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COMPILATION OF SUBMISSIONS 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 Secretariat is circulating herewith, as an addendum to the original compilation of submissions 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 (UNEP/CBD/WG-ABS/7/INF/1), submissions from Brazil (on behalf on the Like-Minded Megadiverse Countries) and Japan.

2. The contributions have been reproduced in the form and language in which they were received.

* Reposted on 25 March for technical reasons.

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SUBMISSION FROM BRAZIL

Submission by Brazil on behalf of the Group of Like-Minded Megadiverse Countries

Protocol on Access and Benefit-Sharing to the Convention on Biological Diversity

I. Objective

Art. XX
Objective

The objective of this Protocol is to effectively implement the provisions in Articles 1, 8(j),15, 16 and 19(2) of the CBD, by:

1- ensuring the fair and equitable sharing of benefits arising out of the utilization of genetic resources, their derivatives and/or associated traditional knowledge;
2- preventing the misappropriation and misuse of genetic resources, their derivatives and/or associated traditional knowledge;
3- securing compliance in user countries with national laws and requirements, including PIC and MAT, of the country providing those resources or of the Party that has acquired those resources in accordance with the CBD.

III. Compliance

1) Development of tools to encourage compliance

Components for further consideration:

(e) Research funding agencies to oblige users research funds to comply with specific ABS requirements

Article XX

Parties shall encourage research, funding and publishing entities to ask for the unique identifier code referred to in the certificate of compliance as part of their application procedures or research results, as appropriate, when genetic resources, derivatives and associated traditional knowledge is involved.

2) Development of tools to monitor compliance

Components to be further elaborated with the aim of incorporating them in the IR:

a) mechanisms for information exchange

Article XX
Information Sharing and the
Access and Benefit-Sharing Clearing-House

1. An Access and Benefit-Sharing Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

(a) Monitor compliance with national ABS legislation and with this Protocol;

(b) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, access and benefit-sharing;

(c) Assist Parties to implement this Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

2. The Access and Benefit-Sharing Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of this Protocol.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-Sharing Clearing-House any information required to be made available to the Access and Benefit-Sharing Clearing-House under this Protocol, and:

(a) Any existing laws, regulations and guidelines for implementation of this Protocol;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Information about national focal point and competent national authority(ies).

(d) List of defaulters of ABS agreements (“name and shame”)

4. The ABS clearing house shall include an international registration of certificates of compliance with national legislation and requirements on access and benefit-sharing, issued by the competent national authority(ies), in accordance with provisions in Articles X, Y and Z;

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

b) Internationally recognized certificate issued by domestic competent authority

Article XX
Competent National Authorities and National Focal Points

1. Each Party shall designate one national focal point for access and benefit-sharing and make any information relevant to ABS available through the clearing-house mechanism. The national focal point shall provide information to the ABS clearing-house mechanism on procedures for acquiring prior informed consent and mutually agreed terms, including benefit-sharing, and on competent national authorities, relevant indigenous and/or local communities and relevant stakeholders.

2. Each Party shall also designate one or more competent national authorities, which shall be responsible for and duly authorized to act on its behalf with respect to the following functions:

(a) performing the administrative functions required by this Protocol, including the emission of certificates of compliance with national legislation and requirements on access and benefit-sharing; and
(b) the receipt, administration and transfer to the financial mechanism of the funds collected through the enforcement of Article X, paragraph…

A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

3. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

4. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 3 above, and shall also make such information available through the ABS Clearing-House.

Article XX
Certificate of compliance

1. Each Party shall issue a Certificate of Compliance, with international legal effectiveness/applicability, which will be a public document issued by the competent national authority, establishing the origin of the genetic resources, and derivatives and associated traditional knowledge and fulfilment of the ABS requirements.

2. This mandatory internationally recognized certificate shall have international legal effectiveness/applicability, and for that purpose shall contain, at a minimum, the following information:

- Name, address and contact details of the competent national authority(ies);
- Details of the provider;
- Details of the user;
- Description of subject matter (genetic resources, their derivatives and/or traditional knowledge);
- Description of uses permitted and restrictions of use;
- A unique identifier code assigned by the competent national authority(ies);
- Geographic location of the access activity;
- Conditions of transfer to third parties;
- Date of issuance of the Certificate;

3. The Certificate shall not include confidential information related to prior informed consent and mutually agreed terms.

4. Each Party shall establish checkpoints for the Certificate of compliance. Checkpoints may include customs control, intellectual property offices, product approval offices and registration points for other commercial applications not covered by IPRs.

Components for further consideration:

(c) Disclosure requirements

Article XX
Disclosure

1. Intellectual property rights applications and product approval applications whose subject matter concerns, is derived from or makes use of genetic resources, derivatives and/or associated traditional knowledge shall disclose the country of origin or source of such genetic resources, derivatives and /or associated traditional knowledge, as well as evidence that provisions regarding prior informed consent, mutually agreed terms and benefit sharing have been complied with, in accordance with the national legislation of the country providing the resources.

2. Each Party shall put in place effective enforcement procedures so as to ensure compliance with the obligations set out in the above paragraph. In particular, each Party shall establish administrative and/or criminal measures for non-disclosure of the relevant information and the dissemination of false information to the national authorities, and shall ensure that administrative and/or judicial authorities have the authority to prevent the further processing of an application and to revoke or render unenforceable an intellectual property right or a product approval when the applicant has, knowingly or with reasonable grounds to know, failed to comply with the obligations in the above paragraph or provided false or fraudulent information.

3. The obligations above-mentioned in paragraph 1 may be met by the presentation of a certificate of compliance with national legislation and requirements on ABS, issued by the country of origin in accordance with Article XX.

3) Development of tools to enforce compliance

Article XX
Enforcement of National ABS Legislation

1.Each Party shall ensure that users of genetic resources, their derivatives and associated traditional knowledge under its jurisdiction comply with the national legislation of the countries of origin of such resources, derivatives and/or traditional knowledge or of the Parties that have acquired the genetic resources in accordance with the Convention, when accessing and/or using such resources, derivatives and/or associated traditional knowledge.

2. Each Party shall take appropriate, effective and proportionate measures to establish sanctions and remedies when users under their jurisdictions have violated national ABS legislation of the countries of origin of genetic resources, derivatives and/or traditional knowledge or of the Parties that have acquired the genetic resources in accordance with the Convention. Among others, the Parties may establish the following sanctions and remedies:

a) The cessation of the acts related to the infraction;

b) Compensation for damages;

c) The withdrawal from the market of products resulting from the infringement;

d) The prohibition on the import or export of goods, materials or any means referred to in the previous paragraph;

e) The necessary action to avoid continuation or repetition of the offence;

f) Publication of the judgement and notification to interested persons at the expense of the person(s) who made the infraction;

g) Criminal penalties for use of genetic resources, derivatives and associated traditional knowledge without compliance with conditions of access and benefit sharing in the country of origin.

h) Other as appropriate.

3. Each Party shall, at the request of any interested Party, cooperate in the investigation and follow up of cases of alleged violations of the national ABS legislation of the country of origin of genetic resources, derivatives and/or associated traditional knowledge or of the Party that has acquired the genetic resources in accordance with the Convention, including prior informed consent and mutually agreed terms.

4. Each Party shall provide timely guidance and information on the types of assistance that are available to nationals of other jurisdictions to ensure that lack of funds and lack of experience with the law of the users are not elements preventing exercise and enforcement of their rights.

IV. Fair and equitable Benefit-sharing

Components to be further elaborated with the aim of incorporating them in the IR:

2) Benefits to be shared in mutually agreed terms

Article XX
Fair and equitable Benefit-sharing

1. Each Party shall stipulate in its national legislation measures to ensure the fair and equitable sharing of the benefits arising out of the use of genetic resources, derivatives and/or associated traditional knowledge. Those measures shall be incorporated in mutually agreed terms and in prior informed consent.

2. The conditions for the equitable sharing of the benefits arising out of the use of traditional knowledge, innovations and practices associated with genetic resources and derivatives shall be stipulated in mutually agreed terms, in accordance with national legislations: a) between the indigenous or local communities and the users; or b) between users and the national authority of the provider country, with active involvement of concerned indigenous and local communities.

3) Monetary and non-monetary benefits

Parties shall establish a financial mechanism for the IR, including a trust-fund for benefit-sharing arrangements.

4) Access to and transfer of technology

Article XX
Access to and Transfer of Technology

Each Party that develops technologies making use of genetic resources, derivatives and/or associated traditional knowledge shall take legislative, administrative or policy measures to facilitate access to, joint development and transfer of those technologies to developing countries that are the origin of such resources, derivatives and/or associated traditional knowledge under mutually agreed terms, in accordance with Article 16 of the Convention.

5) Sharing of results of research and development on mutually agreed terms

Article XX
Sharing of results of research and development

Parties shall establish, taking into account Article 15, paragraph 7, Article 16, paragraph 3 and 4, Article 19, paragraph 1 and 2, and Article 20, paragraph 4 of the Convention, measures to ensure the fair and equitable sharing of benefits from the results of research and development, including through facilitating access to the results of such research and development and through access to and technology transfer, and other utilization of genetic resources, derivatives and/ or associated traditional knowledge, including technology protected by patents and other intellectual property rights on concessional and preferential terms to developing countries, taking into account prior informed consent and mutually agreed terms and respecting national legislations of the country of origin of such resources or the parties that have acquired the resources in accordance with the Convention.

9) Measures to ensure participation and involvement of ILCs in mutually agreed terms and sharing of benefits with TK holders

The elements of the international regime shall be developed and implemented in accordance with Article 8(j) of the Convention on Biological Diversity:
(a) Parties may consider developing, adopting and/or recognizing, as appropriate, sui generis systems for the protection of traditional knowledge, innovations and practices associated to genetic resources and derivatives;
(b) Parties shall recognize and protect the rights of indigenous and local communities to their knowledge, innovations and practices and ensure the equitable sharing of benefits arising from the utilization of the knowledge, innovations and practices associated with genetic resources and derivatives, subject to the national legislation of the countries where these communities are located;
(c) Users shall obtain the prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources and derivatives, in accordance with Article 8(j) of the Convention on Biological Diversity, subject to national legislation of the country where these communities are located.

V. Access

Article XX
Access

States have sovereign rights over their natural resources and the authority to determine access to genetic resources, derivatives and associated tradicional knowledge rests with national Governments and is subject to national legislation.

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 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.
