

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

The Global Industry Coalition (GIC)¹ supports the sovereign right of countries to establish national policies and biosafety regulatory frameworks for the import and cultivation of LMOs, and to take into account SECs in reaching a decision on import under Article 26.1 of the Protocol. Such a consideration must ensure that the SECs arise from the impact of LMOs on the conservation and sustainable use of biological diversity, and must be consistent with a Party's other international obligations. The GIC is concerned that the implementation discussions on Article 26 could lead to biased outcomes that do not respect these limitations, or contribute to consideration of socio-economic impacts that are not scientifically defensible or justifiable, or that would lead to untenable and costly delays in decision-making. *For these reasons, the GIC encourages countries opting to take SECs into account to seek assistance from existing international experts, organizations, and/or experienced countries and not support further development of guidelines and/or guidance procedures for SEC assessments under the Protocol.*

Background

Article 26 of the Protocol provides that Parties may take into account socio-economic considerations 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 socio-economic considerations 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." 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 their seventh meeting (COP/MOP-7), Parties agreed to a number of actions related to Article 26 which will guide the Parties discussions on this issue at COP/MOP-8:

- (i) The Ad Hoc Technical Expert Group on Socio-economic Considerations (AHTEG) was requested to work, in a stepwise approach, on: (i) the further development of conceptual clarity on socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, and (ii) developing an outline for guidance for socio-economic considerations in decision-making.²
- (ii) Parties, Governments and observers were invited to submit comments on the "Elements of a Framework for Conceptual Clarity on Socio-Economic Considerations" contained in the annex to the report of the first meeting of the AHTEG.
- (iii) The Secretariat was requested to: (i) compile information on policies, laws, regulations and guidelines providing for definitions of socio-economic considerations, and practical applications of socio-economic considerations in decision-making on LMOs, including cases where positive and negative socio-economic impacts have been considered; (ii) convene online discussion groups to facilitate the exchange of views, information and experiences on socio-economic considerations; and (iii) commission a study on international agreements that may have relevance to socio-economic considerations.

A. GIC Views on the Role of Socio-economics in Decision-making on LMOs

- The GIC supports the sovereign right of countries to establish national policies and biosafety regulatory frameworks for the import and cultivation of LMOs and to take into account SECs that are voluntarily applicable under Article 26.1 for decision-making on imports of LMOs. The inclusion of SECs in Parties' decision-making on the import of LMOs must be consistent with their international obligations. Trade experts agree that taking SECs into account has a realistic potential to conflict with the rules of international trade agreements. Any decision to exclude the import or cultivation of LMOs based on

¹ 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.

² Note that no funding was available for an in-person AHTEG, so a portion of this work occurred via an online AHTEG discussion instead.

SECs must be compliant with international agreements, based on appropriate and defensible scientific justifications, and not be a result of arbitrary or unjustifiable distinctions.

- Importantly, the GIC also supports the sovereign right of countries not to take into account SECs that do not arise from the impact of LMOs on the conservation and sustainable use of biodiversity; that would not be scientifically defensible, justifiable, or consistent with their international obligations; or, that would lead to untenable and costly delays the Party would incur in decision-making.

B. GIC Views on the Elements for a Draft Decision on Article 26 at COP/MOP-8

Regarding the Revised Framework for Conceptual Clarity

- The Revised framework for conceptual clarity, which already takes into account the GIC recommendations for some of the “General Aspects”, includes in the Operational definition language that SECs under Article 26 may cover a number of aspects, “depending on the national or regional circumstances...”. The GIC strongly supports national biosafety regulatory frameworks that are grounded in legislation and government mandates. As such, the GIC suggests “regional circumstances” is vague verbiage that may be inconsistent with national mandates and should be removed.
- The GIC considers as useful guiding principles the majority of the “General Aspects” as contained in the Revised Framework for Conceptual Clarity as recommended by the AHTEG, to be adapted as appropriate to Parties’ national and regional specificities when addressing SECs, consistent with international obligations.
- However, the GIC has strong concerns with several of these “General Aspects” as currently stated. Annex I provides detailed views of the GIC on each of these “General Aspects”.

Regarding the Proposed Extension of the AHTEG

- **The GIC does not support an extension of the mandate of the AHTEG on SECs.** The primary mandate for the AHTEG would be to engage in further work on the development of guidelines for SEC assessments, and the GIC is of the view that this work is not warranted for the following reasons:
 - The revised framework for conceptual clarity already provides sufficient clarity to Parties who choose to take into account socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity when reaching a decision on import.
 - Efforts to further the codification of SEC guidelines likely will lead to new measures, procedures, or constraints not currently envisioned, and result in nations failing to comply with their international obligations. Given that each country is a member to different international agreements and commitments, the codification of SEC guidelines into a single document intended to serve all countries will create contradictions between international agreements and national commitments. This will result in regulatory uncertainty for Parties to the Protocol, and potentially lead to retaliatory trade restrictions or levies.
 - The establishment of guidelines will greatly undermine the intended flexibility, self-determination, and autonomy inherent to Article 26.1. Undertaking a SEC assessment is a voluntary procedure and Parties are not bound nor required to undertake SEC assessments regarding LMOs; however, it is foreseeable that the establishment of formal guidelines could put pressure on policy makers to incorporate SEC assessment into decision-making. Should formal guidelines be established, member countries could become obligated to undertake a SEC assessment for each and every LMO facing approval.
 - Formalized guidelines for SEC assessments will increase the cost of regulating LMOs for member states and strain their fiscal and human capacity to undertake such assessments. The cost of undertaking SEC assessments can range from hundreds of thousands to millions of dollars, taking many years, all the while, needlessly delaying the use and realization of the benefits of biotechnologies.
 - Countries that opt to take SECs into account are encouraged to seek assistance from international experts, organizations, and/or experienced Parties and other governments. The Biosafety Clearing-House (BCH) presently provides considerable information pertaining to SEC assessments in an efficient and effective format – as referenced by the background document.

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

Annex I
GIC Views on the Revised Framework for Conceptual Clarity on
Socio-economic Considerations

General Aspects

1. *Paragraph 1 of Article 26 provides that Parties may take socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity into account in decision-making on import of living modified organisms.*
 - The GIC supports this principle, provided that the option to include a SEC assessment is explicitly made entirely voluntary.
 - It should also be noted that Paragraph 1 of Article 26 defines the scope of relevant SECs as those “arising from the impact of living modified organisms on the conservation and sustainable use biological diversity, especially with regard to the value of biological diversity in indigenous and local communities.”
2. *A wide range of factors, including socio-economic ones, can influence the conservation and sustainable use of biological diversity.*
 - This statement references factors that are outside the scope of Article 26 and should be omitted. Article 26.1 relates to SECs “arising from the impact of living modified organisms on the conservation and sustainable use biological diversity,” not any SECs that may influence the conservation and sustainable use biological diversity.
 - Furthermore, this principle is far too broad and lacks sufficient relevance to SECs arising from the impact of LMOs to provide any useful information for decision-making.
3. *Taking socio-economic considerations into account in decision-making on living modified organisms must be consistent with relevant international obligations, which include, inter alia, trade agreements, environmental agreements and human rights agreements.*
 - To comply with Article 26.1 any country undertaking a SEC assessment must respect their obligations to all of their international commitments. The GIC supports this principle.
4. *Taking socio-economic considerations into account in decision-making on living modified organisms should be consistent with existing national regulatory frameworks and policies.*
 - The GIC supports this principle to the extent that it encourages countries to ensure that regulatory duplication and overlap are avoided and that existing biosafety regulatory frameworks and policies are World Trade Organization compliant and have not been structured to act as barriers to agricultural innovations, including LMOs.
5. *In taking into account socio-economic considerations, Parties should consider their local, national and regional circumstances, priorities and needs. Such circumstances, priorities and needs could include cultural practices, religious beliefs and practices as well as traditional knowledge and farming practices, in particular those related to the value of biological diversity to indigenous and local communities.*
 - This principle would contribute to greater uncertainty in decision-making and should be revised to reflect the scope of Article 26, i.e. there needs to a connection to a relevant “impact”, or it should be omitted. Socio-economic impact assessments do not lead to clear outcomes with reasonable certainty. Ex-ante assessments rely on assumptions, often including ranges of potential outcomes. Ultimately, the variation in socio-economic issues at local, national and regional levels would make adhering to this principle a significant barrier to decision-making.
 - Methodologies that do not provide a clear means of quantifying an assessment will simply lead to confusion and delays, where adopters’ benefits are not being achieved, which have implications for food security and the environment.
 - As suggested above, the reference to “regional circumstances” should be deleted. The GIC strongly supports national biosafety regulatory frameworks that are grounded in legislation and government mandates, and “regional circumstances” is vague verbiage that may be inconsistent with national mandates.
6. *Taking socio-economic considerations into account in decision-making on living modified organisms should be clear, transparent, and non-discriminatory.*
 - The GIC strongly supports this principle.

7. *Lack of scientific consensus or information on socio-economic effects should not necessarily be interpreted as indicating a particular positive or negative effect, or an absence of an effect.*

- The GIC supports this principle.

8. *The results of any assessment of socio-economic considerations associated with a decision on the import of LMOs should be subject to a review, if new or additional scientific evidence is available.*

- The GIC supports this principle.

9. *Risk assessment and the assessment of socio-economic considerations are distinct processes and may be conducted concurrently or consecutively.*

- The GIC strongly supports this principle, with the caveat that a SEC assessment is entirely voluntary.

10. *Planning and conducting a risk assessment and an assessment of socio-economic considerations may be complementary and both may contribute to the decision making process.*

- While it is true that information resulting from the assessment of socio-economic considerations and from a science-based risk assessment process can contribute to decision-making, it is important to recognize and consider separately both types of information. The outcomes of socio-economic impact assessments are inherently more assumption-based, variable and less certain, while the outcomes of risk assessments are inherently more quantifiable, less variable and more certain.
- Importantly, taking SECs into account should not be used as the basis to undermine the positive results of a science-based risk assessment.

11. *Article 23 of the Protocol creates obligations regarding public awareness and participation. Public participation and consultation, and access to information, may form part of the process of taking socio-economic considerations into account.*

- The GIC agrees that the public should have access to relevant information and be aware of decision-making processes relating to LMOs, consistent with principles of transparent and accountable decision-making. Factually based public participation in the decision-making process relating to the regulation of LMOs can strengthen public support for national decisions.
- The GIC also recognizes the authority and responsibility of national governments to decide how the public may be involved in various decision-making processes. Public participation is necessarily unique to each country's legal system, regulations and traditions. Given this reality, the focus of the Parties in this area should be on the identification of practices that maximize information flow, transparency and public input without overwhelming governmental resources.