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GLOBAL OVERVIEW OF INFORMATION ON SOCIO-ECONOMIC CONSIDERATIONS ARISING FROM THE IMPACT OF LIVING MODIFIED ORGANISMS ON THE CONSERVATION AND SUSTAINABLE USE OF BIOLOGICAL DIVERSITY

INTRODUCTION

1. According to paragraph 1 of Article 26 of the Cartagena Protocol on Biosafety, Parties 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 biodiversity to indigenous and local communities, in reaching a decision on import under their domestic measures implementing the Protocol. In this regard, the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) recognized, in its decision BS-VI/13, the need expressed by several Parties for further guidance when choosing to take into account socio-economic considerations and recalled operational objective 1.7 of the Strategic Plan of the Cartagena Protocol on Biosafety for the period 2011-2020.

2. The sixth meeting of the Parties to the Protocol requested the Executive Secretary, among other things, to compile, take stock of and review information on socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biodiversity, especially with regard to the value of biodiversity to indigenous and local communities, in order to develop a global overview based on existing institutional frameworks, legislation and policies with provisions on socio-economic considerations; capacity-building activities related to biosafety and socio-economic considerations; existing expertise and experience; and other policy initiatives concerning social and economic impact assessments.[1]

3. Accordingly the Executive Secretary commissioned a consultant to develop the present report, which takes stock of and reviews existing information on socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biodiversity, especially with regard to the value of biodiversity to indigenous and local communities, for consideration by an Ad Hoc Technical Expert Group in accordance with the request of the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety.

* UNEP/CBD/BS/AHTEG-SEC/1/1.

[1] Decision BS-VI/13, paragraph 2.

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I. BACKGROUND: SOCIO-ECONOMIC CONSIDERATIONS IN BIOSAFETY DECISION-MAKING

4. The development and application of modern biotechnology and in particular living modified organisms could have significant positive and negative socio-economic and cultural impacts. These impacts must be carefully identified in order to enable appropriate management of the consequences of transferring biotechnology.[2] Living modified organisms are perceived differently around the world, and public views are strongly influenced by the socio-economic changes that will accompany their wide-scale use.[3]

5. Many of the concerns about living modified organisms involve those organisms destined for large-scale release into the environment. Adverse impacts to biodiversity can be the result of a chain of consequences, direct and indirect, intentional or accidental. One key concern is the potential that living modified crops have to cause structural change in agriculture which may threaten food security and biodiversity conservation. Some have the view that the use of socio-economic considerations in decision-making is particularly relevant for countries that are countries of origin and diversity of genetic resources, and countries with large rural and/or indigenous populations,[4] and that it is necessary to be able to link socio-economic impacts with their downstream effects on biodiversity.[5]

6. The option that is available for Parties to take into account socio-economic considerations in paragraph 1 of Article 26 of the Biosafety Protocol, allows for the implementation of a decision-making process that can be tailored to a broad range of environmental, social, economic and cultural circumstances. The provision is the recognition of the sovereign right of a Party to take into account, in import decisions, socio-economic considerations relating to the impacts that living modified organisms have or might have on biodiversity, and it describes the extent to which Parties are entitled to do so.[6]

7. There is a suggestion, on the other hand, that paragraph 1 of Article 26 is voluntary, has a narrow scope, and should not play a prominent role in the implementation of the Protocol.[7] Others suggest that the provision has a broader scope and is an integral part of the implementation of the Protocol.[8]

8. Given that Parties to the Convention on Biological Diversity finally agreed to include Article 26 in the Protocol, it is only logical that Parties could use it to take into account socio-economic considerations, as necessary, based on their social and economic needs and interests, so long as the measures taken are consistent with the Protocol and their other international obligations.[9] The challenge

[2] United Nations General Assembly, *Agenda 21: Programme of Action for Sustainable Development*, chapter 16 at para 38.

[3] Frederic Perron-Welch, "Socioeconomics, Biosafety and Sustainable Development" in Marie-Claire Cordonier Segger, Frederic Perron-Welch & Christine Frison, eds, *Legal Aspects of Implementing the Cartagena Protocol on Biosafety* (New York: Cambridge University Press, 2013) 147 at 147.

[4] Georgina Catacora-Vargas, "Socio-Economic Considerations under the Cartagena Protocol on Biosafety: Insights for Effective Implementation" (2012) 14:3 Asian Biotechnology and Development Review 1.

[5] Doreen Stabinsky, "Bringing Social Analysis Into a Multilateral Environmental Agreement: Social Impact Assessment and the Biosafety Protocol" (2000) 9:3 Journal of Environment & Development 260.

[6] *Ibid*; Perron-Welch, *supra* note at 147; Ruth Mackenzie et al., *An Explanatory Guide to the Cartagena Protocol on Biosafety* (Gland and Cambridge: IUCN, 2003).

[7] Jose Benjamin Falck-Zepeda & Patricia Zambrano, "Socio-economic Considerations in Biosafety and Biotechnology Decision Making: The Cartagena Protocol and National Biosafety Frameworks" (2011) 28:2 Review of Policy Research 171.

[8] Catacora-Vargas, *supra* note; Perron-Welch, *supra* note.

[9] Secretariat of the Convention on Biological Diversity, *supra* note; Worku Damena Yifru, Mai Fujii & Kathryn Garforth, "The Decision-Making Procedures of the Protocol" in Marie-Claire Cordonier Segger, Frederic Perron-Welch & Christine Frison, eds, *Legal Aspects of Implementing the Cartagena Protocol on Biosafety* (New York: Cambridge University Press, 2013) 78; Kathryn Garforth, Worku Damena Yifru & Mai Fujii, "Biosafety, the Cartagena Protocol, and Sustainable Development" in Marie-Claire Cordonier Segger, Frederic Perron-Welch & Christine Frison, eds, *Legal Aspects of Implementing the Cartagena Protocol on Biosafety* (New York: Cambridge University Press, 2013) 19.

lies in identifying the socio-economic considerations and integrating them into decisions that are consistent with international obligations. There is an opportunity to help each other and cooperate in this regard by providing guidance to Parties that choose to implement paragraph 1 of Article 26 as part of their domestic decision-making process in a manner that is compliant with their other international obligations.

9. The Protocol provides, in its Article 10, rules for taking a decision on transboundary movements of living modified organisms intended for introduction into the environment. That provision requires that Parties making a decision take into account potential effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. Where there is a lack of scientific certainty, Parties can take a precautionary approach.[10] A precautionary approach in the socio-economic considerations context could mean that where there is an actual or potential impact on the conservation and sustainable use of biological diversity arising from the transfer, handling and use of a living modified organism, a Party may use paragraph 1 of Article 26 to justify taking into account associated socio-economic considerations when making a decision.[11]

10. Possible ways of taking socio-economic considerations into account include procedures for assessing and addressing socio-economic impacts as part of or separate from risk assessment and management, and subjecting decisions on the import of living modified organisms to prior public consultation processes involving communities that will be directly affected by the decision.[12] Risk assessment procedures under the *Agreement on Sanitary and Phytosanitary Measures* (SPS Agreement) similarly recognize a mix of scientific and socio-economic considerations. Procedures under the SPS Agreement differ depending on whether the risk is to animal or plant life or health, or rather, to human life or health. When assessing risks to plants and animals, members are to take into account economic factors such as the impact that the establishment or spread of a pest or disease could have on the production or sales of the affected crops, as well as the costs of controlling or eradicating it.[13] The *Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress* may have some relevance to the discussion of socio-economic considerations, because it provides definitions for damage (adverse impact) to biodiversity, and remedies for damage suffered. The *Voluntary guidelines on biodiversity-inclusive impact assessment* adopted by the eighth meeting of the Conference of the Parties to the Convention on Biological Diversity may also be of some use in the biosafety context.[14]

II. TRENDS IN LEGISLATION, POLICIES AND INSTITUTIONAL FRAMEWORKS

11. Most countries do not seem to have legislation expressly providing for socio-economic considerations in the process of approving living modified organisms.[15] In 2010, Spök identified only sixteen Parties that took into account socio-economic considerations. Based on our research, however, socio-economic impacts of living modified organisms (LMOs) are considered in legislation, policies and institutional frameworks in a greater number of countries, as detailed below.

(i) Africa

12. African countries are steadily moving towards addressing socio-economic considerations in their domestic legal frameworks, albeit to differing degrees. More than fifteen Parties have specific legislation

[10] Mackenzie et al., *supra* note.

[11] *Ibid.*

[12] *Ibid.*

[13] *Ibid.*

[14] See Guidelines: http://www.cbd.int/doc/decisions/cop-08-dec-28-en.pdf and background document: http://www.cbd.int/doc/publications/imp-bio-eia-and-sea.pdf.

[15] Hartmut Meyer, "Systemic Risks of Genetically Modified Crops: The Need for New Approaches to Risk Assessment" (2011) 23:7 Environmental Sciences Europe.

or references in existing legislation to the consideration of socio-economic impacts of the introduction of living modified organisms. This is in contrast to almost forty Parties which, as of 30 May 2012, have developed national biosafety frameworks.[16] Capacity, in terms of both technical expertise and available resources, are two key challenges to implementation.[17]

13. **Burkina Faso**, as a member of the West African Economic and Monetary Union (UEMOA), addresses socio-economic considerations in *Loi n° 005-2006/AN Portant Regime de Securite en Matiere de Biotechnologie au Burkina Faso*, which sets in place a biosafety regime.[18] Article 30 states that the competent national authority may only issue a permit for the importation of a living modified organism if it benefits the country without causing significant risks to human health or the environment, contributes to sustainable development, and does not affect the socio-economic environment.[19] Article 67 indicates that the user of a living modified organism is responsible for any damage done, including socio-economic harm.[20] Chapter 8.1 of the associated National Biosecurity Regulations outlines that the National Biosafety Agency may issue a permit if it considers the importation of a living modified organism to benefit the country without causing significant risks to human health or the environment,[21] contribute to sustainable development,[22] and does not affect the socio-economic environment.[23]

14. **Cameroon** addresses socio-economic considerations in the *Law to lay down safety regulations governing modern biotechnology in Cameroon*.[24] The second objective of the Law is to provide a mechanism for evaluating and governing the risks associated with the use, release and cross-border movement of living modified organisms, considering the socio-economic effects on human and environmental health in relation to traditional technology.[25] Prior to any use of a living modified organism a strict risk assessment must be done, taking into consideration, on a case-by-case basis, the ecological, socio-economic and ethical consequences, in a scientific manner and on the basis of the precautionary principle, where feasible.[26] Socio-economic considerations are addressed under Part IV of the Law which requires a mandatory assessment of the ethical and socio-economic impacts on local populations. The study, which is at the cost of the applicant,[27] covers effects on health, the traditional market and export earnings, production systems, ethical, moral and social considerations, and the economic value of traditional species likely to be affected by the introduction of the living modified organisms.[28] Lastly, appropriate emergency measures must be developed, in collaboration with the appropriate authorities, in the case of an accidental release, to minimize the socio-economic impact.[29]

15. **Ethiopia** has constitutional provisions that require that health, environmental well-being and the general socio-economic conditions of the country be protected from risks that may arise from modified

[16] UNEP, UNEP-GEF National Biosafety Frameworks Project.

[17] UNEP, Building Biosafety Capacity in Developing Countries: Experiences of the UNEP-GEF Project on Development of National Biosafety Frameworks, at 13, available at http://www.unep.org/Biosafety/files/UNEPGEFstudyVersion170605.pdf.

[18] Burkina Faso, *Loi n° 005-2006/AN Portant Regime de Securite en Matiere de Biotechnologie au Burkina Faso*.

[19] *Ibid.* Article 30.

[20] *Ibid. Article* 67.

[21] Burkina Faso, *DECRET N° 2004-262, Régulation- Règles Nationales en Matière de Sécurité en Biotechnologie au Burkina*, DECRET N° 2004-262/PRES/PM//MECV/ MAHRH/MS, at Ch 8.1(24).

[22] *Ibid.* at Ch 8.1(25).

[23] *Ibid.* at Ch 8.1(26).

[24] Cameroon, *Law N° 2003/006 of 21 April 2003. Law to lay down safety regulations governing modern biotechnology in Cameroon.*

[25] *Ibid.* at s 4(2).

[26] *Ibid.* at s 20(1) and (2).

[27] *Ibid.* at s 32(2).

[28] *Ibid.* at s 32(1).

[29] *Ibid.* at s 33.

organisms.[30] Under the *Proclamation on Biosafety*, the applicant must undertake a risk assessment.[31] The definition of risk includes "direct or indirect, short, medium or long-term danger that may befall… socio-economic or cultural conditions of local communities or the economic condition of the country"[32] and socio-economic impact is defined as "any direct or indirect adverse effect that results from a transaction on the social or cultural conditions, the livelihood or indigenous knowledge systems or technologies of a local community, including on the economy of the country".[33] *Directive Two: Risk Assessment Parameters for Modified Organisms* confirms that socio-economic considerations must be detailed in the risk assessment document, notably the anticipated changes in the existing social or economic conditions or cultural norms resulting from the transaction, including the possible threats to biological diversity, traditional crops or other products, in particular farmers' varieties and sustainable agriculture; the risks likely to be posed by the possibility of substituting traditional crops, products or indigenous technologies with the transaction; the anticipated socio-economic impacts on loss of genetic diversity, employment, market opportunities and, generally, the means of livelihood of the communities likely to be affected; the changes to the biochemistry and usefulness of the species, including "biopharming" with animals, crops or forage plants to produce medicines or other chemicals and the spread of the changed trait and the consequent reduction of the usefulness of the species, especially to local farming or pastoralist communities; those countries or communities outside of Ethiopia likely to be affected by disruptions to their social or economic welfare; and possible effects within Ethiopia or in neighbouring countries which are contrary to the social, cultural, ethical or religious values of communities.[34]

16. **Ghana** addresses socio-economic considerations in Article 21 of the *Biosafety Act, 2011*, which requires that the Board of the National Biosafety Authority take into account socio-economic considerations arising from the impact of a proposed activity and of the genetically modified organisms on the environment in reaching a final decision on an import application.[35] Until new regulations are adopted, the 2007 Regulations remain in force.[36] They state that the National Biosafety Committee shall take a decision based on the results of the risk assessment and, where applicable, comments received from the public and any other socio-economic considerations.[37] The Committee was given the task of elaborating further guidance in the form of Guidelines in line with the national priorities and sustainable development agenda in the area of the socio-economic development of the country,[38] but they have not yet been completed.

17. **Kenya** addresses socio-economic considerations in Article 29(1) of the *Biosafety Act*, which requires the National Biosafety Authority to consider, among other things, socio-economic considerations arising from the impact of the genetically modified organism on the environment.[39]

18. **Madagascar** requires an environmental impact assessment for projects that use living modified organisms; ir must elaborate upon the socio-economic measures envisaged to prevent, reduce and

[30] *Constitution of Ethiopia*, Articles 44 and 92; Ethiopia, *Proclamation on Biosafety (No.655/2009)*, Preamble.

[31] *Proclamation on Biosafety* at Art 6(1).

[32] *Ibid.* at Art 2(9).

[33] *Ibid.* at Art 2(8).

[34] Ethiopia, *Directive No. 02/ 2009 issued to determine Risk Assessment Parameters for Modified Organisms*, at 4.7.

[35] Ghana, *Biosafety Act 2011 – Act 831*, at Article 21(d).

[36] Ghana *Legislative Instrument 1887 (2007) on Biosafety (Management of Biotechnology)*.

[37] *Ibid.* at Art 12(6)(d).

[38] *Ibid.* at Art 26.

[39] Kenya, *The Biosafety Act No.2 of 2009*, at Article 29(1)(e). This only applies for environmental releases.

compensate for the harmful consequences of the project on the environment. These will then be integrated into the environmental management plan for the project.[40]

19. **Mali** provides a governance structure for living modified organisms in the *Loi Relative à la sécurité en Biotechnologie en République du Mali*, which incorporates socio-economic considerations into decision-making by identifying socio-economic considerations in the risk assessment criteria and specifically defining socio-economic impacts.[41] Tight restrictions apply to the issue of a license by the Competent National Authority. Notably, an authorization may not be provided unless the Authority believes or decides that the import, transit, confined use, dissemination/release or placing on the market of a living modified organism or product thereof benefits the country without causing risks or major risks to human health, biodiversity and the environment generally; contributes to sustainable development; has no negative socio-economic impacts; and respects ethical values and takes into account the concerns of communities and does not impact the knowledge and technologies of these communities.[42] Beyond requiring the project to have no negative socio-economic impacts, and contributing to sustainable development in a socially acceptable fashion, if damage does occur, the injured party has considerable time (10 years) to seek redress based on a broad definition of socio-economic harm, including nuisances and damages caused, indirectly or indirectly, by the organism or product thereof to: the economy; social and cultural conditions, notably negative effects on traditional ways of life, knowledge or technologies of one or multiple communities; damages and losses caused by public troubles caused by the organism or product thereof; the total or partial destruction of industrial or agricultural production systems, the loss of harvests, the contamination of soils; the damages caused to biodiversity, to the economy of a region and all other damages and indirect interests.[43] Furthermore, any group or person may bring a claim for redress for any socio-economic harm,[44] with added criminal sanctions of up to 20 years for serious socio-economic impacts.[45]

20. **Mauritius** regulates biosafety through the *Genetically Modified Organisms Act 2004*, which requires the consideration of direct or indirect impacts on the environment and human health,[46] and socio-economic impacts on people and society, when examining an application for a permit to use living modified organisms.[47]

21. **Namibia** regulates living modified organisms through the *Biosafety Act 2006* in order to provide adequate protection to biodiversity, taking into account social, cultural, ethical and economic considerations.[48] In determining if an application for the use of a living modified organism is in the public interest, the Biosafety Council and Minister may take into account the likelihood that the use will contribute to sustainable development, undermine indigenous knowledge or technology, or affect the social and economic advancement of people and society.[49]

22. **Nigeria** adopted the Nigeria Biosafety Guidelines in 2001. They state that decision-making procedures shall take into consideration risk assessment, which involves scientific, socio-economic,

[40] Madagascar, *Decret N° 99-954 du 15 Decembre 1999 modifié par le décret n° 2004-167 du 03 février 2004 relatif à la mise en compatibilité des investissements avec l'environnement (MECIE)*, at Article 11.

[41] Mali, *La Loi Relative à la sécurité en Biotechnologie en République du Mali* (2008), at Article 2(g) and (l).

[42] *Ibid.* at Article 26.

[43] *Ibid.* at Article 63.

[44] *Ibid.* at Article 65.

[45] *Ibid.* at Article 69-70.

[46] Mauritius, *The Genetically Modified Organisms Act, 2004*, at s 6(2)(a).

[47] *Ibid.* at s 6(2)(b).

[48] Namibia, *Biosafety Act 2006*, at Article 2(a).

[49] *Ibid.* at Article 25(5)(c).

cultural and ethical concerns.[50] Socio-economic considerations are subsequently defined as (a) Anticipated changes in the existing social and economic patterns resulting from the introduction of the GMO or product thereof; (b) Possible threats to biological diversity, traditional crops or other products and, in particular, farmers' varieties and sustainable agriculture; (c) Impacts likely to be posed by the possibility of substituting traditional crops, products and indigenous technologies through modern biotechnology outside of their agro-climatic zones; (d) Anticipated social and economic costs due to loss of genetic diversity, employment, market opportunities and in general, means of livelihood of the communities likely to be affected by the introduction of the GMO or product thereof; (e) Possible countries and/or communities to be affected in terms of disruptions to their social and economic welfare; (f) Possible effects which are contrary to the social, cultural, ethical and religious values of communities arising from the use or release of the GMO or product thereof.[51]

23. **Senegal** takes socio-economic considerations into account in the risk assessment via the *Loi sur la biosécurité au Sénégal*.[52] Article 11 outlines that a risk assessment, based on available information, must be conducted on living modified organisms to identify and evaluate potential adverse effects on biodiversity, human/animal health and socio-economic considerations, and to pinpoint potential mitigation measures.[53] Following assessment, the National Biosafety Authority publishes through media channels an invitation for public comment on the application, with any person or organization granted the right to comment.[54] The Minister of the Environment, based on the recommendations made by the National Biosafety Authority, makes the final decision, considering the risk assessment and descriptive information along with specific consideration of the economic, social, ethical, religious and cultural considerations arising from the use.[55] Any damage, including socio-economic, that occurs as a result of the living modified organism use is deemed to be the strict responsibility of the owner.[56]

24. **Togo** as a member of UEMOA addresses socio-economic considerations in the *Loi sur la prévention des risques biotechnologiques* with the goal of preventing risks arising from living modified organisms.[57] Socio-economic considerations are required as a component of the risk assessment process,[58] and are highlighted in the definition of risk assessment.[59] The law defines socio-economic impacts as the direct or indirect effects on the economy; sociocultural practices; livelihood conditions; and endogenous systems of knowledge or technology resulting from the import, dissemination, confined use or placing on the market of genetically modified organisms and products thereof.[60] The legislation is based on the principles of precaution, prevention, polluter pays and public participation as a means to minimize the socio-economic risks arising from living modified organisms.[61] No decision on any use of a living modified organism can occur without an assessment of the impacts on socio-economic considerations, human health, biodiversity and cultural values,[62] and no permit can be issued unless the use of the living

[50] Nigeria, *Nigeria Biosafety Guidelines* (2001) at 7(a).

[51] *Ibid*, Annex I, p 26.

[52] Sénégal, *Loi sur la biosécurité au Sénégal (n° 2009-27 du 8 juillet 2009 portant sur la Biosécurité).*

[53] *Ibid.* at Article 11.

[54] *Ibid.* at Article 12; Annex 2.

[55] *Ibid.* at Article 13.

[56] *Ibid.* at Article 45.

[57] Togo, *Loi 2009-001 sur la prévention des risques biotechnologiques* (2009), at Article 1-2.

[58] *Ibid.* at Article 68.

[59] *Ibid.* at Article 5(7). "Évaluation des risques: mesures visant à estimer les conséquences directes ou indirectes, la probabilité pour que ces conséquences surviennent et l'ampleur de ces impacts potentiels sur la santé humaine et/ou animale, la diversité biologique, les tissus socio-économiques ainsi que les valeurs culturelles de l'utilisation des OGM et/ou de leurs produits dérivés."

[60] *Ibid.* at Article 5(10).

[61] *Ibid.* at Article 6.

[62] *Ibid.* at Article 30.

modified organism is beneficial to the socio-cultural fabric of society, in support of sustainable development, and is sensitive to ethical, religious and community concerns.[63] Any new information pertaining to socio-economic considerations which is found following the issue of the permit must be forwarded to the national authority,[64] with any living modified organism which poses a risk to human health, biodiversity or socio-economic considerations to be destroyed.[65] In evaluating the risks posed by living modified organisms, the assessment focuses on identifying novel characteristics, estimating the likelihood of adverse effects occurring, and appraising the impacts on socio-economic considerations, biodiversity and cultural values.[66] Any damage resulting from the use of the living modified organism, including to the socio-economic considerations and socio-cultural values of the country, and the cost of restoration or rehabilitation,[67] is the responsibility of the permit holder, and a broad definition of socio-economic harm is established.[68]

25. **Zambia** passed the *Biosafety Act* of 2007 to ensure that the use of living modified organisms avoids socio-economic impacts and harms to human and animal health, and is governed by a mechanism for liability and redress for any harm caused.[69] When considering living modified organism applications, no approval shall be given unless there is firm and sufficient evidence of only "minimum risk" posed to human and animal health, traditional crops, and biological diversity.[70] Regardless of the level of evidence, preventative measures to address suspected threats posed by living modified organisms,[71] no application will be approved unless it does not have adverse socio-economic impacts.[72] Article 27 outlines that the National Authority may impose measures as needed to avoid adverse effects on socio-economic conditions,[73] require parties to take such measures to avoid socio-economic harm, and in the case of emergencies, take measures as necessary in the face of an imminent or serious danger,[74] with costs or restoration at the party's expense.[75] Lastly, any person or organization may seek redress for harm to socio-economic conditions.[76] The National Biotechnology and Biosafety Policy adopted in 2003 also has socio-economic impacts as one of its guiding principles – e.g., the direct or indirect effects to the economy, socio or cultural practices, livelihoods, indigenous knowledge systems, or indigenous technologies as a result of the import, contained use, deliberate release or placing on the market of GMO(s) or products thereof.[77]

26. **Zimbabwe** addresses socio-economic considerations under the *National Biotechnology Authority Act* of 2006, which applies to the import, export, contained use, release or placing on the market of any product of biotechnology that is likely to have adverse effect on human health, the environment, the

[63] *Ibid.* at Article 31.

[64] *Ibid.* at Article 34.

[65] *Ibid.* at Article 57.

[66] *Ibid.* at Article 71, 73.

[67] *Ibid.* at Article 97.

[68] *Ibid.* at Article 98. "La responsabilité s'étend aussi aux préjudices causés directement ou indirectement par les OGM et/ou leurs produits dérivés au tissu socio-économique et aux valeurs culturelles. Les préjudices visés par la présente loi sont notamment la destruction totale ou partielle de productions industrielles ou agricoles, la perte de récoltes, la contamination des sols, la perturbation des écosystèmes, la perte de la vie et autres atteintes à la santé humaine ou animale, les perturbations à l'économie d'une zone ou aux valeurs culturelles d'une communauté."

[69] Zambia, *Biosafety Act 2007*, at *Preamble.*

[70] *Ibid.* at Article 18(1); Fourth Schedule – Risk Assessment: (4)(g).

[71] *Ibid.* at Article 18(3).

[72] *Ibid.* at Article 19.

[73] *Ibid.* at Article 27(1)(b).

[74] *Ibid.* at Article 27(1)(e).

[75] *Ibid.* at Article 27(1)(g).

[76] *Ibid.* at Article 37(7).

[77] Zambia, *National Biotechnology and Biosafety Policy* (2003) at 5.5.

economy, national security or social norms and values.[78] The National Biotechnology Board of the National Biotechnology Authority has the power to issue guidelines on the requirements and procedures for the importation and exportation of products of biotechnology that are likely to have an adverse effect on human health, the environment, the economy, national security and social norms and values.[79] It does not appear that such guidelines have been adopted.

(ii) Americas

27. **Belize** requires evaluation of living modified organisms under the Hazard Analysis and Critical Control Point System (HACCP) under the *Belize Agricultural Health Authority Act*.[80] Socio-economic risks are identified in the First Schedule including the spread of food-borne diseases from unmonitored and uncontrolled food products leading to significant losses in foreign currency earnings, reduction in export trade in the food products sector, reduction in tourism, erosion of consumer confidence and increased litigation costs.[81]

28. **Brazil** has two main legal instruments that relate to socio-economic considerations. The *National Biosafety Law (Law 11.105/2005)* indicates that the National Biosafety Council (CNBS) is responsible for analyzing, when so requested by the National Technical Biosafety Commission (CTNBio – the competent national authority), aspects related to the national interest and socio-economic convenience and opportunity of requests for permission for the commercial use of genetically modified organisms and their derivatives.[82] *Decree 5.591/2005,* which regulates the *National Biosafety Law (Law 11.105/2005),* indicates that the CNBS is to evaluate all matters including socio-economic considerations and that the effect of the technical decision from CTNBio, if one had been issued in the specific case, shall be suspended until the final decision by CNBS.[83]

29. **Colombia** addresses socio-economic considerations in *Decreto 4525 of 2005*, which outlines a regulatory framework for living modified organisms that may have adverse effects on the environment and biodiversity, also taking into account risks to human health, agricultural productivity and production.[84] An objective of the risk assessment process is to identify and assess the potential direct and indirect effects on human health, the environment and biodiversity, agricultural production or productivity, and when required, the potential socio-economic effects that may result from the introduction of a living modified organism.[85]

30. **Costa Rica** addresses socio-economic considerations in the *Reglamento para el Desarrollo; Promoción y Fomento de la Actividad Agropecuaria Orgánica*,[86] which provides for measures to protect organic production from the risk of contamination from genetically modified organisms. In considering an application for planting genetically modified organisms and if there exists a reasonable doubt about the potential negative effects on established organic production in the region, the State Phytosanitary Service shall also take into account the potential impacts associated with the technical package associated with the introduction of genetically modified organisms, and the harm to the knowledge, innovations and practices

[78] Zimbabwe, *National Biotechnology Authority Act*, Act 3 of 2006, at Article 3(2)(b).

[79] *Ibid.* at Article 22(2)(k).

[80] Belize, *Belize Agricultural Health Authority Act* (2003).

[81] *Ibid.* at First Schedule.

[82] Brazil, *Law 11.105/2005 (National Biosafety Law)*, at Article 8(1).

[83] Brazil, *Decree 5.591/2005; which regulates Law 11.105/2005*, at Article 50.

[84] Colombia, *Decreto 4525 of 2005*, at Article 2.

[85] *Ibid.* at Article 16(b).

[86] Costa Rica, *Decreto Ejecutivo Nº 35242-MAG-H-MEIC Reglamento para el Desarrollo; Promoción y Fomento de la Actividad Agropecuaria Orgánica*.

of local communities and indigenous peoples related to biodiversity, in accordance with the provisions of the Convention on Biological Diversity.[87]

31. **Cuba** governs biosafety through *Resolución No. 180/2007*, which establishes that the Centro Nacional de Seguridad Biológica (CNSB) is the competent authority for issuing biosafety licenses.[88] In making a decision on a living modified organism, the CNSB must take into account socio-economic considerations resulting directly from the risk posed by the activity proposed.[89]

32. **Mexico** addresses socio-economic considerations in the *Ley de Bioseguridad de Organismos Geneticamente Modificados*.[90] In formulating biosafety policy, the State will cooperate in sharing information on the economic impacts of living modified organisms on indigenous and local communities,[91] support and strengthen scientific and technological research, and encourage the development of sufficient knowledge to evaluate the socio-economic risks associated with a living modified organism.[92] Pursuant to Article 64, the applicant can submit additional ways to study the possible socio-economic impacts of a living modified organism, but the proposed methods must be supported with scientific and technical evidence verifying validity.[93] The National Information System on Biosafety established by CIBIOGEM is also tasked with undertaking studies of the socio-economic impacts of living modified organisms,[94] with particular focus on the socio-economic effects of living modified organisms on indigenous and local communities.[95]

33. **Panama** created the National Biosafety Commission in *Ley No. 48*,[96] which must consider, in addition to technical concepts, the socio-economic and cultural implications of national interest when making a decision regarding living modified organisms, thus ensuring the protection of health, biodiversity and the environment.[97]

34. **Peru** in *Ley* N°27104 outlines the application of the precautionary principle to assess the negative impacts to human health, the environment and biodiversity.[98] The *Reglamento de la Ley de Prevención de Riesgos Derivados del uso de la Biotecnología* outlines that living modified organism registration will only proceed after a risk assessment showing minimal risk to human health, the environment and biodiversity.[99] *Ley* N°29811 passed in 2012, establishes a decade-long moratorium on living modified organisms, covering all living modified organisms regardless of state of development or use,[100] and empowers the National Agricultural Innovation Institute, through the Biotechnology and Competitive

[87] *Ibid.* at Article 55(c).

[88] Cuba, *Resolución No. 180/2007 Reglamento para el otorgamiento de la Autorización de Seguridad Biológica*, at Article 11.

[89] *Ibid.* at Article 26(d).

[90] Mexico, *Ley de Bioseguridad de Organismos Genéticamente Modificados* (2005), available at: http://www.diputados.gob.mx/LeyesBiblio/pdf/LBOGM.pdf.

[91] *Ibid.* at Article 9(17).

[92] *Ibid.* at Article 28.

[93] *Ibid.* at Article 64.

[94] *Ibid.* at Article 108.

[95] *Ibid.* at Article 108(V).

[96] Panama, *Ley No. 48 (de 8 de agosto de 2002) Que crea la Comisión Nacional de Bioseguridad para los Organismos Genéticamente Modificados y dicta otras disposiciones*.

[97] *Ibid.* at Article 9.

[98] Peru, *Ley 27104: Ley de Prevención de Riesgos Derivados del Uso de la Biotecnología* (1999), at Art 10, available at: http://www.inia.gob.pe/genetica/LEY%20N%C2%BA%2027104.pdf.

[99] Peru, *Reglamento de la Ley de Prevención de Riesgos Derivados del uso de la Biotecnología* (DS No. 108-2002-PCM) at Article 19.

[100] Peru, *Ley N°29811: Ley que establece la Moratoria al Ingreso y Producción de Organismos Vivos Modificados al Territorio Nacional por un período de 10 años (DECRETO SUPREMO Nº 008-2012)*, at Article 3(g).

Development Program, to promote native biotechnology to ensure preservation and market competitiveness.[101]

35. **Uruguay** indicates in *Decreto 353/008* that the case-by-case authorization for use of living modified organisms is contingent upon successfully passing a risk assessment which assesses environmental, biodiversity, health and socio-economic considerations.[102]

36. **Venezuela** adopted the *Ley Organica del Ambiente* in 2006.[103] It states that all activities that may degrade the environment, such as the use of LMOs, must be subject to an environmental impact assessment, which includes an environmental and sociocultural impact study;[104] a technical document that integrates the evidence in order to allow for informed decisions on the environmental and social implications of the development proposal.[105] The *Ley de Gestión de la Diversidad Biológica* was also adopted 2008,[106] which states that the management of biotechnology should contribute to poverty reduction, respect for dignity, human rights and the welfare of humanity.[107]

(iii) Asia and Pacific

37. **Indonesia** addresses socio-economic considerations in the 2005 *Regulations on Biosafety*, which are based in the precautionary approach and aimed at contributing to ensuring environmental safety, food safety and or animal feed safety based on an accurate scientific method by considering religious, ethic, socio-cultural and esthetic norms.[108]

38. **Malaysia**, pursuant to the *Biosafety Act, 2007*, empowers the National Biosafety Board to consider socio-economic considerations where there are cases of scientific uncertainty.[109] This is clarified in the Biosafety (Approval and Notification) Regulations 2010 with the socio-economic considerations that may be considered, including (a) the changes in the existing social and economic patterns and means of livelihood of the communities that are likely to be affected by the introduction of the living modified organisms or products of such organisms, and (b) the effects on the religion, social, cultural and ethical values of communities arising from the use or release of the living modified organisms or products of such organisms.[110]

39. **Philippines** identifies, in *Executive Order 514 Establishing the National Biosafety Framework*, that socio-economic, cultural and ethical considerations and risks, particularly to small farmers, indigenous people, women, small business and the research community are to be considered in implementing the domestic regulatory and legal framework around living modified organisms.[111] The National Committee on Biosafety of the Philippines (NCBP), a multi-stakeholder body made up of relevant government departments and representatives from indigenous communities, scientific and

[101] *Ibid.* at Article 24.

[102] Uruguay, *Decreto 353/008. Bioseguridad de vegetales y sus partes genéticamente modificadas (*2008), at Article 1.

[103] Venezuela, *Ley Organica del Ambiente* (2006).

[104] *Ibid.* at Articles 4 and 80.

[105] *Ibid.* at Article 3.

[106] Venezuela, *Ley de Gestión de la Diversidad Biológica* (2008).

[107] *Ibid.* at Article 44.

[108] Indonesia, *Regulation of the Government of the Republic Indonesia on Biosafety of Genetically Engineered Product* (2005), at Article 3.

[109] Malaysia, *Biosafety Act 2007 (Act 678)*, at Article 35.

[110] Malaysia, *Biosafety (Approval and Notification) Regulations 2010*, at Article 25. See also Letchumanan Ramatha & Johnny Andrew, "Socio-economic Aspects in Decision-Making in the Context of the Biosafety Protocol: Malaysia's Experience and Case Studies" (2012) 14:3 Asian Biotechnology and Development Review 19.

[111] Philippines, *Executive Order No. 514 Establishing the National Biosafety Framework* (2006), at Sec 2.5.

economic sectors,[112] may issue guidelines on the conduct of socio-economic impact evaluations of biosafety decisions.[113] The NCBP assists departments in implementing the National Biosafety Framework, monitors progress on implementation, facilitates research and knowledge sharing to better understand the short-term–long-term risks associated with living modified organisms,[114] and supports designated governmental departments in making decisions concerning living modified organism use and research.[115] Lastly, biosafety decisions must be made taking into account socio-economic considerations, consistent with Article 26 of the Protocol, in assessing risks, with a particular regard to the value of biodiversity to indigenous and local communities.[116]

40. **New Zealand** addresses socio-economic considerations in the use of living modified organisms through the *Hazardous Substances and New Organisms Ac*t (HSNO Act), which is aimed at preserving the health and safety of the environment and safeguarding ecosystems by preventing and mitigating negative effects from the use of hazardous substances and new organisms, which include living modified organisms.[117] The Act provides for principles and specifies relevant matters that authorities are required to recognize and take into account in exercising their functions under the Act, which include the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural well-being and for the reasonably foreseeable needs of future generations;[118] the sustainability of all native and valued introduced flora and fauna; the intrinsic value of ecosystems; public health; the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, *waahi tapu*, valued flora and fauna, and other *taonga*; the economic and related benefits and costs of using a particular hazardous substance or new organism, and New Zealand's international obligations.[119]

41. **Republic of Korea** requires the living modified organism to be put under a risk assessment by the central administrative agencies, which shall assess the risk of the subject living modified organism and will decide whether to give approval or not after taking into consideration the social and economic impact of the living modified organism on the value of domestic biological diversity,[120] and may prohibit or restrict the import or production of the living modified organism based on socio-economic considerations.[121]

(iv) Europe

42. **France** regulates genetically modifies organisms under Chapter 5, Title 3 of the Environmental Code, which governs the prevention of pollution, risks and nuisances.[122] The Code states that GMOs cannot be cultivated, commercialized or used except with respect for the environment and public health, agricultural structures, local ecosystems and certified non-GMO production and commercial supply chains, and in all transparency. Authorization decisions cannot be made until an independent and transparent appraisal of risks to the environment and public health is made, assured by collective expertise

[112] *Ibid.*, at Sec. 4.2.

[113] *Ibid.*, at Sec. 4.6.1.5.

[114] *Ibid.*, at Sec 4.6

[115] *Ibid.*, at 4.12.

[116] *Ibid.*, at 5.4.

[117] New Zealand, *Hazardous Substances and New Organisms Act* (1996), at Article 4.

[118] *Ibid.*, at Article 5.

[119] *Ibid.* at Article 6, and Annex F.

[120] Republic of Korea, *The Act on Transboundary Movements of Living Modified Organisms*, Law No. 6448 of 2001, at Article 8 (5).

[121] *Ibid.*, at Article 14(1)(c).

[122] France, *Code de l'environnement*, Partie législative, Livre V : Prévention des pollutions, des risques et des nuisances, Titre III : Organismes génétiquement modifiés.

and conducted according to the principles of competence, plurality, transparency and impartiality. The Code also guarantees the liberty to consume and produce with or without GMOs, so long as it does not adversely affect the integrity of the environment and the particularities of traditional cultures and quality, which is guaranteed in respect for the principles of precaution, prevention, information, participation, the responsibilities inscribed in the Charter of Environment of 2004 and in respect of EU dispositions.[123] France amended its *Code de L'envirironnement* through the adoption of *Loi n° 2008-595 du 25 juin 2008 relative aux organismes génétiquement modifiés* to establish a High Council on Biotechnology, whose objective is to inform the government on all pertinent questions on living modified organisms or any other biotechnology and formulate advice on the evaluation of risks to public health and the environment that may be presented by the confined use or intentional introduction of GMOs, as well as on the subject of biological surveillance. The High Council can investigate any question under its jurisdiction and propose, in case of risk, all measures to protect the environment and public health, and must render an opinion on each application approval or permission for contained use or deliberate release of genetically modified organisms, in accordance with the deadlines set by the European Community, and can carry out all assessments, analyses or studies it deems necessary. The Council is composed of both a Scientific Committee and an Economic, Ethical and Social Committee.[124] For the deliberate release of genetically modified organisms, the President of the High Council forwards the opinion of the Scientific Committee to the Economic, Ethical and Social Committee, which examines the Scientific Committee's advice and elaborates its recommendations. The advice of the High Council, composed of the reports of both committees, is sent to the competent authority. The advice consists of both a risk evaluation and an evaluation of the benefits, and reports on divergent positions expressed.[125]

43. **Italy** in Legislative Decree No. 224 requires the Competent National Authority to consider the compatibility of the deliberate release or the placing on the market of the LMOs and the need for protection of agrobiodiversity, of agricultural systems and the food chain, with particular reference to local products, organic agricultural production and quality when granting an approval.[126]

44. **Latvia** aims to achieve a high level of safety in all stages of circulation of GMOs in order to prevent the negative impact on human and animal health or the environment, to preserve biological diversity, to promote the development of sustainable agriculture and biotechnology, as well as the co-existence of genetically modified crops concurrently with organic and conventional farming.[127] A decision related to the circulation of GMOs must take into account the principle of sustainable development, which provides that the circulation of GMOs may be permitted if the relevant activity is aimed at promotion of the national economic development and the basic principles of sustainable development and preservation of biological diversity specified in the regulatory enactments regulating environmental protection.[128]

45. **Norway** aims to ensure that the production and use of living modified organisms is done in a socially acceptable manner, stating that the purpose of the 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."[129] An impact assessment is used for living modified

[123] *Ibid*, Article L531-2-1.

[124] France, *Environmental Code*, Article L. 531-4.

[125] *Ibid*, Article L. 531-4-1.

[126] Italy, *Legislative Decree N. 224 of 8 July 2003: Enforcement of Directive 2001/18/CE on the deliberate release into the environment of genetically modified organisms*, at Article 2, available at: http://www.governo.it/biotecnologie/fonti_normative/d.%20l.vo%208.7.2003,%20n.224.pdf.

[127] Latvia, *Law On Circulation of Genetically Modified Organisms*, section 2.

[128] *Ibid*, Section 3.

[129] Norway, *Act relating to the production and use of genetically modified organisms* (1993) amended (2005), at Preamble.

organisms for any production and use of living modified organisms, be it contained use[130] or deliberate release,[131] aimed at minimizing the negative socio-economic effects.[132] Further, deliberate release can only occur where no risks to society are present and where the use is likely to benefit society and/or promote sustainable development, with "considerable weight" given in the decision-making process granted to the socio-economic benefits in question.[133] The impact assessment includes a comprehensive description of the living modified organism,[134] an assessment of the risk and magnitude of potential adverse effects (direct, indirect, immediate, delayed, and cumulative),[135] an ongoing monitoring plan,[136] proposed labeling,[137] and conditions for market introduction.[138] Upon renewal, a new assessment must be done, with the results of the ongoing monitoring included.[139]

Summary

46. This research has identified both commonalities and divergence in the approaches employed to consider socio-economic factors when evaluating a living modified organism. Common approaches include (i) the use of a centralized authority, often a National Biosafety Committee, to govern living modified organism assessment and evaluation of socio-economic considerations; (ii) incorporation of socio-economic considerations into the risk assessment criteria and increasingly a specific definition of socio-economic impacts; and (iii) the use of the principles of precaution and public participation as the basis for legislation. Divergences appear in operational aspects of the legislation and the level of prominence that socio-economic considerations are given. Some Parties refined pre-existing legislation to more effectively evaluate socio-economic considerations, but a majority of Parties found the need to craft specific legislation. Parties approach the question of socio-economic evaluation either directly or indirectly. Parties in Latin America and Africa tended to state explicitly that socio-economic considerations were a factor or that the law is intended to prevent socio-economic harm. Parties also outline the scope of socio-economic considerations to differing depths.

47. Cameroon, for example, outlines explicit factors, the focus being indigenous and local communities and precaution; Mali, Togo and Burkina Faso, as members of UEMOA, all require living modified organisms to benefit society, promote sustainable development and have no negative socio-economic impact, to receive a permit. Norway minimizes risks to socio-economic considerations by restricting access to living modified organisms except those which pose no risk to society and by adding considerable weight in decision-making to the benefits to sustainable development. Some Parties identified the need to establish preventative powers. Indonesia and Cameroon, among others, explicitly state that the law is based in the precautionary principle. Zambia, Mali, Togo and Senegal all indicate that the living modified organism owner is responsible for damage, with Togo defining socio-economic damage broadly, and Mali providing for criminal penalties and economic sanctions for offenders. The Republic of Korea may restrict a living modified organism based on socio-economic considerations, and Peru has established a decade-long moratorium on living modified organism importation. Conversely, some Parties have exhibited a higher tolerance for risk and the sustainable use of biotechnology.

[130] *Ibid.* at Sec. 8.

[131] *Ibid.* at Sec. 9.

[132] *Ibid.* at Sec. 11.

[133] *Ibid.* at Sec 10.

[134] Norway, *Regulations relating to impact assessment pursuant to the Gene Technology Act*, at Sec. 13; Annex 1.

[135] *Ibid.* at Sec. 13; Annex 2.

[136] *Ibid.* at Sec. 13; Annex 3.

[137] *Ibid.* at Sec. 13; Annex 4.

[138] *Ibid.* at Sec. 13.

[139] *Ibid.* at Sec. 14.

48. Socio-economic considerations are addressed in a range of manners by Parties in their policies and institutional frameworks. In their policies, some Parties use expansive definitions of SECs while others focused only on health and/or the environment. A key divergence among Parties centred on how socio-economic considerations were going to be incorporated into the decision-making process. Three general routes were observed: (i) address socio-economic considerations in the risk assessment, (ii) have an independent socio-economic considerations assessment, and (iii) evaluate socio-economic considerations through public participation in the decision-making process. The role of public participation, including the participation of experts, was identified by many countries as a useful way to engage broad groups about socio-economic considerations.

III. TRENDS IN CAPACITY-BUILDING ACTIVITIES

(a) FAO Regional Project on Capacity Building in Biosafety of Genetically Modified Crops

49. Countries in Asia are in different stages of research and development of GMOs, and have different capacities to scientifically evaluate, assess as well as manage the benefits and risks associated with the release and commercial use of individual GMO products. Recognizing the need to establish mechanisms for assessing and managing the potential environmental risks associated with GM crops under the Cartagena Protocol on Biosafety, FAO was asked to provide capacity-building to developing countries in supporting the regional harmonization of biosafety standards, regulations and guidelines to foster better use of resources among the countries and improved national capacities for the implementation and enforcement of regulations that would promote acceptance of modified organisms and the products derived from them.

(b) Norwegian Institute of Gene Ecology (GenØk – Centre for Biosafety)

50. The University of Tromsø (Norway), in cooperation with GenØk- Centre for Biosafety, has been offering biosafety courses over the past several years. The courses are designed to provide policymakers, regulators, scientists and NGOs/civil society leaders, specifically from developing countries (ODA countries), with balanced and critical knowledge, and training, in GE/GMO issues. This capacity-building is expected to enable societies to reap the benefits of genetic engineering in a safe and sustainable way by spreading knowledge on a holistic approach to GE/GMO issues. GenØk - Centre for Biosafety was founded in 1998 and is a non-profit, independent research foundation located at the University of Tromsø and the Research Park. The courses are designed to provide countries with scientific and technical capacity for biosafety assessment and regulation in order for them to be able to implement the Cartagena Protocol on Biosafety nationally, conduct scientific risk assessment and risk management, and address other technical biosafety regulation needs. *Holistic Foundations for Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms* is a theoretical and hands-on course for NGO/civil society leaders, senior scientists, policymakers and regulators from developing countries. This 2-week course is a mix of lectures, group discussions, casework and practical laboratory sessions. 40 participants from ODA countries are given full sponsorship. In addition there are 20 places available for participants with sponsorships from other sources.[140]

(c) International Centre for Genetic Engineering and Biotechnology

51. The International Centre for Genetic Engineering and Biotechnology (ICGEB) annually organizes over 20 meetings, workshops and courses in its Components and Member States, covering subjects at the forefront of biomedical research and biotechnology. In 1997, ICGEB established a dedicated Biosafety Unit aimed at providing its Member States with services related to the safe and sustainable use of biotechnology in agriculture, and in particular to the environmental release of genetically modified

[140] See: http://genok.com/capacity-building/.

organisms (GMOs). Since 2009, it has provided practical training in an approach based on problem formulation, in order to link the policy objectives that drive risk analysis to the assessment of the potential impact(s) of the dissemination of specific GMOs, including socio-economic considerations.[141] In 2011, ICGEB developed a consensus-based document, *Guidance for a Fit-for-Purpose Regulatory Framework for GMOs*, as part of the ICGEB biosafety capacity-building project "Assisting the development of effective safety and regulatory systems for the products of modern biotechnology in sub-Saharan Africa", funded by the Bill & Melinda Gates Foundation. It provides a guideline to assist the development and enhancement of a fit-for-purpose and proportionate regulatory framework for GMOs in agriculture in sub-Saharan African countries which includes a set of regulatory principles and considerations that can be adapted to country-specific legislative and regulatory frameworks, as required by specific social and environmental goals.[142]

(d) International Food Policy Research Institute (IFPRI)

52. The IFPRI Program for Biosafety Systems (PBS) contributes to the implementation of the Cartagena Protocol by supporting partner countries as they develop the policy and legal framework, administrative procedures, technically qualified personnel and outreach mechanisms integral to their national biosafety systems. Its programme of work emphasizes sound science-based decision-making and research, while also addressing socio-economic considerations. The Program works with partner countries in Africa and Asia to develop and implement a programme of activities tailored to biosafety needs identified by local collaborators. The PBS is being implemented by a consortium of partner organizations and Consultative Group on International Agricultural Research (CGIAR) centres with the overall goal of facilitating the inclusion of appropriate biosafety regulations within country-led sustainable development strategies. PBS activities include policy analysis and development, risk assessment, capacity-building in regulatory systems, and communication and public outreach. The programme is active in East Africa, West Africa, Southern Africa, and Southeast Asia.[143]

(e) International Symposium on the Biosafety of Genetically Modified Organisms (ISBGMO)

53. ISBGMO is designed for regulatory authorities, technology developers, academics, non-government organizations, and other credible stakeholders involved in biosafety research and policy. The ISBGMO is a biennial international meeting organized by the International Society for Biosafety Research (ISBR), a society whose membership is composed of individuals with an interest in risk assessment and research related to the environmental risks associated with genetically modified organisms. The ISBGMOs have been offered on a biennial basis since 1990, at various locations throughout the world.[144]

(f) Organization of American States

54. The multinational Organization of American States (OAS) launched a biosafety capacity-building project in March 2002, "Biosafety Regulations in Latin America and the Caribbean within the Framework of the International Biosafety Protocol" with the aim of helping countries to overcome identified weaknesses as regards their capacity to implement the Cartagena Protocol. It aimed to coordinate actions among participating countries in order to improve implementation of the Protocol at the regional level. The first phase of the project was initiated in Chile, Colombia and Peru and was focused on the evaluation

[141] Mark Tepfer, Monica Racovita and Wendy Craig "Putting problem formulation at the forefront of GMO risk analysis" 4(1) GM Crops and Food: Biotechnology in Agriculture and the Food Chain 1-6. See also http://www.icgeb.org.

[142] ICGEB, *Guidance for a Fit-for-Purpose Regulatory Framework for GMOs*, available at: http://www.icgeb.org/~bsafesrv/publications/Consensusdocument.html.

[143] IFPRI Biotechnology and Biosafety Policy.

[144] See: http://www.isbgmo.com/.

of policies and national regulatory systems to inform the identification of needs and the development of a series of capacity-building workshops on biosafety. The second phase of the project extended activities to countries of Central America and the Caribbean including Costa Rica, El Salvador, Grenada, Jamaica, Panama and Trinidad and Tobago. As an aspect of the capacity-building project, a methodology for undertaking socio-economic studies was developed.[145]

(g) Regional Agricultural and Environment Initiatives Network-Africa (RAEIN-Africa)

55. Started in 2004, the Southern Africa Biosafety and Environment Programme (BEP) aims to enable Southern African countries to make informed decisions on modern biotechnology as it relates to environment management through development of legal and technical capacity on biosafety and targets all the 13 countries of the Southern African Development Community (SADC) region. The levels of involvement for the participating countries are split into two categories: Category A countries benefit from all the activities under the BEP programme, while Category B countries benefit from some capacity-building activities.[146]

56. Prior to the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP 6), RAEIN-Africa held a training and strategy-building workshop for SADC negotiators to provide southern African countries with an opportunity to develop a shared understanding of the issues addressed by the COP-MOP. The workshop resulted in a list of priority agenda items for engagement by SADC countries in the preparation of their country positions for COP-MOP 6. Twenty negotiators benefited from the training programme, which was designed to provide negotiators with a comprehensive overview of the key issues, including socio-economic considerations, and delegates were provided with background information on the key issues and suggestions on preparing their national position papers. Delegates identified priority areas and issues of strategic importance at the regional level and discussed mechanisms for strengthening their preparations and participation. Through group discussions, deliberations, classifications and analysis of key agenda issues, participants developed a strategy to formulate a regional position. RAEIN-Africa has created a platform that enabled discussions of some of these issues through capacity-building initiatives conducted in the last few years. In this regard, where possible, the Network will continue to facilitate regional dialogue, cooperation and capacity development in order to create a common understanding on socio-economic considerations and risk assessment and risk management.

(h) Union Économique et Monétaire Ouest Africaine (West African Economic and Monetary Union)

57. The Union Économique et Monétaire Ouest Africaine (UEMOA), supported by the World Bank, held a series of capacity development workshops on the Cartagena Protocol on Biosafety in West Africa under the *Programme Regional de Biosécurité en Afrique de l'Ouest*, which aims to help Benin, Burkina Faso, Côte d'Ivoire, Guinea Bissau, Mali, Niger, Senegal, and Togo to establish and implement a shared biosafety regulatory framework by putting in place necessary environmental and social safeguards. Because socio-economic considerations are integrated into the regional regulatory framework on biosafety, and some member states take a strong position on the issue, educating national actors on how to address socio-economic considerations in line with regional and international rules was important.[147]

[145] For more information, see: http://www.cbd.int/doc/meetings/bs/bscmcb-03/information/bscmcb-03-inf-04-en.pdf.

[146] Category A: Lesotho, Malawi, Mozambique, Namibia, Swaziland, Zambia, Zimbabwe; Category B: Angola, Democratic Republic of the Congo, Madagascar, Mauritius, Tanzania.

[147] See UEMOA, *Cadre de Gestion Environnementale et Sociale pour la Biosécurité* for details on the regional framework.

(i) United Nations Environment Programme (UNEP)

58. After the entry into force of the Cartagena Protocol, UNEP, in collaboration with the Global Environment Facility (GEF) under the GEF Initial Strategy on Biosafety, assisted countries in establishing national biosafety frameworks, promoting information sharing and collaboration, especially at the regional and subregional level, and collaborated with other organizations to assist in capacity-building. Workshops were held to assist in institutional capacity development, human resources capacity development and training, risk assessment and management; scientific, technical and institutional collaboration; technology transfer; public awareness, participation and education in biosafety; socio-economic considerations; and information exchange and data management. This resulted in the consideration of socio-economic issues in decision-making in a number of countries.[148]

59. UNEP-GEF, under its Biosafety Programme, is currently running a Regional Project for Implementing National Biosafety Frameworks in the Caribbean Sub-region which is expected to be completed by mid-2015. The project views socio-economic considerations as a key challenge needing special attention. It recognizes the need for guidance on undertaking socio-economic and environmental impact and indicates training in socio-economic impact assessment in the context of LMOs as a capacity-building need in the implementation and operation of national biosafety frameworks in the Caribbean Region. Experience gained in recommending biosafety decisions and biosafety measures, based on LMO risk assessments and science-based criteria coupled with socio-economic considerations, is an expected output of the project.[149]

(j) University of Tsukuba biotechnology-biosafety courses and workshops

60. The University of Tsukuba in Japan offers a one-week biotechnology-biosafety course every year targeted to beginners, and specialized biotechnology programmes are also organized at the university based on bilateral agreements. In-country short modules are offered to 10 major country programmes where the University of Tsukuba has bilateral agreements under MEXT of Japan (including China, Myanmar, Thailand, Tunisia and Viet Nam). Regulatory frameworks, institutional development and implementation of biosafety at the research level are emphasized. Furthermore, workshops are also set up through collaboration with external organizations (IO/NGO) to discuss and develop current knowledge on biosafety.[150]

IV. EXISTING EXPERTISE AND EXPERIENCE

(a) African Centre for Biosafety

61. The African Centre for Biosafety (ACB) supports efforts towards food systems that are equitable and ecologically sustainable, built upon the principles of food sovereignty/agroecology. The ACB provides research, policy, analysis, advocacy and knowledge sharing. For example, the ACB submitted studies from South Africa to the Secretariat of the Convention on Biological Diversity to enrich the discussion. These studies highlight South African experiences regarding the rejection of GM SpuntaG2 potato for commercial release, GM yeast and grapes for wine production, and the lack of success of the Massive Food Production Programme in the Eastern Cape which promotes the use of GM maize for small scale farmers.[151]

[148] UNEP Biosafety Unit. For further information, see: http://www.unep.org/biosafety/Publications.aspx.

[149] Tea García-Huidobro Cabrera, "Biosafety in the Caribbean: Creating capacities through a regional GEF project", PowerPoint presentation, UNEP-GEF, June 2011.

[150] See http://bch.cbd.int/database/record.shtml?documentid=9299.

[151] ACB, online: http://www.acbio.org.za/.

(b) African Union Commission

62. The African Union (AU) succeeded the Organization of African Unity (OAU) in 2002. It was established to promote the socio-economic integration of the African continent and aims to achieve greater unity and solidarity between African countries and peoples, and to foster political and socio-economic integration, stability, democracy, peace and security, sustainable economic growth as well as the protection of human rights. The *African Model Law on Safety in Biotechnology* was developed and finalized in 2001 to provide Africa with a harmonized framework for creating national biosafety laws.[152] The New Partnership for Africa's Development (NEPAD) has established a high-level panel of eminent persons/experts to advise Africa on the scientific, policy and legal issues pertaining to the development, commercialization and application of modern biotechnology, the High-level African Panel on Biotechnology (APB), and the NEPAD Office of Science and Technology established the African Biosafety Network of Expertise (ABNE) under the African Biosciences Initiative (ABI) to provide continent-wide expertise and networking facilities for biotechnology and biosafety.[153]

(c) Action Group on Erosion, Technology and Concentration

63. The Action Group on Erosion, Technology and Concentration (ETC Group) is dedicated to the conservation and sustainable advancement of cultural and ecological diversity and human rights. It publishes material on biosafety issues, supports socially responsible developments of technologies useful to the poor and marginalized, and addresses international governance issues and corporate power.[154]

(d) Groupe de recherche et d'échanges technologiques

64. The Groupe de recherche et d'échanges technologiques (GRET) works in Africa, Asia, Latin America and Europe for fair and sustainable development through projects and programmes that aim to increase the incomes of rural and urban populations, reduce their vulnerability, improve their access to infrastructures and quality utilities, and strengthen their ability to be heard. GRET is involved in natural resources and biodiversity management, in international trade and biosafety negotiations, as well as in agricultural policies and food security issues. It provides its expertise alone or as part of a consortium with organizations from both developing and developed countries. Its approach combines the social sciences and exact sciences, based on the results of applied research and pilot development experiments.[155]

(e) Inter-American Institute for Cooperation on Agriculture

65. The Inter-American Institute for Cooperation on Agriculture (IICA) is the specialized agency for agriculture of the Inter-American System, and has every country in the hemisphere as a member. IICA places its knowledge, experience and strengths at the disposal of its Member Countries through local offices in order to achieve competitive, sustainable and inclusive agriculture in the Americas, such as strengthening the development and safe use of agro-biotechnologies as a key tool for improving the productivity and competitiveness of the agricultural sector and the sustainable use of genetic resources for agriculture and food security.[156]

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[152] GIZ, *Biosafety Policy of the African Union: Background, Instruments, Activities* (African Union Commission, 2011).

[153] The New Partnership for Africa's Development (NEPAD) was fully integrated into the AU as a programme implementation arm in 2009.

[154] See: http://www.etcgroup.org/.

[155] See: http://www.gret.org/activities/mener-des-expertises-en/?lang=en.

[156] See: http://www.iica.int/Eng/Pages/default.aspx.

(f) International Centre for Genetic Engineering and Biotechnology

66. The International Centre for Genetic Engineering and Biotechnology (ICGEB) is an international, nonprofit research organization established as a special project of UNIDO; it became fully autonomous in 1994 and now counts over 60 Member States. The ICGEB provides a scientific and educational environment of the highest standard and conducts innovative research in life sciences for the benefit of developing countries. It strengthens the research capability of its Members through training and funding programmes and advisory services and represents a comprehensive approach to promoting biotechnology internationally.

(g) International Food Policy Research Institute

67. The mission of the International Food Policy Research Institute (IFPRI) is to provide policy solutions that cut hunger and malnutrition. In the field of biosafety, IFPRI supports developing countries by providing research-based information and capacity development that will increase the accuracy and efficiency of their decision-making with respect to biotechnology and biosafety.[157] IFPRI has worked to develop a set of "best practices" for assessing the social and economic impact of genetically engineered crops, the goal being to create a "tool kit" that can be used by national researchers to respond to the information needs of the Cartagena Protocol. IFPRI has also completed a number of case studies that assess the potential economic impact of genetically engineered crops.[158]

(h) International Project on GMO Environmental Risk Assessment Methodologies

68. The International Project on GMO Environmental Risk Assessment Methodologies (GMO ERA Project) is an initiative driven by public sector scientists, most of whom have expertise in environmental science, as well as biotechnology and socio-economics. The project has identified and developed scientific methodologies and teaching tools that can be used for environmental risk assessment (ERA) and management of transgenic plants, in accordance with the Cartagena Protocol on Biosafety and other international agreements. They have published *Problem Formulation and Options Assessment Handbook: A guide to the PFOA process and how to integrate it into environmental risk assessment (ERA) of genetically modified organisms (GMOs)* as part of their capacity-building activities, a set of interlinked modules of questions related to case-specific risk assessment, and corresponding methods and experiments.[159]

(i) Red de Cooperación en Biotecnología Vegetal para América Latina y el Caribe

69. The objective of the FAO-backed Red de Cooperación en Biotecnología Vegetal para América Latina y el Caribe (REDBIO) is to accelerate the process of adaptation and application of plant biotechnology to contribute to the solution of crop production constraints and genetic resources conservation in Latin America and the Caribbean. REDBIO promotes the preparation and application of a Code of Conduct on Plant Biotechnology that will favour, standardize and adapt the use of concerted concepts in biosecurity, regulation, ethics and the socio-economic impact of biotechnology in the countries of the region. REDBIO promotes the preparation and application of a Code of Conduct on Plant Biotechnology that will favour, standardize and adapt the use of concerted concepts in biosecurity, regulation, ethics and the socio-economic impact of biotechnology in the countries of the region.[160]

[157] IFPRI "Biotech and Biosafety Policy: Balancing Biotechnology and Biosafety: A Note from the Director General" (2006).

[158] See: http://www.ifpri.org/ourwork/about/biotech-biosafety.

[159] See: http://www.gmoera.umn.edu/.

[160] See: http://bch.cbd.int/database/record.shtml?documentid=15818.

(j) Regional Agricultural and Environment Initiatives Network-Africa

70. The Regional Agricultural and Environment Initiatives Network–Africa (RAEIN-Africa) is a Southern African network that facilitates and promotes the science, technology, policy and society interface for sustainable livelihoods using innovation systems approaches. Its main focus areas are sustainable management of the environment and agricultural production systems in the SADC region. RAEIN-Africa addresses the adoption of appropriate emerging technologies, building on opportunities available to resource-constrained communities, including indigenous knowledge systems, innovative systems to development and coping, adaptation and mitigation strategies to climate change and interfacing issues within them, while addressing policies that govern access to, safe handling and use of these technologies. Overall, the network facilitates information sharing, knowledge generation, technology generation and evidence-based policy and governance lobbying and advocacy on issues to do with sustainable development in focus areas. The network has active nodes in several SADC countries: Botswana, Malawi, Namibia, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe. It also links to other SADC countries through science and technology authorities.

71. The *Innovation for Sustainable Development and Poverty Reduction: Towards an Enabling Environment for Systems of Innovation in Southern Africa Programme* aims to facilitate and promote the use of the innovation systems approach in addressing identified needs for marginalized communities in the SADC region through innovation platforms facilitated and created with the guidance of the RAEIN-Africa Secretariat to enable the Network to interface science, technology, policy and society. It focuses on three themes: food security and livelihoods, climate change and environment, and policy and governance. Activities are implemented under the *Regulatory Innovation: Breaking Biosafety Boundaries in Southern Africa* and *Innovative Technologies for Enhancement of Production Systems and Management of Environment* projects. RAEIN-Africa has facilitated the establishment of six innovation platforms in six SADC countries (Botswana, Malawi, Namibia, Swaziland, Tanzania and Zambia) with multidisciplinary and multi-stakeholder involvement, including active participation by communities, media, lawyers and entrepreneurs, to ensure relevant development actors take part to enhance effectiveness.[161]

V. OTHER SOCIAL AND ECONOMIC IMPACT ASSESSMENTS

(a) Cost-benefit analysis

72. Cost-benefit analysis compares the expected costs of a proposed action to its projected benefits. It serves the purposes of determining that an act is a sound decision by looking at its justification and feasibility, and providing a basis for comparison by estimating the total expected cost of each option against the total expected benefits to see whether the benefits outweigh the costs, and by how much. This is done through primarily through economic valuation techniques. However, cost-benefit analysis also depends upon quantitative risk assessment prior to economic valuation, including in the estimation of the monetary value of any proposal's health and environmental benefits and costs. This poses problems for cost-benefit analysis, because science often does not generate data sufficient to support a responsible quantitative estimate of predictable and serious consequences, even qualitatively well-understood ones. As a result, cost-benefit analysis calculations used in policy formulation often leave out relevant information from the valuation process. Proponents of cost-benefit analysis have not determined how significant non-quantifiable issues can be considered by policymakers.[162] As a result, it may not be able to

[161] RAEIN-Africa, *Building Bridges: Innovation Systems for Poverty Reduction & Sustainable Development*, Volume 7 (December 2012 - May 2013). http://www.raein-africa.org/.

[162] DM Driesen, "Cost-Benefit Analysis and the Precautionary Principle: Can They be Reconciled?" (2013). See also M Geistfeld, "Reconciling cost-benefit analysis with the principle that safety matters more than money" (2001) 76 NYUL Rev 114.

provide a comprehensive basis for implementing Article 26.1 of the Cartagena Protocol. One example of a cost-benefit approach is the regulatory system in the United States of America, which predates the Protocol and focuses on evaluating the degree and probability of harm to human health and the environment.[163] A multidisciplinary team of experts across agencies (EPA, USDA, FDA) collaborate to conduct risk assessments aimed at risk management. The evaluation of LMOs is done under the EPA Guidelines for Ecological Risk Assessment, with SECs taken into account in the decision-making or risk management part of risk analysis.[164]

(b) Economic impact analysis

73. Economic impact analysis (EIA) examines the effect of a policy, programme, project, activity or event on the economy of a given area (e.g., local, national, global). Economic impact is usually measured in terms of changes in economic growth (output or value added) and associated changes in jobs (employment) and income (wages). Economic impact can be calculated *ex ante* or *ex post facto*. Tort law undertakes an *ex post* analysis of the economic impacts of LMO contamination, demonstrated in cases including StarLink™ corn,[165] Liberty Link Rice 601,[166] and Triffid Flax,[167] among others. Economic damages were also claimed by organic farmers in *Hoffman v. Monsanto Canada Inc.*[168] and Monsanto in *Monsanto Canada Inc. v. Schmeiser*.[169]

(c) Social impact assessment

74. Social impact assessment (SIA) has been practiced for decades (since at least the 1970s). One well-studied example of the social impact of a set of technologies is the impact of the introduction of Green Revolution high-yielding varieties in traditional agricultural systems. Researchers found uneven distribution of benefits and consequences—poor farmers were made poorer and rich farmers richer. In terms of the potential for socio-economic impacts on traditional agricultural systems, there appears to be little difference between impacts seen from the Green Revolution and the products offered by the plant biotechnology industry. New technologies tend to reflect and reinforce existing social structures, and there is no indication that the products of modern biotechnology will be any different.[170] It has already been determined that living modified organisms may pose a threat to food security and impact the fulfilment of the human right to food.

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[163] EPA, Guidelines for Ecological Risk Assessment Federal Register, vol. 63, no. 93, pp. 26846–26924, 1998, at 8 of 124, available at: http://www.epa.gov/raf/publications/pdfs/ECOTXTBX.PDF.

[164] *Ibid.* at 122 of 124.

[165] A class-action lawsuit against StarLink creator Aventis, StarLink maker StarLink Logistics and Avanta USA, owner of StarLink distributor Garst Seed settled in 2001. Aventis agreed in 2001 to compensate farmers and grain elevators up to 25 cents per bushel for tainted corn and other losses. US farmers were paid interest on the $110 million settlement with makers and distributors of genetically altered corn, including up to $2 per acre for farmers who did not grow StarLink corn but suffered from a consumer backlash when it was revealed in the food supply. A third settlement called for $9 million to be paid to consumers who suffered allergic reactions from eating food that contained the GM corn. (Associated Press 2004)

[166] *Liberty Link Case* (USA) - Bayer CropScience will pay up to $750 million to U.S. rice farmers to resolve claims that the company's experimental LibertyLink rice contaminated crops, making them unfit for export, ending lawsuits representing more than 11,000 long-grain rice farmers in Texas, Louisiana, Missouri, Arkansas, and Mississippi. The settlement programme is open to all U.S. farmers who were growing long-grain rice in the 2006-2010 period.

[167] The estimated cost to growers was approximately $30 million, with an additional $50 million in economic harm done to value chains in Europe. See Camille D. Ryan and Stuart J. Smyth, "Economic Implications of Low-level Presence in a Zero-Tolerance European Import Market: The Case of Canadian Triffid Flax" 15(1) AgBioForum, www.agbioforum.org/v15n1/v15n1a03-ryan.htm.

[168] The class action was denied, see *Hoffman v. Monsanto Canada Inc.*, 2005 SKQB, 2007 SKCA 47, leave to appeal to SCC refused.

[169] *Monsanto Canda Inc. v. Schmeiser*, 2004 SCC 34.

[170] Stabinsky, *supra* note.

(d) Socio-economic impact assessment

75. Proposals for the adoption of a distinct socio-economic impact assessment (SEIA) culminated in a publication in 2007 detailing the prospects for such an assessment. Building upon existing assessment methods, the SEIA model proposed can help in assessing the potential consequences on society when a particular technology is being introduced as a participatory assessment tool which maps local knowledge in a particular societal context where a new technology will be introduced. By being participatory and interdisciplinary (e.g., economic, social, cultural, political and ethical aspects), a SEIA entails involvement of different actors/stakeholders and a plurality of aspects in the assessment. Overall, SEIA can help regulators and civil society groups to weigh the potential benefits of GMOs side by side with their potential risks and adverse impacts on the different socio-economic spheres.[171]

(e) Strategic environmental assessment

76. One established assessment tool that may be useful for considering the socio-economic impacts of living modified organisms is the Strategic Environmental Assessment (SEA). SEA allows for the assessment of socio-environmental impacts of policies, programmes and plans. The EU, CBD and OECD guidelines do not yet include GMO projects and biosafety policies under the scope of SEAs. Concepts and case studies are needed to test the applicability and usefulness of integrating SEAs into biosafety systems to allow for the holistic assessment of systemic risks in agro-biotechnology.[172] IFPRI has set out a possible biotechnology SEA process that integrates qualitative and quantitative assessments with a focus on risk assessment and management within the SEA and policy environmental assessment frameworks using the six International Association for Impact Assessment performance criteria for SEAs: integration; sustainability; focus; accountability; participation; and iteration.[173]

(f) Sustainability impact assessment

77. Sustainability assessment is an integrative process that acts as a framework for decision-making on all undertakings—policies, plans and programmes as well as physical undertakings—that may have lasting effects. Some sustainability assessment advocates have argued for approaches that keep the economic, social and ecological pillars quite separate, with integration reserved for the final decision. This is a simple method in cases centred on a single trade-off between immediate economic interests and longer-term ecological values. In most cases, the issues are more complex, the potential options and variations of options are more numerous, and the task of sustainability guided integration cannot properly be reduced to illumination of one key choice at one important decision point.[174] Sustainability assessment typically involves multiple, iterative decisions, beginning well before the final decision, including determining purposes, alternatives, scope, issues for examination, legitimate participants, evaluation criteria, case priorities and information adequacy. Unless sustainability considerations are addressed in an integrated manner throughout the process, starting with the decisions that frame the discussion, the approval is likely to be a business as usual proposal with damage mitigation (e.g., risk analysis and management), instead of a forward-looking and innovative decision that has been carefully conceived,

[171] Elenita C Daño, *Potential Socio-Economic, Cultural and Ethical Impacts of GMOs: Prospects for Socio-Economic Impact Assessment* (Penang, Malaysia: Third World Network, 2007).

[172] Meyer, *supra* note.

[173] Nicholas A Linacre et al., "Strategic environmental assessments for genetically modified organisms" (2006) 24:1 Impact Assessment and Project Appraisal 35.

[174] Robert B Gibson, "Beyond the Pillars: Sustainability Assessment as a Framework for Effective Integration of Social, Economic and Ecological Considerations in Significant Decision-Making" (2006) 8:3 Journal of Environmental Assessment Policy and Management 259.

selected and designed to deliver maximum positive contributions to sustainability (e.g., consideration of socio-economic impacts linked to conservation and sustainable use of biodiversity).[175]

(i) Sustainability appraisal and integrated appraisal (United Kingdom)

78. Sustainability appraisal is a policy tool which provides for the systematic identification and evaluation of the economic, social and environmental impacts of a proposal in the United Kingdom. sustainability appraisal evolved in the 1990s from the environmental appraisal of development plans by local planning authorities, but its application is expanding. Integrated appraisal can be defined as a process of assessing the performance of options or proposals in terms of their economic, social and environmental implications. There are other forms of integration in the context of appraisal, in addition to the simultaneous consideration of economic, social and environmental concerns within one appraisal. This includes vertical integration, also known as tiering, which links together separate impact assessments that are carried out at different stages in the policy, plan, programme and project cycle. Subsequently, the appraisal can be integrated into the decision-making processes.[176]

(ii) Impact assessment (European Commission)

79. Before the European Commission proposes new initiatives it assesses the potential economic, social and environmental consequences that they may have. *Impact assessment* is a process that prepares evidence for political decision makers on the advantages and disadvantages of possible policy options by assessing their potential impact. The Commission has rolled out a wide-ranging impact assessment system based on an integrated approach which analyses both benefits and costs, and addresses all significant economic, social and environmental impacts of possible new initiatives. This ensures that all relevant expertise within the Commission is used, together with inputs from stakeholders. It also enhances the coherence of initiatives across policy areas through a system that is both accountable and transparent. It strives for full involvement of stakeholders. All impact assessments and all opinions of the Impact Assessment Board on their quality are published online once the Commission has adopted the relevant proposal. Impact assessment also helps to explain why an action is necessary at the EU level and why the proposed response is an appropriate choice. It may of course also demonstrate why no action at the EU level should be taken.[177]

(g) Constructive technology assessment

80. Constructive technology assessment takes into account expectations from technology in technology assessment so that the scope for directing technological change is explored. Technologies never operate outside a biophysical and social context, and it is their interaction with their contexts that generates effects, impacts and implications. In the case of technologies that have a wider and long-term impact, assessing impacts is not simple because of the difficulty in accurately assessing all the impacts of technology. In the case of LMOs, their impacts need not be confined to food production and biodiversity. For example, many *ex post* impacts of the Green Revolution on employment, different classes of farmers and women, and socio-economic impacts generally have been identified. Studies have helped to assess the impacts of technology change and developed steps to minimize negative impacts. For instance, the introduction of mechanized farming increased the inequity between small-scale and large-scale farm communities and reduced the availability of agricultural jobs performed by women.[178]

[175] *Ibid*.

[176] See http://www.environment-agency.gov.uk/research/policy/32933.aspx.

[177] European Commission, *Impact Assessment Guidelines* (2009).

[178] Sachin Chaturvedi, Krishna Ravi Srinivas & Pallavi Singh, "Socio-economic Considerations and LMOs: The Case for an Appropriate and Integrated Framework" (2012) 14:3 Asian Biotechnology and Development Review 85.

VI. CONCLUSIONS

81. The Cartagena Protocol provides a framework for international trade in environmentally sound applications of biotechnology in the form of living modified organisms. Because the possible impact of environmental releases of living modified organisms on other species and ecosystems is significant and mostly unexplored, as are the related consequences for societies and economies, and many Parties have limited capacity to cope with the nature and scale of known and potential risks associated with living modified organisms, the Protocol is founded on the precautionary approach. However, the Protocol's rules are a minimum standard, meaning that Parties can adopt a more precautionary approach if their national circumstances demand it. A Party can make scientifically grounded decisions that are more protective of biodiversity than is called for by the Protocol, provided that the decision is consistent with the Party's other obligations under international law.[179]

82. Article 26.1 of the Protocol provides Parties with the right to take into account socio-economic considerations linked to biodiversity resulting from the use of living modified organisms within their import decision-making processes. This may be of particular interest to (1) Parties that are centres of origin and genetic diversity; (2) Parties that have large indigenous or rural populations; and (3) Parties that have important economic and development programmes based on the use of biodiversity.[180] Parties that choose to exercise the right to consider socio-economic considerations need guidance on how to implement Article 26.[181] As raised in online discussions hosted by the Secretariat, the scope of a *decision to import* includes decisions taken by a Party on (1) intentional introduction into the environment; (2) direct use as food, feed or for processing; and (3) contained use. A decision to review a prior decision on import, or to apply a simplified procedure, or apply domestic regulations to specific imports, also fall within this scope.

83. Parties have taken a variety of approaches to considering socio-economic impacts, which can generally be broken down into three clusters: (1) those that take socio-economic impacts into consideration as a part of the risk analysis process; (2) those that take socio-economic impacts into consideration independently from the risk analysis process; and (3) those that do not take socio-economic impacts into consideration at all. Socio-economic assessments can be conducted both prior (*ex ante*) and subsequent (*ex post*) to the release or marketing of a living modified organism.[182] If a Party takes into account socio-economic considerations in a decision to import, it should also do so in the case of living modified organisms developed domestically. This is particularly true for Members to the WTO Agreements, which must consider their obligations related to non-discrimination, non-arbitrariness, and disguised restrictions on trade when implementing Article 26.1.

84. There is no clear definition as to what falls under the scope of the term "socio-economic considerations" and use of the term varies. However, it could mean almost any possible effect that is a consequence of the impacts of living modified organisms on biodiversity. This includes the direct, indirect, intentional, accidental, predicted and unforeseen effects on biodiversity and ecosystems and their use for sustainable development. This suggests that establishing the boundaries of socio-economic assessments will be important.[183] Methodological guidelines should be developed that identify the socio-economic indicators that should be monitored, and establishing rules for data collection. For proper

[179] Marie-Claire Cordonier Segger, Frederic Perron-Welch & Christine Frison, "Introduction" in Marie-Claire Cordonier Segger, Frederic Perron-Welch & Christine Frison, eds, *Legal Aspects of Implementing the Cartagena Protocol on Biosafety* (New York: Cambridge University Press, 2013) 1 at 1 and 10-11.

[180] Catacora-Vargas, *supra* note at 5–6.

[181] Perron-Welch, *supra* note.

[182] Chaturvedi, Srinivas & Singh, *supra* note at 88.

[183] Chaturvedi, Srinivas & Singh, *supra* note; Catacora-Vargas, *supra* note.

operationalization, indicators should be measurable and capable of being estimated in advance. Nine relevant themes and criteria developed by COGEM that may serve as building blocks for socio-economic assessment are: benefit to society, economics and prosperity, health and welfare, local and general food supply, cultural heritage, freedom of choice, safety, biodiversity, and environmental quality. The *Summary Report on the Survey on the Application of and Experience in the use of Socio-Economic Considerations in Decision-Making on Living Modified Organisms* commissioned by the CBD Secretariat also contains the following table which may be useful to consider, as it concretizes some of the findings made in this research study.[184]

Table 1: Socio-economic issues that can be taken into account in reference countries' decision-making compared with ratings of the importance of socio-economic issues included in decision-making

#	Socio-economic issues that can be taken into account in reference countries' decision-making systems for LMOs (Q10)	Importance of socio-economic issues considered in LMO-decision-making (Q15)	
		Method I: ranking system	Method II: scoring system
1	Food security	Food security	Health-related impacts
2	Impacts on market access	Health-related impacts	Coexistence of LMOs
3	Health-related impacts	Coexistence of LMOs	Food security
4	Compliance with biosafety measures	Impacts on market access	Impact on market access
5	Coexistence of LMOs	Compliance with biosafety measures	Compliance with biosafety measures
6	Impacts on biodiversity	Impacts on biodiversity	Macroeconomic impacts
7	Farmers' rights	Economic impacts of changes in pest prevalence	Economic impacts of changes in pest prevalence
8	Economic impacts of changes in pest prevalence	Macroeconomic impacts	Impacts on biodiversity
9	IPRs	Farmers' rights	Impacts on consumer choice
10	Indigenous and local communities	IPRs	Use of pesticides and herbicides

Source: UNEP/CBD/BS/COP-MOP/5/INF/10.

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[184] Online: http://www.cbd.int/doc/meetings/bs/mop-05/information/mop-05-inf-10-en.pdf