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

14 March 2019

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

Dear Ms. Paşca Palmer:

In decision CP-9/13, the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety invited "Parties, other Government, indigenous people and local communities, and relevant organizations to submit information relevant to the work of the online forum and Ad Hoc Technical Expert Group" on Risk Assessment.

In response to the request contained in Notification 2019-009, the United States is pleased to submit the following experience relevant to the risk assessment of Living Modified Organisms. This submission is not intended to be exhaustive, but rather to highlight relevant areas where experience has been gained by governments, public sector institutions, and private sector institutions. This information will also be uploaded into the Biosafety Clearing-House (BCH) shortly.

Thank you for your consideration of this information.

Sincerely,

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

Attachment: Submission on Risk Assessment of Living Modified Organisms

U.S. Submission on Perspectives on Risk Assessment of Living Modified Organisms
In Response to Decision CP-9/13 and Notification 2019-09
14 March 2019

The United States is pleased to provide the following information in response to Decision CP-9/13 and CBD Notification No. 2019-09

a) Experience in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish(detailing how and for which cases); or else, lack of experience in doing so;

The U.S. Government has over 40 years of experience using science-based environmental risk assessment approaches to evaluate the safe use of organisms created using modern biotechnology, including living modified organisms (LMOs). Under the Coordinated Framework for the Regulation of Biotechnology, the Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) work together to ensure products of biotechnology, including LMOs, are safe for consumers, animals, and the environment. The U.S. National Institutes of Health (NIH) also provides guidelines that are based on risk assessment approaches for the safe use of recombinant DNA organisms in research and development (links below).

In actual practice, conducting a risk assessment for an LMO is akin to conducting assessments of non-LMOs with the same or similar characteristics. Risk assessment guidance documents have been developed by numerous international bodies, including: the International Plant Protection Convention (IPPC), the Organization for Economic and Cooperative Development (OECD), the World Organization for Animal Health (OIE), and the World Health Organization (WHO) (links below). The risk assessment approaches described by these bodies focus on the characteristics of organisms and their intended use, rather than on techniques used to modify organisms. The broad range of organisms considered represent diverse biological characteristics and environments, demonstrating that science-based risk assessment approaches already anticipate a range of risk profiles.

At the time of this submission, there are over 2,300 entries within the Biosafety Clearing-House (BCH) regarding risk assessment of LMOs. These assessments have been conducted by diverse countries on a wide range of LMOs examined under different environments. We consider that it is critical for Parties to the Cartagena Protocol on Biosafety (CPB) and the broader Convention on Biological Diversity (CBD) to recognize the wealth of information and experience that already exist regarding risk assessment approaches.

The FDA has conducted an environmental assessment on the LM fish AquAdvantage® Salmon:

- https://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/BiotechnologyProductsatCVMAnimalsandAnimalFood/AnimalswithIntentionalGenomicAlterations/UCM466218.pdf

For the AquAdvantage Salmon, the FDA also conducted an analysis of the potential impacts on the U.S. environment and concluded that the AquAdvantage Salmon would not have significant impacts when produced and grown under the conditions of use for the proposed action:

- https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/BiotechnologyProductsatCVMAnimalsandAnimalFood/AnimalswithIntentionalGenomicAlterations/ucm466350.htm

Other relevant links and resources to support environmental risk assessments include:

United States Coordinated Framework for the Regulation of Biotechnology:
- https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf

United States Environmental Protection Agency (EPA):
- https://www.epa.gov/risk/risk-assessment-guidelines

United States National Institutes of Health (NIH):
- https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html

International Plant Protection Convention (IPPC):
- https://www.ippc.int/en/core-activities/capacity-development/training-material-pest-risk-analysis-based-ippc-standards/
- http://www.fao.org/docrep/009/a0450e/a0450e00.htm
- http://www.acfs.go.th/sps/downloads/34163_ISPM_11_E.pdf

Organization for Economic and Cooperative Development (OECD):
- http://www.oecd.org/chemicalsafety/biotrack/oecdandrisksafetyassessmentinmodernbiotechnology.htm

World Organization for Animal Health (OIE):
- http://www.oie.int/en/our-scientific-expertise/specific-information-and-recommendations/invasive-alien-animal-species/

World Health Organization (WHO):
- http://www.who.int/tdr/publications/year/2014/guide-fmrk-gm-mosquit/en/

b) Challenges experienced or foreseen in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish;

In practice, challenges for novice risk assessors often arise from a lack of experience in conducting science-based risk assessments – challenges that are not necessarily related to the characteristics of the organism being considered. In our view, this is particularly true if the risk assessor is required to consider untested risk assessment approaches that are confusing, contradictory, or in some cases impossible to implement. We consider that in practice, relying

on untested risk assessment methodologies or guidance documents may inadvertently lead risk assessors to contradict their country's existing international obligations.

Annex III of the CPB provides rules and procedures for risk assessments. We believe that those rules and procedures should be applicable for a range of organisms, including LMOs containing engineered gene drives and living modified fish.

The United States encourages countries to look to international entities that have scientific expertise in providing guidance on performing environmental risk assessments, such as those described in our response to (a) in this document.

c) Specific needs (if any) to properly undertake risk assessment of living modified organisms containing engineered gene drives.

The United States maintains that adhering to the principles and methodologies of science-based risk assessment is critical to maximizing benefits and minimizing potential risks associated with any technology, including engineered gene drives. Annex III of the CPB outlines several key features that all sound risk assessments share, regardless of the organism being considered. In the U.S. view, several general themes from Annex III are worth re-emphasizing with regard to the questions posed by this notification. Namely: Risk assessments should be carried out in a scientifically sound and a transparent manner; Risk assessments may take into account information related to the intended use of the organism; Lack of scientific knowledge or consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk to the environment, or an acceptable risk; and When considering an organism, a risk assessment takes into account the receiving environment, the likelihood of adverse effects being realized, the consequences those adverse effects may pose, and whether or not potential risks are acceptable or manageable. By following the above, science-based risk assessment can be conducted flexibly on a range of organisms, regardless of the techniques used to create those organisms.