

Annex

TEMPLATE FOR COMMENTS ON THE REPORT OF THE AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY

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Title of document reviewed:	REPORT OF THE AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY	
Comments on the draft documentation for SBSTTA-22:		
Page #	Para #	Comment
		<p>General comment</p> <p>Thank you for the opportunity to provide comments on this report. The GIC is pleased to contribute to this process. Our comments have been targeted toward ensuring that the statements made in the report are factually accurate to ensure the integrity of the report. For example, the GIC would like to comment on an issue with the overall report, namely, that report is not clear about the level of agreement accorded to each statement. The statements are referenced without any indication of whether they are consensus views of the full AHTEG, or simply statements made by one AHTEG member. The GIC suggests that the report be edited to include this information to ensure it is as accurate and transparent as possible.</p>
3	14, 15(f), 15(h), 16, and 17	<p>There are several references in Section 3.1 to “accelerated rate” or speed of development and it is implied that the speed of development of a technology is cause for greater concern. The operational definition of synthetic biology for the work and further deliberations under the CBD covers adequately the novelty and technological advancement in the area of biotechnology. For the purposes of this discussion, the operational definition is sufficient. 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>

3	14	<p>We suggest to make the following edits to the paragraph: replace “resulting in an increasing” with “that may lead to an increase in the”, so the sentence would be revised to state, “In its deliberations under this agenda item, the AHTEG acknowledged that technological developments within the field of synthetic biology were advancing at an accelerated rate, <i>that might lead to an increase in the</i> resulting in an increasing number of organisms that had been engineered using various tools and techniques.</p> <p>This edit would make the statement more factual. It is not currently established, nor is there a consensus amongst experts on what types or numbers of organisms have already been developed using techniques of synthetic biology. Furthermore, there has not been a clear understanding about what constitutes a “technique of synthetic biology” which would be uniquely applicable to a category of organisms that are distinct from existing LMOs as defined under the Cartagena Protocol.</p>
3	15 (a)	<p>The sentence “a) Some recent synthetic biology techniques expand the range of organisms that can be modified;” is inaccurate as it does not apply to all products of synthetic biology. It should state, “a) Some recent synthetic biology techniques MAY expand...” in order to be a factually correct statement. A vague statement like this adds little value to the scientific discussion because the lack of specificity. Generalizations in the report do not help the reader understand where potential challenges may lay. Adding the conditional word “may” will stress that this statement is not supported currently with evidence or references, nor by information shared in the preceding synthetic biology on-line forums by experts.</p>
3	15(b)	<p>This sentence requires edits again to make it factually correct. We suggest to it should be edited as follows: “(b) Synthesis and <i>assembly</i> of whole genomes and chromosomes is <i>increasingly feasible</i>, now possible and can <i>this might</i> have significant implications on the way modification of organisms is done;”</p> <p>We note that synthesis of whole genomes is not possible today unless it is followed by an assembly step. The implications of such technological developments on the way modification of organisms is done in the future could be quite positive (e.g. increased predictability of outcomes, complete knowledge of the genetic sequence of the organism).</p>
3	15 (c)	<p>We suggest deleting this paragraph. We note that the title of this section “Recent technological developments in the field of synthetic biology” does not allow for such statements to be included as it is discussing supposed applications of gene editing tools. If the paragraph is retained, we suggest the following wording: At the end of the paragraph add the phrase: “; <i>some synthetic biology applications might use gene editing tools.</i>”</p>



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3	15 (f)	<p>We suggest deleting the end of this paragraph.</p> <p>(f) Some recent developments in synthetic biology have advanced to the point at which organisms might be considered for introduction into the environment at an accelerated rate;</p> <p>We believe, as stated in our earlier comment (line 3), that the perception of whether or not developments occur at an accelerated rate is alarmist, very subjective and does not add any value to the discussion. A simple statement that some organism might be considered for introduction into the environment is sufficient here.</p>
3	15 (h)	<p>We suggest deleting this paragraph.</p> <p>We fundamentally disagree with the statement in this sentence since modified organisms can be produced very rapidly with “older tools” as well. However, new tools enable more precise modifications.</p> <p>However, if the paragraph is to be retained, we suggest the following edits: Delete “new”. Add “but also more precise” We believe that with scientific and technological progress the tools that researchers use for making genetic modifications in organisms continuously evolve and become more predictable.</p> <p>Combining new biotechnology tools and automation allows the more rapid <i>but also more precise</i> production of modified organisms;</p>
3	15(i)	<p>What is the relevance of this sentence especially given the use of the term “relatively “open””?</p>
3	15(k)	<p>We suggest deletion of this paragraph.</p> <p>We question the scientific value of the statement, and we are not aware of a category of, “External genome regulation methods” and do not agree that RNA interference could be correctly called such a “method”. In the interest of the scientific accuracy of this report, it is important that the information that is presented here is factual and correct. Unfortunately, the statement in para 15(k) is neither.</p> <p>Should the paragraph be retained, we recommend that edits are made so that the full paragraph would read as follows: External genome regulation methods are being developed, such as RNA interference vectors or reagents being applied in the form of sprays. <i>“RNA interference can be used in various ways, including as externally delivered RNA.”</i></p>

3	16	<p>We suggest deleting “ever increasing”.</p> <p>“The ever increasing speed of development within the field of synthetic biology might pose a challenge to the capacity to conduct risk assessments in some countries.”</p> <p>In line with our general comments made above about labels such as “accelerated rate of development”, we note the use of “ever increasing speed of development” here is a very subjective perception. We strongly recommend that this expression be deleted from the paragraph as indicated below. For the integrity of the report, it is important that it uses correct and factual information. The current sentence implies that not the speed of development in synthetic biology, but the fact that this speed is “ever increasing” is the reason why some countries may encounter challenges in conducting risk assessment.</p>
3	17	<p>We suggest editing this paragraph as follows:</p> <p>recent Some developments in synthetic biology and the continued pace of development may pose challenges to assessing the possible impacts on biodiversity and human health. There might be a need to consider more thoroughly the potential benefits and potential adverse effects at the ecosystem level, particularly for some developments, such as engineered gene drives.”</p> <p>The paragraph implicates synthetic biology broadly while, in fact, only some developments may pose challenges (many others may not). We question what is implied under “recent” and if this is linked to the list under para 15, we note that the majority of so listed recent technological developments are clearly not recent, nor uniquely related to the field of synthetic biology. “Recent” is also a perception that may be shared by some, but not all experts, depending on their actual scientific and technical background.</p> <p>The point of this exercise is to “assess” impacts and not just “understand”.</p> <p>What does it mean to “more thoroughly” consider the potential benefits and adverse effects? More thoroughly than what? How is a reader meant to act on this recommendation?</p>
3	18	<p>There should be reference to practices currently in use. Section 3.1 in general should better reflect real-world experiences that have been documented to date.</p>
3	20	<p>We suggest inserting the word “potential”.</p> <p>The AHTEG noted that regular horizon scanning, monitoring and assessing of developments in the field of synthetic biology could be useful for reviewing new information regarding the <i>potential</i> positive and negative impacts of synthetic biology vis-à-vis the three objectives of the Convention and its Protocols.</p>



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4	22	<p>We suggest deleting the second sentence.</p> <p>The second sentence should be deleted because it speculates without supportive evidence. In fact, this sentence is contradictory to the input from countries that are successfully developing organisms and products using synthetic biology approaches. Also, level of complexity is not an objective or scientifically definable criterion.</p>
4	23	<p>We suggest edits to this paragraph as follows;</p> <p>This sentence should be redrafted to read: <i>“The AHTEG noted that the empirical evidence of the benefits and adverse effects on biodiversity resulting from the organisms, components and products of synthetic biology is limited to the experience gained from LMOs already released into the environment.”</i> The current sentence implies an insufficiency of evidence, but insufficient for what purpose?</p>
4	24 (line 7)	<p>We suggest deleting the word “traditional”</p>
5	25	<p>This paragraph does not appear to reflect real-world experience with LM mosquitos. In particular, the recommendation to prohibit release pending “additional research and guidance” seems to ignore existing experience.</p>
5	25	<p>We suggest editing the sentence in para 25 (lines 12-13) as follows:</p> <p><i>“The AHTEG also noted the potential for the unintended transboundary movements and geographic spread of organisms containing engineered gene drives released into the environment.”</i></p>
5	31	<p>This paragraph should be deleted.</p> <p>While it is interesting that some cultures regard all components of Mother Nature as living, the CBD considers only organisms as biodiversity.</p>
5 & 6	Section 3.4	<p>This entire section needs to place detection in an appropriate context. Detection methods are called out in the Biosafety Protocol (Annex III) and Article 8(g) of the CBD for LMOs (only). Article 7 of the CBD calls for identification and monitoring, which may require detection methods, to support conservation and sustainable use of biodiversity. Article 7(c) calls Parties to “identify processes and categories of activity” that pose risks, and thereby justify monitoring (and detection methods). This section currently ignores this important step of justifying a need for detection methods for synthetic biology applications that are not LMOs.</p>
6	33	<p>This paragraph should be amended by deletion of reference to LMOs that are “indistinguishable from a naturally occurring or conventionally bred counterpart”. It is hard to imagine how an organism that is indistinguishable from its counterpart could meet the criteria of a “novel combination” required to meet the definition of a LMO in the Protocol. Unless a real-world example of an LMO that is indistinguishable from a naturally occurring or conventionally bred counterpart can be presented, this example is irrelevant.</p>

6	35	Relying on traceability and documentation for identity preservation imposes a significant extra cost. This can be seen in the added cost of organic and low-GMO identity preserved materials, where identity preservation is transferred as a cost to the customer. Furthermore, auditing such identity preservation programs is not without significant costs. Therefore, we question the statement that the AHTEG has made in this paragraph in terms of its validity, and more specifically about the accuracy of statement about cost-efficiency. We believe that the opposite is true.
6	35	We do not agree with the use by the AHTEG of the statement “cost-effective” and question what type of information justified such statement here. Did the AHTEG use information where the cost-effectiveness of different tools for traceability is examined? If this was the case, a reference to the source should be provided if this statement is to be retained. We did not see such information shared in the proceeding on-line forums, not in the submissions by Parties, other countries and organisations on synthetic biology.
6	35	To reflect accurately statements made during the AHTEG, this sentence should be edited as follows: “The AHTEG further noted that relying on traceability and documentation for identity preservation <i>might</i> were also <i>be</i> useful and cost-effective tools for identification and monitoring. In addition, regulatory tools, reporting and auditing mechanisms, as well as the use of online databases, such as the Biosafety Clearing-House and the Food Safety platform of the Food and Agriculture Organization of the United Nations, were useful for sharing information on the detection and monitoring of organisms, components and products of synthetic biology.
6	36	The Network of Laboratories for the Detection and Identification of LMOs has not yet been able to produce a handbook for detection of LMOs. Given this track record, we question whether it is realistic to expect that it would be in a position to address the more technically challenging issue of synthetic biology.
6	36	We support the suggestion that the Network could be expanded to bring together experts in the field of analytical chemistry. Furthermore, we strongly believe that the Network needs to be more inclusionary, rather than just limited to governments that in many cases oppose LMO use.
6	37	It is noted that some countries might not have access to tools for the detection, identification and monitoring of organisms, components and products of synthetic biology due to insufficient technical infrastructure and technical capacity, and legal barriers. We note that countries already have these issues with the present LMOs. Additional burdens would be placed on them by additional need for more sophisticated detection methods.
6	37	The suggested solution of “Capacity-building and legal and technological cooperation” to the issue of access and use of tools is both necessary and appropriate. However, we encourage the Network to take advantage of other organizations that have established groups that are able to support this work in a manner that includes qualified experts in this area.
6	38	Many developers have made detection tools freely available for LMOs. However, as smaller entities and even island nations start working with synthetic biology, the cost of providing such tools could be a limiting factor.



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6	40	<p>We suggest edits as follows: “These methodologies might need to be <i>reviewed and, if needed,</i> periodically updated and adapted.”</p> <p>The update and adaptation of risk assessment methodologies could only be done following scientific review and establishing that these are no longer adequate for performing risk assessment. For that reason, we suggest that the phrase “reviewed and if needed” is inserted in the text.</p>
7	41 (b) and (c)	<p>The discussion on risk assessment in this report reflects some of the controversial elements that are now incorporated into the voluntary guidance, which was not adopted at COP-MOP-8, but rather “taken note of”. These two paragraphs refer to the treatment of unknown unknowns in risk assessment. The report would be improved if these paragraphs were premised on new information being available for risk assessment on various effects relevant to risk assessment. Furthermore, the use of the term “knowledge gaps” is vague and highly subjective. Finally, the notion of combinatorial effects was heavily criticized (rejected) by several Parties during the development of the voluntary guidance.</p>
7	41	<p>General comment for the whole paragraph: The suggested updates and adaptations as listed in points (a) lack of suitable comparators, (b) and (c) knowledge gaps, and (d) lack of experience with engineered gene drives do not represent, in our view, challenges to the existing risk assessment methodology. This paragraph should be revised, and we suggest specific edits in the next entry of the comments table.</p>

1. Completed forms can be sent to Secretariat via e-mail at synbio@cbd.int or submitted online at <http://bch.cbd.int/managementcentre/edit/submission.shtml>

2. Additional rows can be added to this table by selecting “Table” followed by “insert” and “rows below”

7	41	<p>41 (line1) Insert the phrase: “<i>identified in the process of review of exiting guidance</i>”</p> <p>41(line 1) at the end of the sentence insert “<i>for knowledge gaps or lack of practical experience in conducting risk assessment of some risk assessors in order to be able to address issues such as these listed below</i>”</p> <p>The edited sentence should read: “Updates and adaptations, <i>identified in the process of review of exiting guidance</i> might be needed to account <i>for knowledge gaps or lack of practical experience in conducting risk assessment of some risk assessors in order to be able to address issues such as these listed below</i>:</p> <p>The suggested edits are necessary, in our view, to reflect the difference in opinions amongst experienced risk assessors compared to those with less experience with risk assessment. We maintain our position that the issues that the AHTEG identified in this paragraph were not with real “knowledge gaps” or deficiencies in risk assessment methodology; but, rather with the level of competence of some individuals in conducting assessments, and the level of technical and scientific understanding of the assessors, particularly those with limited experience.</p>
7	42	<p>This paragraph should also reference the existence of guidance from national authorities. Noting only the voluntary guidance, which has been heavily criticized, is insufficient.</p>
7	44	<p>Given the extensive history of the development of guidance, it is doubtful that there was significant agreement to develop guidance for gene drives especially given the fact that the report earlier acknowledges the limited experience with this technology. Suggested edits are presented in the next line of the table.</p>
7	44	<p>We suggest editing the sentence as follows: “<i>Some</i> AHTEG <i>experts</i> further noted that existing risk assessment considerations and methodologies might not be sufficient or adequate to assess and evaluate the risks that might arise from organisms containing engineered gene drives due to limited experience and the complexity of the potential impacts on the environment. The development or further development of guidelines on risk assessment of organisms containing engineered gene drives by the Convention, other international organizations, national governments and professional bodies would be useful in that regard.”</p> <p>The suggested edits would bring factual correctness to the statement because not all experts that contributed to the work of the AHTEG share this opinion. This view is further supported by the on-line forum discussions preceding the AHTEG face to face meeting, as well as by the submissions made by Parties in the lead-up to the AHTEG.</p>



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8	51 (a)	<p>We suggest editing this paragraph as follows:</p> <p>“(a) Best practices for effective containment of LMOs should be adapted and applied for <i>living modified</i> organisms containing engineered gene drives;”</p>
8	51 (c)	<p>We suggest inserting “living modified” in line 1 of 51 (c):</p> <p>(c) Internationally agreed standards for effective containment of <i>living modified</i> organisms containing engineered gene drives might be useful in order to avoid accidental releases from laboratory facilities.</p> <p>However, it is difficult to imagine how internationally set standards for containment could be sufficiently comprehensive and flexible enough to address the needs on a case-by-case basis without resulting in significant cost and inefficiency.</p>