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GROUP OF TECHNICAL EXPERTS ON AN INTERNATIONALLY RECOGNIZED CERTIFICATE OF ORIGIN/SOURCE/LEGAL PROVENANCE

Lima, 22-25 January 2007 Item 3 of the provisional agenda*

CONSIDERATION OF AN INTERNATIONALLY RECOGNIZED CERTIFICATE OF ORIGIN/SOURCE/LEGAL PROVENANCE

Note by the Executive Secretary

I. INTRODUCTION

- 1. The meeting of the Group of Technical Experts on an internationally recognised certificate of origin/source/legal provenance is being held in accordance with decision VIII/4 C of the Conference of the Parties to the Convention on Biological Diversity (COP).
- 2. In paragraph 1 of this decision, the Conference of the Parties decided "to establish a group of technical experts to explore and elaborate possible options, without prejudging their desirability, for the form, intent and functioning of an internationally recognized certificate of origin/source/legal provenance and analyze its practicality, feasibility, costs and benefits, with a view to achieving the objectives of Article 15 and 8(j) of the Convention. The Expert Group shall provide technical input to the Ad Hoc Open-ended Working Group on Access and Benefit-sharing and will operate in accordance with the following terms of reference:
- (a) Consider the possible rationale, objectives and the need for an internationally recognised certificate of origin/source/legal provenance;
- (b) Define the potential characteristics and features of different options of such an internationally recognised certificate;
- (c) Analyse the distinctions between the options of certificate of origin/source/legal provenance and the implications of each of the options for achieving the objectives of Articles 15 and 8(j) of the Convention;
- (d) Identify associated implementation challenges, including the practicality, feasibility, costs and benefits of the different options, including mutual supportiveness and compatibility with the Convention and other international agreements."

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- 3. This background document has been prepared by the Secretariat to assist the Group in its work. It is only indicative and should not be interpreted as limiting the scope/breadth of issues for consideration. It provides an overview of issues for consideration by the experts based on contributions provided by Parties, organisations and other relevant stakeholders as well as available literature. A list of questions is also included in annex to this document reflecting issues raised by Parties and stakeholders in their contributions to the Secretariat. In addition, the submissions provided by Parties and others have been compiled in document UNEP/CBD/GTE-ABS/1/3.
- 4. It should be noted that although the note covers all the issues included in the terms of reference of the group of technical experts, the issues are not addressed in the same order. Section II provides a general overview of how the issue of an internationally recognised certificate of origin/source/legal provenance arose under the Convention process. Section III examines the potential rationale, need and objectives of an internationally recognised certificate of origin/source/legal provenance. Section IV examines the different options and the potential implications of each of these options in achieving the objectives of Article 15 and 8(j). Section V considers the possible features and characteristics of such a system and section VI considers the implementation challenges, including their practicality, feasibility, costs and benefits, and their compatibility and mutual supportiveness with the Convention and other international agreements.

II. GENERAL BACKGROUND

- 5. The Working Group on Access and Benefit-sharing was established by the Conference of the Parties at its fifth meeting, in 2000, and mandated to develop guidelines and other approaches to assist Parties and stakeholders in addressing access and benefit-sharing. The Working Group successfully negotiated the Bonn Guidelines on access and benefit-sharing, which were adopted by the Conference of the Parties to the Convention at its sixth meeting, in 2002. Recognizing that a package of measures may be necessary to address the different needs of Parties and stakeholders in the implementation of access and benefit-sharing arrangements, the Conference of the Parties also recognized that other approaches could be considered to complement the Bonn Guidelines in order to further assist with the implementation of the access and benefit-sharing provisions of the Convention.
- 6. The issue of an international certificate of origin was first considered within the framework of the Convention at the second meeting of the Working Group on Access and Benefit-sharing, in December 2003, as another potential approach to assist with the implementation of the access and benefit-sharing provisions of the Convention.
- 7. At its seventh meeting, in 2004, the Conference of the Parties emphasized the need to further examine other approaches including an international certificate of origin/source/legal provenance, in particular the operational functionality and cost effectiveness of such an international certificate. Most importantly, the Conference of the Parties mandated the Working Group to negotiate an international regime on access and benefit-sharing. In the terms of reference of the Working group, the list of elements to be considered for inclusion in the international regime includes as one of its elements an "internationally recognised certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge".
- 8. In parallel to the work of the Convention, a number of studies were carried out and workshops held which considered various aspects of a certificate of origin/source/legal provenance and provided input to discussions by the Working Group on Access and Benefit-sharing on this issue. The following provides a general overview of the main issues that have been raised and which deserve further consideration.

III. POTENTIAL RATIONALE, OBJECTIVES AND NEED FOR AN INTERNATIONALLY RECOGNIZED CERTIFICATE OF ORIGIN/SOURCE/LEGAL PROVENANCE

- 9. The concept of certificate has generally been described as a type of passport or permit which would accompany the genetic resource(s) along the whole chain of the access and benefit-sharing process and could be verified at various points of this process, particularly once the genetic resource has left the provider country. It would therefore accompany the genetic resource from the collection phase until the marketing of a resultant product.
- 10. The main objective of an internationally recognised system of certificate of origin/source/legal provenance would be to ensure the traceability of genetic resources from the moment they have been accessed and thereby increase transparency. Such a tool could help to ensure compliance with the access and benefit-sharing provisions of the Convention and provide assurances that requirements related to the legal acquisition of the genetic resources in the country of origin or provider country have been met. The certificate would therefore, on the one hand, assist providers in ensuring that the resources are used in conformity with their national access requirements and, on the other hand, it would provide legal certainty and predictability for users of genetic resources who have obtained a certificate through competent national authorities or who have acquired the genetic resources from an earlier receiver. The system would therefore contribute to building trust and fostering cooperation among users and providers of genetic resources. It has also been suggested that "a certificate of compliance" 1/ rather than a certificate of origin/source/legal provenance may be appropriate to achieve these objectives, as further addressed under section IV below.
- 11. In addition, the establishment of a well designed internationally recognised system of certificates could allow for the development of less restrictive national access procedures, contributing to facilitated access and reduced transaction costs, while providing evidence that users are meeting access requirements.
- 12. As has been underlined in a study carried out by the United Nations University Institute of Advanced Studies:

"One of the greatest tensions in the present debate on ABS is between industry and countries of origin. A certificate system may serve to create a greater synergy between the interests of both, with regards to access to resources, research and development and benefit-sharing. One of the main beneficiaries of a standardized system for demonstrating the origin of biological and genetic resources and of rights to use them would be the private sector. A certificate of origin system which provides evidence of a clean title for use of resources would enhance the value of resources and create greater private sector interest in the natural product market. A the same time, a system of certification would provide increased transparency, facilitate monitoring of use of resources and of compliance with ABS agreements, responding to the interests of provider countries."2/

13. It has been stressed that an international system of certificate of origin/source/legal provenance should not impede research. This issue will be further examined under section V, when considering the potential features and characteristics of a certificate.

^{1/} Proposal put forward in contribution by Australia.

^{2/} Brendan Tobin, David Cunningham, and Kazuo Watanabe, "The feasibility, practicality and cost of a certificate of origin system for genetic resources – Preliminary results of comparative analysis of tracking material in biological resource centres and of proposals for a certification scheme", United Nations University Institute of Advanced Studies, circulated as document UNEP/CBD/WG-ABS/3/INF5 at the third meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, p. 58.

14. When considering the need for an internationally recognised certificate of origin/source/legal provenance, it should be borne in mind that there is a large variety of users of genetic resource (e.g.: various sectors of industry, *ex situ* collections, research institutes) with different internal processes and constraints, and which use different types of genetic resources for different purposes. These factors add to the complexity of establishing one single international system which can meet the needs of all users and providers and, therefore, should be given careful consideration when determining the need for an internationally recognised certificate of origin/source/legal provenance, its scope, and its feasibility and practicality. "Any benefits of using a certificate must be weighed against the practical impact of such a certificate on the real world use of genetic resources, the conservation of those resources and their sustainable use." 3/

IV. DISTINCTIONS BETWEEN THE OPTIONS OF CERTIFICATE OF ORIGIN/SOURCE/LEGAL PROVENANCE AND IMPLICATIONS FOR ACHIEVING THE OBJECTIVES OF ARTICLE 15 AND 8(i)

15. It has generally been suggested that the certificate could be a certificate of origin, a certificate of source, a certificate of legal provenance or a combination thereof. A recent suggestion has been to consider rather a "certificate of compliance" 4. This section first examines the options of a certificate for genetic resources and its implications for achieving the objectives of Article 15. It then considers the options if they were to cover traditional knowledge associated with genetic resources and implications for achieving the objectives of Article 8(j).

A. Distinctions between each of the options and implications for achieving the objectives of Article 15

Certificate of origin of genetic resources

- 16. The term "origin" is used in the Convention in the context of "a country of origin of genetic resources". Article 2 states that the term "means the country which possesses those genetic resources in *in-situ* conditions". It would seem to follow, therefore, that a certificate of origin would indicate the country where the genetic resource was collected from *in situ* sources. It would be granted by a competent national authority in the country of origin and would provide evidence that national access requirements were met.
- 17. The certificate of origin would hence assist in achieving the objectives of Article 15 for genetic resources accessed *in situ*. Indeed the certificate would implicitly provide evidence that the prior informed consent of the competent national authority was obtained upon mutually agreed terms.

Certificate of source of genetic resources

18. Paragraph 3 of Article 15 specifies that for the purposes of the Convention, "the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention." In a restrictive sense, a certificate of source could simply refer to a source that is not a country of origin in geographical terms. Nevertheless, it could also be conceived more broadly to encompass both countries of origin or countries that have acquired the resource in accordance with the Convention. It would therefore simply indicate the place where the genetic resource was obtained. If the resource is obtained *in situ* the source would be the geographical origin of the resources. However if the resource is obtained from an *ex situ* collection, the source would be the collection.

<u>3</u>/ Contribution by the International Chamber of Commerce (ICC).

^{4/} See contribution by Australia.

- 19. If the source is the country of origin, the delivery of a certificate of source would indicate that the prior informed consent of the national authority was obtained and the objectives of Article 15 would be met.
- 20. If the source is a collection and the resource was accessed by the collection after the entry into force of the Convention, the certificate delivered by a competent national authority of the provider country would provide evidence that the resources were accessed in accordance with Article 15.3 of the Convention.
- 21. With respect to both a certificate of origin or source, it has been suggested that the identification of the origin or source may be challenging and expensive to verify, particularly where a species exists in more than one jurisdiction. 5/

Certificate of legal provenance of genetic resources

- 22. A certificate of legal provenance would provide evidence that the resource has been obtained in conformity with the legal requirements of the country from which the resource was accessed. A certificate of legal provenance would hence only be delivered by a country which has set up legal requirements for access to its genetic resources. A certificate of legal provenance would therefore provide evidence that the genetic resource was accessed in accordance with Article 15 of the Convention.
- 23. However, it has been suggested that "the term could possibly also be construed in some jurisdictions as constituting evidence of a legal title or ownership. This should be avoided because, depending on the domestic structure for legal ownership of genetic resources, governments may not have the authority to transfer ownership. In such cases, they may only have the power to grant the right to use a resource, in which case legal ownership is precluded from vesting in the user. For this reason, the term 'legal provenance' does not appear useful and could be misleading." 6/
- An alternative could be to focus the debate on a certificate of compliance. It has been suggested that "a certificate of compliance could support the effective implementation of Article 15. Such a certificate would be issued by domestic authorities to show that a user has fulfilled all access requirements as set out in domestic law. This would serve the paramount objective of ensuring that access is consistent with obligations under the Convention. It would not replace the need for contracts containing mutually agreed terms." 7/
- 25. When considering the options of certificate of origin/source/legal provenance, it has been suggested that since none of the options fully covers all situations, the best approach could be a combination of two or more options as part of an international system.
- 26. Finally, it has been suggested that, in naming the certificate, confusion with existing systems should be avoided. 8/ For example, a certificate of origin (CO) is a document widely used in international trade to certify that goods in a particular export shipment are wholly obtained or produced or manufactured or processed in a particular country.

B. Distinction between each of the options and its implications for achieving the objectives of Article 8(j)

- 27. With respect to Article 8(j), the situation may be more complex. The issue of whether and how a certificate system might cover traditional knowledge associated with genetic resources has not yet been closely examined. When considering this issue, the Group of Technical Experts may wish to take the following into account.
- 28. Article 8(j) provides that:

<u>5</u> /	Ibid.

<u>6</u>/ Ibid.

<u>7</u>/ Ibid.

<u>8</u>/ See contribution by ICC.

"Each Contracting Party shall, as far as possible and as appropriate:

. . .

- (j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices."
- 29. The first question to be addressed is whether a certificate system should cover traditional knowledge and, if so, what would be the practicality, feasibility, costs and benefits of including traditional knowledge in such a system.
- 30. It could be argued that a certificate could be a mechanism to ensure that access and benefit-sharing agreements have been reached with indigenous and local communities when access to traditional knowledge associated with genetic resources is sought. Hence, a certificate system could contribute to preventing the misappropriation of traditional knowledge.
- 31. In considering whether the certificate system should apply to traditional knowledge, a number of practical issues arise. One of them is the identification of the beneficiary: those who provided the traditional knowledge, the community holding the knowledge in the provider country, communities across borders if they are all holders of the knowledge, or the provider country. If the same knowledge is held by more than one community within the same country or across borders how could the certificate system ensure that the approval was obtained from all the knowledge holders and the communities concerned? Another issue is how such a system could be implemented and whether both national and regional frameworks would be necessary. Other issues to consider include the following:
- (a) The fact that traditional knowledge is intangible and may be difficult to track without adequate indigenous infrastructure;
- (b) Ownership is likely expressed collectively by the group or groups, although individuals may be holders of that knowledge.
- 32. As set out in Article 8(j), the obligations of Contracting Parties with respect to traditional knowledge, innovations and practices are subject to national legislation. For those Contracting Parties that have undertaken through their national laws to respect, preserve, maintain and promote the application of such knowledge, with the approval and involvement of the holders, and to encourage the equitable sharing of benefits arising from the utilization of such knowledge, the certificate system may assist them in implementing Article 8(j) and the relevant national legislation.
- 33. Therefore, the implications of the certificate on the implementation of Article 8(j) and in the realization of its benefit-sharing objectives may largely depend on whether or not Parties have put in place national legislation, addressing the issues of access to biodiversity related traditional knowledge and benefit-sharing.
- 34. Assuming that such a certificate were to cover traditional knowledge, the following practical considerations would need to be examined in the development of a certificate:

Certifying the origin of traditional knowledge associated to genetic resources

- 35. The origin of traditional knowledge may be difficult to determine without adequate indigenous infrastructure in place. Different situations can be envisaged, including the following:
- (a) The origin of traditional knowledge associated to a genetic resource may be found in one community living across borders,

(b) The same traditional knowledge may be used by more than one community and it may be difficult to obtain the approval of diverse communities without adequate indigenous infrastructure.

Certifying the source of traditional knowledge associated to genetic resources

36. The source of traditional knowledge associated with a genetic resource used in the development of a particular product will be easier to identify but will not provide evidence that the source is the exclusive owner(s) or holder(s) of that traditional knowledge. Depending on national legislation, the certificate may or may not provide evidence that the approval or prior informed consent of the owners or holders of the traditional knowledge was granted with respect to the use of traditional knowledge.

Certifying the legal provenance of traditional knowledge associated to genetic resources

37. Evidence of the legal provenance of traditional knowledge could only be provided in countries that have adopted national legislation to address access to traditional knowledge of indigenous and local communities. Such a system would therefore not cover all cases of access to traditional knowledge associated with genetic resources.

V. POTENTIAL CHARACTERISTICS AND FEATURES OF AN INTERNATIONALLY RECOGNIZED CERTIFICATE

38. Regardless of the option(s) chosen potential characteristics and features to be considered include the following.

A. Nature of the certificate

39. In considering the development of an internationally recognised certificate of origin/source/legal provenance, thought will need to be given as to whether its use should be voluntary or mandatory. While some have suggested that its use could be voluntary or subject to national legislation9, others have suggested that it must be supported by a legally binding regime in order to be effective and in accordance with its objectives. 10/

B. Scope

40. A clear definition of the scope of the certificate system is a critical element that will determine its effectiveness. There is a need to determine under which circumstances genetic resources are to be covered by the certificate. When examining the scope of the certificate system, a number of issues need to be considered, including:

a) The scope of the certificate in relation to the scope of the Convention

41. It has been argued 11/ that although many of the proposals for a system of certificate of origin/source/legal provenance contained in published literature presuppose that an international certificate system could cover all transfers of genetic resources, this is not in fact possible. Indeed, "Article 15(3) provides that the genetic resources covered by the access and benefit sharing articles of the Convention are 'only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with the Convention'. Accordingly, many transboundary transfers of genetic resources are outside the scope of the Convention, most significantly transfers of material obtained before the Convention entered into force. In many countries, there may also be a range of genetic material that is not subject to a prior informed consent process, as is recognized in paragraph 5 of Article 15, and over which domestic authorities do not

^{9/} See contribution by Norway.

<u>10</u>/ See contribution by Mexico.

^{11/} See contribution by Australia.

exercise control."12/ A number of questions related to the scope of a certificate system have been raised and are included in the annex

- b) Whether the certificate system would apply to genetic resources and to the information derived from genetic resources and whether it would apply to traditional knowledge associated with genetic resources.
- 42. While some argue that the certificate could only be attached to physical property and not to the scientific or traditional knowledge employed in the use of those genetic resources since Article 15 governs access to physical material 13, others argue that the certificate should apply to genetic resources and derivatives from countries of origin and also to associated traditional knowledge of indigenous and local communities 14.
 - c) Whether the certificate will apply to genetic resources used for scientific research and/or commercial use
- 43. A large majority of requests for accessing genetic resources are made for basic research and not for commercial purposes. For example, according to a research carried out in Mexico, 95% of resource use in Mexico is for basic non-commercial research. 15/
- 44. Research institutes have voiced concerns that the added bureaucracy created by the establishment of an international certificate system and resulting additional costs could have a detrimental impact on future research. 16/ The Coordination Mechanism for the Global Taxonomy Initiative, at its meeting in Montreal on 20-21 November 2006, noted the need to ensure that any development or use of a certificate of origin/source/legal provenance would not adversely affect the efficient transfer of materials, or impose excessive costs or regulatory burdens, for identification and non-commercial research.
- 45. Considering that providers are more specifically concerned about regulating access to genetic resources which may lead to commercial use of resources, it has been suggested that genetic resources accessed for scientific purposes could be excluded from the certificate system. However, such an exemption could potentially create a loophole through which resources initially accessed for research purposes could be used for commercial purposes without having obtained the required certificate. To avoid such situations, it has been suggested that certificates could be provided when the intended use of the resource changes from basic research to commercial use. However, the line between basic scientific research and commercial use may also be difficult to draw. Should it be determined when research is aimed at commercial use? When potential commercial use is identified? Or, when applying for a patent?
- 46. An alternative could be to establish facilitated access through a simplified procedure for genetic resources which are to be used for the purposes of basic research.
 - d) The relationship with the Multilateral System of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture
- 47. In order to ensure consistency of regulatory frameworks, it has been argued that genetic resources that fall under the scope of the access and benefit-sharing provisions of the International Treaty on Plant Genetic Resources for Food and Agriculture, when utilized for the purposes of that agreement, should, in

^{12/} Contribution by Australia.

^{13/} See contribution by Australia.

^{14/} See contributions by Brazil and Mexico.

^{15/} See Tom Dedeurwaerdere (CPDR), Sélim Louafi (Iddri), Carmen Richerzhagen (UNU/IAS), Brendan Tobin (UNU/IAS), Roundtable on Practicality, Feasibility and Cost of Certificates of Origin, Workshop Summary, p.2 and Draft Record of Discussions of the International Expert Workshop on Access to Genetic Resources and Benefit-sharing, held in Cuernavaca, Mexico, 24-27 October 2004, p.17.

^{16/} For further information see UNEP/CBD/WG-ABS/3/5, "Analysis of measures to ensure compliance with prior informed consent of the Contracting Party providing genetic resources and mutually agreed terms on which access was granted, and of other approaches, including an international certificate of origin/source/legal provenance – Note by the Executive Secretary", paragraphs 109 to 120 and see document referred to in footnote 2, p. 58.

principle, not be covered by the certificate system. <u>17</u>/ Similarly, genetic resources held in *ex situ* collections of international institutions that have signed agreements with the Governing Body of the International Treaty would not be covered by the certificate system. <u>18</u>/

C. Form

- 48. It has been suggested that the certificate could take various forms: a paper, a barcode, an alphanumeric code or a virtual online certificate. It is argued that the latter could reduce the administrative burden of such a system. 19/
- 49. Although it has been proposed that useful lessons could be drawn from experience with the permit system under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), 20/ it has been argued that the development of a computerized, paperless and centrally administered system may be preferable. Also, while CITES permits are controlled at the border, it is envisaged that the certificate could follow the genetic resource throughout its life cycle and the changing nature of the resource at it goes through different stages of transformation, from research to development. 21/
- 50. It has been suggested that the certificate should meet the following requirements: it should have an internationally recognizable format, though not necessarily standardized, 22/ it should be simple, homogeneous and practical; security features should be established for the verification of its authenticity; it should be easy to verify and entail low administrative costs. 23/
- 51. The certificate could be registered in a central registry or clearing house of certificates based in an international institution, which could be used for verification purposes and would provide information regarding the specific conditions under which the genetic resource was accessed and may be transferred. In other words, the certificate would indicate that prior informed consent has been obtained and that mutually agreed terms have been reached. Information regarding the terms and conditions of access could be obtained through the clearing house mechanism. 24/

D. Information to be contained in a certificate

- 52. As has been suggested, <u>25</u>/ information to be included in a certificate of origin/source/legal provenance could include the following:
 - Particulars of the provider and user
 - Particulars of the indigenous and local communities parties to the agreement
 - Details of genetic resources or traditional knowledge

^{17/} See contribution by Brazil.

^{18/} For further information regarding the application of the International Treaty on Plant Genetic Resources for Food and Agriculture to International Agricultural Research Centres of the Consultative Group on International Agricultural Research see contribution by the International Agriculture Research Centres of the Consultative Group on International Agriculture Research available in document UNEP/CBD/GTE-ABS/3/Add.2.

^{19/} David Cunningham, Brendan Tobin and Kazuo Watanabe, "The feasibility, practicality and cost of a certificate of origin system for genetic resources – Preliminary results of a comparative analysis of tracking material in biological resource centres", United Nations University Institute of Advanced Studies, Yokohama, Japan, October 2004, p. 33.

^{20/} See contribution by Argentina.

^{21/} For further discussion, see Workshop Summary referenced in footnote 18, p. 2.

^{22/} See contribution by Brazil.

^{23/} See contribution by Mexico.

^{24/} For further discussion, see José Carlos Fernandez, "Elements for the design of a Certificate of Legal Provenance", presented at the International Expert Workshop on Access to Genetic Resources and Benefit-sharing, held in Cuernavaca, Mexico, 24-27 October 2004, p. 2.

^{25/} See contribution by India and UNU/IAS Report, "User Measures – Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity", 2nd edition, March 2003, 38.

- Details of the approved use which may be made of the resources
- Details of any restrictions on use
- Period of the agreement
- Conditions relating to transfer of rights to third parties
- Details of the issuing authority
- 53. In addition, it has been suggested that the following information should be included: <u>26</u>/
 - International serial listing
 - Country of origin
 - User country, including details of user country institution
 - Taxonomic identification
 - Issuing date
 - Information for the identification of the material

E. Subject matter of a certificate 27/

- 54. Certificates could be granted for:
 - (a) The access contract and all material collected under it;
 - (b) For a specific collection activity in a defined area for a defined period;
 - (c) For all samples of a specific species or genus;
 - (d) For an individual collection or sample.
- 55. Where resources are easily identifiable and are the subject of specific agreements, it may be appropriate that a certificate be linked to that resource. However where the collection activity focuses on a wide scale collection, in particular random collections and collection of resources which are yet unknown to science, the situation is more complicated. Certification of specific resources would then be impossible due either to lack of taxonomic information, nature of the collection (e.g. soil samples) or the random nature of the collection.

F. Process

56. It has generally been suggested that the certificate would be issued by the competent national authority of the provider country, at the time access is granted, as evidence of compliance with access requirements. Specific requirements regarding the delivery of the certificate may vary from one country to another, depending on national regimes for access and benefit-sharing. 28/ Some have suggested that agreement should be reached at the international level on the conditions for the issuance of a certificate, 29/ while others have suggested that although the certificate and conditions related to its delivery may vary from country to country preventing the adoption of a common format, agreement could be reached at the international level on basic common standards/requirements. 30/ These may include: details of the provider and initial user, a description of the material covered, evidence of the prior informed consent of competent national authorities, reference to mutually agreed terms addressing the sharing of benefits. This would assist in facilitating the mutual recognition of certificates issued by

<u>26</u>/ See contributions by Brazil and Mexico.

<u>27</u>/ For further information see presentation by Kathryn Davis entitled "Tracing terms and drawing lines: a view from biodiversity research collections", International Expert Workshop on Access to Genetic Resources and Benefit-sharing, Cape Town, South Africa, 20-23 September 2005 and paper by UNU/IAS referred to in footnote 2, p. 52.

^{28/} See contribution by Mexico.

^{29/} See contribution by Norway.

^{30/} See contributions by Australia, Brazil.

different countries and would provide evidence that basic access requirements have been met. Certificates could then be considered as "internationally recognized".

- 57. It has also been suggested that other options could be considered. The certificate could be issued when the material is collected, when genetic resources are taken out of the country or when intellectual property rights are applied for. 31/
- 58. Verification that a certificate was delivered would be carried out in the country where users of genetic resources are operating, at check points or controls to be established by countries, as further examined below.
- 59. Finally, as mentioned above, while some have suggested that the certificate should accompany the genetic resource and derived information, in order to ensure traceability, 32/ others are of the opinion that the certificate can only be attached to the physical genetic resource. 33/

G. Controls

60. In order to ensure that access and benefit-sharing requirements are being met throughout the life cycle of the genetic resource, and particularly when the genetic resource has left the provider country, the certificate could be controlled at various points.34/ These checkpoints or controls could include the border, patent offices or the registration points for other types of commercial applications not covered by intellectual property rights. 35/ When the resources are used for non-commercial purposes, the certificate could, for example, be requested in applications for research funding or for the publication of scientific papers.

Border

61. While some have suggested that certificates could be controlled by means of check points at the border, others have questioned the value of establishing such checkpoints due to the nature of genetic resources. Indeed it is difficult to regulate the physical movement of biological resources across borders36. It would also involve considerable investments in terms of training of customs officials, therefore the costs involved may outweigh the potential benefits.

Commercial applications

62. Patent offices: The issue of the disclosure of origin/source/legal provenance in applications for intellectual property rights has been the subject of much debate at the international level, in a number of forums, such as the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO) and the Convention on Biological Diversity. At the national level, a number of countries have already included disclosure requirements in their national legislation thereby obliging patent applicants to disclose the origin of genetic resources used as a condition for the patenting of products based on genetic resources. The certificate could be used in countries which have included a disclosure requirement in intellectual property rights applications for products based on genetic resources and associated traditional knowledge, in order to provide evidence to the patent examiner that ABS requirements have been met without requiring that the patent examiner take any additional steps to verify the conditions of access and use of a genetic resource. 37/

^{31 /} See contribution by New Zealand.

^{32 /} See contribution by Mexico.

^{33 /} See contribution by Australia.

 $[\]underline{34}$ / However, it has been suggested that the certificate should not be verified or required in all steps nor in all transactions (see contribution by Mexico).

<u>35/</u> For further discussion, see document referred to in footnote 2;

^{36/} See contribution by India.

^{37/} See contributions by Brazil, India, Mexico, Norway.

63. Registration points for other commercial applications. 38/: It has been suggested that since many products are not covered by patents, other commercial authorization processes or regulatory processes, such as drug, seed and other product approval procedures, could also be used as checkpoints.

Non-commercial applications

- 64. Publication of scientific papers: As a condition to the publication of articles, scientific journals could require evidence that genetic resources, used as a basis for the findings described in a paper, were acquired in accordance with the access and benefit-sharing requirements of the Convention. This could be an incentive for scientists to ensure they have obtained rights to use relevant resources. In such cases, a certificate of origin/source/legal provenance could serve to demonstrate the right to use resources.
- 65. Applications for research funding: In countries where access and benefit-sharing requirements are prerequisites for the public funding of research and development projects, a certificate could be used by the applicant as evidence that access and benefit-sharing requirements of the provider country are being met in accordance with the Convention and access requirements of the provider country.
- 66. It has been suggested that the criteria for the identification of checkpoints could include transaction costs in monitoring and enforcing the check point and its efficacy. It has also been argued that it may be preferable to establish check points at later stages of product development since genetic resources used at these late stages are fewer than those accessed and are more financially valuable. 39/
- 67. One related issue which may deserve further consideration is the question of when the need for a certificate would be exhausted. In other words, if a certificate is to follow not only the physical genetic resource but also derived products, when does the link between a product and a genetic resource become too tenuous for the certificate to be required. $\frac{40}{}$
- 68. Alternatively, it has been argued that no system of check points or controls could be workable since no system of certificates could comprehensively cover all transfers of genetic resources. 41/

H. Institutional measures

69. The establishment of an international system of certificate of origin/source/legal provenance would require that a number of institutional measures be taken both at the national and international levels each of which will have human, technical and financial implications.

National level

70. At the national level, it would be necessary to establish competent national authorities and institutional mechanisms to issue the certificate through appropriate legislative and/or regulatory measures. Adequate mechanisms would also be needed to verify and monitor certificates of origin delivered by competent national authorities in user countries through check points or controls. To the extent possible, the system could build on existing institutions.

International level

- 71. At the international level, a certain level of harmonization may be required. For example, agreement could be reached on a set of minimum criteria for obtaining the certificate such as the identification of the origin/source/legal provenance of the genetic resources and/or traditional knowledge and prior informed consent of the competent national authority in the providing country. A model certificate could also be developed.
- 72. In addition, an international registry or database containing information on all certificates issued could serve as a clearing-house mechanism for exchange of information on the terms and conditions

^{38/} See contribution by Brazil, Mexico.

^{39/} See UNEP/CBD/WG-ABS/5/3 - For further discussion, see document referred to in footnote 27, p. 3;

<u>40</u>/ Ibid.

^{41 /} See contribution by Australia.

under which certificates were delivered. The registry or database could be accessed by national authorities, including border authorities, patent offices and other product approval authorities for information on the certificates delivered. In addition, national authorities, such as patent offices could notify a clearing house mechanism when they receive an application for a patent based on or making use of genetic resources. 42/

73. Details regarding storage of information and access would need to be clarified. This international mechanism could also be in charge of monitoring certificates.

I. Compliance

- 74. It has been suggested that mechanisms of sanction and compensation should be established to address situations of non-compliance. More specifically, it has been suggested that mechanisms should be established to ensure that competent national authorities can take action against users that do not obtain the certificate or violate obligations attached to the certificate. 43/
- 75. It has also been suggested however that evidence of compliance with access requirements cannot replace the need for mutually agreed terms which stipulates terms for use, subsequent transfer and benefit-sharing. Indeed, a certificate issued at the point of access cannot provide evidence of subsequent compliance by a user with the terms of a contract. 44/
- 76. With respect to costs associated to compliance, it has been proposed that these should be kept to a minimum so as not to discourage research by creating financial disincentives through high compliance costs. 45/
 - VI. ASSOCIATED IMPLEMENTATION CHALLENGES, INCLUDING THEIR PRACTICALITY, FEASIBILITY, COSTS AND BENEFITS, AND THEIR MUTUAL SUPPORTIVENESS AND COMPATIBILITY WITH THE CONVENTION AND OTHER INTERNATIONAL AGREEMENTS

A. Implementation challenges

- 77. Before examining the implementation challenges associated with the establishment of an internationally recognised certificate of origin/source/legal provenance, it may be useful to highlight the potential benefits of such a system.
- 78. A fundamental question which could be addressed in order to determine the potential benefits of such a system is the extent of bioprospecting. As mentioned above, a large majority of genetic resources are accessed for research purposes. Researchers involved in basic research have warned against the potential negative impact of a certificate system which could be an additional burden to already complex procedures related to the treatment of accessed resources. Therefore, assessing the importance of genetic resources used for commercial purposes worldwide may be useful to determine whether the benefits of such a system outweigh the costs.
- 79. Apart from this fundamental question, potential benefits of such a system may include the following: <u>46</u>/

^{42/} For further discussion on this issue see Miriam Dross and Franziska Wolff, "New Elements of the International Regime on Access and Benefit-sharing of Genetic Resources – the Role of Certificates of Origin" Bfn-Skripten 127, Federal Agency for Nature Conservation, Bonn, Germany, 2005, p. 116.

^{43/} See contribution by Mexico.

^{44/} See contribution by Australia.

^{45/} See contribution by New Zealand.

^{46/} UNEP/CBD/WG-ABS/3/5, paragraph 103.

- Providing greater transparency, legal certainty and mutual trust among parties to access and benefit-sharing arrangements;
- Providing evidence that the genetic resources were obtained with the prior informed consent of the competent authority in the provider country;
- Facilitating the application of user measures by using the certificate as evidence of prior informed consent and mutually agreed terms at control points;
- Creating incentives for compliance with access and benefit-sharing requirements of provider countries;
- Facilitating the monitoring of access and benefit-sharing arrangements through the establishment of a central registry or clearing house mechanism;
- Facilitating the tracking of compliance with the access and benefit-sharing requirements of provider countries.
- 80. The costs associated with the establishment of an international system are difficult to assess. They will be encountered at multiple levels. In addition, it is likely that the costs would impact differently on different institutions. A number of variables would seem to have an influence on the costs of tracking genetic resources for different institutions: the volume of resources managed yearly by an institution, the variety of sources from which resources are accessed that are managed by an institution and are subject to differing legal obligations. 47/ One other fundamental question may be to determine not only what would be the costs but also who would bear the costs of the establishment of such a system.
- 81. The following steps in the establishment of an international system may entail costs related to the establishment of an adequate infrastructure at both national and international levels.
- 82. At the national level, this will involve the establishment of competent national authorities for awarding the certificate and for monitoring the certificate at various control points, the training of human resources, and the establishment of institutions and procedures. Provider countries may meet the same difficulties in establishing a certificate system as they have met in establishing national regimes for access and benefit-sharing. Over 60 countries have entered the process of developing or have developed national regimes related to access to genetic resources and benefit-sharing since the entry into force of the Convention. Therefore, capacity-building and financial resources may be needed for developing countries and particularly the least developed among them to ensure that national systems can be set up to support an international documentation system.
- 83. At the international level, a central institution serving as the clearing house mechanism, keeping a central database tracking and monitoring genetic resources accessed worldwide may be needed, requiring human, technical and financial resources.
- 84. Although the costs related to the establishment of an internationally recognised certificate of origin/source/legal provenance are difficult to estimate, a number of steps could be taken to minimize the costs of such an international system by avoiding increased bureaucracy and administrative complexity. They include: 48/
 - Using existing tracking procedures where possible
 - Using existing human resources, infrastructure and control points
 - Minimising the creation of new levels of bureaucracy
 - Promoting automatic issuance of the relevant certificate upon compliance with specific criteria, such as completion of a material transfer agreement or an access and benefit-sharing agreement
 - Promoting consolidation of existing permitting requirements with any new certification system
 - Promoting paperless systems

<u>47</u>/ See document referred to in footnote 2.

^{48/} Ibid., p. 50.

- Establishing minimum criteria for the management of documentation at the entry and exit point of the system without attempting to harmonize existing systems established by provider countries and user institutions/companies.
- 85. Also countries have set up national access and benefit-sharing regimes which are very diverse in the procedures they have established and may be difficult to harmonize. The establishment of minimum standards would therefore also be more practical in the establishment of a system of certificates at the national level.
- 86. In order to ensure the feasibility and practicality of such a system, when conceptualizing the design of such a system, the different needs and interests of users and providers, including the research community, the private sector, provider countries and indigenous and local communities need to be taken into account. For the system to be successful, a bottom-up approach will be needed. As highlighted in the Workshop Summary of a roundtable carried out on the practicality, feasibility and costs of certificates of origin:

"The commitment of industry associations and research associations to the building of a system of certificates of origin is seen as a key element in reaching acceptability. Indeed, for efficient and legitimate governance of a system of certificates of origin one has to look beyond the law, in direction of the network of institutions on which the implementation will depend." 49/

- 87. It was suggested that pilot projects, both country and sector-based, should be promoted to assess the feasibility of a certificate system in countries with different infrastructures and to evaluate further commercial practices and systems including those of intermediaries and end users of genetic resources.
- 88. The need for a fact-based assessment of the full costs and benefits associated with any proposed certificate system was stressed in order to ascertain that the costs do not outweigh the benefits for most countries. This assessment would include an analysis of the volume of materials covered by such a system; a life-cycle analysis of specimens and certificates; models for developing electronic certificates and the legal impediment to adopting this in individual countries; and personnel and systems needs for both users and providers to implement and maintain the system. 50
- 89. Finally, the Coordination Mechanism for the Global Taxonomy Initiative, at its meeting in Montreal on 20-21 November 2006, noted the relevance of taxonomic expertise for consideration of the feasibility, practicality and cost of possible certificates of origin/source/legal provenance, and noted the availability of members of the Coordination Mechanism to provide inputs.

B. Compatibility with the Convention and with other international agreements

- 90. Considering that one of the main objectives of such an international system would be to assist with the implementation of the access and benefit-sharing provisions of the Convention, it follows that it will be designed in a manner that is compatible with the Convention. Little consideration has been given thus far to the issue of the compatibility of such a system with other international agreements.
- 91. The FAO International Treaty on Plant Genetic Resources for Food and Agriculture was developed in harmony with the Convention. A certificate system under the Convention would likely not apply to genetic resources covered by the Multilateral System of the International Treaty or held in *ex situ* collections of international institutions that have signed agreements with the Governing Body of the International Treaty. 51/ Such a certificate system would therefore be complementary to the regime of access and benefit-sharing set up by the International Treaty under the Multilateral System.

<u>49/</u> See Workshop Summary referenced in footnote 18, p. 4.

<u>50/</u> Contribution by the United States of America.

⁵¹/ For further information, see text of the International Treaty on Plant Genetic Resources for Food and Agriculture, in particular articles 11 and 15.

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92. The interface with WTO Agreements and WIPO conventions and treaties may need to be further examined. It has been suggested that "[a]ny system should be designed without unnecessary impacts on trade to avoid any conflicts with the WTO". 52/ Potential impacts on the international trade and intellectual property systems will likely depend on the scope, design and application of such an internationally recognized certificate.

Annex

QUESTIONS FOR CONSIDERATION

Rationale/Objectives/Need

- Is there a need for an internationally recognized certificate of origin/source/legal provenance? What are its objectives and rationale?
- Is there evidence of a need: What practical problems exist? How frequently do they arise? What is the nature and extent of their consequences?
- How will any scheme achieve those objectives and what other means are there for doing so?

Distinctions between the options of certificate of origin/source/legal provenance and implications for achieving the objectives of Articles 15 and 8(j) of the Convention

- What type of certificate system is needed: a certificate of origin, source or legal provenance? Or a combination thereof? What about a certificate of compliance? Should the certificate system cover traditional knowledge?
- If there is more than one country of origin for a particular genetic resource, will those wishing to acquire a genetic resource be required to apply for a certificate only from the country providing the genetic resource or from every country in which that resource is now found in situ?
- Will the system promote the wider application of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity?
- How would a certificate system ensure the continued approval and involvement of traditional knowledge holders in accordance with national legislation, and in particular after access to the material? For instance in situations where mutually agreed terms around traditional knowledge prohibited some uses as offensive to the knowledge holders?

Potential characteristics and features

Nature

• Will participation in the system be compulsory or optional for Parties to the Convention on Biological Diversity?

Scope

- Will the scope of the certificate system coincide with the scope of the Convention?
- Will human genetic resources be excluded?
- Will the certificate system apply to ex situ collections? If so, will it apply to genetic resources included in *ex situ* collections which were acquired prior to the entry into force of the Convention?
- Will the certificate be required for a genetic resource acquired after the Convention came into force but before the new system is implemented?
- Will the certificate system apply to genetic resources found in countries which have not regulated access and benefit-sharing?

- If the certificate system does not apply to countries which are not Parties to the CBD, what will be the impact in terms of the effectiveness of the system?
- How can genetic resources covered by the system be distinguished from those that are not?
- Will derivatives fall within the scope of the scheme and, if so, how are they to be defined?
- Is the certificate for genetic resources "in the form received", does it apply to the presence of components or even to derivatives based upon (or even on knowledge from) the material accessed?
- Will (and if so how will) the scheme apply to genetic resources acquired from or originating in a country which is not a Party to the Convention on Biological Diversity but which is processed and or traded in a Part to the Convention?
- Will biological materials, such as chemical extracts and essential oils, be freely useable without a certificate?
- Will the certificate apply to genetic resources used for scientific research and/or commercial use?
- How will the certificate apply in situations where genetic resources used for scientific research result in commercializable discoveries?
- Will the certificate cover access to traditional knowledge associated with genetic resources?

Form

• What will be the form of the certificate? Paper, barcode, alphanumeric code or virtual online certificate?

Subject matter

What information should be contained in a certificate?

Process

- Who will issue certificates? On what basis?
- Will the certificate be attached to the physical genetic resource or should it also follow the information and/or product derived from the genetic resource?

Controls

- Are controls or check points workable if a certificate system does not cover all transfers of genetic resources?
- Which commercial authorization processes could provide useful points of control?

Compliance

- What will be the sanction for use of a non-certified genetic resource?
- Should additional characteristics and features be considered?

Implementation challenges and compatibility with the Convention and other international agreements

Benefits

• What are the potential benefits of such a system?

Costs

- Who will bear the costs associated with the implementation of a certificate system?
- Will each Party have the resources to implement a certificate system for genetic resources found within its borders?
- What will the financial costs of setting up and implementing the system be to individual countries and any relevant international institutions?

Practicality, feasibility

• Is the implementation of such a system practical and feasible?

Compatibility with other agreements

- Would an internationally recognized certificate system be mutually supportive and compatible with other international agreements?
- Would a certificate system be compatible with the international trade system and the intellectual property system?
