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Annex

INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING

In accordance with the Convention on Biological Diversity,

Nature

The international regime could be composed of one or more instruments within a set of principles, norms, rules and decision-making procedures legally-binding and/or non-binding.

[Potential] Objectives

To endeavour to create conditions to [facilitate] [regulate] access to genetic resources for environmentally sound uses by other Parties and not to impose restrictions that run counter to the objectives of this Convention.

To ensure the fair and equitable sharing of the monetary and non-monetary benefits arising from the use of [such] [genetic] resources and associated traditional knowledge, taking into account that the three objectives of the Convention are interlinked.

[To establish a mechanism providing certainty about the [legal provenance] [origin] [source] of genetic resources].

[[Subject to national legislation] To [protect] [respect, preserve and maintain the traditional knowledge of] the [rights] of indigenous and local communities to their traditional knowledge, innovations and practices [associated to genetic resources and derivatives] [related to the conservation and sustainable use of biological diversity] and to [encourage] [ensure] the fair and equitable sharing of the monetary and non-monetary benefits arising from the utilization of their knowledge, [consistent with human rights obligations] [subject to national legislation of the countries where these communities are located] [and applicable international law]].

[To ensure compliance with PIC in the context of MAT of countries of origin and of indigenous and local communities.]

To contribute to the effective implementation of articles 15, 8(j) [and 16 to 19] and the three objectives of the convention.

The conservation and sustainable use of biological diversity.

[To prevent the misappropriation and misuse of genetic resources, their derivatives and associated traditional knowledge]

[To ensure that fair and equitable sharing of benefits flow to the countries of origin of the genetic resources]

[[Promote] [Ensure] compliance with prior informed consent of the providing countries and of indigenous and local communities and mutually agreed terms;]

[Ensure and enforce the rights and obligations of users of genetic resources;]

[Ensure mutual supportiveness with relevant existing international instruments and processes] [and that they are supportive of and do not run counter to the objectives of the convention].

[Contribute or promote capacity-building and [to ensure] technology transfer to developing countries, in particular least developed countries and small island developing States]

Scope

1. The international regime applies to, [in accordance with national legislation and other international obligations]:

(a) Access to genetic resources [and derivatives and products] [subject to the national legislation of the country of origin];

(b) [[Conditions to facilitate access to and] transboundary [movement] [utilisation] of genetic resources [and derivatives and products] [or associated traditional knowledge]]

(c) Fair and equitable sharing of the monetary and non-monetary benefits arising out the utilization of genetic resources [and their derivatives and/or] associated traditional knowledge [and, where appropriate, their derivatives and products], in the context of mutually agreed terms [based on prior informed consent] [in accordance with the national legislation of the country of origin].

(d) [[Protection of] [Respect, preserve and maintain] traditional knowledge, innovations and practices of indigenous and local communities [embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity] [associated to genetic resources] [and their derivatives and products] in accordance with national legislation].

2. [The international regime applies to all genetic resources and associated traditional knowledge, innovations and practices and benefits arising from the utilization of such resources.]

3. [The international regime will not apply to the plant genetic resources [of those plant species] that are considered by [under annex 1 of] the International Treaty on Plant Genetic Resources for Food and Agriculture [or by the Commission on Genetic Resources for Food and Agriculture], [when those resources are used for the purposes of that Treaty].

4. [The international regime is without prejudice to the FAO International Treaty on Plant Genetic Resources for Food and Agriculture and will take into account the work of the WIPO/IGC on the intellectual property aspects of *sui generis* systems for the protection of traditional knowledge and folklore against misappropriation and misuse].

5. [The international regime ensures mutual supportiveness and complementarity with relevant existing international instruments and processes] [and that they are supportive of and do not run counter to the objectives of the Convention].

6. [The international regime will not apply to human genetic resources].

7. [The scope of the regime would be in compliance with national access and benefit-sharing regimes relating to the genetic resources within national jurisdictions [, in the context of the international trade and exchange of these genetic resources]].

[Potential] Elements [to be considered for inclusion in the international regime]

Access to genetic resources [and derivatives and products]

1. [States have sovereign rights over their own genetic resources, and the authority to determine access rests with national Governments and is subject to national legislation.]

2. [[Subject to national legislation,] conditions for access to genetic resources [derivatives and products] shall be [dependent upon] [related to] benefit sharing arrangements].

3. Access procedures shall be clear, simple and transparent and provide legal certainty to different kinds of users and providers of genetic resources with a view to the effective implementation of Article 15, [paragraph 2], of the Convention on Biological Diversity.

4. [Parties] [Countries of origin] providing genetic resources, [derivatives and products][, including countries of origin,] in accordance with Article 2 and Article 15 of the Convention [may] [shall] establish measures requiring that access to such genetic resources [derivatives and products] [for specific uses] shall be subject to prior informed consent.

5. [Parties that are not countries of origin of genetic resources or their derivatives they hold shall not give access to those genetic resources without the prior informed consent of the countries of origin of those genetic resources.]

6. [Where the countries of origin of genetic resources or derivatives can not be identified, the Parties in whose territories those genetic resources or derivatives are found will grant access to users on behalf of the international community.]

7. Mutually agreed terms for access to and specific uses of genetic resources [or derivatives], in accordance with Article 15, paragraph 4 of the Convention on Biological Diversity[, may include conditions for transfer of such genetic resources [or derivatives] to third parties, subject to national legislation of countries of origin].

[Recognition and protection of] traditional knowledge associated with genetic resources [derivatives and products]

The elements of the international regime should 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, [international,] national and local *sui generis* [models] [systems] for the protection of traditional knowledge, innovations and practices associated to genetic resources, [derivatives and products;]]

(b) [Subject to its national legislation,] Parties [should] [recognize and protect the rights] [respect, preserve and maintain knowledge, innovations and

practices] of indigenous and local communities and [ensure] [encourage] the equitable sharing of benefits arising from the utilisation of such knowledge, innovations and practices [regarding benefit-sharing derived from their traditional knowledge associated with genetic resources, [derivatives and products,] subject to the national legislation of the countries where these communities are located [and to applicable international law];

(c) [[Users [Parties] should comply with the prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources, [derivatives and products] in accordance with Article 8(j) of the Convention on Biological Diversity, subject to national legislation of the country where these communities are located [and to applicable international law]].

(d) [Access and benefit sharing arrangements relating to traditional knowledge should be implemented in the context of national ABS regimes.]

Fair and equitable benefit-sharing

1. [Minimum conditions for the fair and equitable sharing of the benefits arising out of the use of genetic resources, derivatives or products shall be stipulated in relevant national [access] legislations [or] [and] under the international regime] and [shall] [may] be taken into consideration in mutually agreed terms [shall] [may] be based on prior informed consent between the provider and user of given resources.]

2. [Mutually agreed terms conditions may stipulate benefit-sharing arrangements regarding derivatives and products of genetic resources]

3. The conditions for the sharing of the benefits arising out of the use of traditional knowledge, innovations or practices and associated [with] genetic resources [derivatives and products] [will] [may] be stipulated in mutually agreed terms [between users and the competent national authority of the provider country with active involvement of concerned indigenous and local communities] [between the indigenous or local communities and the users, and where appropriate with the involvement of the provider country].

4. [Mutually agreed terms may contain provisions on whether intellectual property rights may be sought and if so under what conditions.]

5. Mutually agreed terms may stipulate monetary and/or non-monetary conditions for the use of genetic resources, [their derivatives and/or products] and associated traditional knowledge, innovations and practices.

6. [The international regime should establish basic benefit-sharing [obligations] [conditions], including the distribution of benefits through the financial mechanism, to be applicable in the absence of specific provisions in access arrangements.]

7. [Where the country of origin of the genetic resources or derivatives accessed cannot be identified, the monetary benefits there from shall accrue to the financial mechanism and the non-monetary benefits shall be made available to those Parties that need them.]

8. [Parties should establish, taking into account 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 technology transfer, and other utilization of genetic resources, [derivatives and products] and associated traditional knowledge, taking into account prior informed consent and mutually agreed terms and respecting national legislations of the country providing genetic resources.]

9. [Parties that develop technologies making use of genetic resources, derivatives and product should establish national legislation to facilitate access to and transfer of those technologies to developing countries that are the origin of such resources under mutually agreed terms.]

10. [Clarification of the actual nature of benefit sharing, emphasizing the need for differentiation of commercial versus non-commercial uses of genetic resources with resulting differentiated obligations/expectations.]

11. [Practical and enforceable benefit sharing clauses in material transfer agreements as agreed to between the providers and the users.]

12. [Benefits should be directed in such a way as to promote conservation and sustainable use of biological diversity [in countries of origin of genetic resources.]]

13. [Benefit sharing arrangements should not be limited to mutually agreed terms when these arrangements are supporting prior informed consent.]

[Disclosure [of [legal provenance] [origin] [prior informed consent and benefit-sharing]

1. Intellectual property rights applications whose subject matter [concerns or makes use of] [is directly based on] genetic resources [and/or derivatives and products] and/or associated traditional knowledge should disclose the country of origin or source of such genetic resources, [derivatives and products] or associated traditional knowledge[, as well as evidence that provisions regarding prior informed consent and benefit sharing have been complied with, in accordance with the national legislation of the country providing the resources].

2. [National legislation shall provide for remedies to sanction lack of compliance with the requirements set out in the above paragraph which must include inter alia revocation of the intellectual property rights in question, as well as co-ownership of the IPR and its transfer.]

3. [If the disclosed information is incorrect or incomplete, effective, proportionate and dissuasive sanctions should be envisaged outside the field of patent law.]]

[[Certificate of origin] [International certificate of [origin/source]/legal provenance]

1. The international regime may establish an international certificate of origin/source/legal provenance of genetic resources, [derivatives and/or products] to be issued by the [provider country] [country of origin].

2. The international regime [may] [shall] establish a system to certify the [origin/source/legal provenance of genetic resources] [legal utilization of

traditional knowledge, innovations or practices of indigenous and local communities associated to genetic resources].

3. Such certificates of origin/source/legal provenance [or utilization] may be [an integral part] [evidence] of PIC and MAT arrangements.

4. [Such certificates of origin/source/legal provenance [or utilization] and, if existing, evidence of PIC and MAT related arrangements may be a precondition for patentability and other intellectually property applications.]

5. [An international certificate of origin/source/legal provenance could be an element of an international regime.]

6. [The potential needs, objectives, desirable characteristics/features, implementation, challenges, including costs and legislative implications of such an international certificate, are to be further explored.]

7. [The certificate of origin/source/legal provenance may be used as a means of complying with the disclosure requirements according to national legislation.]]

Implementation, monitoring and reporting

1. [Parties shall establish] mechanisms for monitoring implementation as well as reporting procedures [may be considered] for the international regime.

2. [Parties [may] [shall] develop national legislation[, as appropriate,] for the implementation of the international regime.]

[Compliance and enforcement]

1. [Recipients of genetic material, [derivatives and products] shall make no applications for patents related to such genetic materials, [derivatives or products] without the PIC of the [provider country] [country of origin.] [Non compliance of this provision shall, *inter alia*, result in the rejection of the patent application and where necessary the revocation of such patent.]

2. [Parties [may] [shall] develop national legislation[, as appropriate,] for the implementation of the international regime.]

3. [Each Party must comply with national legislation of the [countries providing genetic resources, derivatives and products] [country of origin], [including countries of origin], regarding access and benefit-sharing when accessing and/or using genetic resources, [derivatives and products] and associated traditional knowledge.]

4. [The international regime [may] [shall] ensure that whatever terms and conditions that may be stipulated under mutually agreed terms are complied with and enforced.]

5. [The international regime [may] [shall] contain] cooperative procedures and institutional mechanisms to [[promote] and [ensure]] compliance [may be considered for the international regime].

6. [International regime [shall] [may] contain measures to ensure compliance with the prior informed consent of [Parties] [indigenous and local communities regarding access to their traditional knowledge, innovations and practices associated with genetic resources[, derivatives and products].]]

7. [International regime [shall] [may] contain measures to [[promote] and [ensure]] compliance with the prior informed consent of the country providing genetic resources, [derivatives and products] including countries of origin, in accordance with Article 15, paragraph 3, of the Convention on Biological Diversity.]

8. [International regime [shall] [may] contain measures to prevent misappropriation and unauthorized access and use of genetic resources [, their derivatives and products] and associated traditional knowledge, innovations and practices.]

9. [Parties should take measures to ensure that genetic resources utilized within their jurisdiction comply with the Convention on Biological Diversity and the conditions under which access was granted.]

10. [Create mechanisms to facilitate collaboration among relevant enforcement agencies in both provider and user countries.]

11. [Without prejudice to specific remedies concerning IPR applications, national legislations shall provide for sanctions to prevent the use of genetic resources, derivatives and associated traditional knowledge without compliance with provisions of the international regime, in particular those related to access and benefit-sharing legislations from countries of origin.]

12. [The following are considered acts or cases of misappropriation:

(a) Use of genetic resources, their derivatives and products and/or associated traditional knowledge without compliance with the provisions of the international regime;

(b) Any acquisition, appropriation or utilization of genetic resources, their derivatives and products and/or associated traditional knowledge by unfair or illicit means;

(c) Deriving commercial benefits from the acquisition, appropriation or utilization of genetic resource, derivatives and products and/or associated traditional knowledge when the person, using genetic resource, derivatives and products, knows, or is negligent in failing to know, that these were acquired or appropriated by unfair means;

(d) Other commercial activities contrary to honest practices that gain in equitable benefit from the genetic resource, derivatives and product and/or associated traditional knowledge.]

[(e) Use of genetic resources, their derivatives and products and/or associated traditional knowledge for purposes other than for which it was accessed; and]

[(f) Obtaining unauthorized information that can be used for the reconstitution of genetic resources, derivatives or products or traditional knowledge.]

[Access to justice

1. Measures to [facilitate] [ensure] access to justice and redress.

2. Measures to [guarantee and] facilitate access to justice and redress, including administrative and judicial remedies, as well as alternative dispute resolution mechanisms [by providers and users].]

[Dispute settlement mechanism]

1. [Parties [shall] [may] establish a dispute settlement mechanism for the international regime.]

2. [Provisions of Article 27 of the Convention on Biological Diversity shall apply with respect to the settlement of disputes under the international regime.]

[Financial mechanism]

Parties [shall] [may] establish a financial mechanism for the international regime including for benefit-sharing arrangements.]

Capacity-building [and technology transfer]

1. The international regime should include provisions for the building and enhancement of capacity in developing countries, least developed countries and small-island developing states, as well as countries with economies in transition, for the implementation of the international regime at national, regional and international levels.

2. [Measures for effective technology transfer and cooperation so as to support the generation of social, economic and environmental benefits.]

3. [Building of human, institutional and scientific capacities including for putting in place a legal mechanism, taking into account Articles 18, 19 and 20.4 of the Convention.]

[Institutional support]

1. [Existing non-legislative international measures that support or promote the effective implementation of Articles 15, 8(j) and the three objectives of the Convention are identified and recognized.]

2. Environmentally sound research utilizing genetic resources and associated traditional knowledge is promoted, and commercial and non-commercial scientific research, including taxonomic research, are distinguished.

[Non-Parties]