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MATTERS CONCERNING INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE – AN OVERVIEW

Document prepared by the Secretariat

TABLE OF CONTENTS

1. The WIPO General Assembly, at its Twenty-Sixth Session, held in Geneva from September 26 to October 3, 2000, established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("the Committee"). During the informal consultations which led to the establishment of the Committee, the Member States identified three primary themes which they wished to discuss, namely intellectual property issues that arise in the context of (i) access to genetic resources and benefit-sharing, (ii) the protection of traditional knowledge, innovations and creativity, and (iii) the protection of expressions of folklore, including handicrafts.

2. A basic substantive framework on the themes identified by the Member States was presented to the General Assembly in document WO/GA/26/6. Whereas that document only catalogued the intellectual property issues that arise under the three themes, the present document seeks to elaborate those issues more substantively. It also indicates linkages, similarities and differences between the themes; illustrates interfaces between intellectual property and genetic resources, traditional knowledge and folklore; and identifies possible tasks which the Member States may consider to set themselves in the Committee.

I. INTRODUCTION

3. Intellectual property issues related to genetic resources, traditional knowledge and folklore have emerged in a wide range of policy areas, including food and agriculture, biological diversity and the environment, human rights, cultural policy, trade and economic development. For example, intellectual property rights have been granted for uses of plants which form part of traditional knowledge systems in the agricultural, health and environmental fields. Traditional designs, songs and dances have been used by the entertainment and fashion industries to create works which are protected by intellectual property. Discussions about such uses of genetic resources, traditional knowledge and folklore have linked the protection of intellectual property to policy objectives as diverse as the promotion of free trade, environmental conservation, food security, cultural diversity, etc. These linkages, established by discussions in other international fora, have significant technical, administrative and policy implications for the intellectual property system.

4. As the specialized United Nations agency responsible for the promotion of intellectual property, WIPO has been requested by its Member States to provide a forum where they may discuss the intellectual property implications of those linkages, which were raised, but not fully addressed, in other fora. The Member States decided to treat the three themes together, because from the intellectual property point of view these themes share certain common characteristics.[1] These include, *inter alia*, three shared characteristics which query, each one in different ways, the basic concept of human intellectual activity that underpins modern intellectual property rights.[2]

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[1] See document WO/GA/26/10, paragraphs 50, 54, 59. See also '*A Policy and Action Agenda for the Future*.' Meeting Statement. WIPO Inter-Regional Meeting on Intellectual Property and Traditional Knowledge, Chiang Rai, Thailand, November 9 to 11, 2000 ("the Chiang Rai Statement").

[2] The Convention Establishing the World Intellectual Property Organization (1967) provides that intellectual property includes "all … rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields." (Article 2(viii))

5. The first common characteristic of the three themes before the Committee is that the concept of "common heritage" has been applied to genetic resources,[3] traditional knowledge,[4] and folklore.[5] The intangible elements of this common heritage were available for use and, from the intellectual property point of view, were considered to be in the public domain. The primary international policy objective was the preservation of the common heritage. Other creators and innovators could freely utilize elements of this heritage from the public domain in their creations and innovations, which might then give rise to intellectual property rights.

6. In recent years, new technologies and scientific discoveries have generated unprecedented ways for creators and innovators to utilize certain elements of this common heritage, and consequently attention has shifted from the preservation towards the utilization of such heritage. Certain elements of the common heritage are now seen as resources (i.e., material of actual or potential value) which are provided to the innovator or creator, rather than being freely available to him in the public domain. Hence the public domain status of the material has been called into question.

7. The equity of intellectual property rights is discussed not only in the balance between the rights of the creator and society as the user of his creation, but also in the balance of rights between the creator and society as the provider of heritage resources which he utilizes in his creation. This is the case especially where the provider has conserved the common heritage for generations under *in-situ* conditions, i.e. in the surroundings where the resource developed its distinctive properties. This principle concerning the equity of intellectual property is now applied in the discussions on genetic resources, traditional knowledge and folklore.

8. The second common characteristic of genetic resources, traditional knowledge and folklore is that they constitute subject matter which transforms and evolves beyond the logic of individualized human intellectual activity. Genetic resources complicate the boundaries of human innovation, because they are self-replicating, living resources. Similarly, the traditions which underlie traditional knowledge and folklore evolve across individuals and generations. In both contexts, human creativity and innovation create considerable value. However, in both cases the resource reproduces and transforms itself in a logic that lies beyond, and is independent of, the individualized creativity and innovation from which existing intellectual property rights result. Because of this distinctive quality, there have been discussions under each theme about a possible need to establish new and specific intellectual property standards, which address their unique nature.

9. The third common characteristic is that each theme cuts across a spectrum between formal and informal innovation and creativity. Informal innovators and creators have raised

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[3] Genetic resource policy was based on "the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction." (Article 1, International Undertaking on Plant Genetic Resources (1983))

[4] For example, "[m]ovable cultural property representing the different cultures forms part of the common heritage of mankind." (Preamble, Recommendation for the Protection of Movable Cultural Property (1964))

[5] For example, "folklore forms part of the universal heritage of humanity" (Recommendation on the Safeguarding of Traditional Culture and Folklore (1989), Preamble); "folklore represents an important part of the living cultural heritage of the nation" (UNESCO-WIPO Model Provisions for National Laws on the Protection of Expressions of Folklore for Illicit Exploitation and Other Prejudicial Actions (1982), Preamble)

new claims for intellectual property protection.[6] The cross-cutting nature of the subject matter has increasingly introduced a new *quid-pro-quo* rationale into the discussion on intellectual property in these areas. According to this reasoning, the creation of new intellectual property rights for formal innovations in a certain subject matter is seen as contingent upon the creation of cognate rights for informal innovations relating to the same or similar subject matter. An early expression of this rationale occurred in 1989 in the field of plant genetic resources for food and agriculture, in the form of two simultaneously adopted resolutions, one recognizing farmers' rights and the other recognizing plant breeders' rights.[7] This rationale has since been extended to the three themes of genetic resources, traditional knowledge and folklore in a variety of international fora and processes.[8]

10. This document provides background information for the discussions of the Member States in the following structure: Section II identifies the interfaces between intellectual property and genetic resources, traditional knowledge and folklore. Section III provides a review of WIPO's past work on those interfaces and the intellectual property issues they raise. Section IV elaborates those issues substantively, following the structure set out in Part III of document WO/GA/26/6, and provides possible tasks which the Member States may consider to set themselves in respect of the main issues. Annex 3 sets out the prevalent use of terms, as defined or agreed upon in international discussions and instruments on the three themes before the Committee. Finally, Annex 4 collates the possible tasks which the Member States may consider to set themselves and which were identified in Section IV of the present document.

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[6] 'Informal innovators' have been defined as "countries, communities and individuals, generally working at the local level, that have through generations developed and conserved local technologies and products including plant genetic resources without having obtained formal recognition of their innovative labor or right related to it."
The complementary definition of 'formal innovators' includes a reference to intellectual property rights: "each physical or juridical person developing new technologies and products, that could be a private or a researcher working in formally recognized governmental or non-governmental institutions whose inventions may be formally recognized through the intellectual property rights system."
See, Article 3, draft FAO International Code of Conduct on Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources ("the draft FAO Code of Conduct on Plant Biotechnology").

[7] See, Resolutions 4/89 and 5/89, adopted by the Twenty-fifth Session of the FAO Conference, Rome, November 11 to 29, 1989, and incorporated into the International Undertaking as Annexes I and II, respectively.

[8] The draft FAO Code of Conduct on Plant Biotechnology has as one of its objectives "to balance the rights of formal and informal innovators" (Article 1.5). The revision of the International Undertaking recognizes modern intellectual property rights as well as "the enormous contribution which farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the … development of plant genetic resources" (Chairman's Elements Derived from the Montreux Meeting, 19-22 January 1999, element 5).

II. INTERFACES BETWEEN INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

11. A distinction which is frequently used and may be of assistance in identifying the intellectual property attributions of genetic resources, traditional knowledge and folklore is the distinction between *in-situ* and *ex-situ* use. The present Section applies this distinction to identify interfaces between intellectual property rights and genetic resources, traditional knowledge and folklore. These interfaces are identified through examples which illustrate some, but by no means all, possible connections between intellectual property rights and the three themes before the Committee. The following discussion of *ex-situ* utilization, including Annex 1, focuses on genetic resources. However, an *ex-situ* chain of value addition may be observed *mutatis mutandis* in the areas of traditional knowledge and folklore.[9]

Ex-situ utilization

12. With the emergence of new technologies in applied biology, the possibilities of *ex-situ* utilization of genetic resources and associated traditional knowledge are increasing in several industrial sectors.[10] Like in any industry, this utilization begins with certain raw materials which are processed through several steps of value-addition in order to produce a final product of potential commercial value. At each of these stages, human innovation and creativity and massive investments in research and development add considerable value to the initial resource. Intellectual property is critical in protecting the legal rights arising from this innovation and creativity. In combination, these successive stages of value addition form a value-chain which is set out in Annex 1. The summary diagram in Annex 1 does not represent an exhaustive or declaratory overview of genetic resource utilization. It provides a simplified outline for framing the role of intellectual property rights in the *ex-situ* utilization of genetic resources.

13. An important input for human innovation and creativity in applied biology is genetic resources and, in some cases, associated traditional knowledge.[11] Genetic resources may be accessed for utilization either from *in-situ* conditions or from extensive *ex-situ* collections, such as those of the International Agricultural Research Centers (IARCs) of the Consultative Group on International Agricultural Research (CGIAR). They may be accessed under bilateral access agreements or, if present negotiations in the agricultural sector succeed, under a Multilateral System for facilitated access to plant genetic resources for food and agriculture.

14. An increasingly important utilization of genetic resources concerns the acquisition, analysis and processing of genome information[12] contained in them, which is undertaken by

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[9] See document WIPO/IPTK/RT/99/3, 'What Is Traditional Knowledge? Understanding the Value Chain.'

[10] Surveys among genetic resource-users have described these industries to include the following seven sectors: (1) the botanical medicines industry, (2) pharmaceutical industry, (3) seeds industry for crop development; (4) horticulture; (5) crop protection industry; (6) cosmetics and natural personal care industry; and (7) biotechnology industries in fields other than healthcare and agriculture.

[11] The prevalent definition of the term "genetic resources" is given in Annex 3.

[12] A 'genome' is the sum-total of the genes in a haploid set of chromosomes. See Annex 3.

the disciplines of genomics and bioinformatics. 'Genomics' has been defined as "a scientific discipline that encompasses all aspects of genome information acquisition, processing, storage, distribution, analysis, and interpretation. This activity combines the tools and techniques of mathematics, computer science, and biology to produce a variety of molecular maps of genomes, including DNA and protein sequences, with the aim of understanding the biological significance of such data."[13] Genomics is becoming the most fruitful approach to the acquisition of new information in applied biology and is finding application in many industrial sectors which utilize genetic resources. In the field of genomics and bioinformatics the most relevant intellectual property rights are copyright, *sui generis* protection of non-original databases, patents, trade secrets and, to some extent, trademarks.

15. The consequence of the rapid advances in structural and functional genomics is a very large quantity of data. The acquisition of relational databases of genomic and other biological information, as well as the development of efficient methods for searching and viewing these data, constitutes the discipline of bioinformatics. Bioinformatics, or biological informatics, has been defined as the "interdisciplinary scientific area that brings the advantages of computational science, networking capabilities, and information science and technology to bear on biological data" and has been characterized as "an enabling discipline for all modern biology."[14] In 1999 the OECD Working Group on Biological Informatics identified numerous emerging intellectual property issues in bioinformatics, in particular the *sui generis* protection of non-original databases.[15]

16. The data processed by genomics and bioinformatics are in turn inputs to biotechnological research and development in the narrow sense. "Biotechnology" includes "any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific uses."[16] Biotechnological inventions fall into three categories: they are the processes for the creation or modification of living organisms and biological material, the results of such processes, and the use of such results. In the diagram of Annex 1, plant breeding is included in this category because plant breeding *applies* genetic principles and practices to the *development* of individuals, cultivars or varieties, which are more suited to the needs of man. The most relevant intellectual property rights at this stage of *ex-situ* utilization of genetic resources are patents, plant breeders' rights and trade secrets.[17]

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[13] National Technical Information Service, U.S. Department of Commerce. *Understanding Our Genetic Inheritance: The U.S. Human Genome Project: The First Five Years, FY 1991-1995*. Appendix 6.

[14] OECD. *Report of the Working Group on Biological Informatics*. OECD Megascience Forum. Paris: OECD, 1999: 2.

[15] Other intellectual property questions regarding bioinformatics which the OECD identified include: "(i) does the scope of sovereignty cover biological samples collected before the coming into force of the Convention [on Biological Diversity]? (ii) what is the connection between sovereignty of physical specimens of genetic resources and access to data about them?; (iii) are human genetic resources included in the field of application of the Convention?;" (iv) the problem of intellectual property of biological information is connected to the problem of ownership of the media where that information is stored; (v) in contractual agreements for access to genetic resources, it is common practice that the owner of biological material retains ownership of the research results arising from the use of that material. *Ibid.*, 11.

[16] Article 2, CBD.

[17] The intellectual property issues in this field are addressed in more detail under Subsection IV.B.3 on the legal protection of biotechnological inventions, below.

17. The output which results from biotechnological research and development includes, *inter alia*, commercial biological products and processes. These are made, sold and offered for sale on the marketplace. The most relevant intellectual property rights at this stage of *ex-situ* utilization are patents, trademarks and other distinctive signs, trade secrets, and plant breeders' rights. As Annex 1 shows, intellectual property rights are a fundamental precondition for the *ex-situ* utilization of genetic resources at all these stages of value addition.

In-situ conservation and utilization

18. The *in-situ* utilization of genetic resources, traditional knowledge and folklore may be best illustrated through an example of how a biological resource is used at the local level. Annex 2 sets out such a local utilization pattern for a plant variety, namely a tree. As the example illustrates, the various components of the genetic resource, such as fruits, seeds, leaves, branches, etc., are utilized within a complex and dynamic system of local knowledge and practices for a multiplicity of purposes, including medicinal, agricultural, local industrial, food, and local livelihood purposes. The exemplified traditional knowledge system is not declaratory and its basic characteristics apply similarly to traditional knowledge and folklore which are not associated to the use of genetic resources. While these knowledge systems are often based on traditions, they also constitute a source of ongoing innovation and creativity, as the social and environmental conditions of resource utilization continuously change. Certain elements of such knowledge systems interact with various intellectual property regimes. There are multiple interfaces with trade secrets, patents, plant variety protection, trademarks, copyright and related rights. Besides the interfaces with modern intellectual property systems, certain elements of traditional knowledge systems are also protected by customary laws of the local communities. The nature of these intellectual property-like customary laws and their interfaces with modern intellectual property are not yet sufficiently explored and require further study. Annex 2 exemplifies a "traditional knowledge system," which constitutes a common framework for the *in-situ* conservation and utilization of genetic resources. Folkloric traditions constitute important parts of such traditional knowledge systems.

Suggested common approaches

19. As the foregoing examples illustrate, the intellectual property issues before the Committee cover a wide range of issues and contexts. Ensuring coherence of the work will therefore require certain choices from the Committee, regarding the discussion of the substance and the organization of work under the Committee. Recognizing the need for coherent and substantive work on these diverse issues, this document takes a common approach to all the themes before the Committee in respect of three specific aspects.

20. The first common approach concerns the use of terms and reflects the need for a more rigorous use of terminology in all three themes. The Member States have emphasized that the Committee will "rely upon a shared understanding of the meaning of certain terms, such as "genetic resources," … to which attention should be given at the outset."[18] However, many relevant terms are already defined in other international instruments dealing with genetic resources, traditional knowledge or folklore. The present document proposes to adopt the

[18] WO/GA/26/6, paragraph 20. See also paragraphs 29, 52, 59 and 66 of WO/GA/26/10.

prevalent use of relevant terms, since international discussions have centered around this use and the Committee may capitalize on such internationally agreed terms and the decades of specialized work which they reflect. In order to specify the prevalent use of terms, the paper reviews existing definitions and descriptions of terms in Annex 3. As the Annex reflects, terminology is more clearly defined in the contexts of genetic resources and folklore. However, in the general area of "traditional knowledge" terminology remains diffused and requires further clarification. This situation in the field of traditional knowledge is reflected in Section IV.B.1, entitled "Terminological and conceptual issues."

21. Secondly, the document takes a common approach to the process aspects of the Intergovernmental Committee, taking into account the decisions of the General Assembly[19] and the rules of procedure of the Committee.[20] Document WO/GA/26/6 provides that the first session of the Committee should determine "the agenda of items on which work should proceed" (paragraph 17). To facilitate the identification of possible items on which work could proceed under each theme, the present document proposes possible tasks related to each main issue before the Committee for the consideration of the Member States. Document WO/GA/26/6 also proposed that the first session "would determine the priority accorded to these various items" (paragraph 17). A complete list of possible tasks identified in the course of this document is provided in Annex 4.

22. Thirdly, the document takes a common approach to the substance of the intellectual property issues under consideration by the Committee. It recognizes that the substance of the three themes before the Committee is highly complex and has been subject to discussions and widely differing opinions in other fora. Mindful of such differing views, the document proposes to address those issues in a purely technical manner. The document seeks to provide a factual and technical account of the intellectual property issues arising in these areas. It limits itself exclusively to the intellectual property-specific issues of the three themes and leaves other aspects of genetic resources, traditional knowledge and folklore to the relevant international fora and processes.

III. WIPO'S WORK ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

23. Since the 1998-99 biennium, issues related to intellectual property and genetic resources, traditional knowledge and folklore have been addressed in regular activities under WIPO's exploratory Main Program 11 on "Global Intellectual Property Issues." The activities on intellectual property and genetic resources began with a study on the role of intellectual property rights in the sharing of benefits arising from the use of biological resources and associated traditional knowledge. The study was commissioned jointly with the United Nations Environment Programme (UNEP) and resulted in three case studies, which provide lessons as to how the effective protection of intellectual property rights can support the sharing of benefits arising from the use of genetic resources.[21]

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[19] See document WO/GA/26/10, paragraph 71.

[20] Document WIPO/GRTKF/IC/1/2 provides information concerning procedural and organizational matters and makes proposals regarding rules of procedure.

[21] The documents, reports and studies referred to in this Section are available at the WIPO WebPages on 'Biotechnology' (*http://www.wipo.int/biotech/documents/index.html*) and on 'Traditional Knowledge' (*http://www.wipo.int/traditionalknowledge/documents/index.html*).

24. Issues related to intellectual property and genetic resources were also discussed by Member States at the third session of the Standing Committee on the Law of Patents (SCP), which took place in Geneva from September 6 to 14, 1999. The SCP requested the International Bureau to include the issue of protection of biological and genetic resources on the agenda of a Working Group on Biotechnological Inventions, to be convened at WIPO in November 1999. The SCP further invited the International Bureau to take steps to convene a separate meeting involving a larger number of Member States early in 2000, to consider that issue.[22]

25. The Working Group on Biotechnology, at its meeting on November 8 and 9, 1999, recommended the establishment of nine projects related to the protection of inventions in the field of biotechnology. The Working Group decided to establish a questionnaire for the purpose of gathering information about the protection of biotechnological inventions, including certain aspects regarding intellectual property and genetic resources, in the Member States of WIPO. The Secretariat of WIPO sent a questionnaire to the Member States and has compiled information from the responses received in reply to the questionnaire in document WIPO/GRTKF/IC/1/6.

26. In response to the invitation issued by the SCP, WIPO organized a Meeting on Intellectual Property and Genetic Resources on April 17 and 18, 2000. The Meeting addressed issues that generally are raised in the context of access to, and *in-situ* preservation of, genetic resources in their direct or indirect relationship with intellectual property. The Chairman's Conclusions from the Meeting state that the exchange of views that took place at the Meeting produced a clear consensus that:

> "WIPO should facilitate the continuation of consultations among Member States in coordination with the other concerned international organizations, through the conduct of appropriate legal and technical studies, and through the setting up of an appropriate forum within WIPO for future work."

27. Before the Diplomatic Conference for the Adoption of the Patent Law Treaty from May 11 to June 2, 2000, the Director General of WIPO conducted informal consultations concerning formalities in relation to the question of genetic resources. As the outcome of the consultations, a statement was agreed upon among the various regional groups and read out by the Director General during the Conference, the relevant part of which is as follows:

> "Member State discussions concerning genetic resources will continue at WIPO. The format of such discussions will be left to the Director General's discretion, in consultation with WIPO Member States."

28. Following the Diplomatic Conference, consultations with Member States took place regarding the format and content of such discussions. As a result of the consultations, it was proposed that a distinct body should be established within WIPO to facilitate such discussions and that, in addition to the issue of genetic resources, the discussions should also include the results of WIPO's previous work on the related fields of traditional knowledge and expressions of folklore.

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[22] See document SCP/3/11, paragraph 208.

29. WIPO began its work on "traditional knowledge, innovations and creativity" (traditional knowledge) in the 1998-99 biennium. Two Roundtables were convened regarding the protection of traditional knowledge and a series of nine fact-finding missions on traditional knowledge, innovations and creativity (FFMs) were undertaken. The objective of the FFMs was "to identify and explore the intellectual property needs and expectations of new beneficiaries, including the holders of indigenous knowledge and innovations." A draft Report on all the fact-finding missions was made available for public comment in paper form and on the WIPO website.[23] Comments received were taken into account in producing a revised Report on the Intellectual Property Needs and Expectations of Traditional Knowledge Holders ("the FFM Report"), which was published in 2001.

30. WIPO's work on "expressions of folklore," which are a subset of traditional knowledge, began as early as 1978 in cooperation with the United Nations Educational, Scientific and Cultural Organization (UNESCO). It has thus progressed to a more advanced stage than the work on traditional knowledge in general. A concrete outcome of this work was the adoption in 1982 of the "Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions" (the Model Provisions). Most recently, WIPO and UNESCO conducted four Regional Consultations on the Protection of Expressions of Folklore, each of which adopted resolutions or recommendations with proposals for future work. In addition, it is worth noting that the WIPO Performances and Phonograms Treaty (WPPT) of 1996 already makes explicit reference to expressions of folklore.[24]

31. From November 9 to 11, 2000, WIPO organized an Inter-Regional Meeting in Chiang Rai, Thailand, which addressed intellectual property issues within all the three themes of genetic resources, traditional knowledge and folklore. 28 Member States attended the Meeting and adopted 'A Policy and Action Agenda for the Future' which welcomed "the decision of the Member States of WIPO to establish … the Intergovernmental Committee" and recommended, among other things, that WIPO should "facilitate, support and contribute to the work of the Committee by continuing to conduct the exploratory activities and practical pilot projects and studies on these issues of the kind undertaken by WIPO thus far."[25]

IV. INTELLECTUAL PROPERTY ISSUES FOR CONSIDERATION BY THE INTERGOVERNMENTAL COMMITTEE

32. This Section develops substantively the three themes of the Committee within the structure set out in Part III of document WO/GA/26/6 (paragraphs 20 to 24). That document divided the individual themes into several subsections each. The subsections group the intellectual property issues under that specific theme. The present elaboration of the issues follows the order of subsections set out in document WO/GA/26/6. Each subsection concludes with a possible task which the Member States may wish to consider setting themselves within the Intergovernmental Committee.

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[23] Located at <*http://www.wipo.int/traditionalknowledge/report*>.

[24] For the purpose of WPPT performers who are accorded protection include "'performers' who are actors, singers, musicians, dancers, and other persons who act, sing, deliver, play in, interpret, or otherwise perform literary or artistic works *or expressions of folklore*."

[25] Preamble and Recommendation 3(e), Chiang Rai Statement.

IV.A. Genetic Resources

33. Genetic resources have a double nature: they are physical material and the carriers of hereditary information which is capable of self-replication. This double nature gives rise to a conceptual tension between physical property in germplasm on the one hand and intellectual property rights in intangible elements of genetic resources which constitute inventions, trade secrets or new plant varieties on the other. While this tension arises in most intellectual property subject matter, such as books or distinctive signs, certain intangible elements of genetic resources are capable of self-replication. Genetic resources were in the past considered a common heritage of mankind and, as such, were subject to a free-flow paradigm, in particular as regards plant genetic resources for food and agriculture. There was little interference in the free flow of genetic resources, except for some phytosanitary controls or quarantine regulations. However, with the increasing *ex-situ* utilization of genetic resources (see Part II above and Annex 1) and their increasing actual or potential value, the free flow paradigm of genetic resources is giving way to new regulatory conditions. On the one hand, the provider countries of genetic resources are beginning to assert sovereign control over their germplasm, and, on the other hand, *ex-situ* users of genetic resources are claiming intellectual property rights over improved germplasm which they have developed through breeding or modern biotechnologies. In this regard, patents and plant breeder's rights provide incentives for improved conservation and utilization of genetic resources.[26]

34. Discussions in several multilateral fora on access to genetic resources and benefit-sharing have given rise to a wide range of intellectual property issues. The four sections under this theme have been chosen because the interface between intellectual property protection and access to genetic resources arises within four different frameworks, namely (i) contractual agreements for access to genetic resources and benefit-sharing; (ii) legislative, administrative and policy measures at the national and regional levels to regulate access to genetic resources; (iii) multilateral systems for facilitated access to genetic resources and benefit-sharing; and (iv) existing intellectual property frameworks for the legal protection of biotechnological inventions.

IV.A.1 Contractual agreements for access to genetic resources and benefit-sharing

35. Contractual arrangements are currently the most common legal tool for regulating access to genetic resources and benefit-sharing.[27] However, most genetic resource transfers are not limited to a simple user/provider relationship. Agreements are thus used between two or more parties to transfer genetic material for a number of purposes, including *ex-situ* conservation (e.g. in genebanks), research and development, commercial exploitation, or a combination thereof.

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[26] The incentive for development of new varieties is, in itself, an important driver for effective conservation of plant genetic resources. The genetic resources contained in protected varieties often represent the most valuable genetic resources since they are necessary for the production of high yielding, high quality crops with good pest and disease resistance. A further important feature of the *sui generis* system developed by the International Union for the Protection of New Varieties of Plants (UPOV) is the "breeder's exemption" which specifically allows the use of all protected varieties in further breeding work thereby increasing the range of genetic resources available in the development of new varieties.

[27] See UNEP/CBD/COP/5/8: paragraph 53.

36. The contractual agreements take a variety of forms, from letter statements attached to a shipment of germplasm to detailed and formally negotiated contracts. This range of contractual agreements has increasingly been referred to collectively as "Material Transfer Agreements" (MTAs). MTAs are regarded as subject to trade secret law. The genetic resource which is transferred under the MTA constitutes the 'trade secret.'

37. An increasing range of stakeholders is using MTAs for genetic resource transfers and have made efforts to formalize and standardize their agreements in order to lower the transaction costs of negotiating separate agreements for each transfer. Such stakeholders include public sector research institutions[28] as well as private sector initiatives,[29] in both the pharmaceutical[30] and the agricultural sectors[31] as well as genebanks and other *ex-situ* collections of genetic resources.[32]

38. Intellectual property-related clauses are some of the most important provisions of MTAs and typically include five provisions, *inter alia*:

(i) *Utilization allowed 'for research purposes only':* in the public sector, MTAs mostly permit the free use of the genetic resource for research purposes only, with the possible obligation to share royalties should commercial products arise from the use. This clause is common where the germplasm provider wants to permit scientific uses of the material, but wants to reserve all commercial rights that may arise from the research.[33]

(ii) *Obligation not to file patent applications*: some MTAs include clauses which provide that the recipient shall not seek to patent the genetic material or genes found in the material.[34]

(iii) *Provisions to share intellectual property rights:* An alternative approach of managing patent rights for genetic resources, which were transferred by MTA, is to carefully spell out the rights and responsibilities of patenting the products or processes which are the outcome of resource utilization, as well as the ownership rights in the resulting patents. Such

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[28] See the *Uniform Biological Material Transfer Agreements* and other standard MTAs developed by the National Institute of Health (NIH) in the United States of America.

[29] For example, a "Draft Biodiversity Prospecting Contract" was developed from the widely publicized 1991 agreement between Merck & Co and the Costa Rica Biodiversity Institute (INBio). See, World Resource Institute (WRI) *Biodiversity Prospecting: Using Genetic Resources for Sustainable Development*. WRI, 1993: Annex II.

[30] See the 'Letter-of-Collection Agreement' developed by the National Cancer Institute (see, UNEP/CBD/COP/4/Inf.7, paragraphs 7, 10 and Annex II).

[31] See the Standard MTA used by the International Agricultural Research Centers (IARCs) of the Consultative Group on International Agricultural Research (CGIAR) under the 1994 Agreements between the FAO and eleven IARCs (Articles 3(b) and 6 of the Agreements).

[32] For example 19 botanical gardens adopted common 'Model Material Acquisition Agreements' and the 'Model Material Supply Agreement,' as part of their 'Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit-Sharing' (Annexes II and III).

[33] It is important to emphasize that this issue is not the same as the 'research exemption' in patent law. While that follows statutory or case law criteria, the issue here is what constitutes the meaning of "research purposes" as a term used in contracts.

[34] For example, see the MTA used by several IARCs of the CGIAR.

MTAs specify at the outset how to allocate rights and are often used in the collaboration between small 'biotechnology startups' and large industrial partners. Commonly, the most difficult problem is the allocation of rights to unexpected inventions.

(iv) *Provisions to share royalties from intellectual property rights*: The most common pattern of distributing profits from the commercial exploitation is to leave the negotiation of such distribution to be undertaken later in the event that there are any profits. However, the duty to negotiate may not necessarily lead to an agreement, and for such cases MTAs often include arbitration procedures to determine a reasonable royalty, in case the parties are unable to do so.

(v) *Progeny and derivative material*: Of particular importance is the scope of subject matter covered by an MTA, on which the genetic resource provider seeks to protect his rights. Normally, such protection extends to the derivatives of the genetic resource. An important problem in this respect is to determine what constitutes "a derivative" and what does not. A common approach is to agree upon a definition of "derived product" and make the MTA applicable to the provided genetic resources and its derived products.

(vi) *Grant-back licenses*: Under a 'grant-back clause,' the genetic resource provider ensures the right to use any patented inventions that may derive from the transferred genetic resource by obliging the genetic resource recipient to give the provider a non-exclusive, royalty-free license under any such inventions it may patent.

(vii) *Obligation to defer publication*: MTAs may stipulate that publications based on the transferred genetic resource shall be deferred for a certain time, so that patent applications can first be drafted and filed. Parties may also agree to report to each other on any actions they may take with respect to patents to facilitate the filing of applications and to protect their mutual rights to royalties.

39. Several international instruments which regulate the transfer of genetic resources internationally refer to MTAs. For example, the FAO International Code of Conduct for Plant Germplasm Collection and Transfer (1993), sets out the responsibilities of collectors, donors, sponsors, users and curators of plant genetic resources. Among these responsibilities, curators are to "take practical steps, *inter alia* by the use of material transfer agreements to promote the objectives of this code, including the sharing of benefits derived from collected germplasm by the users with the local communities, farmers and host countries" (Article 13.3).

40. Nevertheless, increasing controversy and confusion have surrounded the intellectual property clauses of MTAs for genetic resources. This controversy has arisen because the changing environment of genetic resource policy requires that the intellectual property clauses of the agreements reflect a carefully crafted balance between the policy objectives of conservation, food security, etc. and the interests of various stakeholders. However, the genetic resource expert fora in which these clauses and policies are discussed, do not necessarily have at their disposal the required intellectual property expertise to develop technically accurate and balanced intellectual property clauses.

41. *Possible Task A.1:* In order to provide a practical intellectual property contribution to these processes and fora, the Intergovernmental Committee may wish to consider the development of "guide contractual practices," guidelines, and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing, taking

into account the specific nature and needs of different stakeholders, different genetic resources, and different transfers within different sectors of genetic resource policy.

IV.A.2 Legislative, administrative and policy measures to regulate access to genetic resources and benefit-sharing

42. Beyond the law of contract, intellectual property issues on genetic resources are rapidly arising as sovereign States exercise their authority to determine access to their genetic resources by developing legal and policy frameworks to regulate such access. Such access frameworks may interface in multiple ways with national intellectual property legislation, in particular patent laws. A Panel of Experts on Access and Benefit-sharing convened by the CBD identified two primary issues: (i) intellectual property rights as a possible "international measure to support prior informed consent" and (ii) the recording of interests in inventions that arise from access to or use of genetic resources.

43. In its discussion on prior informed consent, the Panel noted that Parties should investigate intellectual property rights as incentive-based "measures to support, in user countries, prior informed consent requirements in provider countries."[35]

44. The second issue concerns the recording of ownership interests in inventions which arise from access to or use of genetic resources. This concept proposes to establish a requirement that patent documents shall disclose the origin of the genetic resources used in the development of inventions and/or provide evidence that the resource was acquired legally. Proposals with differing versions of this general concept have been put forward in a number of multilateral fora, including the World Trade Organization,[36] the CBD;[37] the United Nations Conference on Trade and Development (UNCTAD);[38] and WIPO.[39] There is an acknowledged need in other multilateral fora, that this issue be examined from an intellectual property point of view within the appropriate multilateral fora with the necessary technical intellectual property expertise.

45. Within WIPO it has been proposed to undertake a project to evaluate various means for recording ownership interests in inventions arising out of private-public collaborative research and similar projects.[40] The WIPO Working Group on Biotechnology proposed "to undertake an evaluation of practices and means used to identify and protect the interests of the various parties that take part in research and development of biotechnology inventions," including the providers of genetic resources and other biological resources.[41] Aspects for further discussion may include: (i) whether the proposed requirement would also apply when the invention, for which the application is filed, concerns synthesized substances that were isolated or derived from active compounds of an accessed genetic resource and, if so, what is an agreed definition of "derived"; (ii) whether and how the requirement would apply for genetic

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[35] UNEP/CBD/COP/5/8; paragraph 125.
[36] See, *inter alia*, documents IP/C/W/195, WT/GC/W/233.
[37] See Decision IV/8, paragraph 3 and Annex; Decision V/26, paragraph A.15(d); UNEP/CBD/COP/5/8: paragraph 127.
[38] See TD/B/COM.1/EM.13/3, paragraph 17.
[39] See SCP/3/10, WIPO/IP/GR/00/2, WIPO/IP/GR/00/4.
[40] Project C-2, document WIPO/BIOT/WG/99/1.
[41] See, document WIPO/BIOT/WG/99/1, paragraphs 46 to 48.

resources accessed from multilateral systems for facilitated access to genetic resources, which may be established in the agricultural sector; and (iii) what would be the consequences of non-compliance with the requirement, ranging from a fine to invalidation or revocation of the patent. From the intellectual property point of view, existing standards on the availability, scope and use of patents, such as those set out in Articles 27, 29, 32 and 62 of the TRIPS Agreement, may afford some guidance as to how those WIPO Member States which are also WTO Members may address this concept.

46. Beyond these two primary issues, a range of additional intellectual property questions arise in the development of national access frameworks. In their development of national and regional access legislation for genetic resources, States and regional integration organizations are looking for specialized intellectual property advice on such interfaces, which is not readily available from the other multilateral fora and intergovernmental organizations involved in sectoral genetic resource policies. Various requests for intellectual property-specific guidance have therefore been issued to WIPO from its Member States and intergovernmental organizations, fora or processes. In order to provide such requested guidance, the Intergovernmental Committee may consider the option of developing intellectual property advice and recommendations for those organizations, fora or processes.

47. *Possible Task A.2:* Considering the previous discussions in WIPO on intellectual property and genetic resources, the proposals of the WIPO Working Group on Biotechnology, and the need expressed in other fora, the Intergovernmental Committee may wish to consider the development of appropriate provisions or guidelines for national patent laws which facilitate consistency with measures of States concerning access to genetic resources and which are consistent with existing international intellectual property standards.

IV.A.3 Multilateral systems for facilitated access to genetic resources and benefit-sharing

48. In the area of plant genetic resources for food and agriculture (PGRFA), the bilateral approach to access and benefit-sharing may not provide adequate solutions to the special nature and needs of agriculture.[42] This raises a specific set of intellectual property issues that should be addressed separately and may require the development of specialized intellectual property-based mechanisms in the field of plant genetic resources for food and agriculture.

49. The special nature of PGRFA [43] derives, *inter alia*, from three distinctive features of these genetic resources: (i) PGRFA and their free flow are a fundamental precondition for global food security; (ii) because of the diffusion of agriculture and its major crops, it is very difficult to trace PGRFA to a particular country of origin; and (iii) there is a strong interdependence of countries with respect to PGRFA, because the agriculture of all countries

[42] In its Resolution 3, the Conference for the adoption of the CBD "*recognizes* the need to seek solutions to outstanding matters concerning plant genetic resources" in the area of food and agriculture (paragraph 4, Resolution 3, Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity).

[43] In document CPGR-6/95/REP, paragraph 67, the FAO Commission on Plant Genetic Resources For Food and Agriculture stresses the special nature and needs of agriculture, which are reflected in the *Report on the State of the World's Plant Genetic Resources for Food and Agriculture*.

is dependent on a supply of genetic resources from other parts of the world.[44] In order to address the characteristics of PGRFA, governments are in the process of establishing a Multilateral System of Access and Benefit-Sharing for PGRFA ("the MLS") in the context of the revision of the International Undertaking on Plant Genetic Resources for Food and Agriculture ("the Undertaking"), which is being facilitated by the Commission on Genetic Resources for Food and Agriculture (CGRFA) of the FAO.

50. The International Undertaking is an instrument to promote international harmony in matters concerning access to PGRFA. The objective of the revised Undertaking is the conservation and sustainable use of PGRFA and the sharing of the benefits arising from their use for sustainable agriculture and food security.[45]

51. Within the discussions for the revision of the Undertaking at the FAO, governments have raised several intellectual property issues which relate to the matters under consideration by the Intergovernmental Committee. These issues arise in the context of the draft provisions of the revised Undertaking on facilitated access to PGRFA (Article 13) and on benefit-sharing (Article 14).[46] Article 14 covers benefit-sharing in respect of exchange of information, access to and transfer of technology, capacity building, and the sharing of benefits on commercialization. In particular, the current Composite Draft Text of the revised Undertaking includes a provision for the sharing of benefits on commercialization, which provides for an intellectual property-based benefit-sharing mechanism[47] (Article 14.2(d)(iv)[48]).

52. In its current form the provision stipulates, *inter alia*, that whenever the use of genetic resources accessed under the MLS results in a product which is covered by an intellectual property right that restricts utilization of that product for research and plant breeding, the right holder shall pay a certain royalty on the commercial exploitation of that product into a benefit-sharing mechanism. The provision sets out different obligations if the product is covered by intellectual property rights which do not restrict further research and plant breeding and it provides for a review of the provisions of

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[44] The FAO *Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture* (1996) sets out seven special features of PGRFA (paragraph 7(a) to (h)).
The CBD Panel of Experts on Access and Benefit-Sharing recognized the uniqueness of PGRFA and identified four distinct characteristics (see, Report of the Panel of Experts on Access and Benefit-Sharing, UNEP/CBD/COP/5/8, paragraph 64).

[45] Article 1.1, draft revised Undertaking. For the current Composite Draft Text of the draft revised Undertaking, see 'Composite Draft Text of the International Undertaking on Plant Genetic Resources, Incorporating: The Texts of Article 15, Negotiated During the Commission's Eighth Regular Session; the Texts of Articles 11, 12, 13, 14, 16, 17, 18, 20 and 21, as Negotiated at the First to Fifth Inter-Sessional Meetings of the Contact Group' (FAO document CGRFA/CG-6/01/2)

[46] See document CGRFA/CG-6/01/2.

[47] The concept of such a mechanism was first introduced into the Composite Draft Text following a private sector proposal from the International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL) and was revised during the negotiations at subsequent meetings of the Contact Group of the CGRFA (See documents CGRFA-8/99/Inf.9; CGRFA/CG-3/00/2; CGRFA/CG-4/00/2, CGRFA/CG-5/01/2 and CGRFA/CG-6/01/2).

[48] Four countries stated that they do not agree with the text of Article 14.2(d)(iv). See CGRFA/CG-6/01/2.

Article 14.2(d)(iv) by the Governing Body within five years of the entry into force of the revised Undertaking.

53. If the revision of the International Undertaking is concluded and the present provision forms part of the MLS, practical work would have to be undertaken to develop possible legal and institutional frameworks for the implementation of this intellectual property-based benefit-sharing mechanism within the framework of the revised Undertaking in a manner that concords with the international intellectual property system. If such a mechanism were to be implemented in the context of the Multilateral System, its administration might require considerable expertise and experience with the administration of international intellectual property system, in particular patent information systems.

54. *Possible Task A.3:* Based on the above-mentioned developments, the Intergovernmental Committee may wish to consider, subject to the conclusion of the revision of the International Undertaking, the desirability and feasibility of practical and low-cost mechanisms to implement intellectual property-based benefit-sharing arrangements under multilateral systems for access to genetic resources and benefit-sharing, which are consistent with international intellectual property standards and focus in particular on plant genetic resources for food and agriculture.

IV.A.4 Protection of biotechnological inventions, including certain related administrative and procedural issues

55. Intellectual property issues that arise in the context of the legal protection of biotechnological inventions can be classified into five main groups: (i) legal standards related to the scope and character of patent protection for biotechnological inventions; (ii) issues related to the use of intellectual property rights in biotechnological inventions, such as licensing; (iii) administrative and procedural issues related to the examination of patent applications directed to biotechnological inventions; (iv) the relationship between patents and other forms of intellectual property protection for biotechnological inventions; and (v) the nature of the relationship between the development and commercialization of biotechnological inventions and other policy considerations, such as moral, ethical, and environmental considerations, including the conservation and sustainable use of biological diversity, and the protection of animal and human health.

56. In November 1999, WIPO convened a Working Group on Biotechnology, which proposed that WIPO study nine topics within these five categories of issues (WIPO/BIOT/WG/99/1). One particularly significant issue in the context of genetic resources concerns the availability and scope of patent protection in respect of biotechnology inventions which consist of structures and compositions derived or isolated from naturally occurring living organisms and certain types of “early stage” biotechnological inventions (e.g., inventions consisting of so-called “expressed sequence tags”). This issue is relevant to the decisions of Member States in several fora, dealing with sectoral genetic resource policies, such as in agriculture or medicinal plants, as well as, within WIPO, the SCP.

57. Recent debates on the legal protection of biotechnological inventions have called into question what, in the meaning of patent law, constitutes an “invention” with regard to materials isolated or derived from naturally occurring living organisms. In many jurisdictions, this question has been put in terms of defining the distinction between “invention” versus “discovery.” Some of these discussions focus on the issue of whether an

organism, *per se*, can be patented and in what form. The WIPO Questionnaire on the protection of biotechnological inventions included several questions which relate to these issues. For information on the Member States' responses to these questions see document WIPO/GRTKF/IC/1/6.[49] Other discussions focus on whether substances, including DNA sequences corresponding to genes found in a genetic resource, or proteins isolated from that resource, can be patented.

58. For these biotechnology inventions, the current application of three specific patent law standards has been subject to debate, namely: (i) the application of the requirement for industrial applicability or "utility"; (ii) the application of the standard of non-obviousness or inventive step; and (iii) the assessment of claim scope in relation to disclosure. The concerns that have been expressed in certain WIPO Member States and international fora about the application of these three standards in relation to these two classes of biotechnological inventions have included, *inter alia*, three issues:

(a) Often the claims in granted patents afford a scope of protection that encompasses later stage or downstream inventions. The question has been raised whether this inhibits further research and development in applied biology;
(b) It has been said that genes are products of nature and that an inventor who isolates or sequences a gene from a genetic resource does not actually invent a patentable composition of matter;
(c) In the context of PGRFA, it has been observed that the patenting of gene sequences and expressed sequence tags may inhibit the free flow of genetic resources which is considered critical to food security and agriculture.

59. Based on the proposals of the Biotechnology Working Group, the International Bureau of WIPO issued a questionnaire on practices related to the protection of biotechnological inventions under the patent and plant variety protection systems of WIPO Member States. Fifty-seven countries responded to at least one question posed in the WIPO questionnaire. Information from the responses received from the Member States was compiled and a summary was prepared of practices related to the protection of biotechnological inventions in WIPO Member States (Project A-1).

60. *Possible Task A.4:* Member States may wish to review, on the basis of information compiled in the summary of practices related to the protection of biotechnology inventions in Member States and recalling the work of the SCP, the application of legal standards concerning the availability and scope of patent protection to structures and compositions derived or isolated from naturally occurring living organisms and to early stage biotechnology inventions, with a view to producing guidelines on the application of such standards in the field of genetic resources.

Possible Task A.5: The Intergovernmental Committee may wish to consider if it is possible to improve the management of genetic resources by exploring methods by which the genetic resources in the form of protected varieties may be integrated into overall plans for effective conservation.

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[49] See, in particular, information from Member State responses to questions 1, 2, 3, 5 and 6 of the Questionnaire.

61. In each of the contexts discussed above certain intellectual property issues arise with regard to the protection of traditional knowledge related to genetic resources. These issues will be dealt with separately in Section IV.B.

62. The Intergovernmental Committee is invited to take note of the foregoing intellectual property issues related to genetic resources and to adopt and prioritize tasks on intellectual property and genetic resources, in particular those identified in paragraphs 41, 47, 54, and 60, above.

IV.B. Traditional Knowledge

63. In recent years, the Member States have expressed increasing interest in intellectual property issues related to traditional knowledge, innovations and creativity. These issues reflect two concerns which have been articulated in the field of traditional knowledge: first, the availability of intellectual property protection for traditional knowledge holders,[50] and, second, the acquisition by parties other than the traditional knowledge holders of intellectual property rights over traditional knowledge-based creations and innovations.[51] Based on WIPO's previous work related to traditional knowledge, intellectual property issues in this field can be grouped into four categories, as set out in document WO/GA/26/6.[52] The following four sections develop the substantive issues arising in these four main categories.

IV.B.1 Terminological and conceptual issues

64. Intellectual property issues within this Section fall into two categories, namely terminological and conceptual issues. The first category of issues arises from the need to identify the terms which will facilitate the discussions of the Member States on the scope of subject matter for which protection is sought. Annex 3 sets out the prevalent use of relevant terms in international discussions regarding traditional knowledge. As Annex 3 indicates, different sets of terms are being applied to the subject matter of traditional knowledge, depending on the subfield, policy area, and international instruments to which the discussions relate. This variation in terminology may result from the importance of traditional knowledge to a wide range of policy areas and the broad scope of traditional knowledge, including all creations in the industrial, literary, artistic and scientific domains.

65. Given this highly diverse and dynamic nature of traditional knowledge it may not be possible to develop a singular and exclusive definition of the term. However, such a singular definition may not be necessary in order to delimit the scope of subject matter for which protection is sought. This approach has been taken in a number of international instruments in the field of intellectual property. For example, Article 2.1, Berne Convention for the

[50] This concern requests that traditional knowledge holders should be able to protect their knowledge.

[51] This concern requests that parties other than traditional knowledge holders should not be able to protect unmodified traditional knowledge. The apprehension is based on cases where third parties have acquired intellectual property rights, such as patents, over traditional knowledge elements without acknowledgement of or authorization from the customary knowledge holders.

[52] Paragraph 23.

Protection of Literary and Artistic Works ("the Berne Convention"), does not include an exclusive definition for the meaning of "literary and artistic works," but rather provides a non-exhaustive enumeration of subject matter in order to demarcate the categories of creations which are protected under the Convention.[53] Certain other international agreements in the field of intellectual property are silent in defining a singular term which describes the totality of protected subject matter.[54] At the national level, many laws dealing with the protection of inventions do not define the term "invention."[55] Nevertheless, an agreed terminology may assist the Member States in delimiting the subject matter in respect of which they may discuss the establishment of intellectual property standards.

66. The second category of issues in this Section concerns four conceptual questions that will need to be addressed in order to make systems and standards for the protection of traditional knowledge clear, practical and accessible to traditional knowledge holders. These issues include (i) agreement on the principles and objectives of traditional knowledge protection; (ii) understanding the interfaces between the formal intellectual property system and customary legal systems which apply to traditional knowledge in local and indigenous communities; (iii) developing methods to deal with the collectivity of creation, innovation and ownership in certain traditional knowledge systems; and (iv) developing means to tackle legal and administrative problems related to "regional traditional knowledge."

67. The first conceptual issue concerns the objectives and principles of intellectual property protection for traditional knowledge.[56] Some objectives which certain Member States have already articulated include that protection of traditional knowledge should additionally promote:

(a) respect for, and preservation of, traditional knowledge systems;
(b) fair and equitable distribution of benefits arising from the use of traditional knowledge;

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[53] Article 2.1 stipulates that "[t]he expression 'literary and artistic works' *shall include* every production in the literary, scientific and artistic domain" (emphasis added). This inclusive characterization is illustrated by the words "such as" and a non-exhaustive enumeration of examples, which illustrate the categories of subject matter falling within the scope of protected subject matter. Over time new categories have been added to the non-exhaustive list (e.g., "choreographic and architectural works" were added in 1908 at the Berlin Revision Conference, "oral works" at the 1928 Rome Revision Conference, etc.).

[54] The Paris Convention for the Protection of Industrial Property (1979) ("the Paris Convention") does not provide an exclusive definition of the meaning of terms which describe the subject matter protected by industrial property rights, such as "invention," "industrial design," distinctive signs, etc. The TRIPS Agreement, finally, does not define the terms by which it describes the subject matter covered by the rights for which it establishes international standards.

[55] However, the WIPO Model Law for Developing Countries on Inventions (1979) does provide a definition. Within the traditional knowledge area, the UNESCO-WIPO Model Provisions for National Laws do not define the term "folklore" *per se*. The Preamble merely considers "that folklore represents an important part of the living cultural heritage of the nation" (first recital, Model Provisions).

[56] For the purposes of this document, the term "protection" refers to matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights relating to traditional knowledge (in the meaning of Articles 3 and 4, TRIPS Agreement, on National Treatment and Most-favoured Nation Treatment).

(c) increased use of traditional knowledge;
(d) creation of legal and economic systems for traditional knowledge holders and their communities, and
(e) protection of traditional knowledge in the context of the conservation of biological diversity.[57]

68. The second conceptual issue concerns the interface between the formal intellectual property system and the customary legal systems which already exist for the protection of traditional knowledge within some indigenous and local communities. During previous WIPO activities, Member States and representatives of traditional knowledge holders have indicated that many traditional societies have developed highly sophisticated and effective customary intellectual property systems. To a large extent these systems have, until now, remained invisible from the point of view of the formal intellectual property system. However, customary legal systems, including those pertaining to traditional knowledge, are referred to in many traditional knowledge-related declarations[58] and international instruments.[59] Hence, the Member States have identified a need to further study the relationship between customary protection of traditional knowledge and the intellectual property system.[60]

69. The third conceptual issue concerns the collectivity of creation, ownership and custodianship which prevails in certain communities and traditional knowledge systems. It is felt that traditional knowledge is communally developed, transmitted, and shared, and that the current intellectual property system does not fully address the need of traditional knowledge holding communities for collective or community rights. While collectivity of creation and ownership may not be the only aspects of traditional knowledge systems in all cases, Member States have still identified the need to develop legal solutions which address the needs of the communities for a recognition of their collective rights to their collective knowledge.

70. The fourth conceptual issue, namely the question of "regional traditional knowledge," raises complex legal and administrative challenges. These include: (1) defining the legal competence of national or regional authorities to authorize the utilization of traditional knowledge which may form part of the national heritage of several countries; (2) establishing administrative rules and regulations which would regulate authorization procedures for several communities and even countries; (3) defining arrangements in a situation where traditional knowledge is shared by two or more countries, some of which are Parties to an international Treaty on traditional knowledge protection and others which are not; (4)

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[57] See, document WO/GA/26/9, Annex I. Additionally, other intergovernmental processes have identified basic objectives for traditional knowledge protection, see document UNEP/CBD/WG8J/1/2, paragraph 17(c).

[58] See, for example, the Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples (1992) and the Julayinbul Statement on Indigenous Intellectual Property Rights (1993).

[59] See, Article 8, ILO Convention 169; Articles 12 and 33, Draft United Nations Declaration on the Rights of Indigenous Peoples (1994); and Principle 4, 'Principles and Guidelines for the Protection of the Heritage of Indigenous People,' United Nations Sub-Commission on Prevention of Discrimination and Protection of Minorities.

[60] The WIPO Program and Budget for 2000-2001 provides for "a study on customary law and regulatory systems that apply to the protection of knowledge, innovations and creativity in local and traditional communities, including conclusions relevant for the formal intellectual property system" (Main Program 11).

defining the allocation of royalties that may arise from authorized commercial exploitation of regional traditional knowledge between different concerned communities and/or countries; (5) defining criteria, and procedures for their application, to determine when an element of traditional knowledge is national or regional; and (6) settling disputes that may arise about such determinations.

71. *Possible Task B.1*: Based on the current use of relevant terms as set out in Annex 3, the Intergovernmental Committee may wish to delineate the scope of subject matter in respect of which the Member States wish to discuss the application of intellectual property protection for the purpose of having a definition of the term "traditional knowledge."

IV.B.2 Standards concerning the availability, scope and use of intellectual property rights in traditional knowledge

72. There is currently a rapid evolution of standards for the protection of intellectual property in the field of traditional knowledge in a number of WIPO Member States. As of January 1, 2001, at least 22 countries and 3 regional integration organizations had made, or were in the process of making, available specific legal protection for traditional knowledge-related subject matter.[61] Such protection is being made available in two ways: first, the application of existing standards to traditional knowledge subject matter, and, second, the development of new intellectual property standards for the protection of traditional knowledge.

73. The use of existing standards to make available traditional knowledge protection may take, *inter alia*, the following forms:

(i) *Trademarks.* Traditional communities are seeking to register collective and certification trade marks to establish signs under which goods emanating from their community or group, or manufactured in accordance with particular methods or standards, can be sold.

(ii) *Geographical indications.* Some traditional knowledge holders are considering the registration of geographical indications, as contemplated internationally in the Lisbon Agreement for the Protection of Appellations of Origin and their International Registration (1979) and the Protection under the Madrid Agreement for the Repression of False and Deceptive Indications of Source (1891).

(iii) *Patents*. Attempts have been made for the collective filing of patent applications by associations of traditional knowledge holders on behalf of their members, in order to share the filing costs. Proposals have also been put forward to include in patent applications, which claim traditional knowledge-based inventions, an indication that the traditional knowledge and/or biological resource has been obtained with the prior informed consent (PIC) of the country or community of origin.

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[61] See documents WIPO/IPTK/RT/99/6A; WIPO/IPTK/RT/99/6B; TD/B/COM.1/EM.13/2; TD/B/COM.1/EM.13/3; UNEP/CBD/WG8J/1/2; UNEP/CBD/COP/5/5; and *Report of the Interregional Workshop on Intellectual Property Rights in the Context of Traditional Medicine*, Bangkok, December 6 to 8, 2000.

(iv) *Copyright and Related Rights*. Traditional knowledge holders have sought to protect their "moral rights" using the moral rights concept in copyright. They have also expressed an interest in protecting compilations of traditional knowledge documentation through the concept of original and non-original database protection. Related rights may indirectly protect traditional knowledge through the protection of the rights of performers. There have also been debates on utilizing the *domain public payant* system in respect of traditional knowledge, under which royalties continue to be paid for the use of literary and musical works in the public domain.

(v) *Unfair Competition*. There have been extensive debates on protecting certain elements of traditional knowledge by using trade secrecy as well as the law of "passing off".

74. New standards for traditional knowledge protection are, nevertheless, being developed, mostly in the form of *sui generis* legislation to protect elements of traditional knowledge not covered by existing intellectual property systems.[62] For example, several countries are developing *sui generis* systems for the protection of traditional medicine. In the course of past and present WIPO activities directed at testing the applicability of existing intellectual property tools to traditional knowledge, [63] Member States and traditional knowledge holders have pointed to limitations which are inherent to existing intellectual property tools and have articulated a need for the development of new intellectual property tools to protect forms of traditional knowledge not covered by existing intellectual property tools.

75. WIPO has developed a model for *sui generis* protection of certain traditional knowledge-related subject matter in cooperation with UNESCO, namely the UNESCO-WIPO Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions (1982) (see Section IV.C.1 below). Whereas the Model Provisions are limited to expressions of folklore, several intergovernmental processes have identified 'common elements of national *sui generis* legislation' to protect the full scope of traditional knowledge subject matter.[64] Additionally, several non-governmental organizations have developed national models for *sui generis* protection of traditional knowledge.[65] There is also a binding international instrument currently in force, which

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[62] See UNCTAD document TD/B/COM.1/EM.13/2, paragraph 47.

[63] The Global Intellectual Property Issues Program of the WIPO Program and Budget for the 2000-2001 biennium includes "a feasibility study on the use of intellectual property law or practice to protect traditional knowledge, innovations and creativity" (Main Program 11). Discussions on the applicability of existing intellectual property tools to traditional knowledge were also conducted in the FFMs. See, in particular the chapter "Summary, Reflections and Conclusions" of the FFM Report.

[64] See, recommended "common elements" for national *sui generis* legislation for traditional knowledge protection in document TD/B/COM.1/EM.13/3, paragraph 34.
See also "Possible Elements of *Sui Generis* Legislation to Protect the Knowledge, Innovations and Practices of Local and Indigenous Communities" in document UNEP/CBD/COP/5/8, Annex VI; and "Principles and Guidelines for the Protection of the Heritage of Indigenous People," elaborated by the Sub-Commission on Prevention of Discrimination and Protection of Minorities.

[65] These include, *inter alia*, "A Conceptual Framework and Essential Elements of a Rights Regime for the Protection of Indigenous Rights and Biodiversity" (1996) by the Third World Network; the "Model Biodiversity Related Community Intellectual Rights Act" (1997) by the Research

[Footnote continued on next page]

establishes obligations for Contracting Parties to provide legal protection for traditional knowledge-related subject matter.[66]

76. The need for, and importance of, international frameworks for traditional knowledge protection was stressed during past WIPO activities.[67] Member States have requested WIPO to facilitate discussions on the possibility of establishing international standards for the availability, scope and use of intellectual property rights in respect of traditional knowledge.[68] New intellectual property standards could be accommodated within the broad concept of "intellectual property" in the WIPO Convention, which provides that "intellectual property shall include existing intellectual property rights "*and* all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields."[69] The Committee provides a forum for the Member States to take up the discussions which they had recommended during past WIPO activities.

77. *Possible Task B.2:* The Member States may wish to compile, compare and assess information on the availability and scope of intellectual property protection for traditional knowledge within the scope of subject matter which was delimited under Task B.1 and identify any elements of the agreed subject matter which require additional protection.

IV.B.3 Certain criteria for the application of technical elements of standards, including legal criteria for the definition of prior art and administrative and procedural issues related to examination of patent applications

78. In the field of traditional knowledge, public concern has focused on the adequate recognition of traditional knowledge as prior art during the examination of patent applications for traditional knowledge-based inventions. While the definition of prior art varies widely in different patent laws, it is recalled that this issue forms part of the current work of the SCP. "Prior art" generally speaking refers to the entire body of knowledge which was available to the public before the filing date or, if priority is claimed, before the priority date, of a patent application. The Patent Cooperation Treaty (PCT) provides a definition of "prior art"[70] for

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[Footnote continued from previous page]

Foundation for Science, Technology and Ecology; and the "Intellectual Integrity Framework" (1994) by the Rural Advancement Foundation International.

66 The United Nations Convention to Combat Desertification in Those Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa (1994) provides that Parties shall:

"*protect*, promote and use in particular relevant traditional and local technology, knowledge, know-how and practices and, to that end, they undertake to: […] (b) ensure that such technology, knowledge, know-how and practices are adequately *protected* and that local populations benefit directly, on an equitable basis and as mutually agreed, from any commercial utilization of them or from any technological development derived therefrom" (Article 18.2(b), emphasis added).

67 See the Chiang Rai Statement.

68 See, Chiang Rai Statement and documents WIPO-UNESCO/FOLK/ASIA/99/1, WIPO-UNESCO/FOLK/ARAB/99/1, WIPO-UNESCO/FOLK/LAC/99/1.

69 This open-ended definition of intellectual property is contained in the WIPO Convention, Article 2(viii).

70 Rule 33.1(a) of the PCT states that for the purposes of International Searches, "relevant prior art shall consist of everything which has been made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) and which is capable

[Footnote continued on next page]

the purposes of the International Search to which international applications are subject.[71] However, for the purposes of national searches, prior art in some countries includes everything that has been made available to the public anywhere in the world by any means, whereas in other countries, non-written disclosures, such as oral disclosures, or use outside their jurisdiction, do not form part of the prior art, and thus do not constitute a bar to patentability. Issues which the Member States could discuss in this category include the meaning of "availability to the public" in relation to traditional knowledge and of "means of making available to the public" in relation to traditional knowledge documentation.

79. An array of practical issues concerns administrative and procedural modifications in the examination of patent applications which might significantly enhance the ability of patent examiners to assemble and review the prior art relevant to an application. Issues in this category include: the lack of availability of databases of non-patent prior art literature with traditional knowledge documentation data; the unavailability of classification tools for traditional knowledge which are required in order to integrate traditional knowledge into existing classifications systems of patent documents;[72] and a lack of bibliographic details about traditional knowledge-related gazettes, articles and newsletters in the PCT minimum documentation list.

80. *Possible Task B.3:* The Member States may wish to consider revising existing criteria and developing new criteria which would allow the effective integration of traditional knowledge documentation into searchable prior art.

IV.B.4 Enforcement of rights in traditional knowledge

81. Intellectual property rights for the protection of traditional knowledge will be ineffective unless they are enforceable by traditional knowledge holders in practice. The primary needs arising in this respect can be described in three categories: (i) the availability of fair and equitable procedures concerning the enforcement of intellectual property rights by traditional knowledge holders; (ii) organizational and legal capacity of traditional knowledge holders to enforce their rights, if any; and (iii) institutional arrangements which facilitate the enforcement of intellectual property rights in traditional knowledge.

[Footnote continued from previous page]

of being of assistance in determining that the claimed invention is or is not new and that it does or does not involve an inventive step (i.e., that it is or is not obvious), provided that the making available to the public occurred prior to the international filing date." Of particular importance for traditional knowledge is that, "[w]hen any written disclosure refers to an oral disclosure, use, exhibition, or other means whereby the contents of the written disclosure were made available to the public, and such making available to the public occurred on a date prior to the international filing date, the international search report shall separately mention that fact and the date on which it occurred if the making available to the public of the written disclosure occurred on a date which is the same as, or later than, the international filing date." (Rule 33.1(b), PCT)

[71] Article 15.2, PCT.

[72] The Committee of Experts of the Special Union for the International Patent Classification (IPC), at its Thirteenth Session, held from February 19 to 23, 2001, created a Traditional Knowledge Task Force to elaborate advice on the development of a "Traditional Knowledge Resource Classification" and its relation to the IPC. The Intergovernmental Committee may wish to consider the advice elaborated in the Report of the Task Force.

82. During past WIPO activities,[73] Member States have highlighted that existing procedures concerning the enforcement of intellectual property rights are not perceived to be fair and equitable[74] from the point of view of traditional knowledge holders. They have called for effective and appropriate means for the enforcement of traditional knowledge-related intellectual property rights, taking into account differences in national legislation. The most urgent need in this respect is to reduce the transaction costs for enforcement of their rights by traditional knowledge holders, since at present enforcement and infringement proceedings are prohibitively costly and complicated for them.

83. On the other hand, problems with enforcement go beyond the law and extend to human and other resources within enforcement agencies and traditional communities. A second issue therefore concerns a lack of human resources and organizational capacity among traditional knowledge holders. Economic and social circumstances of local communities are such that they are without the organizational, economic and political strength to embark on a full use of the options provided theoretically by the intellectual property system.

84. At a practical level, communities need to be enabled to enforce the rights they may hold. The few Legal Aid organization which exist, have difficulty raising funds for cases concerning intellectual property. In particular, assistance and training for traditional knowledge holders in the negotiation and enforcement of contracts was highlighted as a priority issue during past WIPO activities.

85. A third enforcement-related issue concerns the need for institutional structures to manage and enforce rights in traditional knowledge. Calls for local institutional strengthening to protect traditional knowledge have often been made. These included the development of multi-sectoral national institutions (including the legal, environmental, trade and economic sectors) for a coordinated exercise and enforcement of rights in traditional knowledge. Proposed models of effective institutional arrangements exist for certain fields of traditional knowledge, such as handicrafts, based on comparative studies of existing institutional arrangements in countries (see paragraph 102 for a detailed description of such proposals).

86. *Possible Task B.4:* The Member States may wish to consider ways of assisting traditional knowledge holders in relation to the enforcement of intellectual property rights, in particular by assisting them to strengthen their capacity to enforce their rights.

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[73] See, Chiang Rai Statement and FFM Report.

[74] The TRIPS Agreement provides that "[p]rocedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated and costly" (Article 41.2).

87. Because folklore constitutes an important part of traditional knowledge, in each of the subsections discussed above certain intellectual property issues arise with regard to the protection of expressions of folklore. The advanced nature of the work on expressions of folklore merits a consideration of these issues on their own terms. These issues are therefore addressed separately in Section IV.C.

88. The Intergovernmental Committee is invited to take note of the foregoing intellectual property issues related to traditional knowledge and to adopt and prioritize tasks on intellectual property and traditional knowledge, in particular those identified in paragraphs 71, 77, 80, and 86, above.

IV.C Expressions of Folklore

89. Expressions of folklore are a subset of traditional knowledge, on the protection of which WIPO has undertaken extensive work over the past thirty years, mostly in cooperation with UNESCO. This work has produced, *inter alia*, the UNESCO-WIPO Model Provisions (1982). These provisions provide a *sui generis* model for intellectual property-type protection of traditional knowledge-related subject matter which has been widely used in WIPO Member States.

90. During the informal consultations referred to in paragraph 1, the Member States considered that the advanced stage of the work on expressions of folklore merits the distinct consideration of this subject matter as a separate theme. They indicated that their experiences since the adoption of the Model Provisions have shown a need for the provisions to be updated in two respects: (i) improving the protection system for tangible expressions of folklore, in particular the important issue of handicrafts, and (ii) extending the protection of expressions of folklore of a given country beyond the borders of the country concerned.

91. The following sections provide a description of (i) the main articles of the Model Provisions, (ii) the issue which the Member States have identified regarding the protection of tangible expressions, in particular handicrafts, and (iii) the issue of extending protection to countries other than the country where an expression of folklore originated.

IV.C.1 The WIPO-UNESCO Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions

92. The Member States began discussions on the protection of folklore at the WIPO Governing Bodies in 1978. At their request, WIPO and UNESCO convened several meetings of a Committee of Governmental Experts, which led to the adoption of the Model Provisions in 1982.

93. The Model Provisions seek to maintain a balance between protection against abuses of expressions of folklore, on the one hand, and of the freedom and encouragement of further development and dissemination of folklore, on the other. They take into account that expressions of folklore form a living body of human culture which should not be stifled by

too rigid protection. It also considered that any protection system should be practical and effective, rather than a system of imaginative requirements unworkable in reality.

94. The Model Provisions do not necessarily have to form a separate law; they might constitute, for example, a chapter of an intellectual property code or of a law dealing with all aspects of the preservation and promotion of national folklore. The Model Provisions are designed with the intention of leaving enough room for national laws to adopt a system of protection best corresponding to the conditions existing in the countries concerned.

Acts against which expressions of folklore are protected

95. There are two main categories of acts against which, under the Model Provisions, expressions of folklore are protected, namely, "illicit exploitation" and "other prejudicial actions." "*Illicit exploitation"* of an expression of folklore is understood in the Model Provisions as any utilization made both with gainful intent and outside the traditional or customary context, without authorization by a competent authority or the community concerned. Section 1 distinguishes between cases where copies of expressions are involved and cases where copies of expressions are not necessarily involved. In the first category of cases, the acts requiring authorization are publication, reproduction and distribution; in the second category of cases, the acts requiring authorization are public recitation, public performance, transmission by wireless means or by wire and "any other form of communication to the public."

96. *"Other prejudicial actions"* which may be detrimental to expressions of folklore are identified as four cases of offenses subject to penal sanctions (Section 6). Firstly, Section 5 requires that, in any printed publications or communication to the public of an *identifiable* expression of folklore, its source be indicated in an appropriate manner by mentioning the community and/or geographic place from where the expression has been derived. Secondly, any unauthorized utilization of an expression of folklore where authorization is required constitutes an offense. Thirdly, misleading the public by creating the impression that an expression of folklore is derived from a given community when, in fact, it is not is also punishable. This is essentially a form of "passing off." Fourthly, it is an offense if, in the case of public uses, expressions of folklore are distorted in any direct or indirect manner "prejudicial to the cultural interests of the community concerned." All four acts mentioned above only qualify as offenses if they are committed willfully.

Authorization of utilizations of expressions of folklore

97. There are two aspects of the authorization of utilization which the Model Provisions regulate, namely (i) the entity entitled to authorize, and (ii) the process of authorization. When the Model Provisions determine the *entity entitled to authorize the utilization* of expressions of folklore, they alternatively refer to "competent authority" and "community concerned," avoiding the term "owner." They do not deal with the question of the ownership of expressions of folklore since this may be regulated in different ways from one country to another. "Competent authority" is to be understood as any person or body entitled to carry out functions specified in the Model Provisions. Authorities may be already existing institutions or newly established ones.

98. Where the community as such is entitled to permit or prevent utilizations of its expressions of folklore the community would act in its capacity as owner of the expressions

concerned.[75] As regards the *process of authorization*, the Model Provisions stipulate that an authorization must be preceded by an application submitted to the competent authority.[76]

99. The Model Provisions allow, but do not make mandatory, collecting *fees for authorizations*.[77] They also determine that the collected fees must be used to promote national folklore or national culture in general.

Sanctions

100. Sanctions should be provided for each type of offense determined by the Model Provisions, in accordance with the penal law of each country concerned. The two main types of possible punishments are fines and imprisonment. Which of these sanctions should apply, what other kinds of punishment could be provided for, and whether the sanctions should be applicable separately or in conjunction, depends on the nature of the offense, the importance of the interests to be protected and the regulations adopted in a given country concerning similar offenses. Consequently, the Model Provisions do not suggest any specific punishment; they are confined to the requirement of penal remedy, leaving it up to national legislation to specify its form and measure. Seizure and other similar measures apply, in the case of any violation of the law, to both objects and receipts.[78]

101. *Possible Task C.1:* As recommended in four Regional Consultations on the Protection of Expressions of Folklore,[79] the Member States may wish to consider updating the UNESCO-WIPO Model Provisions on the Protection of Expressions of Folklore to take into account developments and new forms of commercial exploitation which have evolved since the adoption of the Model Provisions in 1982.

IV.C.2 Protection of handicrafts and other tangible expressions of folklore

102. Most handicrafts are considered to be a part of tangible expressions of folklore. However, the protection of handicrafts poses specific questions for intellectual property, given their particular relevance for the international trade in goods and for the export industries of numerous Member States.[80] Intergovernmental organizations have developed model frameworks for the protection of handicrafts. For example, a proposed "Structural Framework for the Protection of Crafts"[81] has been developed that proposes a tripartite

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[75] There would be no supervisory authority to control how the community exercises its relevant rights.

[76] Section 10(1).

[77] Section 10(2).

[78] Section 7.

[79] For details on the four Regional Consultations on the Protection of Expressions of Folklore, which were convened by WIPO and UNESCO in 1999, see paragraphs 112 and 113. For the recommendations of the four Regional Consultations, see documents WIPO-UNESCO/FOLK/AFR/99/1 ("Resolutions"); WIPO-UNESCO/FOLK/ASIA/99/1 ("Resolutions"); WIPO-UNESCO/FOLK/ARAB /99/1 ("Recommendation"); WIPO-UNESCO/FOLK/LAC /99/1 ("Recommendation").

[80] World imports of the most significant craft item, carpets and kilims, were estimated at US$ 2 billion in1997. *International Trade Forum* Issue 4/1999: 7.

[81] See, Part III, International Trade Center (ITC) and UNESCO. *Overview of Legal and Other Measures to Protect Original Craft Items*. ITC/UNESCO, 1996 (document no. CLT-96/WS/5).

structure, in which existing guild chambers of crafts people and a 'National Society for Original Crafts Items' (NSOCI) would answer to a 'National Crafts Directorate.' Within this institutional arrangement, the NSOCI would be located under the national intellectual property office and would have the task of administering and enforcing intellectual property rights of craftspeople.[82] Such a role could be undertaken by the same institutions which act as the "competent authority" in respect of granting authorizations for the utilization of expressions of folklore, as proposed in the UNESCO-WIPO Model Provisions.

103. At the Thirty-Fourth Series of Meetings of the Assemblies of the Member States of WIPO, held from September 20 to 29, 1999, one Group of WIPO Member States expressed the view "that the need for a suitable mechanism and agreed norms for the protection of handicraft was shared by the developing countries" (A/34/16, paragraph 29). This need was further elaborated by another Group of WIPO Member States at the Twenty-Sixth Session of the WIPO General Assembly, held in Geneva from September 26 to October 3, 2000 (WO/GA/26/9, Annex II) with a view to specific proposals for the work of the Intergovernmental Committee. It was proposed to address two groups of questions pertaining to the protection of handicrafts.

104. The first group of questions contains problems whose solutions could be found within the existing intellectual property system. In this category possible improvements for the protection of handicrafts were mentioned specifically with respect to the following branches of intellectual property law: copyright, industrial designs, trademarks, trade names, geographical indications and appellations of origin. The second category of questions which these Member States suggested the Committee should address were questions which required the creation of new disciplines and provisions so that their protection may be established at the international level. These issues include balancing the private and public domains and recognizing collective rights in respect of the protection of handicrafts.

105. This Group of WIPO Member States proposed two concrete tasks which the Intergovernmental Committee should undertake in respect of protection of handicrafts by the industrial design system: Firstly, the Committee could consider the extent to which style, production methods and other specific characteristics of works of art and textile and three-dimensional craft could be recognized and protected against unauthorized copying, use and commercial exploitation. Secondly, the Committee could study and recommend ways of streamlining the industrial design protection systems embodied in national and regional laws, inclining them towards procedures involving a deposit or registration without any novelty examination or anticipation search.

106. *Possible Task C.2:* The Member States may wish to consider improving the protection of handicrafts and other tangible expressions of folklore by undertaking the tasks proposed by a certain Group of WIPO Member States and referred to in paragraph 105.

IV.C.3 Efforts to establish an international system of *sui generis* protection for expressions of folklore

107. In 1982 the UNESCO-WIPO Model Provisions were adopted with the intention of paving the way for regional and international protection, since many countries consider it of

[82] See, *ibid.*, 10-11.

paramount importance to protect expressions of folklore also beyond the frontiers of the countries in which they originate. By extending their applicability, national provisions might promote regional or international protection.

108. In order to further such a process, the Model Provisions provide for their application to expressions of folklore of foreign origin either subject to reciprocity or on the basis of international treaties.[83] Numerous Member States have, however, stressed that international measures would be indispensable for extending the protection of expressions of folklore of a given country beyond the borders of the country concerned.

109. In 1984 WIPO and UNESCO followed such suggestions when they jointly convened a Group of Experts on the International Protection of Expressions of Folklore by Intellectual Property. The Group of Experts was asked to consider the need for the international protection of expressions of folklore and had at their disposal a draft treaty which was based on the Model Provisions and outlined a similar protection system at the international level, applying the principle of "national treatment." However, at the time a majority of the participants considered it premature to establish an international treaty.

110. In December 1996, the Committee of Experts on a Possible Protocol to the Berne Convention and the Committee of Experts on a Possible Instrument for the Protection of the Rights of Performers and Producers of Phonograms, recommended "that provision should be made for the organization of an international forum in order to explore issues concerning the preservation and protection of expressions of folklore, intellectual property aspects of folklore, and the harmonization of the different regional interests."[84]

111. Accordingly, the "UNESCO/WIPO World Forum on the Protection of Folklore" was held in Phuket, Thailand, in April 1997, and adopted a Plan of Action[85] which records, *inter alia*, that "[t]he participants were of the view that at present there is no international standard protection for folklore and that the copyright regime is not adequate to ensure such protection." It further suggested that "Regional consultative fora should take place" and that a Committee of Experts should be set up, which "should complete the drafting of a new international agreement on the *sui generis* protection of folklore … in view of the possible convocation of a Diplomatic Conference".

112. Pursuant to the first suggestion quoted above, WIPO organized four regional consultations on the protection of expressions of folklore, which were attended in total by 63 Governments of WIPO Member States, 11 intergovernmental organizations, and five non-governmental organizations.[86] Each of the four regional consultations adopted resolutions or recommendations which include proposals for future work.[87] All the four

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[83] Section 14.

[84] See document BCP/CE/VI/16-INR/CE/V/14, paragraph 269.

[85] The Plan of Action records that "[t]he participants from the Governments of the United States of America and the United Kingdom expressly stated that they could not associate themselves with the plan of action."

[86] The regional consultations were held for African countries in Pretoria, South Africa (March 1999), for countries of Asia and the Pacific region in Hanoi, Viet Nam (April 1999); for Arab countries in Tunis, Tunisia (May 1999); and for Latin America and the Caribbean in Quito, Ecuador (June 1999).

[87] See documents WIPO-UNESCO/FOLK/AFR/99/1 ("Resolutions");

[Footnote continued on next page]

regional consultations recommended that WIPO and UNESCO should increase and intensify their work in the field of folklore protection. The recommendations unanimously specify that future work in these areas should include the development of an effective international regime for the protection of expressions of folklore.

113. Recommendations for the legal protection of folklore focused on the development of a *sui generis* form of legal protection at the international level. One consultation stated that "[e]ffective protection of traditional knowledge and folklore at national and international levels requires *sui generis* legislation." It recommended that WIPO and UNESCO should

> "[i]nitiate steps for development of a *sui generis* form of binding legal protection at national and international levels for the protection of traditional knowledge and folklore, taking into account the technological, legal, social, cultural and commercial developments which have taken place since the Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions (1982) were concluded." (Recommendation 3)[88]

It further recommended that WIPO and UNESCO should "[e]stablish a Standing Committee on Traditional Knowledge and Folklore … to facilitate the process of establishing legal protection of folklore and traditional knowledge. The Standing Committee will, *inter alia*, implement Recommendation 3 above." (Recommendation 4). Three of four regional consultations endorsed the recommendation for the establishment of a WIPO Standing Committee to facilitate this future work.[89]

114. *Possible Task C.3:* The Member States may wish to take up the recommendations and resolutions which they developed in the Regional Consultations as described in paragraph 113 and discuss ways forward with those recommendations.

115. The Intergovernmental Committee is invited to take note of the foregoing intellectual property issues related to expressions of folklore and to adopt and prioritize tasks on intellectual property and expressions of folklore, in particular those identified in paragraphs 101, 106, and 114, above.

[Footnote continued from previous page]

WIPO-UNESCO/FOLK/ASIA/99/1 ("Resolutions"); WIPO-UNESCO/FOLK/ARAB /99/1 ("Recommendation"); WIPO-UNESCO/FOLK/LAC /99/1 ("Recommendation"). The four documents are referenced collectively below as the Recommendations, and individually as the African, Asia/Pacific, Arab and LAC Recommendations.

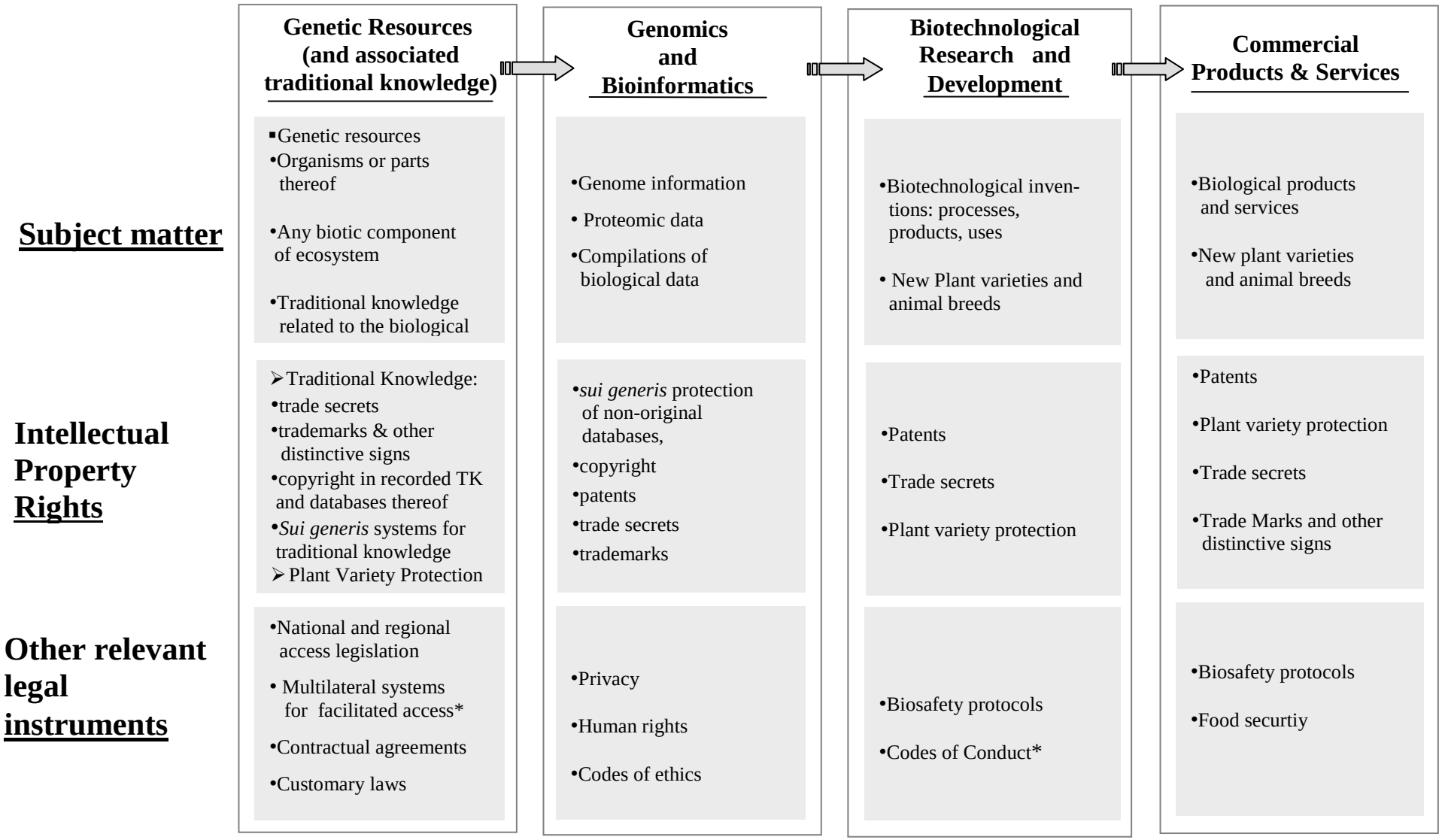
88 Asia/Pacific Recommendation, Recommendation 3.

89 Arab, Asia/Pacific and LAC Recommendations.

ANNEX 1

EX-SITU UTILIZATION OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

Value Chain: value-added downstream

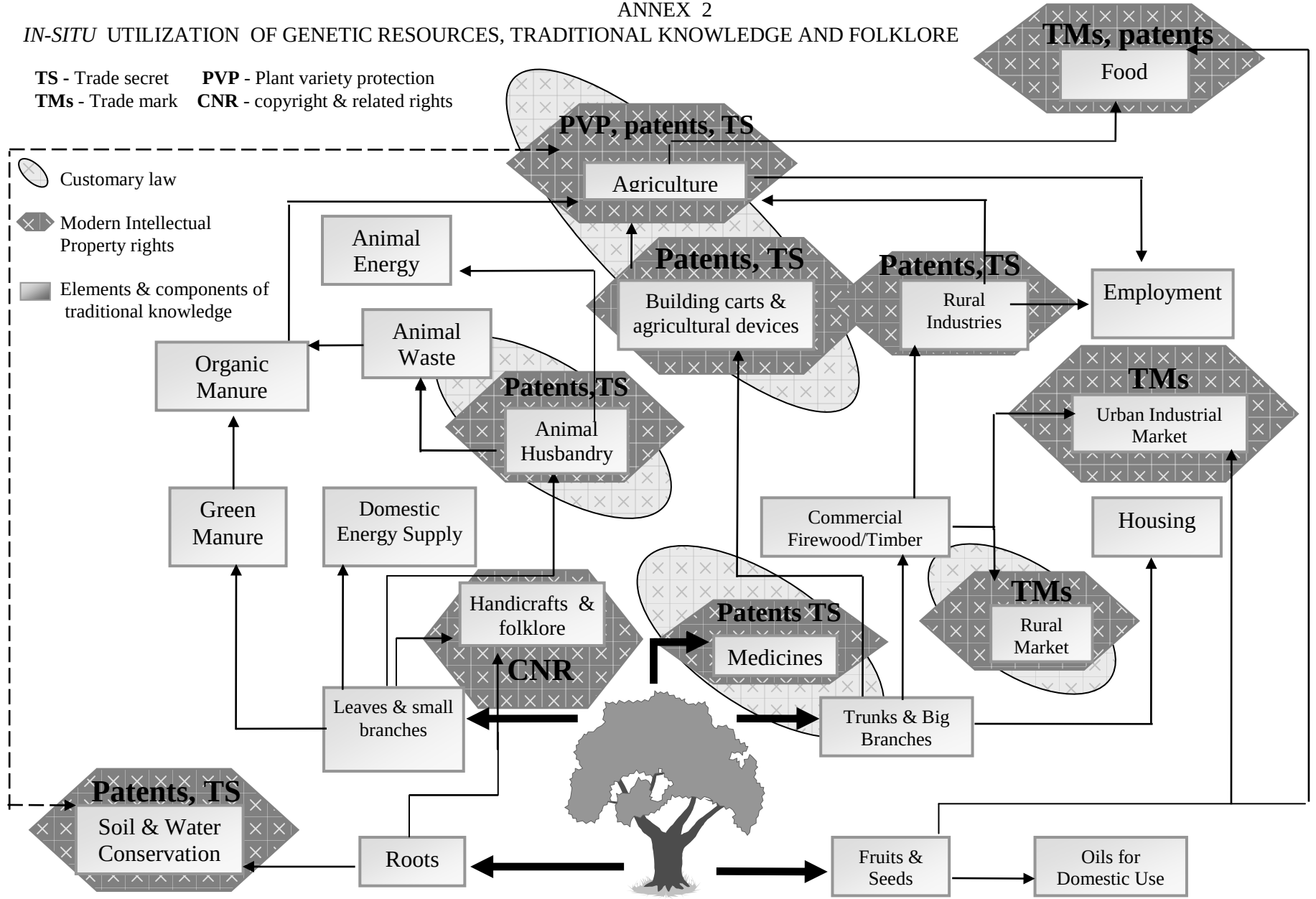


*- Legal instruments under consideration

[Annex 2 follows]

ANNEX 2

IN-SITU UTILIZATION OF GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE



Adapted from Bandyopadhvay, et.al., 1981(C)

[Annex 3 follows]

ANNEX 3

Prevalent Use of Relevant Terms

A. Genetic Resources

(Terms: genetic resources; genetic material; biological resources; plant genetic resources; plant genetic resources for food and agriculture)

In the context of discussions on genetic resources, relevant terms have been defined by international fora working on this theme. In keeping with that prevalent use of terms, for the purposes of this document and unless expressly otherwise stated:

(i) '*genetic resources*' means "genetic material of actual or potential value."[90]

(ii) '*genetic material*' means "any material of plant, animal, microbial or other origin containing functional units of heredity." "Functional units of heredity" are considered to include whole organisms, parts of organisms, and biochemical extracts from tissue samples that contain deoxyribonucleic acid (DNA) or, in some cases, ribonucleic acid (RNA), such as genes, plasmids, etc. The 'functionality' of a 'unit of heredity' is a matter of interpretation which is highly dependent on the evolution of modern biotechnology.[91]

(iii) '*biological resources*' means "genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity."[92] Genetic resources form one category of biological resources.

(iv) '*plant genetic resources*' means "germplasm or genetic material of actual or potential value" in the context of international rules for the exploration and collection of plant genetic resources.[93] The terms "genetic material" or "plant germplasm" in this context mean "reproductive or vegetative propagating material of plants."[94]

(v) in the area of "*plant genetic resources for food and agriculture*" (PGRFA), the term "plant genetic resources"[95] means "the reproductive or vegetative propagating material of the following categories of plants:

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[90] Article 2, CBD.

[91] Article 2, CBD. While it is not specified which actual or potential value of the resource is meant, a range of qualities are listed which confer value to the components of biodiversity, including genetic resources: the Contracting Parties adopted the CBD conscious of "the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of biological diversity and its components." (Preamble, CBD, first recital). The implied distinction between genetic material and genetic resource maybe therefore be of a merely theoretical nature.

[92] Article 2, CBD. Whereas genetic resources are defined as being "of actual or potential value," "biological resources" are defined as resources "with actual or potential *use or* value for humanity."

[93] FAO International Code of Conduct for Plant Germplasm Collecting and Transfer (1993), Article 2.8

[94] Ibid., Article 2.9

[95] International Undertaking on Plant Genetic Resources (1983), Article 2.1(a)

(a) cultivated varieties (cultivars)[96] in current use and newly developed varieties;
(b) obsolete cultivars;[97]
(b) primitive cultivars (landraces);[98]
(d) wild and weed species,[99] near relatives of cultivated varieties; and
(e) special genetic stocks (including elite and current breeders' lines[100] and mutants[101])."

B. Traditional Knowledge

(Terms: indigenous knowledge; indigenous communities, peoples and nations; traditional medicine; traditional knowledge, innovations and practices; traditional and local knowledge, technology, know-how and practices)

In the context of discussions on traditional knowledge, relevant terms have been defined by international fora working on this theme. In keeping with that prevalent use of terms, for the purposes of this document and unless expressly otherwise stated:

(i) "*indigenous knowledge*" refers to the knowledge held by "indigenous peoples."[102]

(ii) "*indigenous communities, peoples and nations*" means "those which, having a historical continuity with 'pre-invasion' and pre-colonial societies that developed on their territories, consider themselves distinct from other sectors of the societies now prevailing in those countries, or parts of them. They form at present non-dominant sectors of society and are determined to preserve, develop and transmit to future generations their ancestral

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[96] 'Cultivars,' or 'cultivated varieties,' are varieties of a plant produced by selective breeding, which has been specifically improved for agricultural or horticultural purposes and is grown in cultivated conditions.

[97] 'Obsolete cultivars' refers to formal and informal cultivated varieties which have fallen into disuse and are no longer on the list of traded varieties in those countries which maintain such lists. This does not necessarily correspond to the formal lists for seed certification.

[98] Primitive cultivars, or landraces, are crops grown under traditional agricultural systems, which have not undergone much improvement and which, in many cases, have developed from landraces selected by farmers. They are often associated with a specific region or indigenous or local communities and are identifiable by vernacular names.

[99] Weeds are plant species which are adapted to grow in disturbed or open habitats.

[100] The terms "current breeders' line" and "elite lines" are overlapping, since, in plant breeding, a "*line*" refer to a group of genetically uniform individuals formed from the selfing of a common homozygotous parent and an "*elite*" refers to germplasm which has been manipulated for use in breeding programs, including advanced, inbred and pure lines.

[101] "*Mutants*," i.e. plants which have acquired a heritable variation as a result of mutation, are created by mutation breeding through the use of mutagenic genetics and are used to create variability within a species and alter characteristics. Some of the altered characteristics may be agriculturally useful and can be further selected by the breeder.

[102] See, Preamble, Draft Declaration on the Rights of Indigenous Populations.

territories, and their ethnic identities, as the basis of their continued existence as peoples, in accordance with their own cultural patterns, social institutions and legal systems."[103]

(iii) "*traditional medicine*" means "the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses. The terms complementary/alternative/non-conventional medicine are used interchangeably with traditional medicine in some countries."[104]

(iv) "*knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity*" or abbreviations of this term generally refer to Articles 8(j), 10(c), 17.2 and 18.4 of the Convention on Biological Diversity (CBD), but are not defined in Article 2, CBD. However, in this context "traditional knowledge" has been noted by the Executive Secretary of the CBD as "a term used to describe a body of knowledge built by a group of people through generations living in close contact with nature. It includes a system of classification, a set of empirical observations about the local environment, and a system of self-management that governs resource use. […] In the context of knowledge, *innovation* is a feature of indigenous and local communities whereby tradition acts as a filter through which innovation occurs. In this context, it is traditional methods of research and application and not always particular pieces of knowledge that persist. *Practices* should therefore be seen as the manifestations of knowledge and innovation."[105]

(v) "*local and traditional knowledge*"[106] and "*traditional and local technology, knowledge, know-how and practices*"[107] generally refer to Articles 16(g), 17.1(c), 18.2(a)-(d) of the United Nations Convention to Combat Desertification in Those Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa. In this context, "traditional knowledge" means subject matter which "consists of practical (instrumental) and normative (enabling) knowledge about the ecological, socio-economic and cultural environment. Traditional knowledge is people-centered (generated and transmitted by people as knowledgeable, competent and entitled actors), systemic (inter-sectoral and holistic), experimental (empirical and practical), transmitted from one generation to the next and

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[103] document E/CN.4/Sub.2/1986/7 and Add. 1-4, "Study of the Problem of Discrimination Against Indigenous Populations," prepared by Special Rapporteur of the United Nations Sub-Commission on Prevention of Discrimination and Protection of Minorities, Mr. J. Martínez Cobo. Further definitions of the terms "indigenous peoples" and "tribal peoples" are contained in Article 1 of the Indigenous and Tribal Peoples Convention of the International Labor Organization (ILO) ("ILO Convention 169). As in document E/CN.4/Sub.2/1986/7 and Add. 1-4, self-identification as indigenous or tribal is regarded as a fundamental criterion for determining the groups to which the provisions of the term apply (ILO Convention 169, Article 2).

[104] See *WHO General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine.* Document WHO/EDM/TRM/2000.

[105] See, UNEP/CBD/TKBD/1/2: paragraphs 84 and 86, emphasis added.

[106] Article 16(g), United Nations Convention to Combat Desertification in Those Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa (1994) ("the UNCCD").

[107] Articles 17.1(c), 18.2(a) and (b), UNCCD.

culturally valorized. This type of knowledge promotes diversity; it valorizes and reproduces the local (internal) resources."[108]

(vi) "*traditional knowledge, innovations and creativity*," refers to the creative and innovative aspect of traditional knowledge systems and a preliminary working definition of this term has been used by WIPO for the purposes of its own work from an intellectual property point of view.[109]

C. Expressions of Folklore

(Terms: folklore; expressions of folklore; verbal expressions of folklore; musical expressions of folklore; expressions by action; tangible expressions of folklore; artisanal products)

In the context of discussions on expressions of folklore, relevant terms have been defined by international fora working on this theme. In keeping with that prevalent use of terms, for the purposes of this document and unless expressly otherwise stated:

(i) "*folklore*" means "all literary, artistic and scientific works created on national territory by authors presumed to be nationals of such countries or by ethnic communities, passed from generation to generation and constituting one of the basic elements of the traditional cultural heritage;"[110]

(ii) "*expressions of folklore*" means "productions consisting of characteristic elements of the traditional artistic heritage developed and maintained by a community of [a country] or by individuals reflecting the traditional artistic expectations of such a community;"[111]

(iii) "*verbal expressions*" include "folk tales, folk poetry and riddles;"

(iv) "*musical expressions*" include "folk songs and instrumental music;"

(v) "*expressions by action*" include "folk dances, plays and artistic forms of rituals;"

(vi) "*tangible expressions*" include "drawings, paintings, carvings, sculptures, pottery, terracotta, mosaic, woodwork, metalware, jewelry, basket weaving, needlework, textiles, carpets, costumes; musical instruments; [architectural forms]."

(vii) "*artisanal products*" means "those produced by artisans, either completely by hand, or with help of hand-tools or even mechanical means, as long as the direct manual contribution of the artisan remains the most substantial component of the finished product.

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[108] See 'Common Understanding of the Term Traditional Knowledge.' Document ICCD/COP(4)/CST/2, paragraph 30.

[109] See, Chapter 5 on 'Terminology' of the *FFM Report*.

[110] See, Section 18.(iv), Tunis Model Law on Copyright for Developing Countries ("the Model Law") (1976)

[111] See, Section 2, UNESCO-WIPO Model Provisions.

These are produced without restriction in terms of quantity and using raw materials from sustainable resources. The special nature of artisanal products derives from their distinctive features, which can be utilitarian, aesthetic, artistic, creative, culturally attached, decorative, functional, traditional, religiously and socially symbolic and significant."[112]

[Annex 4 follows]

[112] This definition was adopted by the UNESCO/ITC International Symposium on Crafts and the International Market: Trade and Customs Codification. Manila, Philippines, October 1999. See, International Trade Center (ITC). *ITC's Strategy for the Promotion of Trade in Artisanal Products from Developing Countries and Economies in Transition.* UNCTAD/WTO, 1999: paragraph 6.

ANNEX 4

Possible tasks which the Member States may wish to set themselves for their discussions in the Intergovernmental Committee, as identified in Section IV of the present document.

A. Genetic Resources

A.1 In order to provide a practical intellectual property contribution to other processes and fora working on genetic resources, the Intergovernmental Committee may wish to consider the development of "guide contractual practices," guidelines, and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing, taking into account the specific nature and needs of different stakeholders, different genetic resources, and different transfers within different sectors of genetic resource policy.

A.2 Considering the previous discussions in WIPO on intellectual property and genetic resources, the proposals of the WIPO Working Group on Biotechnology, and the need expressed in other fora, the Intergovernmental Committee may wish to consider the development of appropriate provisions or guidelines for national patent laws which facilitate consistency with measures of States concerning access to genetic resources and which are consistent with existing international intellectual property standards.

A.3 Based on the above-mentioned developments, the Intergovernmental Committee may wish to consider, subject to the conclusion of the revision of the International Undertaking, the desirability and feasibility of practical and low-cost mechanisms to implement intellectual property-based benefit-sharing arrangements under multilateral systems for access to genetic resources and benefit-sharing, which are consistent with international intellectual property standards and focus in particular on plant genetic resources for food and agriculture.

A.4 Member States may wish to review, on the basis of information compiled in the summary of practices related to the protection of biotechnology inventions in Member States and recalling the work of the SCP, the application of legal standards concerning the availability and scope of patent protection to structures and compositions derived or isolated from naturally occurring living organisms and to early stage biotechnology inventions, with a view to producing guidelines on the application of such standards in the field of genetic resources.

A.5 The Intergovernmental Committee may wish to consider if it is possible to improve the management of genetic resources by exploring methods by which the genetic resources in the form of protected varieties may be integrated into overall plans for effective conservation.

B. Traditional Knowledge

B.1 Based on the current use of relevant terms as set out in Annex 3, the Intergovernmental Committee may wish to delineate the scope of subject matter in respect of which the Member States wish to discuss the application of intellectual property protection, for the purpose of having a definition of the term "traditional knowledge."

B.2 The Member States may wish to compile, compare and assess information on the availability and scope of intellectual property protection for traditional knowledge within the

scope of subject matter which was delimited under Task B.1 and identify any elements of the agreed subject matter which require additional protection.

B.3 The Member States may wish to consider revising existing criteria and developing new criteria which would allow the effective integration of traditional knowledge documentation into searchable prior art.

B.4 The Member States may wish to consider ways of assisting traditional knowledge holders in relation to the enforcement of intellectual property rights, in particular by assisting them to strengthen their capacity to enforce their rights.

C. Expressions of Folklore

C.1 As recommended in four Regional Consultations on the Protection of Expressions of Folklore, the Member States may wish to consider updating the UNESCO-WIPO Model Provisions on the Protection of Expressions of Folklore to take into account developments and new forms of commercial exploitation which have evolved since the adoption of the Model Provisions in 1982.

C.2 The Member States may wish to consider improving the protection of handicrafts and other tangible expressions of folklore by undertaking the tasks proposed by a certain Group of WIPO Member States.

C.3 The Member States may wish to take up the recommendations and resolutions which they developed in the Regional Consultations on the Protection of Expressions of Folklore and discuss ways forward with those recommendations.

[End of Annex 4 and of document]