

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

The GIC¹ is pleased to submit its views and 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 Ad Hoc Technical Expert Group on socio-economic considerations as follows:

General Principles

1. *Paragraph 1 of Article 26 provides that Parties may take socio-economic considerations into account in decision-making on living modified organisms.*

- The GIC supports this principle, provided that the option to include an 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. *Taking socio-economic considerations into account in decision-making on living modified organisms should be consistent with relevant international obligations, which include 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.

3. *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 WTO compliant and have not been structured to act as barriers to agricultural innovations, including LMOs.

4. *In taking socio-economic considerations into account, Parties should consider their local, national and regional circumstances, cultural practices, priorities and needs, in particular those related to the value of biological diversity to indigenous and local communities.*

- The lack of quantifiable methodologies available to undertake assessments of this nature, and the variation in socio-economic issues at local, national and regional levels, make this principle quite problematic. The GIC supports a free and open market for LMOs where adopters are free to decide for themselves whether or not to adopt new technologies like ag biotech-derived crops. 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, and in many cases prolonging food insecurity and impacts on the environment.

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.

5. *Taking socio-economic considerations into account in decision-making on living modified organisms should be clear, transparent, and non-discriminatory.*

- The GIC supports this principle.

6. *Human health-related issues arising from impacts of living modified organisms on the conservation and sustainable use of biological diversity should also form part of socio-economic considerations, provided that they are not already addressed in the risk assessment.*

- The assessment of human health safety is part of standard science-based risk assessments and the GIC believes that it would be an inefficient use of resources to duplicate this assessment as part of a SEC assessment.

7. *A situation of uncertainty or insufficient information on socio-economic impacts should not prevent socio-economic considerations from being taken into account in reaching a decision.*

- The GIC strongly disagrees with this principle. Any decision to take socio-economic impacts into consideration must fall within the scope of Paragraph 1 of Article 26, and must occur only after a scientific evaluation is completed.
- The methodology employed to undertake each SEC assessment must produce a quantifiable result, consistent with Parties' international obligations; otherwise any regulations imposed could act as significant barriers to trade.
- In addition, any decisions taken that rely on insufficient information do not meet any reasonable threshold for decision-making based on science, and will have needlessly wasted resources and be incapable of providing information to decision-makers that is useful in their regulatory decision-making process.

8. *Conservation and sustainable use of biological diversity relies on a wide range of elements, including socio-economic ones, which supports the application of sustainability principles.*

- The scope proposed in the framework is inclusive of a broad range of issues that may potentially be connected to SECs, and consideration of all of these will ultimately lead to conflicting information for decision-makers. SEC assessments must be clearly articulated, consistent with principles of transparent and accountable decision-making, and undertaken using quantifiable methodologies that are sufficiently adaptable to particular local circumstances. Most importantly, SEC assessments must comply with the scope prescribed by Article 26.1. As worded, this principle lacks sufficient specificity or clarity and provides little utility for enabling SEC assessment.

9. *Planning and conducting risk assessments and taking socio-economic considerations into account may be complementary in the decision-making process.*

- There may indeed be complementarities, if countries determine that taking SECs into account in decision-making is warranted, feasible and desirable, but the GIC strongly believes that SEC assessment information should not be considered mandatory nor used as the basis to reject the positive results of a science-based risk assessment.

10. *Public participation and consultation 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.

Methodological Considerations

1. Scope

The scope as defined is overly-broad and reflects an intention to be inclusive of all possible issues that may potentially be connected to SECs rather than adhere to the constraints inherent in the language of Article 26.1. The GIC does not support this approach and believes it could lead to outcomes that do not respect these limitations, or contribute to consideration of baseless socio-economic impacts, or lead to untenable and costly delays in decision-making.

- Ecological and human health-related considerations are included as part of standardized science-based risk assessments. Including both of these areas as part of a SEC methodological assessment would be a duplication of effort and lead to data that would not provide any further information or insights for decision-makers, wasting scarce resources in many developing countries.
- A substantial challenge for including cultural / traditional / religious / ethical issues as part of a SEC assessment is that there are no quantifiable methodologies available that are capable of providing clear, transparent and concise information to aid regulators in their decision-making process. Standard methodologies that have been applied to these issues with other technologies have been variations of citizen consensus models that are incapable of providing quantifiable data to regulators
- Economic and social issues can be included only when quantifiable models are available to be utilized.

2. Methodological Approaches

A wide array of methodological approaches **is not available** to examine SECs in a way that would provide a quantifiable result, consistent with Parties' international obligations, and principles of transparent and accountable decision-making. In fact, there are extremely limited methodological approaches available that are capable of providing clear, informative results to decision-makers.

- SEC assessments should only be performed where there is existing benchmark data that is capable of informing decision-makers about the impact of the LMO under review. Without existing baseline data, no SEC assessment is capable of informing decision-makers as to whether the LMO may improve or harm the existing situation.
- Only methodologies that have the ability to deliver quantifiable results and that have been previously applied and been proven to provide information that assists decision-makers should be considered for application. Paragraph of Article 26 encourages Parties to exchange this type of information.

3. Factors affecting Methodological Approaches

While variations in socio-economic issues may exist at the sub-national level, any SEC methodology that is applied has to be able to reconcile the various sub-national data into a single, cohesive result that is informative for decision-makers.

Points to Consider

As stated above, the scope, elements and dimensions as presented are overly broad and reflect an intention to be inclusive of all possible SECs rather than adhere to the constraints inherent in the language of Article 26.1. The GIC encourages countries opting to take SECs into account to seek assistance from existing international experts, organizations, and/or experienced countries, as encouraged by Article 26.2, and not support further development of guidelines and/or guidance procedures for SEC assessments under the Protocol.

- Utmost care must be taken to ensure that assessment of SECs is compliant with Parties' international obligations. Elements of SECs that are not scientifically quantifiable and are not consistent with established risk assessment guidelines and methodologies could violate the Parties' obligations.
- The rationale for including SEC assessment as part of a biosafety regulatory framework has to be clearly articulated, of a scope that is consistent with the constraints of Article 26, and compliant with international obligations. Any SEC assessment must provide clear, concise and specific information to regulators to aid their decision-making processes.

Annex I

Sources of Additional Information and Expertise

Falck-Zepeda, J. (2009) Socio-Economic Considerations, Article 26.1 of the Cartagena Protocol on Biosafety: What are the Issues and What is at Stake? *AgBioForum* 12 (1): 90-107.

Falck-Zepeda, J., Wesseler, J. and Smyth, S.J. (2013) The Current Status of the Debates on Socio-economic Regulatory Assessments: Positions and Policies in Canada, The USA, the EU and Developing Countries. *World Review of Science, Technology and Sustainable Development* 10 (4): 203-227.

Horna, D., Zambrano, P. and Falck-Zepeda, J. (eds.). (2013) *Socioeconomic Considerations in Biosafety Decisionmaking: Methods and Implementation*. Washington, DC: International Food Policy Research Institute.

Ludlow, K., Smyth, S. J. and Falck-Zepeda, J. (eds.). (2014) *Socio-Economic Considerations in Biotechnology Regulations*. New York: Springer Publishers.

Smyth, S.J. and Falck-Zepeda, J. (2013) Socio-economic Considerations and Trade Agreements, *Journal of International Law and Trade Policy* 14 (1), 18-38.