificate system in provider countries, the Parties of CBD could monitor compliance of individual use of genetic resources with ABS domestic laws of provider countries by making use of information gathered at the clearing-house.

(c) Notification of and report on compliance with ABS national laws

Again on the basis of the above-mentioned certificate in provider countries, information-sharing would be further enhanced if provider countries are obliged to notify or report to the CBD clearing house the individual uses of genetic resources that is certified as in compliance with domestic laws.

<Implications and challenges>

There mechanisms mentioned above would enhance information-sharing among provider countries and user countries, and they could be very effective in preventing the use of genetic resources that is in non-compliance with ABS domestic laws.

However, adopting the certificate system in provider countries is a prerequisite for these mechanisms, and therefore the same challenges pointed out in preceding paragraphs must be overcome here.

(4) Disclosure requirement in the patent system

<Possible mechanisms>

Applicants would be required to disclose information on the source/origin of the used genetic resources in the process for the patent applications.

<Implications>

-From the viewpoints of providers, some assume, it becomes easier to prevent the use of genetic resources from being employed in the development of products if information on the use of genetic resources or on its compliance is disclosed through patent disclosure requirement or some other method.

-From the viewpoints of users, some assume, it may make users more conscious of the ABS issues and prevent unintentional bio-piracy if the disclosure of information on the use of genetic resources is required at the time of patent application or in any other occasions.

<Challenges>

-It is hardly justifiable in light of objectives of patent system to make the source/origin disclosure one of requirements for granting patent. There is a serious concern that such disclosure requirement would undermine the smooth operation of patent system. More precisely, the obligation of the source/origin-disclosure in patent applications would lead to an undue burden for applicants and reduce the legal certainty in patent system since it is difficult to define clearly for what categories of patent applications the disclosure is required.

-It should also be reminded that the introduction of the requirement would restrain patent applications, and would eventually result in reduction of benefits through utilization of patent system, which means that providers of genetic resources may earn less return of benefits as well.

<Solutions to be discussed>

Patent system does not cover all the situations where the use of genetic resources create industrial benefits (e.g. the exclusive use of trade secret such as manufacturing know-how). For the purpose of obtaining information on the use of genetic resources, the disclosure requirement in patent applications is too costly a method to be introduced. If the objective is to obtain information such as the use of genetic resources, such objective could be achieved by publicizing certificates of compliance with ABS domestic laws or other alternative measures such as information disclosure system outside the framework of patent system.

## 2. Compliance with ABS agreements

### (1) Investigations of non-compliance by a third party

<Possible mechanisms>

A third-party body could be established to investigate if the mutually agreed terms (MATs) are actually observed and the benefits are shared in a fair and equitable manner as stipulated in the MATs. The third party body would initiate investigation in response to the request from the government, providers or users, and report the findings of investigation to them.

<Implications>

The fact findings conducted by the third party investigating body, which ensures fairness and impartiality, would provide reliable information on compliance or non-compliance to the governments, providers and users.

<Challenges>

-If the third party body is established and mandated by domestic legislation of provider countries, the investigations are likely to be conducted more from provider's point of view, the neutrality of the findings will be difficult to maintain.

-It is quite difficult to oblige users to cooperate with the investigation when they are outside the provider countries.

-In the first place, since the body will not be able to conduct a compulsory investigation, if the users refuse the investigation, the completion of investigation cannot be guaranteed.

<Solutions to be discussed>

-Participation of foreign investigators could enhance the reliability of findings since they are expected to be neutral to either providers or users.

-It could also enhance the objectivity and make users easily accept the result of findings if users are given the chance to make a rebuttal to them, or if the investigation findings as well as providers' arguments are disclosed.

(2) ABS-specialized ADR (Alternative Dispute Resolution)

<Possible mechanisms>

The creation of Alternative Dispute Resolution (ADR) mechanism specialized

in ABS would be considered, taking into account the peculiarities of ABS disputes, as well as following the precedents examples such as existing ADR mechanisms provided by New York Convention (1958 UN Convention on the Recognition and Enforcement of Foreign Arbitral Awards) and Permanent Court of Arbitration (PCA).

<Implications>

Awards would be given with enhanced efficiency and accuracy with less time spent on arbitral proceedings since the peculiarities of ABS would be well reflected. Furthermore, this expected efficiency would contribute to reducing the burden of cost and time on users or providers who may resort to this mechanism for solutions.

<Challenges>

-It is uncertain whether sufficient number of cases would be filed to the courts so as to recover the costs to create or maintain such specific ADR mechanism.

-Given the fact that the use of genetic resources varies to the great extent by sectors and situations, it is questionable if we can find the appropriate ADR mechanism which suits every sector or situation.

<Solutions to be discussed>

Further consideration should be made to see if there could be an effective ADR mechanism specific to ABS-disputes, taking into account the peculiarities of ABS-disputes and commonalities among different sectors.

### (3) Strengthening of information exchange

<Possible mechanisms>

The content of ABS agreements concluded between users and providers would be notified to governments of both user and provider countries. Then the governments would inform the CBD Secretariat of some part of the information received, thereby creating wider information exchange.

<Implications>

-With information provided, the government would be in a position to monitor the compliance of individual agreements between providers and users, and this monitoring would have an effect of encouraging users and providers to abide by the provision in ABS agreements.

<Challenges>

Since it would be practically difficult for ABS domestic laws to oblige users and providers to notify the contents of individual ABS agreements to the government, they are hardly expected to submit such information.

<Solutions to be discussed>

While it is difficult to oblige users and providers to submit all relevant information on ABS agreement including names of users and providers and the details of benefit-sharing rule, we can consider a mechanism requiring only certain types of information whose provision and sharing is clearly beneficial.

### (4) Model clauses and check list

<Possible mechanisms>

Check lists and model clauses of agreements could be drafted by identifying items that can be recommended for inclusion in the ABS agreements between users and providers.

<Implications>

By following check lists or model clauses at the conclusion of ABS agreements, users and providers could easily include, in ABS agreements, the most appropriate stipulations on modality of benefit sharing and rules for dispute resolution.

<Challenges>

-With unique nature of each of various sectors and individual use of genetic resources, it is difficult to identify clauses that can be applied to all sectors and cases. Confining items to the minimum would have a risk of reducing its usefulness, while wider coverage of items could lessen the relevance of included items.

-Given the voluntary nature of model clauses or check lists, their implementation cannot be guaranteed.

<Solutions to be discussed>

-The model clauses or check lists could be more flexible and effective if they are drafted both with cross-cutting items and items that are specific to particular sectors, or if optional clauses or lists are presented depending on circumstances.

-The mechanism for information-sharing among countries through notification would enable them to monitor if model clauses or check lists are actually implemented, giving encouraging effects for many providers and users to use the mechanism.

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