

**Revision of risk assessment study “Application of Annex 1 of decision CP-9/13 to living modified fish” after the online forum.**

<b>Observations</b>	<b>Post numbers related to the observation</b>	<b>Actions taken</b>
The selection criteria for respondents of the questionnaire not included in the methodology of the study.	10138, 10146	Further explanatory text added to first paragraph of section 4.2.
Suggestion to include environmental impacts of the aquaculture of non-LM fish as a baseline for assess impacts of LM fish cultivation.	10138, 10146, 10188	Sentence added to paragraph 12 of the executive summary and relevant resource added to Section 6.3.7 to capture this view. The study also contains reference to relevant resources in Annex 5 for non-LM fish comparisons.
Due to their motility, LM fish have the potential for transboundary movements, which may pose challenges to risk assessment.	10125, 10214	Sentences added to paragraph 11 of the executive summary and in section 8c to reflect the potential for transboundary movements.
Precautionary principle was not mentioned in the study.	10151, 10214	Sentence added to section 8.1 (b) to mention the precautionary principle in the study .
Limited information is available on aquatic environments and generating data for risk assessment.	10136, 10158, 10173, 10178, 10213	Sentence added to section 8.1 (d) to reflect this viewpoint. Additionally, challenges regarding complexities of aquatic environments can be found in the last paragraph of section 7.2.
Gaps in training for regulators may pose challenges to risk assessors.	10123, 10142, 10151,	Sentence added to section 8.1 (d) to reflect this viewpoint.
The need for capacity-building and information sharing was stressed.	10121, 10123, 10124, 10126, 10138, 10140, 10150, 10158, 10165, 10173, 10188, 10194, 10196, 10205, 10217	Sentence added to paragraph 9 in the executive summary to capture the importance of capacity-building. The study additionally contains relevant text in section 6.4.3.
Suggestion to include information on environmental releases of non-modified fish.	10140	Examples of Atlantic salmon (see section 6.4.2 – Glover et al. (2017) and reference by Cowx et al (2010)) and tropical fish (see section 6.4.1 – Lawson et al. (2017)) have been added to the study.
An example of ornamental fish escape in Florida was provided as a supplementing reference for the study.	10150	References (Tuckett et al. and Lawson et al. 2017) have been included in section 6.4.1 and included in the list of references.

An additional reference was provided for environmental impact of non-modified fish release from aquaculture facilities.	10150	Reference (Glover et al., 2017) cited in section 6.4.2 and included in the list of references.
Uncertainty analysis was highlighted as an integral part of each risk assessment of LMOs for environmental release, which can principally be done on a case-by-case basis. An example of such analysis was provided to complement the study.	10173	Reference to European Food Safety Authority uncertainty analysis guidance added to reference list.
More information on pleiotrophic effects, data gaps and uncertainties requested for inclusion in study.	10205, 10214	No action taken. Discussion of challenges related to fish biology are discussed in section 6.4. However, uncertainty analysis is now cover by inclusion of a reference to European Food Safety Authority uncertainty analysis guidance added to reference list.
Risk assessment document for pink salmon provided as an example of non-modified, non-native fish introduction into environment.	10205	VKM report (2020) added to section 6.3.7 and to list of references.
More information on GloFish requested in sections 5.3.7 (fluorescent trait) and 6.1 (commercialization).	10211	No action taken. The study details different aspects of GloFish®, such as fluorescent traits in section 5.3.7, as well as commercialization, regulation and risk assessment in section 6.1.
Risk assessments performed on fluorescent ornamental fish provided as a relevant example for the study.	10211	Reference to Department of Fisheries and Oceans (2019) incorporated in section 6.4.1 and in reference list.
Correction for growth rate differences between diploid and triploid Atlantic salmon noted.	10211	Phrase stating triploid salmon grow faster deleted in section 6.2.
Corrections for citations and bibliographic information were provided for a few referenced documents.	10211	Devlin et al. (1995) deleted from section 5.3.1; Description from Jha (2010) added to section 6.4.1; Clarifying information provided in section 6.4.2 and inclusion of

		references Leggatt et al. (2014) and DFO (2018).
Importance of identifying non-modified comparator species for risk assessment.	10211	The study mentioned comparators and baselines in the sections 6, 8.1c and 8.1d.
Suggestion for a more detailed discussion of the routes of exposure.	10214	No action taken. Information on routes of exposure can be found within the guidance documents referred to in section 6.3.
Suggestion to include information on interactions with centres of origin.	10214	No action taken. Interactions with wild-type organisms and within centres of origin are covered by the guidance documents referred to in section 6.3, as well as the references Kapuscinski et al. (2007) and Cowx et al. (2010).
Risk assessment of contained-use AquAdvantage salmon in United States of America shared as a relevant example.	10219	A reference to the application by the company to the United States of America's Food and Drug Administration added to section 6.2.
Limited scientific information is available on most fish species. In particular, fish species have greater genetic diversity compared to modified plants and thus will require considerable effort to create a baseline to compare to.	10201	No action taken. Challenges regarding the biology of fish species are mentioned in the second paragraph of section 8.1 (c) and the paragraph in section 8.1 (d).
Risk assessment of LM fish should always be performed on a case-by-case basis.	10123, 10140, 10165, 10173, 10186, 10188, 10194, 10211	No action taken. The case-by-case nature of risk assessment of LM fish can be specified in sections 6.3.1, 6.5.1, 8.1 (e), Annex 4 and Annex 5.
Challenges to conducting risk assessments on LM fish have been a lack of information about LMO rather than inadequacy of a risk assessment framework.	10196	No action taken. Information on risk assessment frameworks for LM fish is provided in section 7.2. The lack of information regarding fish biology can be found in the second paragraph of section 8.1 (c) and in section 8.1 (d).