



United States Department of State
*Bureau of Oceans and International
Environmental and Scientific Affairs*
Washington, D.C. 20520

31 May 2019

Ms. Cristiana Paşca Palmer
Executive Secretary
Convention on Biological Diversity
413 St. Jacques Street West, Suite 800
Montreal, Quebec H2Y 1N9 CANADA

Dear Ms. Paşca Palmer:

The United States appreciates the invitation to provide peer review comments in response to the Secretariat's 6 March 2019 Notification No. 2019-031. In response, we are pleased to share U.S. preliminary experiences using the voluntary Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety. We are pleased to have the opportunity to share our views attached and note that this submission is not intended to be exhaustive, but rather to highlight several themes and considerations that we believe to be relevant to the voluntary Guidance (Attachment 1).

We are also pleased to nominate participants for the September 2019 online discussions on socio-economic considerations. Our nominees look forward to participating in the discussion, and we appreciate your consideration (Attachment 2).

Sincerely,

A handwritten signature in cursive script that reads "Barbara M. De Rosa-Joynt".

Barbara M. De Rosa-Joynt
Division Chief for Biodiversity
U.S. National Focal Point for the
Convention on Biological Diversity

Attachments: As stated.

U.S. Submission on Socio-Economic Considerations
31 May 2019

The United States is pleased to provide the following information in response to CBD Notification No. 2019-031

Over the past 40 years, the United States has become the largest global producer of living modified organisms (LMOs) and gained considerable experience in the “safe transfer, handling, and use of LMOs.” Farmers, ranchers, and consumers all over the world have gained significant, positive socioeconomic benefits and contributed to environmental sustainability by using LMOs. In previous submissions, the United States, other governments, and stakeholders have described these outcomes in detail. In light of these experiences, the United States appreciates the opportunity to provide perspectives on the voluntary Guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety (CPB) (hereafter the voluntary Guidance). The United States is of the view that if Parties use this voluntary Guidance, it should be done in a manner consistent with the Cartagena Protocol, as well as the country’s existing international obligations under other agreements.

(a)(i) Preliminary experiences using the voluntary Guidance

Given the short time since the conclusion of the Ninth Meeting of the Parties (MOP-9), the United States notes that countries and interested stakeholders have had very limited time to consider the voluntary Guidance. Without more time to deliberate, we consider it to be difficult to evaluate the content of the voluntary Guidance and whether it is consistent with the CPB, and to determine the voluntary Guidance’s relevance to obligations under other international agreements.

The United States also notes that Parties have not decided on a definition of the term “socio-economic considerations” and that it may be difficult to compare experiences regarding the voluntary Guidance if countries use different definitions for this term. Thus, we believe that Parties may also benefit from more time to deliberate on their own national priorities and needs.

The United States has reviewed the voluntary Guidance and notes several concerns regarding the language used in the document as compared to the text of Article 26.

1. **Article 26 describes a limited scope for socio-economic considerations, which is obscured in the voluntary Guidance.** Objectives are specified in the text of the CPB. Article 26 paragraph 1 states (emphasis added):

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

In simplified language, the paragraph above states that parties may (but are not required to) evaluate socio-economic considerations arising from the impact of an LMO on conservation and sustainable use of biological diversity. Thus, in cases when an LMO does not result in an impact on biological diversity, we consider that socio-economic considerations fall outside the scope of Article 26. In the U.S. opinion, the voluntary Guidance uses general language that does not align with the limited scope of Article 26 described above and could be misleading.

2. **The title of the voluntary Guidance:** We are of the view that the voluntary Guidance could indicate the nature of Article 26 by formally incorporating “Voluntary” into the title of the document.
3. **Parties have not decided on a definition of socioeconomic considerations:** As described in decision 8/13, Parties took note of the operational definition of socioeconomic considerations within the revised Framework for Conceptual Clarity. Several Parties acknowledged concerns with the operational definition for socio-economic considerations: a) the operational definition references “ecological aspects,” which are environmental variables, not socioeconomic variables; b) more broadly, socio-economic factors are difficult to generalize across different cultures and countries. For context, we believe it would be useful if the voluntary Guidance could acknowledge that Parties have not formally adopted the operational definition.
4. **“The overall assessment process” in the voluntary Guidance is misleadingly broad:**

The steps outlined in the “overall assessment process” should be tailored to be focused on decisions related to the import of LMOs, in line with Article 26.

Stage A (a): Parties planning a socioeconomic assessment in “Stage A” of the voluntary Guidance are required to follow the objectives and provisions articulated in the CPB. However, the “preparations for assessment” described in Stage A encourage countries to blend national protection goals into socio-economic assessments conducted under the CPB. We believe this may create confusion regarding the scope of CPB and make it difficult for Parties to distinguish between an international obligation and a domestic priority.

Stage B: Broad language in the voluntary Guidance, such as “food security,” “nutritional status,” or “relation between the impact of the LMO and socio-economic effects,” contemplate socio-economic considerations that are broader than Article 26. Additionally, it is our view that ecological and other environmental factors should be considered during a risk assessment conducted in line with Article 15 – not under socio-economic considerations in Article 26.

5. **Elements of the voluntary Guidance may be inconsistent with international obligations.** Stage B of the voluntary Guidance states that when assessing socio-economic effects, “other accepted approaches where scientific methods are not applicable” can be used. Many other internationally binding agreements, such as the World Trade Organization’s Agreement on Sanitary and Phytosanitary Issues (WTO-SPS) and/or other bilateral or regional trade

agreements, require that a measure bear a rational and objective relationship to the scientific evidence and to the risk assessment. We consider that incorporating non-scientific factors into a decision regarding an LMO that are at odds with a science-based risk assessment may place countries in conflict with other legally binding agreements. Parties acknowledged this in decision 9/14 with the following language: “nothing in the voluntary Guidance can be interpreted or used to support non-tariff barriers to trade.” We believe that taking into account socio-economic considerations should not result in a decision regarding an LMO that is at odds with the results of a risk assessment based on measurable, scientifically validated approaches. In our view, the voluntary Guidance should not encourage outcomes that could put Parties at jeopardy of their international obligations.

(a)(ii) Examples of methodologies and applications of socio-economic considerations, in the light of the elements of the voluntary Guidance, preferably in the form of case studies

The United States maintains that socio-economic assessments should remain distinct from risk assessments and occur after a risk assessment is completed. We consider that if a science-based environmental risk assessment identifies potential adverse effects of an LMO on the conservation and sustainable use of biological diversity, policymakers can assess socio-economic factors when conducting the risk management planning phase. Article 26 makes this distinction between risk assessment and socio-economic assessments clear, by focusing on LMOs with an impact on the conservation and sustainable use of biological diversity.

From the U.S. perspective, the voluntary Guidance does not recognize the difficulty in conducting *ex ante* assessments of socio-economic factors. In our experience, it is possible to gather sufficient information and analyze the nature of the social and economic changes associated with a new technology once a technology has been in use for several years. In the case of a number of genetically engineered crops used by American farmers, the Economic Research Service of the U.S. Department of Agriculture (USDA-ERS) has researched, analyzed, and reported on the nature of the socio-economic changes associated with specific crop varieties. Examples can be found at <https://www.ers.usda.gov/topics/farm-practices-management/biotechnology/>. However, it would not have been possible to draw valid conclusions regarding these crops at the time that research and development began. Our experiences have shown us that without scientifically validated data, economists cannot necessarily predict how free markets, and as an extension individuals, will respond to the presence of new technologies.

For any policy decision, sound risk management plans use a weight of evidence approach that balances potential benefits with potential risks. The United States maintains that such weight of evidence approaches – based in measurable data using scientific methods – are the best ways to consider socio-economic factors when making a policy decision. Without quantifiable data, we consider that incorporating perceived socio-economic factors into an assessment is speculative and undermines a policymaker’s ability to make the best-informed decision.



Nomination Form for Participation in Online Discussion Groups on Socio-Economic Considerations

Fields marked with an asterisk are mandatory

General information	
1. Title:	<input type="checkbox"/> Mr. <input checked="" type="checkbox"/> Ms. <input type="checkbox"/> Dr. <input type="checkbox"/> Prof. <input type="checkbox"/> Other (specify): <Text entry>
2. First name:*	Julia
3. Middle name:	Marie
4. Last or Family name:*	Doherty
Work related information	
5. Job title:	Deputy Assistant U.S. Trade Representative
6. Employer / Organization*	Office of the U.S. Trade Representative
7. Acronym: ¹	USTR
8. Department / Division / Unit:	Agricultural Affaris
9. Type of organization:	<input type="checkbox"/> Academic or research institute <input checked="" type="checkbox"/> Government agency <input type="checkbox"/> Intergovernmental organization (IGO) <input type="checkbox"/> Non-governmental organization (NGO) <input type="checkbox"/> Private sector (business and industry) <input type="checkbox"/> Regional economic integration organization <input type="checkbox"/> UN and other specialized agency of the UN Common System <input type="checkbox"/> Other (specify): <Text entry>

¹ Abbreviation of the long name of an organization. Examples: EA, SCBD.

Coordinates	
10. Address:	600 17 th Street NW
11. City:*	Washington
12. State or Province:	DC
13. Country:*	USA
14. Postal or Zip code:	20850
15. Phone number: ^{2*}	202-395-9559
16. Fax number: ³	none
17. Email address:*	jdoherly@ustr.eop.gov
18. Websites ⁴ :	www.ustr.gov

Nominee's experience with socio-economic considerations	
19. Work experience on socio-economic considerations (please list employers and relevant tasks performed):	<p>Ms. Doherty has 16 years of experience working at the U.S. Trade Representative (USTR), where she has participated in negotiations related to trade, regulation, and international cooperation surrounding biotechnology products--a subset of which meet the definition of a "living modified organism" (LMO) in the context of the CPB. Ms. Doherty's experience at USTR will be valuable in the online forum on socioeconomic considerations, because she can share perspectives on how diverse international agreements and instruments strive to balance socioeconomic factors with science-based risk assessment approaches surrounding LMOs. Ms. Doherty's experience regarding existing international obligations surrounding LMOs will be valuable for any country interested in understanding and incorporating socioeconomic factors into its decision-making process. In addition, she will be able to contribute perspectives on the economic and social benefits to trade in LMOs consistent with the sustainable development goals of the World Trade Organization.</p>

² Please use the following format: + [country code] [city code] [telephone number] [extension, if necessary]; Example: +1 514 288-2220 ext 221 (where 1 = North America, 514 = Montreal, 288-2220 = CBD Secretariat number, ext 221 = direct extension to the switchboard).

³ See footnote above.

⁴ Please provide the URL of the website (e.g. <http://bch.cbd.int>) and the name of the website (e.g. "Biosafety Clearing-House").

20. Relevant educational background:	Ms. Doherty holds a Master in Arts in economics from the University of Maryland College Park and a Bachelor of Arts in Economics and Political Science from Indiana University Bloomington.
21. Relevant publications:	<p>Singly or in collaboration with other Members, Ms Doherty led the development and submission of the following papers to the World Trade Organization (recent partial list):</p> <p>"Risk Communication: Identifying Resources of Practical Use to Members", Contribution of the United States, October 2015 (G/SPS/GEN/1456)</p> <p>"Public Consultation: WTO SPS Committee Workshop on Transparency", Contribution of the United States, June 2017 (G/SPS/W/294/Rev.1)</p> <p>"Workshop on Pesticide Maximum Residue Levels (MRLs): Possible Next Steps for Consideration by the SPS Committee", Contribution of Kenya, Uganda and the United States, March 2017 (G/SPS/W292)</p> <p>"Trade in Food and Agriculture", Joint Statement of Ministers of Argentina, Brazil, Canada, Costa Rica, Colombia, Uruguay, Panama, Madagascar, Dominican Republic, Peru, Chile, Kenya, Uganda, Japan, Guatemala, Paraguay and the United States WT/MIN(17)/5</p> <p>"Pesticide MRLs: Recommendations for Endorsement by the SPS Committee in its Fifth Review of the Operation and Implementation of the SPS Agreement", Contribution of Argentina, Australia, Brazil, Canada, Chile, Colombia, Costa Rica, Dominican Republic, Japan, Kenya, Madagascar, New Zealand, Panama, Paraguay, Peru, Uganda, the United States and Uruguay, June 2018 (G/SPS/W/292/Rev.4)</p> <p>"The Role of the WTO SPS Agreement in Enabling Access to Tools and Technologies: A Case Study on Fall Armyworm", Contribution of Brazil, Kenya, Madagascar, Paraguay, the United States and Uruguay, September 2018 (G/SPS/W/305)</p> <p>"International Statement on Agricultural Application of Precision Biotechnology", Contribution of Argentina, Australia, Brazil, Canada, Guatemala, Honduras, Paraguay, the United States and Uruguay, November 2018 (G/SPS/GEN/1658/Rev.3)</p>

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General information	
22. Title:	<input type="checkbox"/> Mr. <input type="checkbox"/> Ms. <input checked="" type="checkbox"/> Dr. <input type="checkbox"/> Prof. <input type="checkbox"/> Other (specify): <Text entry>
23. First name:*	Amanda
24. Middle name:	<Text entry>
25. Last or Family name:*	Pierce
Work related information	
26. Job title:	Biologist
27. Employer / Organization*	U.S. Environmental Protection Agency
28. Acronym: ⁵	EPA
29. Department / Division / Unit:	Office of Pesticide Programs
30. Type of organization:	<input type="checkbox"/> Academic or research institute <input checked="" type="checkbox"/> Government agency <input type="checkbox"/> Intergovernmental organization (IGO) <input type="checkbox"/> Non-governmental organization (NGO) <input type="checkbox"/> Private sector (business and industry) <input type="checkbox"/> Regional economic integration organization <input type="checkbox"/> UN and other specialized agency of the UN Common System <input type="checkbox"/> Other (specify): <Text entry>

⁵ Abbreviation of the long name of an organization. Examples: EA, SCBD.

Coordinates	
31. Address:	<Text entry>
32. City:*	Washington
33. State or Province:	<Text entry>
34. Country:*	United States of America
35. Postal or Zip code:	<Text entry>
36. Phone number: ^{6*}	703-347-0561
37. Fax number: ⁷	<Text entry>
38. Email address:*	pierce.amanda@epa.gov
39. Websites ⁸ :	<URL and website name>

Nominee's experience with socio-economic considerations	
40. Work experience on socio-economic considerations (please list employers and relevant tasks performed):	<p>As an employee of the U.S. EPA, Dr. Pierce is involved in the authorization of certain products of biotechnology that fall within the definition of "living modified organisms" ("LMOs") under the CPB. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), U.S. law requires that registered pesticides do not cause "unreasonable adverse effects on man or the environment". As a risk/benefit statute, FIFRA defines unreasonable adverse effects as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." As an expert in biotechnology regulation, Dr. Pierce's experience at the U.S. EPA will be valuable in contributing to the discussion on socioeconomic considerations. She will be able to discuss how the United States conducts cost-benefit analysis that balance economic and social issues within the context of environmental assessments. Dr. Pierce can also lend her experience to the online forum by sharing how the U.S. EPA considers socioeconomic</p>

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⁷ See footnote above.

⁸ Please provide the URL of the website (e.g. <http://bch.cbd.int>) and the name of the website (e.g. "Biosafety Clearing-House").

	factors during risk management discussions that occur after a risk assessment approach has been completed.
41. Relevant educational background:	Ph.D., Biology. Population Biology, Ecology, and Evolution.
42. Relevant publications:	<p>EPA's approach for regulation of biotechnology for use in pest management is described at the following location:</p> <p>https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/epas-regulation-biotechnology-use-pest-management</p> <p>EPA's guidelines for preparing economic analysis:</p> <p>https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses</p>