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REGIONAL ONLINE REAL-TIME CONFERENCES ON SOCIO-ECONOMIC CONSIDERATIONS IN DECISION-MAKING CONCERNING LIVING MODIFIED ORGANISMS WEOG and CEE, 13 June 2013 Asia-Pacific, 17 June 2013 Africa, 20 June 2013 GRULAC (Spanish), 27 June 2013

SOCIO-ECONOMIC CONSIDERATIONS

SUMMARY OF THE ONLINE DISCUSSIONS OF MARCH-APRIL 2013

BACKGROUND

1. The sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 6) requested the Executive Secretary, among other things, to convene online discussion groups and regional online real-time conferences to facilitate and synthesize the exchange of views, information and experiences on socio-economic considerations among Parties, other Governments, relevant organizations and indigenous and local communities in the context of paragraph 1 of Article 26 of the Protocol (paragraph 3, decision BS-VI/13).

2. The Secretariat convened online discussions on socio-economic considerations from 11 March 2013 to 16 April 2013. A total of 113 people were registered for the discussions and 49 of them have made at least one intervention. A total of 297 messages were posted. 52 percent of these messages were posted from people located in developed countries and 48 percent from developing countries.

3. Participants discussed issues and exchanged views, information and experiences on socioeconomic considerations on the basis of the following guiding questions proposed by the Secretariat:

- ✓ What is your understanding of "a decision on import"? How do you understand its scope? Does it matter whether a decision is taken under the Protocol (Article 10) or under domestic measures implementing the Protocol?
- ✓ What are "socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity"? What is your understanding of the wording "arising from the impact"?

- ✓ How could the value of biological diversity to indigenous and local communities be measured or determined?
- ✓ Can you think of any criteria that a Party may apply in order to ensure that the socio-economic considerations that it takes into account in reaching import decision are consistent with international obligations? Are there international obligations which exclude socio-economic considerations or limit the scope of such considerations?

4. Each set of questions was followed by a brief note highlighting some information relevant to the questions that participants may wish to take into account during the discussions. At the end of the discussions on the specific questions, participants had the opportunity to bring up any item for discussion, including suggestion on possible issues that need to be further addressed in the subsequent phases of the process.

5. Part I of this document provides a summary of the core issues raised and the views expressed in the context of the four set of questions mentioned above. Part II of the document is a compilation of specific information relevant to socio-economic considerations contributed by participants as part of the discussions summarized in Part I. The compilation contains information shared with the online group relating to national approaches, decision processes, elements of socio-economic considerations, provisions of international agreements, and reference materials such as books, articles and papers addressing issues relevant to socioeconomic considerations.¹

PART I

SUMMARY OF CORE ISSUES AND VIEWS

A. Understanding the meaning and scope of the term "decision to import" in paragraph 1 of Article 26

6. There is the view shared by participants that taking into account socio-economic considerations in reaching a decision to import a living modified organism is a sovereign right of a country and thus Article 26 is optional and does not present any mandatory requirements. Also, there seems to be a general understanding that if a country decides to take into account socio-economic considerations in reaching a decision to import a living modified organism, such considerations should also apply to a living modified organism developed domestically by that country.

7. It is noted that a decision to import includes a decision that may be taken by a Party whether to import a living modified organism for intentional introduction into the environment; for direct use as food, feed or for processing; or for contained use. It is also mentioned that a decision to review a prior decision, or to apply a simplified procedure, or domestic regulations with respect to specific imports, fall within the scope of the 'decision to import' referred to in paragraph 1 of Article 26 of the Protocol. Some participants argued that the need for socio-economic assessments should depend on whether the living modified organism to be imported is intended for intentional introduction (release) into the environment.

8. Some participants stated that a decision to import could be taken under the Protocol or under domestic measures as specified in paragraph 1 of Article 26 of the Protocol, while others believed that in practical terms, any decision to import is subject to domestic regulations that is consistent with the Protocol or adopted to implement the Protocol. For some of the participants, despite the fact that decision needs to be based on risk assessment in accordance with the Protocol, socio-economic considerations are

¹ The transcript of all messages posted online is available on the Socioeconomic Portal: <u>http://bch.cbd.int/onlineconferences/portal_art26/se_forum_discussiongroups.shtml</u>

not and should not be part of risk assessment. But others argued that both risk assessment and socio-economic considerations should be an integral part of the regulatory process that applies to a decision to import living modified organisms for different uses.

9. A number of participants supported a case-by-case decision to import and thus case-by-case socio-economic assessments for each living modified organisms that requires regulatory approval. However, others argued that socio-economic assessments are expensive processes and, therefore, it is better to have these assessments conducted for each class of events or traits such as insect resistant or herbicide tolerant living modified crops instead of requiring assessments for each event.

10. In the view of some participants, a decision to import is linked with a number of other provisions of the Protocol, including public participation in decision-taking as specified in Article 23. Public participation could be used as a means to integrate socio-economic considerations. Some participants expressed reservations on the usefulness of socio-economic assessments conducted prior to the adoption of the technology (ex-ante) and without a history of experience with the living modified organism in question. But others argued that some important questions of socio-economic nature, including whether there is any real social and/or economic need for the organism to be introduced into the existing production system, could be answered prior to importing the living modified organism taking into account the precautionary approach.²

B. Understanding what socio-economic considerations are

11. The issue of the scope of what constitutes legitimate socio-economic considerations found divergent opinions among participants. As seen from the discussion in the foregoing section, understanding when and how socio-economic considerations may be taken into account plays also a vital role in understanding the considerations or the possible socio-economic factors themselves.

1. Defining socio-economic considerations

12. The Protocol refers, in paragraph 1, Article 26, to "socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity". Some understand this reference as a sequential or cause and effect relationship between impact on biological diversity and socio-economic considerations. According to this understanding, the existence (potential or actual) impact on biological diversity due to the introduction of living modified organisms should be the trigger for socio-economic considerations. Impact, according to these participants, should be both beneficial and adverse. Some in this category also suggest that cost-benefit analysis may be an appropriate first step before proceeding with full-fledged socio-economic assessment.

13. Other participants, on the other hand, argue that impacts on the conservation and sustainable use of biological diversity are wide ranging that necessitate an equally broader ecological and socio-economic perspectives. According to some of these participants, conservation and particularly sustainable use of biological diversity have intrinsically socio-economic dimensions. Conservation and sustainable use are concepts characterized by the interactions of people and communities with biodiversity in a given ecological, social and economic system(s). Therefore, argue these participants, the wording in paragraph 1, Article 26 does not restrict impact to those effects on the physical environment only. Cost-benefit analysis may be useful as a simple economic evaluation, but not an adequate tool to assess socio-economic consequences that cannot be valued in monetary terms, as well as cumulative and long term effects.

 $^{^{2}}$ The issues identified and the views expressed under this section have strong link and relevance to the discussions in the context of the next set of questions.

Page 4

14. Some participants provided a list of socio-economic considerations, including a compilation of elements identified through previous surveys. Others shared their national experiences in terms of developing guidelines, proposals, or criteria used to determine socio-economic considerations. A number of participants suggested that the "Guidelines for incorporating biodiversity-related issues into the environmental impact assessment legislation and/or processes and in strategic environmental assessment" contained in the annex to decision VI-7, and the "Voluntary guidelines on biodiversity-inclusive environmental impact assessment" contained in the annex to decision VI-7, provide useful guidance to Parties on the meaning and scope of impacts on conservation and sustainable use of biological diversity.

One of the criteria shared by some participants and that seems to have received wider attention is 15. "sustainability". Generally, the criterion is about assessing a living modified organism from the perspective of its contribution to sustainable development and in the long-term. Assessing the contribution and impacts of living modified organisms to sustainable development over the long-term timescale allows for more latent or concealed impacts to be taken into account. It is further argued that the environmental. social approach to evaluate the and economic sustainability of the introduction/importation of a living modified organism provides a good framework for identifying elements of socio-economic considerations that may be appropriate to specific local circumstances and thus may be taken into account in decision taking.

16. Some participants put forward a list of scenarios of positive and negative impact on biological diversity that may result (directly or indirectly) from the adoption of living modified organisms where socio-economic considerations may or may not be appropriate. As regards including benefits in socio-economic assessments, a number of participants emphasized the need for applying the same rigor as assessing adverse effects. According to these participants, if benefits are going to be considered and weighed against socio-economic risks, the claimed benefits need to be equally analyzed as the alleged risks with a view to determine whether they are real and sustainable – benefits that would be available in the long-term.

17. Participants recognize that each country has a different set of socio-economic conditions, policies and priorities. Some countries support a comprehensive assessment of social, economic and even cultural/ethical implications of introducing a living modified organism, while others will be satisfied with limited risk assessment and cost-benefit analysis of the technology. Therefore, each country should be able to ask questions appropriate to its conditions. Participants seem to share the view that the task of defining the scope and details of socioeconomic considerations in the context of Article 26 of the Cartagena Protocol on Biosafety rests with individual Parties that opted to take into account these considerations in reaching a decision.

2. When to take socio-economic assessments

18. A number of participants argued in favour of conducting socio-economic assessments both prior and subsequent to the release or marketing of the living modified organism – technically known as *ex ante*, assessments prior to release; and *ex post*, assessments after release, also known as post-marketing monitoring. A few others were, however, of the view that *ex post* assessments are much more worth to explore socio-economic impacts based on real data and information, unlike *ex ante* where assessments have to rely on assumptions and/or modeling.

19. Some supported socio-economic assessments separate from and subsequent to risk assessments. They argued that it is prudent to have a sequential process where risk assessment is completed first and then any consideration of socio-economic assessment may follow only if the risk assessment identifies some safety issues or concerns that may be included in the scope of risk management. However, others while amenable to the idea of separating socio-economic assessments from risk assessments, believed that the two assessments should not necessarily be sequential. They also argued that the scope of socio-

economic assessments goes beyond the perimeters of risk assessment and thus the outcome of the latter should not always form the basis to determine the need for and the nature of socio-economic assessments.

3. How to take into account socio-economic considerations

20. Some participants highlighted some standards or principles that they believe should guide socioeconomic assessments. For some, the most important ones include adopting long-term assessment criteria, broad conceptualization of conservation and sustainable use of biological diversity, precautionary approach, public participation, and sustainability of benefits. For others the most important standards include the adoption of a transparent and fair procedure, elements of best practice, burden of proof, clear and simple approach, and cost and time efficiency. While these two sets of guiding principles may not be necessarily mutually exclusive, some have questioned the veracity of some of the principles.

21. Some participants stated that access to information by users of living modified organisms or researchers is constrained due to confidentiality and proprietary rights which in turn have restricted the scope and quality of *ex post* socio-economic assessments. In that regard, access to complete information about a particular living modified organism or a class of living modified organisms – herbicide tolerant or pest resistant – needs to be one of the important guiding principles to achieve comprehensive and objective socio-economic assessments that facilitate decision-taking.

22. Participants share the view that appropriate methodologies necessary to assess all potential socioeconomic considerations are not yet fully developed. In that regard, some participants expressed the view that the absence of methodology does not constitute a sufficient ground to exclude socio-economic concerns associated with living modified organisms. They further argue that like risk assessment, socioeconomic assessments should be seen as learning processes. On the other hand, others argue that socioeconomics is so vast that one cannot realistically assesses each and every potential socio-economic change that may be induced by the adoption of living modified organisms. According to these participants, socio-economic assessments should be conducted by the right experts and meet standards of excellence.

C. Determining the value of biological diversity to indigenous and local communities

23. A number of participants put forward or supported various considerations underlying the valuation process of biodiversity to indigenous and local communities. They highlighted the provisions of some international agreements, declarations and guidelines, in particular the International Labor Organization Convention 169, the United Nations Declaration on the Rights of Indigenous Peoples, and the Akwé: Kon Voluntary Guidelines for the Conduct of Cultural, Environmental and Social Impact Assessments regarding Developments Proposed to Take Place on, or which are likely to Impact on, Sacred Sites and on Lands and Waters Traditionally Occupied or Used by Indigenous and Local Communities, as providing insight to the conceptualization and application of valuation of biological diversity to indigenous communities.

24. Some participants identified what they believed were possible threats to the indigenous and local communities arising from impacts on biological diversity due to the adoption of living modified organisms, including loss of traditional lands, loss of access to plant genetic resources including threats to Farmers' Rights, and any associated losses in farmers' innovation, knowledge, selection, saving and exchange of seeds/propagating material and sustainable agricultural practices, all of which may be posed by GMOs directly or indirectly, should especially be taken into account. Other participants have, however, argued that a distinction should be made between the wider problem arising from the expansion of agriculture and the specific impacts of adopting living modified organisms. It was widely agreed among participants that the value placed on biological diversity by indigenous communities is high and due care should be taken to avoid disruption in the maintenance of livelihoods.

25. Some participants indicated that any effort to identify the value that indigenous and local communities attach to biological diversity should begin by establishing procedure for a consultative process with these communities and by seeking their views or consent, as appropriate, as regards matters that affect their lives, including the introduction of living modified organisms. Key voices within the community, such as women, who in many cases are caring for the environment, and the elders, who are the custodians of indigenous knowledge associated with biological diversity must be heard prior to taking a decision. It is argued that such consultative processes along with a context and background of the community would help in identifying the significance of the biological diversity to the community in terms of being a source of food, fodder, employment, income generation etc. These factors could then be measured against the changes that the introduction of living modified organisms might have to the socio-economic settings of the communities.

26. Other participants argued, however, that indigenous and local communities are not homogenous; they have different levels of dependence on biological diversity and different capabilities to meaningfully engage in examining the pros and cons of living modified organisms which involve highly technical and scientific information and therefore national and local governments are more suitably placed to take the responsibility of weighing the needs and possible impacts within the specific contexts of these communities in their jurisdiction, and taking appropriate decision.

27. It is noted that defining the value of biological diversity requires estimating the economic value of the changes that the introduction of living modified organisms is generating on biological diversity contrasted with the value of the benefits generated in specific locations, using economic methods that allow for internalizing costs of the losses of biological diversity and ecosystems or ecosystem services.

28. In terms of accurately measuring the value of biodiversity to indigenous and local communities, participants acknowledged the limitations imposed by conventional economics and some valuation models. It is recognized that some methods are available or are being developed (such as The Economics of Ecosystems and Biodiversity) for the economic valuation of biodiversity and ecosystems services. However, some participants argued that the existing valuation models have failed to account for the full economic, social, cultural and intrinsic values of biological diversity. According to a number of participants, there is a long way to go to adequately fill the existing gaps in determining the value of biological diversity to society in general and to indigenous and local communities in particular. In this regard, others expressed the view that regulators should be able to work on best available data and knowledge about the risks of a living modified organism that may cause impact on biological diversity and determine the course of action appropriate to the environment and users, including indigenous and local communities.

D. Consistency of socio-economic considerations with international legal obligations

29. Participants identified various international agreements which were generally accepted as having provisions that need to be observed when taking into account socio-economic considerations in reaching a decision about the adoption or import of living modified organisms. These agreements could fall into three broad categories, namely: (i) trade agreements, (ii) environmental agreements, and (iii) human rights agreements. It is noted that trade agreements have some specific rules that draw the boundary beyond which socioeconomic considerations may be seen as becoming a means to unduly restrict trade in living modified organisms, while environmental and human rights agreements, on the other hand, possess various provisions which strongly reinforce, and sometimes demand, the consideration of socio-economic factors in order to protect biological diversity and communities whose lives depend on the maintenance of such diversity, in particular local and indigenous communities, including farmers.

30. The agreements identified include: the Convention on Biological Diversity (in particular Article 8(j), and some of the Aichi Biodiversity Targets and decisions of the Conference of the Parties); the International Treaty on Plant Genetic Resources for Food and Agriculture (in particular Article Art. 5 on

Conservation, Art. 6 on Sustainable Use, and Art. 9 on Farmers' Rights); the United Nations Declaration on the Rights of Indigenous Peoples; General Agreement on Tariffs and Trade under the World Trade Organization (WTO) framework (in particular Article III.4 on national treatment, and Article XX, on General Exceptions where import restrictions may be justified on the grounds of public moral, protecting human, animal, or plant life and health, and relating to the conservation of exhaustible natural resources); other WTO Agreements such as the Agreement on Sanitary and Phytosanitary Measures (SPS) (in particular its Articles 5.3, 5.7).

31. Some participants reiterated their view that once a living modified organism is considered safe through risk assessment, the choice whether to adopt such organism should be left to the users/market. These participants imply that socio-economic considerations are prone to causing undue restrictions to trade and thus not consistent with trade rules. Some indicated that the principle of substantial equivalence as accepted in world trade may make it difficult to demonstrate that a living modified organism is not "like" its non-genetically modified counterpart. However, others argued that socio-economic considerations are legitimate in the context of paragraph 1 of Article 26 of the Cartagena Protocol on Biosafety as long as they are not applied arbitrarily and in a discriminatory way, and not used as disguised restriction to trade. They further argued that there is no universally shared understanding of the principle of substantial equivalence or the concept of "like product", and furthermore, the fact that there are rules and procedures, both at national and international level, that are meant to specifically regulate living modified organisms, demonstrates that these organisms are different from their non-genetically modified counterparts.

32. Some participants noted that given the reality of gene flow, for example, one's choice to cultivate living modified crops could adversely affect neighbouring farmer's choice not to, justifying the need for socio-economic assessments in order to forge balance between such competing choices and farming systems. They further noted that ignoring socio-economic considerations for fear of causing conflict with international trade obligations is not compatible with sustainable development. According to these participants there are no existing risk assessment or trade rules that a priori exclude legitimate socio-economic considerations.

33. Others expressed the view that given the difference in socio-economic realities among different regions and countries as well as in the interpretations of the international rules, there are likely to be more exceptions than generalities and, therefore, there is a need for a more subtle and sophisticated approach in regulating living modified organisms.

PART II

COMPILATION OF SOME SPECIFIC SUGGESTIONS AND INFORMATION CONTRIBUTED TO THE ONLINE FORUM

A. Decision-taking and socio-economic considerations

1. National approaches and experiences

1. **Honduras**, the biosafety guidelines for use of biotechnology fall within the Phytosanitary Law, which makes a clear distinction between risk assessment, which measures biological factors, and risk management, where socio-economic considerations are included to shape policy and implementation. Socio-economic considerations are not included in the risk assessment process. The risk assessment is done strictly by professionals with credentials in the relevant technical fields involved in each case-by case risk assessment. Risk management however, is participatory in nature, involving many stakeholder groups, and is aimed at supporting and promoting sustainable agricultural production, especially for food crops relevant to food security.

2. **Niger** has adopted the precautionary approach in taking into account socio-economic considerations in biosafety law. The 3N initiative (Nigeriens feed Nigeriens) was highlighted as a means to encourage farmers to produce more food through a decision on seeds import. Under UEMOA,³ Niger is one of eight African countries participating in a common legal framework on LMOs which incorporates socio-economic considerations for the protection of regional biodiversity. The common program issues directives for import and export to regulate and control risk associated to species in cross-border situation. Socio-economic considerations are included in all imports for intentional introduction of LMOs into the environment for direct use, food and feeding, and any aspect which can have an impact on agricultural practices.

3. **South Africa**, by virtue of their domestic legislation, includes SECs but leaves the application open to each specific case. Legislation provides for public notices in national and/or regional press depending on commercial or contained use, outlining the contact details of the registrar where comments can be made in the decision-making process. The decision-making body (the Executive Council) includes five national government departments (Environmental Affairs, Health, Agriculture, Forestry and Fisheries, Trade and Industry, and Science and Technology), each of which bring their relevant expertise and policy approach to the table. This Executive Council is informed by a Scientific Advisory Committee comprising of independent (publically-funded) scientists with expertise relevant to different aspects of biosafety. Decisions are based on a risk-benefit approach (rather than merely precautionary), to highlight the socio-economic advantages and impacts equally.

4. **For India**, while SECs are part of the process for regulation of LMO in apprising the cost-benefit of a particular LMO to be introduced. However, in application, effectively assessing SECs on import remains largely a theoretical exercise at present. SECs are very important for India which is a predominantly agrarian society, as a crucial means to compare the best available farming practices and ensure economic and socio-cultural implications and ethical considerations are taken into account.

5. **The European Union** has quite a strict system of authorizing LMO imports. Decisions are determined on a case-by-case basis (focusing on the scope of the application) and have to be based on the outcomes of an extensive risk assessment. While the EU legal framework provides for taking socio economic considerations (designated as "other legitimate factors") into account little has been done thus far.

³ UEMOA: Benin, Burkina Faso, Côte d 'Ivoire , Giunée Bissau, Mali, Niger Senegal and Togo.

6. **New Zealand** has legislation that pre-dates the Protocol by four years but is compliant with it. In NZ any GMO imported - a transboundary movement - must have an approval whether or not it is for contained use, for food, feed, or for processing, or for a deliberate release into the environment. New Zealand makes a specific decision, based on a risk assessment (RA), on the importation of an LMO. Five different areas are considered in the RA process: environmental considerations, human health considerations, Maori cultural and spiritual values, social and community considerations and economic considerations. There are two main forms of import: (i) import decision where the LMOs is for use in containment and (ii) 'release' into the open environment. Where the LMO is to be used in containment the approval will impose controls to mitigate any risk identified in the risk assessment and the containment facility must be approved. Where an LMO is to be released into the environment there are two types of approval - one acknowledges that there may be some risks but that these can be mitigated by controls and as such the LMO continues to be regulated. The other type is where no risks can be identified and therefore no mitigating controls are required.

7. **For the Philippines**, the decision to import is based on a country' regulations and the scope covers importation for contained use, field test and commercial propagation and addresses transboundary movement or trade between parties and non-parties to the Cartagena Protocol. Non-parties have to comply with Philippines biosafety regulations, which have been formulated consistent with the Cartagena Protocol.

8. **Norway:** socio-economic considerations are included in the Norwegian Gene Technology Act:

Sec. 1 Purpose of the Act: The purpose of this Act is to ensure that the production and use of genetically modified organisms and the production of cloned animals take place in an ethically justifiable and socially acceptable manner, in accordance with the principle of sustainable development and without adverse effects on health and the environment.

Sec. 10 Requirements relating to approval: The deliberate release of genetically modified organisms may only be approved when there is no risk of adverse effects on health or the environment. In deciding whether or not to grant an application, considerable weight shall also be given to whether the deliberate release will be of benefit to society and is likely to promote sustainable development.

9. **The United States of America** has a unique regulatory policy for LMOs which predates the Protocol. Experienced experts across agencies (economists, sociologists, anthropologists, geographers etc) collaborate to conduct such assessments using a robust science based research process to ensure quality, transparency, and consistency. This rigorous multiagency framework evaluates LMOs using to assess impacts to human health, animal health and the environment, and applies to contained use, intentional release, and use for food, feed and processing and does not differentiate between foreign or domestic origin. If SECs are to be taken into account they are most appropriately addressed in the decision-making or risk management part of risk analysis.

2. Suggested options of processes for decision-taking

Option 1:

(i) Define a decision making standard and a process for inclusion or assessment;

(ii) Define elements describing "benefits", "costs" and "harm" and ways to weigh evidence between competing claims. This will have to be consistent with risk assessments procedure and probably the Nagoya – Kuala Lumpur Supplementary on Liability and Redress;

(iii) Explore sequential processes such that applications for containment and confinement are not required to have a socioeconomic study. Applications for general release or for food, feed or for processing undergo the risk assessment as defined elsewhere in the Protocol and Annexes. Then if and only if the event is defined as "safe" it may undergo a socio-economic assessment if an issue is raised about the application;

(iv) Require a socioeconomic study for class of events within a crop (e.g. insect resistant cotton, herbicide tolerant soybeans). It would be a waste of time and resources to require socio-economic assessment for each event submitted to the regulatory agency.

Option 2:

(i) Notification of export of a living modified organisms;

(ii) Risk assessment of the living modified organism by the importing country - Risk assessment is conducted according to Annex III of the Protocol. ("Roadmap", which is a guidance document developed by ad hoc technical expert group, has been still under testing.) Potential "risks", (they are not "impacts"), would be/ or not be identified;

(iii) Environmental impact assessment (EIA) of the decision of import or cultivation (Optional);

(iv) If the importing country would like to conduct EIA of the decision of the import or cultivation of the LMO in the country, the importing country may /or may not conduct EIA on the decision. EIA can be conducted referring to "Voluntary Guidelines on Biodiversity-Inclusive Environmental Impact Assessment" (UNEP/CBD/COP/DEC/VIII/28), depending on the needs of EIA and the resources, such as time and budget;

(v) Potential "impacts" on the conservation and sustainable use of biological diversity would be identified. "EIA is a process of evaluating the likely environmental impacts of a proposed project or development, taking into account inter-related socio-economic, cultural and human-health impacts, both beneficial and adverse."(UNEP/CBD/COP/DEC/VIII/28);

(vi) Also socio-economic considerations arising from such "impacts" would be identified, especially with regard to the value of biological diversity to indigenous and local communities. When making a decision, the import country may take into account the socio-economic considerations, consistent with its international obligations;

(vii) Making decision.

Option 3:

(i) SEC assessment should: (i) be applied for all types of imports of LMOs, such as for contained use, FFP and intended to release into environment; (ii) done on case-by-case base for all types of LMOs intended to be introduced into a country, as well as while LMOs is internally produced and intended to be used inside of the country; and (iii) SECs should be part of decision making process under the domestic law, based on a SEC assessment as part of the decision making process;

(ii) SEC may be a component of the risk assessment procedure, or assessed via a separate procedure, based on the policies of each individual Party;

(iii) The Risk assessment document is a part of notification process and is to be done by producer/importer, based on scientific data, while the SEC assessment should involve domestic experts aware with actual internal political, economic and social processes in the country and evaluating the

possible macro and micro-economic impacts, public perception of LMOs, and assessment of possible public tension;

(iv) Collaboration, regionally and internationally, is important to ensure safety in neighboring countries, and as a means to elaborate guidance for SEC assessment, developing a common methodology, arching questions, scenarios and recommendations to help build regional capacity related to LMOs.

B. Elements of socio-economic considerations

1. Elements of socio-economic considerations recapped from 2011 Online Forum

(i) Food security;

(ii) Impacts on knowledge and technics innovation;

(iii) Impact on preservation of traditional knowledge useful for the preservation of biodiversity and traditional medicines;

- (iv) Impacts on food diversity and links with health;
- (v) Social, economic, cultural impacts of land use changes;
- (vi) Impacts on farmer' rights (intellectual property);
- (vii) Impacts on traditional markets organization;
- (viii) Impacts on access to market;
- (ix) Impacts on land ownership;
- (x) Impacts on employment and work;
- (xi) Impacts on farmers' migration to the towns;
- (xii) Impacts on change in pest(s) prevalence;
- (xiii) Global net benefices/costs ratio (financial and yield benefices);

(xiv) Global resources efficiency of the agro-ecosystem (use in water, energy, renewable and non-renewable inputs);

- (xv) Macroeconomic impacts;
- (xvi) Impacts on global earth environment, biodiversity;
- (xvii) Coexistence. Contamination.

2. Further suggestions of elements

Social considerations:

(i) **Impacts on farmers' rights**: Potential consequences of LMOs on the traditional practice of farmers in saving, reusing, sharing, exchanging, and selling farm-saved seeds to save seeds are high. The inherent right of farmers to seed saving and exchange is legally protected by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) under the Food and Agriculture Organization (FAO). Governments are entrusted to protect farmers' rights through national legislation, a task which has not been easy for many countries that have also committed to protect IPRs of seed companies under international trade agreements, such as the Agreement on Trade- Related Aspects of Intellectual Property Rights (TRIPS) of the WTO.

(ii) **Impacts on women and gender role:** The introduction of LMOs can have a profound impact on women and gender roles through influences market access, labor roles and economic benefits.

In many countries men dominate commercial agriculture, and women have the primary responsibility of raising and caring for the children and tending to the home and often home farm. The vital role played by women must be considered in relation to LMO introduction.

(iii) **Consumer concerns**: Price matters for most consumers, especially in developing countries, however it is not the only factor that determines consumer responses to new products introduced in the market. Consumer acceptance is highly influenced by cultural and ethical values, and perceptions on health and environmental safety of the product.

Economic considerations:

(iv) **Trade**: The ability of developing countries to compete in the international market if they decide to venture into commercial production of GM crops. Although GM crops promise to address specific problems related to particular pests and diseases, the quality of the product largely depends on the conditions in which they are produced and the management practices under which they are grown.

(v) **Markets**: The price of agricultural commodities is highly sensitive to and dictated by supply and demand, GMOs that promise yield improvements may affect market behavior. Particularly vulnerable are developing countries whose economies are highly dependent on the production and export of specific agricultural products.

(vi) **Income security**: Economic cost-benefit analyses taking into account the specific farming practices and conditions of farmers, which illustrates operational costs eclipsing profit forcing expansion.

(vii) **Rural labor**: The situation in industrial agriculture predominant in developed countries, where the cost and availability of labor is a major production cost, is vastly different from the situation in household-based farming that characterizes agriculture in many developing countries where labor is readily available, abundant and often cheap. For instance, the introduction of herbicide-resistant GM crops that eliminates the need for weeding or tilling of the soil during land preparation will potentially have grave long-term impacts on rural labor.

(viii) **Income and wealth distribution**: Companies that develop GMO products intend to recoup their investments on research and development, through the intellectual property rights (IPR) system and marketing schemes. In situations where the GM variety is more expensive than the non-GM, companies may adopt a targeted marketing scheme that primarily offers its GM to rich and middle-income farmers who can afford the higher cost of seeds. If the companies' claims with regards to their products are real, those who will benefit from this promise are obviously those farmers who can afford the cost of seeds and who already have relatively high income to start with. This situation will expectedly aggravate the problem of income inequality and wealth distribution in the rural areas.

(ix) **Control over tools:** In relation to production in the particular context where the technology is introduced, questions arise like will the dissemination of GM seeds provide opportunities for poor farmers to have some control over the tools of production, or will it further entrench control of particular segments of the community over farm inputs, processing and marketing?

(x) **Food security**: With the cultivation of GM crops in the developing world, household food security may face the threat of conversion of land areas traditionally planted with food crops for the production of commodity crops for industrial use and export.

(xi) **Food aid**: Many poor countries are confronted by emergency situations that inhibit farmers from producing their own food, particularly in areas affected by war, widespread conflicts, natural calamities, drought, and famine. In those situation countries should be able to formulate its

position in procuring food aid from sources that could assure GMO-free food supply, whenever possible and available.

(xii) **Co-existence and Gene flow**: The risk of transfer of pollen is particularly high for crosspollinating crops, such as corn and canola. Producers of non-GM crops risk having their crops contaminated by nearby GM crops whose pollen can travel long distances by wind or with the aid of insects. This situation is expected to be much more complicated in most developing countries where landholdings are much smaller and distances between farms are much shorter. In addition to this GMO contamination of conventional crops, and of wild and weedy relatives, poses serious threats to biodiversity and the genetic base for long-term food security.

(xiii) **Organic agriculture**: Organic agricultural products have increasingly become important to the economy of many developing countries in recent years. Organic certification standards generally do not allow GMO contents. Should contamination of organic crops occur, farmers would lose the organic certification status for those crops and the premium prices they command?

(xiv) **Intellectual properties rights:** Concerns about the implications of IPRs for GMOs extend beyond the economic sphere. This includes impacts of IPRs on public access to knowledge and technological innovations.

3. Norwegian proposed criteria for socio-economic considerations relating to herbicide tolerant living modified crops:

1. Food safety, food security and food quality:

- a. Does the HR plant contribute to reduced/increased input costs per production unit?
- b. Does the yield per area unit increase/decrease?
- c. What is the purpose of the HR plant; will it be used for food, feed or fuel?

d. Are the content and amount of herbicide residues (the active ingredients of the herbicide) in the food altered?

e. May products of the HR plant cause acute, chronic or long-term health impacts (toxic, immunologic, including allergenic, or anti-nutritional impacts)?

f. Does the HR plant contribute to better nutrition in regards to composition, amount in energy content?

g. Does the HR plant have properties that contribute to better preservation during storage?

2. Animal health and welfare:

a. Does the product from the HR plant contribute to increased/reduced feed quality?

b. Same as 1.e.

3. Living conditions and profitability for the farmers cultivating the GMOs, including farmers' rights, duties, health and safety (short-term (less than 5 years) and long-term (more than 20 years) impacts)

- a. Health/safety:
 - i. Does altered use of herbicide(s) affect farmers'/farmworkers' health positively/negatively?
 - ii. Do the farmers/farmworkers get HSE-training and equipment needed related to the application of the herbicide(s) to be used with the HR plant?

b. Contracts/conditions:

- i. Are there limitations in the access to seeds, breach of contract, or information about the products to be used (seeds, spraying plans, herbicides/pesticides)
- c. Cost and income development:
 - i. Do the farmers' input costs increase/decrease?
 - ii. Does the HR plant alter the need for other short term and long term input such as production plan, spraying programme, deployment of labour, machines and equipment?
 - iii. Will future resistance problems reduce long-term profitability?
- d. Agronomic conditions:
 - i. What agronomic conditions is the HR plant developed for?
- e. Right to seeds:
 - i. Are farmers cultivating the HR crop allowed to save, exchange and sell seeds from their own harvest?

4. Living conditions and profitability in the production area (short-term (less than 5 years) and long-term (more than 20 years) impacts)

- a. Health/safety:
 - i. Does the use of herbicides change over time and is the population's health affected negatively/positively?
- b. Other farmers' democratic rights and profitability
 - i. Is there a coexistence regulation, and are measures implemented?
 - ii. Is there a system for preventing spread of the HT crop to other, non-GM crops?
 - iii. Will other farmers be more/less affected by weeds?
- c. Employment
 - i. Does cultivation of the HR plant create increased/reduced employment locally, regionally and nationally?
 - ii. Does cultivation of the HR plant create increased/reduced employment for women?
- d. Land ownership
 - i. Does the cultivation of HR crops alter ownership related to land and seeds in the area?
- e. Advantages for consumers
 - i. Does the cultivation of the HR plant create increased/reduced benefits for the consumer?
- f. Surveillance/logistics
 - i. Does the HR plant increase/decrease the need for surveillance and logistics?
- 5. Conservation of biodiversity:

a. What regulations does the cultivating country have for herbicide use and are these regulations implemented?

b. Is the HR plant cultivated in an area defined as centre of origin or centre of diversity for the corresponding non-GM plant?

c. Does the HR plant contribute to a greater expansion of monoculture?

d. Is the HR plant freely accessible to further plant breeding?

e. Is the economy in the cultivating country negatively affected by reduced biodiversity?

6. Free choice of future agricultural system

a. Does cultivation of the HR plant exclude a shift to other agricultural systems in the future, such as organic or non-GM agriculture?

4. Elements from the Voluntary guidelines on biodiversity-inclusive environmental impact assessment (Annex to decision VIII/28 of the Conference of the Parties to the Convention on Biological Diversity)

(i) Would the intended activity affect the biophysical environment directly or indirectly in such a manner or cause such biological changes that it will increase risks of extinction of genotypes, cultivars, varieties, populations of species, or the chance of loss of habitats or ecosystems?

(ii) Would the intended activity surpass the maximum sustainable yield, the carrying capacity of a habitat/ecosystem or the maximum allowable disturbance level of a resource, population, or ecosystem, taking into account the full spectrum of values of that resource, population or ecosystem?

(iii) Would the intended activity result in changes to the access to, and/or rights over biological resources?

(iv) Would the intended activity lead, either directly or indirectly, to serious damage or total loss of (an) ecosystem(s), or land-use type(s), thus leading to a loss of ecosystem services of scientific/ecological value, or of cultural value?

(v) Does the intended activity affect the sustainable human exploitation of (an) ecosystem(s) or land-use type(s) in such manner that the exploitation becomes destructive or non-sustainable (i.e. the loss of ecosystem services of social and/or economic value)?

(vi) Would the intended activity cause a direct or indirect loss of a population of a species?

(vii) Would the intended activity affect sustainable use of a population of a species?

(viii) Would the intended activity result in extinction of a population of a localized endemic species of scientific, ecological, or cultural value?

(ix) Does the intended activity cause a local loss of varieties/cultivars/breeds of cultivated plants and/or domesticated animals and their relatives, genes or genomes of social, scientific and economic importance?

5. Scenarios to illustrate socio-economic considerations outside of impact on biodiversity

Example 1 – The reduced use of pesticide(s) and the associated increase in number of beneficial predatory insects in the case of a pest resistant crop (e.g., Bt cotton). In this situation, there are no potential adverse impacts on biodiversity or SEC arising from impacts on biodiversity. There is however a number of SEC that arise but they are not from impacts on biodiversity. These include: (1) Reduced exposure of workers to pesticides; (2) Reduced production costs for farmers due to reduced use of pesticides and fossil fuels; and (3) Reduced production costs for farmers due to reduced use of pesticides and fossil fuels.

Example 2 – As a pest resistant crop is grown over larger areas it has been demonstrated that target pest

populations decrease, resulting in reduced pest pressure in adjacent fields, including conventional crops. As in the previous case, there are no potential adverse impacts on biodiversity or SEC arising from impacts on biodiversity but there are SEC that do not arise from impacts on biodiversity, e.g., reduction of production costs and/or increased productivity for farmers in adjacent fields.

Example 3 - In the case where resistance emerges to a pest resistant crop (e.g., because functional refuges were not present), then the substitution of broad spectrum insecticides for microbial pesticides that are no longer effective due to resistance development could have localized impacts on biodiversity. SEC in this case might arise as farmers may have increased production costs due to the need to use other pesticides in adjacent fields to manage resistance. SEC not arising from impacts on biodiversity could include increased production costs in the pest resistant crop due to use of alternative pest management approaches.

There are other examples of SEC that do not arise from impacts on biodiversity, such as:

- Perceived ethical or spiritual issues or religious values;
- Micro-economic changes at the individual, household or community level;
- Changes in product availability/impacts on consumer choice;
- Economic loss if out-crossing of GM pollen results in noncompliance with thresholds; and
- Displacement of economic activity in case a GM product appears in high demand by farmers.

6. Recommendations on socio-economic considerations from an independent Committee of Scientific Experts (UK)

- (i) Take account of benefits as well as risks,
- (ii) Be evidence based,

(iii) Recognize that an opportunity will often be needed to assess the impact of novel crops and practices on a limited scale, before widespread use,

(iv) Be based on comparative assessment with current crops and practices,

(v) Protect and nurture opportunities for innovation and therefore choice of comparator should take care to avoid the rejection of novel crops and practices while retaining more damaging established crops and practices,

- (vi) Be straightforward to apply,
- (vii) Be sensitive to the competitiveness of all sectors of [UK] agriculture.

C. Socio-economic considerations from impacts with regard to the value of biological diversity to indigenous and local communities

1. Excerpt from the Explanatory Guide to the Cartagena Protocol on Biosafety on the possible value of biological diversity to indigenous and local communities⁴

"Socio-economic considerations with respect to the value of biological diversity to indigenous and local communities may also refer to the impact of introduction of LMOs on the ability of indigenous and local communities to make use of the biological diversity upon which their community's survival and traditional livelihood depends. These socio-economic considerations may include, inter alia, the impact that decisions on imports or other domestic LMO regulatory measures may have on:

⁴ Mackenzie, Ruth, Burhenne-Guilmin, Françoise, La Viña, et. Al. An Explanatory Guide to the Cartagena Protocol on Biosafety (IUCN: Gland, Switzerland and Cambridge, UK, 2003) at para 632, available at: <u>http://data.iucn.org/dbtw-wpd/edocs/EPLP-046.pdf.</u>

a) the continued existence and range of diversity of the biological resources in the areas inhabited or used by indigenous or local communities;

b) the loss of access to genetic and other natural resources, previously available to indigenous or local communities in their territories; or

c) the loss of cultural traditions, knowledge, and practices in a particular indigenous or local community as a result of the loss of biological diversity in their territory"

2. Elements from Akwé: Kon Voluntary Guidelines⁵

Paragraph 27: In determining the scope of a cultural impact assessment, the following should be considered:

(i) Possible impacts on continued customary use of biological resources;

(ii) Possible impacts on the respect, preservation, protection and maintenance of traditional knowledge, innovations and practices;

- (iii) Protocols;
- (iv) Possible impacts on sacred sites and associated ritual or ceremonial activities;
- (v) Respect for the need for cultural privacy; and
- (vi) Possible impacts on the exercise of customary laws.

Paragraph 43: In determining the scope of a social impact assessment, the following should be considered:

- (i) Baseline studies;
- (ii) Economic considerations;
- (iii) Possible impacts on traditional systems of land tenure and other uses of natural resources;
- (iv) Gender considerations;
- (v) Generational considerations;
- (vi) Health and safety aspects;
- (vii) Effects on social cohesion;
- (viii) Traditional lifestyles; and
- (ix) The possible impact on access to biological resources for livelihoods.

Paragraph 52: The following general considerations should also be taken into account when carrying out an impact assessment for a development proposed to take place on, or which is likely to impact on, sacred sites and on lands and waters traditionally occupied or used by indigenous and local communities:

- (i) Prior informed consent of the affected indigenous and local communities;
- (ii) Gender considerations;
- (iii) Impact assessments and community development plans;

⁵ Secretariat of the Convention on Biological Diversity, Akwé: Kon Voluntary Guidelines for the Conduct of Cultural, Environmental and Social Impact Assessment regarding Developments Proposed to Take Place on, or which are Likely to Impact on, Sacred Sites and on Lands and Waters Traditionally Occupied or Used by Indigenous and Local Communities Montreal (2004), available at: <u>https://www.cbd.int/doc/publications/akwe-brochure-en.pdf.</u> [Akwé: Kon Voluntary Guidelines]

Page 18

(iv) Legal considerations;

(v) Ownership, protection and control of traditional knowledge, innovations and practices and technologies used in cultural, environmental and social impact assessment processes;

- (vi) Mitigation and threat-abatement measures;
- (vii) Need for transparency; and
- (viii) Establishment of review and dispute resolution procedures.

D. International obligations and socio-economic considerations

Excerpts of provisions

(i) General Agreement on Tariffs and Trade (GATT)

Article III: National Treatment on Internal Taxation and Regulation

4. The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. The provisions of this paragraph shall not prevent the application of differential internal transportation charges which are based exclusively on the economic operation of the means of transport and not on the nationality of the product.

Article XX: General Exceptions

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

- (a) necessary to protect public morals;
- (b) necessary to protect human, animal or plant life or health;

(c) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption.

(ii) The World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)

Article 5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to

obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

Annex A: Definitions

3. International standards, guidelines and recommendations

(a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;

(b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;

(c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and

(d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.

(iii) Convention on Biological Diversity

Article 8: In-situ Conservation

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;

Article 10: Sustainable Use of Components of Biological Diversity

(c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;

(iv) International Treaty on Plant Genetic Resources for Food and Agriculture

Article 5 - Conservation, Exploration, Collection, Characterization, Evaluation and Documentation of Plant Genetic Resources for Food and Agriculture

5.1 Each Contracting Party shall, subject to national legislation, and in cooperation with other Contracting Parties where appropriate, promote an integrated approach to the exploration, conservation and sustainable use of plant genetic resources for food and agriculture and shall in particular, as appropriate:

(a) Survey and inventory plant genetic resources for food and agriculture, taking into account the status and degree of variation in existing populations, including those that are of potential use and, as feasible, assess any threats to them;

(b) Promote the collection of plant genetic resources for food and agriculture and relevant associated information on those plant genetic resources that are under threat or are of potential use;

(c) Promote or support, as appropriate, farmers and local communities' efforts to manage and conserve on-farm their plant genetic resources for food and agriculture;

(d) Promote in situ conservation of wild crop relatives and wild plants for food production, including in protected areas, by supporting, inter alia, the efforts of indigenous and local communities;

(e) Cooperate to promote the development of an efficient and sustainable system of ex situ conservation, giving due attention to the need for adequate documentation, characterization, regeneration and evaluation, and promote the development and transfer of appropriate technologies for this purpose with a view to improving the sustainable use of plant genetic resources for food and agriculture;

(f) Monitor the maintenance of the viability, degree of variation, and the genetic integrity of collections of plant genetic resources for food and agriculture.

5.2 The Contracting Parties shall, as appropriate, take steps to minimize or, if possible, eliminate threats to plant genetic resources for food and agriculture.

Article 6 – Sustainable Use of Plant Genetic Resources

6.1 The Contracting Parties shall develop and maintain appropriate policy and legal measures that promote the sustainable use of plant genetic resources for food and agriculture.

6.2 The sustainable use of plant genetic resources for food and agriculture may include such measures as:

(a) pursuing fair agricultural policies that promote, as appropriate, the development and maintenance of diverse farming systems that enhance the sustainable use of agricultural biological diversity and other natural resources;

(b) strengthening research which enhances and conserves biological diversity by maximizing intra- and inter-specific variation for the benefit of farmers, especially those who generate and use their own varieties and apply ecological principles in maintaining soil fertility and in combating diseases, weeds and pests;

(c) promoting, as appropriate, plant breeding efforts which, with the participation of farmers, particularly in developing countries, strengthen the capacity to develop varieties particularly adapted to social, economic and ecological conditions, including in marginal areas;

(d) broadening the genetic base of crops and increasing the range of genetic diversity available to farmers;

(e) promoting, as appropriate, the expanded use of local and locally adapted crops, varieties and underutilized species;

(f) supporting, as appropriate, the wider use of diversity of varieties and species in on-farm management, conservation and sustainable use of crops and creating strong links to plant breeding and agricultural development in order to reduce crop vulnerability and genetic erosion, and promote increased world food production compatible with sustainable development; and

(g) reviewing, and, as appropriate, adjusting breeding strategies and regulations concerning variety release and seed distribution.

9.1 The Contracting Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.

9.2 The Contracting Parties agree that the responsibility for realizing Farmers's Rights, as they relate to plant genetic resources for food and agriculture, rests with national governments. In accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers's Rights, including:

(a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;

(b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and

(c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

9.3 Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate.

E. Reference materials

1. Books, articles and papers

1. Socio-economic Considerations in Biosafety and Biotechnology Decision Making: The Cartagena Protocol and National Biosafety Frameworks. Falck-Zepeda, J.B. and P. Zambrano. 2011. Review of Policy Research. 28(2): 171-195.

http://dx.doi.org/10.1111/j.1541-1338.2011.00488.x

Abstract: The article contributes to the ongoing policy dialogue by discussing issues related to socio-economic assessment including scope, timing, inclusion modalities, methods, decision-making rules and standards, and the integration of socio-economic assessments in biosafety and/or biotechnology approval processes. The article also discusses the implications of such inclusion for technology flows and public and private sector R&D. If inclusion is not done properly, it may negatively impact technology flows especially from the public sector and render an unworkable biosafety system.

2. **Measuring the contribution of Bt cotton adoption to India's cotton yields leap**. Gruere, G. and Y. Sun. IFPRI Discussion Paper 01170, International Food Policy Research Institute (IFPRI), Washington, DC.

http://www.ifpri.org/sites/default/files/publications/ifpridp01170.pdf

Abstract: The study examines the contribution of Bt cotton adoption to long- term average cotton yields in India using a panel data analysis of production variables in nine Indian cotton-producing states from 1975 to 2009. The results show that Bt cotton contributed 19 percent of total yield growth over time, or between 0.3 percent and 0.4 percent per percentage adoption every year since its introduction. Besides Bt cotton, the use of fertilizer and the increased adoption of hybrid seeds appear to have contributed to the yield increase over time. However, if official Bt cotton adoption contributed to increased yield after 2005, unofficial Bt cotton might also have been part of the observed increase of yields starting in 2002, the year of its official introduction in India.

3. Estimates and Implications of the Costs of Compliance with Biosafety Regulations in Developing Countries: The case of the Philippines and Indonesia. Falck Zepeda, J., J. Yorobe, Jr., B. Amir Husin, A. Manalo, E. Lokollo, G. Ramon, P. Zambrano and Sutrisno GM Crops and Food: Biotechnology and Agriculture in the Food Chain. Volume 3, Issue 1 January/February/March 2012

http://www.landesbioscience.com/journals/gmcrops/article/18727/?nocache=668315680

Abstract: The article provides estimates for the cost of compliance for a set of technologies in Indonesia, the Philippines and other countries. The costs vary from US \$100,000 to 1.7 million. They are estimates of regulatory costs and do not include product development or deployment costs. Cost estimates need to be compared with potential gains when the technology is introduced in these countries and the gains in knowledge accumulate during the biosafety assessment process. Although the cost of compliance is important, time delays and uncertainty are even more important and may have an adverse impact on innovations reaching farmers.

4. **Measuring the economic impacts of transgenic crops in developing agriculture during the first decade: Approaches, findings, and future directions**. Smale, Melinda; Zambrano, Patricia; Gruère, Guillaume P.; Falck-Zepeda, Jose´ Benjamin; Matuschke, Ira; Horna, Daniela; Nagarajan, Latha; Yerramareddy, Indira; Jones, Hannah. 2009. Food Policy Review 10. Washington, D.C. International Food Policy Research Institute (IFPRI).

http://www.ifpri.org/sites/default/files/publications/pv10.pdf http://dx.doi.org/10.2499/0896295117FPRev10

Abstract: The review explores whether biotech crops can benefit poor farmers. The authors examine the issue by emphasizing the methods applied to empirical data from developing countries, because these methods influence the nature of economists' findings and how they interpret them. The authors consider the economic impacts of biotech crops not only on farmers, but also on consumers, the agricultural sector as a whole, and international trade.

 Socio-economic Considerations under the Cartagena Protocol on Biosafety: Insights for Effective Implementation. Catacora Vargas, Georgina. Asian Biotechnology and Development Review. Special issue on Biosafety and Socio-economic Considerations. Vol. 14. No. 3. November 2012. ISSN: 0972-7566.

Catacora-12-SEC context CPB-RIS_ABDR-Nov12.pdf

Abstract: The article points out the interrelationships of Article 26 with other provisions of the Protocol.

6. A latent class approach to investigating demand for genetically modified banana in Uganda Agricultural Economics. Kikulwe, E.M., E. Birol, J. Wesseler, J. Falck-Zepeda. 2010. 42(5):547-560. First published online 21 Jan 2011.

http://dx.doi.org/10.1111/j.1574-0862.2010.00529.x

Abstract: The study explores consumer acceptance and valuation of a genetically modified (GM) staple food crop in a developing country prior to its commercialization. It focuses on the hypothetical introduction of a disease-resistant GM banana variety in Uganda, where bananas are among the most important staple crops. A choice experiment is used to investigate consumer preferences for various attributes related to the banana (such as bunch size, technology, producer benefit, and price) and examine their opinions on GM foodstuff. Choice data come from 421 banana-consuming households randomly selected from three regions of Uganda. A latent class model is used to investigate the heterogeneity in consumers' preferences for selected attributes related to the banana and to profile consumers who are more or less likely to accept GM bananas.

7. Socio-Economic Aspects in the Assessment of GMOs-Options for Action. (Study by the Environment Agency of Austria. 2011.)

http://www.umweltbundesamt.at/aktuell/publikationen/publikationssuche/publikationsdetail/?pub_id=1941

Abstract: The study discusses the socio-economic aspects of the cultivation of genetically modified organisms (GMOs), a topic emerging at the international level as well as in the European Union. It provides a basis for ongoing discussions regarding the possible consideration of socio-economic aspects in GMO authorisation procedures.

In this respect, the report gives an overview of the legal and political as well as the scientific background of a socio-economic assessment of GMO cultivation. Experiences with socio-economic assessments are discussed and important issues identified. In addition, a catalogue of assessment criteria is presented, focusing mainly on aspects which are of major relevance for Austria, as well as on the risks and potential negative effects of GMO cultivation.

8. Socio-economic aspects of GMOs: Building Blocks for an EU Sustainability Assessment of Genetically Modified Crops (Advisory Committee Report, Committee on Genetic Modification (COGEM) of The Netherlands).

http://www.cogem.net/index.cfm/en/publications/publicatie/socio-economic-aspects-of-gmo-s

Abstract: The report identifies several socio-economic aspects related to GMO's and categorizes them in 9 main themes from the perspective of sustainability (in terms of people, planet and profit).

9. **Sustainability of current GM crop cultivation:** Review of people, planet, profit effects of agricultural production of GM crops, based on cases of soybean, maize and cotton (Wageningen University in cooperation with CREM and Aidenvironment).

http://edepot.wur.nl/166665

Abstract: The report describes three case studies in which the impact in terms of sustainability was determined for GMO's imported to the Netherlands.

10. Pest tradeoffs in technology: reduced damage by caterpillars in Bt cotton benefits aphids' by Steffen Hagenbucher Et al. March 2013.

http://dx.doi.org/10.1098/rspb.2013.0042

Abstract: The rapid adoption of genetically engineered (GE) plants that express insecticidal Cry proteins derived from *Bacillus thuringiensis* (Bt) has raised concerns about their potential impact on non-target organisms. This includes the possibility that non-target herbivores develop into pests. Although studies have now reported increased populations of non-target herbivores in Bt cotton, the underlying mechanisms are not fully understood. The article proposes that lack of herbivore-induced secondary metabolites in Bt cotton represents a mechanism that benefits non-target herbivores.

11. **Biosafety Data as Confidential Business Information**. Nielsen KM (member of the GMO panels of the European Food Safety Authority and the Norwegian Scientific Committee for Food Safety). March 2013. PLoS Biol 11(3): e1001499. doi:10.1371/journal.pbio.1001499.

http://www.plosbiology.org/article/info%3Adoi%2F10.1371%2Fjournal.pbio.1001499

Page 24

Abstract: The article examines the justification of CBI claims on the data used to establish the safety of GMOs intended for commercialization and recommends major changes for the benefit of consumers, citizens, and GM developers.

12. Genetically Modified Organisms - A Summary of Potential Adverse Effects Relevant to Sustainable Development (GenØk Biosafety Report 2011/02. Report commissioned from GenØk - Centre for Biosafety by Nordic Ecolabel.)

http://www.biosafety-info.net/file_dir/18317253864f17c9dd59ff7.pdf

Abstract: The report emphasizes that the potential impacts of GMOs take place along their life cycle and value chain. In this sense, assessments only at specific stages (commonly at open field production or consumption) are incomplete, limiting the holistic understanding of impacts and their intertwined nature. This is consistent with findings in the literature review, carried out to identify potential effects along the value chain of GMOs, which show the potential multiple links and combinatorial effects of GMOs at different stages (e.g., from their research and development (R&D) to commercialization). Another feature of this report is that it focuses on potential adverse effects of GMOs (particularly GM crops) that may impact sustainable development.

13. **Perspectives on the Role of Science and Technology in Sustainable Development** (A report of the U.S. Congress, Office of Technology Assessment). OTA-ENV-609 (Washington, DC: U.S. Government Printing Office, September 1994)

http://www.fas.org/ota/reports/9422.pdf

Abstract: This report examines an array of sustainable development definitions and discusses their common elements. Current agriculture, energy, and industry technologies are described as well as the strides being made in education, communication, and information technologies that could support sustainable development. Access to these technologies, however, remains a challenge for many in developing and industrial countries alike. Several central issues are discussed that have clear policy implications. First, sustainable international development involves multiple themes that cross U.S. foreign and domestic policy boundaries (e.g., energy efficiency, sustainable agriculture, and resource conservation); thus, coordinating these policies will be fundamental. Second, eliminating institutional, social, economic, and political barriers to sustainable development is 1 likely to be a key challenge. Finally, developing and disseminating technologies that can advance sustainability will require significant collaboration and investment on the parts of industrial and developing countries.

14. Socio-economic Considerations and International Trade Agreements. Smyth, Stuart and J. Falck-Zepeda. 2013 (forthcoming). Estey Centre Journal of International Law and Trade Policy.

https://bch.cbd.int/cms/ui/forums/attachment.aspx?id=911.

Advance draft (some minor reviews and additions pending including discussion on membership in agreements, CPB lack of a dispute settlement mechanism, and a clarification of the use of "narrow" scope of Article 26 in the article).

15. **Treaties in Collision? The Biosafety Protocol and the World Trade Organization Agreements**. Sabrina Safrin. The American Journal of International Law, Vol. 96, No. 3, pp. 606-628, July 2002.

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=658561

Abstract: In the event of a conflict between the requirements of the Biosafety Protocol, a multilateral agreement governing the trade in genetically modified organisms, and the requirements of the General Agreement on Tariffs and Trade and associated agreements

(collectively WTO Agreements), which treaty's requirements prevail? This question lies as the legal heart of the perceived conflict between trade globalization and environmental protection. This issue is particularly timely given the present trade dispute between the United States and European Union over the European Union's restrictions on the importation of genetically modified agricultural commodities.

16. The Biosafety Protocol: Multilateral Agreement on Protecting the Environment or Protectionist Club? Anna L Hobbs, Jill E Hobbs, William A Kerr. Journal of World Trade 39(2): 281±300, 2005.

https://www.cbd.int/doc/articles/2005/A-00435.pdf

The article examines whether the Biosafety Protocol can act as an effective multilateral protector of biodiversity that balances the risks that environmental sustainability may be threatened by the introduction of living modified organisms (LMOs)2 with the risks that considerable opportunities for substantial human benefits will be forgone if the use of LMOs is overly restricted. It takes a look at the Biosafety Protocol with its need to balance these two risks in mind.

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The article explores one dimension of the World Trade Organization (WTO) international legal framework relevant for food safety regimes. Rather than looking at individual norms, the article tries to understand what regulatory philosophies are compatible with this international legal regime.

Against this background, it is investigated whether the interpretation of concepts such as 'risk assessment' and 'insufficiency of scientific evidence' is consistent throughout jurisprudence on the Sanitary and Phytosanitary (SPS) Agreement and whether the interpretative choices made by the WTO 'courts' are rooted in different approaches to risk.

18. Economics literature about the impacts of genetically engineered crops in developing economies: bECON library.

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2. Laws and Guidelines

1. Norwegian Gene Technology Act

http://www.regjeringen.no/en/doc/Laws/Acts/gene-technology-act.html?id=173031

The Act requires that contribution to sustainable development, benefit to society and ethical considerations should be taken into account when evaluating an LMO. The Norwegian Biotechnology Advisory Board has worked with the operationalization of these criteria.

http://www.bion.no/filarkiv/2010/07/2009_11_18_diskusjonsnotat_baerekraft_engelsk.pdf

Parts of this operationalization are taken into the **Regulations on Impact Assessme**nt pursuant to the Gene Technology Act:

http://www.regjeringen.no/en/dep/md/documents-and-publications/acts-andregulations/regulations/2005/regulations-relating-to-impact-assessmen.html?id=440455

2. **SAFA guidelines: Sustainability of Food and Agriculture Systems** (Food and Agricultural Organization)

http://www.fao.org/nr/sustainability/sustainability-assessments-safa/en/

A test version of the sustainability assessment guidelines is available at: <u>http://www.fao.org/docrep/017/ap773e/ap773e.pdf</u> and is being piloted in several countries.

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