



International Chamber of Commerce

The world business organization

Nagoya Protocol Implementation in the EU: Comments on a possible due diligence system and the EU Timber Regulation

*Developed by the Task force on the Convention on Biological
Diversity/Access and Benefit Sharing*

General comments on a possible due diligence system

The International Chamber of Commerce' ("ICC") greatly appreciated the recent discussions between its members and DG Environment on the possibility of putting into place a due diligence system as part of the EU's implementation of the Nagoya Protocol ("Protocol").

We understand that the aim would be to set up a system to allow monitoring of adherence by companies to due diligence requirements relating to ABS, as an alternative to monitoring individual transactions.

ICC members believes that such a due diligence system could be a possible option for business if

- the financial and administrative burdens associated with such a system are reasonable and do not outweigh possible benefits, including from the perspective of SMEs;
- the scope of the obligations is clearly defined so that companies know to which activities and to which genetic resources and associated traditional knowledge due diligence requirements must be applied;
- due diligence requirements are based as much as possible on existing company processes and procedures;
- such requirements are flexible enough to be adapted to the situations in different sectors.

If a due diligence system is combined with check points, ICC members suggest a single check point, which could be the competent (national) authority, preferably one at EU level. Other checkpoints which have been suggested - such as customs, IP offices, or marketing approval authorities - would not be appropriate as they would create legal uncertainty and/or trade blockages for companies that would severely hamper business operations.

In view of the very tight time frame within which the European Commission is working, we believe that it would be preferable for any regulation or directive to set out the elements of a system at a high level and to provide for more detailed measures if necessary in later implementing instruments. This would allow more time to properly consider the implications of specific obligations for users, which is necessary in this very new and untested area of regulation.

Comments on elements of the EU Timber Regulation as a basis for a possible ABS due diligence system

We understand that one of the possible models for a due diligence system is the EU's regulation regarding the introduction of illegally harvested timber into the EU market (Regulation No. 995/2010) (hereinafter "Timber Regulation").

While certain elements of the Timber Regulation could be considered as a model for implementation of the Protocol, we retain certain concerns regarding the implementation of such provisions with respect to genetic resources and associated traditional knowledge, and emphasize that these elements would need to be adapted to the particular context of the Protocol.

ICC's Task Force on the CBD/ABS would like share the following comments on elements of the Timber Regulation as a possible model for implementation of the Protocol:

Clear definitions (Article 2)

ICC members support having clear definitions of important terms, as in Article 2 of the Timber Regulation, but these have to be appropriate to, and consistent with, the Protocol. Such definitions should clearly delineate the scope and coverage of the regulation/directive and specifically exclude from the application of the regulation/directive, materials and activities not intended to be covered by the Protocol, such as commodities and any use of genetic resources not coming within the definition of "utilization" as defined in the Protocol (e.g. trading and testing).

- Scope (Article 2(a)) – ICC members support clearly defining the scope of genetic resources and associated traditional knowledge that the regulation/directive will cover, as in the Timber Regulation, in a manner fully consistent with the definitions of the Nagoya Protocol. To avoid any ambiguity, commodities should be explicitly excluded from the scope of the regulation/directive.
- Utilization (Article 2(b)) – ICC members support defining what the regulation/directive will cover (i.e., a clarification of what will constitute "utilization" within the EU¹, defined as "to conduct research and development..." in the Nagoya Protocol).

Due diligence system (Article 4(2))

ICC members believe that a due diligence requirement could be a possible option if the scope of genetic resources and associated traditional knowledge is clearly defined and if the financial and administrative burdens associated with such a system are reasonable, including from the perspective of SMEs. Due diligence requirements should be based as much as possible on existing company processes and procedures, a principle which is also reflected in preamble 18 of the Timber Regulation².

- Illustrative list of due diligence elements (Article 6) – ICC members support including an illustrative list of elements which could constitute an appropriate due diligence system. This might include:
 - description of the genetic resource received and, if applicable, associated traditional knowledge;

¹ For example, testing should not constitute "utilization" and an activity that the regulation will cover.

² This states "*in order to avoid any unnecessary administrative burden, operators already using systems or procedures which comply with the requirements of this Regulation should not be required to set up new systems.*"

- name and address of the immediate up-stream provider(s));
- material transfer agreements, if applicable.

Recognition of Third-Party Verification Organizations (Article 8)

The Timber Regulation recognizes that audits should not be conducted in an arbitrary manner and should be based only on relevant and substantiated concerns. ICC members support incorporating that principle into the implementation of the Protocol. Checks to verify compliance with a due diligence system should not be conducted in an arbitrary way, but only when there are relevant and substantiated concerns. ICC members support giving users the opportunity to meet their due diligence requirements through reliance on third-party accredited organizations, as described in Article 8 of the Timber Regulation.

Competent Authorities (Article 7)

In contrast to the Timber Regulation, ICC members support one EU-wide competent authority, preferably the same entity as the focal point. That competent authority would also be the most logical entity to serve as the “checkpoint” as envisioned by Article 17 of the Protocol. We also stress that the Competent Authority/checkpoint envisioned should not include authorities from different regulatory areas (for example the Regulation should not include intellectual property offices, marketing approval authorities or customs as part of the Competent Authority/checkpoint).

Imposition of Penalties Only for Violations of the Protocol (Article 19)

Similar to the Timber Regulation, penalties should be appropriate, proportionate and effective, and should only be imposed for adjudged violations of national provisions implemented under the Protocol in the European Union, and not for failures to conduct appropriate diligence in the absence of evidence that any such provisions were violated. Entities that can demonstrate compliance with due diligence requirements should benefit from a presumption of compliance with the ABS requirements of countries where GRs are sourced (safe harbour principle). Such a safe harbor would incentivize due diligence actions while protecting covered entities that have undertaken the required steps. Non-adherence to due diligence standards/principles should not, however, be considered as evidence of misappropriation or shift the burden of proof to the user.

Creation of an Implementation Period (Preamble)

ICC members support the creation of an implementation period before the regulations would come into effect. This period would be similar to that described in the Preamble to the Timber Regulation, covered entities and competent authorities “should be given a reasonable period in order to prepare themselves to meet the requirements of this Regulation.”

Prospective Application

The regulation/directive should apply prospectively and explicitly exempt genetic materials accessed prior to the implementation of the regulation/directive, whether or not utilized after its entry into force.

ICC remains committed to working with the EU on the implementation of the Protocol and would welcome additional opportunities to provide more detailed input on a possible due diligence system at a later date.