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# SYNTHESIS OF THE INTERVENTIONS FROM THE OPEN-ENDED ONLINE FORUM

*Note by the Executive Secretary*

## I. INTRODUCTION

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

2. In addition, the Conference of the Parties serving as the meeting to the Parties to the Cartagena Protocol on Biosafety requested the Executive Secretary to commission a study informing the application of annex I to decision CP-9/13 to (a) LMOs containing engineered gene drives, and (b) living modified fish to facilitate the process for the identification and prioritization of specific issues regarding risk assessment of living modified organisms with a view to developing further guidance, and to present it to the open-ended online forum and AHTEG on Risk Assessment and Risk Management.

3. Based on the above, the Open-ended Online Forum on Risk Assessment was convened from 20 January to 1 February 2020, and was moderated by Ms. Marja Ruohonen-Lehto, from Finland.

4. The total number of participants registered for the Forum was 199. Of this total, 149 were from Parties, 4 were from non-Parties, 45 were from Organizations and 1 represented indigenous peoples and local communities.

5. A total of 59 participants were active, and 96 interventions were made. Out of this total, 56 interventions were made by Parties, 4 by non-Parties, 36 by organizations. There were no interventions made by representatives of indigenous peoples and local communities(IPLCs).

6. The following table shows a breakdown of the interventions per topic:

| Topic number | Number of interventions | Number of participants who made interventions |
|---|---|---|
| 1 | 65 | 48 |
| 2 | 31 | 27 |

7. Two topics were identified for discussion under the forum as follows:

(a) Topic 1: Discussion of draft study applying annex I of decision CP-9/13 to living modified organisms containing engineered gene drives;

(b) Topic 2: Discussion of draft study applying annex I of decision CP-9/13 to living modified fish.

8. The online discussions under these topics were based on the draft studies commissioned to inform the application of annex I of decision CP-9/13, which were made available for the discussions. Participants were also invited to consult the submissions received in response to notifications 2019-009 and 2017-035, which relate to the process for the identification and prioritization of specific issues regarding risk assessment of LMOs.

9. In making their interventions, participants were encouraged to focus their comments on the substance of the studies rather than on editorial suggestions, and to share information that:

(a) Could complement the studies, which may include: further development of concepts, explanatory comments, relevant resources, bibliographic references, among others;

(b) Could identify any information gaps or factual errors;

(c) Is relevant to one or more of the aspects of annex I to decision CP-9/13.

10. The present document provides a synthesis of the views shared through the online forum. For a full account of all views, it is recommended to refer to the original online interventions through the Biosafety Clearing-House (https://bch.cbd.int/onlineconferences/forum_ra/discussion.shtml). In addition to the synthesis of the two topics, the links and references provided by various forum participants as additional sources of information are included in document CBD/CP/RA/AHTEG/2020/1/INF/3, which contains a list of references on risk assessment.

## II. SYNTHESIS OF INTERVENTIONS

11. The interventions are synthetized based on the guiding statements suggested by the moderator. However, it is worth noting that sometimes the information shared could be aligned with more than one of the guiding statements.

### Topic 1. Discussion of draft study applying annex I of decision CP-9/13 to living modified organisms containing engineered gene drives

*(a) Information that could complement the studies, which may include: further development of concepts, explanatory comments, relevant resources, bibliographic references, among others*

12. General comments about the study indicated that it provided a good overview of the field of engineered gene drives in relation to risk assessment and that it can be considered a good start for discussions. It was also pointed out that the study presents a good description of the technology and issues of concern.

13. Some participants mentioned that the study has taken a very narrow definition of gene drives, noting that in general, gene drives are any genetic mechanism that can distort segregation of traits, and indicating that gene drives are not limited to organisms that are reproducing through meiotic pathways.[1]

14. On the other hand, others have commented that the understanding of the term “gene drive” as being restricted to sexually-reproducing species (as is the case in the draft study), is consistent with definitions generally used in scientific literature, academies, biosafety advisory boards and regulatory offices. Examples of literature where this concept is used were provided.[2] Along the same vein, some

[1] Lorenzo, V. Microbial Biotechnology (2017) 10(5), 995– 998. doi:10.1111/1751-7915.12816

[2] NASEM (2016): In this report gene drives are defined as systems of biased inheritance in which the ability of a genetic element to pass from a parent to its offspring through sexual reproduction is enhanced.

Australian Academy of Science (2017): “A number of basic criteria are required for a synthetic gene drive to work. Firstly, the organism must reproduce sexually.”

participants recommend sticking to the widely accepted definition of gene drives as systems that result in significantly super-Mendelian inheritance in sexually reproducing species. It was therefore proposed that the scope of the study be clarified and that any limitations of the study because of its scope should also be highlighted. It was also proposed by some participants that discussion of other types of selfish genetic elements[3] could be included in an annex of the study.

15. Other comments in relation to the scope of the study pointed out that it is not feasible to capture all possible scenarios in relation to gene drives in the document, suggesting that it may be helpful to limit the scope to the most likely cases of organisms containing engineered gene drives moving to practical applications, including examples of those that may be expected to be released into the environment in the coming 10 years.

16. Another suggestion was made in relation to the importance for the study to stress more explicitly the possibility to draw on familiarity/experience with some well-established insect vector/pest control strategies when framing the risk assessment of gene drive modified insects, while others were of the view that sterile insect technique (SIT) and Wolbachia for instance, should not be considered under the familiarity concept. On a similar note, it was noted that the technologies that are identified as the most relevant experiences to inform risk assessment are generally limited to mosquito genetic control. It was also pointed out that with regard to ecological significance, there are other control technologies in wide use that could be informative, e.g. biocontrol and conventional population suppression methods.

17. It was also mentioned that it would be useful to specify in the study that the understanding of natural gene drive systems over the last century has provided considerable insights into how gene drives work and how they spread, and that in some cases, this could provide useful baseline information for the risk assessment of engineered gene drives. Others agreed with this suggestion but mentioned that natural gene drives should not be taken as baselines.

18. An issue that was extensively discussed under this topic was the selection of comparators for the risk assessment. In this respect, a participant suggested that it would be helpful to indicate in the study that the deliberate release of any organism containing engineered gene drives should be compared to a range of comparators (including alternative solutions) to allow harms to be appropriately considered. Some participants also referred to possible comparisons with Wolbachia infested mosquitos, as well as traditional and newer SIT designs, while others indicated that for either domesticated or wild species containing engineered gene drives, the comparator would continue to include the non-modified organism.

19. Similarly, it was also discussed that some of the current risk assessment principles such as the comparative approach may not be fit for purpose in the context of the study.

20. Regarding clarity of concepts, it was suggested that the study could clarify better the difference between methodology and specific information needs to conduct risk assessment.

21. In relation to the statements made in the study, the following comments were made: some of the statements made in the study are not applicable to all cases of organisms containing engineered gene

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ZKBS (2016): Gene drive systems are understood to be genetic elements or gene constructs that expedite their own spread in populations of sexually reproducing organisms by being inherited to more than 50% of the offspring"

RIVM (2016): "A gene drive is only effective in organisms that reproduce sexually."

NEPAD (2018): Gene drives are systems of biased inheritance in which the ability of a genetic element to pass from a parent to its offspring through sexual reproduction is enhanced (National Academies of Sciences & Medicine, 2016; Sinkins & Gould, 2006).

OGTR (2019): "Gene drives are genetic elements that are favoured for inheritance, and which can therefore spread through populations at a greater rate than genes with standard Mendelian inheritance. Gene drives can only spread from sexually reproducing parents to their offspring"

[3] Selfish genetic elements can be considered DNA sequences that are transmitted to viable offspring at greater than Mendelian frequencies (Cash et al., 2019; https://doi.org/10.1002/ece3.5876) or stretches of DNA that enhance their own transmission related to the 'host' genome (Werren, 2011; https://doi.org/10.1073/pnas.1102343108).

drives, and therefore it was suggested that it would be helpful to clarify to which gene drive cases or categories the statements apply; the lines of evidence used to substantiate some statements and their weight are not always obvious, recommending that this could be addressed by making the statements more specific about the sources of evidence used to substantiate them.

22. In relation to citations in the study about the examples of post-release surveillance of Wolbachia infected *Aedes aegypti* mosquitoes, it was mentioned that the study should acknowledge that these mosquitoes are known to have dispersal distances that are significantly smaller than, for example, the dominant Anopheline malaria vectors in Africa, arguing that it has important implications for post-release monitoring strategies. In this respect, it was also pointed out that genetically engineered gene drives typically require multiple generations to establish the desired effect in the target populations, which could cause a broad range of unintended effects in the next generation, pointing that there is no such process involved in the Wolbachia system or with techniques used in SIT. Thus, suggesting that if any comparison is made, these differences should be stated in the report.

23. Another issue that was extensively discussed through the forum was the need for the study to capture the issue of public consultations in relation to the risk assessment process. It was mentioned that engineered gene drive applications will require public consultation and would need to consider the interests of IPLCs. Along these lines, it was also suggested that the study should refer to ethical issues associated with potential risks from organisms containing engineered gene drives, in particular in relation to the "social amplification of risk", which is a term used to cover a variety of social and psychological factors that influence people's perception or judgment about the level, seriousness and degree of threat associated with a given risk.

24. In relation to potential effects from the release of organisms containing engineered gene drives, it was mentioned that the study should clarify that potential effects on future generations associated with the introduction of engineered gene drives should not be assessed in the same way as risks of domesticated crop plants which are meant to be cultivated for a specific timeframe in the field.

25. A participant pointed out that the concept of the "receiving environment" is often defined by the authors in a conservative manner, indicating that this may affect considerations on the entire likely affected area.

26. Some comments pointed out areas of the study that could be stressed more such as:

(a) Indication that risk assessment can only be performed on a case-by-case basis, and not in a general manner;

(b) Indication that in contrast to genetically modified plants, there is little experience with risk assessment of living modified insects;

(c) The importance to assess the potential environmental impacts of organisms containing engineered gene drives in light of the effects of the environmental impacts of current control techniques and other methods currently in use.

27. In relation to the mention in the study about organisms containing engineered gene drives targeting non-managed environments, it was suggested to note that in some cases, the release of these organisms into unmanaged environments will require that an Environmental Impact Assessment (EIA) is conducted to evaluate the likely environmental impacts of the intended release.

28. A participant noted that the study indicates that "some applications are close to being released in trials", and suggested that it will be helpful to clarify that in the context of the Cartagena Protocol, organisms with gene drives fall under the definition of LMOs and that the AIA procedure requires authorization for releases that fall under that procedure. In relation to the same statement on the study, another participant indicated that more detailed explanation about these trials and any potential risk assessments undertaken for them would be desirable.

29. It was suggested that the study should consider the fact that categorizing gene drives will not be as straightforward in practice as it is attempted in theory, and that differences between suppression and modification drives are important for risk assessment.

30. A participant recommended that the study should stress that knowledge gaps and lack of ecological modelling tools probably hinder the execution of a sound (ecological) risk assessment currently, but also in the near future.

31. In relation to clarity on the study's content and use of terms, some suggestions were made such as: (a) when discussing resistance evolution, the study should distinguish the following issues: probability of resistance evolution, impact on gene drive efficacy, impact in terms of risks and potential use as a confinement strategy; (b) the study could use terminology of "population modification" rather than "population replacement", indicating that in such strategies, the gene drive does not replace a pre-existing population with a new population; (c) to avoid the confusion between "off-target mutations" and "off-target effects" it would be advisable to distinguish between off-target mutagenesis from activity of the CRISPR-Cas system (that may lead to off-target mutations), and the impact of off-target mutations in terms of risks.

32. Some participants mentioned that the issue of the precautionary principle seems to have been poorly considered in the study, while others were of the view that the precautionary approach should not be confused with risk assessment.

33. It was also mentioned that the report would benefit from indicating how the selection of stakeholders was done and how this information is used in the report.

*(b) Identification of any information gaps or factual errors*

34. The following issues were pointed out as possible errors in the study by different forum participants:

(a) Gene drives in non-sexually reproducing organisms are not based on mating potential. Therefore, the study is incorrect to conclude that "since gene drives are based on mating potential, the potential for exchange with related species is very species specific";

(b) The wording used in the title of Annex I is misleading, as an extensive literature search has been performed instead of a systematic review;

(c) The study presents a misleading comparison when referring to methods of biocontrol such as the Wolbachia infection in mosquitos, since the risks emerging from the Wolbachia system cannot always be compared to those of organisms containing engineered gene drives. It was suggested that the differences are pointed out.

(d) The indication in the study that the concept of the "receiving environment" needs to be revisited is not accurate, noting that it is not the concept that needs to be revisited, but rather the amount and type of data required on the receiving environment;

(e) A number of aspects that are mentioned in the report to be specific for insects with a gene drive, are actually only related to the fact that living modified insects are able to spread and propagate, and are not directly related to the gene drive itself;

(f) The study's assertion that technologies for population replacement are likely to induce less ecological harm than population suppression technologies, because the former does entail the removal of a population, is a generalisation that ignores important case-by-case differences between target species, and the possibility of other risk pathways, such as horizontal gene transfer;

(g) Isolated locations such as islands do not constitute a form of biological or molecular confinement as stated in the study;

(h) The study fails to recognise that there are also risks to biodiversity associated with removing invasive species, indicating that any suggestions that removing invasive species, by default, would be beneficial to ecosystems and biodiversity ignores previous experiences where in extreme cases, removal of an invasive species has resulted in serious ecosystem degradation that required expensive reparatory actions (TWN);

(i) The study is inaccurate when it states that "in line with the precautionary approach, scientific uncertainty must be reduced in order to advance through research and development", since this is not the principal objective of the precautionary principle.

35. The following issues were raised by forum participants as potential gaps in the study:

(a) The study omits mention of control methods such as traditional and newer SIT;

(b) The study omits to mention issues such as uncertainty when using laboratory-based observations to predict outcomes in the field;

(c) While the study acknowledges that robust modelling will be required to support risk assessment, it fails to recognise that such knowledge is difficult to obtain for a system that continues to perform genetic engineering once released (i.e. introducing a modification tool rather than a finished product);

(d) The study missed an important opportunity by limiting the interviews to competent national authorities and risk assessors. Important insights can be gained from: 1) developers of gene drives and 2) population modelers directly examining the dynamics of gene drive organisms;

(e) In relation to the "stock-taking exercise" of annex I to decision CP-9/13, there is no mention in the study of the activities and procedures used by the World Health Organization's (WHO) Vector Control Advisory Group (VCAG), which reviews a wide variety of new vector control methods, including mosquitoes containing engineered gene drives;

(f) The study should include a detailed listing of all the LMOs with engineered gene drives currently being developed (including the gene drive systems employed), and species where feasibility is being explored with preliminary work. Table 5 in the study is a helpful step in this direction, however much important information is not included;

(g) The listing of the considerations on risk assessment as given in the report are insufficient. For example, the issue of evolution (and not just evolution of resistance to homing endonuclease gene (HEG)-based gene drive) is not given any mention;

(h) The report fails to acknowledge that any deployment of a gene drive as part of a stepwise-approach is effectively an open release, even if performed on island locations;

(i) There is a gap in how the study raises fundamental challenges for risk assessment that come from the distinguishing features of organisms containing engineered gene drives. An example was provided indicating that while off-target and unintended effects at the molecular level may potentially be assessed with current LMOs before an environmental release, this may not be the case for organisms containing engineered gene drives, as there is no 'final' product, but instead the release of a genetically modified organism that will continue to function in wild populations. Therefore, potential next generation effects of these processes occurring continuously over time will not have been considered to the same extent as with current LMOs. On the other hand, others were of the view that organisms containing engineered gene drives can be seen as a finished product, pointing out that authorized events are passed on to offspring and this process is assessed during risk assessment and generally included in the authorization;

(j) The study refers to resistance development as a means for confinement of organisms containing engineered gene drives, and it fails to take into consideration that control strategies that are based on resistance development as a confinement method are subject to high uncertainty;

(k) It was mentioned that the issues of evolution and co-evolution are not properly addressed in the study. At the same time, it was also pointed out that to assess evolution and co-evolution at the species level and moreover at the ecosystem level will probably take hundreds or thousands of years to have enough evidence that a positive or negative selection pressure was introduced by an engineered gene drive;

(l) The study should explicitly recognise that there is potential for outcomes and hazards that have not been anticipated, like the so called 'unknown unknowns';

(m) The study reflects a narrow view on biodiversity that is characterized by terms like "keystone species", while it should be broader since organisms containing engineering gene drives may have the capacity to negatively impact all areas of biodiversity.

*(c) Information that is relevant to one or more of the aspects of annex I to decision CP-9/13*

36. An issue that was raised several times during the forum from various participants was the need for capacity-building programmes in relation to the risk assessment of organisms containing engineered gene drives. Scientific knowledge and understanding of gene drives and the application of risk assessment methodologies were pointed out as potential areas for support. It was also noted that more research and development and capacity-building are needed to tackle the technical and methodological challenges of risk assessment and monitoring. Other participants also referred to the fact that apart from technical capacity, infrastructure capacity will also be needed in order to collect the data required for risk assessment. Regional cooperation and integrated approaches to risk assessment were also mentioned as something important to consider given that organisms containing engineered gene drives may spread outside the intended geographical area, including across national borders.

37. In relation to the main challenges for risk assessment, some participants were of the view that the study should stress the difference between challenges to the risk assessment methodology and challenges relating to obtaining information required to inform the risk assessment. Along these lines, some participants considered that the main challenge is linked to the level of practical experience of the risk assessors rather than on the suitability of the current methodologies, while others indicated that the challenges might call for the development of specific methodologies, models and datasets. In addition, it was also pointed out that even having a sound methodology, if the necessary information is missing, this will not result in a sound risk assessment. The design and implementation of post-release monitoring strategies that are capable of generating the evidence necessary to confidently test risk predictions was also flagged as a challenge.

38. It was also noted that when assessing organisms containing engineered gene drives, access to the right scientific information and expertise were a challenge, and the Biosafety Clearing House (BCH) as well as other processes for information exchange under the CBD were seen as a valuable tool to raise awareness about resources and expertise that are available.

39. The difficulty associated with the assessment for the use of the gene drive technology was also pointed out as a challenge in light of the fact that there could be potential benefits and potential adverse effects at the same time from proposed applications of organisms containing engineered gene drives.

40. It was noted that the European Food Safety Authority (EFSA) will soon launch the draft GMO Panel scientific opinion on "the evaluation of existing EFSA guidelines for their adequacy for the molecular characterisation and environmental risk assessment of genetically modified insects with synthetically engineered gene drives" for public consultation, and several forum participants recognised the importance that these documents could have for future discussions.

41. A participant mentioned that the references provided under section 5.2 of the study cover many relevant aspects of environmental risk assessment of organisms containing engineered gene drives but cannot be considered as existing guidance documents as such.

42. The fact that gene drives will modify organisms in the field was flagged as something that required some thought in terms of what the risk assessment will entail and what information will be accepted to support the analysis. The use of models to help predict ecological effects and estimate certain risks was mentioned as a potential useful tool to support risk assessment. It was also mentioned that robust models will be a valuable tool since they could improve the understanding of potential effects on a population at an ecosystem level, and they could improve the understanding of what kind and quality of data are required to feed a model to obtain robust results. Likewise, it was noted that for organisms containing engineered gene drives, theoretical modelling exercises address the spread and functionality of specific gene drive constructs, while potential ecological implications have been discussed on a theoretical level only. In addition, it was pointed out that the long-term aspect of monitoring will need to be addressed.

43. In relation to the step-wise approach for risk assessment, it was suggested that more thought would need to go into the risk assessment for the field releases, the conditions under which this would be released if accepted and the risk management measures associated to them.

44. It was mentioned that the selection of protection goals for the risk assessment will have to be formulated by different stakeholders and not only the scientific community.

45. A participant pointed out that it was not yet agreed how the criteria in annex I to decision CP-9/13 will be applied to inform a decision.

46. A participant indicated that the types of drives that do not require sexual reproduction to either propagate or distort (also called selfish genetic elements in some literature) fall under the criteria listed in annex I, in particular criterion "c", because their specific technical or methodological challenges are not addressed in existing guidance, indicating that existing reviews from the National Academies of Sciences, Engineering, and Medicine of the United States and the Office of the Gene Technology Regulator of the Government of Australia and others have been exclusive to meiotic drives.

47. Concerning criterion "d" in annex I (challenges in addressing the specific issue are clearly described), it was mentioned that this need to be done on a case by case basis and focused on realistically foreseeable applications.

48. In relation to criterion "e (i)" a participant noted that while the theoretical eradication of a species would be clearly an irreversible effect, whether it is also a serious and adverse effect on biodiversity needs to be established on a case by case basis for each application. In relation to point (iv) of the same criterion, which refers to applications that are already, or are likely to be, commercialized or in use somewhere in the world, the participant noted that if there are any organisms containing engineered gene drives close to being released, then they should be described in the study as a source of information which can provide specific examples that could be useful for risk assessment.

*(d) Other comments*

49. Some participants also shared their views regarding the need for guidance for organisms containing engineered gene drives, with views being divided between those that believe there is no need for guidance, and those who believed that guidance or an outline for the assessment of organisms containing engineered gene drives are needed. It was also noted by a participant that a general guidance document for this purpose may be difficult to develop due to the many different scenarios that should be considered (e.g. biology of the organism, the specific gene drive system, the potential receiving environment, etc). It was indicated that the development of a document outlining the general principles and considerations that should be taken into account when conducting risk assessment of organisms containing engineered gene drives could be useful.

**Topic 2: Discussion of draft study applying annex I of decision CP-9/13 to living modified fish**

50. As with topic 1, the synthesis of the interventions below follows the guiding questions suggested by the moderator.

*(a) Information that could complement the studies, which may include: further development of concepts, explanatory comments, relevant resources, bibliographic references, among others*

51. Overall, participants found the draft study provided a good overview on the topic of living modified fish, and considered it a good basis for discussion. It was also indicated that existing risk assessment documents and guidance were well-presented in the document.

52. It was noted that the study's distinction between ornamental fish and fish for food purposes was useful.

53. Through the interventions some suggestions were also made such as:

(a) The section on AquAdvantage Salmon would benefit from taking a more generic approach regarding growth enhancement as a trait that has been altered in many species of fish;

(b) Additional data should be included on gaps and uncertainties as well as on examples where fish may escape into the environment;

(c) More information on the criteria used to select the countries and stakeholders that were contacted with the specific questions in the questionnaire should be provided;

(d) More data could be included on environmental effects resulting from current aquaculture with non-living modified fish, that can serve as baseline for the risk assessment of living modified fish;

(e) Replacing the use of "improve" by a term such as "enhance", arguing that from an ecological point of view such "improvements" (as referred to in the study) would mostly not be perceived as such;

(f) Including information that will cover a wider spectrum of potential receiving environments as well as a full range of potential hazards. In this respect it was also noted that to gather that information would be an additional exercise on its own.

*(b) Identification of any information gaps or factual errors*

54. The following issues were raised by forum participants as potential gaps in the study:

(a) The precautionary principle was not mentioned;

(b) Potential effects on the next generation effects were not detailed;

(c) There is no reference to process-induced changes (i.e. due to the insertion site, possible gene or gene regulation disruption, small mutations or alterations arisen).

*(c) Information that is relevant to one or more of the aspects of annex I of decision CP-9/13*

55. The need for capacity-building, sharing of experiences and information was mentioned several times during the online forum. Also, reference was made to the current experience in performing risk assessment on living modified fish by some countries, and that countries facing challenges related to risk assessment of living modified fish may take advantage of that experience.

56. In relation to existing challenges, the following were pointed out: limited information available on marine and aquatic environments including baseline information on fish biology and ecology in different environments; high levels of uncertainty for some fish species, selection of comparators for risk assessment of living modified fish; generating experimental data under natural conditions; the fact that impacts may occur in international waters, in the context of identifying who should be responsible for the risk assessment; and need for further training for regulators on risk assessment issues.

57. The suitability of current risk assessment methodologies to assess next generation effects was also pointed out as a challenge, with others having an opposing view, indicating that it is the lack of information about the LMO that poses a challenge rather than the inadequacy of the risk assessment methodologies. In this regard, views also diverged on how these challenges could be addressed, with some considering that

new or adapted guidelines could help, and others indicating that the challenges cannot be addressed by new guidance on a specific topic, but rather by more capacity-building activities promoting sharing of experiences and information. It was also pointed out that some of the challenges identified are generally associated with the environmental release of non-domesticated species but not specific to living modified fish.

58. Finally, a comment was made about the need to think on how the set of criteria from annex I to decision CP-9/13 could be improved to better perform the task to identify and prioritize specific issues.

*(d) Other comments*

59. The need for guidance was also widely discussed during the online forum, with divergent views on whether new guidance should be developed. It was noted that existing guidance for risk assessment of LMOs provide a good basis on how to proceed and they can be used for living modified fish. In this respect, some noted that this guidance could benefit from being adapted according to each case, while others pointed out that risk assessment of living modified fish is always case-specific and a guidance document cannot provide protocols for individual events or situations. The BCH was mentioned as a platform where experiences, relevant documents and training materials could be shared.

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