Article 16. Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing for Traditional Knowledge Associated with Genetic Resources

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.

2. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

1 Overview

Article 16 creates a set of novel international obligations, going much beyond the CBD, which was silent on ABS related to traditional knowledge and therefore also on questions related to compliance in that connection. Article 16 was subject to arduous negotiations, due to a divergence of views as to whether other international processes such as negotiations under WIPO should provide for the protection of traditional knowledge\(^1\) or whether the Protocol should

\(^1\) It was opposed in particular by the EU, who preferred that the issue be dealt with in the framework of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore: Lago Candeira and Silvestri, “Challenges in the Implementation of the Nagoya Protocol,” op. cit., 292.
create a comprehensive compliance system that would apply both to the utilization of genetic resources and to the utilization of traditional knowledge.²

Specifically, Article 16 creates a series of obligations for Parties with respect to compliance by traditional knowledge users: 1) an obligation to adopt user-side domestic measures to ‘provide’ for the respect by users of domestic ABS requirements of ‘other Parties where indigenous and local communities [providing PIC on traditional knowledge] are located’³ regarding community PIC and MAT concerning traditional knowledge utilization;⁴ 2) an obligation to enforce domestic user-side measures in relation to users’ non-compliance with domestic ABS requirements of other Parties related to community PIC and MAT on access to traditional knowledge; and 3) an obligation to cooperate in addressing the violation of domestic ABS measures on traditional knowledge.

The following sections will briefly recapitulate the findings related to the interpretation of Article 15, which (given similarity in structure and wording) are of relevance for the interpretation of Article 16, and then discuss key asymmetries in the provisions of the Protocol on users’ compliance in relation to traditional knowledge as opposed to users’ compliance in relation to genetic resources.

2 Similarities and Differences vis-à-vis Article 15

Article 16 mirrors the structure and wording of Article 15. The general observations made with regard to the latter’s rationale also apply here.⁵ Some of the more specific arguments made in relation to the interpretation of the text of Article 15 are summarized below for ease of reference.

The obligation under Article 16(1) to adopt user-side measures on compliance with traditional knowledge applies to ‘each Party,’ in order to underline that all countries should take such measures in recognition of the fact that no Party is uniquely a provider or user country. It also indicates that countries where traditional knowledge is not present should enact user measures in relation to ABS from the utilization of traditional knowledge located in

² Greiber et al., *Explanatory Guide*, op. cit., 168. On the lack of definition of utilization of traditional knowledge, see this commentary on Article 2, section 3.
³ This expression is considered more specific than the reference to ‘other Party’ in Nagoya Protocol Article 15: Chiarolla, “Role of Private International Law,” op. cit., 441; and this commentary on Article 15, section 3.1.
⁴ I.e., measures adopted under Nagoya Protocol Article 7. See this commentary on Article 7.
⁵ See this commentary on Article 15, section 2.
The obligation to ‘provide’ respect for other Parties’ national ABS frameworks entails at the very least confirming that users have complied with the PIC requirement and established MAT in accordance with the other Parties’ domestic ABS framework. In other words, Parties are to exercise due diligence\(^6\) in order to confirm that the users under their jurisdiction respected the applicable domestic framework of the provider country on PIC and MAT. While therefore the Protocol does not require user-side measures for the direct extraterritorial enforcement of domestic ABS frameworks of other Parties in relation to traditional knowledge, these could still be given some extraterritorial application. It has in fact been argued that in as far as instances of non-compliance with PIC and MAT have to be determined in the user-country jurisdiction, provider-country Parties’ domestic ABS frameworks would need to be relied upon in user-country courts to qualify the disputed facts on the merit.\(^7\)

The obligation in Article 16(1), however, contains the qualification ‘as appropriate,’ which is not present in Article 15(1), thereby indicating that while Parties are still obliged to fulfill this obligation, they have a larger margin of discretion in choosing the means of implementation.\(^8\) In that regard, it may also be useful to recall that the reference to ‘appropriate, effective and proportionate’ user-side measures can be interpreted as implying the need to also provide an opportunity for recourse under the provider country’s legal system in case of disputes arising from non-compliance with user-side measures related to traditional knowledge.\(^9\) This qualification may also point to the challenge that might be encountered by a user country becoming aware of misappropriation of traditional knowledge from a provider country where no domestic ABS framework related to traditional knowledge is in place. In such a hypothetical scenario, the user country may find itself in the impossibility to apply its user-side compliance measures, as these would not be triggered by a violation of the provider country’s domestic ABS framework. It can be speculated that in this case the concerned Parties, and possibly also representatives of indigenous and local communities,\(^10\) may bring the case to the Protocol’s compliance mechanism.\(^11\)

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\(^6\) See Conclusions to this commentary, section 3.

\(^7\) Chiarolla, ‘Role of Private International Law,’ op. cit., 440.

\(^8\) See Introduction to this commentary, section 5 and fn. 227.

\(^9\) Chiarolla, ‘Role of Private International Law,’ op. cit., 434 and 439.

\(^10\) See this commentary on Article 30, section 3.2.

\(^11\) This commentary on Article 30, section 3. It may also be observed that this could be a case in which the establishment of an international ombudsman (discussed in this commentary on Article 30, section 3.2) may be particularly useful.
The interpretative difficulty arising from the difference in wording between the provider country’s domestic ABS measures on traditional knowledge mentioned in Article 16(1) and those that are to be adopted under Article 7,\textsuperscript{12} should be addressed through systemic and effectiveness-oriented interpretation. Accordingly, administrative or policy measures adopted under Article 7 could amount to ‘regulatory requirements’ for the purposes of Article 16(1), as long as they are properly publicized, capable of comprehension, prospective, internally coherent and containing clear indications on issuing PIC and establishing MAT in writing, and on benefit-sharing. The absence of any domestic measure amounting to domestic ‘regulatory requirements’ on ABS from traditional knowledge would deprive provider countries of the possibility to trigger user countries’ international obligations concerning users’ compliance under Article 16.

Article 16(2) creates an obligation for Parties to establish domestically how breaches of domestic user-side measures on compliance with other Parties’ domestic ABS requirements related to traditional knowledge will be identified and sanctioned. Non-compliance by users under Article 16(2) is constituted by a breach of the measures taken by the Party where traditional knowledge is utilized, and not directly by a breach of other Parties’ domestic ABS frameworks provisions on access to traditional knowledge (i.e., violation of PIC and MAT requirements). Nonetheless, in practice, the breach of the user country’s measures on compliance is inextricably linked to the breach of the other Party’s domestic framework on PIC and MAT. Similarly to Article 15(2), this obligation presupposes that Parties will actively detect instances where users in their jurisdiction are in a situation of non-compliance vis-à-vis other Parties’ domestic ABS frameworks on traditional knowledge.

Article 16(3) creates an obligation for all Parties to cooperate in following up on specific cases of alleged violations of Parties’ domestic ABS frameworks in as far as they concern traditional knowledge, even where there is no proof of actual violation of the provider country’s ABS legislation and not necessarily with regard only to possible violations of specific requirements on PIC and MAT.

Given the novelty of Article 16, this provision appears as one of the most challenging to implement at the national level, as it will present unprecedented legal questions, particularly with regard to the cross-cutting obligation under the Protocol to take due regard to indigenous and local communities’

\textsuperscript{12} Article 7 simply refers to the adoption of ‘measures’ (and not more specifically ‘legislative, administrative or policy measures’ on benefit-sharing arising from the utilization of traditional knowledge called for in Article 6(5)).
customary laws\textsuperscript{13} and the duty under general international law to interpret and apply this provision in the light of relevant international human rights standards.\textsuperscript{14} In the light of the open-ended drafting of Article 16, the Protocol’s governing body may initiate a process to consider best practices in implementing Article 16 and possibly provide some guidance on this matter in the future.\textsuperscript{15} This may also become necessary in case of subsequent developments in other relevant international processes. For this reason, the first review of the Protocol\textsuperscript{16} is expected to assess in particular the implementation of Article 16 in light of developments in other relevant international organizations, including, \textit{inter alia}, WIPO,\textsuperscript{17} provided that they do not run counter to the CBD and the Protocol objectives.\textsuperscript{18} It should be finally noted that the implementation of Article 16 may be facilitated by, and fuel, efforts to make indigenous and local communities’ customary laws and procedures better understood by governments and users.\textsuperscript{19}

\section{Lack of Parallel Provisions on Compliance Concerning ABS Related to Genetic Resources and ABS Related to Traditional Knowledge}

International obligations related to users’ compliance with domestic ABS frameworks related to traditional knowledge, similarly to those related to genetic resources, may be expected to be triggered by monitoring activities,\textsuperscript{20} which are addressed in Article 17. That provision, however, only focuses on monitoring utilization of genetic resources, and makes no reference to traditional knowledge. Therefore, the Protocol establishes no obligation for Parties’ checkpoints to collect information on PIC and MAT relating to traditional knowledge utilization. Similarly, the internationally recognized certificate of compliance does not seem to relate to traditional knowledge associated

\begin{itemize}
\item Nagoya Protocol Article 12(1) and this commentary on Article 12, section 2. See also CBD Working Group on ABS, “Study on compliance in relation to the customary law of indigenous and local communities, national law, across jurisdictions, and international law” (6 March 2009) UN Doc UNEP/CBD/WG-ABS/7/INF/5.
\item See Introduction to this commentary, section 4.
\item Nagoya Protocol Article 26(4)(a). See this commentary on Article 26, section 2.
\item See this commentary on Article 25.
\item See this commentary on Article 4, section 3.1.
\item CBD Decision 10/1, paragraph 6.
\item Nagoya Protocol Article 12: see this commentary on Article 12, section 2.
\item See this commentary on Article 15, section 4.
\end{itemize}
with genetic resources: its minimum information requirements make no reference to it.\textsuperscript{21}

This arguably reflects the fact that the Protocol negotiators were unclear whether it would be feasible to include traditional knowledge in the internationally recognized certificate of compliance.\textsuperscript{22} The effect of this omission seems to be a serious loophole in the Protocol with regard to implementation of Article 16, particularly since most biopiracy cases to date have related to IPRs with regard to traditional knowledge associated with genetic resources. In turn, it could be argued that the requirement for checkpoints to collect or receive, as appropriate, ‘relevant information’ related to PIC and the establishment of MAT\textsuperscript{23} implies also PIC and MAT requirements concerning traditional knowledge, and if provided for in domestic ABS frameworks, such information would need to be supplied by the user.\textsuperscript{24} This extensive interpretation would be based on the preambular reference to the interrelationship between genetic resources and traditional knowledge, and their inseparable nature for indigenous and local communities.\textsuperscript{25} This interpretation could also possibly be supported by the reference to ‘subject-matter’ as information to be mandatorily included in the internationally recognized certificate.\textsuperscript{26}

Conversely, it has been argued that the omission of traditional knowledge from this provision was intentional, as negotiators had specifically considered and then decided against including it in Article 17,\textsuperscript{27} with a view to leaving regulatory space for the WIPO negotiations to address compliance with ABS on traditional knowledge.\textsuperscript{28} In order to ensure the effective implementation

\textsuperscript{21} As laid out in Nagoya Protocol Article 17(4). See this commentary on Article 17, section 3.
\textsuperscript{23} Nagoya Protocol Article 17(1)(a)(i).
\textsuperscript{24} In accordance with Nagoya Protocol Article 17(1)(a)(ii): see Gurdial Nijar Singh, \textit{The Nagoya Protocol: Analysis and Implementation Options for Developing Countries}, op. cit., II.
\textsuperscript{25} Nagoya Protocol Preamble, 22nd paragraph.
\textsuperscript{26} Nagoya Protocol Article 17(4)(f).
\textsuperscript{27} Greiber et al., \textit{Explanatory Guide}, op. cit., 174. This may be based also on the requirement, discussed above, to include in the review of the effectiveness of the Protocol a specific discussion on Article 16 and progress in WIPO negotiations: CBD Decision 10/1, paragraph 6.
\textsuperscript{28} Lago Candeira and Silvestri, “Challenges in the Implementation of the Nagoya Protocol,” op. cit., 292. However, it remains to be clarified why the same solution was not adopted for genetic resources, as the WIPO negotiations cover both genetic resources and traditional
of the traditional knowledge-related provisions of the Protocol, in particular in the absence of progress under WIPO, the Protocol’s governing body should consider developing guidance on how Parties may include traditional knowledge in the internationally recognized certificate of compliance, since the Protocol only sets out the minimum information that must be contained in the certificate, and does not exclude expanding its content to other issues. The Protocol’s governing body could address this issue when considering whether the WIPO negotiations outcome is in support of and does not run counter to the objectives of the CBD and Protocol in this regard. In alternative, Parties to the Protocol may consider (collectively or individually) whether to take into consideration future guidance to be developed under the Convention on the unlawful appropriation of traditional knowledge and other relevant work, under the CBD Work Programme on Article 8(j) and related provisions.

In the absence of international rules or guidance on this matter, provider countries would be well advised to include requirements related to the monitoring of traditional knowledge in their national ABS frameworks, including requiring inclusion of monitoring obligations in national permits, as well as in MAT.

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29 Nagoya Protocol Article 26(4)(a). See this commentary on Article 26, section 2.
30 Nagoya Protocol Article 17(4).
31 See this commentary on Article 4, section 3.1.
33 CBD Working Group on Article 8(j), Recommendation 8/5 on sui generis systems for the protection of traditional knowledge in “Report of the eighth meeting of the Article 8(j) Working Group” UNEP/CBD/COP/12/5, Annex.
34 We are grateful to Ruth Mackenzie for drawing our attention to this point. See this commentary on Article 18, section 5, about easier enforceability in a transnational context of MAT than of PIC.