



## Monitoring compliance: Disclosure requirements and the international certificate

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To solve problems related to the monitoring and traceability of genetic resources, ABS negotiations have focused on the development of some form of certificate of origin/source/legal provenance - more recently called a "certificate of compliance." Closely linked to this tool is the discussion on a requirement to disclose the origin of genetic resources and associated traditional knowledge in intellectual property (IP) applications.

The current draft protocol addresses both the certificate and the disclosure of origin in the same article. The issues are grouped under the heading of monitoring and tracking the utilisation of genetic resources and associated traditional knowledge - a provision that is heavily bracketed.

### General considerations

The idea and premise of the certificate is to prevent or minimise problems generated by the existence of two different jurisdictions for ABS arrangements - that of the place where the material is collected and that of the place where research and development activities are carried out. Such an internationally recognised document would make it possible to check the legality of access at the place where the activity (patent application, product approval, etc.) generates value and to follow the subsequent use of the resources and corresponding benefit sharing. At the same time, this approach supposedly would favour the creation of simpler access systems in provider countries. Existing control mechanisms would be applied, via the certificate, at the later stages of research and development, thus helping to make the regulations on access more flexible. This implies that the documentation would need to pass through the various buyers, while the monitoring points would be reserved only for certain milestones in the research and development process. These monitoring points could be related to - among others - product approval, intellectual property right (IPRs) applications, publications and the presentation of funding proposals.

Decision VIII/4C of the CBD Conference of the Parties established a Group of Technical and Legal Experts (GTLE) tasked with considering and developing an internationally recognised certificate of origin/source/legal provenance. The GTLE agreed that the basic role of any certificate system would be to provide evidence of compliance with national ABS legislation. This could be achieved by establishing a system of national certificates with standard features that would allow for their recognition internationally. The GTLE identified a number of points common to all proposals for a certificate. One such commonality among proposals was a requirement that the certificate be presented at specific checkpoints in the user countries, such as in conjunction with patent applications and IP applications in general. Most certificate proposals also envisaged a system of checkpoints at which disclosure of the certificate of origin would be required for the purposes of processing IP applications, among other things. Compliance with disclosure requirements would thus be facilitated, since an internationally recognised certificate could act as evidence of conformity with national and international law.

The inclusion and discussion of disclosure requirements and the use of the certificate in patent applications have both been con-

tentious issues during the protocol negotiations. This naturally touches on trade related intellectual property issues and the WTO Agreement on Trade-Related Intellectual Property Rights (TRIPS). In this context, developing countries in particular have suggested that the TRIPS Agreement should be amended to require patent applicants to disclose one or more of the following: the source and origin of any genetic material and/or any related traditional knowledge used in a claimed invention; evidence of prior informed consent (PIC) from the competent authority of the country of origin; and evidence of fair and equitable benefit sharing.

Proponents of disclosure requirements argue that this would help support compliance with the CBD provisions on access to genetic resources and benefit sharing. In response, other countries have expressed contrary views. In their opinion, a modification is unnecessary, as the CBD requirements should be implemented through corresponding contracts at the national level, and the TRIPS Agreement is not the appropriate instrument to regulate ABS. In any case, this discussion continues to influence the ongoing protocol negotiations, and the relationship between the TRIPS Agreement and the future protocol is likely to shape the actual design of a disclosure requirement mandated by the ABS Protocol.

Similarly, the certificate, depending on its design, may raise international trade issues. Considering that the certificate could be a document accompanying the transfer/export (international trade) of genetic resources, its role should also be analysed in the context of the relevant rules of the WTO. These rules include those related to nondiscrimination (the most-favored nation principle and the national treatment principle) as well as the appropriate measures in the Agreement on Technical Barriers to Trade (TBT). The TBT Agreement governs the elaboration and use of technical regulations, standards and conformity assessment procedures, specifying that they should not create unnecessary obstacles to international trade.

### The international certificate of compliance

Despite the fact that the certificate has been generally accepted as a potential tool for monitoring the use of genetic resources, its actual design is still far from clear. In fact, paragraph five of Article 13 calls for the "[first] Conference of the Parties serving as the meeting of the Parties to this Protocol [after the entry into force of this Protocol] to [decide on the minimum content] [consider additional modalities] of the internationally recognised certificate of compliance [system], taking into account the need to minimise transaction costs and to ensure feasibility, practicality and flexibility]."

Moreover, the actual design critically depends on the domestic implementation processes. Some countries have already taken first steps towards a certificates system by, for example, providing an on-line searchable database of access permits granted (Australia), or including provisions in their ABS laws allowing the grant of certificates (e.g., Bhutan, Costa Rica). These countries need to ensure that the final protocol does not run counter to their efforts, but allows the use of their approach. Other countries that have not yet implemented domestic legislation, on

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the other hand, need to ensure that no future decisions are impeded by the protocol. In that regard, Article 13 provides a list of “example” measures that [could] or [shall] be taken, “as appropriate” (in different ordering depending on the paragraphs). While this approach provides for the necessary flexibility, such wording also results in a high degree of ambiguity and has been criticised for lacking concrete requirements. This is particularly true for the use of the wording “as appropriate” and a reference to “domestic legislation.” If the international certificate and/or the disclosure requirement are only directed at showing that prior informed consent and mutually agreed terms requirements have been met “in accordance with domestic/national legislation” and not international law, the objectives of the protocol might be met only in the remote future, as the design of such legislation in many countries might take years. This is particularly true for countries with fewer resources and/or less stable domestic legal and political systems.

In that regard, several important aspects of the certificate still require further negotiation, including, inter alia, the following:

- The specific check points, including the role of IP offices;
- Details of the content of the certificate, (e.g., the mandatory or indicative minimum content);
- Design (whether a unique identifier would be required, etc) and operation of the certificate (whether it would be registered or made available to the ABS-Clearing House Mechanism, its relation with the ABS permit, etc);
- Coverage of the certificate: whether to include, in addition to genetic resources, associated traditional knowledge;
- The nature of the certificate: a voluntary or mandatory mechanism, the different values of each option, and
- Sanctions in cases of non-compliance (regulated in Article 13 *bis*).

Even if parties address these outstanding issues, a number of challenges - both from the perspective of the user and provider - remain with regard to the successful implementation of the certificate. Firstly, it is important that countries have a clear understanding of the certificate’s role and function in achieving benefit sharing. The certificate does not guarantee, *per se*, the fair and equitable distribution of benefits or the fairness of a negotiation covered by a certificate. This aspect will require further measures that need to be carefully aligned. Moreover, from the perspective of the country granting the certificates, the issuance of the instrument must not create unnecessary (and additional) obstacles and delays to the ABS permitting system or impede or complicate the flow of genetic resources. Capacity building will be required to achieve this objective. Thirdly, check-points and credible sanctions in case of non-compliance that would induce compliance need to be carefully determined. Finally, from the perspective of the country where the check points would be located, further clarity is required on when a certificate should be presented and what would trigger its presentation. This last point might also require capacity building efforts.

## The disclosure requirement

The current bracketed language of the draft protocol refers to “disclosure of relevant information” and assumes the existence of “appropriate check points”. This is most visible in Article 13 as shown above. In addition, Article 12 of the draft protocol

intentionally includes the disclosure requirements in IP applications (patents and plant varieties), but mixes it with general provisions regarding disclosure of information. Here, a number of relevant issues still need to be decided, inter alia: the nature of the disclosure requirements (mandatory or voluntary); the appropriate check points (e.g., IP offices as the relevant check point for the disclosure of origin, as has been previously proposed); and the sanctions in case of non-compliance.

However, the draft wording used so far is rather vague with regard to some key elements of the disclosure of origin. For instance, what information is supposed to be disclosed? What is the source or origin of the genetic resources? There is no reference to other elements to be checked - except if the certificate of compliance is utilised as a mechanism to comply with the disclosure requirements - such as proof of PIC, mutually agreed terms and benefit sharing provisions. Sanctions for non-compliance seem to be targeting IP applications due to the use of the words “claims” and “application.” They do not, however, address the possible cancellation, revocation or declaration of non enforceability of the IP if the disclosure requirement has not been complied with and the IP title was (wrongly) granted.

In practice, a “soft version” of the disclosure - if compared with what has been proposed previously by developing countries in the ABS Working Group or at the WTO - is currently included in the protocol. The purpose may be to accommodate some countries that already are opposed to disclosure requirements (both in the WTO and the CBD). The drafting of the disclosure requirements in Article 13 of the draft protocol could respond to this approach.

The potential inclusion - even of this soft version of the disclosure requirements in the ABS Protocol - may impact the current negotiations at the WTO. The possibility, exact scope, and precise content of a potential amendment of the WTO is still uncertain - whether sanctions for noncompliance will fall outside patent law or not, the necessity of proving compliance with PIC and benefit sharing, etc. - as well as the amendment *per se*. Considering the large membership of the WTO and its economic relevance for the contracting parties, this amendment would promote a more effective integration of the disclosure of origin in the IP system (and in the national laws) and would promote broad implementation of the instrument. It would also be subject to the WTO Dispute Settlement procedures. In this case, the CBD may provide assistance and coordination in developing and implementing disclosure requirements by clarifying terms and instruments, including the role of the certificate of compliance in disclosure.

Finally, the disclosure of origin could have limited impact in preventing misappropriation of genetic resources unless it is accompanied by other relevant user measures, such as access to justice and the creation of collaborative mechanisms between countries to address cases of non-compliance with national ABS legislation and agreements. As a disclosure requirement will not be sufficient alone as it should be complemented by clear and articulated benefit sharing obligations in the protocol. Thus, unlike some other outstanding issues in the protocol, the international certificate and the related - yet distinctive - disclosure requirement are issues that might take shape only at a later stage and during the actual implementation.