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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

I. INTRODUCTION

1. At its seventh meeting, the Conference of the Parties, in decision VII/19 E, considered measures to support compliance with prior informed consent of the Contracting Party providing genetic resources and mutually agreed terms on which access was granted in Contracting Parties with users of such resources under their jurisdiction.

2. In paragraph 2 of this decision, the Conference of the Parties invited Parties and Governments "to continue taking appropriate and practical measures to support compliance with prior informed consent of the Contracting Parties providing such resources, including countries of origin, in accordance with article 2 and Article 15, paragraph 3, of the Convention, and of the indigenous and local communities providing associated traditional knowledge, and with mutually agreed terms on which access was granted."

3. In paragraph 10 of the same decision, the Conference of the Parties requested the Executive Secretary "to gather information, with the assistance of Parties, Governments and relevant international organizations, and to undertake further analysis relating to:

(a) Specific measures to support and ensure compliance with national legislation, prior informed consent of the Contracting Parties providing such resources, including countries of origin, in accordance with Article 2 and Article 15, paragraph 3, of the Convention, and of the indigenous and local communities providing associated traditional knowledge, and with mutually agreed terms on which access was granted;

(b) Existing measures to support compliance with national, regional, and international legal instruments;

* UNEP/CBD/WG-ABS/3/1.

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(c) The extent and level of unauthorized access and misappropriation of genetic resources and traditional knowledge;

(d) Access and benefit-sharing arrangements existing in specific sectors;

(e) Administrative and judicial remedies available in countries with users under their jurisdiction and in international agreements regarding non-compliance with the prior informed consent requirements and mutually agreed terms;

(f) Existing practices and trends with regard to commercial and other utilization of genetic resources and the generation of benefits;

(g) Measures that preserve and promote legal certainty for users over the terms and conditions of access and use; and

(h) Prepare a compilation of the information received and make this compilation available for the consideration of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing at its third meeting."

4. In response to this request, a notification was sent out to Parties, Governments, relevant organizations and other relevant stakeholders, inviting them to provide information in relation to the points raised in paragraph 10. The submissions received by the Secretariat are available as an information document (UNEP/CBD/WG-ABS/3/INF/1). In addition, section II of the present document provides an overview of measures taken by Governments to assist with the implementation of access and benefit-sharing provisions, particularly those listed under paragraph 10 (a), (b), (e) and (g). Work is still being carried out on issues under paragraph 10 (c), (d) and (f) and will be made available at the next meeting of the Working Group on Access and Benefit-Sharing.

5. In its decision VII/19 C, paragraph 1, the Conference of the Parties considered "other approaches, as set out in decision VI/24 B". The Conference of the Parties "invited Parties, Governments, relevant organizations, indigenous and local communities, and all relevant stakeholders, to submit to the Secretariat their views and relevant information on additional approaches as well as regional, national and local experiences on existing approaches, including codes of ethics".

6. In paragraph 2 of the same decision, the Conference of the Parties requested "the Executive Secretary to further compile information on existing complementary measures and approaches, and experiences with their implementation, and to disseminate such information to Parties, Governments, relevant organizations, indigenous and local communities and all relevant stakeholders through, *inter alia*, the clearing-house mechanism of the Convention" and in paragraph 3 requested "the Open-ended Working Group on Access and Benefit-Sharing to further consider the issue of additional approaches, in a cost effective way at an appropriate time, and, to this end, requests the Executive Secretary to prepare a report on the basis of the submissions received."

7. Section III provides an update of existing approaches to assist Parties and stakeholders with access and benefit-sharing implementation. Additional approaches, such as an international certificate of origin/source/legal provenance and the development of an access and benefit-sharing management tool are also examined in this section. Finally, section IV suggests a number of recommendations for further action.

II. OVERVIEW OF MEASURES TAKEN BY GOVERNMENTS TO ASSIST WITH THE IMPLEMENTATION OF ABS PROVISIONS, PARTICULARLY IN CONTRACTING PARTIES WITH USERS UNDER THEIR JURISDICTION

A. Specific measures to support and ensure compliance with national legislation, prior informed consent of the Contracting Parties providing such resources, including of the countries of origin, and of the indigenous and local communities providing associated traditional knowledge, and with mutually agreed terms on which access was granted.

8. At the second meeting of the Working Group on Access and Benefit-Sharing, Parties examined potential user measures and an overview of these types of measures was provided (UNEP/CBD/WG-ABS/2/2). The following provides illustrations of measures which have been taken by Governments with users under their jurisdiction to facilitate compliance with prior informed consent and mutually agreed terms. Actions taken by users, at the stakeholder level, such as institutional policies, codes of conduct and corporate policies are addressed in section III under "other approaches". This section also addresses measures taken by Governments, as providers of genetic resources, to ensure compliance with prior informed consent and mutually agreed terms.

1. Measures taken by Governments with users under their jurisdiction to ensure compliance with prior informed consent (PIC) and mutually agreed terms (MAT)

Awareness raising/ Public outreach

9. Actions undertaken by the European Commission in order to raise the awareness of users with respect to their obligations under the Convention on Biological Diversity, include:

(a) The creation of a European network of access and benefit-sharing focal points and/or competent national authorities – building on existing networks, which could be connected through the European Community Biodiversity Clearing-House Mechanism (EC-CHM);

(b) The establishment of a specific section on access and benefit-sharing on the European Community Biodiversity Clearing-House Mechanism. Such a section could contain the text of the Bonn Guidelines together with an explanation of their relevance to different European stakeholders' profiles. As suggested by the European Community in its submission, the EC-CHM could become an important channel to inform stakeholders of their rights and obligations internationally, including in relation to other international instruments such as the International Treaty on Plant Genetic Resources on Food and Agriculture; in the EC, and in the Member States. For this purpose, appropriate links with, *inter alia*, the Convention on Biological Diversity and Member States' Biodiversity Clearing Houses could be provided;

(c) The setting up of a register of stakeholders' groups on this clearing house mechanism.

10. According to the European Community submission, the integration of the access and benefit-sharing issue into the European Community process on Corporate Social Responsibility is also envisaged.

11. It is also stated in the European Community submission that "the European Commission placed a contract to identify the most cost-effective way of establishing a European network of access and benefit-sharing focal points; to collect all relevant information to be fed into a specific section of the EC-CHM devoted to the issue of access and benefit-sharing; and to widely publicise the EC-CHM website with all relevant stakeholder groups encouraging them to register with the EC-CHM." It was expected that this work should be concluded by April 2005.

12. Also of relevance to awareness raising, "As a follow-up to the European Community Communication, the Commission has also created an inter-departmental working group on indigenous issues which aims at promoting European Community action in this field and ensuring its coherence throughout the wide array of policies relevant to indigenous peoples, including environment, development cooperation, human rights, trade and intellectual property. The group is in the process of defining its work plan."

13. A number of actions which were undertaken by Governments to implement the Bonn Guidelines are also relevant under this section.

14. Finland's Ministry of Environment has translated the Bonn Guidelines into Finnish to facilitate the implementation of access and benefit-sharing at the national level. A national access and benefit-sharing working group was also to be established in the fall 2004, to be formed of different ministries and stakeholders. According to national discussions in Finland the need to disseminate information on the Convention on Biological Diversity, access and benefit-sharing and more particularly the Bonn Guidelines was emphasized. The need to analyse ways and means to implement the Bonn Guidelines was also stressed by the Government of Finland. 1/

15. In Denmark, in the fall of 2004 a meeting was to be organized with potential users of genetic resources to promote the Bonn Guidelines. The intention was also for this meeting to gather information on professional codes of ethics developed by academic societies or institutions in order to promote the application of the Bonn Guidelines as part of these codes. Awareness raising campaigns have also been used to promote the Bonn Guidelines.

16. In Spain, a workshop is to be organized at the beginning of 2005 with a view to informing different actors, including users and providers, involved in the access and benefit-sharing process.

17. Following an enquiry by the Swedish Scientific Council in 2003 among Swedish Universities to gather experiences and lessons learned in relation to the issue of access and benefit-sharing and to investigate the awareness to the Bonn Guidelines among Swedish universities, it was found that awareness to the Guidelines needed to be increased significantly, especially in central university administration bodies. National researchers expressed the need for more practical guidance. As a response to this demand, a handbook for researchers interested in obtaining genetic material from other countries is being prepared by the Swedish Scientific Council on Biological Diversity, in cooperation with the Swedish International Development Cooperation Agency, in order to facilitate research, essential for the conservation of biological diversity, and to enhance compliance with the Guidelines and national legislation. In addition, discussions are underway in Sweden on who is responsible for compliance with the regulations: the researchers, their employers or the financing bodies. Although this issue remains unresolved, awareness to the issue appears to be increasing among scientists and financing institutions.

18. In Norway, a national seminar was organized under the auspices of the National Genetic Resource Council in order to inform relevant actors, including users of genetic resources, of the Bonn Guidelines. In addition, the Nordic Genetic Resource Council is publishing a brochure, in Nordic languages and Finnish, to inform relevant actors with respect to the Bonn Guidelines. 2/

19. In France, in 2003, the Ministry of Industry organized a meeting to reflect upon access to genetic resources and benefit-sharing for different industry sectors, during which the Bonn Guidelines were disseminated. In addition, the evolution of the legal framework for access and benefit-sharing and the Bonn Guidelines are presented in a large number of specialized forums, such as botanic gardens and others. 3/

20. Finally, national websites, such as those developed in the Netherlands and the United Kingdom, 4/ are useful instruments in raising awareness among providers and users on access and benefit-sharing, including relevant policies and other measures.

1/ Available in annex to European Community submission

2/ See submission by Norway.

3/ See submission by France in annex to European Community submission.

4/ For further information see: www.defra.orv.uk/science/GeneticResources and www.absfocalpoint.nl

Information exchange and gathering

21. In Germany, the German Environment Ministry commissioned a study aimed at exploring "German users" of genetic resources originating from foreign countries and their knowledge of access and benefit-sharing regulations. The study which focuses on awareness to and the use of the Bonn Guidelines by "users" and "stakeholders" was to be finalized by end of September 2004.

22. In Belgium, a new project is to be initiated soon to examine methods to evaluate the economic value of microbial resources, as this was considered important information when starting negotiations on benefit-sharing. The project is also to propose standard documents to be used when transferring microbial resources, such as accession documents and Material Transfer Agreements.

23. Over the last year, the United Kingdom has undertaken a review of the practical implementation of ABS, including the use of the Bonn Guidelines, by the United Kingdom based stakeholders. The final report is not yet available. It is interesting to note that those organizations most knowledgeable of the Convention on Biological Diversity and the Bonn Guidelines are generally large and more actively involved stakeholders in the use, development, conservation and trade in genetic resources. The ongoing review on implementation will include specific recommendations for the dissemination on access and benefit-sharing in general and the Bonn Guidelines in particular, by means of, for example, the improvement of web pages and further contact and discussion with stakeholders.

Policy developments

24. In the Netherlands, the Government has expanded cooperation with commerce, research and social organizations by means of a policy document entitled "Sources of existence: Conservation and the sustainable use of genetic diversity" (2002). This document outlines the main Dutch policy which calls upon businesses, institutions and individuals to deal carefully with regulations, legislation and policy convened internationally or instituted in other countries.

25. Work carried out by the Nordic Genetic Resources Council on access and benefit-sharing resulted in a Nordic Ministerial Declaration in August 2003. The Ministerial Declaration on Access and Rights to Genetic Resources, 2003, establishes principles and objectives on how Nordic countries should address issues related to access and rights to genetic resources. 5/

26. In Norway, an expert committee was appointed in April 2001 by the Norwegian Government in order to strengthen legal measures for the protection of biodiversity in Norway. Access to genetic resources and benefit-sharing, an area not yet subject to legislation in Norway, are identified as a priority issue in this legislative work. As Norway is considered both a provider and user of genetic resources, the mandate of the committee is to propose legislation addressing both access to genetic resources in Norway and the use of genetic resources from foreign countries used in Norway. Among other instruments, the Bonn Guidelines are to be used by the committee as input to this work. The Committee is to submit its legislative proposal by the end of 2004. This will be followed by a broad Government hearing.

Support to stakeholder initiatives

27. Stakeholders initiatives are examined in the section dealing with other approaches, however it should be noted under this section covering Government initiatives that some Governments have supported stakeholder initiatives through various means.

28. For example, as stated in the European Community submission, "the European Commission continues to lend support to the implementation of institutional policies and codes of conduct on access and benefit-sharing by stakeholder groups, including for *ex situ* collections. The Commission has supported in the past the development of the Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC) 6/ by the Belgian Co-ordinated Collections of Micro-organisms (BCCM), together with 16 other organizations from around the world. At present, the

5/ See submission by Norway.

6/ http://www.belspo.be/bccm/mosaicc.

Commission is financing a follow-up of the MOSAICC project aimed at providing validated reliable methods for the value assessment of microbial resources. Such methods are necessary to put a socially, economically and environmentally sound 'price' on genetic resources and therefore facilitate benefit-sharing. The project also aims to develop validated model documents to enable traceability of microbial resources (origin, transfer and transport)." 7/

Incentive measures

29. Denmark and Sweden provide examples of situations where access and benefit-sharing requirements are to be met as a prerequisite for funding. In Denmark, as set out in the submission, providers of funding for research and development projects are to be contacted to include the application of the Bonn Guidelines as parts of the conditions for funding. In Sweden, a policy adopted by the Swedish International Development Cooperation Agency requires the establishment of a material transfer agreement between the provider and receiver of genetic material in research cooperation activities financed by the Agency that involve genetic material.

30. The potential role of the European Community Eco-Management and Audit Scheme (EMAS) as a voluntary certification scheme for organizations that comply with the Bonn Guidelines was also mentioned by the European Community in its submission. "EMAS is a voluntary scheme for organizations willing to commit themselves to evaluate and improve their environmental performance". 8/ As stated in the European Community communication, "Such a scheme would serve the purpose of helping users to improve their overall environmental performance, including in relation to access and benefit-sharing but would not alter their legal obligations." 9/

Disclosure of origin of genetic resources and associated traditional knowledge in intellectual property rights applications

31. The note by the Executive Secretary on the role of intellectual property rights in access and benefit-sharing arrangements, including national and regional experiences (UNEP/CBD/WG-ABS/2/3) provides an overview of existing national and regional experiences related to the issue of disclosure of origin of genetic resources in intellectual property rights applications. The following provides information regarding recent developments provided by Parties.

32. The European Community Communication launched a debate in the EU on the issue of "disclosure of origin" of genetic resources and traditional knowledge (TK) in patent applications. 10/ Several meetings have been convened involving intellectual property and biodiversity experts. As a result, the EU is working on different options and will be ready to further discuss them at future meetings of the WIPO Inter-Governmental Committee.

33. Denmark has revised its Patent law with a provision requiring that patent applicants provide information on the origin of the genetic resources used in the invention for which a patent is applied for. In cases of non-compliance, no sanctions are provided in the patent system, however under criminal law, sanctions are established regarding the provision of false information to public authorities. 11/

34. In Sweden, a new provision on the disclosure of origin of biological material of plant or animal origin in patent applications came into force on 1 May 2004, in accordance with article 5 of the Patents Regulations (SFS 2004:162) under the Patent Act. The article provides that if the origin is unknown, it shall be stated. It is also provided that "lack of information on the geographical origin or on the

7/ European Community submission, p. 3, available in document UNEP/CBD/WG-ABS/INF/1.

8/ Communication from the Commission to the European Parliament and the Council, "The Implementation by the European Community of the "Bonn Guidelines" on Access to Genetic Resources and Benefit-sharing under the Convention on Biological Diversity", Brussels, 23.12.2003, COM(2003) 821 final, p. 22.

9/ For further discussion, see ibid.

10/ For further discussion see ibid, p. 17 to 21.

11/ Submission by Denmark in annex to the European Community submission.

knowledge of the applicant regarding the origin is without prejudice to the processing of the patent application or the validity of rights arising from a granted patent." 12/

35. In Norway, the objective of the new paragraph 8(b) of the Patent law is to support compliance with prior informed consent of the Contracting Party providing the resources. It provides that:

> "If an invention concerns or uses biological material, the patent application shall include information on the country from which the inventor collected or received the material (the providing country). If it follows from national law in the providing country that access to biological material shall be subject to prior consent, the application shall inform on whether such consent has been obtained.
>
> "If the providing country is not the same as the country of origin of the biological material, the application shall also inform on the country of origin. The country of origin means the country from which the material was collected from *in situ* sources. If it follows from national law in the country of origin that access to biological material shall be subject to prior consent, the application shall inform on whether such consent has been obtained. If information dealt with under this subsection is not known, the applicant shall provide information on that.
>
> "The duty to provide information under first and second subsection applies even if the inventor has altered the structure of the received material. The duty to provide information does not apply to biological material derived from the human body.
>
> "Infringement of the duty to provide information is subject to penalty in accordance with the General Civil Penal Code, §166. The duty to provide information is without prejudice to the processing of patent applications or the validity of granted patents."

36. According to the General Civil Penal Code, failure to provide information or providing false information carries criminal penalties (e.g. fines or imprisonment). The amended law entered into force on 1 February 2004.

37. As stated in the submission by Norway, these information requirements are not applicable to international patent applications submitted through the Patent Cooperation system, as this would be contrary to the obligations pursuant to the Patent Cooperation Treaty.

B. Measures taken by provider countries to ensure compliance with PIC, including of indigenous and local communities providing associated traditional knowledge and mutually agreed terms

38. Measures have also been taken by provider countries to support and ensure compliance with their national legislation on access and benefit-sharing and to ensure the prior informed consent of indigenous and local communities.

39. As stated by Brazil:

> "Brazil has taken specific measures to support and ensure compliance with national legislation. The competent Brazilian authority – the Genetic Heritage Management Council (CGEN) – has been operative and several authorizations for access to genetic resources and for access to traditional knowledge associated to genetic resources were granted, always in accordance with prior informed consent requirements. The competent authority has also clarified some terms in order to facilitate the adequate understanding of the process by the Contracting Parties and the national legislation has been largely informed to the interested parties."

12/ Submission by Sweden in annex to the European Community submission.

40. Some countries have also provided examples of measures taken to ensure the prior informed consent of indigenous and local communities. For example, in Venezuela, in a project of the "Instituto de Ideas Avanzadas del Ministerio de Ciencia y Technologia" related to the characterization of populations of plants with medicinal potential in the Bioregion of the plains of the Orinoco, prior informed consent is being instituted in communities of the region in order to access traditional knowledge related to the use of medicinal plants.

41. According to the submission in Colombia and Andean Pact countries more generally, a number of measures have been developed to address the prior informed consent of relevant communities which include the following:

(a) Decree 1391 of 8 August 1996 by which is created the National Commission of Indigenous Territories and the Permanent Table of Coordination with indigenous communities and other provisions are prescribed, which has as objective to coordinate between these and the State the administrative and legislative decisions susceptible of affecting them and to evaluate the execution of the indigenous policy of the State. The functions of the Permanent Coordination Bureauare the following ones:

- To adopt principles, criteria and procedures regarding biodiversity, genetic resources, collective intellectual property and related cultural rights, within the framework of the special legislation pertaining to indigenous communities;
- To previously coordinate with indigenous peoples and organizations the positions and official proposals to protect indigenous rights regarding access to genetic resources, biodiversity and protection of traditional knowledge, innovations and practices that the Colombian Government presents in international instances within the framework of agreements and covenants subscribed and ratified by Colombia;
- To coordinate the development of indigenous constitutional rights regarding biodiversity, genetic resources, and collective property intellectual and associated cultural rights and legislation.

(b) Decree 2248 of 22 December 1995 by which the High Level Consultative Commission for Black Communities is created, attached to the Ministry of the Interior and made up of government members and members of black communities, and whose function is to serve as instance of dialogue between black communities and the national government, and to serve as space of debate of regulations decree- bills of Law 70 of 1993.

(c) Decree 1320 of 13 July 1998 by which prior consultation with indigenous and black communities for the exploitation of renewable natural resources within its territory is regulated, and whose aim is to analyze the environmental, social and cultural impact that can be caused to an indigenous or black community as a result of the exploitation of natural resources within its territory, and the measures to protect its integrity.

(d) Andean decision 486 on a common regime on industrial property provides that an application for intellectual property rights must be accompanied by an access contract and evidence of prior informed consent of indigenous or Afro-American or local communities (article 26). In addition, a patent shall be invalidated where no access contract has been presented or there is no evidence that traditional knowledge was obtained with the consent of indigenous, Afro-American or local communities (article 75).

C. Existing measures to support compliance with national, regional and international legal instruments

42. Compliance measures developed at the national and regional level were examined in document UNEP/CBD/WG-ABS/3/2, which provides an analysis of existing national, regional and international legal instruments related to access and benefit-sharing.

43. National measures examined in this document are those contained in the database on access and benefit-sharing measures available on the website of the Convention on Biological Diversity. The following is based on the examination of compliance measures in some national regimes which have addressed access and benefit-sharing in greater detail. 13/

44. The instruments examined generally include provisions dealing with compliance. These provisions may cover, depending on the country, monitoring, reporting, enforcement, infractions/offences, penalties/sanctions and dispute resolution.

45. Only few measures address monitoring, reporting and enforcement to ensure compliance with access and benefit-sharing measures. Mechanisms established in certain countries include the appointment of inspectors, the involvement of civil society for monitoring purposes and reporting requirements imposed upon users. 14/

46. The measures generally indicate that any infraction to the provisions of the legislation, regulation or guidelines and any unauthorized access to genetic or biological resources will be subject to sanctions. Moreover, many measures indicate that the non-respect of the clauses of an agreement related to access and benefit-sharing will also be subject to sanctions. In addition, certain measures, such as the Biodiversity Act of the State of Queensland 15/ and the South Africa Biodiversity Act 16/ provide for sanctions in the case where a person gives false or misleading documents or information in an application for a collection permit.

47. The sanctions have many similarities from one measure to the other. They range from a written warning, to a fine (in some cases, a scale of fines is included), a seizure of samples, the suspension of the sale of product, the revocation/cancellation of the permission or license of access, the revocation of the agreement, a ban on undertaking prospecting of biological and genetic resources and, finally, imprisonment. Certain provisions also address dispute settlement mechanisms, such as the draft Philippines guidelines. 17/

48. Four regional agreements related to access and benefit-sharing are also examined in document UNEP/CBD/WG-ABS/3/2: Andean Pact decision 391 on the Common Regime on Access to Genetic Resources; the draft Central American agreement on access to genetic resources and bio-chemical resources and related traditional knowledge; the draft ASEAN Framework Agreement on access to biological and genetic resources; and, the African Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders, for the Regulation of Access to Biological Resources. The following provides an overview of how these agreements have addressed compliance measures:

49. The regional instruments generally provide for sanctions in specific circumstances, such as access to genetic resources without authorization or prior informed consent, and the non-respect of the terms of the contract or of the legislation on access and benefit-sharing. Depending on the agreement, sanctions may include the revocation of the authorization to access (article 14 of the African Model Law), the termination/nullification of a contract (article 39 of decision 391, article 19 of the Central American Agreement), fines and other civil and criminal sanctions.

13/ The measures adopted were adopted by the following countries: Australia, Bolivia, Brazil, Costa Rica, Guyana, India, Malawi, Philippines, Peru, South Africa, Vanuatu and Venezuela.

14/ In Australia, the Biodiversity Act of the State of Queensland Act, in part 8, includes elaborate provisions on monitoring and enforcement. It provides for the appointment of inspectors and details the powers and duties of these inspectors. The Costa Rica Rules, in article 20, provide that the Technical Office will carry out verification and control duties through inspections on the site where access is granted. In the case of the Philippines, the draft bioprospecting guidelines, under section 26, indicate that the Government encourages the role of civil society in monitoring the implementation of bioprospecting undertaking. It also states, under section 22, that the resource user shall submit an Annual Progress report to the implementing agencies concerned.

15/ See article 52 of the Queensland Biodiversity Act.

16/ See article 93 a) of the South Africa Biodiversity Act.

17/ Section 30 of the draft Philippines Guidelines covers conflict resolution.

50. The draft ASEAN agreement provides that disputes between a resource user and a member State shall be settled at the national level in accordance with the provisions of the national access regulation (article 9). In the draft Central American Agreement, appropriate legal mechanisms to prevent biopiracy of genetic recourses, biochemicals and associated traditional knowledge are to be established by member states at the national level to implement administrative, civil and criminal sanctions (article 27).

51. At the international level, apart from the Convention on Biological Diversity, the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) is the only international instrument to directly address access and benefit-sharing.

52. The ITPGRFA contains a number of provisions dealing with compliance with MTAs and its own provisions. Article 21 provides for compliance with the Treaty as a whole. Under Article 12.5, compliance with material transfer agreements under the Treaty is provided for by Contracting Parties establishing mechanisms for access to justice in their own jurisdictions. Provisions on dispute settlement concerning the interpretation or application of the Treaty are included under Article 22 of the Treaty. Dispute settlement mechanisms range from voluntary measures, such as negotiation and mediation to compulsory dispute settlement through arbitration in accordance with Part 1 of annex 2 of the Treaty or reference to the International Court of Justice. According to the FAO submission:

> "Compliance with the provisions of the Multilateral System (and all other aspects of the Treaty) by Contracting Parties will be promoted through procedures and mechanisms to be determined by the Governing Body (Article 21 of the Treaty). Contractual disputes arising under the standard MTA will be determined under normal national contract law, or in such other way as may be specified in the standard MTA."

D. Administrative and judicial remedies available in countries with users under their jurisdiction regarding non-compliance with prior informed consent and mutually agreed terms

53. As reported above, a number of countries with users under their jurisdiction are still at the preliminary stages of raising the awareness of potential users of genetic resources. Based on the information made available to the Secretariat, administrative and judicial remedies available in countries with users under their jurisdiction regarding non-compliance with prior informed consent and mutually agreed terms, have been limited to those which apply in cases of non-compliance with disclosure requirements in patent applications.

54. Disclosure requirements included in patent legislation in Denmark, Sweden and Norway have been examined above. The following points to the provisions of these measures dealing with non-compliance.

55. As mentioned above, Denmark has revised its Patent law with a provision requiring that patent applicants provide information on the origin of the genetic resources used in the invention for which a patent is applied for. In cases of non-compliance, no sanctions are provided in the patent system. However, under criminal law sanctions are established regarding the provision of false information to public authorities.

56. As also referred to above, in Sweden, a new provision on the disclosure of origin of biological material of plant or animal origin in patent applications came into force on 1 May 2004, in accordance with article 5 of the Patents Regulations (SFS 2004:162) under the Patent Act. The article provides that if the origin is unknown, it shall be stated. It is also provided that "lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without prejudice to the processing of the patent application or the validity of rights arising from a granted patent."

57. In Norway, the new paragraph 8(b) of the Patent Act is to support compliance with prior informed consent of the Contracting Party providing the resources. Infringement of the duty to provide information is subject to penalty in accordance with the General Civil Penal Code §166. The duty to

provide information is however without prejudice to the processing of patent applications or the validity of granted patents. The General Civil Penal Code §166 reads as follows:

> "Any person shall be liable to fines or imprisonment for a term not exceeding two years who gives false testimony in court or before a notary public or in any statement presented to the court by him as a party to or legal representative in a case, or who orally or in writing gives false testimony to any public authority in a case in which he is obliged to give such testimony, or where the testimony is intended to serve as proof.
>
> "The same penalty shall apply to any person who causes or is accessory to causing testimony known to him to be false to be given by another person in any of the above-mentioned cases."

58. Generally, in situations of non-compliance with prior informed consent and mutually agreed terms, it is not clear from the information provided by Parties whether provider countries or stakeholders from those countries would have access to the courts in user countries in order to enforce their rights. The following excerpts of submissions by Parties regarding this issue provides some indications of possible remedies in cases of non-compliance which may deserve to be further explored.

59. The European Community submission addresses this issue in the following terms:

> "Enforcement problems in relation to access and benefit-sharing national laws and agreements can arise. Possibilities to prevent these situations need to be further studied on the basis of experience gained under international law in the enforcement of foreign judgements. Experiences in the field of intellectual property, in relation to the issue of entitlement to apply for or be granted a patent, could also provide inputs to solve enforcement problems.
>
> "One alternative dispute resolution system that could help addressing these problems is arbitration. For instance, it could prove helpful, under the terms of a MTA, for parties to agree to submit their disputes to a specific arbitration system available under international law whose decisions would be enforceable in a great number of States. Arbitration procedures are normally faster and less expensive than court proceedings and could therefore prove more attractive than court proceedings. Another problem that could arise in relation to access and benefit-sharing disputes concerns the possibility for providers to obtain information and access to justice in the countries where the users are located. In this respect, countries' access and benefit-sharing focal point could play a facilitator role by providing information, including on the legal system of their country. Moreover, controversies between providers and users located in different countries could be presented to the Conference of the Parties on access and benefit-sharing and mediated by national authorities."

60. As illustrated by the following excerpt of the submission by France (in annex to the European Community submission), existing administrative and judicial remedies available in user countries may also be applicable in situations of non-compliance with prior informed consent and mutually agreed terms. The French submission provides an interesting overview of existing administrative and judicial procedures applicable in France, including to foreigners, in situations of conflict arising in the context of a commercial contract:

> "France is a party to a number of private international law multilateral agreements addressing disputes related to economic issues, which may be applicable to access and benefit-sharing agreements, such as:
>
> - conflict of laws and jurisdiction (European Community Convention on the Law Applicable to Contractual Obligations (Rome, 1980), Convention on the Law Applicable to Agency (The Hague, 1978))
>
> - Conciliation (Resolution 57/18 UNGA)

- Arbitration (The New Civil Code of Procedure governs international arbitration in its articles 1492 to 1507)

- Judicial cooperation at the different procedural stages:

- Investigation through the Convention on the Taking Evidence Abroad in Civil or Commercial Matters (The Hague, 1970);

- Notification of judicial actions, through the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters (The Hague, 1965);

- Enforcement of arbitral awards through the United Nations Convention on the Recognition and Enforcement of Foreign Arbitral Awards (New York, 1965);

- This is complemented by a regime of judicial assistance defined by law no 91-1266, 18 December 1991.

Legislative and administrative provisions therefore exist in France for the different aspects of the settlement of economic disputes concerning private entities."

61. The submission by Spain provides some indications as to how this issue could be addressed in Spain:18/

"In Spain it is clear that institutions from and/or countries party to the Convention on Biological Diversity could use all the judicial remedies under civil law to redress a situation of non-compliance with article 15 of the Convention. Under article 96 of the Spanish Constitution article 15 would be self executing (direct effect) and there is no doubt that Spanish courts could hear and remedy any case in which article 15 has not been respected whenever anybody having enough standing (and the law on standing is very open) might bring a case under contract law (if there is evidence of disregarding an MTA) or under general civil actions (civil damage caused by somebody's conduct) whenever the use of the genetic resource has not been subject to any MTA, or PIC."

62. The Colombian submission provides that:

"The Criminal (Penal) Code (Law 599 of 2000), in his article 328 establishes that: "Everyone who through breach of the existing legislation introduces, exploits, transports, deals illegally, trades, takes advantage or profits from the specimens, products or parts of fauna, forest, floral, hydro-biological resources of threatened species or species in danger of extinction or of genetic resources, will be sentenced to imprisonment of two (2) to five (5) years and a fine of up to ten thousand (10,000) times the current monthly minimum wage."

D. Measures that preserve and promote legal certainty for users over the terms and conditions of access and use

63. The importance of legal certainty and clarity was already recognised at the first meeting of the Panel of Experts on Access and Benefit-sharing, held in Costa Rica, in October 1999. In paragraph 54 of the Report, under the section dealing with "Mutually agreed terms and contractual approaches", it was stated that: " Legal certainty and clarity facilitate access to and use of genetic resources and contribute to mutually agreed terms in line with the aims of the Convention. To this end, Governments should define roles, ownership and authority to determine access. In this regard, attention needs to be paid to community interests, tenure and other property rights. In addition, countries should be aware of other relevant legal obligations". 19/

18/ Submission by Spain in annex to EC submission.

19/ Document UNEP/CBD/COP/5/8.

64. Furthermore in the "General Conclusions" section, paragraph 152 states the following: "Legal certainty and clarity facilitates access to and use of genetic resources and contributes to mutually agreed terms in line with the aims of the Convention. In the absence of full and clear legislation and national strategies for access and benefit-sharing, voluntary measures and guidelines may be adopted by Parties to help ensure they meet the objectives of the Convention. Alternatively, this can be achieved by endorsement of individual access and benefit-sharing agreements by Governments". 20/

The Bonn Guidelines

65. The Bonn Guidelines on Access and Benefit-sharing, adopted at the sixth meeting of the Conference of the Parties, in April 2002, also recognize the importance of legal certainty and clarity both in the establishment of national administrative, legislative and regulatory measures and in the development of access and benefit-sharing arrangements.

66. The Bonn Guidelines establish "legal certainty and clarity" as one of the basic principles of prior informed consent in paragraph 26 (a) and as a basic requirement for mutually agreed terms in paragraph 42 (a).

67. With respect to prior informed consent, the following elements, as set out in paragraph 27 of the Guidelines, contribute to legal certainty:

(a) Competent national authority(ies) granting or providing for evidence of prior informed consent;

(b) Timing and deadlines;

(c) Specification of use;

(d) Procedures for obtaining prior informed consent;

(e) Mechanisms for consultation of relevant stakeholders;

(f) Process.

68. Guidance provided with respect to these elements which contribute to legal certainty include the following, highlighted in bold for the purposes of this document:

(a) With respect to competent national authorities:

- "Prior informed consent for access to *in situ* genetic resources shall be obtained from the Contracting Party providing such resources, **through its competent national authority(ies)**, unless otherwise determined by that Party. (paragraph 28);
- In accordance with national legislation, prior informed consent may be required from different levels of Government. **Requirements** for obtaining prior informed consent (national/provincial/local) in the provider **should therefore be specified**. (paragraph 29);
- National procedures should facilitate the involvement of all relevant stakeholders from the community to the government level, aiming at **simplicity and clarity**. (paragraph 30);
- For *ex situ* collections, prior informed consent should be obtained **from the competent national authority(ies) and/or the body governing the *ex situ* collection** concerned as appropriate. (paragraph 32)".

(b) With respect to timing and deadlines:

- "Prior informed consent is to be sought **adequately in advance** to be meaningful for both those seeking and for those granting access. Decisions on applications for

20/ Ibid.

access to genetic resources should also be taken within a **reasonable period of time**." (par. 33)

(c) Under the paragraph for specification of use: "…. Permitted uses should be clearly stipulated and further prior informed consent for changes or unforeseen uses should be required…."(par. 34);

(d) Paragraph 36 also provides a useful list of information which can be included in an application for access, which could also contribute to legal certainty and clarity.

(e) Under "Process", legal certaintly and clarity will be ensured through the following:

- " Applications for access…and decisions …to grant access to genetic resources or not shall be documented **in written form**."(par. 38);
- "The procedures for obtaining an access permit/licence should be **transparent and accessible** by any interested party."(par. 40).

69. Under the section on mutually agreed terms, the indicative list of mutually agreed terms provided in paragraph 44 and guidance provided with respect to benefit-sharing under paragraphs 45 to 50 should also contribute to legal certainty and clarity.

Implementation of the Bonn Guidelines

70. Limited information has been made available to date with respect to experience gained in the implementation of the Bonn Guidelines, particularly from countries which are providers of genetic resources. It is likely that once the Bonn Guidelines have been widely used and implemented in the development of national access and benefit-sharing regimes, there may be greater harmonization among national regimes and these regimes will likely provide a greater extent of legal certainty to foreign users of their genetic resources.

Current situation

71. As demonstrated in paragraphs 115–188 of the analysis of existing national, regional and international legal instruments relating to access and benefit-sharing and experience gained in their implementation, including identification of gaps (UNEP/CBD/WG-ABS/3/2) a majority of Parties to the Convention have yet to adopt specific access and benefit-sharing measures. Some countries have adapted existing frameworks while others have either adopted or are in the process of adopting measures. In a number of these countries the national systems are therefore incomplete. However, there is a clear attempt to establish specific rules governing access and benefit-sharing thus contributing to legal certainty.

72. In the absence of specific access and benefit-sharing provisions, the scope of resources and activities regulated by law are often unclear. Certain legislations adopted for other purposes, prior to the Convention on Biological Diversity may apply to genetic resources. Consequently the body of law within a country may be incomplete, difficult to identify and national competent authorities may vary depending on the location of the resource and property rights within a specific country.

73. According to some experts, the lack of clear national access regimes and the lack of harmonization between countries which have developed access and benefit-sharing regimes raises serious concerns among users. They find it difficult to comply with legal requirements in different provider countries, because such requirements differ from one country to another.

Information provided by Parties

74. On the issue of legal certainty, the following views and information were provided by Parties:

75. The European Community submission addressed legal certainty in the following manner:

"Compliance with national, regional and international instruments will always be facilitated when these instruments are clear, transparent and non-discriminatory so that they encourage

rather than discourage sustainable access and use of genetic resources. The implementation of the Bonn Guidelines can facilitate the development of instruments that present these characteristics. The appointment of National Focal Points and/or Competent National Authorities is particularly important in this respect."

76. Japan highlighted the following elements of relevance to legal certainty and clarity:

"After the Convention on Biological Diversity came into force, the experiences of researchers in academia and the private sector indicated the emergence of elements that adversely affect access to genetic resources in providing countries. These include:

"(i) Insufficient information about contact points for applications and approvals and about procedures for access to genetic resources;

"(ii) Unpredictabililty in the time necessary for obtaining approvals and permits; and

"(iii) Incertainty in the execution of the contract.

"As a result, it has become difficult for users to access genetic resources in many countries, in spite of the provisions of the Convention on Biological Diversity that the aim of fair and equitable sharing of benefits arising form the use of genetic resources". 21/

77. Finally, Colombia provided the following information regarding existing measures which contribute to legal certainty for users of genetic resources:

"Andean Community Decision 391 of 1996 establishes in its article 26 the information that must be brought by the applicant for access to genetics resources. According to national legislation, this information is the following:

"a) Identification of the applicant;

"b) Documents that prove the applicant legal competency to sign a contract;

"c) Identification of the supplier that will provide the access (to the genetic and biological resources and knowledge associated with genetic resources);

"d) Identification of the person or supporting national institution;

"e) Identification and Curriculum Vitae of the person in charge of the project and of its work group;

"f) The activity of access that is requested;

"g) The locality or area in which the access will take place, including its geographic coordinates.

"Resolution 620 of 1997, in its article 15, indicates the information that must be presented by the applicant in addition to what is established in decision 391.

"Also, Resolution 414 of the Andean Community adopts a referential model of request of access to genetic resources; and Resolution 415 adopts a model of access contract to genetics resources."

21/ See submission by Japan, section addressing "Current influence of the CBD on research and commercialisation".

III. APPROACHES TO ASSIST WITH THE IMPLEMENTATION OF ACCESS AND BENEFIT-SHARING, INCLUDING CONSIDERATION OF AN INTERNATIONAL CERTIFICATE OF ORIGIN/SOURCE/LEGAL PROVENANCE

78. At its seventh meeting, the Conference of the Parties stressed the need to further examine other approaches set out in decision VI/24 B, and additional approaches such as interregional and bilateral arrangements as well as an international certificate of origin/source/legal provenance, in particular the operational functionality and cost effectiveness of such an international certificate. On the basis of information provided by Parties and other relevant stakeholders, the Conference of the Parties requested the Executive Secretary to further compile information on existing complementary measures and approaches, and experiences with their implementation, to disseminate such information and to prepare a report on the issue of additional approaches, on the basis of submissions received.

79. The following sub-sections provides an update of existing approaches and examines additional approaches, such as an international certificate of origin/source/legal provenance and the access and benefit-sharing management tool recently developed.

A. Existing approaches

80. In document UNEP/CBD/WG-ABS/2/2 an overview of existing approaches adopted by different actors, including Governments, institutions, professional associations, the private sector and inter-governmental organizations to manage access to genetic resources and benefit-sharing, was provided. The approaches examined included: regional instruments which provide guidance at the regional level; specific instruments elaborated for the agricultural sector which take into account the specificities of plant genetic resources for food and agriculture; codes of conduct and guidelines developed by specific user groups, such as botanical gardens, culture collections and certain professional associations which respond to the particular needs of their constituents. Reference was also made to corporate policies of some private companies.

81. This section examines guidelines and codes of conduct not addressed in document UNEP/CBD/WG-ABS/2/2. These were developed by professional societies or organizations and by the private sector.

82. **Professional societies or organizations.** A number of professional research societies in fields such as anthropology, ethnobiology, pharmacognosy and ecology have developed documents to articulate ethical values embedded in research and set standards for best practice. These documents are variously referred to as codes of ethics, voluntary codes, codes of practice, statements on ethics, guidelines and research protocols. 22/ These different approaches vary and may contain both principles/codes of ethics and practical research guidelines.

83. A number of codes of ethics or guidelines relevant to biodiversity research have been developed for researchers in fields such as anthropology, ethnobiology, pharmacognosy and ecology and address issues related to access and benefit-sharing. They include the following: the American Anthropological Association (AAA) Code of Ethics (June 1998 version); the International Society of Ethnobiology (ISE) Code of Ethics (1998) and Guidelines for Research, Collections, Databases and Publications (Draft 3, 1998); the American Society of Pharmacognosy (ASP) Guidelines for Members (1992); the Society for Economic Botany (SEB) Guidelines of Professional Ethics of the Society for Economic Botany (1995); the Pew Conservation Fellows Biodiversity Research Protocols: Guidelines for Researchers and Local Communities Interested in Accessing, Exploring and Studying Biodiversity (1996); and the Manila Declaration concerning the Ethical Utilization of Asian Biological Resources (1992) Codes of Ethics for Foreign Collectors of Biological Samples (Appendix 1) Contract Guidelines (Appendix 2).

22/ For further information, see "Professional society standards for biodiversity research: codes of ethics and research guidelines" by Sarah A Laird and Darrell A Posey, Chapter 2 of the publication by S. Laird entitled "Biodiversity and Traditional Knowledge – Equitable Partnerships in Practice", Conservation Series, Peoples and Plants, Earthscan Publications, 2002.

84. Elements of these codes of ethics and research guidelines generally address prior informed consent, research behaviour including benefit-sharing and the publication and distribution of data. 23/

85. **The private sector.** Although little information with respect to existing policies of the private sector relating to access to genetic resources and benefit-sharing is available, reports from certain companies provide interesting insights regarding the access and benefit-sharing policies of these companies.

86. For example, as stated in the Novo Group Environmental and Social Report 2000: "internal guiding principles and procedures are in place in Novozymes and Novo Nordisk to assure compliance for the convention with regard to use of genetic resources. Thereby we are able to track the origin of our samples of microorganisms, and all future patent applications and publications will state the country of origin of gene material covered by the Convention." The report also states that: "The Novo Group will proactively contribute to the implementation of the objectives of the Convention. In order to do this we have formulated the following guiding principles, which we will do our outmost to live up to for all material covered by the Convention:

(a) No microbial strain or natural material obtained without proper prior informed consent from the country of origin will be included in screening;

(b) All materials screened should be covered by contracts and/or material transfer agreements;

(c) Conditions should be on mutually agreed terms and should include benefit-sharing, IPRs and technology transfer arrangements where appropriate;

(d) Contracts should be cleared by the proper authority in the country of origin;

(e) The country of origin will be mentioned in relevant publications and patent applications".

87. Another example is included in GlaxoSmithKline's 2003 Report on Sustainability in Environment, Health and Safety, 24/ which includes GlaxoSmithKline's Position on biodiversity and access and benefit-sharing:

" - Natural resource materials are potentially valuable sources of novel biologically active molecules which, once identified and their properties fully analysed, can serve as model for the invention of new, lifesaving medicines.

"- GSK recognises that all nations have sovereignty over the biological resources and indigenous knowledge within their national boundaries….

"- GlaxoSmithKline's drug discovery efforts increasingly focus on high-throughput screening of synthetic chemical compounds. We therefore have limited interest in natural material collecting and screening programmes. However, where screening programmes are in place, the company supports the principles enshrined in the Convention on Biological Diversity (CBD).

"- In the event of GlaxoSmithKline developing a commercial product from our natural material screening programmes, GlaxoSmithKline will ensure a clear benefit is returned to the country of origin. This benefit-sharing may amount to payment of fair and reasonable royalties or other means determined by mutual agreement on a case-by-case basis.

"- GlaxoSmithKline has a number of patents based on natural products and it is possible that more patents will arise from our screening programmes.

"Specifically GlaxoSmithKline has always undertaken to:

23/ For further details see table 2.1 of Chapter 2 of the publication entitled: "S. Laird, Biodiversity and Traditional Knowledge – Equitable Partnerships in Practice", Conservation Series, Peoples and Plants, Earthscan Publications, 2002.

24/ See http://www.gsk.com/financial/reps03/EHS03/GSKehs-36.htm.

- "Work with organizations and suppliers with the expertise and legal authority to collect plant and other natural material samples. These include botanic gardens, universities and research institutes around the world;
- "Ensure that the governments in developing countries are informed of and consent to the nature and extent of any proposed natural materials collection;
- "(…)
- "where appropriate, collaborate with organisations to educate and train local people in collecting and screening skills
- "ensure an agreed benefit is returned directly or indirectly to the country of origin in the event of GlaxoSmithKline developing a commercial product based on a natural material."

B. Additional approaches

88. This section examines issues related to an international certificate of origin/source/legal provenance, in particular the operational functionality and cost effectiveness of such a system based on available information and the access and benefit-sharing Management Tool Project, a new instrument developed to assist with the implementation of access and benefit-sharing arrangements.

Certificate of origin/source/legal provenance

89. Since the last meeting of the Working Group on access and benefit-sharing in December of 2003, and following the seventh meeting of the Conference of the Parties further thought has been given to the issue of a certificate of origin/source/legal provenance. A project was initiated by the United Nations University – Institute of Advanced Studies (UNU-IAS), an International Experts Workshop on Access to Genetic Resources and Benefit-sharing organized by Mexico and Canada in October 2004 considered the issue and a workshop was organized by the Institut du Développement Durable et des Relations Internationales (IDDRI) and (UNU) in November 2004. 25/ Based on the work carried out to date on this issue, the following provides an overview of the evolution of this concept and highlights further issues for consideration.

General description

90. The certificate has generally been described as a type of passport or permit which accompanies the genetic resource(s) along its life cycle and can be verified at various points of its life cycle and more importantly once the genetic resource(s) has left the provider country. As stated in the European Community submission, "it could accompany the genetic resources from the collection phase until the marketing of the product which makes use of them and therefore increase transparency and traceability".

91. The certificate could provide a guarantee that requirements related to the legal acquisition of genetic resources in the country of origin or provider country have been met. The certificate would hence ensure legal certainty for users and ensure providers that their resources are used in conformity with legal obligations.

92. The certificate of origin/source/legal provenance could contribute to building trust among users and providers of genetic resources. It may, on the one hand, reduce pressures in the provider countries to adopt restrictive legislation on access and benefit-sharing and, on the other hand, provide users with greater legal certainty and provide evidence that users are meeting access and benefit-sharing requirements. 26/

25/ It should be noted that the report of this meeting was not available when this document was drafted, therefore the outcomes of this workshop are not reflected in this document.

26/ M. Ruiz, C. Fernandez and T. Young, «Regional Workshop on the Synergies between the Convention on Biological Diversity and the CITES regarding Access to Genetic Resources and Distribution of Benefits : The Role of Certificates of Origin – Preliminary Report », Lima, Peru, 17-18 November 2003, p.10-11;

Operation of the system

Information covered by the certificate and format

93. It has been suggested that the certificate could take various forms. It could be a paper, a barcode or a virtual online certificate. It has been suggested that the latter could reduce the administrative burden of such a system. 27/ If the certificate took the form of a number or code attached to the genetic resource, it could be registered in a central registry or clearing house of certificates 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. 28/

Check points

94. If an international system of certificate of origin/source/legal provenance were to be established, the verification of the certificate could be carried out at various "check-points". These could include the border, patent offices or the registration points for other types of commercial applications not covered by intellectual property rights. 29/ 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. It has been suggested that the criteria for the identification of check-points 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. 30/ The value of establishing check-points at the border is being questioned, indeed controls at the border would in practice be difficult to carry out due to the nature of genetic resources and would also involve considerable investments in terms of training of customs officials, therefore the costs involved may outweigh the potential benefits.

95. One related issue which may deserve further consideration is the question of the trigger, that is when does the link between a product and a genetic resource become too tenuous for the certificate to be required. 31/

Certificate of origin/source/legal provenance

96. In cases where the identification of the origin, that is the country where the genetic resource was obtained *in situ*, may prove difficult if not impossible to obtain, it has been suggested that a certificate of source or legal provenance could be awarded. The certificate of source would provide information on the place where the genetic resource was obtained, which may not be the country of origin of the resources but could be an *ex situ* collection for example. Alternatively, the certificate of legal provenance would provide assurance that the resource has been accessed in accordance with the legal requirements of the provider country.

Certificate awarded to one or more samples of genetic resources

97. Another issue is whether a certificate should be awarded to one sample or to multiple samples covered by a contract. In the event that the certificate was awarded to all samples covered by a particular contract, it has been suggested that the contract registered by the competent national authority in the

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27/ 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;

28/ 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;

29/ For further discussion, see footnote 27, p. 33;

30/ For further discussion, see footnote 28, p. 3;

31/ Ibid.

provider country could be consulted by a third party in order to obtain information with respect to the initial terms and conditions under which the resources were accessed. At later stages of research and development, codification would be added to the certificate in order to identify the specimens, isolated compounds or other. Finally, it is suggested that transfer to third parties could be subject to the terms and conditions of the initial access agreement or to standard terms and conditions previously established by the provider. 32/

Infrastructure needed

98. In order to establish an international system of certificate of origin/source/legal provenance, a number of steps would need to be taken both at the national and international levels.

99. At the national level, it would be necessary to establish competent national authorities and institutional mechanisms to issue the certificate based on the prior informed consent of relevant national authorities, and adequate mechanisms would also be needed to monitor and recognize certificates of origin delivered by competent national authorities in foreign countries.

100. 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. In addition, an international registry containing information on all certificates emitted could serve as a clearing-house mechanism for exchange of information on the terms and conditions under which certificates were emitted. Details regarding storage of information and access would need to be clarified.

101. The costs involved in setting up such a system at both national and international levels should not be underestimated. Considerable investments may be required in terms of human, technical and financial resources. For this reason, should Parties wish to pursue this option, further work may be needed to assess whether the benefits would outweigh the costs.

102. Additional issues for consideration in the establishment of the system include the possibility of setting up differentiated system for research and commercial utilisation, the treatment of non-Parties to the Convention on Biological Diversity, provisions to deal with *ex situ* pre-Convention on Biological Diversity collections, how to deal with pre and post Convention on Biological Diversity genetic resources and pre- and post-certificate genetic resources, how would a certificate of origin/source/legal provenance apply to traditional knowledge; what would happen if the genetic resource is available from more than one country and traditional knowledge from more than one community; measure to be set up for penalties, liability and redress, and eventually dispute settlement. 33/

Advantages and limitations of an international certificate system 34/

103. An international certificate system presents both advantages and limitations. Advantages may include the following: the certificate provides evidence that genetic resources were obtained with the prior informed consent of the relevant authority in the provider country; it facilitates the application of user measures; the verification of the certificates at check-points creates incentives for compliance with access and benefit-sharing requirements of provider countries; monitoring of access and benefit-sharing arrangements is facilitated through the establishment of a central registry or clearing house mechanism; and finally, the system creates greater transparency, legal certainty and mutual trust among parties to access and benefit-sharing arrangements.

104. However, it has also been argued that the certificate system has some limitations: the certificate ensures that prior informed consent was obtained from competent national authorities in provider

32/ For further discussion, see footnote 27, p.32.

33/ For further discussion see documents in footnote 28, p.4 and footnote 27, pp. 33-34.

34/ For further discussion, see footnote 28, p. 4.

countries, however it does not ensure that mutually agreed terms, including the sharing of benefits will be met; the certificate does not substitute the need to develop national access and benefit-sharing legislation; the certificate should address the management of *ex situ* collections in order to be effective; and, the system may be difficult to adapt to some sectors.

Further work to be carried out

105. Research is being carried out by UNU on certificates of origin in conjunction with major collections of biological resources such as the Smithsonian Institute (United States of America), the Royal Botanic Gardens, Kew (United Kingdom), INBio (Costa Rica), commercial users of genetic resources in Japan and selected microorganism collections. Case-studies carried out by these institutions, covering a range of plant, animal and microbial genetic resources examine how different institutions are tracking the receival, storage and dispersal of various kinds of genetic resources. Preliminary results show a range of technological and legal approaches to tracking genetic resources. The studies also highlight the potential implications of a new certificate of origin/source/legal provenance on their work.

106. The analysis carried out by UNU suggests potential models for an internationally recognized certificate of origin and concludes that extensive research is still required to determine how these models could be implemented in practice. Case-studies could be carried out in provider countries to determine the feasibility of establishing a certificate system. UNU also suggests that the feasibility of a certificate system for traditional knowledge could be investigated. Case-studies could also be carried out to determine the feasibility of implementing a certificate system for different industry sectors which have different ways of doing business, range from multinationals to small and medium sized enterprises and involve different actors.

107. The consideration of certificates of origin/source/legal provenance in the context of collections such as the Smithsonian Institution and Royal Botanic Gardens, Kew, have highlighted interesting points for consideration in examining the feasibility, practicality and costs of a certificate of origin/source/legal provenance. It is important to stress that a large majority of accessions to genetic resources is for scientific, not for commercial purposes. For example, in Mexico "less than 1 in 1000 Mexican permits for collection of biological material are destined for biotechnology end uses". 35/ Therefore it essential to ensure that access is facilitated for research purposes.

108. The case-studies related to the Smithsonian Institution, Royal Botanic Gardens, Kew, and microbial biological resource centers, usefully describe the existing systems in place for accessing, exchanging and transferring different types of genetic resources within and between relevant institutions. These case-studies highlight the constraints they are faced with and the potential implications of an international system of certificate in continuing their work.

109. At both the Smithsonian Institution and Royal Botanic Gardens, Kew, tracking procedures are used for the receival, storage and dispersal of genetic resources. However, concerns have been expressed that any additional costs entailed by the setting up of an international system of certificate of origin which would require modifications to their existing systems and consequently additional costs could have serious implications on future research.

110. As stated by the authors of the Smithsonian case-study:

> "Movement of specimens across borders is an important aspect of access. It is fundamental in taxonomy (the describing and naming of taxa) and systematics (studying the evolutionary relationship between species). Museums of the world have collaborated for centuries – sharing collections, loaning specimens for research and education, and collaborating in the field and the laboratory. The access and benefit-sharing process has seriously undermined these

35/ Draft Record of Discussions of the International Experts Workshop on Access to Genetic Resources and Benefit-sharing, held in Cuernavaca, Mexico, 24-27 October 2004, p. 17.

> fundamental and necessary collaborations by making it difficult to impossible to collect or legally move new or existing specimens". 36/

111. The Smithsonian case-study also states that:

> "Scientists unanimously agree that most of the species of the world are not yet described and named. Basic discovery, analysis and naming of the biota is the core work of natural science collections organisations". 37/

112. Therefore access and benefit-sharing regulations should aim to facilitate taxonomic, systematics and ecological research.

113. The Smithsonian case-study suggests that the solution is "a dual tracking system: expedited transactions for basic science (regardless of its funding source) and heightened scrutiny and increased obligations for applied and commercially oriented research. A generic material transfer agreement (MTA) that allows for free movement of specimens for basic research is imperative for the survival of museums and non-commercial research". 38/

114. It is important to keep in mind that a large majority of genetic resources are accessed for scientific purposes, and that in cases of commercialization, there is an important lag-time between collecting, research, extraction, product development and commercialization, including possible patenting. Experience presented at an International Expert Workshop on access and benefit-sharing, with respect to the International Cooperative Biodiversity Group (ICBG), demonstrated that "despite 10 years of work, $30 million in funding, the work of many partners and the review of 500 compounds, no new drugs have been created". 39/ However, it was noted that considerable non-monetary benefits had been shared, in terms of training, technology transfer and so on. According to information provided in the submission by Japan, "in the pharmaceutical industry, Japanese experts reported that 17 Japanese companies used 290 thousand samples of resources (natural and chemical) for screening for drug discovery. Other surveys show it generally takes 10-12 years and costs up to $800 million to commercialise one drug". 40/

115. The Royal Botanic Gardens case study focuses on two major Kew collections: the Herbarium and the Millenium Seed Bank which relate to two different types of biological material: preserved plant specimens and living germplasm. It is interesting to note that "the practical systems in place at Kew to acquire, study, track and transfer these different types of material are distinct, as are the potential uses for such material. Any scheme to introduce a system of certification needs to reflect such differences". 41/

116. Taking into account the already complex and time consuming procedures to access genetic resources, the authors of the Kew case-study have expressed concern with respect to the introduction of a system which would add to the already complex process of obtaining prior informed consent for scientific research. As an example, the case-stydy states that under Kew's Millenium Seed Project, the average

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36/ Leonard Hirsch and Ana Cristina Villegas, "The Smithsonian Institution: The life of natural history museum specimens", p. 8, in 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.

37/ Ibid.

38/ Ibid, p. 11.

39/ See footnote 35, presentation by Joshua Rosenthal.

40/ Report on Cooperative Research Project on Conservation of biological diversity and the Sustainable use (Japan Bio-indutry Association 1997), referred to in the submission by Japan contained in document UNEP/CBD/WG-ABS/3/INF/1.

41/ Kate Davis, Phyllida Middlemiss, Alan Paton and Clare Tenner, "The Royal Botanic Gardens, Kew: Herbarium and Millenium Seed Bank", p. 13, in 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.

time taken to set up effective long-standing scientific partnerships is around 19 months, before project activities begin". 42/

117. According to the authors of the Kew case-study,

> "it can already be very time-consuming and costly to obtain prior informed consent for scientific research such as is carried out by Kew. Any system that added to this process could be extremely burdensome to botanical institutions, where the main purpose underlying access is non-commercial scientific research, education or conservation, not commercial use. Further the costs of implementing the degree of change suggested by a system of certification are likely to be at the direct expense of basic biodiversity-related research. Indeed, a system of certification could lead to a large decrease of scientific material. This in turn would lead to in-country institutions gaining fewer authoritative names on specimens from experts in the global scientific community, weakened capacity to conduct biodiversity inventories, and fewer opportunities for biologists to pursue research at regional or global levels, at a time when such studies are proving increasingly invaluable for targeting of conservation efforts". 43/

118. Less concern was expressed with respect to a possible international system of certificate in the case-study on microbial genetic resources. According to the case study on microbial biological resource centres:

> "Accession practices vary between microbial collections. A range of information is required for the deposit of a new strain or to accompany that are provided to other collections or researchers. In most cases, this information is databased either partially or fully. If material were provided under a certificate of origin number, there would be little incremental cost in entering this number and associating it with the culture or the existing accession number of the culture and subcultures subsequently provided to third parties.
>
> For microbial collections with comprehensive CBD policies and adequate computer resources adoption of a certificate of origin number would not be problematic or expensive. However many collections lack basic computing facilities and implementation would be more costly". 44/

119. In conclusion, taking into account that a majority of genetic resources are accessed for scientific purposes, if such an international certificate system were to be developed, it would have to be developed in a way that ensures that access to genetic resources is facilitated for research purposes while ensuring that proper controls are established for those genetic resources used for commercial purposes. This may be one of the most important challenges to be addressed by such a system.

120. Further analysis of the practical implications of such a system are needed. At this stage, it is difficult to assess the costs of such a system as there are still many undefined variables.

42/ Ibid, p. 14.

43/ Ibid, p. 17.

44/ David Cunningham, "Microbial biological resource centres: An overview", p. 22, in 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.

ABS Management Tool Project *45/*

121. Another approach recently developed to assist with the implementation of access and benefit-sharing arrangements by both providers and users of genetic resources is the ABS Management Tool Project.

122. As described in the phase 1 project report:

> "The objective of this project is to develop a management tool that can give practical guidance to providers of genetic resources in making decisions about access; to users in seeking access; and to providers and users in the negotiation of agreements and their implementation and monitoring. The tool is intended to be applicable for all relevant stages of use of genetic resources. It has been designed to be practical, efficient and effective". 46/

123. The report further states that

> "The management tool was conceived to include the following elements: a set of substantive requirements to guide access and benefit-sharing practices; a management system to guide its structured applications; and an outline of approaches for assurance (conformity assessment) not yet developed". 47/

124. The project is intended to benefit individual organizations, communities and other groups, as users or providers of genetic resources. The management tool is for use by: companies and private enterprises, large and small, in various sectors; local communities; indigenous peoples; public and private research institutions; holders of *ex situ* collections; intermediaries and universities. It is meant to apply to all stages of use of genetic resources, including pre-access, access, research, development, and commercialization. Also guidance provided by the tool is relevant to access and use of both *in situ* and *ex situ* genetic resources.

125. It should be noted that this tool is based on the Bonn Guidelines and other relevant existing codes of conduct, standards and guidelines relevant to access and benefit-sharing activities.

126. The management tool is formed of three parts:

(a) Access and benefit-sharing practice standards which address the following key elements of access and benefit-sharing: prior informed consent, mutually agreed terms, benefit-sharing, conservation and sustainable use, traditional knowledge, innovations and practices; community and indigenous peoples participation; information and transparency.

(b) A management process framework which includes, *inter alia*, "process guidance on development of an access and benefit-sharing policy statement; decision-making on relevant access and benefit-sharing practice standards; implementation steps including objectives, monitoring and consideration of international assurance; identification and tracking of genetic resources; responsibilities and accountabilities; and, resource requirements". 48/

45/ For further details regarding the ABS Management Tool Project, see Jorge Cabrera, George Greene, Stratos Inc., Tom Rotherham, IISD, "Phase 1 Project Report ABS Management Tool Project", and "Summary – ABS Management Tool Project", October 2004. The project is funded by the Swiss State Secretariat for Economic Affairs (SECO) and is being carried out by the International Institute for Sustainable Development (IISD), Stratos Inc, and Jorge Cabrera.

46/ Jorge Cabrera, George Greene, Stratos Inc., Tom Rotherham, IISD, "Phase 1 Project Report ABS Management Tool Project", October 2004, p. 5.

47/ Ibid, p.6.

48/ Jorge Cabrera, George Greene, Stratos Inc., Tom Rotherham, IISD, "Summary – ABS Management Tool Project", October 2004, p. 1.

(c) A supporting toolkit to be developed based on experience which could include model access and benefit-sharing contracts, material transfer agreements; sector or industry-specific guidelines; community or region-specific guidelines; and customary frameworks.

127. For each of the access and benefit-sharing practice standards, requirements and guidance include: a core commitment of the user to follow good practice; guidance to assist the user and provider in achieving the core commitment; guidance on documentation practices to enhance accountability and transparency; and finally, implementation challenges are to be addressed in order to make implementation of the access and benefit-sharing practice standard more effective.

128. The project is to be implemented in three phases. The first phase developed a working draft of the management tool. The second phase is to undertake broad stakeholder consultations to assess support for the tool and to gather comments/suggestions on its content. The third phase is intented to test a revised management tool through specific pilot studies.

129. The first phase has been completed. The second phase of project is to run from September 2004 until December 2006. During this period the working draft ABS Management Tool is to be disseminated for public input and field testing and then to be revised in light of comments and experience gathered with its use through pilot projects.

IV. CONCLUSIONS AND RECOMMENDATIONS

130. Noting that the development of measures to support compliance with prior informed consent of the Contracting Party providing genetic resources and mutually agreed terms on which access was granted in Contracting Parties with users under their jurisdiction, is still at its initial stages, the Working Group may wish to recommend to the Conference of the Parties:

(a) To further urge Parties with users under their jurisdiction to take appropriate legislative, administrative and regulatory measures to support compliance with prior informed consent of the Contracting Party providing genetic resources and with mutually agreed terms on which access was granted;

(b) To invite Parties to provide information to the Secretariat on the measures taken to ensure compliance with prior informed consent and mutually agreed terms.

131. Noting that further work is needed on administrative and judicial remedies available in countries with users under their jurisdiction regarding non-compliance with prior informed consent and mutually agreed terms, the Working Group may wish to recommend to the Conference of the Parties to invite Parties to review existing judicial and administrative remedies available under their national jurisdiction with a view to ensuring that appropriate remedies are available to address situations of non-compliance with access and benefit-sharing requirements.

132. Recognizing that legal certainty and clarity facilitate access to and use of genetic resources and contribute to mutually agreed terms in line with the objectives of the Convention, the Working Group may wish to recommend that the Conference of the Parties invite Parties, Governments, indigenous and local communities and all relevant stakeholders to continue to promote the implementation of the Bonn Guidelines, with a view to providing greater legal certainty and clarity in the development of national administrative, legislative and regulatory measures on access and benefit-sharing and in the elaboration of mutually agreed terms

133. On the issue of other approaches, the Working Group may wish to recommend that the Conference of the Parties invite Parties, Governments and relevant international organizations and non-governmental organizations to provide their views on the practical implications, at national and international levels, of an international certificate of origin/source/legal provenance, in order to assist the Conference of the Parties in its assessment of the practicability and feasibility of such a system and to ensure that the costs do not outweigh the benefits.
