
BY L. VAL GIDDINGS | FEBRUARY 2012

An Ad Hoc Technical Experts Group (AHTEG) on risk assessment and risk management was established by the Conference of the Parties to the Cartagena Protocol on Biosafety\(^1\) (Biosafety Protocol), a subsidiary agreement under the Convention on Biological Diversity at the 4\(^{th}\) Meeting of the Parties (MOP) in 2008.\(^2\) The AHTEG was tasked with providing assistance to Parties in risk assessment and management, and the mandate instructed the AHTEG to meet twice prior to the fifth Meeting of the Parties (MOP).\(^3\)

In the first meeting, in April 2009, the AHTEG was directed to “[d]evelop a ‘Roadmap’, such as a flowchart” to assist Parties conducting risk assessments according to Annex III of the Biosafety Protocol. The AHTEG was also instructed to consider the need for guidance on specific topics in risk assessment, produce modalities for the development of these documents, and prepare a report for review in the second meeting of the AHTEG. The intent was that this second meeting would review and finalize the “Roadmap” and: (1) make recommendations “on how to integrate the “Roadmap” and tools for retrieval of guidance materials”; (2) review the action plan concerning the modalities produced in the first meeting; (3) “consider possible modalities for cooperation in identifying living modified organisms that may have adverse effects”; and (4) prepare a report for MOP.

This paper examines the progress of the AHTEG toward a successful outcome by considering several questions: how did it operate; how did it consider input from AHTEG members and external experts; will the ongoing work produce a useful product? And importantly, is existing experience with risk assessment of LMOs being used? Information available to registered participants in the Open-ended Expert Group was used as well as
relevant information publicly available on the Biosafety Protocol Secretariat’s website.\textsuperscript{4} Based on the stark divergence of positions apparent in those sources it seems unlikely that a credible path to a successful outcome from this AHTEG can be found by MOP-6 in October 2012, as mandated.

**BACKGROUND**

The Convention on Biological Diversity (CBD) was undertaken to enable and coordinate efforts by the international community to address threats to biodiversity, and to advance its safe and sustainable use. The growing threats to biodiversity may comprise the single most important environmental challenge facing the planet, as the increasing wave of species lost due to human activities threatens to rival the massive extinction events defining major geological epochs in the history of life on earth.\textsuperscript{5} This biodiversity is the irreplaceable foundation for all biological ecosystem services, and for all agricultural production, and is essential to food security. In the face of a global economic crisis, it is impossible to overstate the importance of efficiently using limited resources available to address threats to these vital assets.

AHTEGs are a useful *temporary* mechanism whereby the Parties can address specific technical questions in a timely and efficient manner. AHTEGs are convened pursuant to MOP decisions and must ensure that their expert groups make measurable progress in accord with the Parties’ mandate and the rules under which these groups operate. Two AHTEGs on risk assessment have been convened to date. The first AHTEG on risk assessment in 2005 was a good example of one that led to a successful and efficient outcome.\textsuperscript{6} The current AHTEG suffers by comparison. It has been on-going since April 2009 having met four times face-to-face (5 days each time), and numerous times through online fora. Yet the draft documents to date, despite numerous iterations of the Chair’s texts, show no evidence of approaching agreement on the guidance or conclusion of the process as shown by comments from the AHTEG and Open-ended Forum participants.

**AHTEG AND HISTORY OF THE NEED FOR GUIDANCE**

As mentioned above, there have been two distinct AHTEGs on risk assessment in the Biosafety Protocol implementation process. The first of these met after MOP-2, in 2005 in Rome. Its mandate was ”to further consider the nature and scope of existing approaches to risk assessment, evaluate such approaches and identify any gaps, and identify capacity-building needs.”\textsuperscript{7}

The outcome of this AHTEG was communicated to MOP-3.\textsuperscript{8} Noteworthy to this review and the current AHTEG were the following conclusions:

- “At this time, further generic guidance that is applicable to all assessments of risk as outlined in Annex III of the Protocol (e.g., all types of organisms, traits and all types of hazards) is not a priority.”
- “Rather, there may be a need for specific types of guidance to address, for example, particular types of living modified organisms or particular uses of living modified organisms.” (The report went on to elaborate examples for potential follow up)
“There is a great deal of existing information”, and there are “limitations in the accessibility of existing information.”

In other words, the 2005 AHTEG concluded that there was no need for general guidance based on Annex III, and that accessibility of the existing information was unsatisfactory. However, the AHTEG also concluded that there may be some cases where existing guidance is not sufficient to address the specific (new) case. Consistent with the conclusion of the 2005 AHTEG, paragraph 37 of UNEP/CBD/BS/COP-MOP/3/9 noted that two out of three submissions by Parties on their views on risk assessment stated that “additional guidance expanding on the Protocol text is not necessary”. Subsequently, the Parties’ decision at MOP-3 prudently called for a compilation of existing information from Parties and decided to take up the matter of “guidance on specific aspects of risk assessment” at MOP-4.

MOP-4 Forward

One observes a puzzling turn of events from MOP-4 onward. Document UNEP/CBD/BS/COP-MOP/4/10 misquotes the conclusion from the AHTEG of 2005 to read “the [expert group] identified the need for additional guidance on specific aspects of risk assessment” (emphasis added). Whereas the report itself, in fact, merely suggested some specific cases “where existing guidance may not be sufficient” depending on details of the case. In addition in the interim between MOP-3 and MOP-4, a regional workshop occurred in Canada, which concluded that there “There may be a need to develop specific methodologies and …protocols for generating data necessary to conduct risk assessments… especially for transgenic fish, trees and viruses” and that “There is insufficient guidance on how to perform risk assessment for GM fish and viruses.” Understandably, the elements of the draft decision reiterate this conclusion (and the need to continue to gather existing information), and recommend formation of an AHTEG “to identify modalities and scientific criteria for the development of guidance material on specific aspects of risk assessment.” (paragraph 42.b. UNEP/CBD/BS/COP-MOP/4/10). Given the nature of the information and recommendations from two expert groups over three years, it is unclear how the decisions of earlier MOPs were expanded as described in the terms of reference for the AHTEG in the Annex to decision BS-IV/11, which directs the AHTEG to:

- Develop a "Roadmap", e.g. a flowchart, on steps for conducting a risk assessment in accordance with Annex III to the Protocol with examples of existing guidance documents for each of step, which would be finalized at the second meeting of the AHTEG and then integrated with other guidance into the Biosafety Clearing-House;
- Prioritize the identified needs for further guidance (this element of the decision had specific suggestions);
- Define an action plan to produce modalities for developing guidance documents on specific aspects of risk assessment and risk management identified as priorities; and
- Prepare a detailed summary of terms and procedures for reviewing possible modalities for developing guidance, which would be used at the second
meeting of the AHTEG where they would consider possible modalities for cooperation in identifying living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Based on these instructions, the AHTEG then met from April 20-24, 2009 in Montreal; and from 20-23 April, 2010 in Ljubljana, Slovenia. Funding from the Netherlands enabled an additional face-to-face meeting in Den Haag October 12-14, 2009. This meeting was called in the hopes to resolve widely diverging opinions on key aspects of the Roadmap (e.g., the treatment of uncertainty and the extent of molecular analysis needed in a risk assessment). At MOP-5 (11-15 October, 2010 in Nagoya, Japan) the Parties reviewed the results of these efforts and provided yet further guidance, which was taken on board as the process moved to the third AHTEG meeting (30 May – 3 June, 2011) in Mexico City, Mexico. The result of this substantial investment of time and energy is a process of producing “evergreen” chair’s texts toward no obvious useful goal. Even more concerning is that every subsequent draft document is no closer to consensus than its predecessors, as demonstrated by comments received during online fora. To date, over 430 individual responses have been submitted in an online format; and over 160 of these targeted the Roadmap, which has now been “tested” 2 times using the on-line approach. In their submission made based on a request for scientific review dated 4-February 2011, the Netherlands, who have a representative on the AHTEG, characterized the Roadmap as “the scores [...] are ‘good’, but still, many improvements are needed, as indicated in the section-by-section review. As such, the document is ‘good’, but not ‘good enough.’” While some might say that the Roadmap is “improving” based on scores in the first and second tests, it still ranks as less than good when the data for “usefulness” are analyzed.13

From November 30 to December 15, the Roadmap and the specific guidance documents underwent yet another round of testing where comments were received from 12 Parties, 3 Organizations on two individuals from the Open-ended working group; again with widely varying results.

At this point it is appropriate to ask a number of questions:

- Is the Roadmap being developed by the AHTEG what the MOP requested? Will it become something a Party’s National Focal Point or other regulatory authority can use to evaluate an existing risk assessment and apply it to a request for permission to conduct an LMO field trial or commercial launch in his/her country?

- Similarly, are the documents on special topics in risk assessment what the Parties requested at MOP-4? Will they become something a Party’s National Focal Point can use in conducting a risk assessment?

- How are comments received during online fora incorporated (or not) into the revised chair’s text? Will it lead to a productive outcome?
• What should Parties expect from the “peer review” and how will this be approached?

There are also important questions about how the AHTEG is setting priorities for specific topics on risk assessment. Why were topics like fish, viruses and pharma-plants, considered as the main topics during the Canada-Norway meeting in Montreal in 2009, “deprioritized” at the first meeting of the AHTEG? Is the newest draft document on monitoring a logical next priority on which Parties must have new guidance from the AHTEG before they can consider how to do a risk assessment and enable safe use of LMOs in their countries? The questions concerning process and meeting the needs of the Parties are too many to list here. Reassuring answers to these questions are not self-evident, but let us consider some of them.

The Roadmap

The MOP-4 text requested the AHTEG to create a "Roadmap", e.g. a flowchart, on steps for conducting a risk assessment in accordance with Annex III to the Protocol with examples of existing guidance documents for each step.\(^\text{14}\) The AHTEG chair’s Roadmap text (referring to the version of 15 September 2011) does not fulfill this request. In its 14 pages there is one diagram that could be viewed as a flowchart, if it were edited to reflect how risk assessment actually supports decision-making, but there are no examples, and the text focuses on plant biotechnology situations without giving consideration to other applications (e.g. microorganisms in bioremediation, animal vaccines, or other situations of public health interest). While, the text repeats much of Annex III, in some cases it goes beyond it and, as noted by many commenters, includes confusing and sometimes contrived language making it difficult to use by those for who English is not their first language. Often the additional recommendations run counter to the experience of those who have actually reviewed dossiers as part of an official request for regulatory approval. The abundant expert advice and guidance noted in paragraph 3 of Annex III of the Biosafety Protocol and referred to by the AHTEG of 2005 are not reflected in the chair’s text, despite numerous iterations. One must question why this is the case since such material is easily located and widely used by the global community involved with risk assessment and management of LMOs.\(^\text{15}\) The existing chair’s text does not provide coherent guidance nor does it ease access to the wealth of practical, case-specific experience assessing and managing risks associated with LMOs that has been compiled by individual nations that have successfully and safely carried out field trials and commercialized LMOs. As such, the Roadmap fails the basic principle of information exchange highlighted in Article 17 of the CBD. It should be a simple task to reference two internationally recognized databases (ILSI CERA and ICGEB both of which support the BCH) that contain examples demonstrating how competent national regulatory authorities have successfully completed risk assessments for LMOs including all of the specific LMOs any Party is most likely to encounter, yet these citations are absent from the Roadmap.\(^\text{16}\) As such, the chair’s text fails the basic request that has been made over many years, which is to organize the vast body of materials on risk assessment in a manner that links them to the simply, but appropriately, articulated language of Annex III.
Guidance on Specific Topics in Risk Assessment

The second task from the MOP was to “prioritize the identified needs for further guidance [and] define an action plan to produce modalities for developing guidance documents on specific aspects of risk assessment and risk management identified as priorities…” Here, we asked if the documents on special topics in risk assessment are indeed what the Parties requested in the decision from MOP-4? Some relevant critical questions include:

- Are the topics treated the ones the Parties wanted to see addressed? The topics identified during the Canada-Norway meeting were discarded over a choice made by the AHTEG during its first meeting without consultation, much less consensus of the Parties. The next two topics came out of a consultation made during an online forum apparently without consultation of the National Focal Points.

- Is the kind of information provided what the Parties were expecting? A careful review of the current drafts shows that they suffer from a high level of redundancy with the Roadmap, and Annex III. Several of them are conspicuously lacking in citations to the relevant literature, though this is sometimes because there is little to cite, (e.g., mosquitoes, stress tolerance). In light of the Roadmap, will they become something a Party’s National Focal Point can use in conducting a risk assessment?

No reassuring answers are apparent. The five current draft documents present a striking lack of consistency of format, content and approach. Nothing in these documents appears to be a “modality” for developing guidance, they are not rooted in the wealth of existing experience and they don’t necessarily address the topics of concern of Parties. They represent, again, chair’s texts that are highly debated in the online fora, and national competent authorities with experience in the topics considered the usefulness of the information they present questionable.

In sum, these additional guidance documents do not meet the criteria the MOP asked the AHTEG to satisfy, and offer little but confusing and redundant reiterations of material already available in the literature and in the Roadmap, or, in a perplexing misplacement of priorities, wholly inadequate treatments of topics obviously far in the future by comparison to others that are before Parties now. Importantly, we find strong support for this judgment in the comments made during the online fora.

Problems with the AHTEG process

Perhaps the fundamental problem with this AHTEG and primary reason why it is unlikely to produce products useful for Parties relates directly to the process itself. Three elements are highlighted here: (1) selection of experts; (2) reliance on chair’s text rather than consensus; and (3) procedural transparency relating to decisions on if and how to include expert input by the chairs in subsequent versions.

Selection of Experts:

The Secretariat of the CBD must apply the rules outlined in the Rules, Procedures and Mechanisms Applicable to Processes under the Cartagena Protocol on Biosafety17. These
Rules prescribe that subsidiary bodies must include representational balance from Parties in the UN regions, and gender, while also providing some representation to non-Parties and organizations. These rules do require that experts are “qualified.” Ignoring that the rules were not followed since 19 representatives from 17 Parties serve on the AHTEG, the political value of such an approach to multilateral meetings has been proven time and again. But experience and expertise with LMO risk assessment and commercial use is not uniformly distributed among countries of the world.18 Of the members participating in the most recent AHTEG meeting, only two came from countries among the top fifteen ranked by area cultivating LMOs in 2010 (Brazil, China). Only one of these individuals has had substantial involvement with a functional regulatory system. Six came from countries entirely lacking in biosafety regulations or frameworks when the process began, and two countries have two representatives each on the panel.

<table>
<thead>
<tr>
<th>Parties</th>
<th>Austria, Belize, Brazil, China, Croatia, Cuba, Egypt, Germany, Japan, Malaysia (2), Mexico, Moldova, Netherlands, Niger, Nigeria (2), Norway, and Slovenia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Parties</td>
<td>Australia, Canada, United States</td>
</tr>
<tr>
<td>Observers</td>
<td>Acción Ecológica (Ecuador), Federation of German Scientists, Global Industry Coalition (2), Public Research and Regulation Initiative, and University of Canterbury</td>
</tr>
</tbody>
</table>

Table, List of AHTEG Participants (28 in total)

Furthermore, the AHTEG includes two individuals who, while lacking hands on experience in a functioning regulatory system, are nevertheless well known as anti-GM activists (which is, of course, within the prerogative of a National Focal Point). The lack of experience in conducting regulatory reviews within the AHTEG, the lack of expertise with many of the topics, and the absence of any mechanism to overcome these inadequacies will continue to be a challenge for as long as selection criteria are subordinated to political considerations. But this exclusion of qualified experts is inconsistent with the rules under which AHTEGs are supposed to operate (see: Rules, Procedures and Mechanisms Applicable to Processes under the Cartagena Protocol on Biosafety, chapter 6, section H in particular).

Chair’s Text & Consensus:
As noted above the AHTEG does not operate under a consensus process like other international expert bodies that have developed guidance in the past (e.g. OECD). Rather, they follow a process where the chair of a particular guidance document proposes text, presumably based on input. Chairs have the unenviable task of reconciling highly divergent views from a wide diversity of perspectives, not all of which come from bona fide experts in
the subject, and some of whom show by their actions that they are highly biased toward seeing that no decision, or a “no” decision is made regardless of the LMO. One can only expect confusing and conflicted text to result from such a process. Numerous request have been made by experts and AHTEG members to finish the Roadmap, which is the core document that all others point to, and only then continuing the work of subject specific guidance documents, but the chair of the AHTEG claimed that a mandate was given by the MOP to work in parallel: “a mandate was given by the COP/MOP-5 which clearly requests from the AHTEG and Open-ended Forum that the work on the Guidance on Risk Assessment of Living Modified Organisms (which includes the Roadmap) should progress in parallel to the development of the additional guidance” (Helmut Gaugitsch, AHTEG Chair, November 18, 2011).

One must ask, is this truly the substance of the mandate from MOP to follow a process, or should one interpret the needs of Parties to be a useful outcome?

Transparency:
When examining the transparency of the process, fairly high marks should be given because the record of comments received and new versions of texts have been readily available for analysis. Two important aspects, however, are not clear—if and how comments were included (or excluded) in drafting subsequent iterations, and how priorities were established. These two issues are likely to be challenging because the rules for AHTEGs (cited above) are essentially silent on these matters. A careful review of subsequent versions of guidance fails to reveal any clear basis upon which a comment would be included. In fact, the most recent version of the monitoring and LM Tree guidance documents omit any response to many comments from those with extensive experience in risk assessment. In addition, we noted above that the work undertaken by the AHTEG after the first meeting in Montreal appears to be in direct conflict with earlier recommendations. A logical question, then, is: how were the priorities established and under what rules? It is unclear from UNEP/CBD/BS/COP-MOP/5/INF/13 under what rules the priority setting exercise for development of special guidance occurred, and by what process three topics were chosen when Annex II shows only two were given the highest priority? There is no indication of any reason that justifies how trees, ranked (in annex II of 5/INF/13) in ninth position, after monitoring, specific receiving environments, microorganisms and viruses, transgenic pharmaplants, and even transgenic crops, were vaulted over these and back into the top tier. This was certainly not justified by the documented discussions. Further, it is important to understand under what rules of procedure was the AHTEG allowed to demote several topics that had long been identified as important in MOP documents? The answers to these questions should be of great interest to the MOP.

Is the AHTEG taking advantage of existing experience on LMOs?
One of the most intriguing questions to arise in this analysis concerns whether or not the AHTEG is taking advantage of the considerable body of knowledge that has been accumulated through many countries experiences approving and using LMOs. The Biosafety Protocol was developed “to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use [of LMOs]”. One would expect, then, to see the AHTEG’s work use examples of how Parties and non-Parties have accomplished the
safe transfer, handling and use of LMOs. Such information exchange would be consistent with Article 17 of the CBD when it is done in a manner that informs Parties to meet the objectives of the Biosafety Protocol and its parent convention. The unsatisfactory work products from this AHTEG to date suggest more fundamental, underlying problems with the approach this particular AHTEG has taken. Some of these are apparent upon examination. They include the following:

1. The AHTEG fails to tap efficiently or effectively the most readily available expertise, as the charge from the decision of the Parties stipulated it should. Instead it appears to inflate the views and influence of some with little or no practical experience, e.g., the Norwegian experience, which to date has never completed a risk assessment at the request of a potential registrant. A dispassionate observer might wonder if some members of the AHTEG might be using this process to advance points of view and proposals that were rejected in the negotiating process of the Protocol itself.

2. The AHTEG is duplicating work that has been done by bodies with a much higher concentration of experience and expertise (e.g., OECD expert groups), and has failed to make the work of these expert bodies accessible to Parties, despite being specifically instructed to do so.

3. Not only do the existing draft documents duplicate the work of established, recognised, and experienced authorities, as well as the Roadmap, they do so in a way that obscures more than it clarifies. Data gathered by the Secretariat itself, polling National Focal Points, indicate the existing drafts fall short of providing advice or guidance that would be helpful to a regulatory authority with no experience confronting an application for a permit to conduct an LMO field trial, nor do they direct such individuals to any of the numerous recognized repositories of experience in this field.

4. After six years during which experience in conducting risk assessments on LMOs has increased dramatically around the world – experience which demonstrates clear economic, environmental and human health benefits flowing from these products - this experience gained has not been disseminated through the AHTEG drafts, and none of the assistance that was intended to flow from the work of the AHTEG to Parties needing it most is actually accessible to those Parties. The existing draft documents, as judged by the comments in ongoing online fora, are far from consensus.

CONCLUSION

The AHTEG appears to be engaged in work that will never result in materials useful to Parties wishing to build regulatory capacity in a manner that is compliant with the Biosafety Protocol. After years of effort and great expense, it has produced six heavily debated Chair’s texts that are not close to, and are not approaching consensus, falling conspicuously short of meeting the AHTEG mandates, as instructed in MOP decisions. This AHTEG appears to be mired in a number of flawed processes to the detriment of the resulting products.
Since 2005, the area planted annually in LMOs worldwide has gone from 90 to 148 million hectares, with a cumulative global total well in excess of 2.7 billion hectares.\textsuperscript{20} The number of farmers growing crops improved through biotechnology has increased from 8.5 million to 15.4 million, of whom 14.4 are smallholders in developing countries. The number of countries seeing such crops planted grew from 21 to 29. The economic and environmental benefits of these innovations have been significant, and widely shared.\textsuperscript{21} These data tell us several things: first, LMOs are a widely and rapidly adopted technology in both the developed and developing world; second, it is unreasonable that, given this wealth of widely shared and positive experience, an AHTEG cannot produce a guidance document showing Parties with little or no experience in decision-making how Annex III has been/can be applied in the risk assessment. Third, that the presumption of unique hazards to biodiversity associated with LMOs has been contradicted by data and experience, and the justification for the Protocol itself is flawed.

It is not in the interests of parties to the Biosafety Protocol and CBD that the AHTEG should continue to consume time, energy, and resources while following a path towards no useful or valid outcome. The parties should address the question of whether this is an efficient and responsible use of limited resources during the next MOP in India in October 2012.
ENDNOTES

1  Referring to “…ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.” Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Article 1.

2  COP/MOP/BS-IV/11.


4  www.cbd.int/biosafety


6  COP/MOP/BS-II/9.

7  http://bch.cbd.int/protocol/cpb_art15_info.shtml

8  UNEP/CBD/BS/COP-MOP/3/9

9  http://www.cbd.int/doc/?meeting=TEGRA-01

10  COP/MOP/BS-III/11; A total of 155 citations were received: UNEP/CBD/BS/COP-MOP/4/INF/22: www.cbd.int/MOP4/doc/


13  We analyzed the results received on questions 2 and 3 from the February 2, 2011 request for scientific review that asked to evaluate the usefulness of the Roadmap for scientific soundness and introductions into various receiving environments. The average score among 31 respondents was 2.65 for Question 2 and 2.55 for Question 3. Noting that a score of 3 or 4 was considered to be good or better, the Roadmap is still less than useful.

14  See the Annex to decision BS-IV/11 at http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=11690

15  See http://www.oecd.org/dataoecd/21/12/48464394.pdf and http://www.oecd.org/dataoecd/26/9/45840073.pdf and http://www.oecd.org/document/6/0,3746,en_2649_34385_45848902_1_1_1_1,00.html; also http://www.oecd.org/document/0,3746,en_2649_33905_1933504_1_1_1_1,00.html; and also http://www.nap.edu/catalog.php?record_id=9889#toc.


19  Norway’s “GenØK Center for Biosafety” inexplicably has 2 staff members on the AHTEG, one originally from the US and one from New Zealand.

20  ISAAABrief 42-10 at http://www.isaaa.org/resources/publications/briefs/42/default.asp

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