



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

Fourth meeting

Granada, Spain, 30 January to 3 February 2006

Item 6 of the provisional agenda\*

**INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING**

*Consolidated text of the comments and proposals contained in submissions by parties, Governments and organizations regarding the international regime*

*Note by the Executive Secretary*

**I. INTRODUCTION**

1. At its third meeting, the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, in paragraph 3 of its recommendation 3/1, invited Parties, Governments, indigenous and local communities, international organizations and all relevant stakeholders to submit to the Executive Secretary written comments and proposals on items in annex I to the recommendation as soon as possible and, in any case, no later than three months prior to the fourth meeting of the Working Group.
2. In paragraph 4 of the same recommendation, the Working Group requested the Executive Secretary to prepare a compilation and a consolidated text of the comments and proposals submitted by Parties, Governments, international organizations, indigenous and local communities and all relevant stakeholders for consideration by the fourth meetings of the Working Group on Access and Benefit-sharing and the Working Group on Article 8(j), pursuant to decisions VII/16 and VII/19 D.
3. Through notification 2005-044 dated 14 April 2005, the Executive Secretary invited Parties, Governments, indigenous and local communities, international organizations and all relevant stakeholders submit comments and proposals on items contained in annex I to the recommendation. Submissions were received from the following Parties and other Governments: Canada, Costa Rica, Czech Republic, Ethiopia, European Community, India, Japan, Mexico, Norway, and the United States of America. The following international organizations and stakeholders also submitted comments and proposals: the Food and Agriculture Organization of the United Nations (FAO); the International Union for the Protection of New Varieties of Plants (UPOV); the Australian APEC Study Centre; the International Federation of Organic Agriculture Movements (IFOAM), Bonn, the Research Foundation for Science, Technology and Ecology, New Delhi, and the Greens/European Free Alliance in the European Parliament, Brussels (joint submission); and the Pharmaceutical

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Research and Manufacturers of America. A compilation of the full text of these submissions is contained in an information document (UNEP/CBD/WG-ABS/4/INF/3).

4. The Executive Secretary has prepared the present consolidated text of comments and proposals to assist Parties in their further consideration of the items contained in annex I to recommendation 3/1 of the third meeting of the Working Group on Access and Benefit-sharing. Section II of the document contains general comments by Parties, Governments, international organizations, indigenous and local communities and all relevant stakeholders on the international regime and the items in annex I. Section III contains the more specific comments and proposals regarding each item in annex I of recommendation 3/1 under the various sub-headings of that annex. Finally, the annex to the present document contains a revised annex I to recommendation 3/1 including additional proposals submitted by Parties, Governments and organizations.

## II. GENERAL COMMENTS

### European Community

The European Union welcomes the progress achieved at the third meeting of the Open-Ended Working Group on Access and Benefit-sharing. The European Union is concerned, however, about the number of additional options and elements that have been added to an already long list of potential options and elements of the international regime. It seems to us that further discussions should focus on those aspects that – following an analysis of gaps in existing national, regional and international legal and other instruments – are fundamental to achieving a practicable, transparent, and efficient international regime to promote and safeguard the facilitated access to genetic resources and the fair and equitable sharing of benefits arising out of their utilization. In this context, the European Union wishes to record that it supports the following options and elements listed in annex A:

As regards Annex I, No. 2 on scope, the European Union supports option 6, as this is the closest to decision VII/19, as copied above in italics before the new options.

With respect to Annex I, No. 3 on potential objectives, the European Union supports Option 5.

As regards Annex I, No. 4 on elements to be considered for inclusion in the international regime, the European Union notes that this section follows the same structure as the matrix contained in Annex B. The European Union's comprehensive views on these elements are included in the information provided in the matrix.

With respect to Annex I, No. 5 on potential additional elements and options identified, the European Union does not support the addition of the further options and elements identified by the Third Open-Ended Working Group, since the mandate given by COP-7 is sufficiently comprehensive.

The European Union believes that the main emphasis should now be focused on the gap analysis.

### Japan

If providing countries are too strict in regulating access to genetic resources, this will lead to user companies being reluctant to access such resources. This would mean that commercial benefits would not be generated. There would be few benefits to share with providing countries. This outcome would be unfortunate for users, providers, and all other stakeholders.

Facilitating access to genetic resources will build a win-win situation among providers and users through the use of these resources.

### Mexico

The use of genetic resources refers to the direct usage of genetic material or indirect usage through the information derived or from materials expressed by the original genetic material with commercial purposes. This also means that the recollection of material for other purposes falls out of the scope of the international Regime. If there would be a change in the intention of the use of the collected

material originally with scientific purposes to a use with commercial purposes, this modification would also be subject to the regime.

### **Norway**

In general, Norway is of the opinion that the list of options and elements should be narrowed down. The negotiations of an international regime should focus on issues to be addressed at the international level.

Norway believes that most of the options are already included in section 4 of annex I. With regard to additional elements, Norway agrees that the focus should primarily be on the elements listed in option 1 under section 5 A.

### **International Union for the Protection of New Varieties of Plants (UPOV)**

The UPOV Convention is not an instrument relating to access and benefit-sharing. However, as explained more fully in the comments on Annex A (annex I of this document), there are certain measures under consideration in the international regime, in particular concerning disclosure of origin in relation to applications for intellectual property rights, which could be contrary to the UPOV Convention. Therefore, in the same manner as CBD wishes to ensure that “intellectual property rights do not undermine the international regime”, we would request that consideration is made that any measure pursued in the international regime do not undermine plant variety protection according to the UPOV Convention. For its part UPOV supports the view that the CBD and relevant international instruments dealing with intellectual property rights, including the UPOV Convention, should be mutually supportive.

UPOV considers that plant breeding is a fundamental aspect of the sustainable use and development of genetic resources. It is of the opinion that access to genetic resources is a key requirement for sustainable and substantial progress in plant breeding. The concept of the “breeder’s exemption” in the UPOV Convention, whereby acts done for the purpose of breeding other varieties are not subject to any restriction, reflects the view of UPOV that the worldwide community of breeders needs access to all forms of breeding material to sustain greatest progress in plant breeding and, thereby, to maximize the use of genetic resources for the benefit of society. In addition, the UPOV Convention has inherent benefit-sharing principles in the form of the breeder’s exemption and other exceptions to the breeder’s right and UPOV is concerned about any other measures for benefit-sharing which could introduce unnecessary barriers to progress in breeding and the utilization of genetic resources. UPOV urges the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing to recognize these principles and, therefore, of the UPOV Convention.

### **Australian APEC Study Centre**

A legally binding international regime to regulate access to and benefit sharing from genetic resources is strongly opposed.

This constitutes onerous regulation which will be likely to stop bioprospecting altogether. It will deter general investment in biotechnology in the countries which adopt such a system.

Using a legally binding international instrument to set the terms of access to genetic resources and to stipulate how equitable sharing of resources is to be achieved will transfer responsibility for this from national governments to an international secretariat. This will reduce the capacity of Governments to develop approaches which best suit the distinct characteristics of their biodiversity.

If a legally binding regime included rights to establish an international system of regulated certification of the legality of genetic resource materials, this would create a powerful disincentive for companies to explore naturally occurring genetic resources.

Proposals to include in such a regime a right for Governments to have a say over how any product, even patented, which was developed from a genetic resource was to be used, will undermine intellectual property law and undermine use of property rights to manage access to genetic resources.

Any party to such a regime will deny itself the opportunity to secure investment in development of biotechnology industries. It will deny itself the opportunity to secure royalties which can be used for more effective management of the nation's biodiversity.

**International Federation of Organic Agriculture Movements (IFOAM), Bonn, Research Foundation for Science, Technology and Ecology, New Delhi, and The Greens/European Free Alliance in the European Parliament, Brussels**

On the question of whether the international regime should be legally binding, we think that, in principle, it must be—although, in practice, that depends on the character of the instrument as finally agreed. We are convinced that we would never have obtained the justice we sought if the European Patent Convention had not been legally binding. The patentees in our case fought to maintain their control over the Neem product they had claimed, and it is difficult to imagine that we would have emerged victorious in a system which was not legally binding. It would be idealistic to expect those who stand to gain the most financially from biopiracy patents to renounce them out of respect for a voluntary code of conduct. The international regime will have to have teeth to acquire any relevance among already existing systems which ARE legally binding.

A striking example of this is the “Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits arising from their Utilization”. This non-legally binding set of guidelines was adopted by the European Commission with much fanfare, and yet this has in no way prevented the EU itself and some of its individual Member States from negotiating bilateral Free Trade Agreements which impose even more demanding patenting requirements on the poor country partners than TRIPs (which, in its present form, runs counter to the ABS approach).

On the question of scope: We would strongly urge the Working Group to retain the broadest possible formulations of the targeted resources. Although we understand that the term “genetic resources” is used for historical reasons, we would nonetheless like to take this opportunity to propose the broader term biological resources to replace it. “Biological resources” would include genetic resources, whereas “genetic resources” is a more restrictive term. For example, it would be more accurate to describe the subject of the patent we challenged as having been derived from a “biological resource”, since the genetic (DNA, reproductive) aspects of the material were not relevant to the claimed innovation.

Furthermore, the term “genetic resources” would indicate that the scope is primarily intended to cover “inventions” based on genetic modification, manipulation, and engineering of the genetic material. We do not wish for the International Regime on ABS to become the new cover for patents on life, which we oppose.

The terms “derivatives and products”, as in Option 3, should be retained.

The use of the term “protection”, in association with “traditional knowledge, innovations and practices associated with genetic resources” – which has apparently garnered wide agreement, appearing in all six options as point [c]- is nonetheless questionable for us. We think it could lead to confusion, as the same term is used in connection with intellectual property rights. A different term such as safeguarding or conservation may be helpful in order to distinguish legal instruments developed specifically for traditional ownership. However, as community innovation may be considered to be a form of collective intellectual property, it may be that the patent instrument could be successfully adapted to cover it. In this case, the word “protection” would be appropriate.

With regard to the Potential Objectives of the Regime: We disagree that a primary objective of this instrument should be to create conditions to facilitate access to genetic resources and traditional knowledge (although we understand the historic reasons for inclusion of the point). In our view, such facilitated access may naturally arise as a result of the correct functioning of the Regime, and as the confidence of the source communities is rebuilt; this cannot be its reason d'être. The objective of the International Regime should remain clearly focused on preventing the theft of biodiversity and traditional

knowledge. We would therefore propose the formulation “regulate access to resources” rather than “facilitate”.

In any event, we would disagree with an objective of insuring access to genetic resources in a non-discriminatory fashion; on the contrary, conflicts regarding access should be resolved on the basis of a principle of positive discrimination which recognizes a priority in the utilization and exploitation of biological resources and traditional knowledge to be accorded to parties from the countries of origin.

Under Measures for implementing the International Regime, there should be exploration of a mechanism to suspend the effect of patents based on traditional knowledge or biological resources which are disputed according to the provisions of the Regime, during the period required to resolve the matter.

Under 4 Elements: Ensuring benefit-sharing, we note that assigning a monetary value to biodiversity and traditional knowledge is problematic, and agree with wording to provide options for non-monetary forms of compensation, which may be more appropriate or preferred by the communities concerned in some cases.

### **III. SPECIFIC COMMENTS AND PROPOSALS FROM PARTIES, GOVERNMENTS AND ORGANIZATIONS ON ITEMS IN ANNEX I**

#### **A. *Nature***

##### **Canada**

Canada is of the view that the current statement on “nature” is appropriate at this time, given the early stages of discussions on ABS:

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.

As the ABSWG is currently in the midst of a gap analysis, it is premature to conclude at this time whether or not any new instrument is called for. It is therefore equally premature to comment on the form and legal status of any new instrument.

##### **Costa Rica**

The international regime must be legally binding.

##### **Mexico**

At present, we have a general framework given by the CBD which is legally binding, which does not need to be modified. What needs to be negotiated under the framework of the International Regime are the necessary measures that will allow to implement the existent dispositions within the Convention in an effective and efficient way.

To achieve this, several instruments will be needed:

(a) A group of legally binding measures, negotiated under the CBD, of which elements will be further elaborated;

(b) A set of measures taken in other international fora in order to enable and/or make obligatory the national measures necessary for the sound operation of the regime.

To comply with the obligations generated by these instruments, countries will be required, in turn, to make the necessary changes into their regulatory systems and frameworks.

While it is clear that the instrument proposed in paragraph 2(a) should be legally binding, it is considered that further analysis is required to decide on the most adequate legal format (i.e Protocol, Convention Annex, etc.). The case of implementation, as well as the capacity to enforce compliance should be some of the criteria that should be used to decide on the specific format for the legally binding instrument. This instrument represents the central component of the International Regime to be negotiated under the CBD.

With regard to the instruments referred in paragraph 2 (b), these have to do with areas that are interrelated and that require a certain degree of modification. Some of the issues to be addressed directly in other fora include measures related to intellectual property rights, traditional knowledge and genetic resources outside national jurisdictions.

## ***B. Scope***

### **Canada**

Canada is of the view that the scope of the international regime should be harmonized with the scope of the Convention on Biological Diversity, the International Treaty on Plant Genetic Resources and other relevant international instruments, and cover:

- The facilitation of access to genetic resources (in a non-discriminatory fashion);
- The promotion and safeguarding of the fair and equitable sharing of the benefits arising out of the utilization of genetic resources and associated traditional knowledge—in the context of mutually agreed terms.

In our view, option 4, with the addition of a reference to “mutually agreed terms”, best reflects our ideas on scope. Options 2 and 6 are also of interest.

We note the term “protection” of traditional knowledge associated with genetic resources is viewed as rather limiting. Considerations around TK associated with genetic resources could also include its promotion, among other things, and we are open to discussions on this matter. We remain of the view that the scope of ABS should encompass TK only if associated with genetic resources.

We also note that a number of the options under “scope” presume that there will be a legally binding instrument, which contradicts the neutral stance of the current text under “nature”, cited above. Canada further believes that the “nature” of the instrument is not an appropriate issue for the “scope” section of the paper.

### **Costa Rica**

#### *Scope*

We support the wording in Option 1.

### **Japan**

The legally binding and/or non-binding instrument(s) should apply to:

- (a) Facilitated access to genetic resources in a non-discriminatory fashion.
- (b) Fair and equitable sharing of the benefits arising out of the utilization of genetic resources in the context of mutually agreed terms.
- (c) Protection of traditional knowledge, innovations and practices associated with genetic resources.

### **Mexico**

The scope of the International Regime includes as general subjects:

- (a) The access and benefit sharing derived from the usage of the genetic resources;
- (b) The knowledge, innovations and traditional practices associated with genetic resources.

In terms of the regulation needs, the following elements must be considered:

- a) The access and use of genetic resources, as well as the different intermediate processes, including the derivatives and the intellectual property rights.
- b) The genetic resources inside and outside the national jurisdiction.

- c) The access and utilization of knowledge, innovations and traditional practices associated to the genetic resources, including their own intellectual property rights.
- d) Benefit-sharing

### **Norway**

Norway supports option 6. With regard to elements to be covered Norway also supports the contents of option 5.

## **C. Potential objectives**

### **Canada**

Discussion of an objective was not included in the terms of reference given to the ABSWG by COP-7. Rather, the mandate is to “elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions in Article 15 and Article 8(j) and the three objectives of the Convention”.

Therefore the objective of any regime on access and benefit-sharing should: (1) reflect the objectives of the Convention (2) aim to effectively implement the Convention’s provisions on access and benefit-sharing.

In that vein, we support Option 4.

### **Costa Rica**

Option 5 covers all of the issues discussed in the various WG-ABS meetings, which is why we believe it to be the best option.

### **Japan**

(i) To prevent the unauthorized access and use of genetic resources, to ensure that fair and equitable sharing of benefits flow to the providers of the genetic resources and to reinforce national legislations.

(ii) To provide effective protection for the traditional knowledge of indigenous and local communities associated with genetic resources, subject to the national legislation of the countries where these communities are located.

(iii) To create conditions to facilitate access to genetic resources for environmentally sound uses.

(iv) To ensure compliance with prior informed consent of providers and of indigenous and local communities, as well as mutually agreed terms, and support the implementation of and compliance with national legislation.

### **Norway**

Norway supports option 5.

## **D. Elements to be considered for inclusion in the international regime, clustered by subject matter**

### *1. Access*

### **Canada**

The international regime must fully and appropriately address access to genetic resources, as without access, there will be no benefit-sharing. That access is a key part of our negotiations is illustrated

in our mandate from COP-7: “to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions in Article 15 and 8 (j) of the Convention and the three objectives of the Convention.”

### **Costa Rica**

Access: Access measures must establish clear and expeditious procedures, defined by Competent Authority. The measures must provide guidance to define national laws or regulations.

### **Mexico**

To explore practical options that, without hindering national sovereignty, could facilitate the legal access to genetic resources with the aim to promote its wider use and provide certainty to relevant stakeholders.

## *2. Ensuring benefit-sharing*

### **Costa Rica**

The measures must ensure the equitable sharing of economic, social, environmental, scientific or spiritual benefits, including potential commercial gains in the short, medium and long term.

The measures must provide guidance to Parties in the drafting of national regulations or laws that include provisions for all possible options with regard to benefit sharing.

### **Mexico**

Consider and develop, as appropriate, complementary approaches for benefit sharing in cases where the contractual approach is limited in order to comply with the benefit sharing obligations. This could include an international financial mechanism with contributions by Parties linked to monetary benefits derived from the use of genetic resources;

In particular the possible development of “baseline provisions” to apply in cases where there are no legal terms mutually agreed for benefit sharing or when it is not possible to demonstrate the compliance with the CBD provisions (via the Certificate) which ensure that the user distributes minimum benefits such as a rate of royalties, single payments, etc. It is possible to identify several cases for which the following provisions would apply, such as:

- i. When benefits originated in areas beyond the national jurisdiction;
- ii. When the origin is unknown;
- iii. When the number of genetic resources makes it impossible to negotiate terms in an individual manner;
- iv. Other

## *3. Promoting benefit-sharing*

### **Costa Rica**

The measures must provide for mandatory generation, on the part of developed countries, of collaborative research in provider countries in particular. The measures must provide for terms regarding the type of technology transfer or information generation derived from the research and directed toward national capacity-building.

### **Mexico**

A package of measures in user countries to promote compliance with provisions of CBD regarding benefit sharing and support compliance with national access laws. This should include incentives at national level to the users of genetic resources. Despite its potential, this component is often overlooked in the analysis of the problem. These measures could include a wide range of measures at



national level, such as: fiscal benefits, criteria for allocation of public funds for research, criteria for financing public research institutions, direct investment within the framework of collaboration agreements, etc;

Related to the previous element, a package of incentives, including economic ones, in order to promote the transfer of technology and research in countries providing genetic resources, as well as to promote the sharing the results of research.

4. *Recognition and protection of rights of indigenous and local communities*

**Costa Rica**

The measures of the international regime must provide guidance to States so that their legislation expressly protects and recognizes traditional knowledge, as well as the practices and innovations of indigenous peoples and local communities linked to the use of biodiversity elements and related knowledge. Compliance with benefit sharing for the use of traditional knowledge must be a part of prior informed consent, and be mandatory for those who use such knowledge.

5. *Derivatives*

**Costa Rica**

Seeing as access to derivatives is the most frequent use of genetic resources, and given the principle of a State's sovereignty over the management of its genetic resources, derivatives must be covered by national regulations, and the international regime must provide for measures for access to derivatives, subject to prior informed consent and the sharing of benefits arising from their use.

**Mexico**

To clarify and take measures regarding the notion of derivatives, as well as reaching an international understanding on the notion of utilization. These with a view to clarify and define the reach of benefit sharing obligations and access conditions.

6. *Promotion and enforcement mechanisms of the international regime and compliance with PIC and MAT*

**Canada**

Compliance with national ABS measures will be more likely if there are in place transparent, non-discriminatory, and practical measures within relevant national and sub-national jurisdictions. Furthermore, given the differences in national contexts and the potential differences in national legislation, these measures should have "common requirements" which incorporate the fundamental elements and objectives of ABS.

In the case of PIC, the concept should apply to both providers and users of GR and TK. Compliance with a PIC requirement can only be ensured through a transparent, efficient and timely administrative process. As a central component of an ABS regime, a PIC system centred in national legislation, consistent with the Bonn Guidelines, would be essential to facilitate access to genetic resources and traditional knowledge in a fashion respectful of cultural and legal circumstances at the national, sub-national and local levels.

PIC is crucial to the credibility and legitimacy of an ABS regime. Its efficiency will be measured on the basis of whether there is continued access to GR and associated TK and whether users of genetic resources can obtain PIC without undue delays or excessive administrative burdens.

Developing a PIC system respectful of the social organization of indigenous communities and their spiritual and cultural values is crucial. This is particularly challenging in countries which multiple jurisdictions and pluralistic legal systems where there are communities with varying legal situations, cultural traditions and customary practices.

Developing a PIC system which can accommodate traditional knowledge associated to genetic resources must start from three key considerations:

- The need to ensure the proper identification of the knowledge holder(s) (i.e. community, family, individual, etc.),
- Respect for the various decision-making processes of Indigenous communities.
- The importance of clarity, fairness and a common understanding of the implications of granting PIC both for the providers and users of the TK.

### **Costa Rica**

Measures under the international regime must guarantee to Parties that the following measures will be established: monitoring and control measures, measures to establish restrictions on and cancellations of requests for access, and measures to sanction unauthorized access or non-compliance with the conditions under which a permit to access genetic resources was granted, including compliance with mutually agreed terms between the interested party and the provider of genetic resources.

### **Mexico**

A package of measures in countries with users under their jurisdiction to promote compliance with access provisions.

The creation of a certificate of legal precedence that can be verified at different check points and located at late stages of the research and development processes as well as at the moment of commercialization of biotechnological products with the view of providing certainty to users and providers and which would identify and acknowledge the contribution of traditional knowledge which is eventually used.

### **International Union for the Protection of New Varieties of Plants (UPOV)**

With regard to any requirement for a declaration that the genetic material has been lawfully acquired or proof that a prior informed consent concerning the access of the genetic material has been obtained, UPOV encourages the principles of transparency and ethical behaviour in the course of conducting breeding activities and, in this regard, the access to the genetic material used for the development of a new variety should be done respecting the legal framework of the country of origin of the genetic material. However, the UPOV Convention requires that the breeder's right should not be subject to any further or different conditions than the ones required to obtain protection. UPOV notes that this is consistent with Article 15 of the CBD, which provides that the determination of the access to genetic resources rests with the national governments and is subject to national legislation. Furthermore, UPOV considers that the competent authority for the grant of the breeder's rights is not in a position to verify whether the access to genetic material has taken place in accordance with the applicable law in this field.

## *6. Functioning of the international regime*

### **Canada**

One proposal designed to help track the origin of genetic resources and associated TK is a requirement to disclose of origin/source/legal provenance of genetic resources (GR) and associated traditional knowledge (TK) in patent applications. This issue has been the subject of intense debate both at WIPO and WTO TRIPS-Council.

In this context, further assessment of the impacts of such a requirement is needed, both on the existing national and international IP systems as well as on the users of genetic resources and associated TK. Currently, Canada is consulting with relevant stakeholders in an effort to determine whether disclosure of origin/source of genetic resources is the optimal solution for ensuring benefit-sharing and

complying with an ABS system. Canada has taken seriously the views expressed by many countries in their proposals to WIPO and WTO TRIPS-Council and supports the continuation of discussions in these fora as well as the CBD.

Should there be a requirement to disclose the origin of a genetic resource in a patent application or other database, accurate information on the origin of the resource will be needed all along the genetic resource “use chain”, from in situ collection to research to, where applicable, commercialization. The burden of such a system would likely have to be carried even by those who may not be obtaining a direct financial benefit. The burden of responsibility for ensuring proper disclosure should be shared by all actors along the “use chain”, including, and most importantly, the country of origin of the resource. How that burden should be divided is a question that remains little explored. Evaluating the practicality of the obligation would require a preliminary two-tier approach; the nature of the information that would need to be disclosed and the consequences that would follow from non-compliance. For instance, different burdens would likely be entailed depending on whether disclosure was of country of origin or of source. In the context of a patent application, the former would require that the resource was tracked from where it was first discovered while the latter would require that the resource was tracked only from where it was most recently accessed. Likewise, sanctions could vary between cases of insufficient, wrongful or lack of disclosure.

The selection of the appropriate mechanism regarding compliance with an ABS system presents a challenge as it may entail consideration of issues such as organization, monitoring, administrative costs, effectiveness and jurisdiction. Then would follow the determination of whether disclosure of origin/source of genetic resources is the optimal solution for ensuring benefit-sharing and complying with an ABS system. Indeed, other solutions have been put forward both nationally and internationally in order to achieve such compliance. Continued further analysis of such options would make a useful contribution in defining optimal policy choices.

Nevertheless, until other key elements for compliance with an ABS system –i.e. PIC and MAT systems-- are in place, the practicality of disclosure, whether mandatory or voluntary, remains unclear.

### **Costa Rica**

Insofar as possible, the Open-ended Working Group should discuss the need for a financial mechanism, within the CBD framework, to give Contracting Parties the option of applying for economic resources for the possible implementation of commitments entered into under the international regime.

With regard to an internationally recognized certificate, the issue is being discussed by the WG/ABS and the attempt should be made to have Parties address the matter in their national legislation. For its part, the Open-ended Working Group must make an effort to recommend, to the Conference of the Parties at its next meeting, international recognition of certificates of origin/legal provenance that are backed by national legislation. In other words, if a Party’s legislation includes stipulations regarding certificates of origin/legal provenance, such certificates should be recognized internationally. Costa Rica believes that the certificates of origin/legal provenance should be revised fundamentally, but not exclusively, as part of patent applications or in various cases of knowledge protection involving genetic resources.

### **International Union for the Protection of New Varieties of Plants (UPOV)**

The requirement for “distinctness” in the UPOV Convention means that protection shall only be granted after an examination to determine if the variety is clearly distinguishable from all other varieties, whose existence is a matter of common knowledge at the date of filing of the application, regardless of the geographical origin. Furthermore, the UPOV Convention provides that, if it is discovered that a breeder’s right has been granted for a variety that was not distinct, that rights shall be declared null and void.

The breeder is usually required, in a technical questionnaire that accompanies his application for protection, to provide information concerning the breeding history and genetic origin of the variety. UPOV encourages information on the origin of the plant material, used in the breeding of the variety to be

provided where this facilitates the examination mentioned above, but could not accept this as an additional condition of protection since the UPOV Convention provides that protection should be granted to plant varieties fulfilling the conditions of novelty, distinctness, uniformity, stability and a suitable denomination and does not allow any further or different conditions for protection. Indeed, in certain cases, for technical reasons, applicants may find it difficult, or impossible, to identify the exact geographic origin of all the material used for breeding purposes.

Thus, if a country decides, in the frame of its overall policy, to introduce a mechanism for the disclosure of countries of origin or geographical origin of genetic resources, such a mechanism should not be introduced in a narrow sense, as a condition for plant variety protection. A separate mechanism from the plant variety protection legislation, such as that used for phytosanitary requirements, could be applied uniformly to all activities concerning the commercialization of varieties, including, for example, seed quality or other marketing-related regulations.

#### 7. *Poverty eradication*

##### **Costa Rica**

The international regime must provide for measures that are coherent with other processes or working groups within the CBD framework that address actions aimed at poverty eradication, linked mainly to conservation and sustainable use of biodiversity. The measures must be addressed under the issue of fair and equitable sharing of resources arising from the use of genetic resources.

#### 8. *Relevant elements of existing instruments and processes, including*

##### **Mexico**

Regulatory coordination with other forums and international existing instruments and processes: to develop measures, in collaboration with the relevant forums, in order to create check points at key stages of the R&D and commercialization of genetic resources. Specifically, with respect to the intellectual property right procedures, where the Certificate of Legal Provenance should be included as a requirement in applications for intellectual property rights that make use of had used genetic resources as a key element in its development.

Consistent regulation for the diverse types of genetic resources

a. To clarify the legal situation of *ex situ* collections, and to take measures to incorporate them to the regime with a view that utilization of genetic resources from such sources has some basic obligation that recognize the value of genetic resources as a global environmental service and share the benefits;

b. An international agreement on the legal situation of genetic resources that are outside national jurisdiction, such as deep sea beds and Antarctica and seek to incorporate some kind of benefit sharing obligation on *uses* derived from such resources in recognition of the value of this global environmental service.

##### **Norway**

In the context of the list of relevant instruments and processes, Norway is of the opinion that there is a need to identify synergies amongst the various instruments/fora. (e.g. fora dealing with IPR issues (WIPO, TRIPs, Paris Convention etc.) as well as organisations dealing with genetic resources (CBD, FAO), in order to create an international regime based on one or more instruments. Therefore, an element stating the mutually supportiveness and complementarity of an international regime and existing international legal instruments and processes (ITPGRFA, WIPO, TRIPs Council etc.) should be added.

##### **International Union for the Protection of New Varieties of Plants (UPOV)**

UPOV supports the view that the Convention on Biological Diversity (CBD) and relevant international instruments dealing with intellectual property rights, including the UPOV Convention, should be mutually supportive.

Since the legislation on access to genetic material and the legislation dealing with the grant of breeder's rights pursue different objectives, have different scopes of application and require a different administrative structure to monitor their implementation, UPOV considers that it is appropriate to include them in different legislation, although such legislation should be compatible and mutually supportive.

Mechanisms of benefit-sharing should take into account the need for a relationship of mutual supportiveness in respect of the essential principles of the UPOV system of plant variety protection and, in particular, of the breeder's exemption provision.

*E. Potential additional elements and options identified*

**Costa Rica**

It can be observed that many of the additional elements found in the proposed list are already part of the original proposal for elements of an international regime. Nevertheless, it is important to retain certain elements: the measures established under the international regime must provide guidance to develop national legislation and administrative measures for access to genetic resources. They must also provide for the establishment of minimum sanction or observance measures. The establishment of measures to ensure communication, information and awareness-raising on the issue should also be retained. The international regime's measures must promote mutual supportiveness between the CBD and other international legal instruments that deal with the issue of intellectual property rights. The regime must also address measures to promote collaborative research, to be developed particularly in countries that are providers of genetic resources, and measures to ensure the provision of technical assistance and technology transfer.

*Annex*

**INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING <sup>1/</sup>**

**1. 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.*

**2. Scope**

*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; (i)*

*Traditional knowledge, innovations and practices in accordance with Article 8(j). (ii)*

*Option 1:*

The legally binding instrument should apply to:

- (a) Access to genetic resources;
- (b) Fair and equitable sharing of the benefits arising out of the utilization of genetic resources and their derivatives and products in the context of mutually agreed terms;
- (c) Protection of traditional knowledge, innovations and practices associated with genetic resources and their derivatives.

*Option 2:*

The legally binding and/or non-binding instrument(s) should apply to:

- (a) Facilitate access to genetic resources in a non-discriminatory fashion;
- (b) Fair and equitable sharing of the benefits arising out of the utilization of genetic resources in the context of mutually agreed terms;
- (c) Protection of traditional knowledge, innovations and practices associated with genetic resources.

*Option 3:*

The legally binding instrument should apply to:

- (a) Access to genetic resources;
- (b) Fair and equitable sharing of the benefits arising out of the utilization of genetic resources and their derivatives and products in the context of mutually agreed terms;
- (c) Protection of traditional knowledge, innovations and practices associated with genetic resources, their derivatives and products.

*Option 4:*

Facilitation of access to genetic resources in a non-discriminatory fashion and the promotion and safeguarding of fair and equitable sharing of the benefits arising out of the utilization of genetic resources and associated traditional knowledge in accordance with relevant provisions of the Convention on Biological Diversity and in harmony with the International Treaty on Plant Genetic Resources and other relevant international instruments.

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<sup>1/</sup> Italicized text, excluding side-headings, indicates text reproduced without change from the terms of reference of the Working Group in the annex to decision VII/19 D. The Roman numerals in parenthesis at the end of an entry refer to its numbering under the corresponding heading in those terms of reference.

*Option 5:*

The international regime should apply to:

- (a) Access to genetic resources;
- (b) Fair and equitable sharing of the benefits arising out of the utilization of genetic resources in the context of mutually agreed terms;
- (c) Protection of traditional knowledge, innovations and practices associated with genetic resources.

*Option 6:*

Subject to further refinement, the international regime could be composed of one or more instruments at different levels of implementation (national, regional and international) and of a different nature (including intergovernmental agreements, codes of conduct, national legislation, contracts, ethics, commissions) within a set of principles, norms, rules and decision-making procedures within the framework of the Convention on Biological Diversity that apply to:

- (a) Access to genetic resources;
- (b) Fair and equitable sharing of the benefits arising out of the utilization of genetic resources in the context of mutually agreed terms;
- (c) Protection of traditional knowledge, innovations and practices associated with genetic resources.

*Option 7 (Ethiopia)*

1. This Protocol shall apply to the facilitation for users of access to objects and the fair and equitable sharing by the providers and users of the benefits that accrue from the commercial and other applications by the users of the accessed objects.
2. This Protocol shall also apply to cooperation between providers and users in accessing biological resources for conservation, research and teaching.
3. Any use of accessed objects for any purpose not covered by the provisions of this Protocol is prohibited unless it is covered by an agreement based on a prior informed consent between the country of origin and the user.
4. This Protocol shall not affect the customary access, exchange or use of any object among local communities.

**3. Potential objectives**

*Option 1:*

(i) To prevent the unauthorized access and use of genetic resources to ensure that fair and equitable sharing of benefits flow to the providers of the genetic resources and to reinforce national legislations.

(ii) To provide effective protection for the traditional knowledge of indigenous and local communities associated with genetic resources, subject to the national legislation of the countries where these communities are located.

(iii) Create conditions to facilitate access to genetic resources for environmentally sound uses.

(iv) Ensure compliance with prior informed consent of providers and of indigenous and local communities, and mutually agreed terms and support the implementation of and compliance with national legislation.

*Option 2:*

(i) To prevent the continued misappropriation and misuse of genetic resources and their derivatives to ensure that fair and equitable sharing of benefits flow to the countries of origin of the genetic resources and to reinforce national legislations;

(ii) To provide effective protection for the rights of indigenous and/or local communities in relation to their traditional knowledge associated with genetic resources and derivatives, subject to the national legislation of the countries where these communities are located;

(iii) To establish international measures to support the aforementioned objective.

*Option 3:*

(i) To prevent the continued misappropriation and misuse of genetic resources, their derivatives and products to ensure that fair and equitable sharing of benefits flow to the countries of origin of the genetic resources and to reinforce national legislations;

(ii) To provide effective protection for the traditional knowledge of indigenous and local communities associated with genetic resources, their derivatives and products, subject to the national legislation of the countries where these communities are located;

(iii) To create conditions to facilitate access to genetic resources for environmentally sound uses;

(iv) To ensure compliance with prior informed consent of countries of origin and of indigenous and local communities, and mutually agreed terms and support the implementation of and compliance with national legislation.

*Option 4:*

The objective of the international regime is:

(i) The conservation and sustainable use of biological diversity;

(ii) Facilitated access to genetic resources;

(iii) The fair and equitable sharing of the benefits arising out of the utilization of genetic resources and associated traditional knowledge.

*Option 5:*

(i) Contribute to the effective implementation of Articles 15 and 8(j) and the three objectives of the Convention;

(ii) Facilitate access to genetic resources;

(iii) Support the implementation of and compliance with national legislation and international law;

(iv) Promote compliance with prior informed consent of the providing countries and of indigenous and local communities and mutually agreed terms;

(v) Promote and safeguard the fair and equitable sharing of benefits;

(vi) Ensure and enforce the rights and obligations of users of genetic resources;

(vii) Protect the rights of indigenous and local communities to their traditional knowledge related to genetic resources consistent with international human rights obligations.

*Option 6:*

(i) Contribute to the effective implementation of Articles 15 and 8(j) and the three objectives of the Convention;



- (ii) Ensure compliance with the prior informed consent and mutually agreed terms of provider countries, including of indigenous and local communities;
- (iii) Ensure mutual supportiveness with relevant existing international instruments and processes.

*Option 7 (Mexico)*

- a. The fair and equitable distribution of benefits derived from the utilization of genetic resources through more favourable conditions to negotiate terms of distribution of benefits as well as of other approaches when it is necessary.
- b. To extend the capacity to use the genetic resources through research and development, the transfer of technology, in particular, in developing countries
- c. To facilitate the access to the genetic resources through measures that provide certainty to both suppliers and users.

*Option 8 (Ethiopia)*

The objectives of this Protocol are the facilitated access to, and the fair and equitable sharing of the benefits arising from, the use of biological resources and community knowledge and technologies for improving human life and for the conservation and sustainable use of biological diversity.

**4. Elements to be considered for inclusion in the international regime, clustered by subject matter**

*Access*

Measures to promote facilitated access to genetic resources for environmentally sound uses according to Article 15, paragraph 2, of the Convention on Biological Diversity; (iv)

*Ensuring benefit-sharing*

Measures to ensure the fair and equitable sharing of benefits from the results of research and development and the benefits arising from the commercial and other utilization of genetic resources in accordance with Articles 15, paragraph 7, 16, and 19 paragraphs 1 and 2 of the Convention. (ii)

Measures to ensure the sharing of benefits arising from the commercial and other utilization of genetic resources and their derivatives and products, in the context of mutually agreed terms. (vi)

Measures for benefit-sharing including, *inter alia*, monetary and non-monetary benefits, and effective technology transfer and cooperation so as to support the generation of social, economic and environmental benefits. (iii)

*Promoting benefit-sharing*

Measures to promote and encourage collaborative scientific research, as well as research for commercial purposes and commercialization, consistent with Articles 8(j), 10, 15, paragraph 6, paragraph 7 and Articles 16, 18 and 19 of the Convention. (i)

Measures to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources. (v)

*Recognition and protection of rights of indigenous and local communities*

Recognition and protection of the rights of indigenous and local communities over their traditional knowledge associated to genetic resources subject to the national legislation of the countries where these communities are located. (xv)

Customary law and traditional cultural practices of indigenous and local communities. (xvi)

Code of ethics/Code of conduct/Models of prior informed consent or other instruments in order to ensure fair and equitable sharing of benefits with indigenous and local communities. (xviii)

Measures to ensure compliance with prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources, in accordance with Article 8(j). (x)

*Derivatives*

Addressing the issue of derivatives. (xii)

*Promotion and enforcement mechanisms of the international regime and compliance with PIC and MAT*

Monitoring, compliance and enforcement. (xx)

Dispute settlement, and/or arbitration, if and when necessary. (xxi)

Measures to ensure compliance with the mutually agreed terms on which genetic resources were granted and to prevent the unauthorized access and use of genetic resources consistent with the Convention on Biological Diversity. (xi)

Measures to ensure compliance with national legislations on access and benefit-sharing, prior informed consent and mutually agreed terms, consistent with the Convention on Biological Diversity. (ix)

*Functioning of the international regime*

Measures to facilitate the functioning of the regime at the local, national, subregional, regional and international levels, bearing in mind the transboundary nature of the distribution of some in situ genetic resources and associated traditional knowledge. (viii)

Means to support the implementation of the international regime within the framework of the Convention. (xix)

Institutional issues to support the implementation of the international regime within the framework of the Convention. (xxii)

Internationally recognized certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge. (xiii)

Disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights. (xiv)

Capacity-building measures based on country needs. (xvii)

*Poverty eradication*

Measures to promote access and benefit-sharing arrangements that contribute to the achievement of the Millennium Development Goals, in particular on poverty eradication and environmental sustainability. (vii)

*Relevant elements of existing instruments and processes, including: (xxiii)*

- Convention on Biological Diversity;
- Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization;
- The International Treaty on Plant Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations;
- The Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations;
- Current national legislative, administrative and policy measures implementing Article 15 of the Convention on Biological Diversity;
- The United Nations Permanent Forum on Indigenous Issues;

- Outcomes of the Working Group on Article 8(j);
- The Agreement on Trade-related Aspects of Intellectual Property Rights and other World Trade Organization agreements;
- World Intellectual Property Organization conventions and treaties;
- International Convention for the Protection of New Varieties of Plants;
- Regional agreements;
- Codes of conduct and other approaches developed by specific user groups or for specific genetic resources, including model contractual agreements;
- African Model Law on the Rights of Communities, Farmers, Breeders, and on Access to Biological Resources;
- Decision 391 of the Andean Community;
- Decision 486 of the Andean Community;
- United Nations Convention on the Law of the Sea;
- Agenda 21;
- Rio Declaration on Environment and Development;
- Convention on International Trade in Endangered Species of Wild Fauna and Flora;
- Antarctic Treaty;
- The Universal Declaration of Human Rights;
- The International Covenant on Civil and Political Rights;
- The International Covenant on Economic, Social and Cultural Rights.

## 5. **Potential additional elements and options identified**

Members of the Working Group also suggested a number of additional elements and options. These are reproduced hereunder as part of the process for elaborating and negotiating the international regime for the consideration of the Working Group within the framework of the Convention on Biological Diversity and the terms of reference adopted by the Conference of the Parties, at its next meeting:

### A. *Option 1*

Among the elements listed in the annex to decision VII/19 D of the Conference of the Parties, the legally-binding instrument should **primarily** focus on the following:

- I. Measures to ensure compliance by users with national legislations of the countries of origin or countries providing genetic resources where that country has satisfied conditions which qualify it to be considered as country of origin on access and benefit-sharing, prior informed consent and mutually agreed terms;
- II. Measures to ensure compliance with prior informed consent of, either:
  - (a) Indigenous and / or local communities for the access to their traditional knowledge, innovations and practices associated with genetic resources and/or associated knowledge and their derivatives; and/or,
  - (b) Country(s) of origin for the access to genetic resources associated to traditional knowledge.

- III. Measures to ensure compliance with mutually agreed terms on which genetic resources were granted.
- IV. Measures to prevent unauthorized access and use of genetic resources, their derivatives and associated traditional knowledge, innovations and practices.
- V. Measures to ensure and guarantee monitoring, compliance and enforcement of rights of countries of origin of genetic resources and their derivatives, whether established by national legislations or otherwise, by users and their countries through the international regime.
- VI. Disclosure of legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights;
- VII. Internationally recognized certificate of legal provenance of genetic resources that should include evidence of compliance with access legislation (including prior informed consent and mutually agreed terms);
- VIII. The requirements to obtain the certificate will be nationally defined, considering the provisions in the Convention on Biological Diversity;
- IX. Vision of the certificate: a standardized code that accompanies the biological material and is passed to all extracts, derivatives or information, through the least expensive channels, in a way that it can be shown at specific and relevant checkpoints in the research and development process (including product approval and intellectual property). There should be high cost of non-disclosure in order to induce users to behave legally. The specific conditions for access should be included in a clearing-house, so that users/authorities/interested parties can check the conditions;
- X. Criteria for international recognition of the certificate shall be established in the legally-binding instrument;
- XI. Measures to ensure the fair and equitable sharing of benefits from the results of research and development and the benefits arising from the commercial and other utilization of genetic resources in accordance with Articles 15 paragraph 7, 16 and 19 paragraph 1 and 2 of the Convention;
- XII. Recognition and protection of the rights of indigenous and/or local communities over their traditional knowledge associated to genetic resources, subject to the national legislation of the countries where these communities are located;
- XIII. Monitoring, compliance and enforcement;
- XIV. Rules for access to and transfer of technology on the basis of Article 16 of the Convention;
- XV. Measures for benefit sharing including, *inter alia*, monetary and non-monetary benefits and effective technology transfer and cooperation so as to support the generation of social, economic and environmental benefits;
- XVI. Rules to strengthen the international cooperation in particular South – South cooperation;
- XVII. Building of human, institutional and scientific capacities including for putting in place the legal mechanism, taking into account Articles 18 and 19 of the Convention;
- XVIII. An institutional mechanism for implementation of the legally-binding instrument.

**B. Option 2**

*Benefit-sharing*

- (i) Measures to ensure the fair and equitable sharing of benefits arising from the use of traditional knowledge, innovations and practices of indigenous and local communities

- associated with genetic resources and their derivatives and ensure that those benefits flow to those communities.
- (ii) Measures to guarantee the transfer of technology to the countries of origin of the genetic resources and their derivatives under fair and most favourable terms, including on concessional and preferential terms.
  - (iii) Relevant measures for communication, education and public awareness.

*Compliance with the national legislation*

- (i) Measures to prevent the unauthorized use of genetic resources, their derivatives and associated traditional knowledge, innovations and practices at the international level.
- (ii) Measures to ensure the compliance of national legislation on access from countries of origin of genetic resources and their derivatives beyond their national jurisdiction.
- (iii) Legislative, administrative and policy measures in developed country users of genetic resources and their derivatives to guarantee the respect of the rights of developing countries of origin over those resources.

*Implementation of the international regime*

- (i) Financial mechanisms and other ways and means to guarantee the effective implementation of the international regime.

*Compliance and dispute settlement*

- (i) Measures related to repatriation and compensation.
- (ii) Measures to ensure access to justice.

**C. Option 3 (Norway)**

*Norway is of the opinion that the international regime should:*

- Promote facilitated access to genetic resources for environmentally sound uses
- Promote and ensure benefit-sharing for example by developing standard provisions on benefit-sharing to be included in the context of mutually agreed terms.
- Recognize and protect the rights of indigenous peoples and local communities over their traditional knowledge associated with genetic resources in relation to prior informed consent and mutually agreed terms
- The regime needs to address the issue of derivatives
- Include measures to ensure compliance with national legislation on ABS and PIC and MAT (*inter alia* a legally binding commitment by the user to comply)
- Include a monitoring mechanism
- Include a system under the Convention on Biological Diversity for an internationally recognized certificate of origin/source/legal provenance of genetic resources. This is subject to further exploration of the modalities of such a certificate.
- The discussions on disclosure of origin/source/legal provenance/PIC needs to be further pursued at the multilateral level within the TRIPs Council and WIPO Patent Cooperation Treaty.
- Capacity-building, technology transfer and financial resources are necessary elements of an international regime.

**D. Additional elements**

- Measures that support the development of national administrative, legislative and regulatory regimes.

- Establish international minimum standards for compliance with national legislations.
- Promote the establishment of appropriate measures by Parties with users under their jurisdiction.
- Measures to ensure recognition and protection of the rights of indigenous women as holders and protectors of traditional knowledge and genetic resources.
- Measures to protect the rights of indigenous peoples to the genetic resources originating in indigenous lands and territories.
- Measures to clarify national access laws.
- Measures to prevent misappropriation of genetic resources, their derivatives and products as well as traditional knowledge.
- Measures to ensure non-discriminatory access.
- Measures to ensure communication, information and awareness raising.
- Measures to ensure access to information in regulating access on access and benefit-sharing of genetic resources and associated traditional knowledge.
- Measures to ensure access to justice.
- Measures to ensure that intellectual property rights do not undermine the international regime.
- Measures to ensure mutual supportiveness between the Convention on Biological Diversity and intellectual property rights-related treaties.
- Measures to promote the carrying out of research and development and joint ventures in the country of origin as provided for in Article 15, paragraph 6, of the Convention.
- Measures to promote the carrying out of research and development and joint ventures in the providing countries as provided for in Article 15, paragraph 6, of the Convention.
- Relationship with other international legal instruments.
- Nationally recognized certificate of origin/source/legal provenance of genetic resources and their derivatives and associated traditional knowledge as well as rules of customary law.
- Measures to prevent the unauthorized access and use of genetic resources and traditional knowledge.
- Measures to ensure disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge as a precondition for the registration and commercialization of new products based on genetic resources and/or associated traditional knowledge.
- Measures to ensure the effective provision of technical assistance and technology transfer, especially to developing countries.

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