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## Discussion Paper



Prepared by ICC Commission on Intellectual Property

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# Traditional knowledge associated with genetic resources

Submission to the CBD ABS Technical Expert Group on  
Traditional Knowledge Associated with Genetic Resources

## Highlights

- Guiding principles
- Access and use of genetic resources and associated traditional knowledge
- Community and customary procedures for regulating access
- Local communities' prior informed consent: basis and supporting measures
- Transboundary availability of traditional knowledge
- Traditional knowledge and certificates
- Definition of traditional knowledge

# Traditional knowledge associated with genetic resources

## Submission to the CBD ABS Technical Expert Group on Traditional Knowledge Associated with Genetic Resources

### Introduction

Business has consistently demonstrated its desire to engage constructively as a stakeholder in the negotiations to an International Regime (IR) for Access and Benefit-Sharing (ABS). It therefore welcomes the opportunity to present its views on the treatment of traditional knowledge (TK) associated with genetic resources (GR) in the ABS IR. The business community has been an active participant in negotiations on access to and the sharing of benefits from genetic resources, even before the entry into force of the Convention on Biological Diversity (CBD) in 1993. The business delegation, coordinated by the International Chamber of Commerce (ICC), today represents various business sectors with diverse interests in genetic resources and associated traditional knowledge and their sustainable commercial uses. These include agricultural biotechnology, animal breeding, cosmetics, farming, flavors and fragrances, forestry, herbal medicines and supplements, industrial biotechnology, pets, pharmaceutical and bio-pharmaceutical products, and plant breeding (listed in alphabetical order).

Specifically with respect to TK relating to GR, business shares a common interest with indigenous and local communities in greater transparency, predictability, and a balance of benefits against costs of proposed ABS regulations at both the national and international level. Business underscores its continuing commitment to commercialization of GR and associated TK only with the prior informed consent (PIC) of relevant stakeholders and on mutually agreed terms (MAT), consistent with the Bonn Guidelines.

On this basis, ICC offers the following views on the issues under consideration by the Technical Expert Group on Traditional Knowledge Associated with Genetic Resources.

### Guiding Principles

Development of ABS IR elements relating to TK associated with GR should be limited to effective implementation of Article 8(j). It is widely accepted that sovereign rights and responsibilities relating to genetic resources and policies relating to traditional knowledge vest with Contracting Parties.<sup>1</sup> Article 8(j) of the CBD states that each Contracting Party shall:

“Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.”<sup>2</sup>

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<sup>1</sup> CBD Article 3 notes the principle of sovereign rights of states to exploit natural resources, and corresponding responsibility to prevent harm to the environment.

<sup>2</sup> CBD Article 8(j)

CBD Contracting Parties are obliged to put in place national legislation or otherwise formulate policies needed to encourage an enabling environment for generation of commercial benefits from the sustainable use of GR relating to TK - and thereby promote equitable sharing of benefits with indigenous and local communities.

Two important points flow from this.

First, the entity best equipped to manage TK of indigenous and local communities is the CBD member country. Indeed, this is also expressed in the Bonn Guidelines,<sup>3</sup> which represents the consensus of the Parties, and to which ICC has reiterated its commitment. Thus, access to such knowledge and information should be managed by CBD member countries, specifically via National Focal Points (Sect. 13, Bonn Guidelines) and Competent National Authorities (Sect. 14, Bonn Guidelines). It may often be the case that an indigenous or local community is domiciled in more than one CBD member state, and in such instances, the affected member states should together determine how they will address issues of prior informed consent so as to provide certainty to the provider community and to potential users of the TK. Regardless how the issue of transboundary TK is ultimately handled, it must provide legal certainty to stakeholders, so that legitimate ABS agreements with indigenous and local communities cannot later be challenged by third parties in other jurisdictions on the basis of the same associated TK.<sup>4</sup>

Second, all ABS stakeholders will benefit from a clear, transparent and finite understanding of “associated traditional knowledge” as applied to the IR. It is difficult to overstate the importance of clarity: it is an essential ingredient to encourage engagement of both users and providers in the ABS-related activities needed to generate benefits from sustainable use of GR (with or without associated TK).

With regard to “associated traditional knowledge,” it is a fundamental principle that information and knowledge that is in the public domain should be considered prior art against later patent applications. This means that traditional knowledge already in the public domain cannot be patented. Similarly, information and knowledge that is in the public domain, or that legitimately enters the public domain, should not be classified as related TK for purposes of benefit-sharing under the ABS IR. Individuals, indigenous and local communities and others are entitled to retain and use the knowledge that they already have. Information in the public domain, however, should be available for use by researchers, business and other users without need to seek prior informed consent (PIC) or otherwise being subject to the ABS IR. It is both unjust and impractical to attempt to prevent or control existing uses of material in the public domain.

The IR should not seek to restrict what can otherwise be achieved in mutually agreed terms (MAT) through the systematic use of contracts between users and providers of genetic resources and associated TK. Such contracts may take the form of Material Transfer Agreements (MTAs) or other such agreements. As ICC submissions have noted previously, ABS agreements can specify terms and conditions for access and benefit-sharing, conditions or restrictions on the use of the accessed genetic resource (and any associated TK), commercial terms, conditions for transfer, dispute settlement mechanisms, choice of governing law, term, and mechanisms for termination of the agreement. Contractual agreements, which are commonplace in ethical international business, can be tailored to respect CBD standards, as implemented by national law, and are enforceable under the judicial systems of CBD member states. Such ABS agreements are and remain the best mechanism to ensure PIC and MAT and to anticipate and possibly avoid future conflicts.<sup>5</sup>

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3 *The” Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization”, were adopted by COP Decision VI/24 to assist countries in the implementation of CBD ABS provisions, including Articles 8(j), 10(c), 15, 16 and 19, and are available online at [www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf](http://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf). The Bonn Guidelines represent the consensus of CBD Members and also have the continuing support and commitment of ICC members.*

4 *See discussion below of TK databases and registries, which may provide greater transparency and facilitate this process, pp. 6 - 8.*

5 *As noted by the Report of the Compliance TEG, “even in the absence of ABS legislation a contract could still be*

Noting the above general principles, ICC provides the following responses to the specific questions posed to the group of technical and legal experts on TK associated with genetic resources.

**a) What is the relationship between access and use of genetic resources and associated traditional knowledge?**

As noted in previous ICC submissions, business remains committed to the voluntary Bonn Guidelines, with the principles of prior informed consent (PIC) and mutually agreed terms (MAT) for access and use of GR - with or without associated TK. Many have expressed concerns about the unauthorized use of traditional knowledge associated with genetic resources and suggested that such use has enabled development and commercialization of products, without subsequent benefit-sharing. However, evidence suggests that research involving genetic resources is often carried out without any corresponding use of the associated TK. For example, a recent ABS case study on the Griffith University/Astra Zeneca natural product discovery collaboration reported that TK did not dictate which genetic resources were collected and studied. In fact, information about possible traditional uses of the collected genetic resources was not transferred to the participating researchers.<sup>6</sup>

Similarly, many claims exist about the origin of the rosy periwinkle plant, and the supposed improper reliance on its associated TK in the historic discovery and subsequent commercial development of the vinca alkaloids, vincristine and vinblastine, for the treatment of cancer. However, evidence suggests that the TK associated with the rosy periwinkle plant related to anti-diabetes properties and not anti-cancer properties. Furthermore, the plant, which grows wild throughout semi-tropical areas of the world, was used as a traditional medicine to combat diabetes, not in Madagascar, as often claimed, but in Jamaica.<sup>7</sup> These examples raise important questions about the transboundary nature of genetic resources and associated TK, as well as the divergence between traditional uses of GR and subsequent scientific research.

Nonetheless, business recognizes that concerns remain relating to misuse or misappropriation of TK related to GR. Therefore business supports a fact-based approach, with agreed parameters, to clearly identify the magnitude of the problem. This would help to suggest suitable measures to prevent it, and thereby contribute to the success of the ABS IR overall.

**b) What practical impacts should the negotiations of the international regime take into account based on the range of community level procedures and customary systems of indigenous and local communities for regulating access to traditional knowledge associated with genetic resources at the community level?**

ICC believes that the National Focal Point and National Competent Authority of each CBD Member State are best suited to ensuring that ABS is in accordance with community level procedures, that indigenous and local communities have granted prior informed consent to such use, and that all potential holders of the TK associated with GR have been consulted.<sup>8</sup> Businesses seek to pursue good-faith consultations with legitimate ABS stakeholders. For such consultations, an effective National Focal Point and a designated Competent National Authority both play a critical role. National regimes must not only articulate national standards for meeting ABS interests of the sovereign state,

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*concluded between a provider and a user, in accordance with existing administrative and regulatory mechanisms. This contract could provide for a range of provisions to facilitate compliance with the contract, including a dispute settlement clause.” UNEP/CBD/WG-ABS/7/3, 10 February 2009, p. 7.*

6 S. Laird, et al., *The Griffith University AstraZeneca Partnership for Natural Product Discovery – An Access & Benefit Sharing Case Study* (2008), See especially, page 25, United Nations University Institute of Advanced Studies. Available at: [http://www.ias.unu.edu/sub\\_page.aspx?catID=111&ddlID=681](http://www.ias.unu.edu/sub_page.aspx?catID=111&ddlID=681).

7 Zenk, M.H., and Jeunger, M., *Evolution and current status of the phytochemistry of nitrogenous compounds*, *Phytochemistry*, 68 (2007) 2757-2772, 2761. Available online at: <http://dx.doi.org/10.1016/j.phytochem.2007.07.009>.

8 As noted by the Report of the Compliance TEG, “Customary laws of indigenous and local communities generally also address natural resources, including genetic resources and associated traditional knowledge. These laws vary between indigenous and local communities in different countries and within countries.” UNEP/CBD/WG-ABS/7/3, 10 February 2009, p. 13. Accordingly, Contracting Parties are in the best position to provide relevant details to business and other ABS stakeholders.

but must also provide guidance and a degree of legal certainty regarding appropriate consultation with indigenous and local communities. Experience has demonstrated that consultation may be pursued in good faith, only to have new claimants emerge after-the-fact to challenge the authority of the groups initially consulted. Such cases, and the failure of states to provide legal certainty in such matters, therefore increase risk. In such cases, the increased risk must be accounted for and may result in lower benefits or, if the uncertainty is too great, may discourage sustainable commercialization of GR and associated TK in the first place.

**c) Identify the range of community level procedures and determine to what extent customary laws of indigenous and local communities regulate access to genetic resources and associated traditional knowledge at the community level and its relevance to the international regime.**

ICC recognizes that community level procedures and customary laws differ between communities, and the level to which these customary laws are incorporated or otherwise recognized in national laws may also vary. The CBD member country, through its National Focal Point or Competent National Authority, is in the best position to ensure that local procedures are identified and communicated to potential users of TK. Because of the divergence in community level procedures and their level of incorporation in national law, and for reasons of ensuring national sovereignty, the international regime should not seek to interfere in or regulate matters of customary laws and local procedures.

**d) To what extent measures to ensure compliance with prior informed consent and mutually agreed terms under Article 15 also support the prior informed consent of indigenous and local communities for the use of their associated traditional knowledge?**

ICC members continue to believe that compliance measures in the IR should be clear, transparent, non-discriminatory and predictable, and should be based on real-world experience. In all cases, proposed compliance measures should be shown to provide benefits that outweigh the costs to CBD Contracting Parties and other ABS stakeholders. These same qualities must also apply to any additional compliance measures adopted specifically to associated TK that falls under the scope of the ABS IR.<sup>9</sup>

One of the central tenets of Article 15 is the right of States to regulate access to their genetic resources, but not in a manner that imposes restrictions contrary to the objectives of the Convention. However, genetic resources that are associated with TK face one special consideration in that States must account for the needs and wishes of indigenous and local communities that are the holders of the TK. Therefore, ensuring compliance with prior informed consent and mutually agreed terms may best be achieved at the country level through legislation, national focal points and competent national authorities.

The recent Compliance TEG Meeting in Tokyo considered a number of possible compliance measures under Article 15 that might also support the prior informed consent of indigenous and local communities to use of their associated traditional knowledge. These include: continuing capacity building,<sup>10</sup> use of written ABS contracts,<sup>11</sup> provision of model clauses for use by ABS stakeholders in written ABS Agreements,<sup>12</sup> and TK databases and registries.<sup>13</sup>

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<sup>9</sup> As noted previously, TK that already has entered the public domain should be excluded from the scope of the ABS IR, even if the GR with which it is associated is accessed after the entry into force of the IR, as such TK has already become freely accessible and cannot be retroactively recaptured. In other words, PIC and MAT should not be required for continuing use of TK in the public domain.

<sup>10</sup> UNEP/CBD/WG-ABS/7/3, 10 February 2009, p. 6.

<sup>11</sup> UNEP/CBD/WG-ABS/7/3, 10 February 2009, p. 9.

<sup>12</sup> UNEP/CBD/WG-ABS/7/3, 10 February 2009, p. 12.

<sup>13</sup> UNEP/CBD/WG-ABS/7/3, 10 February 2009, p. 9.

With respect to TK databases and registries, it was noted that: “Traditional knowledge databases or registries that respect prior informed consent of indigenous and local communities can also be helpful to promote compliance with the rights of indigenous and local communities to genetic resources and associated traditional knowledge, and their customary laws, as they could provide proof in litigation and bring transparency and certainty over those practices”.<sup>14</sup> The Government of India has recently reached agreement with the European Patent Office (EPO) on use of India’s TK Digital Library to give the EPO access to the TKDL. This will enable the EPO to conduct more thorough searches of patent applications that may make use of publicly known Indian TK.<sup>15</sup>

**e) Identify elements and procedural aspects for the prior informed consent of holders of associated traditional knowledge when traditional knowledge associated with genetic resources is accessed also taking into account potential transboundary contexts of such associated traditional knowledge and identifying best practice examples.**

When an ABS stakeholder obtains prior informed consent and reaches mutually agreed terms with one provider of GR (with or without associated TK), only to be accused of misappropriation or misuse by a second provider, possibly even in another jurisdiction, a difficult problem arises that the ABS IR needs to address. Particularly in the case of associated TK, the practice or knowledge may belong in more than one indigenous or local community, or may be spread amongst a community that spans more than one member state.

Where multiple countries have genetic resources and associated TK in common, agreements between Contracting Parties could be arranged so that benefits received by one member would share the benefits received with the others.<sup>16</sup> However, attempting to negotiate such an agreement would likely be highly complex and resource-intensive. In any case, such agreement between possible providers of the genetic resource or associated TK in question should not affect the clean title of a business or other ABS stakeholder that has entered into a clear and legitimate ABS Agreement including PIC, MAT and other relevant provisions. In other words, once a user has entered into an ABS agreement in good faith, further demands made either by other countries or indigenous or local communities can only discourage sustainable commercialization of GR and related TK and should not be allowed under the ABS IR.

Use of TK registries and databases, as described above, can go a long way towards providing greater transparency and increasing awareness among all ABS stakeholders to ensure compliance with PIC when TK associated with GR is accessed, both within and across national boundaries.<sup>17</sup> The proposal of Japan in the World Intellectual Property Organization (WIPO) for development of an inter-operable, integrated and comprehensive system of national TK digital libraries<sup>18</sup> may provide the most cost-effective way to address this important issue. In the meantime, India’s pioneering efforts in development of its TK Digital Library at the national level may provide a good example of best practice in this area.

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<sup>14</sup> UNEP/CBD/WG-ABS/7/3, 10 February 2009, p. 15.

<sup>15</sup> “India Partners with EU to prevent India’s traditional medicinal knowledge from Biopiracy,” Government of India Press Information Bureau, 9 February 2009, available online at <http://pib.nic.in/release/release.asp?relid=47343>.

<sup>16</sup> *Similar problems may arise in cases where the genetic resource has properties unrecognized by the indigenous or local community or becomes the subject of multiple research projects, where CBD members should ensure that the ABS IR provides for mutual recognition of ABS agreements between countries.*

<sup>17</sup> *Some remain concerned that a public system of TK databases or digital libraries would provide a “license to steal” by cataloging GR and associated TK and making it publicly accessible. The argument that the mere availability of TKDLs will lead to increased biopiracy is misleading. In fact, any TK that is included in a TKDL would constitute prior art, and would thus not be patentable. This important and basic point is often overlooked in the TKDL debate.*

<sup>18</sup> See WIPO/GRTKF/IC/9/13, April 20, 2006, available online at: [www.wipo.int/edocs/mdocs/tk/en/wipo\\_grtkf\\_ic\\_9/wipo\\_grtkf\\_ic\\_9\\_13.doc](http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_9/wipo_grtkf_ic_9_13.doc).

**f) Is there a basis for prior informed consent for indigenous and local communities relative to traditional knowledge associated to genetic resources in international law? If so, how can it be reflected in the international regime?**

As noted by the Report of the Compliance TEG, private international law provides a number of avenues for settlement and enforcement of ABS disputes, equally available to indigenous and local communities:

"Private international law regulates relationships between private entities across borders. In particular, it seeks to regulate (i) which jurisdiction applies to a dispute; (ii) which laws apply to the dispute; (iii) whether and how eventual decisions or judgements are recognized and may be enforced in another jurisdiction. Each State has its own national rules on conflicts of laws, but some of these may have been harmonized through conventions, guidelines and model laws."

The Report of the Compliance TEG provides a full discussion of available options under private international law.

**g) Assess options, considering the practical difficulties and distinct implementation challenges, for including traditional knowledge associated with genetic resources in a potential internationally recognized certificate issued by the competent domestic authority also by considering the possibility of a declaration on such certificate as to whether there is any associated traditional knowledge and who the relevant holders of traditional knowledge are.**

Practical experience with an internationally recognized certificate of the kind suggested is lacking. ICC members have many doubts about this option.

Despite the fact that certificates have been discussed for some time as a potential mechanism for ensuring compliance, and a group of technical experts was convened to address issues and concerns regarding the application of certificates to genetic resources, there is still very little clarity about how certificates could be applied. Questions remain about the feasibility of applying certificates to genetic resources, the costs and potential bureaucracy associated with certificates, and how certificates would be applied to genetic resources that are located in *ex situ* collections or that were transferred before the entry into force of the CBD. ICC has raised a number of such questions and issues that the Parties must consider and address before an effective and feasible certificates system can be created.

In any case, a certificate system should be held to the same standard as other compliance mechanisms, in that it should provide transparency, predictability, and a reasonable balance of benefits against costs of the proposed system at both the national and international level.

The Report of the Compliance TEG emphasises that all additional compliance mechanisms should have proven effectiveness at reasonable cost, and target areas of greatest need to conserve limited resources;<sup>19</sup>

The Report also lists other significant problems that would be posed by a system of certificates.<sup>20,21</sup>

**h) How to define traditional knowledge associated to genetic resources in the context of access and benefit-sharing?**

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<sup>19</sup> UNEP/CBD/WG-ABS/7/3, 10 February 2009, p.8

<sup>20</sup> *Ibid.* See also ICC submission to the Technical Experts Group on Certification "Issues for consideration by the Group of Technical Experts concerning a Certificate relating to genetic resources", document n° 450/1020, 15 September 2006, available online at [http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual\\_property/Statements/CertificationSubmission\\_to\\_CBD.pdf](http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/CertificationSubmission_to_CBD.pdf)

<sup>21</sup> *Similar questions have been raised in* Tobin, B., *et al.*, Certificates of Clarity or Confusion: The search for a practical, feasible and cost effective system for certifying compliance with PIC and MAT (2008) *United Nations University Institute for Advanced Studies*. Available online at: [http://www.ias.unu.edu/sub\\_page.aspx?catID=111&ddlID=682](http://www.ias.unu.edu/sub_page.aspx?catID=111&ddlID=682).



As the Parties are aware, the issue of how to define traditional knowledge associated with genetic resources has been discussed for many years in various fora. For example, the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) has considered the issue extensively in the context of *sui generis* protection for TK, at least since 2001. Nonetheless, there is still no internationally accepted agreed-upon definition for the term “traditional knowledge” arising from these discussions.

As noted in a previous ICC submission, in considering how to define TK, the Parties may consider that a helpful definition of TK and associated rights would:

- Provide reasonable certainty as to what is protected, and what is not;
- Provide reasonable certainty as to the extent to which subject matter is protected, and what use if any can still be freely made of it (eg, mere possession? private study? research use?);
- Create a clear nexus between the knowledge and the claimant of rights in it;
- Include a requirement of a proper justification for the rights claimed, which should be proportionate and reasonable; and
- Contribute to a fair and effective system for enforcing the rights and adjudicating disputes.

## Conclusions

ICC members appreciate the continuing opportunity to participate pro-actively as a core stakeholder in negotiations of the ABS IR. Business shares in common with indigenous and local communities an interest in greater transparency, predictability and certainty, both for users and providers of associated TK, to prevent future disputes and to encourage the generation and equitable sharing of benefits.

Business believes that there are three points of central importance to create enabling conditions for the sustainable commercialization of TK relating to GR that is needed for creation of benefits. These are:

- A clear framework for ABS stakeholders to reach MAT that will not be open to challenge from third parties with similar related TK, and
- The need to look forward, and not seek to recapture information already in the public domain.
- The need to recognize principles of national sovereignty with regard to existing customary law. National ABS systems must ensure legal certainty, clarity and transparency by suitable reference to community-level procedures and customary systems of indigenous and local communities.

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# The International Chamber of Commerce (ICC)

ICC is the world business organization, a representative body that speaks with authority on behalf of enterprises from all sectors in every part of the world.

The fundamental mission of ICC is to promote trade and investment across frontiers and help business corporations meet the challenges and opportunities of globalization. Its conviction that trade is a powerful force for peace and prosperity dates from the organization's origins early in the last century. The small group of far-sighted business leaders who founded ICC called themselves "the merchants of peace".

ICC has three main activities: rules-setting, dispute resolution and policy. Because its member companies and associations are themselves engaged in international business, ICC has unrivalled authority in making rules that govern the conduct of business across borders. Although these rules are voluntary, they are observed in countless thousands of transactions every day and have become part of the fabric of international trade.

ICC also provides essential services, foremost among them the ICC International Court of Arbitration, the world's leading arbitral institution. Another service is the World Chambers Federation, ICC's worldwide network of chambers of commerce, fostering interaction and exchange of chamber best practice.

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ICC was founded in 1919. Today it groups hundreds of thousands of member companies and associations from over 130 countries. National committees work with their members to address the concerns of business in their countries and convey to their governments the business views formulated by ICC.



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**Policy and Business Practices**

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