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FACILITATING PRIOR INFORMED CONSENT IN THE CONTEXT OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

by Anne Perrault*

INTRODUCTION

This paper traces the evolution of free prior informed consent (“FPIC”) and describes the importance of FPIC to achieving the objectives of the Convention on Biological Diversity (“CBD”). It briefly highlights elements of current approaches to obtaining FPIC from national governments and local communities, identifies limitations to obtaining FPIC, and provides examples of how the Bonn Guidelines do and do not respond to these limitations. The paper does not provide a detailed analysis of all issues related to implementation of FPIC, but rather highlights issues that will, hopefully, promote constructive discussions to advance progress on the implementation of FPIC.

EVOLUTION OF THE CONCEPT OF FREE PRIOR INFORMED CONSENT

The concept of free prior informed consent originated in the medical field as a dialogue between individuals (doctor and patient) to ensure that doctors provided patients with sufficient information to allow each patient to make an informed decision regarding an important health matter.

Subsequently, FPIC came to be viewed as central to securing State sovereignty rights in relations between States. Beginning in 1987, States began to employ FPIC as a tool to control the movement of potentially harmful materials into their territories from exporting States.¹ Currently, in the contexts of hazardous and toxic materials, genetically-engineered organisms, and persistent organic pollutants, States generally have a right to some form of free prior informed consent before these materials are transported into the State. In the context of access to genetic resources, States have a right to free prior informed consent for transport of genetic resources out of the country.²

Most recently, discussions relating to free prior informed consent have centered largely on the rights of indigenous peoples and other local communities to FPIC in various contexts, including logging, mining, resettlement, dam building, and access to genetic resources. These communities view FPIC as central to securing their rights and protecting their vital interests when these activities may affect their interests. Official interpretations of several international instruments, including the Convention on the Elimination of Racial Discrimination; the American Convention on Human Rights; the International Covenant on Economic, Social, and Cultural Rights; and the International Labor Organization Convention 169 Concerning

Indigenous and Tribal Peoples in Independent Countries, indicate that free prior informed consent of indigenous peoples is central to effectuating rights within these conventions, including the rights to culture, self-determination, and property.³ Additionally, in the last few decades, FPIC has been promoted by voluntary guidelines, social and environmental codes, contractual agreements, and political referendums.⁴

FREE PRIOR INFORMED CONSENT IN THE CONTEXT OF ACCESS TO GENETIC RESOURCES

RIGHTS OF NATIONAL GOVERNMENTS AND LOCAL COMMUNITIES TO FREE PRIOR INFORMED CONSENT

Concerns exist about companies, research institutions,

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IUCN - The World Conservation Union was founded in 1948 and brings together states, government agencies and a wide range of NGOs in a unique worldwide partnership. As a Union, IUCN seeks to influence, encourage, and assist societies throughout the world to conserve the integrity and diversity of nature, and to ensure that any use of natural resources is equitable and ecologically sustainable.

CIEL - The Center for International Environmental Law is a public interest, not-for-profit environmental law firm founded in 1989 to strengthen international and comparative environmental law and policy around the world. CIEL provides a full range of environmental legal services in both international and comparative national law, including: policy research and publication, advice and advocacy, education and training, and institution building.

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other entities, and individuals acquiring and using genetic resources and traditional knowledge from biodiversity-rich countries without obtaining free prior informed consent and making arrangements for benefit sharing. Several cases of “bio-piracy” have been documented, including cases in which patents have been obtained in “user” countries.⁵

Discussions concerning the rights of national governments and local communities to manage access to genetic resources and associated traditional knowledge are active within the CBD, the World Intellectual Property Organization (“WIPO”), and the Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPS”). In these fora, however, existing measures relating to these rights may conflict with one another.

The CBD embraces three main objectives: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits resulting from use of genetic resources. The ability to manage access to genetic resources is central to achieving each of these objectives.

The CBD requires that free prior informed consent be obtained from contracting Parties providing access to genetic resources and that these Parties, in turn, “respect, preserve and maintain knowledge, innovations and practices of . . . communities . . . and promote their wider application with the approval and involvement of the holders of such knowledge . . .”⁶ The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of their Utilization (the “Bonn Guidelines”) are voluntary guidelines recently adopted by Parties to elaborate on their obligations and rights with respect to genetic resources and traditional knowledge. The Bonn Guidelines encourage Parties to ensure that free prior informed consent is obtained from communities for access to genetic resources and associated traditional knowledge.⁷

Neither WIPO nor TRIPS recognize the rights of national governments and local communities to free prior informed consent. Current interpretations of the TRIPS Agreement suggest that governments may be violating the TRIPS Agreement when imposing requirements on those seeking a patent to disclose the origin of the genetic resource and provide evidence of FPIC before a patent is issued.⁸ Yet some experts have proposed interpretations of TRIPS provisions that would provide the space for national governments to require evidence of PIC in a manner that is consistent with TRIPS.⁹ Some countries advocate recognition of these requirements.¹⁰ The failure of WIPO and TRIPS to require evidence of FPIC and disclosure of origin could undermine the FPIC requirements in other instruments.

ELEMENTS OF FREE PRIOR INFORMED CONSENT RELATED TO ACCESS TO GENETIC RESOURCES

The application of FPIC in the context of access to genetic resources is distinct from its application in the context of hazardous/toxic wastes and that of genetically-engineered organisms. In the context of access to genetic resources, the country facing potential harm and having the right to free prior informed consent is the country out of which substances may be trans-

ported. Rather than trying to prevent adverse impacts of movement of materials into a country, FPIC instead focuses on preventing exploitation and movement of potentially beneficial materials out of the country, as well as ensuring that benefits derived from use of the materials accrue to the provider country.

Such distinctions necessitate different approaches to implementing free prior informed consent for States. Nevertheless, activities to elaborate FPIC requirements in a hazardous waste or genetically-engineered organism context can inform development of the rights of national governments to FPIC in the genetic resources context. Information concerning what FPIC means, when information should be provided, how responsibilities for developing and providing information are allocated, and how due process concerns are addressed may be used to shape approaches to implementing the rights of national governments to FPIC in the genetic resources context.

Additionally, the Bonn Guidelines provide some guidance on possible elements of FPIC procedures, including: consent of the

[In the context of genetic resources,] FPIC instead focuses on preventing exploitation and movement of potentially beneficial materials out of the country...

national authority and indigenous and local communities; mechanisms for the involvement of stakeholders; reasonable timing and deadlines; specification of the type of uses; direct linkage with mutually agreed terms; detailed procedures for obtaining consent; and a description of the general process for access.

For local communities, FPIC in the context of genetic resources and FPIC in other contexts basically involve the same rights, i.e., the rights of local communities to participate in management of resources on lands they occupy. However, approaches to FPIC in the context of genetic resources are likely to differ from approaches to FPIC in other contexts due to differences between contexts. These include, for example, differences in the abilities of communities to be aware of and physically control the activities (i.e., use of genetic resources may be much more difficult to detect and prevent than the other activities), and differences in the complexities of legal structures that govern use of the resources (i.e., intellectual property laws that may govern

use of certain genetic resources/traditional knowledge may be more complex and rely more on foreign laws than laws that govern use of other resources).

While the definition of FPIC for local communities varies by context, it is generally described as a consultative process whereby the potentially affected community engages in an open dialogue with individuals interested in conducting activities in the area(s) occupied or traditionally used by the affected community. Discussions should occur prior to, and continue throughout, the time that the activity is conducted. Although FPIC procedures may have culturally specific variations, a number of commonalities or “best practices” can be identified from the genetic resources, traditional knowledge, and extractive industries fields.¹¹ Many communities have articulated these procedures. Some ideas include:

- The person seeking access must obtain consent from every affected community in the traditionally recognized manner – according to the customary laws and practices of the concerned community.
- Before seeking consent, the person requesting access should distribute and hold community discussions regarding all relevant information in a culturally appropriate manner – both written and oral, in a language understandable to the local community.
- Relevant information includes: (1) disclosure of proposed objectives, including what one hopes to obtain and the foreseeable consequences of the research, such as social, economic, and environmental effects on the local community, the potential for commercial applications, the quantity of the resource sought, the duration of the activity, and the specific geographical prospecting area; (2) disclosure of legal and financial information, including any affiliations, where money will be coming from, who is in charge, and what/how benefits will be shared with the local community; (3) disclosure of any impact statements (environmental and other) concerning the local activity; (4) disclosure of previous or related activities undertaken by the person seeking access (and by affiliated organizations), including a description of any previous consent plans, how the objective was met, any effects on the community, etc.
- The community at large should be notified of the proposed activities, and informed decisions should be made in a traditionally recognized, culturally appropriate manner. Discussions should be inclusive so that all affected local populations have an opportunity to participate actively.
- Consent should be part of an ongoing process conducted throughout the planning, design, implementation, and evaluation of the project. The

process must include a substantive dialogue through which the community may choose to give or not to give consent.

- Community leaders may revoke consent for legitimate, good faith reasons.

LIMITATIONS TO OBTAINING FREE PRIOR INFORMED CONSENT

Interrelated legal, political, and economic barriers exist for obtaining free prior informed consent. They include, for example, a lack of relevant or effective laws and regulations, burdensome procedures and transaction costs, lack of articulated community procedures, a lack of desire of many communities and some governments to facilitate access, and, perhaps, unrealistic expectations.

Because these resources may serve vital spiritual, cultural, and sustenance needs, the overriding interest of the community may be to protect the resources and ensure continued community access to them.

Despite the rights of national governments to manage access to genetic resources and to require free prior informed consent, many have not acted to adopt or implement national access laws and regulations. Many of the following concerns may prompt this government inaction:

Lack of certainty about approaches to institutional structures, processes, and information

Many governments lack certainty about the institutional structures, processes, and information needed to achieve the dual objectives of facilitating access while ensuring benefit sharing. Uncertainty exists, for example, about how to address the information needed to make informed decisions, and how, when, and from whom consent should be obtained. Additionally, questions remain about what mechanisms are available for enforcement of FPIC requirements and how effective these mechanisms are.

Unwillingness to address divisive issues

Some governments are unwilling to address issues when different groups call for actions that appear antithetical to one another. In many situations, for example, one faction of the population may want to work within the existing intellectual property system, while another (frequently including local communities) may demand that genetic resources and traditional knowledge not be subject to this system.

Lack of certainty about how to address community rights

For some governments, uncertainties exist about how to address local community rights to prior informed consent. Issues raised include those related to what free prior informed consent means in the context of access to genetic resources. Do local communities have the absolute right to say no in every situation? Can this right ever be qualified by a larger public interest, and, if so, under what circumstances and how should this larger public interest be identified?

Lack of security in benefits

Governments may be uncertain about costs to them and benefits to be derived from providing access to genetic resources, particularly when patents will be sought. Benefits for genetic resources may be less obvious or quantifiable than benefits in other resource use contexts, and the issues related to determining these benefits are more complex. Will technology be transferred? How will a patent obtained in another country limit the State's ability to benefit from these genetic resources? Intellectual property issues are very technical and involve legal systems in other countries – systems over which relatively little control exists.

BARRIERS TO OBTAINING FREE PRIOR INFORMED CONSENT

Even when laws and regulations do exist, barriers to obtaining FPIC sometimes persist. These barriers include:

Inadequacy of laws and regulations

Some laws and regulations regulating access respond inadequately to issues related to implementation of FPIC, providing insufficient detail and direction to governments and potential participants.

Lack of articulated community procedures

While most communities have well-established decision-making processes, some communities have not articulated in writing a process by which consent may be obtained from them by outside groups. Articulating these procedures often requires additional financial, personnel, and technical resources.

Lack of desire to facilitate access

Many local communities simply have no interest in facilitating greater access to genetic resources and traditional knowledge, particularly when a patent might be sought for use of the resource. Because these resources may serve vital spiritual, cul-

tural, and sustenance needs, the overriding interest of the community may be to protect the resources and ensure continued community access to them. Additionally, many communities worry that efforts to facilitate access will not adequately consider their interests nor respect their rights.

Burdensome procedures and excessive costs

Many entities seeking access to genetic resources and traditional knowledge believe that laws, regulations, and procedures – particularly those relating to FPIC from local communities – impose unnecessary barriers to access that generate excessive costs. Many scientific institutions, in particular, believe that laws and regulations are too complicated and transaction costs too high, given that their research activities likely pose relatively modest adverse impacts to biodiversity and that their proposed uses are almost always non-commercial. These institutions believe laws and regulations should distinguish between uses and treat them differently.

Unrealistic expectations

Sometimes those seeking access to genetic resources and traditional knowledge expect that the process to obtain consent will be modeled after “Northern” consent processes. These expectations are likely to be unrealistic, particularly when dealing with indigenous communities, given the cultural and value differences between those providing and those using resources. Sometimes governments providing resources expect that fortunes will be made by those seeking to use the resources. Accordingly, they may excessively regulate access to the resources.

EXAMPLES OF HOW THE BONN GUIDELINES RESPOND TO LIMITATIONS

The Bonn Guidelines provide governments with a set of options for responding to many of the limitations to obtaining consent. These include provisions that:

Address institution, process, and information issues

The Guidelines address government uncertainties over how to structure institutions and processes to satisfy queries about how FPIC can be obtained. The Guidelines suggest that a national focal point be established to respond to queries about how FPIC can be acquired, and they embrace recognition of a single national authority from which FPIC can be obtained. Furthermore, they identify and describe possible elements of a free prior informed consent system.

Address some benefit and enforcement issues

To respond to limitations related to trust and enforcement issues, the guidelines identify and promote measures that “user” countries can adopt to help secure sovereignty for provider states over their resources as well as help secure the rights of local communities. The Guidelines raise awareness about the significance of requirements for disclosure of origin and evidence of prior informed consent, which may provide some assurance to governments that their concerns are being heard.

Additionally, the Guidelines require users to ensure “fair and equitable” sharing of benefits, including technology transfer.

Describe and encourage approaches to reducing regulatory obstacles and costs

Several provisions, including those relating to the “basic principles” of an FPIC system, attempt to promote reduction in costs and regulatory obstacles. The Guidelines note, for example, “access to genetic resources should be facilitated at minimum cost.”

Respond to some of the concerns of local communities

The Guidelines respond to some concerns of indigenous and local communities by promoting respect for their customs, traditions, and values as well as encouraging support for capacity building.

OUTSTANDING LIMITATIONS

Despite the potential of the Bonn Guidelines to respond to limitations to obtaining free prior informed consent, many issues remain outstanding. Some of these include:

Addressing indigenous issues

Despite provisions in the Guidelines that support local communities, many indigenous representatives have significant concerns about the phrasing of the Guidelines and how the Guidelines might adversely impact their rights. Several limitations to obtaining consent are rooted in the lack of certainty for indigenous peoples. Indigenous peoples are concerned that the phrasing, “the consent of relevant stakeholders, such as indigenous and local communities, as appropriate to the circumstances and subject to domestic law, should also be obtained,” fails to recognize that their rights to free prior informed consent are recognized by international law and are not derived from national recognition of these rights. The term “stakeholders” fails to recognize that indigenous peoples are “rights holders.”

Recognizing different uses

Scientific institutions and other users suggest that FPIC provisions of the Guidelines do not adequately reflect differences in uses of the resources. As a result, requirements imposed on institutions seeking non-commercial uses of resources may be disproportionate to potential adverse impacts.

Understanding implementation difficulties and the need for user measures

Many collectors/users of genetic resources believe that the guidelines do not evidence an understanding of difficulties associated with implementing user measures. Users point to the difficulties of disclosing origin or providing evidence of FPIC when the user has obtained the resource from someone else or has had the resource for a long period of time in a collection. Furthermore, many users believe that the guidelines fail to capture the essence of the “bio-piracy” problem, which they assert is more acute regarding seeds and animals for which patents will

not be sought, than it is for genetic resources. Additionally, these users suggest that the focus on disclosure of origin is misplaced, because most patent applications already disclose origin.

Enforcing PIC requirements

The Guidelines provide little guidance on how enforcement mechanisms and measures might be structured, and, by virtue of being voluntary, do not provide any mechanism pursuant to which FPIC requirements could be enforced.

CONCLUSION

User and Provider parties share an interest in developing regulations and guidelines for prior informed consent involving the use of genetic material and traditional knowledge. While the interested parties may look to previously established guidelines for free prior informed consent, such as the Bonn Guidelines from the CBD, these guidelines are often more tailored for the original uses of free prior informed consent, such as in the contexts of hazardous and toxic materials and genetically-engineered organisms. The development of effective free prior informed consent in the context of genetic material requires constructive discussions including, though not limited to, user and provider states, user scientists, and provider indigenous communities.



ENDNOTES: PIC in the Context of Genetic Resources

¹ Cairo Guidelines and Principles for the Environmentally Sound Management and Disposal of Hazardous Wastes, June 17, 1987, available at <http://www.unep.org/Documents/Default.asp?DocumentID=100&ArticleID=1663> (last visited July 28, 2004). The Cairo Guidelines and Principles, which later served to inform development of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, adopted by the United Nations Environment Program in 1987, first embraced FPIC in the hazardous waste context.

² See Convention on Biological Diversity, June 5, 1992, available at <http://www.biodiv.org/doc/legal/cbd-en.pdf> (last visited July 28, 2004). As defined in Article 2 of the Convention on Biological Diversity, genetic resources include “any material of plant, animal, microbial or other origin containing functional units of heredity.”

³ For example, within the last two years, the Committee interpreting the Convention on the Elimination of Racial Discrimination issued Recommendation XXIII, which calls for all Parties to the Convention to obtain informed consent of indigenous peoples in all decisions that may concern their rights or interests. *Rights of Indigenous Peoples*, Committee on the Elimination of Racial Discrimination, 51st Sess., General Recommendation 23, annex V, at 122, U.N. Doc. A/52/18 (1987), reprinted in U.N. Doc. HR/IGEN/1/Rev.6 at 212 (2003). In March 2003, the Committee censured Ecuador for “falling short” of meeting prior informed consent requirements for indigenous communities, finding that in the context of resource exploitation on traditional lands, mere consultation was insufficient. *Consideration of Reports Submitted by States Parties Under Article 9 of the Convention: Concluding Observations on Ecuador*, Committee on the Elimination of Racial Discrimination, 62nd Sess., U.N. Doc. CERD/C/62/CO/2 (2003). Botswana was censured the previous year for failing to ensure that prior informed consent was secured prior to resettlement of indigenous communities. *Consideration of Reports Submitted by States Parties Under Article 9 of the Convention: Concluding Observations on Botswana*, Committee on the Elimination of Racial Discrimination, 61st Sess., U.N. Doc. A/57/18 (2002). Additionally, in several recent cases interpreting the American Convention on Human Rights, the Inter-American Court of Human Rights determined that an indigenous community’s right to property was violated by the failure of the State to ensure that prior informed consent had been obtained from the community prior to logging. See e.g., *Mayagna (Sumo) Awastin Community v. Nicaragua*, Case 11.555, (ser. C) no. 79 (Aug. 31, 2001).

⁴ For example, in 2000, the World Commission on Dams issued a set of voluntary FPIC guidelines recognizing the need for “all people whose rights are involved and who bear the risks” to have a role in negotiations. *Report of the World Commission on Dams*, ch. 9 (2000), at <http://www.dams.org/>; In 2004, the Extractive Industries Review, commissioned by the World Bank, recommended implementation of the rights of local communities to prior informed consent as a precondition to World Bank funding of extractive industry projects. See *Final Report of the Extractive Industries Review*, The World Bank Group and Extractive Industries (2004), at <http://www.eireview.org/>.

⁵ Stephen A. Hansen & Justin W. Van Fleet, *Traditional Knowledge and Intellectual Property: A Handbook on Issues and Options for Traditional Knowledge Holders in Protecting their Intellectual Property and Maintaining Biological Diversity*, available at http://shr.aas.org/tek/handbook/handbook_1.pdf (last visited July 28, 2004). Some well-known cases of patent applications over naturally occurring genetic resources, biological discoveries or biological inven-

tions using genetic resources being filed and, in some cases, already granted include: Neem tree (*Azadirachta indica*), Turmeric (*Curcuma longa*), Maca (*Lepidium meyenii*), and the Ayahuasca plant (*Banisteriopsis caapi*).

⁶ Convention on Biological Diversity (“CBD”), June 5, 1992, Art. 8(j), available at <http://www.biodiv.org/doc/legal/cbd-en.pdf> (last visited June 25, 2004). Article 15.5 of the CBD states, “access to genetic resources shall be subject to prior informed consent of the contracting party providing such resources, unless otherwise determined by that Party.” Convention on Biological Diversity, June 5, 1992, Art. 15.5. Article 8(j) directs States to “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.”

⁷ For example, Paragraph 26 of the Guidelines notes that the “consent of stakeholders, such as indigenous and local communities, as appropriate to the circumstances and subject to domestic law, should also be obtained.” See Convention on Biological Diversity, June 5, 1992, COP Decision VI/24, UNEP/CBD/COP/6/6, available at <http://www.biodiv.org/decisions/default.aspx?lg=0&dec=VI/24>.

⁸ These interpretations suggest that the requirements would violate TRIPS Article 27.1, which establishes the substantive conditions of patentability, Article 29, which establishes the formal conditions for granting a patent, and Article 62, which establishes the proceedings for patent acquisition. David Vivas, *Strategies and Experiences to Implement Legal Origin Provisions on Genetic Resources and Traditional Knowledge* (2001) (unpublished manuscript, on file with the Center for International Environmental Law).

⁹ See e.g., Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution*, available at <http://www.law.wustl.edu/journal/2/p371carvalho.pdf> (last visited June 25, 2004).

¹⁰ See Submission by Brazil, Bolivia, Cuba, Dominican Republic, Ecuador, India, Thailand, Peru and Venezuela to the TRIPS Council on 28 May 2003, “The Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge,” at http://www.iprsonline.org/icts/docs/wto_IPCW403.pdf, last visited July 5, 2004. A recent proposal by India, on behalf of a number of other countries, may ensure that this process is recognized as an important aspect of patent applications. The relevant portion of the June 2003 submission reads: “An applicant for a patent relating to biological materials or to traditional knowledge should provide, as a condition to acquiring patent rights: (i) disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention; (ii) evidence of prior informed consent through approval of authorities under the relevant national regimes; and (iii) evidence of fair and equitable benefit sharing under the national regime of the country of origin.”

¹¹ *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice*, in DAMS AND DEVELOPMENT: A NEW FRAMEWORK FOR DECISION (Sarah Laird, ed., 2001), available at <http://www.dams.org/report/>. See also, World Commission on Dams, *World Commission on Dams Guidelines*, in DAMS AND DEVELOPMENT: A NEW FRAMEWORK FOR DECISION (Sarah Laird, ed., 2001), available at <http://www.dams.org/report/> (last visited May 19, 2004).