PEER REVIEW OF THE REPORT OF THE AD HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY

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Comments on the draft documentation for SBSTTA-22:		
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		General comments on report of the AHTEG on Synthetic Biology 2017 Thank you for the opportunity to provide comments and review the report of the AHTEG. As a member of the AHTEG, I appreciate the diversity of opinions expressed during our face-to-face meeting in Montreal in December 2017 and the ensuing challenge to produce a good quality report as an outcome. Reconciling rather opposing views in a "compromise" report on synthetic biology is not an easy task. I welcome the report language that demonstrates the lack of agreement amongst AHTEG members on the majority of points discussed. The consistent use of conditional sentences and expressions such as "might be needed", "might require", etc. correctly expresses the split of opinion in the room and the difficulty to reconcile positions. In addition, a range of technical and scientific issues were discussed in a very limited time frame to the point that the AHTEG did not manage to complete its agenda, and was not able to address Item 4 – Conclusions and ways forward. For a technical subject such as synthetic biology, a sufficient body of scientific literature exists, however it is not referenced or quoted anywhere in the report. This omission reduces the report's overall quality, and unfortunately renders it more a collection of diverse personal views rather than an accurate account of the state of the field today. Targeted and precise questions, instead of the broad and open-ended terms of reference and agenda items as provided to the AHTEG would have been helpful to focus the work of the group and produce a more meaningful and informative document.
3	Section 3.1	**General comments for section 3.1** Multiple references to "accelerated rate" or "increasing speed" of development are made in this section of the report. Such qualifiers reflect personal opinions expressed by some members of the AHTEG. Importantly, this understanding is not a shared opinion amongst all participants in the Montreal meeting. The subjectively perceived rate of development in the area of synthetic biology is not a suitable criterion for identification of "gaps' in existing regulation or risk assessment guidance materials and cannot be a justification for initiating additional work under the Convention and its Protocols.

3	14	It is not currently established, nor was there consensus amongst AHTEG members, as to the types or numbers of organisms that have already been developed or are currently in development using techniques of synthetic biology. While there have been claims that such organisms exist or are in development, there has never been a single concrete example put forward so far. To a large extent, the vagueness and difference of opinion arises because there is no agreement on what can be considered synthetic biology, and more importantly, how it differs from any other modern biotechnology application. In the absence of such agreement, or the possibility of drawing a separating line between modern biotechnology and synthetic biology, any discussion on what organisms are in development, or may be developed in the future, is a matter of personal opinion. The lack of substantive difference between modern biotechnology and synthetic biology puts into question the continuing effort on the subject and whether this is a good and wise use of the limited resources of the CBD. I suggest edits to paragraph 14 that would remove the subjective views on the rate of development as these do not add any factual information to the statement. Edited text of paragraph 14: *In its deliberations under this agenda item, the AHTEG acknowledged that technological developments within the field of synthetic biology may lead to an increase in the number of engineered organisms.*
3	15	**General comments for paragraph 15** Most of the items listed under paragraph 15 "**Recent technological developments in the field of synthetic biology**" are difficult to defend as being recent and, even more so, specific to the field of synthetic biology. In support of this statement, I would like to stress the lack of agreement on what is covered under "synthetic biology" and how it differs from other modern biotechnology tools and other technological developments. The examples provided in this paragraph are not supported by any references. In the absence of verifiable references, the statements presented in paragraph 15 are of little value for informing fact-based discussion on synthetic biology under the Convention and its Protocols. Below I provide editing suggestions and comments per entry.

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3	15 (a)	This vague statement from the AHTEG does not bring any clarity to the discussion. What are these "recent" techniques that expand the range of organisms that could be modified, and what is the baseline that AHTEG is using as a reference? A quick comparison between modern biotechnological applications (including these that some perceive to fit under the umbrella of synthetic biology) and other tools for introduction of genetic changes (such as mutagenesis or crossbreeding that can be applied to any organism) puts into question the validity of the statement in 15 (a). I would suggest the following edits: Para 15 (a) (line 1), Insert "might" The edited text should read: Some recent synthetic biology techniques ***might*** expand the range of organisms that can be modified; This would align the text with other statements in the report that show lack of agreement amongst AHTEG members on the issue.
3	15(b)	Synthesis of whole genomes is not possible today unless it is followed by an assembly step. It is also restricted to a very small number of model microorganisms. In other words, it is not actually a norm for modification of organisms. On the other hand, the longer-term implications of such technological developments on the way modification of organisms may be done in the future could be rather positive due to the increased predictability of outcomes (modifications designed in advance of their introduction to the organism), increased control and knowledge of the genetic sequence of the resulting organism. I would suggest the following edits to the text: Para 15 (b) (line 1) insert "and assembly"; (line 1) delete "now possible at a larger scale" ; (line 1) insert "increasingly feasible"; (line 1) delete "can" ; (line 1-2) insert "this might" and "in the future" The edited text should read: (b) Synthesis ***and assembly*** of whole genomes and chromosomes is ***increasingly feasible*** ~~now~~ ~~possible at a larger scale~~ and ~~can~~ ***this might*** have significant implications on the way modification of organisms is done ***in the future***;

3	15 (c)	This paragraph is addressing the development of tools, namely "various gene editing tools for enabling simultaneous targeting" of several genome loci. I do agree with the inclusion of this item in the list of "recent developments in synthetic biology". Just because new tools are developed that improve on existing processes is not a criterion to classify them as "recent developments in synthetic biology". The AHTEG members were split in their views on whether this entry is a relevant example. The reason why the statement was retained is because some expressed the view that sometimes gene editing tools can also be used in "synthetic biology" (note the absence of agreement what synthetic biology encompasses). And even if that were the case, the example and context provided in paragraph 15 (c) still do not justify the entry. Finally, whether the multiplexing happened in one or multiple steps seems to be of no relevance to the overall statement. I suggest the deletion of the entry.
3	15 (f)	The statement made in this paragraph is too vague to be of value for decision making. Considering the differences in opinions on what constitutes synthetic biology and how it may be different from the broad field of modern biotechnology, it is hard to imagine how specific examples could be provided here. I also disagree with the statement that organisms are considered for introduction into the environment "at an accelerated rate" – what evidence supports this statement? The on-line forum discussion on synthetic biology that preceded the AHTEG 2017 face-to-face meeting did not identify realistic examples of such developments, and some that were discussed included conceptual or very early stage laboratory research that is clearly not producing materials for "release into the environment" at an "accelerated" rate. Also, "considering for introduction" should not imply that more organisms will be introduced in the environment, just because there was a "consideration". Introduction of LMOs into the environment, as we all know, is governed by comprehensive regulatory frameworks worldwide that assess and approve such releases. Whether something will be released into the environment depends on the speed with which regulatory bodies can conduct their assessments, not by the "considerations" of developers. I suggest deleting the sentence. If retained, it should be edited as follows: f) Some recent developments in synthetic biology have advanced to the point at which organisms might be considered for introduction into the environment ***after being evaluated by relevant competent national authorities*** ~~at an accelerated rate~~;

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3	15(g)	Suggest to delete entry as it is not clear why machine learning, artificial intelligence, robotics and "big data" are listed as recent development of synthetic biology. It is stated that these broad fields are "**expected** [emphasis added] to enable rapid prototyping and testing of highly novel organisms". Clearly the use of the word "expected" points to the lack of evidence that this is actually the case and thus makes the entry highly speculative. Furthermore, why should these applications be restricted to the characterisation of "highly novel organisms" where as they can clearly be used for the characterisation of any organisms or systems.
3	15 (h)	The combination of "new biotechnology tools and automation" is claimed to allow "the more rapid production of modified organisms". Even if that were the case, modified organisms are not a new development and should not be associated with synthetic biology. Unless a very specific example can be provided in support of this entry, suggest to delete.
3	15 (i)	Note that modified algae are living modified organisms and thus should not be listed as a "recent technological development in the field of synthetic biology".
3	15 (k)	The phrase "external genome regulation methods" used in this paragraph is of questionable validity. The entry was discussed at length during the AHTEG meeting and the compromise text agreed (that did not improve in any way the scientific validity of the statement) was: "*External genome regulation methods are being developed, such as RNA interference in the form of sprays".* A more comprehensive statement would have been: "*RNA interference can be used in various ways, including as externally applied RNA*." Irrespective of how this statement is worded, I do not understand why RNAi is listed as a recent development in synthetic biology considering that this technology was behind the first commercialised GMO plant product – FlavrSavr tomato in the mid-1990s.
3	16	The statement that the "ever increasing speed of development might pose a challenge" to some countries to their capacity to conduct risk assessment is not stating anything substantially new in the area of LMO risk assessment. Even though LMOs have been around and tested for over 30 years, some countries still lack the capacity to conduct risk assessments of LMOs. The capacity of some countries to conduct risk assessment can be improved by access to practical experience and transfer of knowledge from experienced regulators who have repeatedly pointed out that currently they do not see any challenges with existing risk assessment methodologies.

3	17	Paragraph 17 makes reference to "continued pace of development" as a potential challenge to "our ability to understand the impacts of products on biodiversity". While this may be the opinion of some, it is certainly not a shared opinion, as a number of experienced risk assessors have repeatedly stated that currently there are no gaps in risk assessment methodologies. I would suggest the following edits: Delete "The recent"; "and the continued pace of development"; "more", ", such as engineered gene drives." . Insert "some" The edited sentence should read: "~~The recent~~ ***Some*** developments in synthetic biology ~~and the continued pace of development~~ might pose challenges to the ability to understand 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."~~
3	18	Examples should have been provided here of where existing containment strategies show deficiencies. This would have been helpful in order to understand the concern expressed and would have added value to inform decisions. However, as in many other parts of the AHTEG report, no specific examples were discussed or provided, which reduces the value of the document and its utility as an information source. Adding examples in support of these claims would be helpful. I fully support the recommendation that containment strategies should be commensurate with the risk posed by the organisms, components and products.
3	19	The statement that "[s]ome advances of synthetic biology **might** raise biosecurity concerns in relation to the three objectives of the Convention" should have been elaborated on in more detail and examples would have been very useful to understand what these concerns are. Furthermore, this would have enabled the reader to decide whether the concerns are substantially different to these that are already considered with relation to modern biotechnology and for which there is an adequate international overview through other UN bodies and national frameworks (e.g., The Biological Weapons Convention)
4	20	The expression "could be useful" is well-placed here as there is little agreement within the AHTEG on what exactly should be monitored and by whom. Within the structures of the CBD, a number of mechanisms are already in place to allow the monitoring of developments in any field of interest. i.e. horizon scanning.

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4	Section 3.2	**3.2. Evidence of benefits and adverse effects of organisms, components and products of synthetic biology vis-à-vis the three objectives of the Convention** Section 3.2 deals with **evidence** [emphasis added] of benefits and adverse effects; however, throughout the section, the discussion is linked to "expectations" that these would be similar [if examples of synthetic biology can be finally provided] to what is already established for LMOs. This is not surprising considering the that so far no specific examples could be provided that distinguish synthetic biology and modern biotechnology. In that line of thoughts, a large volume of information already exists qualifying and quantifying the impacts of crop LMOs on the environment. Yet, this evidence was ignored by the AHTEG entirely.
4	22	Para 22 (lines 2-3) states that "the organisms, components and products of synthetic biology were **expected** [emphasis added] to have similar types of positive and negative impacts on biological diversity as classical genetic engineering. The fact that there is an expectation, but no concrete examples were provided is another good illustration of the challenge in the discussions on synthetic biology. To date, no one has actually pinpointed how it is different from other biotechnological applications. Yet, Para 22, lines (3-5) adds that the impacts "**might** be broader and more wide-ranging due to the potential for synthetic biology to produce organisms and biological systems with ranging levels of complexity for use in a range of applications". This is contradictory to the first part of the paragraph where it is "expected" that the effects will be similar. The full paragraph is speculative, not factual and of little value to the discussion if not to highlight (again) to the difference in opinion amongst AHTEG members on the issue of potential benefits and adverse effects. It would be helpful if specific, evidence (not opinion) based examples are included that illustrate the points made by the AHTEG.

4	23	In paragraph 23 the AHTEG notes that "…there was **limited direct empirical evidence** [emphasis added] of the benefits and adverse effects on biodiversity resulting from the organisms, components and products of synthetic biology." The question is what is this "limited direct empirical evidence" that the AHTEG refers to? In the absence of any reference to this "evidence", the discussion again is reduced to guess work and exchange of opinion. However, there is a large (not limited) direct body of evidence demonstrating benefits related to the adoption of plant LMOs over the past 30 years and it is regrettable that this experience is overlooked here. In fact, multiple comments made on the online forum on synthetic biology in 2017 addressed the benefits of LMO adoption that are relevant here and in the record of discussions on synthetic biology. Paragraph 23 directly contradicts paragraph 22 where ATHEG states that so far, no observations could be made on the subject of benefits and adverse effects (only expectations). Which of these two paragraphs is correct? I submit than both paragraphs underline the struggle of the AHTEG to come to a conclusion on any of the discussed topics due to difference of opinion.
4	24	Paragraph 24 pinpoints the utility of complementing the lacking direct empirical evidence with information, data and modelling by extrapolation from existing relevant fields to make judgements about the potential impacts of organisms developed by synthetic biology. However, such approaches will still not construe "evidence" and will necessitate that are tested and fact-checked before informing decisions.
4	25	Para 25 deals with considerations about engineered gene drives. The AHTEG notes that additional research and guidance are needed on the subject without acknowledging the ongoing efforts of the international community to do just that. Examples of relevant references that should have been referenced in this paragraph include but are not limited to: • Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values. The National Academies Press. • Development of a Consensus Pathway for Field Testing Gene Drive-Modified Mosquitoes https://fnih.org/what-we-do/current-research-programs/gene-drive-consensus • OGTR Guidance for IBCs: Regulatory requirements for contained research with GMOs containing engineered gene drives • Synthetic gene drives in Australia: implications of emerging technologies- www.science.org.au/gene-drives

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5	Section 3.3	**3.3. Living organisms developed through synthetic biology that may not be regarded as living modified organisms as per the Cartagena Protocol on Biosafety** In the discussions of the AHTEG on this agenda item, an example was presented by one AHTEG member of a case where a virus was synthesised and assembled in a country where the organism was listed as a quarantine disease of horses. The synthesised virus was identical and thus indistinguishable from the "natural" variant. I found this to be the only realistic example of a living organism developed through "synthetic biology" that may not be regarded as living modified organism as per the Cartagena Protocol on Biosafety and regret that the example was not included in the report. All the examples listed below however are not providing examples of "living organisms" that may not be LMOs as per CPB.
5	28	The paragraphs states that "most living organisms already developed or currently under research and development through techniques of synthetic biology, including organisms containing engineered gene drives" fall under the definition of LMO as per CPB. In principle, if resulting organisms (including engineered gene drives) are covered under the definition of LMO, why should these be discussed under the ambiguous and difficult to define term "synthetic biology"? I have to again invoke the (1) absence of clarity and agreement on what "techniques of synthetic biology" are and how these differ from other tools used in biotechnology; (2) the absence of common understanding on what synthetic biology is and how it deferens from modern biotechnology.
5	31	With deep respect for the beliefs of all peoples, including those of indigenous peoples and local communities that are represented in the forum, I do not understand why such statement is necessary under this section of the report that discusses synthetic biology categorization. The beliefs and customs of peoples and how they perceive nature are not in the scope of the Convention or its Protocols.
5-6		**3.4. Tools to detect and monitor the organisms, components and products of synthetic biology** Detection methods are called out in the Biosafety Protocol and Article 8(g) of the CBD for LMOs. The CBD Article 7 calls for identification and monitoring 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). The AHTEG ignored this important step of justifying a need for detection methods for synthetic biology applications that are not LMOs.

5	32	Paragraph 32 states that methods "currently in use for the detection, identification and monitoring of LMOs **could** also be used for organisms developed through synthetic biology, but those tools **might need** to be updated and adapted." An important point that did not find its way to the final report of the AHTEG is that detection, identification and monitoring of LMOs is mandated by law in some jurisdictions and where this is the case, event-specific detection tools are developed, on a case-by case basis. This implies that, as a default, detection methods are developed on a case-by-case basis. Thus, it is impossible to discuss the topic in a generic way as in the paragraph here.
6	33	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. Consequently, detection of such organism may not be of relevance or be subject to legal obligations. The phrases "might arise", "might be needed" used in this section, further highlight the lack of agreement amongst AHTEG members on when detection methods are needed, and if so, whether additional tools are justifiable to develop.
6	35	During the AHTEG face-to-face meeting, some members of the group addressed the "detection challenge" described in para 33 with a suggestion that is presented in para 35. In para 35 it is suggested that traceability and documentation for identity preservation are "useful and cost-effective tools for identification and monitoring" of indistinguishable organisms. I question the validity of the statement that traceability and documentation for identity preservation are cost-effective solutions. While this statement was integrated in the report, the AHTEG did not see or discuss any evidence or examples of such "cost-effective" systems, and no one submitted supporting information in the preceding on-line fora on synthetic biology, or in the submissions to the calls of the Secretariat. To the contrary, identity preservation and traceability systems typically add significant costs to the products as can be witnessed by the higher prices of organic or denomination of origin labelling schemes, to note but two examples.
6-7		**3.5. Risk management measures, safe use and best practices for safe handling of organisms, components and products of synthetic biology** There was a lengthy discussion in the AHTEG on what is understood under "risk assessment methodologies", and two main interpretations were obvious. One group of AHTEG members understands that the risk assessment methodology is a generic process that can be applied on a case-by-case basis to specific subjects in accordance with Annex III of the Cartagena Protocol. Another group of AHTEG members seemed to confuse "risk assessment methodology" with what in Annex III is listed under "points to consider", and further seemed to misunderstand the concept of the case-by-case risk assessment approach. Due to these fundamental differences in understanding amongst AHTEG members of what constitutes a "risk assessment methodology", I am providing specific comments to each paragraph in the next rows of this comment table.

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6	40	Update and adaptation of risk assessment methodologies, in my view, could only be done following a demonstration that the methodology is no longer addressing the objectives of the risk assessment. The use of the phrase "methodologies **might** need to be periodically updated" indicates, as for many other paragraphs in the AHTEG report, that there is no consensus amongst AHTEG members on the issue. They "might need" or might not need to be periodically updated, and it depends on whether the current framework is sufficiently flexible to accommodate new technological developments. In my view, this is the case. A clear split in opinion is related to risk assessment methodologies. As I indicate in the previous table entry, AHTEG members are not aligned in their understanding of what constitutes a "risk assessment methodology". The absence of alignment in understanding on even such basic concept, points out the need to increase the understanding about fundamentals in risk assessment, rather than to efforts to discuss specific additional or updates of the methodology.
7	41 (a), (b), (c)	The points listed under these three subparagraphs are by no means new to the discussion and have been extensively debated under the Cartagena Protocol Risk Assessment and Risk Management fora over many years without clear progress on the matter. I am of the opinion that currently there are no gaps in existing risk assessment methodology and thus I do not see a need for addressing the issues listed under paragraph 41 (a), (b), (c) as the AHTEG report suggested. The split in AHTEG opinion on the matter is again visible by the use of phrases like "adaptations might be needed".
	41(a)	The question of comparative risk assessment being dependent on the existence of "suitable" comparator has been around for a long time. Some believe that the suitable comparator should be a near isogenic or parental line as close as possible to the LMO (the assessed organism). However, comparative risk assessment can be done to a broad range of comparators without the need for these to be genetically very close *per se*.
	41(b)	Unintended effects are appropriately addressed by the use of relevant assessment end points and these do not necessarily depend on "knowledge", or "knowledge gaps". In my view, "knowledge gaps in assessing unintended effects" do not arise due to what the some AHTEG members call here "complex changes" and "novel traits". As witnessed from the discussion under the Cartagena Protocol on Risk Assessment and Risk Management, challenges in risk assessment are primarily linked to the level of practical expertise of the individual risk assessors, not due to "gaps" in the risk assessment methodology.
	41 (c)	Similar to what is stated in 41(b), "knowledge gaps" can be addressed with the testing of appropriately chosen end-points. However, there is difference in opinion on what assessment end points are relevant in the case of LMO risk assessment and whether "combinatorial and cumulative effects of multiple organisms" are adequate end points for risk assessment.

7	42	During the AHTEG face-to-face meeting, there was discussion on whether it is appropriate to reference the voluntary guidance document produced by the former AHTEG on risk assessment and risk management when it was heavily criticised by Parties of at COP/MOP-8 and was not endorsed by the Parties at this meeting. This paragraph should also reference the existence of extensive guidance from national authorities and other international organisations such as the OECD and WHO.
	43	In paragraph 43 AHTEG indicates a "need to **develop and conduct assessments** [emphasis added] of the **potential** [emphasis added] positive and negative impacts of synthetic biology on the three objectives of the Convention, taking into account the continuing loss of biodiversity, including species extinction and degradation of ecosystems" Considering that AHTEG has also stated in para 23 that "there was limited direct empirical evidence of the benefits and adverse effects on biodiversity resulting from the organisms, components and products of synthetic biology" and in paragraph 22 that "the organisms, components and products of synthetic biology were expected to have similar types of positive and negative impacts on biological diversity as classical genetic engineering", it is relevant to ask how such analysis is to be performed in the lack of evidence and what would be the value of an assessment of the "potential" impacts. While any information, based on observation and data collection, or modelling, has its merits and needs to be considered and openly debated, I would like to note that in the 30 years of commercial use of LMOs in agriculture, no amount of direct empirical evidence has settled the debate about the value of biotechnology. Polarisation of opinion remains despite the substantial amount of direct empirical evidence pointing to the benefits of LMOs in agriculture (see for example Pellegrino et al. 2018. Scientific Reports 8, Article 3113 https://www.nature.com/articles/s41598-018-21284-2).
7	44	In the discussions under this topic, members of the AHTEG had opposing opinions on whether "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". Some AHTEG members did not see challenges with the exiting framework while others did. Therefore, I agree with the way the sentence is worded by using "might" to indicate the split of opinion on the topic. Furthermore, the development or improvement of guidelines should ideally follow, and be informed by experimental data obtained under containment. In the case of engineered gene drives, it appears that this is precisely the case with modelling experiments and contained use work taking place at the moment. Only once observations become available, it will be possible to judge what gaps exit and need addressing.
7	47	I very much support the point made by AHTEG that risk management measures should be imposed to the extent necessary.

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7	48	Risk management measures are applied on a case-by-case basis depending on the risk identified in the process of risk assessment. Therefore, I do not understand the relevance of the AHTEG statement that: [s]trategies might need to be adapted and complemented in order to address specific characteristics if organisms developed through synthetic biology." How could this be done in the absence of actual cases to assess and considering the case-by-case approach in risk assessment?
8		**ITEM 4. CONCLUSIONS AND WAYS FORWARD**
8	54	The AHTEG ran out of time and could not produce "Conclusions and ways forward" under Item 4. Instead, as a way to complete its work, it decided, on the advice of the Secretariat, to reference in paragraph 54 the "outcomes of its deliberations" captured under Item 3, paragraphs 14 to 53. Considering the large discrepancy in views on the subject amongst AHTEG members, it is not surprising that the AHTEG could not produce "conclusions and ways forward". The report of the AHTEG indicates the lack of alignment of its members by the routine use of phrases line "might need", "might be needed", etc. Targeted and precise questions, instead of the broad and open-ended terms of reference and agenda items provided to the AHTEG would have been helpful to focus the work of the group and produce a more meaningful and informative document.