Compliance with Domestic ABS Legislation and Regulatory Requirements

Articles 15-17 of the Nagoya Protocol on Access and Benefit-Sharing

Introduction

Articles 15-17 of the Nagoya Protocol are part of the access and benefit-sharing (ABS) compliance regime introduced by the Protocol. The aim of these provisions is to prevent and react to future cases of so-called misappropriation, i.e. unlawful appropriation of genetic resources or traditional knowledge associated with such resources.

Article 15 refers to compliance of users of genetic resources with domestic ABS legislation or regulatory requirements of provider countries. Article 16 “mirrors” the obligations under Article 15 but with a specific focus on traditional knowledge associated with genetic resources. Article 17 again aims to support the implementation of Article 15 (but not the implementation of Article 16!) by establishing obligations for all Parties to the Protocol to monitor and enhance transparency surrounding the utilization of genetic resources.

It is important to note in this context that every country has the potential to be at the same time a provider and a user of genetic resources and/or traditional knowledge associated with such resources. Therefore, the obligations included in Articles 15-17 of the Nagoya Protocol apply to both developed and developing countries that become a Party to the Protocol.

Understanding Article 15

The focus of Article 15 of the Nagoya Protocol is situations where a genetic resource was accessed without observing legislation requiring prior informed consent (PIC) and establishing mutually agreed terms (MAT) in the provider country. To address such situations, Article 15 sets out an obligation to

- Take so-called user measures – measures against misappropriation (Paragraph 1),
- Enforce these measures (Paragraph 2), and
- Co-operate in cases of alleged misappropriation (Paragraph 3).

Paragraph 1 obliges Parties to take measures that aim at having the utilization of genetic resources within their jurisdiction comply with the internal ABS legislation in force in another Party. In this context, it clarifies the possible types of user measures, the situations to which such user measures apply, as well as their scope.

With regard to types of user measures, Article 15(1) does not determine specific measures, but provides Parties with considerable flexibility in relation to their nature. Parties can choose to take

- Legal measures – that is legislation;
Administrative measures – for example, regulations; or
Policy measures – for instance, a strategy or an action plan.

At the same time, Article 15(1) introduces three qualifiers for whatever measure will be taken:

- **“Appropriateness”** – Each Party shall take those measures which are necessary to provide that genetic resources used within its jurisdiction have been accessed in accordance with PIC (in case PIC is required by the providing country) and that MAT have been established. At the same time, measures should also fit with the legal, political, social, and economic situation of the country in which they are implemented.

- **“Effectiveness”** – The measures should have the potential to be successful in achieving what is intended: that before accessing genetic resources the user will observe the provisions on PIC and MAT of a provider. “Effective” can also be understood as linked to possible sanctions if the measures are not complied with – that is, the measures need to have a certain level of deterrence.

- **“Proportionality”** – This means sufficient and not unnecessarily burdensome in nature and degree. Determination of whether the measure is proportionate or not can only be made on a case-by-case basis.

Regarding the situations to which user measures shall apply, Article 15(1) refers to cases where genetic resources are “utilized” within “its” (a Party’s) jurisdiction. Article 2(c) of the Protocol defines utilization of genetic resources as the research and development part of the innovation chain, including the point where an innovation is moved from development to commercialization. This means that the measures that a Party shall take do not need to extend to subsequent applications and commercialization, an issue which will be addressed by Parties contractually under MAT, hence falling under the scope of Article 18. Furthermore, utilization within “its jurisdiction” refers to a Party’s own territorial jurisdiction over users. This means that a Party’s user measures do not have to cover cases where the utilization takes place in the jurisdictions of other countries.

Regarding the scope of user measures, Article 15(1) does not extend to the whole of the domestic legislation or regulatory requirements of another Party, but only to those on ABS that require that PIC is obtained when accessing a genetic resource and that MAT is established. This means that the measures taken will have to support the verification of the existence of PIC and MAT but not the actual content of such terms or their enforcement. It is important to note that situations where there is a breach of the contractual terms contained in MAT are addressed under Article 18 of the Protocol. Furthermore, it needs to be understood that Article 15(1) oblige each Party to the Protocol, regardless of whether it regulates access to its own genetic resources or not.

When a user does not observe the measures taken in accordance with Paragraph 1, Article 15(2) requires the Party to take further measures. Again, Paragraph 2 does not mention specific measures. Instead, “appropriateness”, “effectiveness” and “proportionality” are listed as necessary qualifiers for such measures. Therefore, Parties are given the necessary flexibility to decide on the measures that are most appropriate to their own legal system and related social, cultural, and economic circumstances (e.g. fines and other sanctions, criminalization of certain acts, or prohibition of using genetic resources when obligations have been violated).
In situations of potential violations of domestic ABS legislation or regulatory requirements, Paragraph 3 requires Parties to co-operate. In this context, it has to be emphasized that it is generally not possible to directly enforce domestic ABS legislation or regulatory requirements outside of a country. Co-operation in a broader sense includes, for instance, sharing investigations and exchanging information. It cannot, however, read as including the issue of recognition of foreign judgments, taking into account that Paragraph 3 refers to a situation that is still at the stage of “alleged” violation. The obligation is qualified by the expression “as far as possible and as appropriate”, giving Parties once more ample flexibility, including a potential refusal to co-operate where a Party considers it as either not possible or not appropriate or both.

**Understanding Article 16**

The objective of Article 16 is to address situations where traditional knowledge associated with genetic resources was accessed without observing legislation requiring PIC or the approval and involvement of indigenous and local communities (ILCs) and establishing MAT in the country where the ILCs are located. Like Article 15, Article 16 consists of an obligation to take user measures (Paragraph 1), to enforce these measures (Paragraph 2), and to co-operate (Paragraph 3).

User measures under Paragraph 1 have to be appropriate, effective, and proportionate, and they can include policy, legislative, or administrative measures. Article 16(1) indicates that the legislation and the regulatory requirements that need to be complied with have to be specific to ABS, and reflect the requirement of PIC or the approval and involvement of the ILCs as well as the establishment of MAT. The obligation under Paragraph 1 does not extend to customary laws, community protocols, and procedures of ILCs referred to under Article 12 unless they have been incorporated in the ABS legislation or regulatory requirements of the Party.

Paragraph 2 requires again each Party to take further appropriate, effective, and proportionate measures where a user within its jurisdiction is found to be in non-compliance with the measures taken by the Party itself in accordance with Paragraph 1. Paragraph 3 requires each Party to co-operate in situations of potential violations of domestic ABS legislation or regulatory requirements of the Party where ILCs are located and that account for obtaining their PIC or approval and involvement and for the establishment of MAT for access to traditional knowledge associated with genetic resources.

It is important to understand that Article 16 needs to be read in conjunction with Article 7 of the Nagoya Protocol, which establishes the obligation for each Party to take measures with the aim of ensuring that the traditional knowledge associated with genetic resources that is held by ILCs is accessed with PIC or with the approval and involvement of these ILCs and that MAT have been established. Article 12 of the Nagoya Protocol also contains certain elements that complement the compliance measures found in Article 16.

**Understanding Article 17**

Article 17 of the Nagoya Protocol has the objective to improve transparency about the use of genetic resources, and thus to support compliance with domestic ABS legislation requiring PIC and the establishment of MAT as well as with user measures. Within Article 17, two distinct parts can be
identified:

- Paragraph 1 institutes the obligation to take certain monitoring measures;
- Paragraphs 2, 3 and 4 refer to the internationally recognized certificate of compliance.

Article 17(1) obliges Parties to undertake at a minimum all three measures listed in Subparagraphs (a)-(c). The qualifier “as appropriate” in the chapeau of Paragraph 1 introduces a certain degree of discretion to each Party when deciding on the nature of these and/or other measures. At the same time, it indicates that the measures that have to be taken need to fit or be relevant to achieve the intended objective.

One or more checkpoints

Paragraph 1(a) obliges each Party to designate one or more checkpoints, i.e. each Party must nominate at least one entity where monitoring will take place. The provision does not prescribe the use of any particular checkpoint, but specifies certain characteristics under (i)–(iv) which have to be fulfilled.

- According to Paragraph 1(a)(i), the main function of designated checkpoints is to “collect” (actively) or “receive” (passively) relevant information, meaning information that is closely connected to the PIC procedure, the source of the genetic resources, the establishment of MAT, and the utilization of genetic resources as defined in Article 2(c).
- According to Paragraph 1(a)(ii), each Party shall compel users to supply at a designated checkpoint the information listed in Subparagraph (a)(i). Furthermore, an obligation to take measures to address situations of non-compliance with the measures requiring the provision of information is incorporated in Subparagraph (a)(ii). While no examples of possible measures are given, they have to be “appropriate, effective and proportionate”.
- Paragraph 1(a)(iii) further stipulates that the information received or collected by the designated checkpoints has to be provided to three actors – relevant national authorities; the Party providing PIC; and the ABS Clearing-House – if it is deemed appropriate by the Party providing PIC and the information is not confidential.
- Paragraph 1(a)(iv) clarifies that checkpoints must be effective, without setting criteria to define effectiveness; that they should be relevant to the utilization of genetic resources; and that they should collect relevant information at, inter alia, any stage of research, development, innovation, pre-commercialization, or commercialization.

It should be noted that possible checkpoints could include customs authorities, patent offices, market approval offices, research funding agencies, and ILC representatives.

MAT provisions on information sharing

In addition to the obligation to designate one or more checkpoints, Paragraph 1(b) obliges each Party to promote that both providers and users include provisions in MAT in order to share information on its implementation. Such provisions can encompass for example reporting requirements.

Use of cost-effective communication tools and systems

Paragraph 1(c) calls for the use of cost-effective communication tools and systems to monitor and to enhance transparency about the utilization of genetic resources (for example, Internet, digital libraries and web registries). “Cost-effective” in this context means that Parties will need to avoid implementing tools and systems that do not keep a balance between the costs involved and the effectiveness of the measure.
Internationally recognized certificate of compliance

Article 17(2) determines what shall constitute an internationally recognized certificate of compliance. It states that an internationally recognized certificate of compliance is a permit or its equivalent produced as evidence of the decision to grant PIC and of the establishment of MAT. It should be made available to the ABS Clearing House pursuant to Article 6(3)(e) of the Protocol. The basic role of the certificate, as stated in Article 17(3), is to provide evidence of compliance with domestic ABS legislation or regulatory requirements that require PIC and the establishment of MAT. Article 17(4) of the Nagoya Protocol provides a list of the minimum information that an internationally recognized certificate of compliance shall contain. It is important to note that the information listed is to be provided only when it is not confidential.

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This Paper has been prepared in the framework of the IUCN-UNEP/GEF Regional Project “Strengthening the implementation of ABS regimes in Latin America and the Caribbean” executed by IUCN-Sur and implemented by UNEP and is available at:  
www.adb.portalces.org

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