

**CARTAGENA PROTOCOL ON BIOSAFETY (Protocol)**  
**Article 26: Socio-economic Considerations (SECs) in Decision-making**  
**on Living Modified Organisms (LMOs)**

**At their next meeting in November 2018, Parties to the Protocol will consider voluntary Guidance for the assessment of SECs that outlines a process-based approach led by regulators and assessors, and appropriately recognizes the knowledge, expertise, and experience each party plays in the assessment of SECs. The Guidance provides a systematic process designed to link national protection goals to socio-economic objectives and to characterize the relationship between the identified impact of the LMO and the relevant socio-economic effects to be assessed. It also recognizes the regulator's authority and responsibility for evaluating results and drawing conclusions for use in decision-making. *The Global Industry Coalition (GIC)<sup>1</sup> encourages countries to: (i) "take note of" the guidance document in its current form; (ii) "invite" Parties and other governments, if applicable, to pilot the assessment process, share their experiences via the BCH, and submit examples of methodologies and applications of the guidance to the Executive Secretary for compilation and consideration by COP/MOP-10; and (iii) oppose extending the mandate of the current AHTEG to supplement the guidance until there has been sufficient use and experience to justify further work.***

**Background**

Article 26 of the Protocol provides that Parties may take into account SECs in reaching a decision on import of LMOs, but only to the extent consistent with that country's other international obligations. Paragraph 1 further limits what may be taken into account by defining SECs as those "arising from the impacts of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities." Notably, this language is permissive and not mandatory – Parties "may" take SECs into account, but are not required to do so. Paragraph 2 requires Parties to cooperate on research and information exchange on any socio-economic impacts of LMOs, especially on indigenous and local communities.

At the eighth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol (COP/MOP-8), Parties extended the mandate of the Ad Hoc Technical Expert Group on SECs (AHTEG) to work on the guidelines envisaged under the outcomes for operational objective 1.7 of the Strategic Plan for the Protocol. To facilitate progress by the AHTEG, the Co-Chairs introduced text entitled, "Draft guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety." This document described a process for conducting an assessment of SECs and avoided specifying parameters to assess, since these would depend on first identifying SECs arising from the impacts of the LMO based on a Party's national priorities and environmental protection goals. The meeting of the AHTEG was held from 9 to 13 October 2017 in Ljubljana, Slovenia. The outcomes from the AHTEG meeting will guide the discussion at COP/MOP-9, taking place from 17 to 29 November 2018 in Sharm El-Sheikh, Egypt.

**A. GIC Views on the AHTEG Process and Outcomes**

The assessment of SECs in the context of Article 26 continues to be a complex and controversial subject. Participants in the AHTEG expressed a range of views that led to extensive debate. Some participants advocated for elements that were prescriptive, arbitrary, or unfeasible, and that could impede the assessment or bias the outcome. Examples include:

- The right to a precautionary approach when a socio-economic effect is unclear or data is lacking
- Consideration of regional circumstances, priorities, and needs
- Use of non-scientific assessment methods
- Evaluation of cumulative or potential irreversible effects
- Demonstrating the sustainability of claimed benefits
- Mandatory monitoring for socio-economic effects

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<sup>1</sup> The Global Industry Coalition (GIC) for the Cartagena Protocol on Biosafety receives input and direction from trade associations representing thousands of companies from all over the world. Participants include associations representing and companies engaged in a variety of industrial sectors such as plant science, seeds, agricultural biotechnology, food production, animal agriculture, human and animal health care, and the environment.

- Formal decision-making process with guidance for evaluating results and drawing conclusions

Parties pushed back on these and similar elements that could lead to an assessment process that is impractical, unachievable or biased, and that would not be compatible with their national laws and procedures. Inclusion of one or more of these elements could result in a guidance document that would impose requirements that are unduly burdensome and undermine the intended flexibility, self-determination, and autonomy inherent to Article 26. Ultimately, these controversial elements were either limited or omitted from the guidance document in order to achieve consensus among Parties participating in the AHTEG. Parties are free to raise objections to undesirable content at COP/MOP-9 but are encouraged to avoid reopening the guidance document for negotiations that could lead to unwanted discussions on previously tabled or new topics, extension of the AHTEG, or both.

## **B. GIC Views on the Elements for a Draft Decision on Article 26 at COP/MOP-9**

The AHTEG recommended that the Parties consider a draft decision at COP/MOP-9 that included the following elements:

15. *The AHTEG recommended that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its ninth meeting:*
  - (a) *Consider the report of the meeting, including the draft “Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety”, as contained in annex II;*
  - (b) *Invite Parties and other Governments to make use, if applicable, of the “Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety”.*

**The GIC supports these recommendations. Parties should establish a pilot phase, during which Parties voluntarily make use of and evaluate the utility of the guidance process.** This will assure that the guidance is implementable and useful before Parties formally accept it.

The guidance is a voluntary, process-based assessment of SECs led by regulators and assessors according to their national regulatory frameworks and procedures. Parties that elect to use the guidance document are guided to identify how national protection goals relate to socio-economic objectives and to write a problem statement that links the specific socio-economic concerns identified by regulators to the assessment of possible socio-economic effects. **The GIC supports this approach because it provides contextual clarity and ensures the basis for socio-economic assessment in the context of Article 26.1 is clear and justified.**

The guidance is not prescriptive nor does it impose requirements on regulators. Instead, it describes a flexible, autonomous process that can be readily adapted to the needs of any Party. Moreover, it emphasizes that the assessment process of SECs, and methods chosen, should be science-based and evidence-based, and lead to defensible results. It also recognizes the knowledge, expertise and experience of assessors, and the important role they play in the assessment of SECs. Often experts need to be directly involved to identify the methodology and appropriate data sources for the assessment of relevant socio-economic effects. Finally, it recognizes the regulator’s authority and responsibility for evaluating results and drawing conclusions for use in decision-making.

16. *The AHTEG noted that further work was needed to supplement the “Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety”, in particular on the application of methodologies and examples of application of socio-economic considerations, and recommended that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its ninth meeting:*
  - (a) *Invite Parties, other Governments and organizations to submit examples of methodologies and applications of socio-economic considerations in the light of the elements of the “Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety” and request the Executive Secretary to compile the information submitted;*

**The GIC believes that it is premature to begin work on supplementing the guidance prior to its use.** Instead, Parties should support the implementation of a pilot phase when Parties voluntarily make use of and evaluate the utility of the guidance process. Parties are encouraged to submit examples of methodologies and applications of socio-economic considerations for compilation to the Executive

Secretary. Obtaining more experience with the existing guidance document will provide information that can guide modifications or improvements, if needed.

The addition of explicit methodologies and examples of the application of SECs would make the guidance more prescriptive, less flexible, and limit the regulator's autonomy when undertaking the assessment of SECs. Parties will have an opportunity to share their experiences via the Biosafety Clearing House (BCH), and to submit examples of methodologies and applications of the guidance to the Executive Secretary for compilation. This information can be considered and appropriate actions taken, as appropriate, at COP-MOP 10.

*(b) Consider the utility of extending the mandate of the AHTEG to supplement the "Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety" making use of the information submitted.*

The mandate of the AHTEG has been fulfilled with the delivery of the guidance document. **The GIC does not support an extension of the mandate of the AHTEG.**

The guidance includes principles for the assessment of SECs, as well as a flexible, autonomous process that can be readily adapted to the needs of any Party. The AHTEG should not be extended until Parties, other Governments and organizations have made use of the guidance, shared their experiences via the BCH, and submitted examples of methodologies and applications of SECs to the Executive Secretary for compilation.

For more information on this and other Protocol implementation issues, please visit <http://croplife.org/plant-biotechnology/cartagena-protocol-on-biosafety/>.