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CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY

Ninth meeting

Sharm El-Sheikh, Egypt, 17-29 November 2018

Item 18 of the provisional agenda*

SOCIO-ECONOMIC CONSIDERATIONS (ARTICLE 26)

Note by the Executive Secretary

I. INTRODUCTION

- 1. In the Strategic Plan for the Cartagena Protocol on Biosafety (2011-2020), socio-economic considerations are addressed under operational objective 1.7: "To, on the basis of research and information exchange, provide relevant guidance on socio-economic considerations that may be taken into account in reaching decisions on the import of living modified organisms". One of the outcomes under this objective refers to "Guidelines regarding socio-economic considerations of living modified organisms developed and used, as appropriate, by Parties".
- 2. At its sixth meeting, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety decided to establish an Ad Hoc Technical Expert Group on Socio-Economic Considerations (AHTEG) to develop conceptual clarity in the context of paragraph 1 of Article 26 of the Protocol (decision <u>BS-VI/13</u>).
- 3. At its seventh meeting, the Conference of the Parties serving as the meeting of the Parties decided to extend the AHTEG to work in a stepwise approach on (a) the further development of conceptual clarity and (b) developing an outline for guidance with a view to making progress towards achieving operational objective 1.7 of the Strategic Plan and its outcomes (decision BS-VII/13).
- 4. At its eighth meeting, the Conference of the Parties serving as the meeting of the Parties noted with regret that a face-to-face meeting of the AHTEG could not be held during the inter-sessional period due to a lack of funds and that as a consequence, certain elements of the AHTEG's mandate could not be addressed. The meeting of the Parties took note of the revised Framework for Conceptual Clarity¹ and decided to extend the mandate of the AHTEG to allow it to meet face-to-face to work on the guidelines envisaged under the outcomes for operational objective 1.7 of the Strategic Plan for the Protocol. The AHTEG was requested to submit a report for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its ninth meeting (decision CP-VIII/13).

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^{*} CBD/CP/MOP/9/1.

¹ See UNEP/CBD/BS/COP-MOP/8/13, annex. The revised Framework for Conceptual Clarity was prepared through an online discussion held from 9 May to 17 June 2016. The discussion was held to enable the AHTEG to undertake certain aspects of its mandate.

II. MEETING OF THE AD HOC TECHNICAL EXPERT GROUP ON SOCIO-ECONOMIC CONSIDERATIONS

- 6. The AHTEG on Socio-economic Considerations held its face-to-face meeting in Ljubljana, from 9 to 13 October 2017 following an offer to host the meeting by the Government of Slovenia and the financial support of the European Union and the Governments of Finland, France and the Netherlands. The meeting was co-chaired by Mr. Andreas Heissenberger (Austria) and Ms. Ranjini Warrier (India). The meeting was attended by 23 experts from the following Parties: Austria; Belarus; Bolivia (Plurinational State of); Brazil; China; Dominican Republic; European Union; France; Germany; Honduras; Hungary; India; Mauritania; Mexico; Niger; Nigeria; Norway; Philippines; Republic of Korea; Republic of Moldova; Slovenia; South Africa; and Thailand. It was also attended by five experts from the following observer countries and organizations: Canada; Third World Network; Global Industry Coalition; GENØK Centre for Biosafety; and International Indigenous Forum on Biodiversity.²
- 7. As per paragraph 2 of decision CP-VIII/13, the AHTEG was mandated to work on the guidelines envisaged under the outcomes for operational objective 1.7 of the Strategic Plan for the Protocol.
- 8. The outcomes of the deliberations of the AHTEG in response to its mandate are set out in paragraphs 8 to 16 of its report, reproduced below. The draft "Guidance on the assessment of socioeconomic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety", agreed to by the AHTEG, is provided in annex II of the report of the AHTEG, and has been reproduced in the annex to the present note.
- 9. The following is a verbatim excerpt from the Report of the Ad Hoc Technical Expert Group on Socio-economic Considerations, under item 3:
 - 8. Under this item, the Co-Chairs introduced the text entitled "Draft guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety" (CBD/CP/SEC/AHTEG/2017/1/2, annex). The Co-Chairs provided further information on the development of the text, which they had prepared to facilitate the discussions of the AHTEG. They explained that the document was based on previous outcomes of the work of the AHTEG, in particular the "Revised Framework for Conceptual Clarity", which had been noted by the Conference of the Parties serving as the meeting of the Parties to the Protocol in decision CP-VIII/13 and also taking into account information provided during the online discussion of the AHTEG. They also explained that submissions made in response to notification 2017-39 as well as other existing guidance documents made available on the Portal on socio-economic considerations had been considered in drafting the Co-Chairs' text.
 - 9. Mr. Heissenberger further indicated the Co-Chairs had chosen to follow a process-based approach in the document, i.e. to focus on how an assessment could be performed, rather than focusing on parameters to be assessed, as the latter highly depended on regional and national circumstances.
 - 10. The AHTEG considered the Co-Chairs' text and agreed that the process-based approach in the Co-Chairs' text was a constructive way forward.
 - 11. The AHTEG elaborated the assessment process contained in the document and revised the sections on "introduction and objective" as well as the "principles for the assessment of socio-economic considerations."
 - 12. During the deliberations, some experts proposed including language on the precautionary approach in the Co-Chairs' text. While agreeing on the importance of the issue,

² The list of participants is contained in annex I of the <u>report of the meeting</u>.

³ The report was made available as CBD/CP/SEC/AHTEG/2017/1/3.

other members did not agree to include that language, as they felt that the precautionary principle addresses decision-making while the Guidance focuses on the process for conducting a socio-economic assessment.

- 13. Furthermore, an expert did not support the inclusion of the examples in the list of areas that can be encompassed by the assessment.
- 14. Following extensive deliberations, the AHTEG agreed on 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 below.
- 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".
- 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;
- (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.

III. SUGGESTED ELEMENTS FOR A DRAFT DECISION

10. The Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider the report of the AHTEG, including the recommendations in paragraphs 15 and 16, as well as the draft "Guidance on the assessment of socio-economic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety" and adopt a decision along the following lines:

Recalling decisions BS-VI/13, BS-VII/13 and CP-VIII/13,

- 1. Welcomes the "Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety";
- 2. *Invites* Parties and other Governments to make use of the "Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety", as appropriate;
- 3. *Invites* 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

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Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety" and *requests* the Executive Secretary to compile the information submitted;

- 4. Decides to extend the Ad Hoc Technical Expert Group on Socio-Economic Considerations with a mandate to supplement the "Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety" with examples of methodologies and applications of socio-economic considerations, taking into account the information submitted in response to paragraph 3 above, for consideration by the tenth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol;
- 5. *Requests* the Executive Secretary, subject to the availability of resources, to convene a face-to-face meeting of the Ad Hoc Technical Expert Group on Socio-Economic Considerations.

Annex

GUIDANCE ON THE ASSESSMENT OF SOCIO-ECONOMIC CONSIDERATIONS IN THE CONTEXT OF ARTICLE 26 OF THE CARTAGENA PROTOCOL ON BIOSAFETY

Introduction and objective

Article 26, paragraph 1, of the Cartagena Protocol on Biosafety states: "The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities."

Parties have a right to take into account socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, although Article 26 does not impose an obligation on Parties to do so.

This document is aimed at providing guidance on the process for assessing socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous peoples and local communities. The document also provides an operational definition and lists important principles for the process of assessing socio-economic effects.

Operational definition

Socio-economic considerations in the context of Article 26 of the Cartagena Protocol may, depending on national or regional circumstances and on national measures to implement the Protocol, cover economic, social, cultural/traditional/religious/ethical aspects, as well as ecological and health-related aspects, if they are not already covered by risk assessment procedures under Article 15 of the Protocol.

Principles for the assessment of socio-economic considerations

If a Party chooses to take socio-economic considerations into account, then there are certain aspects of an assessment of socio-economic effects which should be considered:

- 1. Taking socio-economic considerations into account in decision-making on the import of living modified organisms must be consistent with relevant international obligations, which include, inter alia, trade agreements, environmental agreements and human rights agreements.
- 2. Taking socio-economic considerations into account in decision-making on the import of living modified organisms should be consistent with existing national regulatory frameworks and policies.
- 3. In taking into account socio-economic considerations, Parties should consider their local and national circumstances, priorities and needs as well as, if applicable, regional circumstances, priorities and needs. Such circumstances, priorities and needs could include different cultural practices and religious beliefs and practices as well as indigenous, traditional and local knowledge and practices, in particular those related to the value of biological diversity to indigenous peoples and local communities.
- 4. The assessment process of socio-economic considerations should be science-based and evidence-based and lead to defendable results.
- 5. Lack of knowledge, 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.
- 6. The assessment of socio-economic considerations and the risk assessment may be conducted concurrently, consecutively or in an integrated manner, as applicable. 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.

- 7. Article 23 of the Protocol creates obligations regarding public awareness, education and participation. Public participation and consultation, and access to information, may form part of the process of taking socio-economic considerations into account.
- 8. Where required by national regulatory frameworks, the assessment of socio-economic considerations should involve indigenous peoples and local communities, including obtaining their free, prior and informed consent for participation in the assessment, and their views on any potential introduction of the living modified organism into their territories, taking into account customary laws and community protocols.
- 9. The results of any assessment of socio-economic considerations associated with a decision on the import of living modified organisms may be subject to a review in the light of new relevant information or knowledge or a change in national policy or protection goals.

The overall assessment process

The principles identified above apply throughout the assessment process. The assessment of socio-economic considerations should follow, like any other impact assessment, a systematic approach. This approach could include the following:

Stage A: Preparation for assessment

Stage B: Assessment and evaluation

Step 1: Scoping
Step 2: Assessment

Step 3: Evaluation of results and drawing conclusions

Stage C: Review and monitoring

The stages and steps, which set out an iterative process, are elaborated below.

Stage A: Preparation for assessment

This stage is meant to take stock of existing information and instruments and identify the actors to be involved in the assessment process. This stage is led by regulators and may include the involvement of stakeholders that may be engaged through consultative processes. The following activities may be carried out in the preparatory stage:

- (a) Identifying relevant national legal and policy instruments, as well as responsibilities, protection goals and socio-economic objectives, taking into account regional and international policy and legal instruments;
- (b) Deriving nationally relevant protection goals from regional and international instruments, in particular those provided in the Cartagena Protocol on Biosafety and the Convention on Biological Diversity, where national protection goals are absent;
 - (c) Identifying how national protection goals relate to socio-economic objectives;
- (d) Determining what information is needed to carry out the assessment as a basis for identifying what information is available and what information is missing;
- (e) Identifying relevant actors to be involved in the assessment, including outlining information flows between different actors and determining mechanisms for public participation, paying due regard to applicable requirements concerning free, prior and informed consent.

Stage B: Assessment and evaluation

Step 1: Scoping

This step is aimed at framing and defining the boundaries of the assessment based on the elements identified in Stage A. Scoping is led by regulators.

Based on a problem statement, possible socio-economic effects can be identified for consideration in the assessment. The assessment can encompass the following areas, as appropriate:

- Economic: e.g. effects on income;
- Social: e.g. effects on food security;
- Ecological: e.g. effects on ecosystem functions;
- Cultural/traditional/religious/ethical: e.g. effects on seed saving and exchange practices;
- Human health-related: e.g. effects on nutritional status.

In determining the boundaries of the assessment, the following could also be considered:

- Uses of the living modified organism (e.g. intended, expected);
- Alternatives to address the stated problem;
- Time scale;
- Geographical scale;
- Level of assessment (e.g. macro- or microeconomic, farm-scale, whole supply chain);
- Direct and/or indirect effects;
- Relevant stakeholders.

As the scope of the assessment highly depends on the national or regional circumstances and on national measures implementing the Protocol, it may vary considerably, but should in any case be determined at the beginning of the assessment in order to ensure the credibility and transparency of the process.

Step 2: Assessment

In this step, the possible effects identified in the scoping step are assessed. The assessment may be led by regulators, or by assessors or by a combination of both and may include the involvement of stakeholders that may be engaged through consultative processes. The assessment of socio-economic effects can be carried out *ex ante*, *ex post* or both.

i. Methodology and data

A wide array of methodological approaches is available to assess socio-economic effects, including both quantitative and qualitative methods, as well as participatory approaches. Each method has strengths and limitations; therefore, a combination of different methods may be used, as appropriate. Factors which may influence the choice of the assessment include:

- (a) Information needs of decision makers;
- (b) Data availability (e.g. baselines and data linked to the context of introduction and use of the living modified organism);
- (c) Data sources (e.g. those derived from reports, literature, statistics, surveys and consultations as well as traditional, indigenous and local knowledge);
 - (d) Available assessment capacities.

Methods chosen should be science-based and evidence-based, or be based on other accepted approaches where scientific methods are not applicable, subject to national practices and requirements. Assessment methods should be reliable and applied in a transparent and verifiable manner and may be based on a comparative approach.

ii. Aspects of the assessment

The assessment of socio-economic effects may cover the following aspects:

- Relation between the impact of the living modified organism and the socio-economic effects;
- Beneficial or adverse nature of the effects;
- Likelihood of effects to occur;
- Intensity or magnitude of the effects;
- Possible downstream and cumulative effects;
- Reversibility of the effects;
- Mitigation of the effects;
- Effects on different communities and groups, in particular vulnerable or marginalized groups and indigenous peoples and local communities:
- Anticipated onset and duration of the effects (e.g. sustainability and persistence).

Step 3: Evaluation of results and drawing conclusions

The evaluation of results is meant to analyse the assessment outcomes in an integrated manner, taking into account the context of the introduction of the living modified organism. Based on the evaluation, conclusions are drawn which can be used in decision-making. This step is led by regulators.

The evaluation of assessment outcomes may be based on the following:

- Significance of evaluated effects;
- Distribution of effects among stakeholders;
- Limitations of the applied methods;
- Uncertainties:
- Comparison with available alternatives to the living modified organism;
- Validity of claimed benefits and harms.

Based on the evaluation, conclusions are drawn which can be used in decision-making. In the evaluation process, needs for additional information may be identified, and they have to be clearly stated in the final report.

The evaluation results could be presented to stakeholders for feedback. Feedback received from stakeholders should be included in the final report.

The final report should be submitted to decision makers for consideration.

Stage C: Review and monitoring

Review refers to the re-evaluation of the assessment outcomes in the light of new relevant information or knowledge, or a change in national policy or protection goals. Review is led by regulators.

Monitoring refers to the process of observing socio-economic effects of the living modified organism concerned over time. Monitoring may be led by assessors, regulators or a combination of both, according to the national regulatory framework. If monitoring is conducted, the findings may feed into a review process.