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SYNTHESIS OF SUBMISSIONS ON EXPERIENCES, CHALLENGES AND NEEDS REGARDING RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS CONTAINING ENGINEERED GENE DRIVES AND LIVING MODIFIED FISH

I. INTRODUCTION

1. In decision CP-9/13, paragraph 7, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety decided to consider at its tenth meeting, whether additional guidance materials on risk assessment are needed for (a) living modified organisms containing engineered gene drives and (b) living modified (LM) fish. The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety also decided to establish an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment, and to extend the online forum on risk assessment and risk management in order to assist the AHTEG.

2. In the same decision, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety invited Parties, other Governments, indigenous peoples and local communities, and relevant organizations to submit to the Executive Secretary information relevant to the work of the online forum and the AHTEG.

3. In response to the above mentioned decision, the Executive Secretary issued notification 2019-009 (dated 1 February 2019),[1] inviting Parties, other Governments, relevant organizations and indigenous peoples and local communities to submit information related to:

(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;

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

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

4. The present document summarizes the information submitted in response to notification 2019-009. Section II of the document contains a synthesis of the information submitted. In addition, bibliographic references that were provided through the submissions have been included in document CBD/CP/RA/AHTEG/2020/1/INF/3.

* CBD/CP/RA/AHTEG/2020/1/1.

[1] SCBD/CPU/DC/MA/MW/87798.

II. SYNTHESIS OF INFORMATION

5. A total of 29 submissions were received by the Secretariat, of which 22 were from Parties,[2] 2 from non-Parties,[3] and 5 from organizations.[4] The original submissions are available through the Biosafety Clearing-House at https://bch.cbd.int/onlineconferences/submissions.shtml.

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

6. A number of submissions provided information on experience in undertaking risk assessment of living modified organisms containing engineered gene drives and LM fish. This information is summarized in table 1.

Table 1. Information related to the experience of Parties, non-Parties and organizations in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish

Level of experience	Living modified organisms containing engineered gene drives	Living modified fish
No experience in undertaking risk assessment	Austria, Bangladesh, Brazil, Bulgaria, Czechia, Ethiopia, European Union, Finland, Germany, Iran (Islamic Republic of), Japan, Malaysia, Nigeria, South Africa, Sweden, Zimbabwe, Third World Network	Austria, Bangladesh, Bulgaria, Ethiopia, France, Germany, Iran (Islamic Republic of), Japan, Mexico, Nigeria, Sweden, Zimbabwe
Limited to no experience in undertaking risk assessment	Netherlands	
Experience in undertaking risk assessment	France	Australia, Czechia, European Union, Finland, Malaysia, Netherlands, South Africa, United States of America

7. In addition to the information captured in table 1, some submissions have also provided examples of fishes for which there is experience in undertaking risk assessment, such as salmon, tilapia, common carp, rainbow trout, arctic char, and zebrafish.

8. Some submissions provided information related to aspects, such as:

(a) The many years of experience with risk assessment of living modified organisms (LMOs) in general;

[2] Austria, Bangladesh, Brazil, Bulgaria, Côte d'Ivoire, Czechia, Ethiopia, European Union, Finland, France, Germany, Iran (Islamic Republic of), Japan, Malaysia, Mexico, Netherlands, Nigeria, South Africa, Spain, Sweden, Venezuela (Bolivarian Republic of), and Zimbabwe.

[3] Australia and the United States of America.

[4] African Centre for Biodiversity, Environmental Health Safety Consultancy, Global Industry Coalition, Tesbiotech, Third World Network.

(b) Examples of how local regulations would consider a risk assessment for LM fish and/or organisms containing engineered gene drives;

(c) Conferences attended in relation to this issue;

(d) How protocols developed for the first generation LMOs are adequate or inadequate for addressing organisms containing engineered gene drives.

B. Challenges experienced or foreseen in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish

9. A number of submissions provided information on the challenges experienced or foreseen for undertaking risk assessment of organisms containing engineered gene drives or LM fish. This information is summarized below.

10. Challenges for risk assessment of organisms containing engineered gene drives identified in the submissions were as follows:

(a) It is difficult to predict the behaviour of organisms containing engineered gene drive prior to their release into the environment. Risk estimations may be highly speculative due to the high levels of uncertainty in the assessment of the likelihood of occurrence of adverse effects. Some cited examples of issues that could be difficult to predict prior to environmental release including: long-term effects; probability of resistance evolution and its consequences; possibility of unintended replacement of the target species by another vector species, in case the gene drive seeks elimination of the target species; the spread dynamics of the gene drives, which is dependent on numerous factors including migration and reproduction parameters of the target population, over time and space, etc.;

(b) Difficulties for the environmental risk assessment due to the ability of a trait to potentially spread through a complete population;

(c) Accuracy in predicting the impact to the local receiving environment as the release of these organisms will permanently alter life forms and is possibly irreversible;

(d) In order to effectively assess the potential risks, additional knowledge and information are needed (for example, potential risks have to be assessed by experts with sufficient knowledge in population dynamics and modelling. In addition, assessing the outcrossing potential of organisms containing engineered gene drives is further complicated by a lack of baseline data on genome sequences of potential outcrossing partners to be able to estimate the likelihood of outcrossing;

(e) Difficulty in assessing potential off-target gene effects;

(f) In the case of unintended effects, if they happen, it will be very difficult to remove the organisms from the environment;

(g) Lack of controllability;

(h) Conducting risk assessment in a stepwise manner, that is, from contained use, to field trials and finally to open releases, with the results at each step informing the next step of the risk assessment, (an approach that is common for LMOs), would be difficult depending on the characteristics of the gene drive in question. It may be difficult to perform experimental releases that are limited in time and space. For example, suggestions to perform field trials on islands may be insufficient as a containment measure, as the "isolated release" of organisms containing engineered gene drives may lead to further spread. Therefore, the fact that it may be difficult to carry out experimental releases that are limited in time and space, may result in reduced experimental information on the performance of a gene drive system in the environment prior to a deliberate release or placing on the market;

(i) Due to the design of organisms containing engineered gene drives, a more geographically integrated approach may be required, including regional (multilateral) assessments and decision-making when relevant;

(j) The experience needed to assess organisms containing engineered gene drives is substantially different from the experience with classical LMO applications. This is mainly due to the potential spread of the genetic modification in a population;

(k) There will be a need to update existing risk assessment protocols;

(l) More careful and elaborate risk assessment will be required;

(m) Lack of trained personnel and absence of guidelines;

(n) Insufficient modelling tools.

11. Challenges for risk assessment of LM fish identified in the submissions were as follows:

(a) It is difficult to predict the behaviour of LM Fish which will lead to additional uncertainties. For example: understanding/predicting the adaptability of the LM fish to the general aquatic ecosystem, assessing the possibility of the LM fish becoming an invasive alien species, difficulties in assessing long term and indirect consequences of the spread and interaction of LM fish with wild populations, and hybridization with other varieties of fish, etc.;

(b) Insufficient information for many species on: fish behaviour; what affects fitness and survival; what limits fish capacity to build permanent or semi-permanent populations in the wild; the comparator, especially when it comes to the environmental behaviour, etc. Knowledge on the receiving environment is also complicated and often difficult to obtain;

(c) Many fish species have unique biological and behavioural traits, such as the capability to change sex under certain environmental conditions, which is a challenge for environmental risk assessment;

(d) Permanent or semi-permanent fish populations have so far been identified around the globe, but this can easily change due to climate change and global warming;

(e) Lack of trained personnel and absence of guidelines.

12. In addition to the information on challenges, some submissions have pointed out that perceived challenges to undertaking risk assessment of organisms containing engineered gene drives and LM fish could be managed following an approach similar to the one that has been used in the risk assessment of LMOs, which is case-by-case and based on the principles of Annex III of the Cartagena Protocol.

C. Specific needs (if any) for properly undertaking risk assessment of living modified organisms containing engineered gene drives

13. The following needs were raised through the submissions of information:

(a) Capacity-building, for example, regional forums for discussion and open discussions beyond government and academic sectors;

(b) Training on how to conduct the risk assessment;

(c) More information on socio-economic considerations;

(d) Risk assessment guidelines;

(e) Possible adjustments may be required in the risk assessment framework/schemes;

(f) Regional approaches that involve all potential affected Parties to obtain the necessary information, perform risk assessment together or using methodologies that are recognised by all of them and design and implement monitoring programmes;

(g) Effective containment of laboratory experiments on the possible effects of introducing the organisms with engineered gene drives into the environment;

(h) Modelling studies and the acquisition of baseline data that feed into modelling parameters. For example, improved study designs to test the behaviour of living modified organisms containing engineered gene drives in contained conditions that would mimic an environmental release. In addition, the models to be used will need to be evaluated under different circumstances and scenarios as the interactions can be complex and non-linear;

(i) New modelling studies that move away from focusing on efficacy (as has occurred to date), to focus on ecological and health risks;

(j) Information to carefully design post-release monitoring plans;

(k) Information to assess potential effects of a release such as: population genetics and dynamics, spatial structure of the population and subpopulations, gene flow within and across populations, ecosystem interactions and potential effects on ecosystem services, genome sequences, genetic diversity and functional role of the target species;

(l) For LM mosquitos containing engineered gene drives, specific information should be gathered along the phased-testing pathway and could include: the generation of biological data for the target species, modelling of its environmental behaviour, or the collection of data from releases of increasing scale;

(m) Knowledge and procedures for assessing the gene-drive's long-term effects on ecosystems;

(n) Information on possibilities to control the spread of gene drives.

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