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**INTERGOVERNMENTAL COMMITTEE ON
INTELLECTUAL PROPERTY AND GENETIC RESOURCES,
TRADITIONAL KNOWLEDGE AND FOLKLORE**

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**OPERATIONAL PRINCIPLES FOR INTELLECTUAL PROPERTY CLAUSES OF
CONTRACTUAL AGREEMENTS CONCERNING ACCESS TO GENETIC RESOURCES
AND BENEFIT-SHARING**

Document prepared by the Secretariat

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1. At the first Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“the Committee”), held in Geneva from April 30 to May 3, 2001, the Member States determined the agenda of items on which work should proceed and prioritized certain tasks for the Committee.¹ Under Agenda Item 5.1, “Intellectual Property and Genetic Resources,” the Co-Chair concluded “that it was his sense that task A.1 had been supported by almost all speakers.”² By supporting Task A.1, as identified in document WIPO/GRTKF/IC/1/3,³ the Member States expressed their 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. The present document provides information on existing contractual practices for access and benefit-sharing and related intellectual property clauses, and proposes a two-phased approach for the development of model intellectual property clauses. Since access and benefit-sharing contracts are currently being used for genetic resource transfers in an almost limitless range of situations, the present document solicits directions and decisions from the Member States as to the concrete scenarios and variables for access and benefit-sharing which they wish to address as a matter of priority through the guide practices and model clauses, and provides certain options for operational principles for the development of such guide contractual practices and model intellectual property clauses.

I. INTRODUCTION

2. The task which the Member States supported under Agenda Item 5.1 of the first Session reads as follows:

“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.”

3. According to this task description, the development of guide contractual practices, guidelines and model intellectual property clauses would have to take into account the following considerations, *inter alia*:

- other processes and fora working on genetic resources,
- different sectors of genetic resource policy,
- different access and benefit-sharing frameworks,
- the specific needs of different stakeholders,
- different types of genetic material,
- different types of transfers and uses of genetic resources.

¹ See document WO/GA/26/6, paragraph 17.

² See document WIPO/GRTKF/IC/1/13, paragraph 128. On Task A.1, see in particular paragraphs 25, 48, 49, 61, 107, 108, 109, 110, 111, 113, 114, 116, 118, 121, 123, 124, 125, 126, 127, 130, 132, 148, 154 and 161.

³ See document WIPO/GRTKF/IC/1/3, paragraph 41.

The present document provides background information on the intellectual property aspects of each of these elements, as a basis for the discussions of the Intergovernmental Committee.

4. Contractual arrangements for access and benefit-sharing consist of enforceable agreements between the provider and recipient of the transferred genetic material which create specific rights and obligations for each party. As agreements, they take a wide variety of forms, ranging from letter statements attached to a shipment of germplasm, over Memoranda of Understanding, to detailed and formally negotiated contracts covering extensive cooperation programs between the parties. Contracts are being used for the transfer of a growing range of genetic resources for commercial or non-commercial purposes, or a combination thereof. An increasing number of stakeholders and access frameworks are using contractual agreements for their genetic resource transfers. Such stakeholders include public sector research institutions and private sector companies in all sectors utilizing genetic resources, indigenous peoples and local communities, as well as gene banks and other *ex situ* collections such as botanical gardens. In the estimation of an international expert group, an “almost limitless combination of users, uses and potential uses of genetic resources as a result of the rapid developments in science and technology” has created “a pressing need for flexibility in requirements for mutually agreed terms in contracts.”⁴

5. As the intellectual property aspects for genetic resource utilization become increasingly significant for numerous stakeholders and for the achievement of sectorially specific policy objectives, such as food security, biodiversity conservation, etc., increasing confusion and controversy have surrounded the intellectual property clauses of such contractual agreements. 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. As the relevant body of the United Nations responsible for intellectual property, the Intergovernmental Committee of WIPO has been mandated by the Member States to develop guide contractual practices, guidelines and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing.

6. As Task A.1 indicates, the Committee, when developing guide contractual practices and model intellectual property clauses, would need to take into account the specificities of genetic resource policy that attaches to various sectors, stakeholders and different uses of such materials. Recognizing the need for practical and effective tools to manage intellectual property-related aspects of access to genetic resources, the present document aims to observe the following principles when developing guide contractual practices and model IP clauses:

- (a) simplicity, so that the clauses and guide practices will be accessible to all stakeholders;
- (b) flexibility, so that they can be applied to diverse genetic resource transfers;
- (c) consistency with existing intellectual property standards;
- (d) consistency with the work of other genetic resource fora, such as the CBD, the FAO and its inter-governmental Commission on Genetic Resources for Food and Agriculture. To ensure such consistency the present document takes account of comments of the Secretariats of the CBD, FAO and CGIAR⁵;

⁴ See document UNEP/CBD/COP/5/8, paragraph 102.

⁵ Provided by the International Plant Genetic Resources Institute (IPGRI).

(e) incorporation of process criteria regarding the development of contracts, in particular where there are imbalances in bargaining power or access to information between the parties;

(f) application of typologies, criteria and concepts which are based on the results and conclusions of expert fora in the field of genetic resources;

(g) a cautious approach, in the sense of assessing and examining existing practices and clauses as a first step, and then developing guide contractual practices or model IP-clauses from those existing practices as a second step.

7. Due to “the almost limitless combination of users and uses,” referred to above, it will not be possible to address all types of contractual agreements for access to genetic resources and benefit-sharing at the same time. In addressing the range of different types of contracts this document is based on certain terminological and substantive considerations:

(a) In accordance with the prevalent use of terms, the present document uses the term *material transfer agreement (MTA)* to refer to legal instruments governing “every exchange of genetic resources on a contractual basis, regardless whether benefit-sharing is part of that agreement.”⁶ For example, the private sector has been using the term for a long time for all contracts structuring transactions involving genetic material. In contrast, the terms *access and benefit-sharing agreement* or *contractual agreement on access to genetic resources and benefit-sharing* “describe contracts which additionally take the provisions of the Convention on Biological Diversity (CBD) into account.”⁷

(b) Most genetic resource exchanges involve multiple actors and are not limited to a simple provider/user relationship.⁸ Contractual agreements for access and benefit-sharing, including their intellectual property clauses, need to reflect this complexity in such a way that relevant rights and responsibilities survive the duration of the contract and are transferred to third parties, as appropriate.⁹ Therefore the terms *provider/recipient*, rather than provider/user, are employed in the course of this document to designate the transferor and transferee of the genetic material.

(c) In order to take into account the status and specificities of genetic resource policy in different sectors, the present document refers in detail to recent developments and ongoing work in the specialized fora and processes for access to genetic resources and benefit-sharing.¹⁰

(d) The present document recognizes that the substantive issues concerning contractual agreements for access to genetic resources and benefit-sharing are highly complex and have been subject of differing opinions in other fora. Mindful of such differing views, the document proposes to address the development of guide contractual practices in a purely technical manner. Bearing in mind that contractual agreements are not in themselves intellectual property rights instruments, the document seeks to identify and provide a factual and technical account of the intellectual property issues arising in the context of contractual agreements for access and benefit-sharing. It limits itself exclusively to the intellectual

⁶ See document UNEP/CBD/COP/4/23, paragraph 49, footnote 1.

⁷ *Ibid.*, footnote 1.

⁸ See document UNEP/CBD/COP/5/8, paragraph 67.

⁹ See document UNEP/CBD/COP/5/8, paragraph 69.

¹⁰ For example bodies, such as the Conference of the Parties, the Subsidiary Body on Scientific, Technical and Technological Advice and the Panel of Experts and *Ad Hoc* Open-ended Working Group on Access and Benefit-sharing of the Convention on Biological Diversity and the Commission on Genetic Resources for Food and Agriculture of the United Nations Food and Agriculture Organization. See Section II.B below.

property-specific elements and leaves other aspects of such agreements to the relevant international fora and processes.

8. The present document provides background information for the discussions of the Member States on Task A.1 in the following structure. Part II provides the institutional background of this task by reviewing the past work of WIPO and other relevant organizations in the field of genetic resources. Part III contextualizes contractual agreements on access to genetic resources and benefit-sharing, describing some roles and implications of contractual agreements and their intellectual property clauses within various frameworks for access and benefit-sharing. Part IV of the document provides a sampling of intellectual property clauses from existing contractual agreements which have been analyzed and referred to in previous WIPO documents. Whereas Part IV provides illustrations of existing contractual practices and their intellectual property clauses, Part V addresses the development of guide contractual practices and model intellectual property clauses, in order to solicit further decisions, prioritization and guidance from the Member States on the implementation of Task A.1. Section V.A identifies a set of variables which may be used to systematically describe the almost limitless scenarios of contractual agreements and requests an indication from the Committee as to which variables and scenarios it wishes to address as a matter of priority. Section V.B invites the Committee members to formulate operational principles which should be taken into account in the development of guide contractual practices and model intellectual property clauses, and offers four possible principles. Finally, Section V.C proposes a two-phased approach for next steps towards the implementation of Task A.1, for the consideration of the Member States. Annex 1 provides a glossary of genetic resource terminology, as requested by the Member States at the first Session of the Committee.

II. INSTITUTIONAL BACKGROUND

9. The interfaces between genetic resource policy and intellectual property are complex and multi-dimensional. Different institutions have addressed different aspects thereof, in accordance with their respective mandates and technical expertise. In accordance with its expertise in the field of intellectual property, WIPO's Intergovernmental Committee provides a forum in which the Member States can discuss the intellectual property-specific aspects of access to genetic resources and benefit-sharing. However, in order to avoid duplication of work and maintain a comprehensive view of the multi-dimensional aspects of genetic resource policies before the Committee, the Member States have requested at the first Session of the Committee,¹¹ that WIPO should coordinate its work closely with other relevant intergovernmental fora which are active in the field of genetic resources, in particular the CBD and the United Nations Food and Agriculture Organization (FAO). Following this request by the Member States, the present document takes account of the comments of the Secretariat of the CBD, the FAO Secretariat through its Commission on Genetic Resources for Food and Agriculture, and the Consultative Group for Agricultural Research (CGIAR) through the International Plant Genetic Resources Institute (IPGRI).¹² Through this close institutional cooperation, any work of the Intergovernmental Committee will be consistent with, and complementary to, the work that is being done in the framework of the CBD, the FAO and other international genetic resource fora.

¹¹ See document WIPO/GRTKF/IC/1/13, paragraphs 21, 22, 23, 27, 28, 32, 33, 37, 39, 41, 43, 50, 51, 52, 57, 61, 82, 84, 91, 94, 104, 105, 106, 107, 112, 114, 119, 128 and 155.

¹² Nevertheless, any inaccuracy or incompleteness remains entirely the responsibility of WIPO.

10. Section II.A recalls WIPO's past work on intellectual property and genetic resources, in particular those activities which touched upon intellectual property and contractual agreements. Section II.B, following the instructions of the Member States for close consideration of the work done by the CBD and FAO, reviews the CBD and FAO processes and their history in some detail, as far as they concern intellectual property and contractual agreements for access and benefit-sharing.

II.A WIPO's past work¹³

11. WIPO's 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 by WIPO's Main Program 11 on "Global Intellectual Property Issues" and the United Nations Environment Programme (UNEP). The project 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. The case studies were jointly submitted by WIPO and UNEP to the fifth Conference of the Parties (COP) to the CBD, which took place in Nairobi, Kenya, from May 15 to 26, 2000.

12. 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 the 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.¹⁴

13. 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.

14. 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

¹³ The WIPO documents, reports and studies referred to in Section II.A are available at the WIPO WebPage on 'Global Intellectual Property Issues' <<http://www.wipo.int/globalissues>>, or in paper form, upon request.

¹⁴ See document SCP/3/11, paragraph 208.

of appropriate legal and technical studies, and through the setting up of an appropriate forum within WIPO for future work.”

15. 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 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.”

16. 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 the Intergovernmental Committee should be created and at the Twenty-Sixth Session of the General Assembly, held from September 25 to October 3, 2000, the Member States decided to establish the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.¹⁵

17. The first Session of the Intergovernmental Committee was held in Geneva from April 30 to May 3, 2001. Under Agenda Item 5.1, “Intellectual Property and Genetic Resources,” the Committee considered several possible tasks on intellectual property and genetic resources, as identified in document WIPO/GRTKF/IC/1/3,¹⁶ and the Co-Chair concluded “that it was his sense that task A.1 had been supported by almost all speakers.”¹⁷

II.B Relevant International Fora and Processes

18. Discussions concerning contractual agreements on access to genetic resources and benefit-sharing and their intellectual property clauses have taken place in numerous fora, including the Conference of the Parties (COP), the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), the Intersessional Meetings on the Operations of the Convention (ISOC), the Panel of Experts on Access and Benefit-sharing and the *Ad-hoc* Open-ended Working Group on Access and Benefit-sharing¹⁸ of the Convention on Biological Diversity (CBD); the Commission on Genetic Resources for Food and Agriculture (CGRFA) of the United Nations Food and Agriculture Organization (FAO), including in the context of the current negotiations for the revision of the International Undertaking on Plant Genetic Resources, as well as in the Commission’s Intergovernmental Technical Working Group on Animal and on Plant Genetic Resources for Food and Agriculture. Furthermore, the various International Agricultural Research Centers (IARCs) of the Consultative Group on International Agricultural Research (CGIAR) have adopted policies or resolutions regarding intellectual property and its relationship to access and benefit-sharing contracts for genetic

¹⁵ See document WO/GA/26/6 and WO/GA/26/10, paragraph 71.

¹⁶ See document WIPO/GRTKF/IC/1/3, paragraph 41.

¹⁷ See document WIPO/GRTKF/IC/1/13, paragraph 128. On Task A.1, see in particular paragraphs 25, 48, 49, 61, 107, 108, 109, 110, 111, 113, 114, 116, 118, 121, 123, 124, 125, 126, 127, 130, 132, 148, 154 and 161.

¹⁸ The Working Group will hold its first meeting in Bonn, Germany, from October 22 to 25, 2001. While the Report of the meeting was not available at the time of issuance of this document, it will be by the time of the second Session of the Intergovernmental Committee.

resources. Section II.B reviews the discussions in these fora and processes, as far as they are relevant to the development of guide contractual practices and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing.

II.B.1 Convention on Biological Diversity (CBD)

19. Besides recognizing the authority of national governments to determine access to genetic resources, Article 15, CBD, provides that “access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.”¹⁹ The Executive Secretary of the CBD has noted that “contracts are the most common way of recording ‘mutually agreed terms’.”²⁰

20. Discussions on the implementation of such terms began at the second Conference of the Parties (COP), held in Jakarta, Indonesia, from November 6 to 17, 1995, which considered a Report including ‘Possible elements of guidelines on mutually agreed terms.’²¹ The possible elements which were suggested to Parties for inclusion in access and benefit-sharing arrangements included, *inter alia*, “agreeing on respective *intellectual property rights* over the genetic resources and technologies developed using them.”²² In Decision II/11, the COP requested to further elaborate the survey of measures taken by governments to implement Article 15.

21. Further to this request, the third COP, held in Buenos Aires, Argentina, from November 4 to 15, 1996, considered an elaboration of the survey which noted that “inherent in the phrase “mutually agreed terms” is the expectation of a negotiation between the Party providing genetic resources and a potential user. This aspect of mutually agreed terms points ... to the importance of defining particular elements or features that each agreement should contain.”²³ Consequently, Decision III/15 “*encourages* Governments ... to explore and develop ... guidelines and practices to ensure mutual benefits to providers and users of access measures” and to “conduct analyses of ongoing experiences,” including with intellectual property rights, and to provide information on them.²⁴

22. A note by the Executive Secretary for the fourth COP, observes that “[i]n the absence of access legislation, contracts between providers and users of genetic resources can introduce and clarify benefit-sharing obligations. Even in those countries where access and benefit-sharing measures are in place, these measures often require individual arrangements to be captured in a contract²⁵. Material transfer agreements frequently clarify royalty sharing arrangements between the various parties, and can be a tool for allocating benefits among beneficiaries.”²⁶ Following consideration of these developments, the COP decided in Decision IV/8 to establish a Panel of Experts with the mandate “to draw upon all relevant sources ... in the development of a common understanding of basic concepts and to explore all options for access and benefit sharing on mutually agreed terms including guiding

¹⁹ Article 15.4, CBD.

²⁰ See document UNEP/CBD/COP/4/22, paragraph 32.

²¹ See document UNEP/CBD/COP/2/13, Section H, paragraphs 90 to 92.

²² See document UNEP/CBD/COP/2/13, paragraph 90(d).

²³ See document UNEP/CBD/COP/3/20, paragraph 47.

²⁴ See Decision III/15, paragraphs 5 and 4, respectively.

²⁵ See, for example, the Philippines Executive Order and Implementing Regulations, and Decision 391 of the Andean Pact.

²⁶ See document UNEP/CBD/COP/4/22, paragraph 31.

principles, guidelines, and codes of best practice for access and benefit-sharing arrangements.”²⁷ The Decision lists certain elements which these options might address, such as “[m]utually agreed terms including on benefit-sharing *and intellectual property rights* and technology transfer, where appropriate.”²⁸

23. The Panel of Experts on Access and Benefit-sharing, at its first meeting, held in San José, Costa Rica, from October 4 to 8, 1999, concluded that one of the “key lessons with respect to promoting mutually agreed terms in access and benefit-sharing arrangements” is that “Contractual agreements, for the moment, are the main mechanism for gaining access to genetic resources and delivering benefits.”²⁹ Considering that transaction costs have a significant impact on actual use of genetic resources, the Panel identified “standardized Material Transfer Agreements” as one of the mechanisms to reduce transaction costs.³⁰

24. The Panel agreed that “because of the enormous differences in the circumstances of particular cases of access and benefit-sharing, as well as the evolving nature of the legal regimes to implement the Convention, it would be premature for the Conference of the Parties to develop principles for contractual arrangements.”³¹ Nevertheless, the Panel felt that there are “a number of aspects of ... contractual arrangements for which a common understanding has emerged which could be the basis of any guidelines for such terms and arrangements.”³² In order for stakeholders to have access to relevant information, it was recommended that “[b]etter access to examples of actual contracts, codes of conduct and voluntary guidelines would assist those involved in the process of achieving mutually agreed terms.”³³ The present document provides this kind of examples of actual contracts in Part IV.

25. The fifth COP in Decision V/26 and after considering the Report of the Expert Panel decided, *inter alia*, to establish an *Ad Hoc* Open-Ended Working Group on Access and Benefit-sharing. The Working Group has “the mandate to develop guidelines and other approaches for submission to the Conference of the Parties and to assist Parties and stakeholders in addressing the following elements as relevant to access to genetic resources and benefit-sharing, *inter alia*: terms for prior informed consent and mutually agreed terms; roles, responsibilities and participation of stakeholders; relevant aspects relating to *in situ* and *ex situ* conservation and sustainable use; mechanisms for benefit-sharing, for example through technology transfer and joint research and development; and means to ensure the respect, preservation and maintenance of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity, taking into account, *inter alia*, work by the World Intellectual Property Organization on intellectual property rights issues. The above-mentioned elements should, in particular, serve as inputs when developing and drafting: (a) Legislative, administrative or policy measures on access and benefit-sharing; and (b) Contracts or other arrangements under mutually agreed terms for access and benefit-sharing.”³⁴ Furthermore, the COP decided that one of four “key capacity-building needs” for

²⁷ Decision IV/8, paragraph 3.

²⁸ Decision IV/8, Annex, item 4. Emphasis added.

²⁹ See document UNEP/CBD/COP/5/8, paragraphs 50 and 53.

³⁰ See document UNEP/CBD/COP/5/8, paragraph 56(d).

³¹ See document UNEP/CBD/COP/5/8, paragraph 51.

³² See document UNEP/CBD/COP/5/8, paragraph 52.

³³ See document UNEP/CBD/COP/5/8, paragraph 72.

³⁴ See Decision V/26, paragraph 11.

all stakeholders are contract negotiation skills.³⁵ Finally, the COP also decided to reconvene the Panel of Experts with an extended mandate.

26. The second Meeting of the Panel of Experts on Access and Benefit-sharing, which met in Montreal, Canada, from March 19 to 22, 2001, in accordance with Decision V/26 considered a Note by the Executive Secretary which highlighted certain aspects of developing instruments to assist in the elaboration of fair and equitable contractual arrangements, such as guidelines or model agreements. These aspects of instruments such as model agreements include, *inter alia*, the following:

- To reduce transaction costs, measures could include standard Material Transfer Agreements and Umbrella Agreements, under which repeat access under expedited arrangements can be made;
- Mutually agreed terms should also include provisions on user obligations;
- Different resources and uses require different contractual arrangements. Therefore, to the extent possible, commercial arrangements should be anticipated at the outset.
- Benefits are often generated from the commercialization of derivatives that use genetic resources as a source of innovation, such as synthesized products. In these instances, for fair and equitable benefit-sharing, it is important that the scope of contracts include the full range of biotechnology applications in addition to biological resources accessed;
- In order to reflect the increasing role of intermediaries in contractual arrangements and access-permitting mechanisms, a flexible and simple approach to protect the interest of all parties should be elaborated;
- Parties should be aware of relevant agreements that may pre-date an agreement under development.³⁶

27. In its Report the Expert Panel reached the following conclusion on the intellectual property clauses of access and benefit-sharing contracts: “intellectual property clauses also play a fundamental role in such agreements. There is therefore a need for awareness and capacity-building at all levels, as well as a need to develop up-to-date model intellectual property right clauses. WIPO may be a relevant organization to assist in this regard for these purposes.”³⁷

28. The Report of the second Meeting of the Panel of Experts will be submitted to the first session of the *Ad Hoc* Open-ended Working Group on Access and Benefit-Sharing. The first Session of the Working Group is scheduled to take place in Bonn, Germany, from October 22 to 26, 2001, and the Report of that meeting will be available when the Intergovernmental Committee meets in December 2001.

³⁵ See Decision V/26, paragraph 14(b). This Decision of the COP coincides with the conclusions and recommendations of the WIPO Report on the Intellectual Property Needs of Traditional Knowledge Holders, which concludes that capacity building in contract negotiation skills is a critical need of stakeholders in traditional knowledge and associated genetic resources. For further details, see Section IV.B of this document.

³⁶ See document UNEP/CBD/ABS-EP/2/2, paragraph 37(a)-(g).

³⁷ See document UNEP/CBD/WG-ABS/1/2, paragraph 77(d).

II.B.2 Food and Agriculture Organization (FAO)

29. The FAO, through its Commission on Genetic Resources for Food and Agriculture (CGRFA), coordinates and oversees the development of the Global System on Plant Genetic Resources for Food and Agriculture (“PGRFA”), which includes the currently non-binding International Undertaking on Plant Genetic Resources (1983), the periodic Report on the State of the World’s Plant Genetic Resources for Food and Agriculture, the rolling Global Plan of Action, the World Information and Early Warning System, Codes of Conduct and Guidelines for the Collection and Transfer of Germplasm, the International Network of *Ex Situ* Collections Under the Auspices of the FAO, and networks for *in situ* conservation and crop-related networks. Two components of this Global System refer explicitly to contractual agreements for access to PGRFA and benefit-sharing and are of particular relevance in the context of the present document, namely the International Undertaking on Plant Genetic Resources, as it has currently been re-negotiated, and the International Code of Conduct for Plant Germplasm Collecting and Transfer (1993). Moreover, in the implementation of the International Network of *Ex Situ* Collections under the Auspices of FAO, twelve International Agricultural Research Centres of the Consultative Group on International Agricultural Research (CGIAR) signed agreements with FAO in 1994, placing most of their accessions in the International Network. Through these agreements,³⁸ the Centres recognised the “intergovernmental authority of FAO and its Commission in setting policies for the International Network”. They agreed to hold the designated germplasm “in trust for the benefit of the international community” and “not to claim ownership, or seek intellectual property rights, over the designated germplasm and related information”. The Regional Collection of the International Coconut Genetic Resources Network (COGENT), held by the Governments of India, Indonesia and Côte d’Ivoire have also, since October 1998, been brought into the Network. As noted in section II.B.2(a) below, these matters will now be governed by Article 16 of the revised International Undertaking.

II.B.2(a) International Undertaking On Plant Genetic Resources

30. The International Undertaking was the first comprehensive international agreement dealing with genetic resources for food and agriculture. It was adopted by the FAO Conference in 1983 as an instrument to promote harmony in matters regarding access to plant genetic resources for food and agriculture.³⁹ The Undertaking sought to “ensure that plant genetic resources of economic and/or social interest, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and scientific purposes”.⁴⁰

31. Resolution 3 of the Nairobi Final Act, adopted at the same time as the agreed text of the CBD in May 1992, recognized the need to seek solutions to outstanding matters concerning plant genetic resources, in particular access to *ex situ* collections not addressed by the Convention and the question of Farmers’ Rights.⁴¹ It requested that these matters be addressed within FAO’s forum. In 1993, the FAO Conference adopted Resolution 7/93,

³⁸ Available at <<http://www.fao.org/ag/cgrfa/exsitu.htm>>.

³⁹ See Resolution 8/83 of the Twenty-second Session of the FAO Conference, November 23, 1983.

The International Undertaking forms the Annex to Resolution 8/83.

⁴⁰ Article 1, International Undertaking (1983).

⁴¹ See paragraph 4 of Resolution 3 the Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity.

which requested FAO to provide a forum for inter-governmental negotiations for the revision of the International Undertaking for:

- (a) the adaptation of the International Undertaking on Plant Genetic Resources, in harmony with the CBD;
- (b) consideration of the issue of access on mutually agreed terms to plant genetic resources, including *ex situ* collections not addressed by the CBD; and
- (c) the issue of the realization of Farmers' Rights.

32. The negotiations for the revision of the Undertaking began in November 1994 at the First Extraordinary Session of the CGRFA⁴² and have lasted for seven years. At its Sixth Extraordinary Session, held from June 25 to 30, 2001, the Commission on Genetic Resources for Food and Agriculture adopted the revised International Undertaking, and forwarded it to the Thirty-first Session of the FAO Conference, due to take place in November 2001, for approval as a new legally binding instrument.⁴³

33. Part IV of the draft International Undertaking establishes a Multilateral System of Access and Benefit-Sharing ("the Multilateral System").⁴⁴ This Multilateral System applies to a list of crops decided on the basis of their importance for food security, and in regard of which countries are interdependent.⁴⁵ Crops not on this list are not covered by the Multilateral System. For crops on the list, Article 13.4 of the International Undertaking provides that "facilitated access ... shall be provided pursuant to a standard material transfer agreement (MTA), which shall be adopted by the Governing Body and contain ... the benefit-sharing provisions set forth in Article 14.2d(ii) and other relevant provisions of this Undertaking, and the provision that the recipient of the plant genetic resources for food and agriculture shall require that the conditions of the MTA shall apply to the transfer of plant genetic resources for food and agriculture to another person or entity, as well as to any subsequent transfers of those plant genetic resources for food and agriculture."

34. Under Article 14.2d, which concerns the sharing of monetary and other benefits of commercialization, "Contracting Parties agree that the standard Material Transfer Agreement referred to in Article 13.4 shall include a requirement that a recipient who commercializes a product that is a plant genetic resource for food and agriculture and that incorporates material accessed from the Multilateral System, shall pay to the mechanism referred to in Article 20.3f,⁴⁶ an equitable share of the benefits arising from the commercialization of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make

⁴² At that time still known as the "Commission on Plant Genetic Resources." See document CPGR-Ex1/94/3 for the agreed Mandate, Context, Background and Proposed Process of the revision of the International Undertaking.

⁴³ The text of the International Undertaking as adopted by the Commission is in Appendix B of the Report of that Session (document CGRFA-Ex6/01/REP), available at <http://www.fao.org/ag/cgrfa/docsex6.htm>.

⁴⁴ See the draft text of the revised International Undertaking as adopted by the CGRFA and forwarded to the Director General of FAO for presentation to the FAO Committee on Constitutional and Legal Matters and the FAO Conference, for finalization and adoption, as contained in document CGRFA-Ex6/01/REP.

⁴⁵ The list of crops agreed until now is given in CGRFA-Ex6/01/REP, Appendix B, Annex 1.

⁴⁶ Article 20.3f establishes "as needed, an appropriate mechanism, such as a Trust Fund Account, for receiving and utilising financial resources that will accrue to it for purposes of implementing this Undertaking."

such payment.”⁴⁷ As regards the level of payment, the same Article further specifies that “The Governing Body shall, at its first meeting determine the level, form and manner of the payment, in line with commercial practice. The Governing Body may decide to establish different levels of payment for various categories of recipients who commercialize such products; it may also decide on the need to exempt from such payments small farmers in developing countries and in countries with economies in transition. The Governing Body may, from time to time, review the levels of payment with a view to achieving fair and equitable sharing of benefits, and it may also assess, within a period of five years from the entry into force of this Undertaking, whether the mandatory payment requirement in the MTA shall apply also in cases where such commercialized products are available without restriction to others for further research and breeding.”⁴⁸

35. The Undertaking also addresses the obligations of Contracting Parties to make available legal recourse for the enforcement of such MTAs. It provides that, “Contracting Parties shall ensure that an opportunity to seek recourse is available, consistent with applicable jurisdictional requirements, under their legal systems, in case of contractual disputes arising under such MTAs, recognizing that obligations arising under such MTAs rest exclusively with the parties to those MTAs.”⁴⁹

36. Part V of the International Undertaking establishes “Supporting Components” and includes Article 16, *Ex Situ* Collections of Plant Genetic Resources for Food and Agriculture held by the International Agricultural Research Centers of the Consultative Group on International Agricultural Research and other International Institutions.⁵⁰ These provisions will supplant the current agreements between FAO and the Centers. The intellectual property provisions and other details of the standard MTA currently in use by the IARCs to implement the provisions of these agreements in the transfer of germplasm designated under these agreements is provided under Section II.B.3 below.

II.B.2(b) International Code of Conduct for Plant Germplasm Collecting and Transfer

37. The second component of the Global System on Plant Genetic Resources for Food and Agriculture which refers to access and benefit-sharing contracts is the FAO International Code of Conduct for Plant Germplasm Collecting and Transfer (1993). The objective of the Code is to provide a framework which governments may use in developing national regulations or formulating agreements for the collection of germplasm. Many countries have used the Code in this way. The Code is in line and fully compatible with both the CBD and the International Undertaking. It provides guidelines for the requesting of permits by collectors and for the issuance of such permits by State authorities, and it sets out minimum responsibilities of collectors, sponsors, curators and users of collected germplasm, covering both the collecting and the transfer of germplasm. The Code was negotiated by the Commission on Genetic Resources for Food and Agriculture and adopted by the 1993 FAO Conference as a voluntary instrument. It was agreed that the Code should be adapted to changing needs and circumstances, and updated or amended when appropriate through the Commission.⁵¹

⁴⁷ See Article 14.2(d)(ii), IU. See, document CGRFA-Ex6/01/REP.

⁴⁸ *Ibid.*, 14.2(d)(ii), paragraph 2.

⁴⁹ See Article 14.2(d)(iii), IU.

⁵⁰ See Article 16, IU.

⁵¹ The Code of Conduct is available at <<ftp://ext-ftp.fao.org/waicent/pub/cgrfa8/GS/CCgermpE.pdf>>.

38. In particular, the Code of Conduct 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.”⁵²

II.B.3 International Agricultural Research Centers (IARCs) of the Consultative Group on International Agricultural Research (CGIAR)

39. The CGIAR was created in 1971 and has as its mission “to contribute to food security and poverty eradication in developing countries through research, partnership, capacity building, and policy support, promoting sustainable agricultural development based on the environmentally sound management of natural resources.”⁵³ It currently includes sixteen International Agricultural Research Centers (IARCs). At the International Centers’ Week in 1988 the CGIAR adopted the ‘CGIAR Policy on Plant Genetic Resources,’ which stated that the collections which the CGIAR has assembled as a result of international collaboration are “held in trust for the use of present and future generations of research workers in all countries throughout the world.”⁵⁴ In 1992 the CGIAR adopted the “CGIAR Working Document on Genetic Resources and Intellectual Property,” which it provided as a statement to the 1992 UNCED Conference (the Rio Earth Summit) that adopted the CBD. The Working Document spelled out several points concerning the relationship between the transfer of genetic material and the acquisition and exercise of intellectual property rights by CGIAR Centers. The Working Document stated, among other things, that:

- “Material from the genebanks at the centers will continue to be freely available in accordance with the 1989 CGIAR Policy on Plant Genetic Resources”;
- “Centers do not seek intellectual property protection unless it is absolutely necessary to ensure access by developing countries to new technologies and products”; and
- “[a]ny IPR acquired by a center are exercised without compromising in any manner whatsoever the fundamental position of the CGIAR regarding the free access by developing countries to knowledge, technology, materials and plant genetic resources.”⁵⁵

⁵² See Article 13.3, FAO Code of Conduct. Emphasis added.

⁵³ This is the revised mission statement as reformulated at the International Centers Week in October 1998. The original mission statement can be found in the founding document, the 1971 Resolution entitled ‘Consultative Group on International Agricultural Research. Objectives, Composition and Organizational Structure.’

⁵⁴ See CGIAR. ‘CGIAR Policy on Plant Genetic Resources.’ International Plant Genetic Resource Institute (IPGRI), 1989. The policy statement was published in 1989, but prepared and adopted at the International Centers’ Week in 1988. The statement is silent on intellectual property, but contains a section on the ownership of plant genetic resources and includes the first formal avowal by the CGIAR of its role as a trustee, rather than as a beneficial owner of genetic resources. It states that:

“It is the CGIAR policy that collections assembled as a result of international collaboration should not become the property of any single nation, but should be in trust for the use of present and future generations of research workers in all countries throughout the world.”

⁵⁵ See, ‘CGIAR Working Document on Genetic Resources and Intellectual Property,’ CGIAR (1992). CGIAR Mid-term Meeting. In: *Summary of Proceedings and Decisions*, Istanbul. World Bank, Washington, DC.

40. In response to ongoing concerns about the legal status of CGIAR collections and intellectual property rights, the CGIAR Centres in 1994 signed agreements with FAO, whereby they “hold the designated germplasm in trust for the benefit of the international community, in particular the developing countries in accordance with the International Undertaking on Plant Genetic Resources and the terms and conditions set out in this Agreement”, within the context of the International Network of *Ex Situ* Collections under the Auspices of FAO.⁵⁶ The terms of these agreements stipulate that the germplasm designated in-trust will continue to be made available to all, with the understanding that no intellectual property protection is to be applied to the material. Article 3(b) of the Agreements provides that “[t]he Center shall not claim legal ownership over the designated germplasm, nor shall it seek any IPR over the germplasm or related information.”⁵⁷ Article 10 on ‘Transfer of Designated Germplasm and Related Information’ provides that “[w]here samples of the designated germplasm and/or related information are transferred to any other person or institution, the Center shall ensure that such other person or institution, and any further entity receiving samples of the designated germplasm from such person or institution, are bound by the conditions set out in Article 3(b).”

41. In order to implement these obligations under the FAO-CGIAR Agreements, the Centers which have signed Agreements with the FAO make samples of in-trust germplasm available to requestors under a standard Material Transfer Agreement (MTA). Under this contractual agreement, when the recipient accepts the shipment of germplasm she or he is deemed to accept the terms of the standard MTA, which include the obligation not to claim any ownership or IPRs over the material. The obligations of the recipient include the obligation to ensure that all subsequent parties to whom the material is transferred also honor the same conditions. This policy is implemented by the CGIAR Centers through intellectual property clauses of their standard MTA, which are provided in Text Box 1.

Text Box 1: Sample Intellectual Property Clause:

“The material is held in trust under the terms of an agreement between [Centre] and FAO, and the recipient has no rights to obtain Intellectual Property Rights (IPR) on the germplasm or related information.

...

The recipient, therefore, hereby agrees not to claim ownership over the germplasm to be received, nor to seek IPR over that germplasm or related information. He/She further agrees to ensure that any subsequent person or institution to whom he/she may make samples of the germplasm available, is bound by the same provision and undertakes to pass on the same obligations to future recipients of the germplasm.”

(Material Transfer Agreement, Consultative Group on International Agricultural Research (CGIAR))

42. The revised International Undertaking is expected to be approved by the FAO Conference in November 2001. By Article 16.1a, the Contracting Parties call upon the Centers to sign agreements with the Governing Body of the International Undertaking with regard to their *ex situ* collections according to which, *inter alia*, “plant genetic resources for

⁵⁶ See, FAO-CGIAR ‘*Agreements on Status of Designated Germplasm*,’ Article 3a.

⁵⁷ *Ibid.*, Article 3(b).

food and agriculture listed in Annex I⁵⁸ of this Undertaking and held by the IARCs shall be made available in accordance with the provisions set out in Part IV of this Undertaking”.⁵⁹ Moreover, “plant genetic resources for food and agriculture other than those listed in Annex I of this Undertaking⁶⁰ and collected before its entry into force that are held by IARCs shall be made available in accordance with the provisions of the MTA currently in use pursuant to agreements between the IARCs and the FAO. This MTA shall be amended by agreement by the Governing Body no later than its second regular session, in consultation with the IARCs, in accordance with the relevant provisions of this Undertaking ...”⁶¹. The Centres shall “periodically inform the Governing Body about the MTAs entered into, according to a schedule to be established by the Governing Body”;⁶² moreover, “benefits arising under the above MTA that accrue to the mechanism mentioned in Article 20.3f⁶³ shall be applied, in particular, to the conservation and sustainable use of the plant genetic resources for food and agriculture in question, particularly in national and regional programmes in developing countries and countries with economies in transition, especially in centres of diversity and the least developed countries”.⁶⁴ “The IARCs shall take appropriate measures, in accordance with their capacity, to maintain effective compliance with the conditions of the MTAs, and shall promptly inform the Governing Body of cases of non-compliance”.⁶⁵

43. There are also various other international organizations and processes which have undertaken work on intellectual property-related aspects of contractual agreements for access to genetic resources and benefit-sharing. However, since this review is limited to the fora in respect of which the Member States called for close cooperation and for reasons of space, the scope of this document has been limited to the above-mentioned fora.

III. CONTEXTUALIZING CONTRACTUAL AGREEMENTS FOR ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING

44. Contractual agreements for access to genetic resources and benefit-sharing are formed, interpreted, performed and terminated in the context of a wide range of legal, administrative and policy frameworks for access to genetic resources and benefit-sharing. These policy frameworks and the use of contractual agreements for access and benefit-sharing may mutually affect each other: on the one hand, access and benefit-sharing frameworks may have a direct bearing on the formation, validity, interpretation, performance, breach or termination of the agreements. On the other hand, the extensive use of the law of contract to determine access to, and structure the transfer of, genetic resources may have significant consequences on the public policy objectives which those frameworks seek to implement, such as food security or conservation of genetic resources, if they involve transaction costs that discourage the use of these resources for crop improvement, or displace adequate public sector

⁵⁸ *I.e.*, to which the Multilateral System applies; see paragraph 33 above.

⁵⁹ Article 16.1a; for information on Part IV of the International Undertaking, see paragraphs 33-35 above.

⁶⁰ *I.e.*, to which the Multilateral System does not apply.

⁶¹ Article 16.1b, chapeau.

⁶² Article 16.1b (i).

⁶³ Article 20.3f establishes “as needed, an appropriate mechanism, such as a Trust Fund Account, for receiving and utilizing financial resources that will accrue to it for purposes of implementing this Undertaking.”

⁶⁴ Article 16.1b (iii).

⁶⁵ Article 16.1b (iv).

investment in conservation facilities. For example, stakeholders participating in international agricultural fora have observed the potential detrimental impact of increased use of contractual agreements in access to genetic resources on the policy objectives which governments may seek to pursue in balancing the public and private sectors in the agricultural sector.⁶⁶ It is therefore of critical importance to take into account such frameworks and policy objectives when considering the development of model intellectual property clauses, guidelines and guide contractual practices for access to genetic resources and benefit-sharing. Part III provides a brief and non-exhaustive overview of the most important categories of policy frameworks which are relevant to contractual agreements for access and benefit-sharing. The examples are classified and described under four headings which reflect different categories of frameworks, namely, multilateral systems for access and benefit-sharing; framework agreements for (bilateral) access and benefit-sharing; national legislation for (bilateral) access and benefit-sharing; and non-binding by-laws and statutes which may be relevant to certain contracts.

III.A Multilateral Systems of Access to Genetic Resources and Benefit-sharing

45. A basic distinction among relevant legislative, administrative and policy frameworks may be made between frameworks which implement a bilateral approach for access and benefit-sharing and frameworks which implement a multilateral approach to access and benefit-sharing. The first category typically includes national and regional frameworks which implement the standards set out in the CBD through the application of its operative provisions. The second category concerns an open multilateral system of exchange, which is currently exemplified in the work and functioning of the CGIAR and which includes the multilateral system for access to PGRFA and benefit-sharing in the International Undertaking, expected to be approved by the FAO Conference in November 2001.⁶⁷

46. The Multilateral System (“MLS”) of the International Undertaking is in harmony with the CBD⁶⁸ and has been established because, cognizant of the special characteristics of plant genetic resources for food and agriculture, Contracting Parties to the IU recognize that “in exercise of their sovereign rights over their plant genetic resources for food and agriculture, States may mutually benefit from the creation of an effective multilateral system for facilitated access to a negotiated selection of these resources and for the fair and equitable sharing of benefits arising from their use.”⁶⁹ The MLS is a system through which the Contracting Parties of the International Undertaking “recognize the sovereign rights of States

⁶⁶ The GFAR-2000 Conference, convened in Dresden, Germany, from May 21 to 23, 2000, by the Global Forum on Agricultural Research (GFAR) considered several documents on the promotion of innovative research partnerships in the field of genetic resource management, which address the question of public-private partnerships in agricultural research. See documents GFAR/00/17-04-04, GFAR/00/17-04-03, and GFAR/00/17-04-07.

⁶⁷ Additionally, crop networks which exist regionally usually operate systems of exchange and most countries rely heavily on these systems. These include, for example, the European Cooperative Programme on Crop Genetic Resources Networks (ECP/GR), the West Asia and North Africa Plant Genetic Resources Network (WAWANET), the Southern African Development Community Plant Genetic Resources Centre (SPGRC), the Regional Committee for Southeast Asia and many others.

⁶⁸ See A.1.1, IU. “The objectives of this Undertaking are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security.”

⁶⁹ See, Preamble, paragraph 11, IU.

over their own plant genetic resources for food and agriculture”⁷⁰ and at the same time, in exercise of those rights, “agree to establish a multilateral system, which is efficient, effective and transparent, both to facilitate access to plant genetic resources for food and agriculture, and to share, in a fair and equitable way, the benefits arising from the utilization of these resources, on a complementary and mutually reinforcing basis.” (Article 11)

47. Section II.B.2 above provides a detailed account of the negotiations for, and relevant components of, the draft Multilateral System (“MLS”). Since the MLS was still being finalized and subject to possible amendments prior to adoption as a binding legal instrument at the time of issuance of this document, this section will not review in detail the various components of the MLS which are relevant to contractual agreements on access and benefit-sharing. Certain relevant provisions of the draft revised International Undertaking are referenced in Section II.B.2 above. However, further to the Member State proclamations concerning the desirability of close cooperation with the FAO at the first Session of the Intergovernmental Committee, it is suggested that the Committee take into account the relevant components of the MLS, once it is finalized and work in close cooperation with the FAO Commission on Genetic Resources for Food and Agriculture on any aspects of this task in which the MLS may be relevant or which may be of relevance to the establishment, operation and implementation of the MLS. Furthermore, it may be of importance to take into account intellectual property-related elements and practices of existing crop networks, which regionally operate open systems of exchange.

III.B Framework Agreements on Access and Benefit-sharing

48. A second category which is relevant to access and benefit-sharing contracts are framework agreements on access to genetic resources, which may be under development or in force, such as the draft ASEAN Framework Agreement on Access to Biological and Genetic Resources (“the draft ASEAN Framework Agreement”) or Decision 391 on a Common System on Access to Genetic Resources of the Commission of the Cartagena Agreement. Such framework agreements have been or are being developed by regional economic integration organizations for various reasons, including to set minimum standards for determining access to genetic resources within a region,⁷¹ to ensure that national access regulations are uniform and consistent with the identified minimum standards,⁷² or to strengthen the negotiating capacity of the member countries of the framework agreement⁷³.

49. Certain existing framework agreements provide for the use of contractual agreements as a component of their standard access procedures for all genetic resources in the jurisdiction of the member countries of the framework agreement.⁷⁴ These contractual agreements may be used to establish the specific terms and conditions for access and benefit-sharing in respect of individual genetic resources and associated subject matter, such as derivatives or biodiversity-

⁷⁰ See document CGRFA-Ex6/01/REP, Appendix B, Article 11.

⁷¹ See A.2(e), draft ASEAN Framework Agreement on Access to Biological and Genetic Resources, ASEAN Working Group on Nature Conservation and Biodiversity, 2000.

⁷² See A.2(f), draft ASEAN Framework Agreement.

⁷³ See A.2(e), Decision 391 on a Common System on Access to Genetic Resources.

⁷⁴ Title V, “Access Procedures,” of Decision 391 provides in Chapter I, “General Aspects” that “[a]ll access procedures must include the presentation, admission, publication and approval of an application, *signature of a contract*, issue and publication of the corresponding resolution and a declaratory record of actions linked with such access.” (Article 16, emphasis added)

related traditional knowledge.⁷⁵ Typically, it is required that the terms of the access contract shall comply with the contents of the framework agreement and the national access legislation of the relevant member country of the framework agreement.⁷⁶ In order to protect the interests of the access applicant, it may be important that confidential treatment is given to any information received in connection with the contractual agreement under the provisions of such framework agreements.⁷⁷ The Framework Agreements may also include provisions or measures pertaining to intellectual property issues which may relate to the rights and obligations to be established in the access contracts stipulated by the framework agreement.⁷⁸

50. The standards established in framework agreements are typically implemented into national law through national access legislation for genetic resources. The latter type of legislative framework is reviewed in the next sub-section.

III.C National Legislative, Administrative and Policy Frameworks for Access to Genetic Resources

51. As of 1999, more than thirty countries had reportedly promulgated, or were in the process of developing, national legislation on access to genetic resources and benefit-sharing.⁷⁹ Several national legislative frameworks which are currently in force provide for the use of contractual agreements as a tool of implementing the requirement of mutually agreed terms in determining access to genetic resources under their jurisdiction.⁸⁰ Furthermore, reports proposing the establishment of such national frameworks foresee the use of contractual agreements.⁸¹ Additionally, model laws for access to genetic resources are being developed by regional integration organizations, such as the Organization of African Unity. These model laws also foresee as an implementing tool for national access legislation the use of contractual agreements between the National Competent Authority and the concerned local community or communities on the one hand and the applicant or collector on the other.⁸²

⁷⁵ Article 1 defines “access contract” to mean “an agreement between the Competent National Authority, representing the state, and a person, establishing the terms and conditions for access to genetic resources, their derivatives and, as applicable, related intangible components.”

⁷⁶ Article 33, Decision 391, provides that “[t]he terms of the access contract should comply with the contents of this decision and the national legislation of the Member Countries.”

⁷⁷ Article 19, Decision 391, provides that “[t]he Competent National Authority may give confidential treatment to any information or data which it receives in connection with the access procedure or contract execution which has not been divulged and could be used for disloyal commercial purposes by a third party, except when public knowledge of the same is necessary in order to protect social interests or the environment.”

⁷⁸ See Complementary Measures, Decision 391.

⁷⁹ See Royal Botanical Kew Gardens, *Principles on Access to Genetic Resources and Benefit-sharing, Common Policy Guidelines to Assist with their Implementation and Explanatory Text*. 2001; and ten Kate, Kerry and Laird, Sarah. *The commercial use of biodiversity*. London: Earthscan Publications, 1999: p.4.

⁸⁰ See, for example, the national access legislation of Philippines.

⁸¹ See, for example, the Report of the Commonwealth Public Inquiry on Access to Biological Resources in Commonwealth Areas of the Commonwealth of Australia (2000), which proposes an access scheme under which “either the owner or holder of resources in the particular Commonwealth area, is empowered to negotiate a benefit-sharing contract with the proponent (bioprospector). The contract will be based on a model contract to be developed and agreed by industry, Indigenous organizations and other stakeholders. The model contract will include provisions for benefit sharing through non-monetary and monetary benefits, such as fees, milestone payments and royalties, from sources including ... intellectual property rights.” (p.1).

⁸² See, for example, Articles 7(2) and 8 of the Draft African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to

III.D By-laws, statutes and other non-binding provisions

52. While regional framework agreements and national access legislation provide basic frameworks for access to genetic resources and benefit-sharing, certain institutions and organizations have adopted rules of procedure which reflect the specific objectives and principles of those institutions and organizations in the field of genetic resources. Examples of such institutions or organizations include a large number of botanical gardens from several countries following Common Policy Guidelines, the National Institute of Health (NIH) and the National Cancer Institute (NCI) of the United States of America, etc. Intellectual property-related provisions from contractual agreements reflecting the by-laws and statutes of certain organizations and institutions are provided in Part IV below.⁸³ While the by-laws and statutes of these institutions are not binding on other actors in the genetic resource area, they still contain provisions which will have an effect on the intellectual property clauses of access and benefit-sharing agreements developed and entered into by those organizations and institutions themselves.

IV. SAMPLING OF CONTRACTUAL PROVISIONS

53. Part IV provides a sampling of intellectual property-related clauses, as found in existing contractual agreements which were analyzed or referred to in previous WIPO documents. These sample clauses are provided for illustration only and exemplify how intellectual property aspects of access to genetic resources and benefit-sharing have been addressed in existing agreements. They are provided without any claim to be exhaustive, representative or complete. The present sampling constitutes a random selection of clauses and contracts which happen to be part of previous WIPO documents and related references. In order to be representative, they would have to be the result of a systematic survey, which has not yet been undertaken. Preference has been given to clauses which have been developed in the context of efforts by different stakeholders to elaborate model contractual agreements.

54. The sampling of contractual clauses does not include patent licensing agreements in respect of patented inventions involving improved or modified genetic resources. All the examples of contractual agreements for access and benefit-sharing referred to in Section IV were either published or provided to WIPO in the context of past activities with the understanding that they could be referred to in future publications and documents.

55. Due to the wide range of agreements referred to and summarized under the term "MTA," it is not possible to establish any general or standard structure of such agreements. At the minimum, however, they would have to set out the following elements:

- (i) the parties to the agreement;
- (ii) the scope of the contract;
- (iii) rights and obligations of the genetic resource provider;
- (iv) rights and obligations of the recipient;
- (v) governing law and forum or dispute resolution provisions, and
- (vi) other contractual modalities.

Biological Resources of the Organization of African Unity (OAU), as contained in Annex III of document OAU/AEC/TD/MIN/7(iii).

⁸³ See the sample clauses provided in Text Boxes 14 and 16 below.

Part IV of this document is limited to the *intellectual property-related* clauses of each of these sections. Since intellectual property clauses constitute a very important part of such agreements, they are often contained in a separate section or provision of the agreement⁸⁴ or they may be integrated under the respective rights and obligations of the parties.⁸⁵

56. The present sampling is taken from a wide variety of contractual agreements for access to genetic resources and benefit-sharing and illustrates the diversity and divergence of possible combinations. Some variables on how to analyze this diversity in a systematic way are provided in Section V.A, following the present sampling of clauses.

IV.A Scope of Contract

57. MTAs are subject to the law of contract. Since contractual obligations are voluntarily assumed, the law does not lay down specific rights and duties which it will enforce, but rather sets out certain limiting principles subject to which the parties may create rights and duties for themselves, which the law will uphold. MTAs do not rest upon codified legal statutes defining specific rights and obligations. Instead, reflecting freedom of contract, parties to an MTA have wide discretion in setting the terms of their agreement and tailoring them to the specific needs of individual genetic resource transfers.

58. Contractual agreements for access to genetic resources and benefit-sharing commonly begin by setting out the scope of the agreement. The example given in Text Box 2 illustrates the importance of defining the genetic material covered by the agreement when describing the scope of the contract. Contractual agreements for access and benefit-sharing must contain a definition of the genetic material which they cover and to which the terms of the agreement shall apply. An important aspect of this definition is whether the scope of agreement will cover derivatives, progeny and isolated substances of the transferred material (for an example, see the sample clause provided in Text Box 2).

Text Box 2: Sample Intellectual Property Clause

“1. *Scope of Agreement.* This Agreement applies to the use, handling, sale, distribution and any disposition of the Material, Replicates, and Derivatives. For the purpose of this Agreement, “Material” means any material or portion thereof shipped to the Purchaser. For the purpose of this Agreement, “Replicates” means any biological or chemical material that represents a substantially unmodified copy of the Material. Replicates include but are not limited to material produced by growth of cells or microorganisms or amplification of Material. For the purpose of this Agreement, “Derivative” means material created from the Material that is substantially modified to have new properties. Derivative includes, but is not limited to, recombinant DNA clones made using a vector purchased from the ATCC. This Agreement is subject to the current ATCC Material Purchase Order and signifies Purchaser’s acceptance of the terms and conditions set forth therein.”

(Material Transfer Agreement, American Type Culture Collection (ATCC), Art.1)

⁸⁴ See, for example, the Material Transfer Agreement of the American Type Culture Collection (ATCC).

⁸⁵ See, for example, the Uniform Biological Material Transfer Agreement (UBMTA), Association University Technology Managers (AUTM).

59. In recent years, standard MTAs have been developed for specific types of genetic resources, as distinguished by kingdom and taxonomic origin (i.e., resources of plant, animal, microbial or other origin), by sectorial context (e.g., genetic resources for food and agriculture) or by legal status of the resources (e.g. germplasm acquired prior to, or after, entry into force of the CBD). With each of these distinctions, the type of genetic resources that are defined as the scope of coverage of the agreement may have significant implications for the intellectual property clauses of the agreement. The following paragraphs provide examples of such definitions by several different criteria.

60. First, definitions of genetic material frequently contain a distinction between material of plant, animal, microbial or other origin.⁸⁶ It is often necessary that these differences be reflected in the intellectual property clauses of MTAs. A case in point is the voluntary International Code of Conduct which has been developed for access to and use of micro-organisms.⁸⁷ The “Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct” (MOSAICC) recommends that all transfers of microbial genetic resources occur under a Standard MTA, which includes certain standard intellectual property clauses (see Text Box 18 below).

61. A second consideration regarding scope of coverage concerns whether the contract covers uncharacterized genetic material, which may be transferred inadvertently along with the genetic material for which the MTA was initially drawn up, such as microbes or parasites present in samples of plant material. Some MTAs may explicitly specify in their definitions whether or not “other,” uncharacterized materials transferred in the sample of characterized genetic material, are covered by the terms of the agreement (for an example, see the clause provided in Text Box 3).

Text Box 3: Sample Intellectual Property Clause:

“MATERIAL: Any biological organism, either in whole or in part (including progeny, germplasm and microbial cultures), which is collected within SOURCE COUNTRY, or derivatives prepared from biological organisms which constitute a partially purified or fractionated sub-set, or an unmodified functional sub-unit, and which are not novel, or are not non-obvious, or are products of nature. Examples include, but are not limited to, organisms both endemic and non-endemic (i.e. distributed regionally) such as plants, insects, microbes, animals and marine organisms, and also includes uncharacterized organisms such as microbial life present in samples or parasites transferred adventitiously.”

(Definitions, Model Material Transfer Agreements for Equitable Biodiversity Prospecting (Version One: For Transfer of Biological Resources to Non-Commercial or Non-Profit Organizations) Emphasis added)⁸⁸

⁸⁶ For example, ““Genetic material” means any material of plant, animal, microbial or other origin containing functional units of heredity.” Article 2, CBD.

⁸⁷ The “Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct” (MOSAICC) is a voluntary Code of Conduct which was initiated in 1997. The Code and its MTA provide a contractual tool for the implementation of the CBD at the microbial level, in accordance with other relevant rules of international and national laws.

⁸⁸ See Putterman, Daniel. “Model Material Transfer Agreements for Equitable Biodiversity Prospecting.” *Colorado Journal of International Environmental Law and Policy* 7.1 (1996): 145-173.

62. Under such clauses biological organisms transferred adventitiously but not previously characterized, such as microbes in soil samples, are included in the transferred material (even though termed “undescribed material”) and are covered by the MTA. However, numerous MTAs distinguish between different types of transferred material, including the characterized material transferred in the sample, derivatives, and biological substances derived from organisms by relatively simple manipulations.

63. A third distinction as to scope of coverage, which is of particular importance from the intellectual property point of view, is the distinction between transferred material and derivatives. Genetic resources are mostly transferred for further research and benefits are often generated from the commercialization of derivatives that derive from the transferred material as a source of innovation.⁸⁹ Since patent and plant variety protection as a general rule protects material which has been improved through human innovation, the scope of coverage with respect to derivatives may have significant intellectual property implications. Regarding the adequate scope of contracts the above-mentioned international expert panel on genetic resources concluded that “for fair and equitable benefit-sharing, it is important that the scope of contracts include the full range of biotechnology applications in addition to biological resources accessed.”⁹⁰

64. In typical access and benefit-sharing agreements the scope of coverage extends to the derivatives of the genetic resource. An important problem in this respect is to define what constitutes “a derivative” and what does not. A common approach is to agree upon a definition of the terms “Derived Product” or “Derivative” and make the commitments of the MTA applicable to the provided genetic resources as well as its derived products.⁹¹ In such MTAs, the definition of the scope of the contract distinguishes between the transferred “Material” and the “Derivative” (for example, see the clause provided in Text Box 2 above).

65. A fourth distinction concerns the legal status of the genetic resource at international law. Often, *ex situ* collections of genetic resources, such as genebanks or botanical gardens, hold accessions which were acquired prior to the entry into force of the CBD. The legal status of those resources is still subject to discussions in various international fora and material transfer agreements used by such institutions, e.g. the IARCs of the CGIAR, distinguish between material of different legal status (for an example, see Text Box 4).

Text Box 4: Sample Intellectual Property Clause:

“[Centre] is making the material described in the attached list available as part of its policy of maximizing the utilization of genetic material for research. The material was either developed by [Centre]; or was acquired prior to the entry into force of the Convention on Biological Diversity; or if it was acquired after the entering into force of the Convention on Biological Diversity, it was obtained with the understanding that it could be made freely available for any agricultural research or breeding purposes.”

(Text Box 4 continued on next page)

⁸⁹ See, *Germplasm and Related Information and the Question of Derivatives in the FAO-CGIAR Agreements*. Fowler, C., G. Hawtin, M. Iwanaga, and J. Engels. IPGRI, forthcoming.

⁹⁰ Document UNEP/CBD/COP/5/8, paragraph 66.

⁹¹ Barton, John and Siebeck, Wolfgang. *Material transfer agreements in genetic resources exchange – the case of the International Agricultural Research Centres*. International Plant Genetic Resources Institute, May 1994.

(Text Box 4 continued)

(‘Material Transfer Agreement for Non-plant Genetic Materials (including Micro-organisms, Animals, and Aquatic and Marine Materials),’ Consultative Group on International Agricultural Research (CGIAR))

66. A fifth important criterion concerning the scope of coverage of the agreement is whether it covers traditional knowledge associated with the transferred genetic material. The coverage clause of the Model Material Transfer Agreement for Equitable Bioprospecting referred to in Text Box 3 above goes on to include “traditional uses of, or processes involving, MATERIAL” within the scope of subject matter covered by the access and benefit-sharing agreement in the event that traditional knowledge of indigenous and local communities was involved (for an example, see the sample clause provided in Text Box 5).

Text Box 5: Sample Intellectual Property Clause:

“Biological material covered by this Agreement are defined as follows:

...

INVENTIONS may be created at any time before, during or after the term of this Agreement, and ownership of INVENTIONS as tangible and intellectual property is determined by inventorship. Note that the physical embodiment of self-replicating INVENTIONS such as transgenic plants is the tangible property of the inventor(s). Provider’s Inventions are any INVENTIONS for which inventorship vests solely with PROVIDER. Recipient’s Inventions are any INVENTIONS for which inventorship vests solely with RECIPIENT. Joint Inventions are any INVENTIONS for which inventorship vests with both PROVIDER and RECIPIENT and CONSENTING LOCAL COMMUNITIES and is the shared intellectual and tangible property of PROVIDER and RECIPIENT and CONSENTING LOCAL COMMUNITIES as determined by the Parties’ relative contributions in inventorship. Traditional uses of or processes (“traditional knowledge”) involving MATERIAL may be regarded by CONSENTING LOCAL COMMUNITIES as INVENTIONS for which inventorship vests solely with said communities.

(Definitions, Model Material Transfer Agreements for Equitable Biodiversity Prospecting (Version One: For Transfer of Biological Resources to Non-Commercial or Non-Profit Organizations))

67. In the Report of the above-mentioned Expert Panel on Access and Benefit-sharing, “[t]he Panel of Experts recognizes that the protection of traditional knowledge and access to genetic resources and benefit-sharing are related”⁹² and notes that “[p]rotection measures for traditional knowledge, innovations and practices must be further explored to guarantee the rights of traditional knowledge holders.”⁹³ The intellectual property-related rights of traditional knowledge holders under access and benefit-sharing contracts will be determined by the clauses setting out the rights and obligations of the provider of genetic material, which is addressed in the next Section.

⁹² See document UNEP/CBD/WG-ABS/1/2, paragraph 78.

⁹³ See document UNEP/CBD/WG-ABS/1/2, paragraph 77(b).

IV.B Intellectual Property-related Rights and Obligations of the Provider

68. Contractual agreements for access and benefit-sharing consist of actionable promises by the provider and recipient of the transferred material which create specific rights and obligations for each party. However, the number of parties, actors and stakeholders has rapidly increased in recent years, as genetic resource collection and utilization becomes more specialized and the division of labor more differentiated. For example, collection, preparation and distribution of samples, as well as testing, analysis, product development and marketing may each involve one or several distinct organizations.⁹⁴

69. General obligations of the provider of genetic material typically include the obligation (i) to designate a focal point for the purposes of the agreement; (ii) to allow and facilitate access to the defined genetic material; (iii) to facilitate the contact, as appropriate, with traditional knowledge holders; (iv) to keep information received from the recipient, i.e. the bioprospector, secret; etc.

70. The provider could be (i) a government institution, (ii) a member of the research community or (iii) the private sector, (iv) traditional knowledge holders, or (v) other members of civil society, including NGOs. This typology of actors is a result of surveys of genetic resource policy, aimed at identifying and understanding the relevant stakeholders, which concluded that “in spite of major differences among countries, ... it is striking to note that all the actors interviewed can be classified in a number of broad types ... and there are many common features for each type across countries.”⁹⁵ The above-mentioned expert panel on access to genetic resources concluded that “different requirements for ... mutually agreed terms in contracts may be needed for ... different users.”⁹⁶

71. If the provider of the genetic material is a research institution or a member of the scientific community, the provider will often be conscious of the importance of open access to genetic resources for scientific progress, while at the same time safeguarding the rights of the institution.⁹⁷ Research institutions which have developed and adopted their own specific intellectual property policies, that reflect and balance these interests, may make the agreement subject to the terms and conditions of such policies (for an example, see the Sample Clause provided in Text Box 6).

⁹⁴ See document UNEP/CBD/COP/5/8, paragraph 67.

⁹⁵ Petit, Michel, et. al. *Why Governments Can't Make Policy. The Case of Plant Genetic Resources in the International Arena. Draft for Comment.* International Potato Center (CIP), 2001: pages 34-37.

⁹⁶ See document UNEP/CBD/COP/5/8, paragraph 102.

⁹⁷ See the case of Prof. Pamela Ronald at the University of California at Davis, who initiated a patent-based benefit-sharing mechanism in form of a ‘Genetic Resource Recognition Fund,’ as described in a WIPO-UNEP case study on the role of IPRs in the sharing of benefits arising from the use of biological resources and associated traditional knowledge. See document UNEP/CBD/COP/5/INF/21.

Text Box 6: Sample Intellectual Property Clause:*“5. The ICIPE Intellectual Property Policy*

(a) Except as may be explicitly provided for to the contrary, in this Agreement or any annexes hereto, this Agreement shall be subject to the terms and conditions of the ICIPE Intellectual Property Policy 2000.

(b) The Parties hereby certify that they have read and understood the provisions of the ICIPE Intellectual Property Policy 2000.”

(Agreement for the Transfer of Biological Material and/or Related Information, Schedule 2, *The ICIPE Intellectual Property Policy 2000 and Guide to the ICIPE Intellectual Property Policy 2000*, International Centre for Insect Physiology and Ecology (ICIPE), Nairobi, Kenya, Art.5)

71. Intellectual property clauses used in MTAs may also reflect specific priorities of the research community. For example, when genetic resources are exchanged for research purposes between academic or non-profit institutions, the provider may require the recipient to acknowledge the contributions of the supplied material in the context of any publications that may arise from the use of the genetic resources, in analogy to the citation of a bibliographic reference (for an example, see the Sample Clause provided in Text Box 7).

Text Box 7: Sample Intellectual Property Clause:

“You agree to acknowledge the source of the Biological Material in any publications reporting on your use of it.”

(National Science Foundation draft letter Uniform Biological Material Transfer Agreement, Non-profit to Non-profit, Art.4⁹⁸)

72. In this case the provider of the material retains the right to be acknowledged as the source of the genetic material in any subsequent publication based on the material or any further use made of it. On the other hand, if the provider of the genetic material is a research institution which is providing material it has worked on to private sector companies, and patentable inventions are expected to result from use of the material, the recipient company may demand a review period to review the provider’s manuscripts, abstracts or presentation materials. From the point of view of the researcher, however, this demand may jeopardise the timeliness of his or her publication. MTAs may therefore provide specific time frames (e.g., one to three months) during which intended publications based on the transferred genetic resource shall be deferred, so that patent applications can be filed in the interim (for an example, see the Sample Clause provided in Text Box 8).

⁹⁸ Quoted in Barton/Siebeck, *op.cit.*, p.23.

Text Box 8: Sample Intellectual Property Clause:

“The results of the research may be published by RDO [Research and development organization] personnel working under this MoU, with the joint authorship of designated collaborating members of SRISTI ... President, SRISTI, shall be furnished copies of any proposed publications or presentations at least thirty days in advance of the submission of such proposed publication or presentation ... A no objection certificate shall be provided by SRISTI within a period of 20 days from the receipt of manuscript. If revisions are required concerning confidential information only, such revisions shall be made and manuscript resubmitted as soon as possible. If said information includes patentable subject matter, the publication may be withheld for enough time to permit filing of patent applications.”

(Memorandum of Understanding Between the Society for Research Into Sustainable Technologies and Institutions (SRISTI) and Research and Development Organization (RDO), Art.2.9) Emphasis added)⁹⁹

73. If the genetic resource provider is a private sector company, the company must take into account implications for its competitive position of patents which the recipient may obtain for inventions based upon the transferred material. Such concerns are likely to be reflected in the intellectual property clauses of the access and benefit-sharing agreement which structures the transfer of materials. A common practice in such situations is to incorporate so-called ‘grant-back’ clauses into the relevant agreement, by which the providing private sector company seeks to ensure the right to use patented inventions that may derive from the material it provided. In patent licensing, ‘grant-back’ is a term generally applied to the requirement by a primary licensor that his licensee include in the consideration to be paid for the rights extended a cross-license under related (present or future) patents of the licensee. Through the incorporation of such a clause into an MTA the company which provided the genetic material protects its competitive position in the market, even if the recipient develops a major invention based on the resource (for an example, see the Sample Clause provided in Text Box 9).

Text Box 9: Sample Intellectual Property Clause:

“Recipient will give provider a non-exclusive, royalty-free license under any inventions it may patent that derive from the transferred material or improvements or derivatives thereof.”

(Example Material Transfer Agreement, in: Barton/Siebeck, *op.cit.*, p.21)

74. Such grant-back clauses may have complex implications for the parties to the MTA and have, in some cases, raised concerns under competition law, because a genetic resource provider may seek to extend his dominant market position through such clauses. The fairness and negotiability from the provider’s point of view of such clauses will depend, *inter alia*, on

⁹⁹ See, Chand, P.G.V.S., et. al. “Contracts for ‘Compensating’ Creativity: Framework for Using Market and Non-market Instruments for Rewarding Grassroots Innovation and Creativity.” *Forum Belem: Paths to Sustainable Development*. November 1996, Annexure 2.

the value of the provider's contribution to the improvement of the transferred genetic resource and the magnitude of the competitive concession represented by the transfer of the material in the first place.

75. As genetic resource providers, private sector entities frequently use MTAs in the context of joint research efforts by partnerships of companies, such as collaborations between startup biotechnology firms with large industrial partners. Agreements used in such contexts often authorize the exchange of specified materials between the parties, rule out the transfer of the materials to third parties, and bar use of the materials for any purposes other than the collaborative research project. In such MTAs, the rights and responsibilities of acquiring intellectual property rights for products and processes resulting from the collaboration will be carefully spelled out. Similarly, the ownership rights in the resulting intellectual property will be clearly specified. In such collaboration agreements, the parties are able to agree at the outset how to allocate intellectual property rights, because the expected results from the exchange of genetic material and the collaboration are clearly foreseen. Innumerable variations on such sharing of intellectual property rights exist. For example, one party might receive exclusive rights in one market, while the other party might receive rights in other markets, or the parties might allocate royalties evenly, or reflecting their respective research investments, etc.

76. In cases where both genetic resources and associated traditional knowledge are transferred and the providers are indigenous and local communities, the full and effective participation of indigenous and local communities and their representatives is important in the negotiation process. Past WIPO activities in the field of traditional knowledge have identified specific intellectual property needs of traditional knowledge holders as providers of traditional knowledge associated with genetic resources. In the *WIPO Report on Intellectual Property Needs and Expectations of Traditional Knowledge Holders*, traditional knowledge holders who contributed to the Report concluded that “models for contractual arrangements - in the form of licenses, material transfer agreements, access agreements, information transfer agreements and the like - offer practical tools” for indigenous peoples and other traditional knowledge holders in negotiating fair and equitable access and benefit-sharing agreements. The traditional knowledge holders who had been interviewed made several practical suggestions in this respect. They identified a need for:

- assistance and training for TK holders in the negotiation, drafting, implementation, and enforcement of contracts;
- the development and testing, with the close involvement of local communities, of “best contractual practices” and guidelines and model clauses for contracts, as well as the provision of information on and protection against “unfair contract terms.”¹⁰⁰

77. Existing “Model Material Transfer Agreements for Equitable Bioprospecting” provide examples of intellectual property-related rights and obligations of the local communities. Those agreements also cover traditional knowledge which is transferred with the genetic material as the intellectual property of the indigenous and local communities concerned (for an example, see the clause provided in Text Box 5). These model agreements define the traditional knowledge provided by indigenous and local communities as their intellectual

¹⁰⁰ See WIPO. *WIPO Report on Intellectual Property Needs and Expectations of Traditional Knowledge Holders*. Geneva: WIPO, 2001; page 278.

property. They use trade secrecy as the tool to legally protect this knowledge (for an example, see the sample clauses provided in Box 10).

Text Box 10: Sample Intellectual Property Clause:

“3. (a) MATERIAL or INVENTIONS and/or data pertaining to them may be of potential commercial interest to Parties. Parties shall keep MATERIAL or INVENTIONS and/or data CONFIDENTIAL if requested to in writing Said confidentiality shall apply until Parties are notified in writing by original requesting Party that said confidentiality is no longer required, or until said MATERIAL or INVENTIONS and/or data enter the public domain through the action of parties not signatory to this agreement.

...

9. (a) CONSENTING LOCAL COMMUNITIES agree to transfer MATERIAL derived from land in regular use by said communities, or traditional knowledge regarded by said communities as the intellectual property of said communities, to PROVIDER and RECIPIENT for research use only MATERIAL which is known to be rare or endangered shall not be collected.

(b) Both PROVIDER and RECIPIENT certify that they have explicitly obtained Prior Informed Consent from named CONSENTING LOCAL COMMUNITIES to transfer said MATERIAL or said traditional knowledge. Both PROVIDER and RECIPIENT agree that traditional knowledge, which may be regarded by said communities as the intellectual property of said communities, shall, for purposes of this Agreement, be treated as INVENTIONS for which inventorship vests with said communities. Parties shall treat said traditional knowledge as a trade secret and keep this information CONFIDENTIAL if requested to as in Paragraph 3(a).

(c) Parties shall negotiate compensation for CONSENTING LOCAL COMMUNITIES and record this in Attachment B, according to Terms and Conditions of Consenting Local Community Involvement listed in Attachment C. Failure of Parties to comply with said Terms and Conditions may be grounds for termination of this Agreement and for return of all MATERIAL or INVENTIONS provided by said communities as described in Paragraph 12(b).

...

ATTACHMENT C: Terms and Conditions of Consenting Local Community Involvement

...

4. *Confidentiality.* Both PROVIDER and RECIPIENT acknowledge that traditional knowledge may be regarded by CONSENTING LOCAL COMMUNITIES as their intellectual property. Discussions shall be held on the right for CONSENTING LOCAL COMMUNITIES to treat traditional knowledge as CONFIDENTIAL trade secrets, and if requested, Parties shall utilize confidentiality clause in Paragraph 3(a) of the Material Transfer Agreement. CONSENTING LOCAL COMMUNITIES acknowledge that contracts such as this Agreement may contain proprietary information and must be treated as CONFIDENTIAL. Community’s Authorized Representative is authorized to represent the interests of appropriate CONSENTING LOCAL COMMUNITIES during the negotiations of this Agreement. However said representative shall not divulge the contents of this agreement without written permission from all other Parties. For purposes of informing CONSENTING LOCAL COMMUNITIES, Community’s Authorized Representative may request that a redacted version of this Agreement be prepared.

(Text Box 10 continued on next page)

(Text Box 10 continued)

(Model Material Transfer Agreements for Equitable Biodiversity Prospecting (Version One: For Transfer of Biological Resources to Non-Commercial or Non-Profit Organizations), Art.3(a), 9, and Attachment C, Art.4. Emphasis added.)

78. All the three subparagraphs 9(a), (b) and (c) will apply if ‘Consenting Local Communities’ are parties to the agreement. These Agreements protect the traditional knowledge as trade secrets by explicitly extending Consenting Local Communities the right to require both Provider and Recipient to keep this knowledge confidential. This strategy work around the fact that intellectual property rights such as patents may not be available for significant elements of traditional knowledge, because they do not fulfill the requirements of protection. For purposes of the agreement, traditional knowledge is treated as Inventions which were invented by Consenting Local Communities, and terms and conditions governing its development are essentially identical to those of Inventions created by Provider or Recipient.

79. An important legal tool which enables indigenous and local communities to determine access to their traditional knowledge associated with genetic resources is the provision of prior informed consent. Article 15.5 of the CBD provides that “[a]ccess to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.” While Article 15.5, CBD, requires prior informed consent from Contracting Parties rather than indigenous and local communities, Article 8(j), CBD, provides that the Contracting Parties shall “promote ... wider application [of traditional knowledge, innovations and practices] with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;” (Article 8(j)).

80. In recognition of such provisions, numerous contractual agreements for *in situ* access to genetic resources and benefit-sharing contain clauses which include “prior informed consent” as an obligation for the recipient and provider of the transferred material.

Text Box 11: Sample Intellectual Property Clause:

“9.(b) Both PROVIDER and RECIPIENT certify that they have explicitly obtained Prior Informed Consent from named CONSENTING LOCAL COMMUNITIES to transfer said MATERIAL or said traditional knowledge.

...ATTACHMENT C: Terms and Conditions of Consenting Local Community Involvement ...

2. *Prior Informed Consent*: Obtaining Prior Informed Consent from CONSENTING LOCAL COMMUNITIES for the use of MATERIAL derived from land in regular use by said communities, or for the use of traditional knowledge of said communities, requires that direct discussions be held with said communities, in their local language, on the purpose of the proposed research, the research plan, expected outcomes, rights available to these communities under the law, and their options for participating in and benefitting from the research.”

(Text Box 11 continued on next page)

(Text Box 11 continued)

(Model Material Transfer Agreements for Equitable Biodiversity Prospecting (Version One: For Transfer of Biological Resources to Non-Commercial or Non-Profit Organizations), Art.9(b), and Attachment C, Art.2)

81. Article 2, Attachment C, as provided in Text Box 11 outlines a mechanism for obtaining the prior informed consent of rural communities to trade communal tangible or intellectual property. Prior informed consent, as used in this contractual agreement, is a legal tactic designed to encourage respect for communal property rights. This tactic, combining prior informed consent with use of mutually agreed terms of contractual agreements, represents a practical legal mechanism for defining the intellectual property-related rights of indigenous peoples, local communities and other traditional knowledge holders in contractual agreements for access to genetic resources and benefit-sharing.

82. Several model material transfer agreements and related policies for access to genetic resources and benefit-sharing provide for encouraging statements for the obtention of prior informed consent also with regard to local and indigenous communities, if appropriate (for an example, see Text Box 12):

Text Box 12: Sample Intellectual Property Clause:

“2.3 The signature of [Partner] on any Notification of Transfer will confirm firstly that [Partner] is satisfied that best efforts have been made by [Participating Garden] and/or by [Partner], as appropriate, to obtain all necessary permits, prior informed consents and licenses in connection with the acquisition by [Participating Garden] of the Material and secondly that [Partner] is authorised to acquire and supply the Material to [Participating Garden].”

(Model Material Acquisition Agreement Between [PARTNER INSTITUTION] and [PARTICIPATING GARDEN], Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit-sharing, Article 5.1)

83. This Material Transfer Agreement is a tool for participating botanical gardens to implement the basic Common Policy Guidelines For Participating Botanical Gardens On Access to Genetic Resources and Benefit-sharing. The overall policy provision for Prior Informed Consent, as reflected in the Model Material Acquisition Agreement and the Model Material Supply Agreement, is contained in Article 5.1 of the Common Policy Guidelines (see Text Box 13).

Text Box 13: Sample Intellectual Property Clause:

5.1 Prior Informed Consent

5.1.1 When it collects or otherwise gains access to genetic resources, each Participating Institution will abide by international and national applicable laws, regulations and best practice.

(Text Box 13 continued on next page)

(Text Box 13 continued)

5.1.2 When obtaining access to genetic resources from *in situ* conditions, each Participating Institution will:

a. where required, in accordance with applicable law, obtain, in writing, the prior informed consent of the government of the country of origin;

and will make reasonable and sincere efforts to:

b. obtain and record the prior informed consent of other Stakeholders, as appropriate, for access to and use of the genetic resources concerned and associated knowledge;

(Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit-sharing, Article 5.1)

84. The right of the State providing genetic resources to make access to its resources subject to prior informed consent is at the same time the obligation of the recipient of the material to seek such consent. The intellectual property-related rights and obligations of the recipient are reviewed in the next section.

IV.C Intellectual Property-Related Rights and Obligations of the Recipient

85. Genetic resources are mostly transferred for further research and improvement by the recipient of the material. Since intellectual property rights, generally speaking, protect material which has been improved through human innovation, important provisions of contractual agreements from the intellectual property point of view are the rights and obligations of the recipient of the transferred genetic material.

86. There are numerous typical provisions in access and benefit-sharing contracts which set out non-intellectual property-related obligations of the genetic resource recipient, such as (i) providing a detailed description of the projected research and development of the transferred resource, including the perspectives of commercial utilization, where it is known; (ii) making a lump sum payment and/or committing to the payment of a determined share in future gains; (iii) providing other non-monetary benefits to the resource provider and holders of traditional knowledge associated with the resource, as negotiated; (iv) providing specimen and taxonomic data of collected genetic resources to designated national depositary authorities; etc. These obligations may vary widely, depending on the purpose, parties and jurisdiction of the bioprospection or transfer. However, the present document will provide examples exclusively of the *intellectual property-related* rights and obligations of the recipient of genetic material under access and benefit-sharing contracts.

87. The providers of genetic resources often wish to include an obligation in the contractual agreement that the recipient shall share royalties arising from the commercial use of the transferred material, especially in cases where it is subsequently protected by intellectual property rights. This could be done in numerous ways, all of which have different advantages and disadvantages. First, it can be done by negotiating a full-blown marketing agreement with details on specific royalty provisions. This will provide a high degree of legal certainty and reflect very accurately the interests of the different parties, but the transaction

costs of specifying individual contracts for each transfer may be prohibitively high. Second, it could be done through so-called 'reach-through royalties,' i.e. a specified share of sales or profits from any processes or products that might be developed and patented, following the use of the transferred material as a research tool. Third, institutions often prefer to transfer the material under an agreement that would attempt to give it the right to negotiate for a share of the profits in products and processes derived from that material at the time and in the case that such profits actually arise. Such clauses have been incorporated into standard MTAs which were developed by governmental institutions for the transfer of materials between nonprofit institutions (for an example, see the Sample Clause provided in Text Box 14).

Text Box 14: Sample Intellectual Property Clause

In order to abide by these principles and address the interests of SCO [Source Country Organization], Recipient further agrees that, should an invention derived from the Research Material eventually be developed and marketed by the Recipient, or licensed by Recipient to a company or other institution for development and commercialization (whether the invention is directed to a direct isolate from the Research Material, a product structurally based upon an isolate from the Research Material, a synthetic material for which the Research Material provided a key development lead, or a method of synthesis or use of any aforementioned isolate, product or material), Recipient or Recipient's Licensee(s) will negotiate and enter into an agreement with the appropriate SCO. This agreement between the Recipient and/or Recipient's Licensee(s) and SCO will address the mutual concerns of both parties. Recipient agrees that negotiations between either Recipient or Recipient's Licensee(s) and the SCO must commence prior to the start of clinical development studies that are conducted, directed or sponsored by either Recipient or Recipient's Licensee(s). Negotiations must be completed and an agreement executed prior to the commercial sale of an agent structurally based or isolated from the Research Material. This agreement relating to the agent must be binding upon SCO, Recipient and any Licensee(s) or assignees of Recipient with respect to any intellectual property rights relating to the agent.

(Natural Products Repository Material Transfer Agreement (Model Agreement last approved May 1989), Natural Products Branch of the National Cancer Institute (NCI) of the United States of America, Art.9)

88. Clauses such as the sample provided in Text Box 14 allow the parties not to specify the distribution of profits from commercial use of the transferred material at the time when the access and benefit-sharing contract is signed, but to leave the negotiation of this distribution to take place later in the event that there are profits. Such clauses are used because often it is impossible at the time of the initial transfer for the parties to define reasonable royalties, especially in cases where the commercial product for which the royalties are to be shared may derive from more than one source material. However, the obligation to negotiate may not lead to agreement on appropriate distribution of royalties in all cases. Much, in this respect, depends on the relative bargaining power of the parties. Access and benefit-sharing agreements therefore often include clauses on alternative dispute resolution schemes to define such distributions, if the parties are unable to agree upon them (see section IV.D.1 and Text Boxes 21 and 22 regarding such alternative dispute resolution schemes).

89. In certain cases the genetic resource provider may wish to ensure, or general policy objectives and frameworks may require, that the transferred material remains in the public domain, while at the same time making sure that the material is recognized as deriving from the resource provider. Many genebanks, for example, supply material under terms which prohibit patent protection of the transferred material or its genetic parts and components (see Text Box 1 in Section II.B.3 above). In such cases, MTAs include provisions which state, for example, that the recipient shall take no measures to patent the transferred material or any parts, components or derivatives thereof (for an example, see the Sample Clause provided in Text Box 15).

Text Box 15: Sample Intellectual Property Clause:

“RECIPIENT promises not to use MATERIAL for commercial purposes, nor to obtain intellectual property rights to MATERIAL.”

(Model Material Transfer Agreements for Equitable Biodiversity Prospecting (Version One: For Transfer of Biological Resources to Non-Commercial or Non-Profit Organizations), Art.6(a))

90. Intellectual property clauses of MTAs like the example provided in Text Box 15 prevent patenting of the transferred material and/or specified types of derived products. Such a possibility could also be prevented through the destruction of novelty of the transferred material by disclosing it in a sufficiently clear and complete manner. However, this would work only if the genetic material is fully characterized and relevant genes have been sequenced; otherwise, only an MTA clause can fully bar the recipient from filing patent applications.

91. Short of obliging the recipient not to acquire any intellectual property rights, access and benefit-sharing agreements may provide for joint ownership of intellectual property rights between provider and recipient. In such agreements the recipient of the genetic material agrees that he will only seek intellectual property rights jointly with the provider for inventions developed jointly by both parties. The above-mentioned Panel of Experts on Access and Benefit-sharing has identified “taking into account the possibility of joint ownership of intellectual property rights” as an issue which “could be considered as guiding parameters for contractual agreements”.¹⁰¹ Clauses providing joint ownership have been used in existing MTAs by certain government institutions or government-appointed agencies, which have entered into agreements with genetic resources providers in source countries (for an example, see the Sample Clause provided in Text Box 16).

Text Box 16: Sample Intellectual Property Clause:

“Both [SCO (Source Country Organization)] and DTP/NCI recognize that inventorship will be determined under patent law. DTP/NCI and [SCO] will, as appropriate, jointly seek patent protection on all inventions jointly developed under this MOU by DTP/NCI and [SCO] employees, and will seek appropriate protection abroad, including in [Source country], if appropriate.”

(Text Box 16 continued on next page)

¹⁰¹ See document UNEP/CBD/COP/5/8, paragraph 133(d).

(Text Box 16 continued)

(Memorandum of Understanding Between [Source Country Organization (SCO)] and the Developmental Therapeutics Program (DTP), Division of Cancer Treatment, Diagnosis, and Centers, National Cancer Institute (NCI) of the United States of America, Art.9) Emphasis added)

92. Other contractual agreements might make ownership dependent on inventorship and leave open the possibility of joint-ownership of intellectual property rights. Depending on inventorship, such agreements grant the recipient the right to acquire intellectual property rights over research results based on the transferred material, subject to certain conditions, such as notification and/or written consent of the provider and indigenous and local communities if their traditional knowledge was involved. Often such rights of the recipient to acquire intellectual property rights are tied to his obligations for sharing the benefits arising from the use and potential commercialization of the research results which are protected by intellectual property (for an example, see the Sample Clause provided in Text Box 17).

Text Box 17: Sample Intellectual Property Clause:

“6.(b) Ownership, as intellectual and tangible property, of INVENTIONS created as a result of research performed on MATERIAL shall vest according to inventorship. RECIPIENT may seek intellectual property protection on Recipient’s Inventions and may develop said inventions into commercial products or license said inventions for said development, and shall notify PROVIDER and CONSENTING LOCAL COMMUNITIES of this through RECIPIENT’s periodic research reports.

(c) RECIPIENT may seek intellectual property protection on Joint Inventions or Provider’s Inventions or may develop said inventions into commercial products or license said inventions for commercial development only if authorized in writing by PROVIDER and CONSENTING LOCAL COMMUNITIES to do so.

(d) In seeking to develop INVENTIONS into commercial products or to license INVENTIONS for commercial development, RECIPIENT shall abide by terms described in Attachment E, Terms of Intellectual Property Protection and Commercialization. RECIPIENT shall share a percentage, specified in Attachment B, of all income with PROVIDER and CONSENTING LOCAL COMMUNITIES from licensing commercial development of said INVENTIONS.”

(Model Material Transfer Agreements for Equitable Biodiversity Prospecting (Version Two: For Transfer of Biological Resources to Commercial Organizations), Art.6(b)-(d))

93. The thrust of such clauses is that ownership of inventions depends on inventorship. When an invention is made jointly, it follows that the ownership will also be shared, i.e. there will be joint-ownership. Where joint ownership occurs under such contractual terms, it may be understood as reflecting an application of Article 18 of the CBD, on ‘Technical and Scientific Cooperation,’ which provides, *inter alia*, that “Contracting Parties shall, subject to

mutual agreement, promote the establishment of joint research programmes and joint ventures for the development of technologies relevant to the objectives of this Convention.”¹⁰²

94. Some Model Agreements for transfer of genetic resources differentiate the obligations of the recipient according to the uses which the Recipient makes of the transferred material. In such cases, the definitions section of the agreement spells out different categories of uses and different intellectual property-related obligations are attached for the recipient to each category of use (for an example, see the Sample Clause provided in Text Box 18).

Text Box 18: Sample Intellectual Property Clause:

“The RECIPIENT and the PROVIDER distinguish between the following categories of use of MGRs [“microbial genetic resources”]:

Category 1: Use for test, reference, bioassay, and control (covering only their use within the framework of the corresponding official (inter)national test, bioassay and control protocols); use for training purposes;

Category 2: Use for research purposes;

Category 3: Commercial use. Commercial use of MGRs includes but is not limited to the following activities: sale, patenting, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or license, product development and seeking pre-market approval.

For categories 1 and 2 uses:

The RECIPIENT will not claim ownership over the MGRs received, nor seek intellectual property rights over them or related information. If the RECIPIENT wishes to utilize or exploit such organisms commercially he will first inform the PROVIDER; ...

The RECIPIENT will ensure that any individual or institution to whom the RECIPIENT makes samples of the MGRs available, is bound by the same provision.

For category 3 uses:

In order to ensure adequate benefit sharing with the country of origin and [*“names of those entitled to be rewarded”*], according to the principles of the Convention on Biological Diversity, the RECIPIENT will immediately inform the PROVIDER and the country where the MGRs were originally accessed of the intended commercial use(s) of the MGRs and/or derived technology and/or related information. The terms upon which benefit sharing with the stakeholders takes effect are laid down in annex.

(Model Material Transfer Agreement, ‘Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct’ (MOSAICC), Section II)

95. MOSAICC, the “Micro-Organisms Sustainable use and Access Regulation International Code of Conduct,” was initiated in 1997 and involved twelve partners, including representatives from developing and developed countries, as well as representatives from the

¹⁰² See, A.18.5, CBD.

not-for-profit-sector and the commercial sector. The Model Material Transfer Agreement of MOSAICC implements the provisions of the CBD in respect of microbial genetic resources bound by the CBD through the use of contractual agreements.

96. Indigenous and local communities have been customary users and recipients of genetic resources, through their long-standing use and conservation of local biological resources. Article 10(c), CBD, provides that each Contracting Party shall, as far as possible and as appropriate, “protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements.” Consequently, the above-mentioned Panel of Experts considered “provisions to ensure the continued use of genetic resources and related knowledge” by indigenous and local communities to be a “guiding parameter for contractual agreements.”¹⁰³ Some model agreements which have been developed for the transfer of biological material from indigenous and local communities to commercial or non-commercial recipients provide that any holder or licensee of an intellectual property right which concerns traditional knowledge of the community, shall not act to restrict any customary and non-customary use, production or practices involving the transferred genetic material in the source country (for an example, see the Sample Clause provided in Text Box 19).

Text Box 19: Sample Intellectual Property Clause:

“Should any Party seek intellectual property protection on INVENTIONS which involve traditional knowledge of CONSENTING LOCAL COMMUNITIES, said Party or licensee shall not act to restrict the use or production of, or processes involving, substances utilizing said traditional knowledge, such as phytomedicines or natural pesticides, within SOURCE COUNTRY.”

(Model Material Transfer Agreements for Equitable Biodiversity Prospecting (Version Two: For Transfer of Biological Resources to Commercial Organizations), Attachment E, Art. 3)

97. Besides the intellectual property-related clauses which form the core interest from the point of view of this document, there are certain other standard clauses, which, in practical terms, are closely related to the intellectual property-clauses and should also be taken into consideration. A brief sampling of such standard clauses is provided in Section IV.D below.

IV.D Other Standard Clauses

98. The role of intellectual property clauses in contractual agreements on access to genetic resources and benefit-sharing cannot be sufficiently understood, if it is analyzed in isolation from other provisions of the contract. Indeed, certain standard clauses, which relate closely to the intellectual property-specific provisions, are of interest from the point of view of this document. These clauses are briefly reviewed below under the headings of ‘Dispute Resolution’ and ‘Other Contractual Modalities.’

¹⁰³ See UNEP/CBD/COP/5/8, paragraph 133(b).

IV.D.1 Dispute Resolution

99. No matter how artfully a contract may be drafted and how finely it reflects the concerns of the different parties, the possibility that controversy may arise under an agreement must be contemplated in drafting any kind of contract, including, but not limited to, access and benefit-sharing contracts. Disputes related to the intellectual property-provisions of access and benefit-sharing contracts might arise about a wide variety of issues, such as whether new product developments are covered by the agreement; whether royalties are payable and, if so, their amount; whether contractual restrictions on the use of intellectual property rights might violate competition rules; and a broad range of other matters. Therefore, clauses on dispute resolution are of considerable importance to the intellectual property-related provisions of access and benefit-sharing agreements.

100. Since access and benefit-sharing agreements commonly involve natural or legal persons who are residents or citizens of different countries, questions of jurisdiction and applicable law will frequently arise. In practice, the determination of applicable law in reference to a contract involving foreign elements may be an enterprise of considerable complexity. For example, the rules to be applied may differ depending on whether one is concerned with the validity of the contract, or with its performance or discharge. It is a rule frequently stated, but qualified by so many exceptions as to constitute a principle with some uncertainty, that the parties may determine applicable law by an express manifestation of intention. Considerable differences in commercial law and interpretative viewpoints exist from country to country and therefore existing Model Agreements for Access and Benefit-sharing often leave this question open (for an example, see the clause provided in Text Box 20). With regard to the second issue, i.e. that of jurisdiction, the basic question that needs to be addressed concerns which court shall have jurisdiction to resolve the dispute concerning the contract.

Text Box 20: Sample Intellectual Property Clause:

“5.10 This Agreement is governed by and shall be construed in accordance with [insert appropriate nationality] law.”

(Model Material Acquisition Agreement Between [PARTNER INSTITUTION] and [PARTICIPATING BOTANICAL GARDEN], Common Policy Guidelines on Access to Genetic Resources and Benefit-sharing for Participating Botanical Gardens, Art.5.10)

101. A dispute arising from an access and benefit-sharing contract could be resolved either through state court litigation or through alternative dispute resolution (ADR) schemes, including but not limited to mediation and arbitration. State courts and arbitral tribunals have the power to render a decision which is binding upon the parties and which can be enforced against the losing party. In contrast, mediation is a procedure in which the mediator endeavors, at the request of the parties, to assist them in reaching a mutually satisfactory settlement of their dispute. The mediator does not have any power to impose a settlement on the parties and either party, if it so chooses, may abandon the mediation at any stage prior to the signing of an agreed settlement.

102. In contrast to mediation, arbitration involves the adjudication of rights by a tribunal composed of one or several arbitrators, who have the power to render a decision that is binding on the parties. This procedure may be applied to any dispute, controversy or claim that arises under, or relates to, access and benefit-sharing agreements, including the formation, validity, binding effect, interpretation, performance, breach or termination of such an agreement. Arbitration can take two forms: the first form is *ad hoc* arbitration, where the parties bear the responsibility of setting up the arbitral tribunal that will settle their dispute, and they stipulate the rules that will govern the conduct of the arbitration proceedings without the assistance of a specialized institution. In such cases the contracts include clauses by which the parties determine how the arbitration will be conducted. The General Assembly of the United Nations (UN) has recommended for international commercial contracts the use of the Arbitration Rules of the UN Commission on International Trade Law (UNCITRAL).¹⁰⁴ The UNCITRAL Arbitration Rules were adopted in 1976 by UNCITRAL, a Commission consisting of member States representing the different legal, economic and social systems and geographic regions of the world. Article 1 of the UNCITRAL Arbitration Rules provides a model arbitration clause. By including this clause into an access and benefit-sharing contract the parties to the contract may agree in writing that disputes in relation to that contract shall be referred to arbitration under the UNCITRAL Arbitration Rules (for the UNCITRAL model arbitration clause see Text Box 21).

Text Box 21: UNCITRAL Model Arbitration Clause:

“MODEL ARBITRATION CLAUSE

Any dispute, controversy or claim arising out of or relating to this contract, or the breach, termination or invalidity thereof, shall be settled by arbitration in accordance with the UNCITRAL Arbitration Rules as at present in force.

Note - Parties may wish to consider adding:

- (a) The appointing authority shall be ... (name of institution or person);
- (b) The number of arbitrators shall be ... (one or three);
- (c) The place of arbitration shall be ... (town or country);
- (d) The language(s) to be used in the arbitral proceedings shall be”

(UNCITRAL Arbitration Rules, Section I, Article 1.1, footnote)¹⁰⁵

103. The second form of arbitration is institutional arbitration where the arbitration process is managed with the help of a specialized institution. In institutional arbitration the parties choose to conduct their arbitration procedure in accordance with the rules of, and with the assistance of, an arbitration center or arbitral institution. When relying on a specialized

¹⁰⁴ See, Resolution 31/98, Adopted by the General Assembly of the United Nations on 15 December 1976 (Official Records of the General Assembly, Thirty-first Session, Supplement No. 17 (A/31/17), Chapter V, Section C). Paragraph 1 of Resolution 31/98 “*Recommends* the Arbitration Rules of the United Nations Commission on International Trade Law in the settlement of disputes arising in the context of international commercial relations, particularly by reference to the Arbitration Rules in commercial contracts.”

¹⁰⁵ The UNCITRAL Arbitration Rules may be found in several languages at <http://www.uncitral.org/english/texts/arbitration/arb-rules.html>.

institution, the arbitration may be conducted under rules of the institution, if any, or under the UNCITRAL Arbitration Rules. For example, arbitrations conducted under the UNCITRAL Arbitration Rules may proceed more efficiently if an impartial institution is designated to perform certain functions and to provide certain services in connection with the organization and supervision of arbitral proceedings.

104. One of the possible institutions that may be used for this purpose is the WIPO Arbitration and Mediation Center. The Center was established in 1994 to offer arbitration and mediation services for the resolution of international commercial disputes between private parties. The Center may be designated to offer arbitration and mediation services under the UNCITRAL Arbitration Rules or its own procedures.¹⁰⁶ In general, the Center's role extends to the following main functions:¹⁰⁷

- the Center ensures that the arbitral proceedings get under way smoothly and that the Tribunal, i.e. the arbitrators appointed to rule upon the dispute, is established as required;
- the Center monitors compliance with certain prescribed time limits;
- after the establishment of the Tribunal, the Center may be called upon to take certain decisions which it is either impossible or inappropriate for the Tribunal itself to take, notably decisions on the challenge, release or replacement of an arbitrator;
- the Center will, where the parties so desire, arrange for administrative support services for the arbitration;
- the Center processes the award rendered by the Tribunal.

105. The procedures offered by the Center are widely recognized as particularly appropriate for disputes involving intellectual property. The internationally recognized competence of the Center is reflected in the fact that the Center maintains a list of panelists which have a particular expertise in intellectual property. This comprehensive and regionally balanced roster of panelists, specialized in intellectual property and numerous related fields of law and policy, provides a unique resource for the specialized and balanced arbitration of international intellectual property-related disputes between private parties. Among the services offered by the Center are mediation, arbitration, and mediation followed, in the absence of a settlement, by arbitration. In areas where the state of the law is not that clear, mediation has been favored by parties as their preferred ADR procedure, because this procedure is consensus-based, flexible and the chances of dissatisfaction for either party are smallest. The Center also offers mediation followed, in the absence of a settlement, by arbitration. In this procedure, the arbitration component at the end is useful because it offers an incentive for the parties to reach agreement. For the submission of future disputes under a particular contract, recommended contractual clauses have been developed for mediation under the WIPO Mediation Rules followed, in the absence of a settlement, by arbitration under the WIPO Arbitration Rules (for the recommended clause for this procedure see Text Box 22)

¹⁰⁶ See, *WIPO Services Under the UNCITRAL Arbitration Rules*. Publication 447(E)

¹⁰⁷ This is a very brief summary of the main functions of the Center. For a full account of the functions see <<http://arbiter.wipo.int/center/index.html>> The role of the Center as administering authority is set out in detail in WIPO publication 446(E).

Text Box 22: Sample Intellectual Property Clause:

“Any dispute, controversy or claim arising under, out of or relating to this contract and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be submitted to mediation in accordance with the WIPO Mediation Rules. The place of mediation shall be ... The language to be used in the mediation shall be ...

If, and to the extent that, any such dispute, controversy or claim has not been settled pursuant to the mediation within [60][90] days of the commencement of the mediation, it shall, upon the filing of a Request for Arbitration by either party, be referred to and finally determined by arbitration in accordance with the WIPO Arbitration Rules. Alternatively, if, before the expiration of the said period of [60][90] days, either party fails to participate or to continue to participate in the mediation, the dispute, controversy or claim shall, upon the filing of a Request for Arbitration by the other party, be referred to and finally determined by arbitration in accordance with the WIPO Arbitration Rules. The arbitral tribunal shall consist of [three arbitrators] [a sole arbitrator]. The place of arbitration shall be ... The language to be used in the arbitral proceedings shall be ... The dispute, controversy or claim referred to arbitration shall be decided in accordance with the law of ...”

(WIPO Arbitration and Mediation Center, Recommended Contract Clauses and Submission Agreements)¹⁰⁸

IV.D.2 Other Contractual Modalities

106. Other standard provisions which may be grouped under this heading include clauses concerning term and termination of the agreement, entry into force, cancellation, etc. A provision which deserves particular attention by the drafters of access and benefit-sharing contracts is the termination clause. Typical provisions in MTAs refer to the “life” or “term” of the agreement or provide that the agreement shall terminate under certain conditions. In practice, however, the rights and obligations attaching to an agreement come to an end sequentially and the moment when no significant right or obligation remains could be considered as the “termination” of the agreement (for an example see the sample clause provided in Text Box 23).

Text Box 23: Sample Intellectual Property Clause:

“13. This Agreement will terminate on the earliest of the following dates: (a) when the MATERIAL becomes generally available from third parties, for example, through reagent catalogs or public depositories or (b) on completion of the RECIPIENT’s current research with the MATERIAL, or (c) on thirty (30) days written notice by either party to the other, or (d) on the date specified in an implementing letter, provided that:

(Text Box 23 continued on next page)

¹⁰⁸ See publication 446(E).

(Text Box 23 continued)

(i) if termination should occur under 13(a), the RECIPIENT shall be bound to the PROVIDER by the least restrictive terms applicable to the MATERIAL obtained from the then-available resources; and

(ii) if termination should occur under 13(b) or (d) above, the RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODIFICATIONS; and

(iii) in the event the PROVIDER terminates this Agreement under 13(c) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the PROVIDER will defer the effective date of termination for a period of up to one year, upon request from the RECIPIENT, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODIFICATIONS.

14. Paragraphs 6, 9, and 10 shall survive termination.”

(Uniform Biological Material Transfer Agreement, Association University Technology Managers, Art.13 and 14)

107. As reflected in Text Box 23, Article 14, the drafters of the access and benefit-sharing agreement have to seek out and list all aspects of the negotiated transaction which are intended to outlast the agreement's professed termination. The parties should therefore recognize “termination” as a multi-pronged concept and define each prong separately if every right and obligation under the contract is to end on a certain date or upon certain identifiable events. Because certainty in respect of these matters may be of crucial significance to the parties, the termination clause of access and benefit-sharing agreements deserves the parties' meticulous attention.

V. OPERATIVE PRINCIPLES FOR GUIDE CONTRACTUAL PRACTICES AND MODEL INTELLECTUAL PROPERTY CLAUSES

108. Part V applies certain categories to classify and organize the different types of intellectual property clauses reviewed in Part IV. As the sampling of intellectual property-related clauses in Part IV above illustrates, contractual agreements for access to genetic resources and benefit-sharing encompass “an almost limitless combination of users, uses and potential uses of genetic resources.”¹⁰⁹ An initial challenge is therefore to organize and understand this diversity of agreements and their intellectual property clauses in a systematic way. Section V.A provides a method of systematically describing this seemingly limitless variations of contractual configurations, and Section V.B provides possible principles which

¹⁰⁹ See document UNEP/CBD/COP/5/8, paragraphs 76 and 102.

may be applied across those variations to the intellectual property-specific clauses of the contracts. Finally, Section V.C proposes next steps and a two-stage process for the development of model intellectual property clauses and guide contractual practices for consideration by the Committee members.

V.A Variables and Scenarios to Be Addressed

109. In order to comprehend the countless combinations that may apply to access and benefit-sharing contracts, three basic categories may serve as principal variables to categorize the intellectual property clauses of access and benefit-sharing agreements:

- materials (i.e., type of genetic resources);
- actors (i.e., type of stakeholders);
- uses (i.e., type of transfer and utilization).

The description of Task A.1, which was adopted by the Member States for their discussions, indicated that each of these factors should be taken into account in the development of guide contractual practices and model intellectual property clauses for access and benefit-sharing agreements.¹¹⁰ The following paragraphs therefore explore possible permutations of these variables and their relevance to the intellectual property-related clauses of the access and benefit-sharing contracts. The following paragraphs draw on existing typologies of materials, actors and uses developed by specialized genetic resource fora in order to elaborate the possible permutations of each variable (e.g., different types of genetic material, different types of stakeholders, etc) and the ways in which they are reflected by the intellectual property clauses used in MTAs. In so doing, Section V refers to the intellectual property clauses from existing material transfer agreements which were provided for illustration purposes in Section IV and which correspond to the respective variables.

V.A.1 Materials

110. A basic variable that may be used to distinguish between different contractual agreements and that can serve as an operational distinction to classify the agreements and their intellectual property (“IP”) clauses concerns the type of genetic material which is being transferred. For example, the IP clauses of an MTA are likely to read differently, if they concern the transfer of animal genetic resources for food and agriculture, where trade secrets may be more widely used than patents,¹¹¹ than if they concern the transfer of micro-organisms which are patentable by current international standards.¹¹² Consequently, the above-mentioned Expert Panel on Access and Benefit-sharing concluded that “[d]ifferent resources ... require different contractual arrangements.”¹¹³

111. Types of genetic material transferred under contractual agreements may be distinguished by several criteria, including:

- the degree of human improvement and innovation;
- sectorial types of genetic resources;

¹¹⁰ See document WIPO/GRTKF/IC/1/3, paragraph 41.

¹¹¹ See FAO document CGRFA/WG-AnGR-2/00/4.

¹¹² See Article 27.3(b), TRIPS Agreement.

¹¹³ See document UNEP/CBD/COP/5/8, paragraph 62.

- taxonomic origin of genetic resources;
- conditions under which the resource was accessed, and
- legal status of the resource.

Each of these distinctions classifies genetic resources along different lines and may have a bearing on the intellectual property clauses of contractual agreements for the transfer of the resource in question. They are elaborated below with references to the relevant sample clauses provided in the text boxes of Section IV above.

(i) *Degree of human improvement and innovation* (text boxes 2, 3 and 5): From the intellectual property point of view, the most important distinction is between material which has been improved by human innovation and that which was not. Because intellectual property protects human innovation, the role of intellectual property provisions in contractual agreements is based on this distinction. Human innovation which led to the improvement of the genetic material could be formal or informal, as defined by the draft FAO Code of Conduct on Plant Biotechnology¹¹⁴ (see paragraph 125 below).

(ii) *Sectorial distinctions* (text boxes 1 and 4): As elaborated in sections II.B.2, II.B.3 and III.A above, one fundamental distinction is between sectorial types of genetic resources. Experts in various fora have recognized that “the uniqueness of genetic resources for food and agriculture” requires a “search for distinct solutions for genetic resources for food and agriculture”.¹¹⁵ Indeed, the sample IP clauses in text boxes 1 and 4 above exemplify that genetic resources for food and agriculture, be they of plant, animal, microbial or other origin, are currently being transferred through contractual agreements with intellectual property clauses which reflect specific sectorial policy objectives of the agricultural sector, such as food security, and which are embodied in international agreements and possible future instruments of that sector.

(iii) *Taxonomic origin* (text boxes 1, 4 and 18): The common distinction between genetic material of plant, animal, microbial or other origin may also have a bearing on the intellectual property clauses of access and benefit-sharing agreements.¹¹⁶ Indeed, specialized MTAs have been developed for material of a particular origin, such as microbial or plant origin, which contain differing intellectual property clauses. Consequently, it may be necessary that model intellectual property clauses take into account this distinction.

(iii) *Conditions of acquisition*: A distinction which may have implications on the legal status of the transferred genetic resource is whether it was accessed under *in situ* or *ex situ* conditions.¹¹⁷ This distinction may have intellectual property-related implications in respect of the legal status of the resource at international law and traditional knowledge associated

¹¹⁴ A.3(1), draft FAO Code of Conduct on Plant Biotechnology, defines “informal innovators” 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 rights related to it.”

¹¹⁵ See document UNEP/CBD/COP/5/8, paragraph 63.

¹¹⁶ For example, ““Genetic material” means any material of plant, animal, microbial or other origin containing functional units of heredity.” Article 2, CBD.

¹¹⁷ For example, the access and benefit-sharing provisions of the CBD apply primarily to genetic resources accessed from *in situ* conditions and resources accessed from *ex situ* collections but which were acquired by those collections after entry into force of the Convention.

with the resource. For example, the MOSAICC, referred to in Text Box 18 above, makes a distinction as to the handling of *in situ* and *ex situ* conditions.

(iv) *Legal status of genetic resources* (text boxes 1 and 4): The legal status of genetic resources at international law is of paramount importance to intellectual property clauses of access and benefit-sharing agreements. Depending on where the resource and the parties to the agreement are located, different legal status may apply to the resource. For example, if the agreement concerns a genetic resource which is being provided from *ex situ* conditions, the applicability of the provisions of the CBD depends on whether it was acquired prior to or after entry into force of the CBD. If the transferred material is part of the designated material of an IARC held in trust under the FAO-CGIAR Agreements, the intellectual property policy contained in that Agreement will have to be reflected in the MTA. Furthermore, with the expected approval and entry into force of the revised International Undertaking, plant genetic resources for food and agriculture to which the Multilateral System for Access and Benefit-sharing applies, as well as in-trust materials of the CGIAR and other International Institutions, will be subject to the provisions of the International Undertaking, including in relation to intellectual property.

112. Given the “almost limitless combination” of configurations that may arise with respect to the types of genetic resources covered by contractual agreements for access to genetic resources and benefit-sharing, the development of guide contractual practices and model intellectual property clauses will require certain decisions from the Committee. It may be worth considering to address certain types of genetic resources as a matter of priority, taking into account work on genetic resources being done in other international fora and ensuring the availability of intellectual property rights without discrimination as to the field of technology.

113. The Intergovernmental Committee is invited to take note of different types of genetic resources covered by contractual agreements, as described in paragraphs 110 to 112, and is invited to indicate whether any particular types should be addressed as a matter of priority in the development of guide contractual practices and model IP clauses.

V.A.2 Actors

114. A second variable that has a bearing on contractual agreements and their intellectual property clauses concerns the parties to the agreement and the types of stakeholders involved in its development. For example, when two private sector companies utilizing genetic resources transfer genetic material, they are likely to agree upon different intellectual property clauses than a local or indigenous community entering into a bioprospecting programme with a research institution or pharmaceutical company. Consequently, an expert panel on access to genetic resources concluded that “different requirements for ... mutually agreed terms in contracts may be needed for ... different users.”¹¹⁸ While users and other stakeholders differ from country to country, surveys of genetic resource policy making, aimed at identifying and understanding the relevant stakeholders, have noted that “in spite of major differences among countries, ... it is striking to note that all the actors interviewed can be classified in a number

¹¹⁸ See document UNEP/CBD/COP/5/8, paragraph 102.

of broad types ... and there are many common features for each type across countries.”¹¹⁹ The resulting typology of stakeholders identified four types of actors in the field of genetic resources, namely (a) government institutions (see text boxes 2, 7, 14 and 16); (b) the public sector research community (see text boxes 1, 4, 6 and 23), (c) the private sector (see text box 17 and 19), and (d) civil society (see text box 8). Supplementing this typology with the findings of the CBD Expert Panel, the category of civil society might be further differentiated into non-governmental organisations, indigenous peoples, local communities and other traditional knowledge holders, or a combination of such actors.¹²⁰

115. Depending on which stakeholders enter into an agreement for access and benefit-sharing, the intellectual property clauses of the contract reflect different interests concerning the use and exercise of intellectual property rights in relation to genetic resources.

116. Two additional factors should be taken into account when considering the role of different stakeholders. The first contextual factor which affects the respective role of stakeholders in access and benefit-sharing agreements is that there may be major differences between the actors and their respective bargaining power. Discussions on contractual agreements for access to genetic resources in other fora have concluded that “[g]uidelines or technical assistance may be necessary to ensure that all parties interested in negotiations have access to adequate information and expertise.”¹²¹

117. Second, as genetic resource collection and utilization becomes more specialized and the division of labor in these activities becomes more differentiated, the number of collaborators, actors and stakeholders has increased in recent years. Therefore, most genetic-resource exchanges are not limited to a simple user/provider relationship.¹²² This means that any model intellectual property clauses or guide contractual practices should, as far as possible, be simple and flexible to reflect the widely varying constellations of stakeholders.¹²³

¹¹⁹ Petit, Michel, et. al. *Why Governments Can't Make Policy. The Case of Plant Genetic Resources in the International Arena. Draft for Comment.* International Potato Center (CIP), 2001: pages 34-37.

¹²⁰ In particular, the discussions of the Panel of Experts on Access and Benefit-sharing of the CBD have identified a more detailed list of stakeholders in access and benefit-sharing agreements. These include the following:

- (a) Government agencies concerned with natural resources (including agriculture, including fisheries and forestry, customs, protected areas, health, research, justice);
- (b) the industrial sector (in particular pharmaceutical, plant-health horticultural, personal care and cosmetics, flavouring and fragrance, food and beverage, and other biotechnological companies);
- (c) The scientific and academic communities (including universities and scientific research institutions);
- (d) *Ex situ* conservation facilities (including botanical gardens, zoos, microbial resource centres, universities and research institutions);
- (e) Indigenous and local communities;
- (f) People's organisations;
- (g) Traditional healers (or their associations);
- (h) Non-governmental organisations working in the field of genetic resources.

See document UNEP/CBD/COP/4/23, page 22.

¹²¹ See document UNEP/CBD/COP/2/13, paragraph 22.

¹²² See document UNEP/CBD/COP/5/8, paragraph 67.

¹²³ For example, contractual agreements for a single bioprospecting arrangement have involved as many as eight parties in multiple countries. See, Rosenthal, Joshua. *The International*

118. The Intergovernmental Committee is invited to take note of the different types of stakeholders in genetic resources and is invited to indicate whether the interests, needs and roles of any particular types should be addressed as a matter of priority in the development of guide contractual practices and model IP clauses.

V.A.3 Uses

119. Finally, intellectual property clauses are likely to differ depending on whether the genetic resource is being transferred for use in a commercial or non-commercial context. For example, they will differ, depending on whether a contract concerns transfers for utilization of the genetic resource in an academic research project, a public sector breeding programme, a private sector company or an *ex situ* conservation institution, such as a genebank or botanical garden. Consequently, the Panel of Experts recommended that “[a]ppropriate mutually agreed terms in contractual agreements may vary according to whether the use of genetic resources is scientific or commercial, and, within each of these categories, according to the specific nature of the use.”¹²⁴

120. The most common distinction made is between commercial and non-commercial use. Several reservations have been expressed at the second meeting of the Expert Panel concerning the fact that the distinction between commercial and non-commercial uses does not hold fast in the increasingly commercialized environment of genetic resource utilization today. Nevertheless, in the absence of a better classification of different types of uses, it was decided to employ this distinction, while keeping it under erasure. A second distinction of uses is derived from Article 10(c), CBD, which provides that “customary use of biological resources in accordance with traditional cultural practices” shall be promoted by Contracting Parties. The term “customary use in accordance with traditional cultural practices” has been defined by the Executive Secretary of the CBD in the following manner: “Customary use must take into account the spiritual and ceremonial dimensions of such use in addition to the more strictly economic and subsistence functions. Such use may also entail restrictions in accordance with customary laws: such restrictions must be respected as a necessary function of cultural survival.”¹²⁵

121. In light of this growing complexity, it may be worth considering to address a particular set of actors or relations of actors as a matter of priority. One option would be to address the classical “bioprospecting scenario” where the use of the resource will be commercial and the primary actors are the State of the country of origin, indigenous and local communities, pharmaceutical companies and possible intermediaries. A second possible option could be the intellectual property-related issues arising in the context of public sector conservation and breeding programmes for plant genetic resources for food and agriculture, where the material is of plant origin, the use is non-commercial, and the primary actors are

Cooperative Biodiversity Groups (ICBG) Program. A benefit-sharing case study for the Conference of the Parties to the Convention on Biological Diversity. Submitted to the fourth COP of the CBD, Bratislava, May 4 to 15, 1998.

¹²⁴ See document UNEP/CBD/COP/5/8, paragraph 102.

¹²⁵ See document UNEP/CBD/TKBD/1/2, paragraph 101.

genebanks, public sector research institutions and private sector seed companies. A third option might concern private sector-to-private sector transfers of genetic material which is kept under trade secrecy and withdrawn from public availability for further research and breeding. The possible scenarios are limitless and the Member States are invited to indicate their priorities in terms of materials, actors and uses.

122. The Intergovernmental Committee is invited to take note of the different uses of genetic resources and is invited to indicate whether any particular uses should be addressed as a matter of priority in the development of guide contractual practices and model IP clauses.

V.B Operational Principles for the Development of Guide Contractual Clauses

123. While there is a wide variation of contractual arrangements, which can be categorized and understood through the above-mentioned variables, there are also certain general principles which can apply across all the variations. While Section V.A provided a means of understanding the variation of contractual configurations, the present Section V.B provides certain standards which could be observed across these variations. This could be achieved if the guidelines and model clauses incorporate certain principles. These principles could be identified prior to their embodiment in specific draft model clauses and could serve as a basis for the development of such clauses. For example, at the first Session of the Intergovernmental Committee the Member States have indicated that the guide contractual practices and model clauses shall be non-binding in nature.¹²⁶ The Member States are invited to indicate further such principles for the development of guide contractual practices and model IP clauses.

124. Within the parameters indicated by the Member States in the first Session and those set out in this document, certain possible principles might be identified. The following four possible principles, which cover the full spectrum of materials, actors and uses identified in Section V.A above and reflect the indications of the Member States at the first Session, are offered for consideration of the Member States.

Possible Principle 1:

The IP-related rights and obligations set out in the Model IP clauses should recognize, promote and protect all forms of formal and informal human creativity and innovation, based on, or related to, the transferred genetic resources.

125. Taking into account the specialized mandate of WIPO, the model clauses and guide contractual practices developed by the Committee would be limited to intellectual property-related elements of contractual agreements for access to genetic resources and benefit-sharing. This principle reflects one of the basic objectives of intellectual property, namely to promote human innovation and creativity, and the dissemination and application of its results by granting exclusive rights which result from human intellectual activity. Forms of innovation and creativity based on genetic resources include both formal and informal innovations. In the genetic resource context, *informal innovations* are defined as the innovations of “informal

¹²⁶ See document WIPO/GRTKF/IC/1/13, paragraph 49.

innovators,” namely “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.”¹²⁷ Consequently, *formal innovations* are defined as innovations of “formal innovators,” namely “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.”¹²⁸ A possible principle could be that the model IP clauses should recognize, promote and protect all forms of innovation, including both formal and informal. This principle is already applied and reflected in existing model MTAs such as the one referred to in Text Boxes 5 and 10.

Possible Principle 2:

The IP-related rights and obligations set out in the Model IP Clauses should take into account sectorial characteristics of genetic resources and genetic resource policy objectives and frameworks.

126. At the first Session of the Intergovernmental Committee the Member States provided a strong indication that the work of the Intergovernmental Committee should be consistent with the work of the CBD and the FAO.¹²⁹ This requires that the model IP clauses would take into consideration the sectorial genetic resource policy objectives and frameworks which have been or are being, developed by those fora. These objectives and frameworks should be taken into account while ensuring that patent rights shall be available without discrimination as to the place of invention or the field of technology and whether products are imported or locally produced. It may also imply the application of general principles, guidelines and concepts which have been developed by those fora for access and benefit-sharing in general to the IP-related clauses of contracts. For example, in the case of contracts concluded in the context of the Multilateral System for Access and Benefit-sharing, which is expected to be established under the International Undertaking, the parties would be acting not only in their private interests, but in that of the international community, and this concept could be taken into account in the development of model clauses, in so far as it relates to intellectual property. Furthermore, the Member States suggested with reference to Task A.1 of the Committee that “it would therefore be important to include prior informed consent in contractual arrangements.”¹³⁰ Moreover, the model IP clauses and guide contractual practices would likely be consistent with and reflective of current contractual and commercial practices within those genetic resource sectors.

Possible Principle 3:

The IP-related rights and obligations set out in the Model IP Clauses should ensure the full and effective participation of all relevant stakeholders and address process issues related to contract negotiation and the development of IP clauses for access and benefit-sharing agreements, including in particular traditional knowledge holders where traditional knowledge is covered by the agreement.

¹²⁷ 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”).

¹²⁸ *Ibid.*

¹²⁹ See document WIPO/ GRTKF/IC/1/13, paragraphs 21, 22, 23, 27, 28, 32, 33, 37, 39, 41, 43, 50, 51, 52, 57, 61, 82, 84, 91, 94, 104, 105, 106, 107, 112, 114, 119, 128 and 155.

¹³⁰ See document WIPO/ GRTKF/IC/1/13, paragraph 106.

127. Through this principle, the guide contractual practices would address “process” dimensions of the development of IP clauses for access and benefit-sharing contracts. Specifically, this principle would provide for the full and effective participation of all relevant stakeholders in the development of IP clauses of the access and benefit-sharing agreement. This would imply, in particular, that indigenous peoples, local communities and other traditional knowledge holders should be fully involved in contractual agreements for bioprospecting activities, if their traditional knowledge is being utilized. Furthermore, the simplicity of the clauses and the provision of detailed commentary in clear and practical language should be factors facilitating the attainment of this principle.

Possible Principle 4:

The IP-related rights and obligations set out in the Model IP Clauses should distinguish between different kinds of use of genetic resources, including commercial, non-commercial and customary uses.

128. In keeping with numerous existing model material transfer agreements, the model clauses would distinguish between different uses of genetic resources and would provide specific intellectual property clauses for different categories of uses of the transferred resource. One of the aspects integrated under this principle would be to enable and ensure continued customary use of genetic resources by the customary users of the resources in the local context.

129. In general the model clauses and guide contractual practices would not claim to be exhaustive in covering the limitless variations of materials, actors and uses. They would not claim to be authoritative, but rather would aim to provide a practical starting point for the negotiations of stakeholders, as they develop their own contractual agreements for access and benefit-sharing.

130. The Members of the Intergovernmental Committee are invited to propose principles and specify objectives for the development of guide contractual practices and model IP clauses for access to genetic resources and benefit-sharing, and are invited to comment on the possible principles identified in paragraphs 124 to 129.

V.C Proposals for Next Steps

131. As indicated in paragraph 8 above, this document proposes a two-stage approach for the implementation of Task A.1 of the Committee. Considering the priorities and principles indicated by the Member States under Sections V.A and V.B above respectively, the Intergovernmental Committee may wish to consider the following next steps.

132. It is suggested that, based on the information provided in Part IV and Section V.A above, the Committee members indicate the kinds of scenarios of access to genetic resources which they wish to address with the model clauses. This could be done by indicating the priority materials, actors and uses for which they wish to develop guide contractual practices

and model IP clauses. Several options for priority configurations are provided in paragraph 121 above.

133. Based on the directions provided by the Committee members at the second Session, it is proposed that the International Bureau undertake a systemic survey of actual contractual agreements used in the scenarios which were indicated by the Committee members as areas of priority. This survey might include a questionnaire to be sent to Committee members and other stakeholders, as appropriate. Furthermore, Committee members and other relevant stakeholders would be invited to provide experiences, examples and case studies of contractual practices and agreements for a compilation of existing IP clauses and agreements. This compilation could be prepared by applying the variables identified in Section V.A above and could serve as a basis for the systematic and balanced development of model clauses which reflect the operational principles identified and agreed by the Committee members. Further to the Member State proclamations concerning the desirability of close cooperation with the CBD and FAO at the first Session of the Intergovernmental Committee, it is suggested that the Committee take into account the results of their respective processes and work in close cooperation with the FAO Commission on Genetic Resources for Food and Agriculture and the Secretariat of the CBD on those issues which fall within their respective spheres of competence.

134. Whereas the IP clauses listed in this document were provided merely as examples for illustration purposes, it is proposed that a complete and systematic survey of IP clauses could be undertaken according to the variables and principles identified by the Committee members. Once existing access and benefit-sharing agreements have been compiled through the survey, the variables and principles identified in Sections V.A and V.B may be applied for the development of guide practices and model IP clauses, based on the existing practices and clauses.

VI. CONCLUSION

135. Contractual agreements for access to genetic resources and benefit-sharing currently cover an almost limitless range of combinations of materials, actors and uses of genetic resources as a result of the rapid developments in science and technology. The present document listed examples of intellectual property-related clauses which are currently being used in existing access and benefit-sharing contracts and provided a set of variables to describe this almost limitless range of contractual clauses in a systematic way. Since it will not be possible for the Committee to address all types of contractual agreements for access to genetic resources and benefit-sharing at the same time, the present document solicits further decisions, prioritization and guidance from the Committee members on the variables and scenarios which they wish to address as a matter of priority. Furthermore, the document offers four possible operational principles which could be taken into account in the formulation of guide contractual practices and model intellectual property clauses, and proposes, for the consideration by the Committee members, a two-phased approach for next steps towards the development of model intellectual property clauses and guide contractual practices.

136. The Members of the Intergovernmental Committee are invited to take note of the contents of the present document and provide

guidance on the development of guide contractual practices and model IP clauses for access to genetic resources and benefit-sharing, as requested in paragraphs 113, 118, 122 and 130.

[Annex I follows]

GLOSSARY OF GENETIC RESOURCE TERMINOLOGY
RELATED TO INTELLECTUAL PROPERTY AND GENETIC RESOURCES

At the first Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“the Committee”), held in Geneva from April 30 to May 3, 2001, the Member States emphasized the need for terminological clarity and for adopting internationally agreed uses of relevant terms, thereby capitalizing on decades of specialized work in other international fora.¹³¹ In particular, when deliberating on Task A.1 of the Committee, delegations proposed to begin this exercise with a definitional section for genetic resources.¹³² Further to this proposal, existing international definitions of genetic resource terminology related to Task A.1 are provided in this Annex. The Annex provides the current definitions of the following terms: genetic resources, genetic material, biological resources, plant genetic resources, plant genetic resources for food and agriculture, cultivar, obsolete cultivar, primitive cultivar or landrace, weeds, special genetic stocks, line, elite line, current breeders’ line, mutant.

The term ‘*genetic resources*’ is defined as “genetic material of actual or potential value.”¹³³

‘*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.¹³⁴

While it is not specified which actual or potential value of the resource is meant, a range of qualities which confer value to the components of biodiversity, including genetic resources, are provided: the definition was adopted conscious of “the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of biological diversity and its components.” (Preamble, first recital, CBD) The implied distinction between genetic material and genetic resource may therefore be of a merely theoretical nature. In Decision II/2 the second Conference of the Parties (COP) to the CBD reaffirmed “that human genetic resources are not included within the framework of the Convention”.¹³⁵

The term ‘*biological resources*’ includes “genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.”¹³⁶ Genetic resources form one category of biological resources. Whereas the CBD defines genetic resources as being “of actual or potential value,” it defines “biological resources” as resources “with actual or potential *use or* value for humanity” (Article 2, CBD, emphasis added).

¹³¹ See document WIPO/GRTKF/IC/1/13, paragraphs 21, 22, 23, 27, 28, 32, 33, 37, 39, 41, 43, 50, 51, 52, 57, 61, 82, 84, 91, 94, 104, 105, 106, 107, 112, 114, 119, 128, 155.

¹³² See document WIPO/GRTKF/IC/1/13, paragraph 105.

¹³³ Article 2, CBD.

¹³⁴ Article 2, CBD

¹³⁵ In Decision II/2 of the second Conference of the Parties (COP) to the CBD, Article 2.

¹³⁶ Article 2, CBD

The term '*plant genetic resources*' is defined as "germplasm or genetic material of actual or potential value"¹³⁷ in the context of international rules for the exploration and collection of plant genetic resources. The terms "genetic material" or "plant germplasm" mean "reproductive or vegetative propagating material of plants" in this context (FAO International Code of Conduct for Plant Germplasm Collecting and Transfer (1993)).¹³⁸

In the area of '*plant genetic resources for food and agriculture*' (PGRFA), the International Undertaking on Plant Genetic Resources (1983) defines the term "plant genetic resources" as follows:

"the reproductive or vegetative propagating material of the following categories of plants:

- (i) cultivated varieties (cultivars) in current use and newly developed varieties;
 - (ii) obsolete cultivars;
 - (iii) primitive cultivars (landraces);
 - (iv) wild and weed species, near relatives of cultivated varieties; and
 - (v) special genetic stocks (including elite and current breeders' lines and mutants)"
- (Article 2.1(a))

'*Cultivars*,' or '*cultivated varieties*,' are varieties of a plant produced by selective breeding, which has been specifically improved for agricultural or horticultural purposes and are grown in cultivated conditions. The term '*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].¹³⁹ *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. *Weeds* are plant species which are adapted to grow in disturbed or open habitats.

The fifth category of the definition of plant genetic resources for food and agriculture, "*special genetic stocks*," refers to plant genetic resources under current development by breeders and farmers, which their developers frequently protect by means of trade secrecy. 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 homozygous parent and an "*elite*" refers to germplasm which has been manipulated for use in breeding programs, including advanced, inbred and pure lines. "*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. Therefore, in respect of category (v) "*special genetic stocks*," Resolution 3/91 of the FAO Conference endorsed that

¹³⁷ Article 2.8, FAO International Code of Conduct for Plant Germplasm Collecting and Transfer (1993).

¹³⁸ Article 2.9, *Ibid.*

¹³⁹ This does not necessarily correspond to the formal lists for seed certification. Some countries, e.g. member countries of the European Community, do not allow the trading of seeds which are not on the list. Others, maintain a list, but not all traded seeds are on their relevant lists. Finally, some countries maintain no lists at all (e.g., the United States of America).

“breeders’ lines and farmers’ breeding material should only be available at the discretion of their developers during the period of development.”¹⁴⁰

Various other terms are being negotiated within Article 2 of the revised International Undertaking. Examples of terms already agreed under Article 2 of the revised International Undertaking include “variety,” “*ex situ* collection,” and “centre of origin.”

[Annex II follows]

¹⁴⁰ Paragraph 2, Resolution 3/91 of the Twenty-sixth Session of the FAO Conference, Rome, November 9 to 27, 1991.

LIST OF CONTRACTUAL AGREEMENTS FOR
ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING,
REFERRED TO IN THE PRESENT DOCUMENT

- Standard Material Transfer Agreement, Consultative Group on International Agricultural Research (CGIAR)
- Standard Material Transfer Agreement for Non-plant Genetic Materials (Including Micro-organisms, Animals and Aquatic and Marine Materials), Consultative Group on International Agricultural Research (CGIAR)
- Uniform Biological Material Transfer Agreement (UBMTA), Association University Technology Managers (AUTM)
- Material Transfer Agreement, “Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct” (MOSAICC)
- Material Transfer Agreement, American Type Culture Collection (ATCC)
- Natural Products Repository Material Transfer Agreement (Model Agreement, approved May 1989), Natural Products Branch, National Cancer Institute (NCI) of the United States of America
- Memorandum of Understanding Between [Source Country Organization] and the Developmental Therapeutics Program (DTP), Division of Cancer Treatment, Diagnosis, and Centers, National Cancer Institute (NCI) of the United States of America
- Agreement for the Transfer of Biological Material and/or Related Information, *The ICIPE Intellectual Property Policy 2000 and Guide to the ICIPE Intellectual Property Policy 2000* (Schedule 2), International Centre for Insect Physiology and Ecology (ICIPE), Nairobi, Kenya
- Draft Uniform Biological Material Transfer Agreement, Non-profit to Non-profit; National Science Foundation (NSF) of the United States of America
- Memorandum of Understanding Between the Society for Research Into Sustainable Technologies and Institutions (SRISTI) and Research and Development Organization (RDO), Gujarat, India
- Model Arbitration Clause, Arbitration Rules of the United Nations Commission on International Trade Law
- Model Material Transfer Agreements for Equitable Biodiversity Prospecting (Version One: For Transfer of Biological Resources to Non-Commercial or Non-Profit Organizations)
- Model Material Transfer Agreements for Equitable Biodiversity Prospecting (Version Two: For Transfer of Biological Resources to Commercial Organizations)

- Model Material Acquisition Agreement, Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit-sharing
- Model Material Supply Agreement, Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit-sharing
- Recommended Contractual Clauses and Submission Agreements, WIPO Arbitration and Mediation Center

[End of Annex II and of document]