Advancing Risk Assessment under the Cartagena Protocol on Biosafety

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The Cartagena Protocol on Biosafety, the first Protocol developed under the Convention on Biological Diversity (now there are three), entered into force September 2003. It aims to ensure "the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health". The Protocol has currently 163 parties (as of August 2012).

With decision IV/11 taken during COPMOP IV in Bonn, 2008, the Parties mandated an Ad-Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management to:

"(i) "Develop a "roadmap", such as a flowchart, on the necessary steps to conduct a risk assessment in accordance with Annex III to the Protocol and, for each of these steps, provide examples of relevant guidance documents;

(ii) Taking into consideration the identified need for further guidance on specific aspects of risk assessment, including particular types of (i) living modified organisms (for example, fish, invertebrates, trees, pharmaplants and algae); (ii) introduced traits; and (iii) receiving environments, as well as monitoring of the long-term effects of living modified organisms released in the environment, prioritize the need for further guidance on specific aspects of risk assessment and define which such aspects should be addressed first, taking also into account the need for and relevance of such guidance, and availability of scientific information;"…..

The AHTEG was formed reflecting regionally balance and a diversity of Parties and expertise. Following the rules of procedure Non-Parties and observers from industry, academia and NGOs participated as additional stakeholders in this multi stakeholder but party-driven process. Altogether 27 experts worked together in the AHTEG.

Two years later in Nagoya, the mandate of the existing AHTEG was prolonged and the Parties recommended in their decision V/12 (among other things) that the expert group should:

- coordinate with Parties and other Governments, through their technical and scientific experts, and relevant organizations, **a review process of the first version** of the Guidance;
- **update the common format** for submission of records to the Biosafety Information Resources Centre in order to link its records on risk assessment to specific sections of the Guidance; and
- develop **new guidance** on specific topics or aspects or risk assessment.

As a result of these mandates the AHTEG will present to the upcoming COPMOP VI a singular guidance document comprised of three different parts:

Part I: A Road Map for Risk Assessment, together with a Flowchart

Part II: Additional guidance on specific types of LMO and traits encompassing

- LM plants with stacked genes,
- abiotic stress resistant LM plants,
- LM trees
- LM mosquitos

Part III: Guidance on Monitoring of Living Modified organisms released into the environment.

A first version of the roadmap and the additional guidance on stacked genes, abiotic stress resistence and LM mosquitoes was presented to COPMOP V in Nagoya. Some parties had the feeling that this package needed further scientific assessment and review. This recommendation - reflecting also the diverging views on the way how to translate the principles of conducting an environmental risk assessment of Annex III into real life - became part of the new terms of reference in decision V/12 of Nagoya together with the task to develop additional new guidance according the priorities and needs of the Parties. With their decision to extend the mandate of the AHTEG the COPMOP also strengthened the role of the open-ended expert online discussion forum. Registered national experts from Parties and observ-

ers were asked at multiple rounds to comment on the draft version of the roadmap and the additional guidance of the first period as well as on the newly developed documents on LM trees and Monitoring.

Outcome to date

Worldwide there exist different concepts how to conduct an ERA, what are the protection goals, how to define baselines, which agricultural practise shall be considered and how the precautionary approach may be looked at and integrated. The Cartagena Protocol, and especially its Annex III, defines the agreed steps and main points to consider. However the conversion of the agreed steps into a real life practical tool for the assessment of applications is not an easy task and allows for different options.

With the development of the roadmap and the additional guidance documents Parties have a framework from which they can use and adapt to their conditions, needs and obligations. It reflects wherever needed and asked for different concepts and interpretations. At the same time it is a compromise between different scientific understandings of what is necessary and should be recommended during an ERA.

An important aspect of the whole guidance package is the understanding of it as a living document which can be and should be amended when experience about its usefulness and practicality has been gathered.

Innovation and Strengths of the Roadmap

The outcome of the AHTEG guidance produced a number of innovations and improvements on appraising risks. First, the guidance recognizes that an environmental assessment of risks does not happen in a vacuum, but the criteria and needs from the risk assessment may be informed by other actors or aspects related to those of the environment. Second, the guidance provides clear requirements that information should be of high scientific quality (transparent, reproducible, and if necessary, access to research material and raw data for verification). Third, the guidance recognizes the need for describing the nature and sources of uncertainty in the assessment, and communicating them to decision-makers when assessing the acceptability of risk. Fourth, the guidance recognizes that the risk assessment is a process that may involve a stepwise and iterative advancement where risks at smaller spatial or time scales of release may be assessed before larger releases are permitted to take place. Lastly, analyzing risks within the context of alternative options is also considered as important in the process of step 5 concerning the acceptability of risk.

Weaknesses of the Roadmap

Despite some critical advances in thinking on risk, the guidance contains a few general weaknesses in its approach. Most critically is the overemphasis of the provision for comparative risk assessment. Comparing the composition, performance, and behavior of a LMO in comparison to its conventional counterpart has historically been a cornerstone in LMO risk assessment, however this approach contains a number of flaws and disadvantages that compromise its efficacy as a measure of safety. In the current guidance document, this limitation is apparent in the discussion of the “choice of comparators” which effectively allows the use of very broad comparators – an approach that tends to underestimate differences and overestimate similarity (e.g “equivalence”) between comparators. This ultimately undermines a scientifically robust approach to the comparative feature of the RA.

The other area which the guidance fails to deliver is in providing a link to other aspects of risk that may be taken into consideration in the entire decision-making process – socio-economic issues, legal issues, and ethical issues at the fore. The interface between determining "acceptability" of risks within the context of broader issues is currently subsumed by the technical provisions of risk and safety for decision-making.

Contentious issues

Generally speaking, the guidance has thus far received good support. However, a few issues may undermine its support in the MOP, including the rejection by some to consider "related issues" as part of the guidance and the breadth of monitoring that should be described and possibly required (general vs. specific monitoring) after the release of a LMO into the environment. Whereas in Europe case specific and general monitoring are legal requirements, these provisions do not exist in other national legislations.

There were a number of smaller aspects with diverging views like the use of "omics" technologies as a tool of evaluating differences between a LMO and its conventional counterparts, or the scope of the additional guidance of LM trees (e.g. whether scope covers fruit trees or not).These issues are likely to be discussed in Hyderabad, and the outcomes will largely determine the strength of support for the document package as a whole.

The way forward

The AHTEG agreed upon a set of recommendations which will be made to the MOP in Hyderabad:

Regarding the "Guidance on Risk Assessment of Living Modified Organisms"

1. Endorse the "Guidance on Risk Assessment of Living Modified Organisms".
2. Request the Executive Secretary to make the Guidance available to Parties in all six United Nations languages through the Biosafety Clearing-House (BCH).
3. Encourage Parties, as appropriate, to translate the Guidance into national languages, and make them available in the BCH for wider dissemination.
4. Encourage Parties, other Governments and relevant organisations through their risk assessors and others who are actively involved in risk assessment, to use and test the Guidance in actual cases of risk assessment and share their experiences on its practicality, usefulness and utility through the BCH, their third national reports and any other surveys, interviews and/or questionnaires as may be organized by the Secretariat.
5. Request the Executive Secretary, subject to the availability of funds, to gather and analyse feedback provided by Parties on the practicality, usefulness and utility of the Guidance and make recommendations to the next COP-MOP on possible points for improvement.
6. Establish a mechanism to ensure the regular update of the background documents to the Guidance, as follows:

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Regarding the development of additional guidance on specific topics

7. Extend the mandate of the Open-ended Forum and AHTEG beyond the sixth meeting of the Parties to the Protocol, with revised terms of reference, to develop guidance on new

topics, taking into account any results of use and testing of the revised Guidance, as well as the needs of Parties and the list of topics in Annex IV to this report;

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Regarding capacity-building in risk assessment and risk management

10. Request the Secretariat, subject to the availability of funds, to:

(i) Ensure coherence between the Training Manual on Risk Assessment and Part I of the Guidance (i.e., Roadmap);

(ii) Develop an advance educational package that integrates the Guidance into the Training Manual (e.g., e-learning material);

(iii) Conduct training using the advance educational package for risk assessors, taking into consideration actual cases of risk assessment;

(iv) Follow up on the training exercise by gathering additional feedback from Parties on the practicality, usefulness and utility of the Guidance through online discussions or other means, as appropriate;

(v) Conduct international and/or (sub-) regional workshops on Risk Assessment and Risk Management with special emphasis on applying the Guidance in the process of actual decision making under the procedures of the Protocol.

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Regarding risk assessment in general

12. Urge Parties to provide the BCH with prompt and detailed information on their risk assessments of LMOs for introduction into the environment, including field trials, as well as LMOs for direct use as food, feed, or for processing (LMO-FFPs) with the view to sharing their experiences.

Conclusion

It can be expected that there will be some discussions on the quality of the currently developed guidance reflecting different views on the right way how to implement the principles of Annex III. It was also a contentious issue if the mandate of the current AHTEG should be extended and if there is the need for further guidance.

For some experts of the AHTEG, it was difficult to accept that the Cartagena Protocol is a Protocol to the Convention on Biological Diversity and therefore should also respect and adhere to the principles and recommendations of the Convention. They would prefer to handle the Protocol as a stand alone document.

Besides the further development and improvement of the guidance package, it seems to be of utmost importance to underline and strengthen this coherence to support the overall aim of conservation of biological diversity as the prerequisite for sustainable use. In our opinion, overall outcomes of the AHTEG activities, on the balance, provides good guidance for advanced understanding of risk appraisal that will be useful for the implementaton of risk assessment frameworks to strengthen national biosafety legislation. Despite the challenges ahead, putting the guidance to use will be the best measure of its ability to uphold the core objectives of the Cartagena Protocol.