

**TEMPLATE FOR COMMENTS ON THE DRAFT REPORT OF DISCUSSIONS OF
THE ONLINE FORUM ON RISK ASSESSMENT AND RISK MANAGEMENT
(29 JANUARY-12 FEBRUARY 2018)**

Please find below the input from the Global Industry Coalition (GIC) in response to the invitation to provide a peer review of the draft report of the online forum on risk assessment and risk management.

Paragraph ID #	Suggested change¹	Explanation
N/A	None	The GIC appreciates this opportunity to provide a peer review and commends the moderator for his diligence and hard work to complete this exhaustive report. It is clear that every comment was given careful consideration. The GIC is of the view that the list of guidance information in the Appendix is especially important since it is objective information that the SBSTTA can use. It is also clear that the outcome of this forum is consistent with the history of the discussion on gaps and guidance in risk assessment and risk management under the Biosafety Protocol that has occurred since 2005.
N/A	The GIC suggests quantifying the subjective “many” and “some” language to make it more informative to decision makers.	The report often references “many” and “some” commentators. If there is an objective way to quantify these, it may be helpful to understand if an opinion is truly prevailing or if it was simply a statement made by a small number of participants. In some cases, the report does indicate “one participant” or “a participant from...”. It would be helpful to present a summary as to whether such comments were in alignment with the views expressed by the majority of participants or were rather isolated statements.
N/A	The GIC suggests the report authors add in the introductory text the fact that there was much cross-over among the various discussion groups.	The report does not sufficiently reflect the cross-over among the topics. For example, points made under Topic 1 were very relevant to Topic 3, but this connection is not well reflected in the final report. Making clearer the interconnection between the discussed topics would emphasize the issues that are the most prevalent in the discussion and top of mind for participants.
1	The GIC suggests amending this paragraph to reflect not just the total interventions made, but how many individuals made interventions.	Given that this is a forum of experts, a useful number would be the number of individual participants that made interventions. This would make the introduction to the report more informative. E.g., the discussion on benefits involved a fairly significant number of interventions, but a smaller number of experts.
21	Please add the statement, “An intervention noted that over the past 12 years, about 65 individual topics have been offered as needing guidance”.	This provides important fact regarding the history of negotiations relating to the discussion on risk assessment and risk management and development of additional guidance.
27	The GIC supports and shares the recommendation expressed in this paragraph.	The GIC welcomes the recommendation for efforts to improve knowledge and understanding regarding the objectives, use, general principles, and methodology of risk assessment. Lack of practical knowledge on this matter, in our view, is the main reason why many participants to the forum perceive various gaps and request additional guidance on specific topics.

43	Please link paragraph 43 to Topic 3, paragraphs 47 to 74, to provide better context of the majority view on perceived gaps.	<p>In comparison to the exhaustive list of perceived gaps, a much less prominent comment is made in paragraphs 43 and 81 regarding the majority view of the forum of the lack of gaps in current risk assessment methodologies. The GIC’s view is that this majority view needs to be reinforced. The single paragraph that is included states, “43. Many submitters suggested that existing guidance documents are more than sufficient for any currently conceivable risk assessment, and that there is no need for the development of new guidance, either generally, or for specific organisms or classifications of organisms.”</p> <p>This is a true summary of the view shared amongst the majority of the participants and needs to be highlighted in connection to the discussion that follows in the section about perceived gaps and needs for additional guidance.</p> <p>We note that the majority of entries under topic 3 are not supported by more than one or few submissions and that the majority view, as expressed in paragraphs 43 and 81 is that currently there are no gaps and need for development of new or additional guidance.</p>
47-74	Please see the recommendation for paragraph 46 below for a suggested change.	<p>We note that the views of single participants expressed under these paragraphs are not representative of the majority opinion amongst experts as discussed in our entry for paragraph 43 and in paragraph 81 of the report.</p> <p>Although the majority view of the forum that there are no existing gaps is briefly presented under paragraph 81, the number of perceived “gaps” as identified mostly by single participants create a misleading impression that there are many topics of need for development of further guidance.</p> <p>A stronger statement that underlines the predominant expert opinion is recommended as suggested below</p>
46	Please insert a new paragraph before paragraph 46 to reflect the majority view about the lack of gaps in existing guidance.	<p>As stated above, we strongly recommend that the majority view of the forum is stated right at the beginning of this section as to provide better context as to the views expressed by single contributors regarding perceived gaps and needs for additional guidance.</p> <p>A summary statement that reflects the entries in paragraph 81-90 is an appropriate way to address this.</p>
62-72	A paragraph should be added in this section to better reflect that many interventions stated that, in fact, there are no gaps, and that over the past 12 years approximately 65 unique topics have been raised, including those delineated in para 62.	Paragraphs 62-72 reflect only the discussion on specific gaps as perceived by a portion of the interventions. Importantly, at least two interventions noted that perceptions of gaps are readily explained as individual approaches to address personal knowledge gaps, lack of familiarity with technologies and lack of experience with risk assessment of LMOs. The GIC is concerned that this will send the wrong message to SBSTTA about the need for guidance on synthetic biology.
63	Please delete this paragraph, “Organisms obtained through synthetic biology (Perceived gap (1) above) were put forward by many	Firstly, the pace of development for products of synthetic biology is by no means “rapid”, nor faster than the developments for any of the other potential topics. While one commenter stated this, it is simply an opinion and not a fact,

	<p>submitters because “The rapid pace of development in synthetic biology means that existing risk assessment methodologies would need to be updated and adapted”.”</p>	<p>and cannot be used to justify the need to develop new risk assessment guidance. Secondly, the rate of development is largely irrelevant and cannot be used as a criterion for whether there are gaps in existing regulation and guidance materials and as a justification for establishing additional regulations.</p>
<p>80</p>	<p>The GIC suggests this sentence be clarified to state, “One participant suggested that SBSTTA...”</p>	<p>This is an example of the points the GIC raises regarding the need to specifically quantify the number of participants making a statement. It was only one individual making the comment addressed in this paragraph, yet it is specific enough to be elevated to an actual task for SBSTTA to take on during its next meeting if it is not made clear that this was just one comment made in an extensive discussion on the issue.</p>