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GENETIC RESOURCES: DRAFT INTELLECTUAL PROPERTY GUIDELINES FOR ACCESS AND EQUITABLE BENEFIT-SHARING

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OVERVIEW

1. Since its inception, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee') has worked towards guidelines on the intellectual property (IP) aspects of mutually-acceptable terms in agreements that concern access to genetic resources and equitable sharing of benefits from the use of accessed resources. This work has been aimed at producing a resource, to alert custodians of genetic resources to the practical issues that arise when they elect to enter into agreements on access and benefit-sharing. The Committee's work has been based on an empirical survey of experience in this field, and a database collecting actual terms of agreements. As a first step, the Committee agreed on a set of guiding principles to frame this work, then oversaw the collection and analysis of practical experience in this area, and most recently considered a draft set of guidelines (WIPO/GRTKF/IC/6/5, submitted to the sixth session). It agreed to request further comments on these draft guidelines, so that a further draft could be prepared. The present document therefore provides the required update of this material for the further consideration of the Committee:

- the body of the present document provides background information, essentially reproducing the contents of document WIPO/GRTKF/IC/6/5, with minimal changes to reflect developments at the sixth session; and,

- the Annex provides updated guidelines, which incorporates various responses and comments received at the sixth session of the Committee and subsequently provided by Member States.

I. BACKGROUND

2. Genetic resources can provide an important input for research and the development of new products, in an increasingly broad range of technological and industrial sectors. The terms and conditions of access to genetic resources, the exercise of prior informed consent by the providers of genetic resources, and the resulting arrangements made for the sharing of benefits from their use and development, are critical issues. Existing international law and a number of regional, national and sub-national laws and regulations set the framework for exercising prior informed consent and determining the terms and conditions of access as well as benefit-sharing. Key elements of international law include the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) of the Food and Agricultural Organization (FAO). The CBD, adopted in 1992, provides an international framework for access and benefit-sharing for genetic resources. The ITPGR, adopted in 2001, covers plant genetic resources for food and agriculture (PGRFA) and will establish a multilateral system of access and benefit-sharing for certain PGRFA. In conformity with the access and benefit-sharing provisions of these international instruments, national regimes have been developed to regulate access to genetic resources.

3. The detailed arrangements for specific acts of access and benefit-sharing are often set through permits or negotiated licenses, contracts or agreements (including those termed ‘material transfer agreements’ or MTAs). Such agreements generally operate within the framework of the specific national regimes that govern access to genetic resources, and in line with other laws regulating the environment, public resources, indigenous and community rights and regional development, as well as general contract and property law. There are also broader international guidelines that influence the overall approach taken to such agreements. In particular, to assist with the implementation of the access and benefit-sharing provisions of the CBD, the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization* (‘Bonn Guidelines’) were adopted by the Conference of Parties (COP) of the CBD. The Guidelines are meant to assist Parties to the CBD when developing and drafting legislative, administrative and policy measures on access and benefit-sharing, and also when developing contracts and other arrangements under mutually agreed terms for access and benefit-sharing.

4. Within access and benefit-sharing agreements, the specific arrangements made for intellectual property (IP) management can be crucial in ensuring that they operate to create benefits from access to genetic resources, and in particular to ensure that those benefits are shared equitably and the interests and concerns of the resource providers are fully respected. IP issues that can be determined in agreements include the entitlement to seek IP rights in inventions and other results of research using the resources, ownership and licensing of such derivative IP, responsibility for maintaining and exercising IP rights. Some commentators have pointed to the limitations of contracts as a means of defining and governing relationships in relation to the access and use of genetic resources. However, since this approach is already widely used in the field, and is required under many national genetic resource regulations, stakeholders have called for guidelines on the IP aspects of contracts concerning access and benefit-sharing.

5. As a result, the Committee took up the development of such guidelines from its first meeting as one of its tasks. It has conducted extensive discussions and information gathering on IP aspects of contractual agreements for access to genetic resources and benefit-sharing. This has included:

- developing four general principles, discussed at its second session, as the basis for further development of Guide Contractual Practices, based on compiled existing contracts;
- compiling and agreeing upon a detailed questionnaire, concluded at its third session, and widely distributed since then; and
- a trilingual online database concerning IP aspects of existing agreements or contracts for access and benefit-sharing, launched at the fourth session and further developed at the fifth session.

6. The Committee has therefore completed the first stage of a two-step approach adopted by the Committee at its second session.[1] The agreed second stage of this approach is for the "principles identified [by the Committee to] be applied for the development of guide practices…, based on the existing practices and clauses".[2] The CBD COP has since encouraged WIPO to "make rapid progress in the development of model IP clauses which may be considered for inclusion in contractual agreements when mutually agreed terms are under negotiation."

7. The present document accordingly progresses this second stage, and continues the systematic and balanced development of Guide Contractual Practices on the basis of the identified principles, the database of sample contracts, and the guidance provided by Committee members. For this purpose, the present document builds on the principles that were identified and adopted by the Committee at its second and third sessions for the development of Guide Contractual Practices. The Committee considered draft guidelines at its sixth session (provided in the Annex to WIPO/GRTKF/IC/6/5), and a number of delegations provided comments on them. Other delegations requested further time, as there had been insufficient time to consider document WIPO/GRTKF/IC/6/5, in particular in all languages (the discussion and decisions are reported in WIPO/GRTKF/IC/6/14, paragraphs 111 to 139). Hence the Committee invited further comments and input to be provided by June 30, 2004, so that a revised document (the present document) could be submitted to the Committee at its seventh session.

8. The Annex to the present document contains the updated draft guidelines, which take account of comments at the sixth session and comments since received from several Member States. These guidelines therefore aim to reflect the principles already agreed by the Committee, the directions given by Committee members, and information resources collected over the past two years. The Committee participants are invited to comment on the draft Guide Contractual Practices and to further elaborate the principles which were previously identified. This draft aims to build on the Committee's work so far, and may form the basis for a specific outcome within the terms of the Committee's current mandate. Accordingly, Committee participants are invited to assess and comment on the operational principles and the draft guidelines contained in the Annex. In recognition of the need for the Committee's work on IP aspects of access and benefit-sharing contracts to respect and complement other

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1 See Chair's conclusions (WIPO/GRTKF/IC/2/16, para. 110).

2 See WIPO/GRTKF/IC/2/3, para. 134.

international processes, Part V of the document reviews relevant policy developments taking place in the intergovernmental processes of the CBD and the FAO.

II. INTRODUCTION

9. The important role of IP practices and clauses within contractual arrangements for access to genetic resources and benefit-sharing has been widely recognized in most genetic resource policy processes. It is a specific requirement in a number of regional instruments[3] and of several national laws which have already been considered by the Committee.[4] The CBD Bonn Guidelines also illustrate how access and benefit sharing can provide for the development of 'mutually agreed terms,' and how material transfer agreements may include terms specifically concerning IP. The Bonn Guidelines were developed to provide guidance in the development of 'contracts and other arrangements under mutually agreed terms for access and benefit-sharing.' The Bonn Guidelines indicate that 'mutually agreed terms should be set out in a written agreement,' set out 'guiding parameters for contractual agreements' and provide 'an indicative list of typical mutually agreed terms' which may be applicable in contracts regarding access to genetic resources. These mutually agreed terms typically include specific elements regarding the obtaining, exercise, managing and licensing of IP on products or processes that are developed as a result of the agreed access, as well as IP that is provided in the course of the access.

10. Given the need for closer consideration of these specialized IP clauses, the Committee decided to address IP aspects of contractual arrangements for access and benefit-sharing from the very beginning of its work. At its first session, the Committee supported a Task which would lead to "the development of 'guide contractual practices' … 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."[5] When considering this Task, the Committee decided to take a two-step approach to the development of the Guide Contractual Practices.[6] The first stage of this approach, namely "a systemic survey of actual contractual agreements" in the form of an online database,[7] has been completed. The present document progresses the

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3 For example, the African Union Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources; and Andean Community Decision 391 on a Common Regime on Access to Genetic Resources.

4 In particular, see the detailed discussion in document WIPO/GRTKF/IC/5/9 (Section IV) of three national laws, namely the Brazilian Provisional Measure No. 2.186-16, of August 23, 2001; Panamanian Law No. 20 of June 26, 2000, on the Special Intellectual Property Regime Governing the Collective Rights of Indigenous Peoples for the Protection and Defense of their Cultural Identity and their Traditional Knowledge; and Executive Degree No. 12 of March 20, 2001; and Peruvian Law No. 27811 ("A Law introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources"), published on August 10, 2002. See also the access licensing regime applicable to national parks in the United States of America (document WIPO/GRTKF/IC/4/13).

5 Task A.1, WIPO/GRTKF/IC/1/3. See also WIPO/GRTKF/IC/1/13.

6 The two-step approach was described as follows: first, "a complete and systematic survey of IP clauses could be undertaken ... [Second,] once existing access and benefit-sharing agreements have been compiled through the survey, the variables and principles identified [by the Committee members] may be applied for the development of guide practices and model IP clauses, based on the existing practices and clauses." (WIPO/GRTKF/IC/2/3, para. 134).

7 See WIPO/GRTKF/IC/2/3, para. 133.

second stage by furthering the "principles identified [by Committee members] applied for the development of guide practices",[8] based on the four principles considered at its second session. As noted above, the sixth CBD COP encouraged WIPO to "make rapid progress in the development of model intellectual property clauses which may be considered for inclusion in contractual agreements when mutually agreed terms are under negotiation".

11. Committee members have pointed out that,[9] if developed, any Guide Contractual Practices could have both a capacity-building or informative aspect, and a normative or guidance aspect. As was emphasized by many delegations, the normative aspect of the Guide Contractual Practices would be entirely voluntary.[10] It was stressed that they should not have any effect on the sovereign rights of states to regulate access to the natural resources on their territories, including genetic resources, nor in themselves create any legally binding obligation for parties to access and benefit-sharing arrangements. On the other hand, by articulating the range of options that is available, they would ensure that both parties to the agreement, but especially the provider of genetic resources, would have a stronger basis for making a fully informed choice on specific provisions. The capacity-building aspect lies in their capacity for facilitating awareness raising,[11] information dissemination[12] and strengthening capacity[13] to negotiate IP terms for contractual agreements for access and benefit-sharing. In this respect several technical problems which were identified by Committee members,[14] such as, languages used; responsibility for channeling information from Members to the database; and, inclusion of detailed legal documents in summary form, have been addressed. As Committee members have emphasized, the instructive or information aspect should be enhanced through a thorough and simple commentary on the normative elements of the draft Guide Contractual Practices.[15]

12. This document sets out substantive issues regarding the development of draft Guide Contractual Practices in the following structure: Part III describes the Principles that were adopted or identified by the Committee at its second and third sessions; Part IV describes the

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8 See WIPO/GRTKF/IC/2/3, para. 134.

9 See Australia (WIPO/GRTKF/IC/2/16, para. 68), Turkey (WIPO/GRTKF/IC/2/16, para. 67).

10 See Canada (WIPO/GRTKF/IC/2/16, para. 77), China Switzerland (WIPO/GRTKF/IC/2/16, para. 82), Colombia (WIPO/GRTKF/IC/2/16, para. 58), European Community and its Member States (WIPO/GRTKF/IC/2/16, para. 75), Indonesia (WIPO/GRTKF/IC/2/16, para. 63), Japan Switzerland (WIPO/GRTKF/IC/2/16, para. 76), New Zealand (WIPO/GRTKF/IC/2/16, para. 73), Peru (WIPO/GRTKF/IC/2/16, para. 69), Switzerland (WIPO/GRTKF/IC/2/16, para. 83), United States of America (WIPO/GRTKF/IC/2/16, para. 74), BIO (WIPO/GRTKF/IC/2/16, para. 92), ICC (WIPO/GRTKF/IC/2/16, para. 95), Chair (WIPO/GRTKF/IC/2/16, para. 54 and 96).

11 Similarly, for example, the objectives of the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization ("the Bonn Guidelines") include "to promote awareness on implementation of the relevant provisions of the CBD." (para.11(f), Bonn Guidelines).

12 The objectives of the same instrument further include "To inform the practices and approaches of stakeholders (users and providers) in access and benefit-sharing arrangements." (para. 11(d), Bonn Guidelines).

13 See Australia (WIPO/GRTKF/IC/3/17, para. 38), United States of America (WIPO/GRTKF/IC/3/17, para. 39). The objectives also include "[t]o provide capacity-building to guarantee the effective negotiation and implementation of access and benefit-sharing arrangements, especially to developing countries, in particular least developed countries and small island developing States among them." (para. 11(e), Bonn Guidelines).

14 See European Community and its Member States (WIPO/GRTKF/IC/3/17, para. 32).

15 See Ecuador (WIPO/GRTKF/IC/2/16, para. 55).

previous work of the Committee which forms the basis of the draft Guide Contractual Practices contained in the Annex; Part V describes the international policy context in which these draft Guide Contractual Practices should be framed, including in particular the policy processes of the Convention on Biological Diversity (CBD), the Food and Agriculture Organization of the United Nations (FAO), and the Consultative Group on International Agricultural Research (CGIAR).

III. PRINCIPLES ESTABLISHED BY THE COMMITTEE FOR GUIDE CONTRACTUAL PRACTICES

13. At its second session the Committee identified and considered a set of draft principles for the development of Guide Contractual Practices or model IP clauses which were set out in document WIPO/GRTKF/IC/2/3.[16] The Chair concluded that the draft principles had "found broad support" in the Committee, subject to certain comments and observations, which are summarized below.[17] The principles were identified in document WIPO/GRTKF/IC/2/3 as follows:

> Principle 1: *The IP-related rights and obligations set out in [the Guide Contractual Practices] should recognize, promote and protect all forms of formal and informal human creativity and innovation, based on, or related to, the transferred genetic resources.*
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> Principle 2: *The IP-related rights and obligations set out in [the Guide Contractual Practices] should take into account sectorial characteristics of genetic resources and genetic resource policy objectives and frameworks.*
>
> Principle 3: *The IP-related rights and obligations set out in [the Guide Contractual Practices] 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.*
>
> Principle 4: *The IP-related rights and obligations set out in [the Guide Contractual Practices] should distinguish between different kinds of use of genetic resources, including commercial, non-commercial and customary uses.*

14. In addition to commenting on the four principles identified in document WIPO/GRTKF/IC/2/3, the Committee members also identified certain additional possible principles. The following paragraphs first summarize the comments provided on the four proposed principles and then list the principles additionally identified by Committee members. These comments and principles are reflected in the draft Guide Contractual Practices contained in the Annex to this document.

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.*

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16 See WIPO/GRTKF/IC/2/3, Section V.B, p.50ff.

17 See Chair's conclusions (WIPO/GRTKF/IC/2/16, para. 96).

15. This principle reflects three parameters of the draft Guide Contractual Practices:

(a) the draft Guide Contractual Practices are limited to IP-specific elements of contractual agreements for access and benefit-sharing.[18] All other aspects lie outside WIPO's mandate and are left to the relevant fora and processes, while fully taking into account the legal frameworks and policy guidance which those fora and processes have produced;

(b) the draft Guide Contractual Practices reflect one of the basic objectives of IP, namely to promote human innovation and creativity, and the dissemination and application of its results, in particular the equitable sharing of benefits from access to and use of genetic resources;

(c) the forms of innovation and creativity based on genetic resources which are recognized by the draft Guide Contractual Practices include both formal and informal innovations, [19] and this accordingly entails respect for traditional knowledge (TK) associated with genetic resources.

16. A broad range of Committee members expressed support for this principle.[20] In deliberating on this principle, Committee members made the following comments on its appropriate application:

- the application of the principle should be without prejudice to the legal protection that had to be given to the providers of the genetic resource, the State and its communities;[21]
- if applied indiscriminately, the principle might be too wide;[22]
- the application should take into account that genetic resources in the form in which they existed in nature, and mere discoveries, did not qualify for the recognition of IP rights;[23]
- existing IP agreements should be used as guidance for defining the limits of IP systems;[24]
- the application should involve a clearer use of the terms "creativity" and "innovation", in particular the terms 'formal' and 'informal' innovation;[25] and
- the application should take into account possible *sui generis* protection of TK and genetic resources.[26]

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18 See European Community and its Member States (WIPO/GRTKF/IC/2/16, para. 75).

19 For the definitions of the terms 'informal innovation' and 'formal innovation' in a genetic resource context, see WIPO/GRTKF/IC/1/3, para. 9.

20 See in general document WIPO/GRTKF/IC/2/16.

21 See Ecuador (WIPO/GRTKF/IC/2/16, para. 55).

22 See Chair's conclusions (WIPO/GRTKF/IC/2/16, para. 96).

23 See Ecuador (WIPO/GRTKF/IC/2/16, para. 55), United States of America (WIPO/GRTKF/IC/2/16).

24 See United States of America (WIPO/GRTKF/IC/2/16, para. 74)

25 See Canada (WIPO/GRTKF/IC/2/16, para. 77), China (WIPO/GRTKF/IC/2/16, para. 82), Bolivia, Cuba, Dominican Republic, Ecuador, Panama, Nicaragua, Peru and Venezuela (WIPO/GRTKF/IC/2/3, para. 56), Morocco (WIPO/GRTKF/IC/2/16, para.79) and Switzerland (WIPO/GRTKF/IC/2/16, para. 83).

26 See South Africa (WIPO/GRTKF/IC/2/3, para. 80).

All the comments which were provided by Committee members have been taken into account when applying Principle 1 in the development of the draft Guide Contractual Practices in the Annex.

Principle 2: *The IP-related rights and obligations set out in the Guide Contractual Practices should take into account sectorial characteristics of genetic resources and genetic resource policy objectives and frameworks.*

17. This principle foresees that the Guide Contractual Practices would take into consideration the sectorial genetic resource policy objectives and frameworks which have been, or are being, developed in the relevant international fora. These objectives and frameworks are 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. The principle rests, *inter alia*, on the fact that Committee members have decided that the work of the Committee should be consistent with the work of the CBD and the FAO.[27] It takes account of general principles, guidelines and concepts which have been developed by the relevant fora for access and benefit-sharing. For example, in the case of contracts concluded in the context of the Multilateral System of Access and Benefit-sharing, which will be established under the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGR), the parties would be acting not only in their private interests, but in that of the international community. Furthermore, the Member States suggested since the first session of the Committee that "it would … be important to include prior informed consent in contractual arrangements".[28] Moreover, the guide contractual practices would be consistent with and reflective of current contractual and commercial practices within those genetic resource sectors.

18. At the second session, the Chair concluded that this Principle had found "broad support".[29] In deliberating on this principle, the Committee members made the following comments regarding its appropriate application:

- the application of this principle should be consistent with the interests of the international community as reflected in the major international treaties on genetic resources, such as the CBD and ITPGR;[30]
- the application should provide adequate guidance for the fulfillment of requirements to disclose the source of genetic material used in patented inventions;[31]
- the definitions provided for the application of this principle should also include the term "derivatives";[32]
- the application should cover prior informed consent (PIC) for access to the concerned genetic material;[33] and,
- the application of this principle should be without prejudice to, but should take account of, discussion regarding implementation of the ITPGR.[34]

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27 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.

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

29 See WIPO/Gra\TKF/IC/2/16, paragraph 96.

30 See Ecuador (WIPO/GRTKF/IC/2/16, para. 55).

31 See Bolivia (WIPO/GRTKF/IC/3/17, para. 37), Brazil (WIPO/GRTKF/IC/2/16, para. 59), Peru (WIPO/GRTKF/IC/3/17, para. 37), Venezuela (WIPO/GRTKF/IC/3/17, para. 33).

32 See Brazil (WIPO/GRTKF/IC/3/17, para. 40).

33 See Brazil (WIPO/GRTKF/IC/2/16, para. 59), Peru (WIPO/GRTKF/IC/3/17, para. 37), Bolivia (WIPO/GRTKF/IC/3/17, para. 37).

<u>Principle 3:</u> The IP-related rights and obligations set out in the Guide Contractual Practices 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.

19. 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. Through this principle, the guide contractual practices would address "process" dimensions of the development of IP clauses for access and benefit-sharing contracts. This would imply, in particular, that indigenous peoples, local communities and other TK holders should be fully involved in contractual agreements for bioprospecting activities, if their TK is being utilized. Associated TK will often be intrinsically linked to the genetic resources themselves, and access to the genetic resources may be linked with access to the associated TK. As pointed out by Committee members, this principle could be attained through the simplicity of the Guide Contractual Practices and the provision of detailed commentary in clear and practical language. Committee members expressed general support for draft principle 3.[35] In deliberating on this principle, Committee members made the following comments on its appropriate application:

- the Guide Contractual Practices should include a detailed commentary;[36]
- the Guide Contractual Practices should be written in simple everyday language;[37]
- the Guide Contractual Practices should further specify the terms "relevant stakeholders" and "TK holders";[38]
- the Guide Contractual Practices should aim to promote the effective participation of indigenous and local communities;[39]
- the Guide Contractual Practices should take into account prior informed consent requirements that may apply to genetic resources;[40]
- the Guide Contractual Practices should cover all stakeholders;[41] and
- the Guide Contractual Practices should recognize the intrinsic limitations of contracts, as parties involved might not be in the same negotiating position.[42]

<u>Principle 4:</u> The IP-related rights and obligations set out in the Guide Contractual Practices should distinguish between different kinds of use of genetic resources, including commercial, non-commercial and customary uses.

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34 See Norway (WIPO/GRTKF/IC/2/16, para. 72).

35 E.g. Brazil (WIPO/GRTKF/IC/2/16, para. 59), Canada (WIPO/GRTKF/IC/2/16, para. 77), China (WIPO/GRTKF/IC/2/16, para. 82), Ecuador (WIPO/GRTKF/IC/2/16, para. 55), Morocco (WIPO/GRTKF/IC/2/16, para. 79), United States of America (WIPO/GRTKF/IC/2/16, para. 74), the Saami Council (WIPO/GRTKF/IC/2/16, para. 91).

36 See Ecuador (WIPO/GRTKF/IC/2/3, para. 55).

37 See Ecuador (WIPO/GRTKF/IC/2/3, para. 55).

38 See China (WIPO/GRTKF/IC/2/16, para. 82).

39 See Ecuador (WIPO/GRTKF/IC/2/3, para. 55).

40 See Ecuador (WIPO/GRTKF/IC/2/3, para. 55).

41 See Asian Group (WIPO/GRTKF/IC/2/16); United States of America (WIPO/GRTKF/IC/2/16, para. 74).

42 See Brazil (WIPO/GRTKF/IC/2/16, para. 59), INADEV (WIPO/GRTKF/IC/2/16, para. 88).

20. According to this principle, the Guide Contractual Practices would distinguish between different uses of genetic resources and would provide specific IP considerations 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. While the Chairman concluded at the second session that this Principle had received "broad support", it was also "questioned if Principle 4 on the distinction between various kinds of use had any independent importance".[43] While the Chair summarized that "both the bioprospecting scenario and the public sector conservation and breeding scenario should be included",[44] some Committee members commented that the Guide Contractual Practices should focus on basic research, rather than commercial research.[45] Thus the precise modalities of applying this principle may require some further qualification and elaboration by the Committee Members. Even so, the distinction between commercial and non-commercial usage has been made in many laws and agreements (some definitions of bioprospecting refer, for example, to the commercial potential of genetic resources and associated TK), and a number of laws refer specifically to the need to protect and respect continuing customary uses of genetic resources. Accordingly, these distinctions have been found important in practice.

Additional Possible Principles Identified by Committee Members:

21. Besides the above-mentioned principles, the Chair concluded from the deliberations of the Committee at its second session that "[a]dditional principles, such as those included in the CBD and flexibility and simplicity, should be taken into account."[46] In particular, the Committee members identified the following possible additional principles:

- the Guide Contractual Practices should be non-binding,[47] flexible[48] and simple;[49]
- the Committee's work on the Guide Contractual Practices should be without any prejudice to, and closely coordinated with, the work of the CBD and FAO;[50]
- the IP rights and obligations set out in the Guide Contractual Practices should reflect the requirements of Prior Informed Consent which may apply to genetic resources;[51]

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43 See Chair (WIPO/GRTKF/IC/2/16, para. 96).

44 See Chair (WIPO/GRTKF/IC/2/16, para. 96).

45 See United States of America (WIPO/GRTKF/IC/2/16, para. 74).

46 See Chair (WIPO/GRTKF/IC/2/16, para. 96).

47 See Canada (WIPO/GRTKF/IC/2/16, para. 77), China (WIPO/GRTKF/IC/2/16, para. 82), Colombia (WIPO/GRTKF/IC/2/16, para. 58), European Community and its Member States (WIPO/GRTKF/IC/2/16, para. 75), Indonesia (WIPO/GRTKF/IC/2/16, para. 63), Japan (WIPO/GRTKF/IC/2/16, para. 76), New Zealand (WIPO/GRTKF/IC/2/16, para. 73), Peru (WIPO/GRTKF/IC/2/16, para. 69), Switzerland (WIPO/GRTKF/IC/2/16, para. 83), United States of America (WIPO/GRTKF/IC/2/16, para. 74), BIO (WIPO/GRTKF/IC/2/16, para. 92), ICC (WIPO/GRTKF/IC/2/16, para. 95), Chair (WIPO/GRTKF/IC/2/16, para. 54 and 96).

48 See Canada (WIPO/GRTKF/IC/2/3, para.77), USA (WIPO/GRTKF/IC/2/3, para.74).

49 See European Community and its Member States (WIPO/GRTKF/IC/2/16, para. 75), United States of America (WIPO/GRTKF/IC/2/16, para. 74).

50 See Ecuador (WIPO/GRTKF/IC/2/16, para.55), European Community and its Member States (WIPO/GRTKF/IC/2/16, para.75), Morocco (WIPO/GRTKF/IC/2/16, para.79), Peru (WIPO/GRTKF/IC/2/16, para.69), Singapore (WIPO/GRTKF/IC/2/16, para.66), Switzerland (WIPO/GRTKF/IC/2/16, para.83), Turkey (WIPO/GRTKF/IC/2/16, para.67).

- the Guide Contractual Practices should recognize the sovereign rights of Member States over their genetic resources;
- the Guide Contractual Practices should provide for terms on access to and transfer of technology as established in the CBD;[52] and
- the Guide Contractual Practices should foresee the possibility of a special tribunal established to adjudicate issues surrounding contracts for access to genetic resource and benefit-sharing.[53]

IV. PREVIOUS WORK OF THE COMMITTEE

22. At its first session, the Committee decided to work on this substantive issue and discussed a basic understanding of what that work should look like. At the second session, document WIPO/GRTKF/IC/2/3 identified possible operational principles for IP clauses of contractual agreements concerning access to genetic resources and benefit-sharing. Further study of IP and genetic resources licensing was based on a widely circulated survey (questionnaire WIPO/GRTKF/IC/Q.2) to secure information about relevant contracts and licenses. The responses received to the questionnaire were incorporated into a pilot, on-line database of contractual agreements relating to IP, access to genetic resources and benefit-sharing.[54] At subsequent sessions, subsequent amendments to the pilot, online database were made to reflect the technical and practical realities of incorporating newly received questionnaire responses into an electronic format in as user-friendly a manner as possible, including the use of three languages.[55]

23. The WIPO Contracts Database demonstrates a broad divergence in the approaches taken to the identification and management of IP issues in this area.[56] In essence, these approaches depend on the parties to the contractual arrangement; the type of genetic resource(s) under consideration; and the uses to which those resources may be put. They point, ultimately, to a need to analyze IP issues on a case by case basis, taking into account the broader contractual and research position, and to the need to seek specialized legal advice when considering such matters.[57]

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51 See (WIPO/GRTKF/IC/1/13, para. 106), Ecuador (WIPO/GRTKF/IC/2/3, para. 55), Bolivia, Cuba, Dominican Republic, Ecuador, Panama, Nicaragua, Peru, and Venezuela (WIPO/GRTKF/IC/2/3, para. 56).

52 Algeria (WIPO/GRTKF/IC/2/3, para. 78), Bolivia, Cuba, Dominican Republic, Ecuador, Panama, Nicaragua, Peru, and Venezuela (WIPO/GRTKF/IC/2/3, para. 56), Venezuela (WIPO/GRTKF/IC/2/3, para. 57).

53 See INADEV (WIPO/GRTKF/IC/2/16, para. 88).

54 Based on a proposal set out in document WIPO/GRTKF/IC/3/4 and approved by the Committee at its third session.

55 See WIPO/GRTKF/IC/4/10, paras. 13 to 15.

56 The WIPO Contracts Database contains over 30 contracts and licenses. The key IP-related issues that arise in these contractual arrangements can be broken down as follows: IP (general) - 16 contracts; Patents - 15 contracts; Licensing - 20 contracts; Plant Breeders' Rights - 6 contracts; Copyright - 4 contracts; Trade Secrets - 4 contracts; Distinctive Signs - 2 contracts; Assignment - 14 contracts; Confidentiality - 17 contracts; Ownership - 18 contracts.

57 Clause 14.5 of the Exclusive Variety License Agreement between her Majesty the Queen in Right of Canada, as represented by the Ministry of Agriculture and Agri-Food (AAFC), and the Company states as follows: It is acknowledged by the *Parties* that each has had legal advice to the full extent deemed necessary by each *Party*. Furthermore, the *Parties* acknowledge that neither acted under any duress in negotiating, drafting and executing the *License.*

24. Nonetheless, it is possible to draw out some common features from the contracts contained in the WIPO Contracts Database and to develop an outline which can act as an IP guide and check-list when developing a fair and equitable benefit-sharing package arising out of the use of genetic resources and related information, including, where applicable, TK.[58] This IP guide and check-list is contained in the Annex. Since the draft Guide Contractual Practices needs to heed and complement the international policy context of genetic resources policy making processes, the next section briefly reviews relevant international policy processes outside WIPO.

V. INTERNATIONAL POLICY CONTEXT

25. 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. The main intergovernmental processes and fora in which these policy frameworks are developed include the CBD, the FAO and the Consultative Group on International Agricultural Research (CGIAR). The international context of these processes and the use of contractual agreements 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. Therefore, the current status of work in these policy areas is briefly reviewed in the following sections.

V.A Convention on Biological Diversity(CBD)

Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization

26. In April 2002, the sixth meeting of the Conference of the Parties of the CBD adopted, as part of its Decision VI/24, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (the "Bonn Guidelines").[59] The Guidelines are meant to assist Parties to the CBD when developing and drafting legislative, administrative and policy measures on access and benefit-sharing, and also when developing contracts and other arrangements under mutually agreed terms for access and benefit-sharing. The Bonn Guidelines take into account the work of WIPO, as stated in the provisions regarding relationships to other international regimes:

> "The guidelines should be applied in a manner that is coherent and mutually supportive of the work of relevant international agreements and institutions. The guidelines are without prejudice to the access and benefit-sharing provisions of the FAO International Treaty for Plant Genetic Resources for Food and Agriculture. *Furthermore, the work of*

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[58] For a detailed analysis of the data contained in the WIPO Contracts Database, see document WIPO/GRTKF/IC/5/9.

[59] See Decision VI/24A, Annex.

the World Intellectual Property Organization (WIPO) on issues of relevance to access and benefit-sharing should be taken into account".[60]

27. In parallel to the acknowledgement of WIPO's work in the Bonn Guidelines, members of the Committee have repeatedly emphasized that the draft Guide Contractual Practices under development in the Committee should be without prejudice to the work done by the CBD and FAO, and should be applied in a manner that is coherent and mutually supportive of the work of the CBD and FAO.[61] This concern is reflected in the operational principles considered by the Committee.

28. The Bonn Guidelines, when addressing mutually-agreed terms for access and benefit-sharing, make the following references to the possible role of IP in contractual arrangements for access to genetic resources and benefit-sharing:

(a) Contractual agreements can include the provision for the use of IP rights, including joint research, obligation to implement rights on inventions obtained and to provide licenses by common consent, and the possibility of joint ownership of IP rights, according to the degree of contribution;[62]

(b) Consideration should be given in any Material Transfer Agreement to whether IP rights may be sought, and if so under what conditions and whether any property rights, including IP rights, may be assigned or transferred;[63]

(c) Monetary benefits may include, but not be limited to: payment of royalties, license fees in case of commercialization; and joint ownership of relevant IP rights. Non-monetary benefits may include joint ownership of relevant IP rights.[64]

29. When addressing the role of IPRs in access and benefit-sharing arrangements, the COP in Decision VI/24 encouraged WIPO to "make rapid progress in the development of model intellectual property clauses which may be considered for inclusion in contractual agreements when mutually agreed terms are under negotiation".[65]

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60 See paragraph 10, Bonn Guidelines. Emphasis added.

61 See Asian Group (WIPO/GRTKF/IC/2/16, para. 60), Australia (WIPO/GRTKF/IC/2/16, para.68), Brazil (WIPO/GRTKF/IC/2/16, para. 59), Canada (WIPO/GRTKF/IC/2/16, para. 77), China (WIPO/GRTKF/IC/2/16, para. 82), Colombia (WIPO/GRTKF/IC/2/16, para. 58), Egypt (WIPO/GRTKF/IC/2/16, para. 70), India (WIPO/GRTKF/IC/2/16, para. 62), Ecuador (WIPO/GRTKF/IC/2/16, para. 55), European Community and its Member States (WIPO/GRTKF/IC/2/16, para. 75), Japan (WIPO/GRTKF/IC/2/16, para. 76), Morocco (WIPO/GRTKF/IC/2/16, para. 79), Norway (WIPO/GRTKF/IC/2/16, para. 72), Peru (WIPO/GRTKF/IC/2/16, para. 69), Singapore (WIPO/GRTKF/IC/2/16, para. 66), Switzerland (WIPO/GRTKF/IC/2/16, para. 83), Turkey (WIPO/GRTKF/IC/2/16, para. 67), Venezuela (WIPO/GRTKF/IC/2/16, para. 56).

62 See paragraph 43, Bonn Guidelines.

63 See Appendix I, Bonn Guidelines.

64 See Appendix II, Bonn Guidelines.

65 See Decision VI/24C, para. 9.

International Regime on Access and Benefit-sharing

30. The World Summit on Sustainable Development (WSSD)[66] adopted a Plan of Implementation which called for action to "negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources".[67] In light of this outcome, the issue of an international regime on access and benefit-sharing was addressed as a distinct agenda item by the CBD Inter-sessional Meeting on the Multi-Year Programme of Work of the Conference of the Parties Up To 2010 (MYPOW) in March 2003. The MYPOW recommended that the Ad Hoc Open-ended Working Group on Access and Benefit-sharing should, in its consideration of other approaches, in accordance with its mandate as specified in Decision VI/24A, consider the process, nature, scope, elements and modalities of an international regime and provide advice to the COP on how it may wish to address this issue. The MYPOW invited governments, indigenous and local communities and relevant organizations to provide their views on the process, nature, scope, elements and modalities of an international regime on access to genetic resources and benefit-sharing prior to the second meeting of the Working Group.[68] The Working Group prepared recommendations on the terms of reference for the negotiation of an international regime and its elements, which was be submitted to the COP at its seventh meeting.[69] Several of these elements include IP-related issues and the draft Guide Contractual Practices will take into account further developments and discussions regarding the international regime. The seventh COP duly approved the development of an international regime. (COP Decision VII/19).

V.B Food and Agriculture Organization of the United Nations (FAO)

31. In the area of plant genetic resources for food and agriculture (PGRFA), a bilateral approach to access and benefit-sharing does not provide fully adequate solutions to the special nature and needs of agriculture.[70] The special nature of PGRFA[71] derives, *inter alia*, from three distinctive features of these genetic resources: (i) PGRFA and their free flow are a fundamental precondition for global food security; (ii) because of the diffusion of agriculture and its major crops, it is very difficult to trace PGRFA to a particular country of origin; and (iii) there is a strong interdependence of countries with respect to PGRFA, because the agriculture of all countries is dependent on a supply of genetic resources from other parts of the world.[72]

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66 The WSSD took place in Johannesburg in September 2002.

67 See WSSD Plan of Implementation, para. 44 (o).

68 The Working Group met from December 1 to 5, 2003 in Montreal, Canada.

69 The seventh meeting of the COP took place in February 2004, in Kuala Lumpur, Malaysia.

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

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

72 The FAO *Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture* (1996) sets out seven special features of PGRFA (paragraph 7(a) to (h)). The CBD Panel of Experts on Access and Benefit-Sharing recognized

International Treaty on Plant Genetic Resources for Food and Agriculture

32. In order to address the characteristics of PGRFA, governments have negotiated within the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA) the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR), which will establish a Multilateral System of Access and Benefit-Sharing for PGRFA ("the MLS"). Article 12.4 on facilitated access to PGRFA within the MLS provides that facilitated access shall be provided pursuant to a standard material transfer agreement (MTA), which shall be adopted by the Governing Body of the Treaty and shall contain the access as well as the benefit-sharing provisions in the relevant provisions of the Treaty, 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 PGRFA to another person or entity, as well as to any subsequent transfers of those PGRFA.[73]

33. In adopting the Treaty, the Thirty-first Session of the FAO Conference decided that recommendations on the terms of a standard MTA in accordance with Article 12.4 of the Treaty would be developed and proposed by an Expert Group for consideration by the Interim Committee for the Treaty, and by the first meeting of the Governing Body.[74] Accordingly, the FAO noted at the third session of the Committee that" the multilateral system was based on the understanding that PGRFA in the MLS belong to the international community and therefore it followed rules established multilaterally, examples of which could be found already under the CGIAR, which held hundreds of thousands of plant genetic resources in trust for the international community".[75] Consequently, the FAO noted at the fourth session of the Committee that "such multilateral arrangements should not be conflated with bilateral or contractual systems of access, such as those addressed by the electronic database, and accordingly suggested that a reference to the distinction between multilateral and bilateral systems, and to the International Treaty, be noted" in the various work products of the Committee.[76] The International Treaty entered into force on June 29, 2004.

International Code of Conduct for Plant Germplasm Collecting and Transfer

34. A component of the Global System on PGRFA[77] which refers to access and benefit-sharing contracts is the FAO International Code of Conduct for Plant Germplasm Collecting and Transfer (1993).[78] 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 Treaty. The Code was 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.[79]

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the uniqueness of PGRFA and identified four distinct characteristics (see, Report of the Panel of Experts on Access and Benefit-Sharing, UNEP/CBD/COP/5/8, para. 64).

73 See Article 12.4, ITPGR.

74 See document CGRFA/MIC-1/02/REP, para. 15.

75 See FAO (WIPO/GRTKF/IC/3/17, para. 48).

76 See FAO (WIPO/GRTKF/IC/4/15, para. 165).

77 <http://www.fao.org/ag/cgrfa/PGR.htm#diagram>.

78 <ftp://ext-ftp.fao.org/ag/cgrfa/GS/CCgermpE.pdf>.

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

35. In particular, the Code of Conduct 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. 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".[80]

V.C International Agricultural Research Centers of the Consultative Group on International Agricultural Research (CGIAR)

36. The CGIAR currently includes sixteen International Agricultural Research Centers (IARCs). It 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".[81] Under the ITPGR the IARCs are called upon to sign agreements with the ITPGR Governing Body with regard to their *ex situ* collections, providing, *inter alia*, that PGRFA listed in Annex I of the ITPGR, as well as than those listed in Annex I and collected before the Treaty's entry into force, held by the IARCs shall be made available in accordance with the provisions set out in Part IV of the Treaty.[82]

37. There are also various other international organizations and processes which have undertaken work on IP-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.

V.D International Union for the Protection of New Varieties of Plants (UPOV)

38. Plant varieties represent one of the most important forms of plant genetic resources, and the breeding of new varieties may be one result from access to genetic resources. IP protection has been developed specifically for plant varieties, and such *sui generis* protection, where it is provided, constitutes an important element of the policy and legal that determines the IP implications of access and benefit-sharing. The International Union for the Protection of New Varieties of Plants (UPOV), through the UPOV Convention, provides the only internationally harmonized system of protection in place and comprises 55 member States. The UPOV Convention offers protection to the breeder of a new plant variety, in the form of a "breeder's right", if the variety satisfies the conditions set out in the UPOV Convention. In particular, the variety must be new, distinct, uniform and stable and must be designated by an appropriate denomination.

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

81 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.'

82 See Art.15.1(a) and (b), ITPGR. Part IV of the Treaty concerns the Multilateral System of Access and Benefit-sharing.

39. A recent UPOV document discusses the interaction between the UPOV system and access to genetic resources and benefit-sharing.[83] This document considers issues that may be relevant to contractual arrangements concerning access to genetic resources, where these relate to territories which are covered by the UPOV Convention, in particular access to genetic resources, disclosure of origin, prior informed consent and benefit-sharing, with regard to the "breeder's exemption", subsistence farmers and farm-saved seed.

VI. CONCLUSION

40. IP aspects of contractual agreements for access to genetic resources and benefit-sharing have been a significant focus of the Committee's work on IP and genetic resources. The present document builds on information gathered and principles agreed or identified in the first five sessions of the Committee, in order to advance the task of developing guide contractual practices. It applies those principles in the form of draft Guide Contractual Practices which are contained in the Annex to the present document. The next steps in the Committee's work could be undertaken at three levels:

- developing the operational principles;
- developing model provisions such as those encouraged in the CBD COP decision; and,
- revising and further elaborating the draft Guide Contractual Practices.

41. During its discussion at its seventh session, Committee members may wish to comment further upon the operational principles already identified, with a view to developing them, and could comment on the first draft of the Guide Contractual Practices contained in the Annex of this document. On the basis of this discussion, a revised set of operational principles may be considered for future elaboration or adoption by the Committee. A further revision of the draft guidelines could be developed on the basis of further input received at the seventh session, as well as further comments, input and examples provided to the Secretariat before February 28, 2005. Such guidelines may be consistent with a more general framework for the Committee's work, and could be produced without prejudice to the nature and legal status of the overall outcomes of the Committee.

42. Some of the additional principles identified in earlier Committee discussions have not been addressed in the draft Guide Contractual Practices, because they may entail specific policy decisions or other developments. For example, the proposal that a 'special tribunal be established to adjudicate issues surrounding contracts for access to genetic resources and benefit-sharing' could be in part met by the development of tailor-made alternative dispute resolution procedures, taking account of the specific nature of disputes concerning IP aspects of genetic resources. This could be in line with the proposal, tabled by the Asian Group and China, that 'WIPO should study possibilities of offering alternative dispute resolution services, including but not limited to arbitration and mediation, which are particularly appropriate for the problems involving intellectual property issues related to traditional knowledge and folklore.'[84] Document WIPO/GRTKF/IC/6/6 (paragraphs 62 to 64) discusses

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[83] "Reply of UPOV to the Notification of June 26, 2003, from the Executive Secretary of the Convention on Biological Diversity (CBD)," of October 26, 2003, which is available on the UPOV Website at: <http://www.upov.int/en/news/2003/pdf/cbd_response_oct232003.pdf>.

[84] Document WIPO/GRTKF/IC/2/10; see also the discussion relating to alternative dispute resolution concerning access to genetic resources in document WIPO/GRTKF/IC/2/3.

this issue more generally. The Committee may wish to consider this possibility in relation to genetic resources, including the possibility of a role for the WIPO Arbitration and Mediation Center.

43. The Intergovernmental Committee is invited to note and comment upon the content of this document, the identified operational principles for the development of the Guide Contractual Practices, the possible distillation of model contractual provisions, and the annexed update to the draft Guide Contractual Practices, and to consider the options for future work including those identified in paragraphs 40 to 42, above.

[Annex follows]

ANNEX

DRAFT GUIDE ON INTELLECTUAL PROPERTY ASPECTS OF AGREEMENTS ON ACCESS AND EQUITABLE BENEFIT SHARING RELATING TO GENETIC RESOURCES

Preliminary Note:

International legal standards and community expectations require that prior informed consent applies to access to genetic resources, and benefits from the utilization of genetic resources are shared equitably. This is a fundamental and broad challenge, with legal, political, administrative and practical aspects. These questions are the subject of established international regimes governing genetic resources, and continuing evolution in these forums. Intellectual property (IP) issues arise as one element of this broader framework.

There are concerns that IP rights may be used to appropriate the value of genetic resources without equitably sharing benefits. There are also questions about how to manage IP issues and options so as to ensure equitable benefit-sharing: these include choices variously to avoid IP rights and to transfer genetic resources subject to agreement not to take out certain IP rights; to vest IP rights in the custodian of the genetic resources; or to give rights derived from the use of the resources to the user, subject to various conditions and safeguards, such as rights to receive benefits such as royalties and other payments, access to benefits of research, involvement in community-based development initiatives, contribution to various forms of appropriate social and economic development, and reporting and disclosure obligations. The Bonn Guidelines (discussed below) specify ownership of IP rights as potentially both a monetary benefit and a non-monetary benefit. Practical experience has shown a wide range of options have been chosen by custodians of genetic resources. There is a common need to understand the full range of options, so as to strengthen the decisions of custodians of genetic resources about the best course to take to safeguard and promote their interests.

This draft guide is not intended to promote any particular choice to use IP rights, or to avoid their use, in the context of access and equitable benefit-sharing. These guidelines draw on reported experience from a range of stakeholders to illustrate the range of choices that have been exercised and thereby to provide practical insights and to enhance the practical information available to stakeholders assessing their options when considering access and benefit-sharing. Some stakeholders have expressed concern about the use of IP rights in this context; others have used an array of mechanisms to identify their interests and to structure the benefit-sharing arrangements. In some cases, genetic resources are provided for research and evaluation only, with a requirement to negotiate further terms (including any IP rights) subsequently. Diversity of approaches and options is inevitable, given the range of interests and concerns involved in access and benefit-sharing, and the spectrum of approaches that have been explored.

Any access and benefit-sharing arrangements should conform with the existing international framework – which is essentially set by the legal instruments concerning genetic resources, not IP law in isolation. These arrangements should respond to the further evolution of this framework that various international processes are engaged in. The present draft guidelines are therefore only supplementary and background materials. They should not preclude any outcomes or developments in other fora, nor should they be used to interpret or limit rights and obligations within this framework.

Note on the status of this draft Guide:

These are draft materials only, to serve as the basis for discussion and development, based on the operational principles already established by the Committee. Further improvements could include a series of practical steps, specific examples and case studies, model or illustrative contractual provisions, and graphic representations of key issues and basic practical steps. The evolution of this draft would also need to take account of developments in other international forums.

I. CONTEXT

When can these guidelines be used?

1. This draft Guide provides background information for those who are considering whether, and how, to grant access to genetic resources which they own, control or have custody of. Negotiating and granting access to genetic resources, for research or commercial uses, can raise IP questions. Agreements reached on practical management of IP can influence the overall results of access to genetic resources, and how benefits arising from the access are created and shared equitably: this includes the decision whether to use IP rights at all, and if so under what conditions. Yet access and benefit-sharing occurs within a broader legal framework, and IP issues are only one component of the full range of practical and legal questions that may need to be addressed – in fact, IP issues do not arise at all in some access and benefit-sharing scenarios. So this guide should be seen only as supplementary and subordinate to the general principles and legal regimes that cover access and benefit-sharing for genetic resources. This guide has informal status only, and does not offer not authoritative legal advice nor set a policy direction. They draw on practical experience in a very wide range of access and benefit-sharing scenarios, and provide illustrations of issues that have actually arisen in practice and the various approaches taken to resolving them.

What is access and equitable benefit-sharing?

2. Genetic material includes plant, animal or microbial material that contains the means for passing on characteristics from an ancestor to a descendent through reproduction, or allowing the entire organism to be reproduced (material that 'contains the functional units of heredity' according to the legal definition). Genetic resources are defined as 'genetic material of actual or potential value,' in other words, the idea that genetic resources have at least potential value is essential to their definition. Samples of plants, cells, microbes and other materials can contain valuable genetic information that is useful in research and development – this includes modern biotechnology and genetic engineering, but can be just as important in the creation of products based on natural extracts, the conventional breeding of new plants, and the use of genetic materials such as bacteria in industrial processes (in such traditional industries as baking and brewing, but also in new applications such as mineral processing and environmental management).

3. Genetic resources can therefore provide an important input for research and the development of new products and processes, in an increasingly broad range of technological and industrial sectors. TK is often associated with genetic resources, and this can provide valuable insights into how genetic resources can be preserved, maintained, and used for the benefit of humanity. This leads to concern that when genetic resources are obtained or accessed for research or commercial purposes, the benefits from any research, development and commercial use should be fairly and equitably shared with the providers of the resources, and access to resources should be subject to the prior informed consent of the providers. International legal regimes, and many national laws, have been developed to deal with these concerns, in particular since the negotiation of the Convention on Biological Diversity (CBD) in 1992. The terms and conditions of access to genetic resources, the exercise of prior informed consent by the providers of genetic resources, and the resulting arrangements made for the sharing of benefits from their use and development, are therefore critical issues.

4. International and national laws on genetic resources deal comprehensively with access to genetic resources, their use, and sharing of benefits from their use. These laws and regulations set the framework for exercising prior informed consent and determining the terms and conditions of access. In some cases, the detailed arrangements for access and benefit-sharing can be set through negotiated licenses, contracts or agreements. Typically, a provider of a resource (such as an indigenous community, a government agency, a research institution, or the owner of land on which the resource is exists) reaches an agreement with a resource user (such as a researcher or a company that wants to use the genetic resources.) Such agreements can refer to the intended use of the resources, any restrictions on the use, and the way any benefits resulting from the resource are managed and shared. An agreement or contract can be the practical expression of the *prior informed consent* that international standards require as the legal basis for access to genetic resources.

5. Such agreements generally operate within the framework of specific regimes for genetic resources, and in line other laws regulating the environment, public resources, indigenous and community rights and regional development, as well as general contract and property law. These arrangements are dealt with internationally by such instruments as the CBD and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR). A range of laws, regulations and policies apply at the national, regional and community level, and govern directly how genetic resources are accessed and used. These regimes deal with many issues apart from IP questions. This draft Guide is limited in scope, and only intended to provide information and guidance about *intellectual property aspects* of access to genetic resources. In contrast to the main elements of law and practical guidance relating to access to genetic resources in general, this Guide provides supplementary and secondary information only.

What is the role of intellectual property?

6. Even so, the arrangements made for managing IP can be important in ensuring that an access agreement actually creates benefits from access to genetic resources, shares those benefits equitably, and respects the interests and concerns of the resource providers. When research is done on genetic resources, this can result in inventions that can be eligible for IP rights such as patents. How this IP is managed can influence how benefits are created and shared. So access and benefit-sharing agreements often contain provisions governing how IP rights are obtained and used. Issues dealt with in agreements include the entitlement to seek IP in inventions and other results of research using the resources, ownership and licensing of any such derivative IP, responsibility for maintaining and exercising IP rights, and the arrangements for distributing any financial or other benefits resulting from this derivative IP. Agreements can also require the recipient of the resource to report on any IP that is applied for, and similar developments. Some agreements make access conditional on not seeking IP rights on the material received. How such IP management issues are dealt with in an access and benefit sharing agreement can greatly influence the degree to which the access provider and the resource recipient can achieve their goals and serve their mutual interests.

7. Contracts and agreements do not stand alone – they are subject to national laws and international regimes concerning genetic resources, and the overall legal environment should be respected. Some systems do not provide for contracts or agreements, but operate on direct regulation by government authorities. Some commentators have pointed to the limitations of contracts as a means of defining and governing relationships in relation to the access and use of genetic resources. But some national and regional laws specifically provide for access and benefit-sharing contracts, sometimes subject to specific conditions. And many resource

providers are currently choosing to negotiate and enter into access and benefit-sharing contracts. So they have called for further information about the IP issues and options that arise, to help them identify their interests and achieve their goals. These guidelines are intended to provide practical information and support for those who choose to negotiate terms of access to genetic resources. However, they are limited to IP aspects only, and they are an adjunct and an aid, to be used as a resource, rather than a stand-alone guide to negotiating and concluding contracts and agreements on access and benefit-sharing.

II. GENERAL PROVISIONS

What are the main ideas behind these guidelines?

8. This draft guide may serve both providers and recipients of genetic resources when they negotiate, develop and draft the IP elements of mutually agreed terms for access to genetic resources and benefit-sharing. It illustrates the practical IP issues that providers and recipients are likely to face when negotiating an agreement, contract or licence. It describes some approaches that have been taken in practice, but does not seek to pre-determine actual choices on these approaches. The diversity of national law and of the practical interests of providers and recipients are likely to lead to a wide range of choices when actual provisions are negotiated and drafted. This Guide may therefore support providers and recipients in ensuring that access and benefit-sharing is on equitable, mutually agreed terms, but does not prescribe one template or set of choices.

9. This Guide draws on a wide range of inputs, based on practical experience, in line with the requirements established by the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the Committee). These include inputs from WIPO's Member States and from other stakeholders in response to a questionnaire circulated under the authority of the Committee.

10. The Guide takes into consideration the work of relevant international agreements and institutions such as the CBD, the FAO ITPGR, the FAO Code of Conduct on Germplasm Collection, and the recommendations of the World Summit on Sustainable Development ("WSSD") held in Johannesburg in September 2002 in relation the need to develop practical measures to promote and safeguard the fair and equitable sharing of benefits arising from the use of genetic resources and associated TK, innovations and practices. While the Guide takes into account these legal and policy frameworks, nothing in the Guide shall prejudice the further evolution and implementation of these frameworks, or be construed as an interpretation of relevant instruments or a contribution to their implementation. In particular:

- the CBD is developing an international regime governing the use of genetic resources, and this will be an important legal and practical consideration for providers and users of genetic resources;

- the FAO ITPGR requires the development of a standard materials transfer agreement (MTA) concerning the plant genetic resources covered by that treaty, and this, too, will be a very significant legal and practical factor governing the access and use of these resources.

11. Further, nothing in the draft Guide should be interpreted to affect the sovereign rights of States over their natural resources, including their entitlement to set terms and conditions on access and benefit-sharing.

12. The draft Guide is voluntary and illustrative only. It is no substitute for relevant international, regional or national legislation. It only concerns the IP aspects of access and benefit-sharing, and so they are supplementary and subordinate to the wider laws and policies that govern ownership, access and use of genetic resources.

13. This Guide cannot substitute for specialised legal advice. Prior to entering into any legally binding contractual arrangement setting out mutually agreed terms of access to genetic resources and benefit-sharing, all contracting parties should seek expert legal advice. This is especially important for resource providers who may have limited access to legal advice – effective availability of expert legal advice, including on IP issues, may be one important aspect of ensuring that access is based on prior informed consent.

III. TERMINOLOGY

What are genetic resources and traditional knowledge?

14. This draft Guide is for general reference, so no precise definitions are intended, and the use of terms is not intended to have any legal effect. Contracts or agreements can settle on their own definitions of key terms, for instance with reference to the customary laws of traditional communities. However, for reference, the following definitions may help clarify the range of relevant subject matter.

(a) The CBD defines *genetic resources* as ‘genetic material of actual or potential value’. It defines *genetic material* as ‘any material of plant, animal, microbial or other origin containing functional units of heredity’. Similarly the FAO ITPGR defines*plant genetic resources for food and agriculture* as ‘any genetic material of plant origin of actual or potential value for food and agriculture’ and defines *genetic material* as ‘any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity.’

(b) “Traditional Knowledge” has no agreed international definition. One general way of characterizing TK is knowledge which is:

- generated, preserved and transmitted in a traditional context;
- distinctively associated with the traditional or indigenous culture or community which preserves and transmits it between generations;
- linked to a local or indigenous community through a sense of custodianship, guardianship or cultural responsibility, such as a sense of obligation to preserve the knowledge or a sense that to permit misappropriation or demeaning usage would be harmful or offensive; this relationship may be expressed formally or informally by customary law or practices;
- ‘knowledge’ in the sense that it originates from intellectual activity in a wide range of social, cultural, environmental and technological contexts; and,

– identified by the source community as being TK.[85]

'Traditional' and 'tradition-based' refer to knowledge systems, creations, innovations which: have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and, are continually evolving in response to a changing environment. This does not mean that TK needs to be old, ancient or lacking in innovation, and there are many TK systems that are living, contemporary traditions in spite of their ancient roots.

(c) 'Intellectual property' in one international definition includes 'the rights relating to literary, artistic and scientific works, performances of performing artists, phonograms, and broadcasts, inventions in all fields of human endeavor, scientific discoveries, industrial designs, trademarks, service marks, and commercial names and designations, protection against unfair competition, and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.' Actual access and benefit sharing agreements or contracts may choose to define the scope of relevant 'intellectual property' in a more limited way, consistent with the aims of the agreement.

IV. THE LEGAL CONTEXT

What kinds of contracts and agreements are used?

15. One general principle established under the CBD is that 'access [to genetic resources], where granted, shall be on mutually agreed terms' and 'shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.' This provides the basic legal framework for access and benefit sharing for genetic resources under the national sovereignty of the many countries that adhere to the CBD; other countries seek to apply the same principle. Within this framework, drawing up a contract, agreement or licence is one way of expressing the 'mutually agreed terms,' and may also be a requirement for the grant of prior informed consent by the country providing the resources. Various terms are used in practice – e.g., contract, license and agreement – but the choice of terms is generally not significant in themselves. The important thing is whether the agreement is a general expression of intent, or is legally binding; and if it is legally binding, under what jurisdiction it has effect.

16. In general, the contract, agreement or license relating to access to genetic resources defines the purpose and permitted uses of the accessed resources, and the terms and conditions, including the benefits that the provider is to receive from the recipient. In essence, a contract is a promise or undertaking that can be enforced by law. The actual range of contracts and agreements used in access and benefit-sharing arrangements can differ greatly. In some cases, a national law on genetic resources might specifically require that the provider and recipient agree on an access contract – and in that case, the law might lay down particular conditions that the contract or agreement has to comply with. Even if there is no specific law for access and benefit-sharing, a contract is likely to be governed by general background laws such as the law of contracts and competition law. For example, under many national laws of contract, a contract or agreement can't be enforced if it has been obtained by coercion against the will of either party, or through deception or fraud.

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[85] See documents WIPO/GRTKF/IC/5/8 (paragraph 69) and WIPO/GRTKF/IC/5/12 (paragraph 45).

17. This draft Guide illustrates the various approaches that have been taken in agreeing on IP-related terms for access and benefit-sharing, but only as a general starting point. In any particular transaction and collaboration, the nature and terms of a contract can be tailored to fit the needs of the two partners to create an optimal partnership. In any event, in any potentially legally binding relationship, all parties should normally seek expert advice, with experience in the relevant national legal system (or systems), which can:

(a) Confirm that the agreement properly reflects the underlying access project or research relationship; and,

(b) Clarify whether the rights and obligations are reasonable, fair and legal, and whether and how obligations under the agreement can be enforced if necessary.

Such individual advice cannot be obtained from a consideration of the model or actual agreements of other institutions or organizations; the more that the specific relationship under development is taken as the starting point for contractual negotiations (rather than other agreements developed in other contexts), the more likely that the resulting agreement will be workable and mutually beneficial.

18. In practice, there are many different scenarios involving access to and use of genetic resources and associated TK. Access and benefit-sharing scenarios can differ in terms of:

(a) *Legal jurisdictions and particular national laws* which may govern the contractual relationship between the parties. This is in line with the sovereign rights of States over their natural resources recognized under the CBD, and the principle that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

(b) *Providers and recipients:* these may include the government sector (e.g., government ministries, government agencies (national, regional or local), including those responsible for administration of national parks and government land); commerce or industry (e.g., pharmaceutical, food and agriculture, horticulture, and cosmetics enterprises); research institutions (e.g., universities, gene banks, botanic gardens, microbial collections); custodians of genetic resources and TK holders (e.g. associations of healers, indigenous peoples or local communities, peoples' organizations, traditional farming communities); and others (e.g., private land owner(s), conservation group(s) *etc.*)

(c) *Genetic resources:* this may embrace a wide range of genetic materials, of plant, animal or microbial origin: genetic material may have clear actual value; its potential value may be high; its value may be untested or uncertain; or it may have unforeseen, surprising or unpredictable uses and values in different sectors;

(d) *Agreed or licensed uses of the genetic material and associated TK:* this may define certain uses which are specifically not permitted, or may define conditions governing certain uses, or both: this may range over commercialization (including realizing the market potential of the genetic material and/or TK); research with a commercial objective (in the pharmaceutical, food and agriculture, horticulture, cosmetics and other industries); or scientific or academic research only; it may include research, selection and development for food and agriculture (in particular within the framework of the FAO ITPGR);

(e) *Time frames* within which a particular contract or license may operate: this may set an absolute limit for the licensed use, or establish a timetable for licensed use, with certain milestones that should be met, and subsequent obligations (such as an agreement to negotiate further terms in the event, for instance, that a product is approved for commercialization).

19. Such factors will affect the basic elements of the contract, but will also define and shape the way in which any IP issues are dealt with in a contractual relationship. In some scenarios, there may be no role at all for IP rights. An initial agreement may concentrate on issues that do not non-IP related benefit-sharing, such as research cooperation, evaluation of resources, training and education and technology transfer, and the parties may agree to negotiate a separate commercialization package (including agreement on ownership of IP, right to license the IP, benefit-sharing arising out of any licensing agreement etc.) at a later date, should the need arise, once initial research leads to commercial possibilities. Alternatively, IP rights may have a role to play right from the start of a partnership, often as an integral part of a specific benefit-sharing package, with identifiable short, medium and long-term returns. Finally, IP rights may be incorporated into a distinct series of licensing terms and conditions that reach beyond the field of access and benefit-sharing, and embrace the wider legal and working relationship of the parties.

20. Negotiators are normally advised to think first about the practical arrangement or partnership that they want to enter into, and then to think about how that arrangement should be expressed in legal terms. This is often more effective than limiting the range of cooperation and sharing of benefits to a pre-existing model. Earlier agreements and precedents can be used as guidance on the options, without pre-determining the actual choices made by the provider and recipient in any scenario. For illustration, contractual scenarios relevant to genetic resources range over the following broad categories. Many actual agreements are, in fact, a combination of several of these categories, depending upon the individual circumstances of the collaboration.

(a) *Letters of Intent or Heads of Agreement:* recording preliminary agreement on the overall framework of a proposed collaboration, including any commercial arrangements that may apply, and to ensure that the future negotiations on the details of a contract or license have a solid basis of understanding);

(b) *Confidentiality or Non-Disclosure Agreements*: requiring the recipient of information to keep it confidential, such as information concerning source of genetic resources, associated TK or know-how, which may be used in gaining access to genetic resources for evaluation purposes, developing a research collaboration, or as a condition of employment; such agreements frequently limit the purposes for which such information can be used – depending on the circumstances, this may include limiting its use to evaluation, research, or non-commercial purposes, or limiting it to certain agreed purposes;

(c) *Material Transfer Agreements (MTAs):* common tools in commercial and academic research partnerships involving the transfer of biological materials, such as germplasm, microorganisms and cell cultures; these are used for exchange of materials in various contexts – exchanges between research institutions, and setting conditions for access to public germplasm collections or seed banks, and access by a researcher to *in situ* genetic resources, where the agreement will be between the research institution and the access provider. In most MTAs, a provider agrees to give identified physical material to a recipient, and the recipient agrees to restrict the uses that may be made of that material, and often of any improvements or derivatives;

(d) *Licensing Agreements:* agreements setting out certain permitted use of materials or rights that the provider is entitled to grant, such as agreements to license the use of genetic resources as research tools, or to license the use of associated TK or other IP rights;

(e) *Research Agreements or Research and Development Agreements*: agreements that define various inputs to research and development, including financial, material (including genetic resources) and intellectual contributions, specify various responsibilities in relation to the conduct of research and development of new products or processes, and set out how the monetary and non-monetary benefits from this research and development should be managed and shared.

Further information on these categories of agreements, including illustrative examples, is provided in Appendix II [*not attached to the present draft*].

V. PRELIMINARY CONSIDERATIONS

What to consider in advance of negotiations?

21. Negotiations concerning access to genetic resources should aim to identify and promote the mutual interests of the two parties to the agreement – provider and recipient – so that the agreement captures and expresses an understanding of shared interests and objectives. In some negotiations involving parties with diverse backgrounds, this can entail building respect and understanding for the values and cultural backgrounds. This applies to settling the IP provisions within an agreement should be no different. Before negotiations or discussions occur between a provider of genetic resources and a potential recipient seeking access to the genetic resource, both parties should seek to understand and acknowledge the legitimate interests and objectives of the other party, and should aim in the negotiations to find an approach to IP issues that promotes the common interests of the two parties. The final understanding reached must be good for both parties if it is to form the basis for a lasting, beneficial relationship.

22. One key to an equitable and enduring partnership, and appropriate provisions concerning IP, is a shared understanding of the value of the contributions that are made by each party – on the one hand, the value of genetic resources and associated TK that are being provided, and on the other hand, the value of research, development, risk management and investment that is involved in the use of the resource. Each party may need to understand the limitations of their contributions to the potential arrangement as well as the valuable attributes of their contributions. It will be helpful, for instance, for both parties to recognize the different expectations and perceptions of value that each brings to the discussions.

23. A recipient of genetic resources and associated TK may need to understand that the value of a genetic resource or insight into the workings of biological material (including traditional knowledge) may not be limited to monetary value in the eyes of the provider of that resource or insight. What is viewed by the recipient in simple terms as a raw input for research may be seen by the custodian and provider as a vital part of their heritage, cultural identity and spirituality. The resource and TK, for instance, may be associated with spiritual or cultural values of the provider that can not easily be defined in economic terms or within a brief time-frame. Genetic resources may be the result of many generations of conservation, selection and development by indigenous and local communities. If the resource provider is a

government body, a public agency or a community, broader public interests - e.g. sustainable resource management, environmental protection, social equity, appropriate grass-roots development and technology transfer – are likely to be valued more highly than more immediate technological or commercial goals. Non-monetary and longer-term benefits may be preferred over short-term or monetary benefits.

24. Understanding of the value and use of genetic resources, and associated TK, from the perspective of the public and community interests of the provider, may be the key to reaching an equitable agreement on IP. Indigenous communities and scientists working in academic institutions alike may have committed years, decades or a lifetime of work to arrive at the genetic resource or insight into a particular biological component. Both the resource and the knowledge of its present utility may have developed over generations.

25. The need for prior informed consent from the appropriate individuals and institutions should also be accounted for. For potential users of genetic resources, this includes ensuring legal compliance with any access and benefit-sharing regimes that national governments, local authorities or local custom have established. Detailed guidelines for such prior informed consent procedures are spelt out in the Bonn Guidelines.

26. A provider of genetic resources will also benefit in negotiations from recognizing and understanding the way a potential recipient may evaluate the resources and associated TK. The factors that may be used include:

(a) *alternative source* factor: what alternative sources exist for the material of interest and what are the costs and conditions of access through those alternative sources?

(b) *proximity to market* factor – the cost, in time, money, and scientific or personnel resources, of R&D investments need to fashion a product that might be saleable;

(c) *risk of technical failure* factor – what are the prospects for arriving at a revenue producing product from a scientific standpoint?

(d) *risk of regulatory preclusion* factor – what are the prospects for and costs of obtaining regulatory approval to market a final product?

(e) *alternative investment opportunity* factor - do other investment opportunities exist that offer greater returns or fewer risks?

(f) *authority to consent*factor - is the provider in a position to give prior informed consent, and is consent also required from other parties or government authorities?

Both parties to recognize and understand these different perspectives can increase the likelihood that expectations will be reasonable and that relationships will form that contribute to positive outcomes.

VI. REVIEWING RESOURCES AND SETTING GOALS

How to prepare for negotiations?

27. Before engaging in negotiations on access and benefit-sharing, a provider of genetic resource and associated TK may need to identify and review systematically the assets it can

potentially offer. This assessment may result in an inventory, which could separately account for physical resources and knowledge resources. The legal regimes governing physical resources and knowledge resources may differ, and their legal status are usually distinct, from both IP and valuation standpoints.

28. The inventory process should assist the resource provider to identify the aims and objectives of the intended access, and the uses to which the genetic resources and related information (including TK) may be put. It may also identify what the provider does not want to give access to, or what resources could be held in reserve for possible later access, if the partnership develops successfully. The potential IP outcomes of such uses can then be broken down into individual components. This should ensure that, right from the start, the specific IP implications of any access and use have been identified and that, subsequently, any IP rights and benefits arising from the exploitation of those resources can be properly apportioned and managed. This creates an opportunity for the access provider to identify and achieve broader goals. For instance, this might entail obliging the recipient through the access contract to disclose the origin of genetic resources in patents resulting from the use of the resources, or restricting permitted use to activities compatible with the cultural values of the provider, or ensuring third party access to research results for non-commercial uses or for use in developing countries.

29. The assessment could be supplemented by an analysis of the relevant international, regional and national laws and regulations, including any *sui generis* legislation on the protection of TK and, where applicable, relevant customary laws in those countries where IP rights may be developed and exploited.

30. Potential recipients and providers may enter a preliminary confidentiality agreement to explore potentially common interests. If they then identify mutual interests, a separate access and benefit-sharing agreement may then be negotiated. That subsequent agreement could addresses ownership of IP rights currently existing or that arise in the future, rights to license the IP, and benefit-sharing arising out of any licensing agreement. Alternatively, IP rights may have a role to play right from the start of a partnership, as an integral part of a benefit-sharing package, with identifiable short, medium and long-term returns, or as a distinct series of licensing terms and conditions that reach beyond the field of access and benefit-sharing, and embrace the wider legal and working relationship of the parties.

VII. CONSIDERATION OF IP ISSUES

What kind of intellectual property issues are addressed in access agreements?

A. OVERALL IP ISSUES

31. Among the IP questions confronting the negotiators of access and benefit-sharing agreements are:

(a) what IP could result from the access to the genetic resources?

(b) what conditions or restrictions should apply to seeking and obtaining IP rights?

(c) how should those IP rights be owned, exercised, maintained and licensed?

(d) what approach to obtaining, holding and exercising rights best promotes a mutually beneficial outcome, and the equitable sharing of benefits from the permitted access?

It is crucial to consider in advance what IP is likely to result from the intended access. If access to genetic resources is intended for applied research, it is likely to have IP implications. This is especially so if research collaboration is aimed at developing a commercial product or process. Potential IP on research outcomes and commercialization activities could include a range of IP rights, depending on the direction taken in research and development: these could include patents, plant variety rights, trademarks, geographical indications, designs, trade secrets, and copyright.

32. The parties may therefore need to review the potential IP resulting from the permitted access, and in particular:

(a) what subject matter could *potentially* be covered by IP,

(b) what elements of this material should *actually* be covered by IP (for instance, new products created by the research), and what elements should be excluded (some material transfer agreements, for example, oblige the recipient not to seek IP rights on the transferred material, or require further negotiation and agreement at the stage when basic research begins to deliver outcomes).

33. These basic questions then lead to specific practical IP questions such as:

(a) who will decide whether to acquire IP rights on various categories of subject matter; what kind of consultation and further agreement may be necessary before IP rights are acquired and exercised, if at all;

(b) who will have ownership of IP rights;

(c) licensing arrangements that should apply to ensure access to new technologies;

(d) payment for acquisition and maintenance of IP rights;

(e) who will police and enforce IP rights in the market place;

(f) participation in decisions on sublicensing;

(g) ownership or licensing implications if certain performance standards are not met (for example, if the party that gains access to the resources decides not to develop the resources, or takes too long to do so, then the party giving access may wish to reserve rights over intellectual property and any research outcomes);

(h) obligations to report on any actions taken to take out IP rights, and obligations to disclose the source or conditions of access to the genetic resources.

IP rights are territorial in nature, which means that they can be owned or exercised discretely in various countries. So the decisions made on these questions can specify different arrangements for different territories. For example, the access provider could choose to retain IP rights in the country of origin, but might agree to the partner owning IP rights in other markets. An agreement might specify that licenses be automatically granted to third parties if

the recipient fails to meet certain agreed performance criteria, such as making a new product available in developing countries at a preferential price.

34. If the research activities are wholly academic in nature, and are not aimed at the development of new products or processes, it is nonetheless likely that the parties will wish to create and publish articles and associated data, giving rise to copyright in those publications and related transfer or licensing issues. Privacy and confidentiality issues also may apply – a traditional community may make access condition on non-disclosure of certain traditional knowledge, for instance, and a resource provider may require that the specific origin of a rare or endangered genetic resource be kept confidential. Furthermore, academic research projects may wish to provide, or to use, genetic material that is already subject to third party IP protection. Appropriate warranties may need to be sought or given. [86]

35. For a research relationship involving genetic resources, initial planning of the project should consider the likely outcomes of the collaboration and how IP rights in those outcomes should be handled.[87] This should ensure that, right from the start, any IP rights and potential benefits associated with them can be properly managed. Progressive decisions on IP could be programmed to be taken at key points – for instance, an initial evaluation phase, a review of research proposals and assessment of specific research outcomes. Prospective partners should build into overall project planning such IP issues such as:

(a) What are the possible IP outcomes that could arise from the proposed collaboration?

(b) How important is ownership of these IP rights to the collaborators? What about ownership of improvements and future developments?

(c) How will benefits be shared arising from the successful exploitation of any IP? Who will negotiate and agree the terms of any subsequent licensing arrangement?

(d) What applicable legislation must be taken into consideration when analyzing the above, including relevant international, regional or national laws or regulations, including, where applicable, sui generis legislation on the protection of TK and customary laws?

Implications of joint ownership of IP.

36. Joint ownership of IP rights is one legal option, and may be preferred as one way of ensuring that the provider retains a distinct stake in the outcomes resulting from the access. On the other hand, joint ownership can lead to unexpected practical problems and limitations, and may not always be an appropriate benefit-sharing outcome or mechanism. For example, joint ownership does not necessarily create an entitlement to receive benefits from the other owner's exploitation of the common IP rights. In some jurisdictions, joint ownership of patent rights does not require one owner to share economic benefits with the other owner. In cases of joint ownership, the provider and user of the resources should consider how the responsibilities flowing from co-ownership of IP rights will be apportioned, as ownership

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[86] For instance, a warranty that the provider or licensor holds all legal right, title and interests in and to those IP rights. Alternatively, the provider or licensor may assert that it does not extend any warranties that the use of the material will not infringe any patent, copyright, trademark, or other proprietary rights.

[87] See also WIPO/GRTKF/IC/5/9 at paragraphs 29 – 32.

generally brings with it the costs and responsibilities of securing and maintaining rights, as well as enforcing them;

Defining and sharing benefits from access

37. The crafting of IP provisions in an access agreement can help create benefits resulting both directly and indirectly from the access to genetic resources, and can be integral to ensuring the benefits are shared effectively and equitably. Some benefits may arise directly from the successful creation and exploitation of IP rights, such as through royalties from licensing IP. But benefits can extend beyond simple monetary payments, or the ownership and licensing of IP. The Bonn Guidelines provide an illustrative list of diverse possible monetary and non-monetary benefits from access to genetic resources: this list is attached to these Guide Practices as Appendix I.

38. When the access provider is a government agency, a public institution or other authority (such as a national park authority), or a community organization, a broader conception of benefit-sharing may be more consistent with their interests, values and objectives. For such providers, benefits may be assessed in terms of local development, enhanced environmental management, biodiversity conservation, access to technologies in addition to those resulting from the access, transfer of technologies to developing countries, investment in local research and economic activities, and favorable or social marketing arrangements for agreed derivative products and processes. The need to understand the partners' different value systems applies not just to assessing the values of contributions or inputs to the collaboration: it also applies to assessing the importance and value of prospective benefits. IP provisions of an agreement can be structured to support many of these broader goals, and for this reason, the full range of potential benefits should be reviewed and kept in mind when the specific IP provisions are negotiated. An agreed approach to IP provisions may flow from a comprehensive assessment of the full range of potential benefits, and ways of apportioning and sharing them.

- Specific monetary benefits flowing from the exploitation of IP rights could include: license fees, in the event of a licensing of the IP rights to a third party or the development of, for instance, a fee-paying database; the sale price, in the event of an assignment or sale of the IP right to a third party; royalties, in the event of a successful commercialization of the IP rights, whether as a result of sale, licensing or joint venture; salaries, where provider country nationals are involved in the exploitation of the IP rights;

- Specific non-monetary benefits flowing from the exploitation of IP rights could include: responsibility for filing, maintenance and enforcement of those IP rights; responsibility for the negotiation of any subsequent joint ventures, assignments and/or licensing agreements; capacity building, such as IP-related training and education.

39. Reaching agreement on how to share benefits from exploitation of IP rights will be vital in ensuring an equitable and effective outcome. This can entail agreeing on the value and level of contribution of each party to the access and benefit-sharing arrangement. There is a wide range of potential factors to be discussed and weighed when assessing the relative contribution of the various parties. For example, is a bare resource being provided, or is there considerable associated TK which provides an important lead for researchers? Could associated TK contribute so directly and so significantly to an invention based on the resource that the TK provider is actually a co-inventor? Is the user of the resource expected to invest

heavily in research and development, or is the commercial or technological use of the resource already proven in principle with little additional investment required? What kind of products are intended to result from the research and development – for instance, simple reagents for further research, finished medical products, or industrial materials? Do the genetic resources contribute directly to the finished products, or do they provide one indirect input? Is the value of the genetic resource proven and well established, or is its potential unclear? Should there be an agreement to return to the issue once the actual value of the resource and its potential applications are better known?

Dispute settlement

40. Agreements have to anticipate the need for dispute settlement in the case of general disputes, and there should be an overall dispute settlement provision in the agreement, covering all aspects, not merely IP-related provisions. The various mechanisms for resolving disputes, such as mediation, arbitration and litigation (including the jurisdiction that applies) should be considered and agreed upon, with a view to what is appropriate and effective (especially from the perspective of resource providers if they are confronted with limited capacity in terms of effective use of formal legal systems). Alternative dispute settlement measures such as arbitration and mediation may take account of customary law interests and custodial responsibilities. Where access and benefit-sharing agreements are stipulated under specific national regimes, there may be mandatory requirements for dispute settlement.

41. As a rule, the more the specific terms of an access agreement are based on a shared and full prior understanding of the nature of the access and benefit-sharing partnership and the intended use of the resources, the less is the likelihood of disputes relating to IP provisions. Some IP issues may require specific dispute settlement: for instance, there may be provisions for arbitration on whether or not to proceed with IP protection for a particular innovation, whether or not a research outcome is derived from the accessed genetic resource and is therefore covered by the agreement, and when certain obligations may be triggered, such as an agreement to license IP to a third party in the event that the recipient does not meet certain performance standards.

B. SPECIFIC IP RIGHTS AND ISSUES

Patents

42. A research project based on access to genetic resources may have, as its clear intention, the discovery of a patentable invention and the subsequent licensing and commercial development of that patent. Alternatively, an academic collaboration may inadvertently or unexpectedly result in a patentable invention. The following is a non-comprehensive list of some of the patent-related issues that prospective partners may wish to consider as part of their initial assessment of IP issues,

Is this a project which may result in the creation of a patentable invention?

43. In order to answer this question, consideration will need to be given to the scope of the research to be carried out. Are the resources, and any related information, to be accessed for academic research purposes only, or will they be used in order to create, if possible, a product or a process that provides a new way of doing something, or offers a new technical solution to a known problem? Such a product, process or solution may be eligible for patent protection.

44. The rules for patent protection vary between different national and regional patent laws, so the eligibility for patent protection of a research outcome may be different in different countries. An invention is generally required to be industrially applicable (or useful), new (or novel) and non-obvious (or involve an inventive step), and the invention has to be disclosed in the patent application according to certain standards. There are differences between different laws on what technical subject matter can be protected, including in areas potentially relevant to inventions based on genetic resources. For instance, patent laws may exclude discoveries of materials or substances already existing in nature, scientific theories, plant or animal varieties, or essentially biological processes for the production of such plant and animal varieties, other than microbiological processes, as well as inventions that would contravene public order or morality if they were commercially exploited. So, in many countries, the choice has been made to exclude certain categories of invention that can be directly relevant to the use of genetic resources. Access and benefit-sharing agreements should acknowledge and respect the different scope of patentable subject matter that different national and regional systems provide for.

Should patent protection be obtained?

45. When drafting any contractual arrangement, the scope of the proposed use of the genetic resources and any related information should be clearly defined. This should also clarify whether it is intended for IP rights to be obtained as a result of this use. For instance, if the research is for specified academic purposes only, consideration could be given to both clearly defining the permitted research under the contract and also including a clause stating that no IP rights may be obtained over any genetic resources, progeny or derivatives transferred under the agreement, without the further agreement of the original provider of the material or related information. Such a clause could protect the original grantors of the resources and knowledge in the event of an inadvertent discovery of a potentially patentable invention by an academic researcher.

46. More generally, a clear understanding should be reached about seeking patent protection for inventions derived from the access and use of genetic resources, in the framework of a broader understanding of how equitable sharing of benefits should proceed. The access provider may wish to restrict or otherwise place conditions on the use of patents on inventions that result from access to the resources. A range of options have been used in practice, including:

- precluding any IP rights on any developments based on the access to the resources, as a contractual condition of access (for instance, in MTAs granting access for evaluation purposes or pure research only);

- providing for reporting and consultation in relation to any developments based on the access to resources (so that the user of the resource needs to disclose any potentially patentable invention to the resource provider, when a decision is made as to whether to patent the invention and if so, how and in whose name, and subject to what conditions);

- affirming the right of the user of the resource to seek patents on certain defined inventions, but making this right subject to appropriate arrangements for sharing benefits from the patents and from the use of the resource more generally (see also the option of co-ownership of any patents, discussed below); these may include

obligations to share or pool research results, to provide open access for non-commercial use, research or breeding, to provide preferential access to developing countries or for humanitarian purposes, and to grant licenses in various circumstances consistent with the goals and interests of the resource provider;

- reserving rights, so that if the user of the resource elects not to proceed with research or development, or otherwise fails to generate the expected benefits from the resource, the resource provider might retain an entitlement to take control of new technologies developed under the mutual agreement;

- providing for some research outcomes to be published defensively and for the general public to access them – that is, published so as to ensure they are in the public domain, and preclude any other party from seeking IP rights on them, to preserve 'freedom to operate' for such technologies;

- imposing other conditions concerning patents, such as obliging the user of the resource to mention the source of the genetic resource or conditions of access in any patent application concerning inventions resulting from the access to the resource;

- clarifying the scope of research that the user of the resource may be entitled to undertake, and the implications for IP ownership, such as further development and improvement of the original invention, and applied research to enable industrial use of the invention.

These are only some of the options that can be chosen by the two parties to the access and benefit-sharing arrangement, and finding the right balance of interests that is both equitable and effective in achieving mutual benefit may involve exploring all these options.

If so, who may own such an invention?

47. In contrast, if the research has as its clear objective, the discovery and development of a product, process or technical solution that may be eligible for patent protection, then, as part of an IP audit, consideration should be given to ownership of any resulting patent. The main options are for the user of the resource to Typically, co-ownership accrues with co-inventorship. Nonetheless, the parties can agree that any patent will be jointly owned by the partners, regardless of contribution to the invention. Other, more varied arrangements are also used: for instance, patent rights on resultant inventions could be granted to the recipient, subject to further benefit-sharing, except in the territory of the provider, where patents could be jointly owned or owned by the provider. Some further practical considerations may arise:

(a) In research and educational institutions, such as universities, the employer may be deemed to be the owner of an invention, when the invention is produced by an employee (such as a professional researcher or academic) within the scope of his or her employment. However, this rule may not apply to students involved in a research project on biological material, and they may have distinct rights to an invention, which should be taken into account in structuring IP provisions in an agreement;

(b) The grantor of access to the biological material and to any associated information may have retained certain contractual rights in relation to ownership of, development and

licensing of any patent arising out of research carried out on the material or associated information;

(c) A sponsoring private organization or government body may make certain demands on the ownership, and use of, any patents arising out of research collaboration, even if the researcher retains the basic entitlement to obtain patent rights.

Approaches to ownership of patents

48. Ownership can provide reassurance to the resource providers that they will retain a say over how the resources are developed and used, and how any new technology derived from the genetic resources are developed, used and disseminated. On the other hand, ownership of patents derived from access to genetic resources is unlikely in itself to generate tangible or sufficient benefits for the resource provider, in the absence of a strategy for managing actively a patent portfolio. One practical consideration is that maintaining and exercising a patent portfolio, potentially in several countries, can be complex and entail significant investment. Joint ownership of patents is one possibility, but the implications of various ways of structuring ownership should be considered in advance. In some jurisdictions, if there is more than one owner of IP, then the consent of the other owner(s) must be obtained for an assignment or license; i.e. the agreement of all owners is required for effective development and exploitation of the patent. In other cases, unless the joint owners have agreed differently, each one is free to use the patented invention without being accountable to the others. It may be difficult to arrange three-way partnerships between potential licensees and third parties. For this reason, it can be more practical for one co-owner to license or sell his or her interest in the patent to the other co-owner, subject to continuing access to the technology, payment or other conditions. In some cases, it may be more advantageous to concede ownership of any resulting patent in return for other benefits, such as a free license to use the patented product, process or technical solution, or broader benefits such as guarantees of access to technology for certain third parties, such as public authorities, developing country enterprises or non-commercial researchers.

49. Normally, a patent owner bears the financial and administrative obligations to maintain and to enforce that patent, although contractual agreements can provide for other arrangements. In cases of joint ownership, the parties will need to consider how certain responsibilities are shared, such as making and maintaining a patent application, enforcing the patent in the event of infringement, and negotiating and agreeing the terms of any subsequent licensing arrangement - the organization that carries out research on genetic material may not be competent to develop a commercial product arising out of any successful research, so third parties may need to be involved. How these detailed arrangements are settled should be determined with reference to the overall arrangements set for access and benefit-sharing. For instance, some agreements require that any licensing of patents derived from the access to genetic resources should refer back to the original access and benefit-sharing agreement.

Summary of issues

50. The following points summarize the patent-related issues that may be considered:

(a) Will access to the genetic resources and related information result in the creation of a patentable invention? If not, and where the aim of the access is academic research only, this should be clearly stated in any contractual arrangement, and the purposes of the access clarified accordingly. What is patentable can vary considerable between different countries.

What the access provider and the user of resources believe should be patented will also vary, depending on their perspectives and interests.

(b) What are the agreed arrangements concerning the obtaining of patents for any inventions resulting from the access? How do the access provider and user of the resources agree that patents should be obtained – are there requirements to report on inventions, to agree on specific patenting arrangements, or a general approach for all inventions resulting from the access?

(c) If so, who will be the owner(s) of the resulting patent? Will ownership be dependent upon such issues as the value of the contribution of genetic resources and TK, the level of scientific contribution and other contributions? Will the patent be jointly owned by the provider and user, regardless of contribution to the invention? Or will the access provider retain ownership? Consideration may need to be given to the demands of a sponsoring private organization or government body on the ownership, and use of, any patents arising out of the collaboration.

(d) In cases of joint ownership of a patent, how will responsibilities flowing from co-ownership be apportioned? For instance, relating to filing, maintenance and enforcement. Where will the resources come from to carry out these activities?

(e) What is the most appropriate model for the exploitation of the patent and for the use and dissemination of the new technology developed – for instance, a license, assignment or joint venture? Who will negotiate and agree the terms of any subsequent arrangement to exploit the patent? The parties could negotiate licenses to commercialize the research outcomes, or a separate commercial or industrial partner could be brought in once the research outcomes were proven.

(f) How, when and between whom will any monetary or non-monetary benefits arising from the commercial exploitation of the patent be apportioned? The provider of access to the genetic resources and any related information may retain certain contractual rights in relation to the sharing of benefits, regardless of ownership of the patent itself. Licensing royalties could be shared with the provider; alternatively, the provider may prefer to receive more immediate, short term benefits. In any event, consideration may need to be given to the establishment of specific structures or procedures to ensure that agreed benefits flow back to the provider; for instance, contract monitoring provisions and a benefit-sharing trust fund.

(g) How will the parties maintain confidentiality? The principle of confidentiality plays a central role in the patent system and the leaking of any confidential information into the public domain can adversely affect the securing of future patents. It is therefore vitally important that confidentiality is maintained until adequate protection is in place. Consideration should also be given to agreeing terms related to publications, in order to ensure that prior publication does not destroy any future patent rights.

(h) In carrying out the research, what use may be made of material or data covered by IP owned by others? Do warranties need to be sought, or given, relating to such IP?

Trademarks and geographical indications

51. The following issues relating to trademarks and geographical indications may be considered:

(a) Will access to the genetic resources and related information result in the creation of goods or services, which could be identified by a distinctive sign linking the goods or services back to the provider of the genetic resources? For instance, a word in a local dialect describing the resources in question, or a particular tribal symbol.

(b) If so, does permission need to be sought to use such a word or symbol and, if so, from whom and on what mutually agreed terms? What limitations on the use, for instance to reflect cultural concerns, should be imposed?

(c) Who would own such a trademark? Who would be responsible for the cost of development, registration and upkeep of a trademark, including payment of renewal fees and enforcement?

(d) What would be the most appropriate commercial model for the exploitation of the trademark? It is common practice for trademark owners to license third parties, who operate in different countries, to use their trademarks in those countries. Could the trademark be assigned?

(e) How would any benefits arising from the ownership, use and licensing of the trademark be apportioned? The provider of access to the genetic resources and any related information may retain certain contractual rights in relation to the sharing of benefits, regardless of ownership of the trademark itself.

(f) Are the genetic resources associated with a geographical indication? For example, are the resources linked with a traditional product that is distinctive of the geographical location where the resources are found? Are the genetic resources to be used for a product that has a quality, reputation or other characteristic that is essentially attributable to its geographical origin? What arrangements should be made to respect existing geographical indications, or to seek appropriate protection for geographical indications?

Copyright

52. Copyright may arise when information about genetic resources is recorded, and when accounts of TK are written down or otherwise recorded. Agreement at the time of access on ownership and use of this copyright may be an important question in ensuring an appropriate overall arrangement that reflects the interests of the two parties. The following copyright-related issues may therefore be considered:

(a) Will access to the genetic resources and related information result in the creation of original materials that may be eligible for copyright protection, such as texts, technical drawings or databases? If TK relating to Genetic Resources is recorded, in an article or book, for instance, how will rights and benefits associated with that record be allocated? Particular consideration may need to be given regarding the IP rights in databases. The structure of a database may have IP protection in its own right, without prejudice to any copyright in the information contained in the database.

(b) Who will own the copyright in works that contain TK about genetic resources? In many research institutions, such as universities, the employer, and not the employee/author, is deemed to be the author of a work prepared by an employee within the scope of his or her employment. However, an access agreement may pre-emptively assign ownership of the copyright to the provider of the TK.

(c) In cases of joint authorship, how will responsibilities flowing from co-ownership of copyright be apportioned? Can copyrighted material produced from the collaboration be assigned or otherwise licensed to third parties? If so, on what terms? Consideration may need to be given to entering into a partnership agreement over the management of the joint rights.

(d) Where, and in what format, will the works be published? As a condition of publication, an author may be obliged to sign a Copyright Transfer Agreement, transferring ownership of the copyright to the publishing house. This is standard practice in serials and journals publishing and is designed to ensures maximum international protection against infringement, libel or plagiarism. This will not affect the author's moral rights.

(e) How will monetary and non-monetary benefits arising out of publication of copyright works be shared? The provider of access to the genetic resources and any related information may retain certain contractual rights in relation to the sharing of benefits, regardless of ownership of the copyright itself.

(f) What use may be made of material or data covered by third party IP? Do warranties need to be sought or given relating to third party IP?

Plant Variety Rights

53. Plant varieties represent an important form of plant genetic resource. A plant variety is generally defined as the lowest level of taxonomy (or classification) within the plant kingdom – in other words, a group of plants that is distinct from all other groups of plants within a given species. Thus, a plant variety results from the lowest sub-division of the species.[*]

54. Plant varieties are relevant to access and benefit-sharing in at least two possible ways: (i) the genetic resources that are accessed may be plant varieties; and (ii) because the access to genetic resources may provide genetic inputs to plant breeding that creates new plant varieties. In both cases, there are potential IP questions that should be considered before agreement is reached on the terms of access and benefit-sharing.

55. IP protection has been developed specifically for new plant varieties. Different national systems provide protection through distinct, *sui generis* rights (termed 'plant breeder's rights' or 'plant variety rights'), patents on plant varieties, or both. *Sui generis* plant variety protection is available in many countries. The International Union for the Protection of New Varieties of Plants (UPOV), through the UPOV Convention, provides the only internationally harmonized system of plant variety protection in place. It comprises 55 member States. The UPOV Convention offers protection to the breeder of a new plant variety, in the form of a "breeder's right", if the variety satisfies the conditions set out in the UPOV Convention. In

[*] For details on the nature of plant varieties, see http://www.upov.int/en/about/upov_system.htm#what_is_a_pv

particular, the variety must be new, distinct, uniform and stable and must be designated by an appropriate denomination. When contractual arrangements for access to genetic resources relate to territories covered by the UPOV Convention, they should take account of the implications of the UPOV Convention for access to genetic resources, prior informed consent, and benefit-sharing, with regard to the "breeder's exemption", subsistence farmers and farm-saved seed.[*]

56. The following specific issues concerning plant variety rights may need to be agreed depending on the nature of access to genetic resources and their intended use:

(a) Will access to the genetic resources and related information result in the development of a new plant variety(ies), through breeding or other research activities?

(b) What IP protection may be available for this new variety (ies)? This differs according to the approach taken in national laws. Generally, some form of *sui generis* plant variety right is available. Some countries provide for patent protection of new plant varieties, in addition to plant variety rights or as an alternative.

(c) In what circumstances is it agreed that IP protection should be obtained for new plant varieties resulting from the access to genetic resources?

(d) Who will own the rights for any new plant variety, and how will this differ according to different territories? Will ownership be dependent solely upon contribution to plant breeding? Or will the IP be jointly owned by the provider and user, regardless of contribution to the breeding of the new variety? In cases of joint ownership, how will responsibilities for management and enforcement be apportioned and funded?

(e) How may the plant variety right be commercially exploited, in what territories, and by whom? What forms of licensing the right are agreed as a condition of the original access?

(f) How may any benefits arising from such commercial exploitation be apportioned? As for other areas of IP derived from genetic resources, the provider of access to the genetic resources and any related information may retain certain contractual rights in relation to the sharing of benefits, regardless of ownership of the IP right itself.

Trade Secrets

57. The following issues may arise in relation to confidential or undisclosed information (such as TK which is required by customary law to be disclosed only to certain people, only for certain purposes, or only in certain circumstances):

(a) Will access to the genetic resources and related information result in access to confidential information that may require careful handling and appropriate protection?

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[*] These matters are explained in the "Reply of UPOV to the Notification of June 26, 2003, from the Executive Secretary of the CBD," available at: <http://www.upov.int/en/news/2003/pdf/cbd_response_oct232003.pdf>.

(b) If so, then as a matter of priority, the provider and user of the information should contemplate entering into confidentiality agreement, to protect such information. Such an agreement could include the following terms:

(i) a description of the information covered by the agreement;

(ii) the nature of the protection required;

(iii) the scope of the permitted disclosure (who is authorized to get access to the information, including the need to put in place confidentiality obligations that cover the relevant employees or contractors of the institution receiving the confidential information);

(iv) the scope of permitted use (for technical or commercial evaluation; for non-commercial research; or for the development of a particular commercial product);

(v) ownership and management of any further IP rights that are created as a result of access to the confidential information, such as in the evaluation or testing process;

(vi) time limitations on the permitted use of the confidential information; and

(vii) monitoring and reporting on the use of the confidential information.

C. EXPLOITATION OF IP RIGHTS: LICENSING

58. An IP right does not in itself provide an economic benefit to anyone. For instance, the grant of a patent does not, *per se*, mean that an invention has an economic value and will be commercially viable. Furthermore, commercialization of an IP right, such as a patent, can involve a considerable amount of commercial risk, which may not be acceptable to smaller companies and dedicated research institutions, such as universities. Because of these considerations, many users of genetic resources choose not to commercialize IP rights themselves, but elect between a number of different options to manage those rights so as to get the commercial benefits of their research. Options could include licensing, assignment and joint ventures.

59. Licensing agreements are a particularly common way to exploit IP rights related to genetic resources and related information, including TK. A license agreement is an agreement to permit an inventor to license an IP right, such as a patent or trademark, to others to develop and use commercially, whilst retaining ownership and control of the IP right itself and gaining benefits, such as financial royalties from the commercial development and use. In the event of access for the purposes of commercial or industrial application, a license agreement shall be signed in which terms are provided that ensure due reward for the said access, and in which the equitable distribution of derived benefits is guaranteed.

60. Many providers and users of genetic resources may elect not to address the specific detail of exploitation of IP rights until an IP right has been created, and its potential commercial viability and value has been assessed. However, as part of an IP audit, it may nonetheless be useful to consider the following licensing-related issues, within the context of applicable international, regional or national laws or regulations:

(a) What IP rights arising out of the collaboration may, or may not, be licensed? For instance, the right to use a patented process to produce a specified product, but not the associated trademark;

(b) What kind of license may be granted? Sole, exclusive or non-exclusive? The kind of license granted will influences the scale of royalties, or other payments, made by the

licensee. In which territory(ies) will the license apply? Can a sub-license be granted so that a third party may also use the IP rights in question. If so, to who, and on what terms or conditions?

(c) Do clear milestones need to be identified? If a licensee gains an exclusive license, subject to royalty payments on profits, and then does not use the technology for several years, then some of the value of the IP is effectively lost to the licensor. Licenses will often include obligations on the licensee to develop and apply the licensed technology within a certain time scale.

(d) How will benefits flowing from the exploitation of the IP right be apportioned? It is always difficult to establish a value for IP, especially where it relates to unproven technology that will require a licensee to take a considerable commercial risk. Many licensing agreements consist of a mixture of lump sum payments and royalties, based on the extent of use of the technology. The approach taken to agreeing payments and pricing should be realistic, reflecting possible regulatory delays, especially in the biotechnology industry, and the fact that returns to the licensee can take many years to realize. Providers of genetic resources and related information may prefer to receive more certain up-front payments, rather than longer-term less certain returns.

(e) Who will own IP rights relating to improvements and adaptations to the licensed technology, whether arising from the licensed use of the technology or made by the licensor to the original technology?

(f) Consideration will need to be given as to who may be responsible for ensuring that renewal fees are paid, and the respective roles of the parties in relation to enforcing the licensed IP rights.

Checklist of licensing issues

61. The following issues may need to be addressed when considering how IP rights derived from the access to genetic resources should be licensed. Some of these issues may need to be left open at the initial stage, and settled in detail only when the nature and potential of the results of research and development derived from the genetic resources are better known.

(a) Definitions and Scope (define the IP rights being licensed, such as patents or know how, the purpose of the license and the permitted scope of the licensed use);

(b) Ownership of the IP rights that are being licensed (who retains ownership? In the case of joint ownership, who is entitled to grant licences, under what conditions?);

(c) Grant of licensed rights. The license needs to set out the exact rights that are (and are not) being granted. For instance, the right to use a patented process to produce a specified product, but not the associated trade mark. The use could be limited to research, or non-commercial, purposes;

(d) Sole, exclusive or non-exclusive license. It is important to clarify which one of these options applies to the IP right in question (will the licensor retain the right to use the covered invention, is the license required to be registered with appropriate national authorities, if so, by who?). The kind of license granted will influence the scale of royalties, or other payments, made by the licensee;

(e) Territory. In which territory(ies) does the license apply?

(f) Sub-licenses. Can a sub-license be granted so that a third party may also use the IP rights in question. If so, to who, and on what terms or conditions?

(g) Diligence and Milestones. If a licensee gains an exclusive license, subject to royalty payments on profits, and then does not use the technology for several years, then some of the value of the IP is effectively lost to the licensor. So, licenses will often include obligations on the licensee to develop and apply the licensed technology within a certain time scale. Where possible, certain defined points or milestones should be identified;

(h) Payments and Pricing. There are many potential models for payment. It is always difficult to establish a value for IP, especially where it relates to unproven technology that will require a licensee to take a considerable commercial risk. Many licensing agreements consist of a mixture of lump sum payments and royalties, based on the extent of use of the technology. The need to monitor the use of the invention and to ensure that royalties are paid, as well as checking on diligence and milestone obligations, can lead to requirements for record-keeping, access to accounts etc. The approach taken to agreeing payments and pricing should be realistic, reflecting possible regulatory delays (especially in the biotechnology industry), and the fact that returns to the licensee can take many years to realize.

(i) Confidentiality. There may be a distinct confidentiality agreement, or obligations as to secrecy may be incorporated into the license agreement itself. It may be important to agree the rights of the inventor(s) to publish their research;

(j) Copyright. The license may set out the copyright provisions covering any manuals or other documentation received, and used, as part of the licensing package;

(k) Improvements, grant-back rights and assign-back rights. It is often important to agree who will own IP rights relating to improvements and adaptations to the licensed technology (whether arising from the licensed use of the technology or made by the licensor to the original technology). A ‘grant-back’ clause may give access to a licensor to improvement made by a licensee. However, an exclusive ‘grant-back’ clause may be viewed under national law as anti-competitive commercial behavior. An assign-back clause would entitle the licensor to ownership in patents on any improvements;

(l) Cross-licenses. Under a cross-license, A grants B a license to use A’s IP, and B grants A a license to use B’s IP.

(m) Required Performance. A licensor (especially when granting an exclusive license) may wish to set specific performance targets in order to ensure a certain level of performance from the license agreement. For instance, minimum sales levels. A licensor may be expected to provide the licensee with assistance to exploit the IP effectively (such as training and technical support and advice);

(n) Publication of Research. Terms related to publications may monitor developments in the technology and the licensed activities, and ensure that prior publications does not destroy any future patent rights;

(o) Maintaining and enforcing IP rights. The licensor and licensee will need to agree who is responsible for ensuring that patent renewal fees are paid, and their respective roles in relation to enforcing the licensed IP rights;

(p) Duration of license; Termination; Dispute resolution; and Choice of law. A license will typically include provisions addressing all of these points.

(q) Other issues: these may include a guarantee clause (with provisions on liability and validity of authorizations, including prior informed consent under applicable law), provisions concerning challenges to validity of the IP rights (noting that competition law may not permit this), provisions concerning termination of the agreement before maturity, and provisions for amendment of the terms of the agreement.

VIII. MODEL IP CONTRACTUAL CLAUSES

62. Once answers have been established to the questions raised by the IP assessment, and negotiations have been carried out to reach mutually agreed terms of access and benefit-sharing, appropriate contractual terms and conditions reflecting these negotiations can be drafted. The IP aspects of these negotiations can be included either as part of a wider benefit-sharing package or as stand-alone IP clauses.

63. Examples of actual and model IP clauses in contracts and licenses concerning IP, access to genetic resources and benefit-sharing can be found in the WIPO Contracts Database at: http://www.wipo.int/tk/en/databases/contracts/index.html. The information contained in the WIPO Contracts Database should be viewed as a general starting point, to be interpreted according to the individual circumstances of a particular collaboration. Appendix II contains more detailed discussion and illustrations of the various kinds of agreements that are relevant to access and benefit-sharing.

64. In any event, prior to entering into a legally binding contractual arrangement, all parties should seek expert legal advice from a practitioner with experience in the relevant legal issues, including IP rights, and national legal system, or systems, in question.

[Appendix I follows]

APPENDIX I

MONETARY AND NON-MONETARY BENEFITS

The Bonn Guidelines list the following potential benefits from access and benefit-sharing:

1. Monetary benefits may include, but not be limited to:

   (a) Access fees/fee per sample collected or otherwise acquired;
   (b) Up-front payments;
   (c) Milestone payments;
   (d) Payment of royalties;
   (e) Licence fees in case of commercialization;
   (f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
   (g) Salaries and preferential terms where mutually agreed;
   (h) Research funding;
   (i) Joint ventures;
   (j) Joint ownership of relevant intellectual property rights.

2. Non-monetary benefits may include, but not be limited to:

   (a) Sharing of research and development results;
   (b) Collaboration, cooperation and contribution in scientific research and development programs, particularly biotechnological research activities, where possible in the provider country;
   (c) Participation in product development;
   (d) Collaboration, cooperation and contribution in education and training;
   (e) Admittance to ex situ facilities of genetic resources and to databases;
   (f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favorable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
   (g) Strengthening capacities for technology transfer to user developing country Parties and to Parties that are countries with economies in transition and technology development in the country of origin that provides genetic resources. Also to facilitate abilities of indigenous and local communities to conserve and sustainably use their genetic resources;
   (h) Institutional capacity-building;
   (i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
   (j) Training related to genetic resources with the full participation of providing Parties, and where possible, in such Parties;
   (k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
   (l) Contributions to the local economy;
   (m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in provider countries;
   (n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;

(o) Food and livelihood security benefits;
(p) Social recognition;
(q) Joint ownership of relevant intellectual property rights.

[Appendix II follows]

APPENDIX II

MAIN CATEGORIES OF AGREEMENT AND
EXAMPLES OF PROVISIONS

This Appendix would provide further background information on the main categories of agreement, and would provide examples of actual agreements. It would draw on the Database and follow closely the discussion already provided in document WIPO/GRTKF/IC/5/9.

It is not included in the present draft for reasons of space.

A draft outline of this material is to be provided as document WIPO/GRTKF/IC/7/INF/5.

[End of Annex and of document]