

## THE INTERNATIONAL REGIME

### I. OBJECTIVE 1/

Effectively implement the provisions [in Articles 15, 8(j), 1, 16 and 19.2] of the Convention [and its three objectives], specifically by:

- [[Facilitating] [regulating transparent] access to genetic resources, [their derivatives] [and products] [and associated traditional knowledge]; ]
- Ensuring [the conditions and measures for] the [effective,] fair and equitable sharing of benefits arising out of their utilization, [their derivatives] [and products] [and associated traditional knowledge] [and to prevent their misappropriation and misuse];
- [Securing compliance in user countries with national laws and requirements, including PIC and MAT, of the country [of origin] providing those resources or of the Party that has acquired those resources in accordance with the Convention on Biological Diversity].

[taking into account all rights over those resources, including the rights of indigenous and local communities, and ensuring compliance with PIC.]

### II. SCOPE 2/

#### Option 1 (Consolidated text of submissions made at WG-ABS 6)

1. The international regime on access and benefit-sharing applies to [biological resources,] genetic resources, [derivatives,] [products] as well as [to their] [associated] traditional knowledge, [and derivatives of traditional knowledge associated with genetic resources,] innovations and practices [in accordance with Article 8(j)] [within national jurisdiction and of a transboundary nature] [in accordance with the relevant provisions of the CBD].

[2. Subject to paragraph 1, the international regime on access and benefit-sharing applies to:

(a) [Benefits arising from commercial and other utilization] [from] [genetic resources acquired after] the entry into force of the [international regime] [Convention on Biological Diversity];

[(b) Continuing benefits arising from commercial and other utilization taken prior to the coming into force of the Convention on Biological Diversity.]]

3. The international regime on access and benefit-sharing does not apply to:

(a) [Human genetic resources;]

(b) [Genetic resources that were acquired before the entry into force of the Convention on Biological Diversity on 29 December 1993 [or before the entry into force for a Party];] [Genetic material acquired prior to the national ratification of the Convention on Biological Diversity [and since then cultivated *ex situ*];]

(c) [Genetic material already made freely available by the country of origin;]

(d) [[Species] [listed in Annex I of] [genetic resources covered under] the International Treaty on Plant Genetic Resources for Food and Agriculture [unless they are used beyond the purpose of the said treaty];]

(e) [Genetic resources, including marine genetic resources found in areas beyond national jurisdiction;]

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1/ These proposals were neither negotiated nor agreed.

2/ These proposals were neither negotiated nor agreed.

(f) [Genetic resources located in the Antarctic Treaty Area.]

4. [The international regime on access and benefit-sharing should provide [[flexibility] to respect] existing [and allow for the implementation and potential and further development of other, more] [specialized international access and benefit-sharing systems].]

[5. [In the further elaboration and negotiation of the international regime on access and benefit-sharing [special] [due] [consideration] will given to]:

(a) [Genetic resources covered by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture when these are accessed for research, breeding or training for the purpose for food and agriculture;]

(b) [Animal genetic resources for food and agriculture;]

(c) [Genetic resources within the remit of the FAO Commission on Genetic Resources for Food and Agriculture;]

(d) [The relationship with the International Convention for the Protection of New Varieties of Plants (UPOV);]

(e) [The work within the WIPO [including the] Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore;]

(f) [Marine genetic resources found in areas beyond national jurisdiction;]

(g) [Genetic resources located in the Antarctic Treaty Area.]]

## **Option 2**

The international regime applies to all genetic resources and associated traditional knowledge, innovations and practices covered by the Convention on Biological Diversity, subject to other international obligations, with the exclusion of human genetic resources and genetic resources beyond national jurisdiction.

## **Option 3**

1. Will cover:

- Access to genetic resources and promotion and safeguarding of fair and equitable sharing of the benefits arising out of the utilization of genetic resources in accordance with relevant provisions of the Convention on Biological Diversity;
- Traditional knowledge, innovations and practices in accordance with Article 8(j).

2. Outside the scope will be:

- Genetic resources that were acquired before the entry into force of the Convention on Biological Diversity on 29 December 1993;
- Human genetic resources.

3. The international regime on access and benefit-sharing established in the framework of the Convention on Biological Diversity should provide flexibility to respect existing and allow for the implementation and potential and further development of other, more specialized international access and benefit-sharing systems.

4. Special consideration will be given to:

- Genetic resources covered by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture when these are accessed for research, breeding or training for the purpose for food and agriculture;

- The relationship with the International Convention for the Protection of New Varieties of Plants (UPOV);
- Marine genetic resources found in areas beyond national jurisdiction;
- Genetic resources located in the Antarctic Treaty area;
- Animal genetic resources for food and agriculture;
- Work within the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore;
- Genetic resources within the remit of the FAO Commission on Genetic Resources for Food and Agriculture.

### **III. MAIN COMPONENTS**

#### **A. *Fair and equitable benefit-sharing***

##### *1. Components to be further elaborated with the aim of incorporating them in the international regime*

- 1) ■ Linkage of access to the fair and equitable sharing of benefits
- 2) ■ Benefits to be shared on mutually agreed terms
- 3) ■ Monetary and/or non-monetary benefits
- 4) ■ Access to and transfer of technology
- 5) ■ Sharing of results of research and development on mutually agreed terms
- 6) ■ Effective participation in research activities, and/or joint development in research activities
- 7) ■ Mechanisms to promote equality in negotiations
- 8) ■ Awareness-raising
- 9) ■ Measures to ensure participation and involvement of indigenous and local communities in mutually agreed terms and sharing of benefits with traditional-knowledge holders
- 10) ■ Mechanisms to encourage benefits to be directed toward conservation and sustainable use of biodiversity and socio-economic development, in particular the Millennium Development Goals (MDGs) in accordance with national legislation

##### *2. Components for further consideration*

- 1) Development of international minimum conditions and standards
- 2) Benefit-sharing for every use
- 3) Multilateral benefit-sharing options when origin is not clear or in transboundary situations
- 4) Establishment of trust funds to address transboundary situations
- 5) Development of menus of model clauses for potential inclusion in material transfer agreements
- 6) Enhanced utilization of Bonn Guidelines

## **B. Access to genetic resources <sup>3/</sup>**

### *1. Components to be further elaborated with the aim of incorporating them in the international regime*

- 1) ■ Recognition of the sovereign rights and the authority of Parties to determine access
- 2) ■ Linkage of access to fair and equitable sharing of benefits
- 3) ■ Legal certainty, clarity and transparency of access rules

### *2. Components for further consideration*

- 1) Non-discrimination of access rules
- 2) International access standards (that do not require harmonization of domestic access legislation) to support compliance across jurisdictions
- 3) Internationally developed model domestic legislation
- 4) Minimization of administration and transaction costs
- 5) Simplified access rules for non-commercial research

## **C. Compliance**

### *1. Components to be further elaborated with the aim of incorporating them in the international regime*

- 1) ■ Development of tools to encourage compliance:
  - (a) Awareness-raising activities
- 2) ■ Development of tools to monitor compliance:
  - (a) Mechanisms for information exchange
  - (b) Internationally recognized certificate issued by a domestic competent authority
- 3) ■ Development of tools to enforce compliance

### *2. Components for further consideration*

- 1) Development of tools to encourage compliance:
  - (a) International understanding of misappropriation/misuse
  - (b) Sectoral menus of model clauses for material transfer agreements
  - (c) Codes of conduct for important groups of users
  - (d) Identification of best-practice codes of conduct
  - (e) Research funding agencies to oblige users receiving research funds to comply with specific access and benefit-sharing requirements
  - (f) Unilateral declaration by users
  - (g) International access standards (that do not require harmonization of domestic access legislation) to support compliance across jurisdictions
- 2) Development of tools to monitor compliance:
  - (a) Tracking and reporting systems

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<sup>3/</sup> The title is without prejudice to the eventual scope of the international regime.

- (b) Information technology for tracking
- (c) Disclosure requirements
- (d) Identification of check points
- 3) Development of tools to enforce compliance:
  - (a) Measures to ensure access to justice with the aim of enforcing ABS arrangements
  - (b) Dispute settlement mechanisms:
    - (i) Inter-State
    - (ii) Private international law
    - (iii) Alternative dispute resolution
  - (c) Enforcement of judgments and arbitral awards across jurisdictions
  - (d) Information exchange procedures between national focal points for access and benefit-sharing to help providers obtain relevant information in specific cases of alleged infringements of prior-informed-consent requirements
  - (e) Remedies and sanctions
- 4) Measures to ensure compliance with customary law and local systems of protection

***D. Traditional knowledge associated with genetic resources <sup>4/</sup>***

*1. Components to be further elaborated with the aim of incorporating them in the international regime*

- 1)■ Measures to ensure the fair and equitable sharing with traditional-knowledge holders of benefits arising out of the utilization of traditional knowledge in accordance with Article 8(j) of the Convention on Biological Diversity
- 2)■ Measures to ensure that access to traditional knowledge takes place in accordance with community level procedures
- 3)■ Measures to address the use of traditional knowledge in the context of benefit-sharing arrangements
- 4)■ Identification of best practices to ensure respect for traditional knowledge in ABS related research
- 5)■ Incorporation of traditional knowledge in development of model clauses for material transfer agreements
- 6)■ Identification of individual or authority to grant access in accordance with community level procedures
- 7)■ Access with approval of traditional-knowledge holders
- 8)■ No engineered or coerced access to traditional knowledge

*2. Components for further consideration*

- 1) Prior informed consent of, and mutually agreed terms with, holders of traditional knowledge, including indigenous and local communities, when traditional knowledge is accessed

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<sup>4/</sup> The title is without prejudice to the eventual scope of the international regime.

- 2) Internationally developed guidelines to assist Parties in the development of their domestic legislation and policies
- 3) Declaration to be made on the internationally recognized certificate as to whether there is any associated traditional knowledge and who owners of traditional knowledge are
- 4) Community-level distribution of benefits arising out of traditional knowledge

#### ***E. Capacity***

##### *1. Components to be further elaborated with the aim of incorporating them in the international regime*

- 1) ■ Capacity-building measures at all relevant levels for:
  - (a) Development of national legislation
  - (b) Participation in negotiations, including contract negotiations
  - (c) Information and communication technology
  - (d) Development and use of valuation methods
  - (e) Bioprospecting, associated research and taxonomic studies
  - (f) Monitoring and enforcing compliance
  - (g) Use of access and benefit-sharing for sustainable development
- 2) ■ National capacity self-assessments to be used as a guideline for minimum capacity-building requirements
- 3) ■ Measures for technology transfer and cooperation
- 4) ■ Special capacity-building measures for indigenous and local communities
- 5) ■ Development of menus of model clauses for potential inclusion in material transfer agreements

##### *2. Components for further consideration*

- 1) Establishment of a financial mechanism

#### **IV. NATURE**

##### ***Compilation of proposals on nature 5/***

##### *1. Recommendation of Co-Chairs of the Working Group*

###### **Options**

1. One legally binding instrument
2. A combination of legally binding and non-binding instruments
3. A non-binding instrument

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<sup>5/</sup> These proposals were neither discussed, negotiated nor agreed.

## 2. *Submissions*

### **Option 1**

The international regime should be legally binding. In addition, it should stress more cooperative enforcement between parties and *not* refer conflicts primarily to private international law, which is not only expensive, but also a strain on resource poor countries.

### **Option 2**

1. One legally binding instrument
2. A combination of legally binding and/or non-binding instruments
3. A non-binding instrument

### **Option 3**

The international regime shall be composed of a single legally binding instrument containing a set of principles, norms, rules and compliance and enforcement measures.

### **Option 4**

The nature should be discussed after deliberations of the substance of an international regime are completed. For the time being, Japan suggests the following: the international regime could be composed of one or more non-binding instruments within a set of principles, norms, rules and decision-making procedures.

### **Option 5**

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