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FIRST REGIONAL REAL-TIME ONLINE CONFERENCES ON
RISK ASSESSMENT AND RISK MANAGEMENT UNDER THE
CARTAGENA PROTOCOL ON BIOSAFETY: EUROPE
28 January 2009

REPORT OF THE FIRST REGIONAL REAL-TIME ONLINE CONFERENCES ON RISK ASSESSMENT AND RISK MANAGEMENT UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY: EUROPE

Note by the Executive Secretary

1. At its fourth meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP), in its decision BS-IV/11, established an Open-ended Online Expert Forum on Risk Assessment and Risk Management through the Biosafety Clearing House (BCH). In the same decision, the Parties also established an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management.

2. The Executive Secretary was requested to convene, prior to fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, to be held in October 2010: (i) ad hoc online discussion groups; (ii) two AHTEG meetings; and (iii) at least one real-time online conference per region prior to each of the two AHTEG meetings.

3. In order to implement decision BS-IV/11, the Secretariat, with the approval of the COP-MOP Bureau, launched a continuous process comprising the following events:

(a) An open-ended online forum;

(b) Discussion groups on specific topics;

(c) Two series of regional real-time online conferences (one prior to each AHTEG meeting); and

(d) Two AHTEG meetings.

4. In response to this decision, regional real-time conferences were scheduled for, respectively, Europe, Latin America, Africa and Asia. The objective of the conferences was to identify major issues related to the specific aspects of risk assessment and risk management as outlined in the terms of reference for the AHTEG.

5. Experts in risk assessment who were nominated by Parties for the initial online forum were automatically registered in their respective regional conference. In regions where a low number of experts were nominated, those experts, after consultation, opted to participate in other regional

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conferences. Participants nominated by non-Parties and observers were given the option to participate in one regional conference of their choice. In addition, all forum participants were able to watch the conferences of other regions as "guests". However, guests could not post interventions.

6. The conference for Europe was chaired by Mr. Helmut Gaugitsch from Austria following his approval as Chairperson of the conference by the Bureau of the Conference of the Parties serving as the meeting of the Parties to the Parties. The conference had 12 participants from a total of nine countries (Belgium, Czech Republic, Finland, Germany, Italy, Netherlands, Norway, Republic of Moldova and the United States of America). Two organizations—the Public Research and Regulation Initiative and Monsanto Company—also participated.

7. The online conference took place on 28 January 2009, from 10 a.m. to 2 p.m. GMT, in the form of a "chat room" where participants were able to post written interventions. The conference was organised with the same rules of procedure that apply during regular on-site meeting. Accordingly, participants representing Parties, other Governments and organizations were required to request the floor to make interventions and priority was given to experts from Parties to the Protocol. In the event of technical difficulties, Participants were able to consult the Secretariat through a real-time online "Helpdesk" or by telephone.

8. The complete verbatim transcript of the conference is contained in annex I to this report.

9. The final list of participants is contained in annex II to this report.

10. A synthesis document containing an analysis of all four first regional real-time online conferences will be prepared by the Secretariat for submission to the Ad Hoc Technical Expert Group.

Annex I

FULL TRANSCRIPT OF THE FIRST REGIONAL REAL-TIME ONLINE CONFERENCES ON RISK ASSESSMENT AND RISK MANAGEMENT UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY: EUROPE

Manoela Miranda - UNEP/SCBD/Biosafety - Moderator **10:07 GMT/UTC**

Dear Participants,

Good morning! Welcome to the Regional Real-time Online Conferences on Risk Assessment and Risk Management: Europe. It is a great pleasure for us at the Secretariat to be gathered here with all of you.

As you may know, at its last meeting in Bonn, the COP-MOP established an Open-ended Online Expert Forum on Risk Assessment and Risk Management and an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management.

The Executive Secretary was requested to convene ad hoc online discussion groups, two AHTEG meetings and at least one real-time online conference per region prior to each of the two AHTEG meetings.

Therefore, the Secretariat is implementing a continuous process comprising the following events: a) the establishment of an open-ended online forum, b) discussion groups on specific topics, c) two series of sub-regional real-time conferences (one series prior to each AHTEG meeting), and d) two AHTEG meetings.

Your task in this virtual meeting is extremely important.

On the one hand, the outcome of the regional conferences will serve as a basis for deliberations by the AHTEG, whose first meeting will take place in Montreal from 20 to 24 April 2009.

On the other hand, from the technological point of view, the way we are gathered here today is a breakthrough from the usual face-to-face meetings. Real-time conferences may open a door of infinite possibilities for the exchange of opinions among the Parties and with the Secretariat.

On a technical note, I would kindly ask you to prepare your intervention on the Text Box (center-bottom of the screen) before requesting the floor because, once the floor is given to you, you will have only 60 seconds to send your intervention.

The Secretariat is available to answer questions through the HelpDesk. To access the Helpdesk online, please use the tab in the top-left corner of the screen. In case of emergency a direct phone number to Montreal, Canada, is also available in the top-right corner of the screen.

Without further delay, I would like to welcome all of you to this conference and invite the Chair, Mr. Helmut Gaugitsch from Austria, to preside over the conference.

Helmut Gaugitsch - Chairperson **10:09 GMT/UTC**

Thank you, Secretariat.

Distinguished colleagues,

Good morning. I am honoured to chair this conference which is not only the first of the series of online conferences on risk assessment and risk management of LMOs as mandated by decision BS-IV/11 but also a new experience for many of us. Today it is nearly exactly 9 years since the Cartagena Protocol has been adopted on a cold winter morning in January 2000 in Montreal, so I am happy that our Conference is taking place today!

Our work today will focus primarily on issues regarding the development of a roadmap for conducting risk assessment and then on further guidance materials on specific aspects of risk assessment and risk management. The outcome of all online conferences will serve as inputs for the deliberations by the AHTEG on Risk Assessment and Risk Management of LMOs scheduled 20 – 24 April 2009 in Montreal.

I have asked the Secretariat to send some guiding questions in an effort to maximize our use of the limited time we have at our disposal. I hope they have been useful. I also hope that the technical guidance we have been provided by the Secretariat on this new experience has also been useful. On this note, I declare our conference open.

We will proceed directly to Item 2 of the provisional agenda.

ITEM 2. ORGANIZATIONAL MATTERS

Helmut Gaugitsch - Austria - Chairperson **10:10 GMT/UTC**

I invite you to turn to the provisional agenda contained in document UNEP/CBD/BS/REGCONF-CB-RA&RM/1/1.

The next item before us is the adoption of our agenda. The provisional agenda was prepared by the Secretariat, and it reflects the objective of our task.

Unless you have amendments or objections to any of the items, I propose that we adopt the agenda of the meeting as contained in document UNEP/CBD/BS/REGCONF-CB-RA&RM/1/1.

Helmut Gaugitsch - Austria - Chairperson **10:11 GMT/UTC**

I see no requests for the floor.

The provisional agenda as before us is adopted.

Let us now turn to agenda item 2.2 on organization of work.

Helmut Gaugitsch - Austria - Chairperson **10:12 GMT/UTC**

As you may be aware, our conference today will end at about 14:00 (UTC/GMT). We will have a break of 60 minutes for lunch.

We have three substantive issues on the agenda and I would like to propose that we spend approximately 50 minutes on each.

I would also like to propose that we deploy the Chair's questions as have been distributed by the Secretariat. As mentioned earlier these questions are to help facilitate discussions.

Helmut Gaugitsch - Austria - Chairperson **10:13 GMT/UTC**

I see no objection. The proposed organization of work is adopted.

I will now invite you to turn to item 3 on the agenda.

ITEM 3. SUBSTANTIVE ISSUES

Jaroslava Ovesna - Czech Republic - Party **10:14 GMT/UTC**

I agree we should start, perhaps a short introduction by the chair would be fine

Helmut Gaugitsch - Austria - Chairperson **10:16 GMT/UTC**

Thank you Jaroslava. Yes, I would like to start with the substantive issues. Do you need any more introduction in addition to the one I have given at the beginning?

Jaroslava Ovesna - Czech Republic - Party **10:17 GMT/UTC**

O.K.

Helmut Gaugitsch - Austria - Chairperson **10:17 GMT/UTC**

Thank you! Under this item, our first substantive issue is:

ITEM 3.1. Development of a "roadmap", such as a flowchart, on the necessary steps to conduct a risk assessment in accordance with Annex III to the Protocol.

The face-to-face AHTEG in April will 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;

In your intervention, you may wish to provide:

-> information that may be needed in developing a roadmap/flowchart other than that contained in Methodology and Points to consider of Annex III to the Cartagena Protocol.

-> guidance materials that are directly applicable to the steps and points to consider listed in paragraphs 8 and 9 of Annex III to the Protocol.

Helmut Gaugitsch - Austria - Chairperson **10:18 GMT/UTC**

I will now open the floor for your reactions to the first Chair's guiding question under Item 3.1.:

(a) What information may be needed to produce a roadmap / flowchart, other than those contained in Methodology and Point to consider of Annex III?

The floor is now open.

Hans Bergmans - Netherlands - Party **10:18 GMT/UTC**

In the on line discussion forum on the road map I have made 3 contributions on the way a 'road map' or flow chart might work. The model for the road map that I presented in contribution (1) was nearly completely based on texts from Annex III, as I thought that that would be a good start for the discussion.

Helmut has indicated in his contribution to the discussion that the 'matrix' that many of us use for risk assessment has different titles for the steps of risk assessment, i.e. hazard identification, evaluation of likelihood, evaluation of consequences, evaluation of overall risk, risk management, summary of risk assessment including uncertainty. These steps are in line with many risk assessment systems that I am aware of, including the EU approach.

They differ from the titles in Annex III mainly in the explicit reference to hazard identification. Step 1 in Annex III refers to 'An identification of any novel genotypic and phenotypic characteristics associated with the LMO that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health.'

I think that a reference in step 1 to hazard identification, and to problem formulation as a basis for hazard identification, would help very much.

Helmut Gaugitsch - Austria - Chairperson **10:20 GMT/UTC**

Thank you Hans for your contribution. Obviously no icebreaking necessary for this Conference! I will now turn to the next requests for the floor!

Beatrix Tappeser - Germany - Party **10:21 GMT/UTC**

Once again, good morning everybody. Concerning the roadmap I think, there is some additional material needed on concepts how to implement the recommendation of taking into account the likely receiving environment in the RA. The receiving environment is important in the context of possible cross-hybridizing relatives, but also in the context of the biocoenosis at the place and the ecosystem functions or services this biocoenosis supports – on the agricultural fields, in their neighbourhoods and on a landscape level. An ecological approach tries to integrate the different levels as it is somehow recommended in the ecosytems approach of the CBD. Special aspects of the topic receiving environment are protected areas and threatened species. Of special concern and importance are centers of origin and diversity. There is no guidance up to know how to integrate these aspects into a RA. All together there are quite a number of knowledge gaps and open questions which should be named in roadmap.

There should be more guidance on certain procedures or further methodologies concerning the implementation of the steps laid down in para 8 of annex III.. For example how to identify the right non-target organism important for a receiving environment, exposed to the LMO and supporting ecosystem function and services.

Helmut Gaugitsch - Austria - Chairperson **10:24 GMT/UTC**

Thank you Beatrix for your contribution. If there are no other Parties` requests for the floor I will now give the floor to observers!

Marja Ruohonen-Lehto - Finland - Party **10:25 GMT/UTC**

Hello everybody. Thanks Hans and Beatrix. Reference to Hazard identification in step 1 would be good (problem formulation is not a commonly used term). My thoughts go very much in line with Beatrix - in our national (Finland) guidelines we have a specific step for the environment (it's description etc.). Marja

Helmut Gaugitsch - Austria - Chairperson **10:26 GMT/UTC**

Thank you Marja for your contribution. I will now give the floor to observers!

Piet van der Meer - Horizons sprl / PRRI - Observer **10:26 GMT/UTC**

Hi Helmut,

Good to see you made it through the snow.

Am glad to see you as chair of this sexy digital exercise and that you start with the road map.

In answer to your question what information may be needed to produce a roadmap / flowchart, and following up on Hans's points, I would suggest:

1. The connection of the steps of para 8 with the relevant 'points to consider' of para 9, as suggested by Hans Bergmans in the online discussion

2. Identification of the comparators that are appropriate in the different steps of the risk assessment

3. The overall point of reference for the risk assessment, i.e. what is an adverse effect? (the often so called 'problem formulation'). These points also tie in with the points raised by Beatrix. I agree with her point that it would be helpful to have guidance as to in which cases to assess non target effects and in which non target insects to take - the work of Romeis is very useful in this respect

Helmut Gaugitsch - Austria - Chairperson **10:28 GMT/UTC**

Thank you Piet, there are further requests for the floor, so we are going to continue with this very fruitful exchange!

Beatrix Tappeser - Germany - Party **10:28 GMT/UTC**

As a first and very important step a matrix should be developed where the single steps of a risk assessment as laid down in the Annex III Para 8 are combined with the existing guidance documents submitted to the secretariat. Hans started such an endeavor in his submission to the discussion forum. To go one step further the methodology and the points to consider should be combined with all of the submitted guidance material and it should be analysed which points are specifically taken up and how far the guidance is developed: eg :are there information on tests, test strategies, problems and short comings of test designs – statistical power of test designs etc. This matrix should developed as such that it gives an overview and as a toolbox what is available for which aspects. see also Hilbeck et al. I can deliver the publication later.

Helmut Gaugitsch - Austria - Chairperson **10:29 GMT/UTC**

Thank you Beatrix for concrete and practical suggestions based on previous interventions. Any further requests for the floor before we move on?

Maria Antonietta Toscano - Italy - Party **10:30 GMT/UTC**

I think that in practical application, we should not forget that living organisms, (as obviously genetically modified organisms) normally are subject to a selective pressure that induces genetical adaptation to environment. In which way may we consider the possibility of normal selective changes, in development of a roadmap based upon scientific, biological and ecological perspectives?

Helmut Gaugitsch - Austria - Chairperson **10:31 GMT/UTC**

Thank you Maria Antonietta for your concrete and valid question. We move on to further interventions!

Marja Ruohonen-Lehto - Finland - Party **10:31 GMT/UTC**

I would like to support the matrix approach and move "one step forward" as suggested by Beatrix. Marja

David Quist - Norway - Party **10:32 GMT/UTC**

One aspect not mentioned in this hazard identification scheme that we have been thinking about here in Norway relates to viewing within the context of a risk assessment inclusive the GMO, its intended recipient environment, AND specific management and use practices from the intended use of the GMO product. That is, it is useful from a practical and biological standpoint to recognize that a GMOs use should not be thought of as existing in a vacuum, independent of the management practices that are required to utilize the benefits from intended use (e.g. herbicide tolerance systems). Thus, an integrative approach that encompasses planned use should be considered.

Helmut Gaugitsch - Austria - Chairperson **10:33 GMT/UTC**

This was at the last second, David, well done! We move on!

Jaroslava Ovesna - Czech Republic - Party **10:33 GMT/UTC**

In connection with GMO we should consider impact of changing agricultural practices as such (e.g. herbicide treatment leading to changing soil quality, weedy societies changes) and its impact on biodiversity. Specific chemical treatment should not be separated. Matrix approach is usually O.k. Norway already came up with agricultural practice

Beatrix Tappeser - Germany - Party **10:34 GMT/UTC**

One organisational question. Do you, Helmut, want to proceed to Item 3.2 or to the second question of item 3.1 because I have one additional submission concerning item 3.1, question b.

Helmut Gaugitsch - Austria - Chairperson **10:35 GMT/UTC**

So far only the first guiding question is open for discussion. I will very soon move to 3.1, question b, before then moving to 3.2.

Philippe Baret - Belgium - Party **10:35 GMT/UTC**

Thank you Mr Chairman and good morning everybody. I fully agree with Beatrix. There is a lot of guidelines developed. For example, EFSA is developing guidelines on statistical considerations. The issues of assessment are twofold: one the one hand, guidelines are required to address well known issues with existing methodologies. On the other hand, open questions, such as non target species, require the development of new approaches. It we don't take into consideration these two dimensions, the risk is high to focus only on the "well-known issues.

Marja Ruohonen-Lehto - Finland - Party **10:36 GMT/UTC**

When I commented earlier on the "Finnish approach" (developed at the Finnish Environment Institute for our internal use) we have included in step 2 environmental factors, release methods and conditions. This comment is in reference to David's comment. Marja

Helmut Gaugitsch - Austria - Chairperson **10:37 GMT/UTC**

Thank you colleagues so far and congratulations! If there is no other Party requesting the floor I will now give the floor once more to an observer and then we move to the next guiding question!

Piet van der Meer - Horizons sprl / PRRI - Observer **10:37 GMT/UTC**

Aree with Beatrixe's suggestion of the matrix, and her proposal to provide background documents. Helmut, what is the approach we take for making back ground documents available ? Send them to Sec? As regards Maria's point: selective pressure is indeed a key parameter in the RA. Agree with David's and Jaroslava's point that we should of course not look at a GMO in isolation, this is the comparative nature of RA.

Manoela Miranda - UNEP/SCBD/Biosafety - Moderator **10:38 GMT/UTC**

Dear Piet, dear all, if you have additional guidance materials, which you would like to submit in connection with the roadmap, please send it to the Secretariat and we will post them on the Online Forum.

Philippe Baret - Belgium - Party **10:38 GMT/UTC**

Concerning agricultural practices, a specific issue we encountered in Belgium is the extension of results of field trials (often achieved in very artificial conditions) to real life agricultural practices. For example, change of scales, heterogeneity, spatio-temporal considerations are often absent of field trials.

Helmut Gaugitsch - Austria - Chairperson **10:39 GMT/UTC**

Dear colleagues, I thank all for your informative interventions. This was very useful and a good start!

I would now like to move on to the next guiding question under the Item 3.1.:

(b) Which additional guidance materials are DIRECTLY RELEVANT to each risk assessment step listed in paragraph 8? Please specify name of the document and which step it is related to.

I will now open the floor for your reactions.

Hans Bergmans - Netherlands - Party **10:41 GMT/UTC**

In my 2nd contribution I have already indicated a number of documents, and quite some information is of course already available at the BIRC. But, thinking of what documents would be useful, I feel that it would also be good to discuss what type of documents are needed at the different steps of risk assessment.

I would propose that such a discussion can be held based on the submissions that are received. The discussion would take into account what questions are actually tackled by the suggested documents, whether the documents cover all relevant questions, whether we want to have a certain standard for documents, how to handle conflicting evidence, etc.

This would help very much to identify information gaps, and to start looking for the missing information, if it is decided to take such an active approach. Maybe this is not something for the present discussion, but I do think it is something the AHTEG should look into.

Helmut Gaugitsch - Austria - Chairperson **10:43 GMT/UTC**

Thank you Hans, we are going to move on to the next interventions.

Beatrix Tappeser - Germany - Party **10:43 GMT/UTC**

Here some concrete proposals for directly relevant guidance material for para 8f) concerning monitoring The monitoring should take place in exposed areas, preferably cultivated fields plus their environment. The number and location of monitoring sites and regions needs to be sufficient to support statistical analysis of results based on good scientific practice.

Similar to the selection of indicator organisms for the risk assessment there should also be selection criteria for indicator organisms for the monitoring of long-term LMO effects. An important criterion for their selection is the potential to indicate LMO-induced changes. This depends on interrelationships with the LMO, the spatial indicator distribution, its abundance and its importance for ecosystem functions.

An example for a decision support procedure targeting LMO monitoring is given by :

Graef, F., Züghart, W., Hommel, B., Heinrich, U., Stachow, U. & Werner, A., 2005: Methodological scheme for designing the monitoring of genetically modified crops at the regional scale. Env. Monitoring and Assessment 111, 1-3: 1-26.

Helmut Gaugitsch - Austria - Chairperson **10:45 GMT/UTC**

Thank you Beatrix for your suggestions. Are there any colleagues from Parties who want to take the floor on this guiding question before I give the floor to observers?

Jaroslava Ovesna - Czech Republic - Party **10:45 GMT/UTC**

Do we need more guidance material on specific issue - e.g. GM for bioremediation - accumulation of relatively toxic compounds or metabolites of the toxic compound in the particular GM

Helmut Gaugitsch - Austria - Chairperson **10:47 GMT/UTC**

Thank you Jaroslava, this in my point of view seems to be related more to Agenda Item 3.2, question c. You may come back to it at the later stage! We now move on!

Maria Antonietta Toscano - Italy - Party **10:47 GMT/UTC**

I agree with Philippe Baret and others. But I think that guidelines existing now are too many and generally based only statistic and theoric basilar points. Many of them are some years old. We should introduce some approach in line with recent development of scientific notices upon LMO, and try to create more practical guidelines.

Philippe Baret - Belgium - Party **10:48 GMT/UTC**

I agree with Hans. We need to identify gaps of knowledge. In accordance with Maria, we have also to take into consideration the dynamics nature of guidance material. I suggest to give a status to the different documents we discuss : published scientific papers, technical reports and other non-peer reviewed material, project of guidelines, approved guidelines or guidance material.

Helmut Gaugitsch - Austria - Chairperson **10:49 GMT/UTC**

Thank you Philippe for a very concrete suggestion. Any comments on this and other related points?

Beatrix Tappeser - Germany - Party **10:49 GMT/UTC**

I like to support Maria. We should have a deeper look into the existing material and take into account new knowledge which has emerged

Hans Bergmans - Netherlands - Party **10:49 GMT/UTC**

Maria's point is valid, and indicates that there should be some consensus mechanism how to validate and review available information. Agree with Philippe.

Helmut Gaugitsch - Austria - Chairperson **10:51 GMT/UTC**

Thank you all, there seems to be a lot of common ground here, great! We need to be inclusive on the one hand but also establish a way of how to use the amount of guidance available. Any other Parties wishing to contribute to this exchange?

Piet van der Meer - Horizons sprl / PRRI - Observer **10:52 GMT/UTC**

to name one document I suddenly thought of as relevant to the steps of RA: the PRRI guide on risk assessment for releases of GMOs - this guide is not limited to one particular step, but in fact discusses all steps of Annex III in a systematic, practical way. PRRI is currently working on an update and expansion Having said that, I agree with Hans's point that the exercise of sorting out the documentation may be a bit difficult for this discussion and better be done in for example the AHTEG. Maria is right that there is indeed an incredible abundance of material available. I like Philippe's suggestion to sort this out a bit of the befeit of novice risk assessors. PS: I like this feature that after getting the floor you still have time to add thoughts. Wish only that the 'send' button be green in stead of that scary red.

Helmut Gaugitsch - Austria - Chairperson **10:54 GMT/UTC**

Thank you Piet. I am glad that the red colour did not prevent you from submitting your thoughts. Any comments?

David Quist - Norway - Party **10:55 GMT/UTC**

Related to Marias point, the analytical methods and statistical treatments applied that work so well in conventional scientific question are often inappropriate for risk science: evaluating/estimating consequences and providing sound recommendations. So with respect to points b - e, analytical frameworks should be relevant to the system under consideration, and should help infer biological significance and size-effect outcomes of within possible use and exposure scenarios that the GMO under question. Currently, standard hypothesis testing tends to be uninformative for evaluating risk of biological or ecological effects in most cases (see Anderson, 2000), J Wildlife M 64(4):912-923

As a result, arbitrary setting of P-values in current hypothesis testing schemes are more statements about phenomena that did not occur, rather than a explicit statement based on evidence of an actual observed event (that comes from actual data).

Alternative analytical strategies are needed that give greater insight into size effects, which a null hypothesis test provide little information that can advance science and knowledge of a particular question. Bayesian approaches, alternative tests, perhaps Kullback-Leibler informational approaches may prove more useful in formulating model-selection criteria. “biological significance should be emphasized over statistical significance” (Yoccoz, 1991).

Further, hypothesis tests are limited in utility for inferring what models can help infer size-effect relationships that may be included in more comprehensive testing schemata.

Helmut Gaugitsch - Austria - Chairperson **10:56 GMT/UTC**

Thank you David for your concrete contribution. Any more requests fro the floor before I will soon move to the next agenda item?

Hans Bergmans - Netherlands - Party **10:57 GMT/UTC**

I agree with David for what I understand of statistics. It is a general point that hypothesis making and testing differs between 'normal' science and risk assessment science.

Maria Antonietta Toscano - Italy - Party **10:57 GMT/UTC**

I agree with David Quist. Before applying statistical methods, we need to have cases!

Piet van der Meer - Horizons sprl / PRRI - Observer **10:58 GMT/UTC**

Agree - this also ties back again to the problem formulation, as it starts with hypothesis formulation - something the folks in AHTEG hopefully find time to chew on more

Helmut Gaugitsch - Austria - Chairperson **10:59 GMT/UTC**

Thank you all, the AHTEG will be happy with this task, I am sure. Any more comments?

Helmut Gaugitsch - Austria - Chairperson **11:00 GMT/UTC**

Colleagues, thank you very much again. This was a very rich discussion!

We shall now move on to the next substantive issue on the agenda:

ITEM 3.2. Development of further guidance material on specific aspects of risk assessment and risk management.

The AHTEG shall also prioritize the need for further guidance on specific aspects of risk assessment and define which aspects should be addressed first, taking also into account the need for and relevance of such guidance, and availability of scientific information.

In your interventions, you are invited to recommend to the AHTEG, as appropriate, the topics of our earlier Discussion Groups in order of priority:

(a) Risk assessment and risk management of transgenic fish;

(b) Risk assessment and risk management of transgenic trees;

(c) Risk assessment and risk management of transgenic microorganisms and viruses;

(d) Risk assessment and risk management of transgenic pharmaplants;

(e) Risk assessment and risk management of LMOs with stacked genes or traits;

(f) Post-release monitoring and long-term effects of LMOs released into the environment; and

(g) Risk assessment and risk management of specific receiving environments;

taking into consideration the availability of scientific information on these topics, the main knowledge gaps, and any other specific aspects of risk assessment and risk management that may be considered for the development of guidance materials.

Helmut Gaugitsch - Austria - Chairperson **11:01 GMT/UTC**

I see Philippe requesting the floor, is this still on the previous item?

Philippe Baret - Belgium - Party **11:01 GMT/UTC**

Last contribution to the previous point. Sorry. I agree with David on sensu stricto statistics. We are to be aware that specific tools are developed for assessments of non experimental design. In economics and social sciences for example, very sophisticated model are available to take into considerations the diversity in populations and environments. Perhaps we should think about inviting an expert of this field at one of the next meeting.

Jaroslava Ovesna - Czech Republic - Party **11:02 GMT/UTC**

Just remark Statistics and probabilities is O.K., but we know, correct approaches have to be applied. It should be fine to specify which statistical treatments are acceptable for the nature- reliable approaches and definition of basic data (quantity, quality) to be processed should be defined (guideline)

Beatrix Tappeser - Germany - Party **11:03 GMT/UTC**

Sorry I have also some additional remarks to the last point Agricultural practice and impacts of agriculture on biodiversity are quite different in the different regions/receiving environments. Baseline data are not easy to collect and will show high variability. On the other hand the convention and the decisions of the different Conferences of the Parties demand improvements concerning losses of biodiversity. Modern intense agriculture practice has contributed to biodiversity loss. This has to be mirrored in the under-standing of baselines and comparisons and taken into account when it comes to “the evaluation of the likelihood “and “an evaluation of the consequences should these adverse effects be realised” as laid down in Annex III para 8) b&c

Statistics and data collection - the experimental design, as mentioned - are of utmost importance because this frames the possibility to detect effects and the detection thresholds.

There are knowledge gaps and missing guidance how to assess indirect effects and delayed effects and to integrate these into the LMO RA. Modelling may be one approach to better assess effects over the long run.

There is also further guidance needed how to transform the results of small scale releases to large scale commercial releases. And last but not least to get some insight into possible cumulative effects is a major challenge not yet resolved on the conceptual and methodological level. Again modelling approaches could be a valuable tool.

Post market monitoring can be used inter alia to improve the models. These issues should be of some priority

Helmut Gaugitsch - Austria - Chairperson **11:04 GMT/UTC**

Thank you colleagues for your final comments on statistics, all very valid and we will have to think about it in the subsequent steps. I will now move to the next item as suggested before!

Helmut Gaugitsch - Austria - Chairperson **11:04 GMT/UTC**

I will now open the floor for your reactions to the first Chair's guiding question under Item 3.2.:

(a) Which of the specific topics discussed in the Discussion Groups should be prioritized by the AHTEG for the development of further guidance?

The floor is open for your reactions.

Helmut Gaugitsch - Austria - Chairperson **11:07 GMT/UTC**

No one requesting the floor? I cannot believe that. Who would like to break the ice? OK Hans again, thats great!

Hans Bergmans - Netherlands - Party **11:07 GMT/UTC**

On prioritization: First priority is to get the Road map working for what we are already familiar with. Receiving environment is an important issue, as Beatrix already indicated. Next priority would be trees and micro-organisms, but that is strictly from my point of view. Fish are quite important too, and so are pharmaplants. I don't think we will have many discussions on stacked genes: we will probably agree the easiest on that one, so for that reason (and because it is actual) it might get priority. Long term effects and monitoring might be difficult to tackle, but that's no good reason not to do it.

Beatrix Tappeser - Germany - Party **11:08 GMT/UTC**

As a high priority I would recommend: Guidance is needed which modelling approaches are the most appropriate to do an assessment of the time scale and spatial distribution of out crossing of those tree species considered for release and which data gaps have to be closed to develop/implement such modelling approaches. To my understanding such models would be a prerequisite to solid RA of transgenic trees

Helmut Gaugitsch - Austria - Chairperson **11:09 GMT/UTC**

Thank you Hans and Beatrix, I am now giving the floor to Philippe.

Philippe Baret - Belgium - Party **11:10 GMT/UTC**

Concerning transgenic trees, there is a lot of expertise work for the moment in Belgium (and I guess in France, Germany and the Netherlands) on transgenic poplars used to produce biofuels. This issue is certainly of importance for the Belgian party. Specific issues are: how to disentangle risk of the proposed technology (poplar) and of the global issues (biofuels) how to extrapolate three or five year trial on a small plot to a whole region for decades.

Helmut Gaugitsch - Austria - Chairperson **11:11 GMT/UTC**

Thank you very much Philippe, good questions on a very important topic. Any other colleagues from Parties who wish to take the floor before I invite observers?

Jaroslava Ovesna - Czech Republic - Party **11:12 GMT/UTC**

Our priorities are as follows roadmap first

(f) Post-release monitoring and long-term effects of LMOs released into the environment; and

(g) Risk assessment and risk management of specific receiving environments (b) Risk assessment and risk management of transgenic trees; (e) Risk assessment and risk management of LMOs with stacked genes or traits; (d) Risk assessment and risk management of transgenic pharmaplants; (a) Risk assessment and risk management of transgenic fish (;

Helmut Gaugitsch - Austria - Chairperson **11:12 GMT/UTC**

Thank you Jaroslava, very concrete. I give the floor to David!

David Quist - Norway - Party **11:13 GMT/UTC**

I agree with Hans the issue of stacked varieties should be a priority. Pharmaplants, many of which utilize transplastomics and may confer some unique risk-relevant considerations, also deserve treatment. Also, we are very interested in the issue of transgenic fish here in Norway and perhaps that is obvious!

Marja Ruohonen-Lehto - Finland - Party **11:14 GMT/UTC**

I would like to support the prioritation of work on GM trees - there is a clear need for that. I would also consider as first steps to look at (f) Post-release monitoring and long-term effects of LMOs released into the environment; and (g) Risk assessment and risk management of specific receiving environments. This is a demanding job and should be started a.s.a.p. and relates to all other issues we've discussed. Marja

Beatrix Tappeser - Germany - Party **11:15 GMT/UTC**

It is a very sensitive question how to extrapolate from small scale to large scale. That is not only relevant fro trees but in the context of all different uses of LMOs as mentioned Therefore I like to underline Philippe’s point. And taking up Hans point and Jaroslava’s priorities on monitoring I think that the importance of targeted selection of LMO monitoring indicators is not yet adequately perceived. There are knowledge gaps with regard to regional monitoring designs. Further guidance can be provided by

Graef, et al., 2005:. Env. Monitoring and Assessment 111, 1-3: 1-26.

Hans Bergmans - Netherlands - Party **11:16 GMT/UTC**

Philippe's issue on how to disentangle risk from global issues is quite important, but probably not so much in the context of the AHTEG, except to state that such a disentanglement is necessary. Could this be more an issue for the socio-economic discussions?

Helmut Gaugitsch - Austria - Chairperson **11:18 GMT/UTC**

Hans you are raising a very important point. This has to be taken into account in our further discussions. Issues are certainly interlinked but also have to be dealt with in a structured way in order to be manageable! Any more requests for the floor from Parties?

David Quist - Norway - Party **11:18 GMT/UTC**

I should also mention the GM microbes and viruses. We have been working steadfastly on biosafety issues regarding the use of orthopox viruses and vectors for vaccines, and it seems the more we investigate, the more interesting biosafety questions we uncover!

Helmut Gaugitsch - Austria - Chairperson **11:19 GMT/UTC**

OK colleagues, I will now give the floor to observers!

Piet van der Meer - Horizons sprl / PRRI - Observer **11:19 GMT/UTC**

Helmut, Fully concur with the point that the road map is key, and that the AHTEG best focus on that first (including the role of receiving environments). As regards your question in which following order the AHTEG should discuss the specific items listed, I would advise to make a listing on the basis of what we expect to come first for releases. The outcome of the JRC meeting (Seville, November 2008) on GMOs in the pipeline could be helpful here - they are preparing a matrix of GMOs in the pipeline at the moment. I can send the info to the Sec Based on what I see passing by in reports and emails, I would agree with that practical guidance for RA for field trials with GM trees would be welcome, yet advise to leave out of the discussion of AHTEG the socio-economic aspects. As regards Pharma Plants: isn't there for now the focus more on containment/confinement?

Helmut Gaugitsch - Austria - Chairperson **11:20 GMT/UTC**

Thank you Piet, I have reactions from Parties to that! Philippe then Beatrix!

Philippe Baret - Belgium - Party **11:21 GMT/UTC**

I agree with Hans. I should keep the socio-economic for a further discussion.

Beatrix Tappeser - Germany - Party **11:21 GMT/UTC**

Coming back to the monitoring issues I think that monitoring methodologies should be further developed and possibly harmonised as to produce comparable information across different regions. Existing agronomic and environmental monitoring programmes can assist to monitor LMOs and produce standardised monitoring data. They also can provide baseline data. The last point is: Where and how is monitoring data going to be collected and the information exchanged? Every CDB party by its own? This requires further discussion.

Hans Bergmans - Netherlands - Party **11:23 GMT/UTC**

Just to come back to David's intervention, and yes, I quite agree - there are many questions out there. But, I think that one criterion for prioritization is to work on questions that we can solve first. That does not mean that the other questions raised are not important, though!

Helmut Gaugitsch - Austria - Chairperson **11:23 GMT/UTC**

Thank you colleagues, I will now give the floor again to observers before we then go to the next guiding question!

Thomas Nickson - Monsanto Company - Observer **11:24 GMT/UTC**

I am interested to learn how others interpret the term "guidance". Could this be more basic research that contributes to the current body of knowledge as a first step? Or, do people interpret guidance as a definitive work that is truly meant to guide scientists conducting risk assessments? It might be reasonable to assume that a road map would be a high priority because it could be more definitive, based on more experience. The other topic seems scientifically very broad and they might better be addressed through peer reviewed publication followed by validation. It is also reasonable to expect a better outcome from an AHTEG to be something more general like a roadmap. Along what Hans suggested, should higher priority for an AHTEG be given to work that has higher likelihood of success? I believe it would be ill-advised to pursue much work at this time on pharmaplants for reasons given in the previous online forum. These plants are likely to be regulated, and rarely would one request their deregulation.

Helmut Gaugitsch - Austria - Chairperson **11:25 GMT/UTC**

Thank you Thomas. There are a few more Parties requesting the floor and then we move on!

Beatrix Tappeser - Germany - Party **11:25 GMT/UTC**

I think pharmaplants are a very special and important issue too. Given the approaches for confinement and containment these are issues by itself

David Quist - Norway - Party **11:26 GMT/UTC**

Yes Piet, that is the point, there has been perhaps too much focus on containment/confinement issues and not enough on the issues of transgene expression fidelity and stability, transmissibility to bacterial counterparts, protein characterizations...all which (in reference to Hans comment) are all very solvable in the near term. To Thomas point. I would say "based on experience" and actual evidence...

Helmut Gaugitsch - Austria - Chairperson **11:27 GMT/UTC**

Thank you colleagues for the interventions.

I will now move to the second guiding question under the Item 3.2.:

(b) Is there enough scientific information available for developing guidance materials on the topics above and which are the main knowledge gaps?

I will now open the floor for your reactions.

Helmut Gaugitsch - Austria - Chairperson **11:30 GMT/UTC**

Dear colleagues, probably you have provided answers to this question before and there is no need to add anything here. But, certainly, if you would like to add some issues, I would welcome this very much. If not, then we will soon move on to the nxet guiding question! OK there are rquests for the floor now, great!

Jaroslava Ovesna - Czech Republic - Party **11:30 GMT/UTC**

Definitely not. There are publications describing special issues (Bt toxin vs. non target species), but missing information on many other topics, due to necessity of large-scale experiments. It is difficult to extrapolate and make general conclusions based on available knowledge.

Hans Bergmans - Netherlands - Party **11:31 GMT/UTC**

I don't have answers here. But, procedurally, and in agreement with the terms of reference for the AHTEG, I think this could also be a question that is put to experts in the intersessional period between the first and second AHTEG.

Helmut Gaugitsch - Austria - Chairperson **11:32 GMT/UTC**

OK, thank you Jaroslava and Hans. 2 clear responses. Hans, I agree that this is a clear task for the AHTEG to discuss!

Beatrix Tappeser - Germany - Party **11:33 GMT/UTC**

I think we have to analyse the existing guidance material. As I mentioned I would also see guidance material as a tool box for risk assessors but there are definitely knowledge gaps. Quite some have been adressed. I agree with Hans we should raise that at the first or second AHTEG meeting.

Philippe Baret - Belgium - Party **11:33 GMT/UTC**

The issue is not only a question of quantity of information but a question of nature of information and methods. We have to identify gap of knowledge in both topics and methods. For some topics, there is no literature, for other topics there is a lot of literature but this literature is very difficult to extrapolate to risk assessment.

Maria Antonietta Toscano - Italy - Party **11:33 GMT/UTC**

Existing guidelines does not take in consideration extreme variability of bacteria and the extreme difficulty to be studied and monitorized, due to great capacity to live in all substrates modifying their metabolism. If this is true for normal existing bacteria, it is more evident for genetically modified bacteria. Lack of data is evident, but also difficulty to obtain information base on metabolic, cultural and genetic changes is evident.

Helmut Gaugitsch - Austria - Chairperson **11:36 GMT/UTC**

Thank you colleagues, you clearly referred to the knowledge gaps we face and the need to address this from a "topics" and "methods" approach. Any further requests from Parties before I give the floor to observers? OK, David you have the floor!

David Quist - Norway - Party **11:36 GMT/UTC**

Thank you Helmut. Perhaps a gap may exist not only in WHAT questions need to be asked, but HOW we are asking them...It seems there is a need for a more formal treatment of exactly how uncertainty, error and evidence validity are addressed in a risk assessment. This should be a focus of the AHTEG.

Hans Bergmans - Netherlands - Party **11:37 GMT/UTC**

Well, I do have a general answer still: in most cases it's base line information that we are missing most, which is basically what Maria is indicating, and this is valid for most of our questions.

Philippe Baret - Belgium - Party **11:37 GMT/UTC**

I fully agree with David

Beatrix Tappeser - Germany - Party **11:38 GMT/UTC**

To come to a very concrete point. My impression is that quite often there are not enough and targeted data taken from field tests before a commercial release is applied for - eg concerning non-targets or soil life. There is room for some improvement. A second aspect is what David just raised: we have no real methodology concerning uncertainty analysis though it is very important for an overall assessment

Helmut Gaugitsch - Austria - Chairperson **11:39 GMT/UTC**

OK, very stimulating conversation. I now give the floor to observers. Piet and then Tom!

Piet van der Meer - Horizons sprl / PRRI - Observer **11:39 GMT/UTC**

There is indeed a wealth of scientific knowledge and experience available that directly or indirectly can be used for RA. The key question is how to filter that. I agree that it is probably best to start looking at all the materials that were submitted to the CBD Sec over the last few weeks, and place that in the matrix that was suggested earlier - i.e. work for the AHTEG and/or in between AHTEGs

Thomas Nickson - Monsanto Company - Observer **11:40 GMT/UTC**

One of the emerging fields is Problem Formulation, the important first step in risk assessment. In my opinion, there are important gaps in knowledge of applying these principles to the critically important process of linking environmental protection goals to assessment endpoints, construction of a sufficiently detailed conceptual model including good risk hypotheses. All these are necessary first steps before an analysis plan. This idea would be to develop the details of how to design an appropriate risk assessment based on experience. More work needs to be done on the underlying concepts of risk assessment as well as the ecological, toxicological and genetic basis of GMOs. This seems to be somewhat in agreement with David's suggestion.

Philippe Baret - Belgium - Party **11:41 GMT/UTC**

Considering interventions of Hans and David, I think we have to consider both flows: from base information to guidance but also relay the requirements of risk assessors to the providers of base line information. We need a formal treatment of this point.

Hans Bergmans - Netherlands - Party **11:43 GMT/UTC**

I agree that problem formulation is an important first step. I think that we are already doing this implicitly in our hazard identification, but it could and probably should be approached in a more structured way.

Beatrix Tappeser - Germany - Party **11:45 GMT/UTC**

Problem formulation or hazard identification is the first important step. It frames the whole assessment. I agree that we should deal with that point in a more structured way.

Helmut Gaugitsch - Austria - Chairperson **11:46 GMT/UTC**

Thank you all, I give the floor again to observers and then we move on!

Thomas Nickson - Monsanto Company - Observer **11:46 GMT/UTC**

Piet's suggestion is very important. It has been requested at earlier MoPs to organize the existing information.

Maria Antonietta Toscano - Italy - Party **11:46 GMT/UTC**

I agree. In consideration that RA is too generic, may be useful focalise WHAT we think prioritary in evaluation of risk and step by step flow a rational way to go on.

Marja Ruohonen-Lehto - Finland - Party **11:47 GMT/UTC**

Just a comment - the biggest problem in hazard identification is not maybe whether we do it in a structured way but we do not seem to always agree/have a clear picture what a hazard is!

Piet van der Meer - Horizons sprl / PRRI - Observer **11:49 GMT/UTC**

Hi Marja, that is exactly the reason why we need a more in depth discussion as to what we consider as adverse effects - this is the very heart of problem formulation - hope AHTEG will spend time on that

Thomas Nickson - Monsanto Company - Observer **11:49 GMT/UTC**

Marja is absolutely correct! This is what risk assessment is so challenging. Regulators must have this clear view of what constitutes a hazard. Science cannot identify hazards.

Helmut Gaugitsch - Austria - Chairperson **11:49 GMT/UTC**

OK colleagues, if there are no more requests for the floor under this question we will move on to the next one!

Helmut Gaugitsch - Austria - Chairperson **11:50 GMT/UTC**

Thank you for the interventions.

Before we break, I would like to proceed to the third and last guiding question under the Item 3.2.:

(c) Are there other specific aspects of risk assessment and risk management that should be given priority to for the development of guidance materials?

I will now open the floor for your reactions.

Helmut Gaugitsch - Austria - Chairperson **11:50 GMT/UTC**

This was fast David, you have the floor!

David Quist - Norway - Party **11:50 GMT/UTC**

OK, real quick then! The National Academy of Science in the USA issued a report in November 2008 titled “Science and Decisions: Advancing risk assessment (2008)” On problem formulation and Risk Assessment:

"Good design involves bringing risk managers, risk assessors, and various stakeholders together early in the process to determine the major factors to be considered, the decision-making context, and the timeline and depth needed to ensure that the right questions are being asked in the context of the assessment." p. 5

Helmut Gaugitsch - Austria - Chairperson **11:53 GMT/UTC**

Thank you David. Beatrix is next!

Beatrix Tappeser - Germany - Party **11:53 GMT/UTC**

Though it has been mentioned before but I want to underline it once more: uncertainty analysis is an essential part of an overall assessment and we need to spend some more thoughts on that

Helmut Gaugitsch - Austria - Chairperson **11:54 GMT/UTC**

Thank you Beatrix! Are there any more Parties who would like to take the floor before I will invite observers?

Thomas Nickson - Monsanto Company - Observer **11:55 GMT/UTC**

Does organizing the existing information fit here? If so, determining the categories for organizing it or HOW the information is organized would be critical.

Maria Antonietta Toscano - Italy - Party **11:56 GMT/UTC**

I agree with David Quist. So, may be possible translate this theoric and valid basis taking in consideration these points and applying them to the different situations case by case.

Helmut Gaugitsch - Austria - Chairperson **11:57 GMT/UTC**

Thank you so far. Any more comments?

David Quist - Norway - Party **11:57 GMT/UTC**

Thomas: As a sort of evidence-based meta analysis? Weight of evidence approach? Power tests on existing scientific data? Ideas?

Hans Bergmans - Netherlands - Party **11:57 GMT/UTC**

Tom, organizing the information is one goal of the road map: I suggested using the crossroads in the road map as 'pegs' to organize the information (my contribution 3 in the online forum discussion).

Helmut Gaugitsch - Austria - Chairperson **11:58 GMT/UTC**

Thank you David and Hans. I like this truly interactive type of discussion!

Philippe Baret - Belgium - Party **11:59 GMT/UTC**

I agree with Thomas but we have to adopt a balanced approach. If we start to address all the existing information, we will never start the work on the uncertainties and the gaps of knowledge. I suggest that we consider two kind of actors: those able to process the existing information and those able to formulate the problem as stated by David. They are often different persons.

Thomas Nickson - Monsanto Company - Observer **12:00 GMT/UTC**

To David's question: I'm thinking at an even higher level of organization, but your suggestion is good. Many peer reviewed publications could be identified and organized for use in meta-analysis. Marvier et al used the literature first to abstract more specific information from the specific scientists.

Beatrix Tappeser - Germany - Party **12:00 GMT/UTC**

Good point by Philippe to start a parallel process.

Piet van der Meer - Horizons sprl / PRRI - Observer **12:02 GMT/UTC**

I too agree with Philippe's suggestion to work in parallel on both approaches that ultimately serve the same goal,

Manoela Miranda - UNEP/SCBD/Biosafety - Moderator **12:03 GMT/UTC**

Dear all, if you may, please send me later (per email) the complete references of the articles/materials you have mentioned here and I will compile a list to be published on the Online Forum and also submitted to the AHTEG.

Maria Antonietta Toscano - Italy - Party **12:03 GMT/UTC**

I agree with Baret. As I said before, statistical methods as evidence-based meta analysis are very good, but before it is important that other persons provide to obtain and collects data!

Jaroslava Ovesna - Czech Republic - Party **12:04 GMT/UTC**

e should refer as well the contribution presented on the ISBR conference 2008, I'm not sure whether the proceedings are available in an electronic version.

Helmut Gaugitsch - Austria - Chairperson **12:05 GMT/UTC**

Dear colleagues, I thank you all for your participation and interesting interventions that we had so far.

I suggested in the beginning that we break for lunch for one hour. But it is running so well that I would like to keep the momentum and suggest that we break now but only for 15 minutes. In case there are no objections from your side we will do that. So please respond only if you object to my suggestion, thank you!

Beatrix Tappeser - Germany - Party **12:06 GMT/UTC**

Helmut I would prefer to have at least 30 minutes

Jaroslava Ovesna - Czech Republic - Party **12:07 GMT/UTC**

I need 30 minutes, if possible thanks

Philippe Baret - Belgium - Party **12:07 GMT/UTC**

I agree with Beatrix. 30 minutes will be fine.

Piet van der Meer - Horizons sprl / PRRI - Observer **12:07 GMT/UTC**

Dear friends –

I have standing next to me a five year old angel who tells me that papa's computer game has already invaded long enough our Wednesday afternoon together in the swimming pool

I have to go.

I wish you all a fruitful continuation of your debate; I enjoyed participating in it, but now have to yield to more powerful forces

Again my compliments to the Sec for identifying this setting and setting it up

Ciao !

Piet

Maria Antonietta Toscano - Italy - Party **12:08 GMT/UTC**

Yes, I agree with others. For me 30 minutes are right.

Helmut Gaugitsch - Austria - Chairperson **12:08 GMT/UTC**

Thank you Piet, very understandable. Ciao and thanks for your contributions. OK, 30 Minutes then, any objections?

Helmut Gaugitsch - Austria - Chairperson **12:09 GMT/UTC**

Thank you for your cooperation. We shall continue our discussion on the next substantive issue on the agenda (Item 3.3) as soon as we return from the break.

I kindly ask you to be back to your computers in exactly 30 minutes as we still have a discussion ahead of us.

The meeting is adjourned until 12:40 (UTC/GMT).

Manoela Miranda - UNEP/SCBD/Biosafety - Moderator **12:40 GMT/UTC**

Welcome back. I would like to invite the Chair to re-start the meeting.

Helmut Gaugitsch - Austria - Chairperson **12:41 GMT/UTC**

Distinguished delegates,

Welcome back to our conference. I hope you had time to rest a bit and, without further ado, we should move on and start our discussion on the third and last substantive issue on the agenda:

ITEM 3.3. Defining an action plan for the development of guidance materials on specific prioritized aspects as well as the "roadmap".

The AHTEG shall define an action plan to produce, prior to the second meeting of the Group, modalities for the development of guidance documents on the specific aspects that were identified as priorities and

for testing of the roadmap. This action plan should include the details of a process for monitoring and reviewing the progress made on each of the specific aspects.

You are invited to provide recommendations to the AHTEG on the action plan for the development of guidance materials and the roadmap. Furthermore, you may also wish to identify the experts you deem necessary for the development of guidance materials and the roadmap.

Helmut Gaugitsch - Austria - Chairperson **12:42 GMT/UTC**

To guide our discussions on this item, I would like to propose that we focus the interventions on the Chair's first guiding question under item 3.3.:

(a) Do you have any suggestion to the AHTEG on how to define its action plan for the development of guidance materials and the roadmap?

The floor is open for your interventions.

Beatrix Tappeser - Germany - Party **12:44 GMT/UTC**

I think the action plan should follow some how an emergency scheme. During our discussion and the online discussion forum gaps and priorities have been addressed. The secretariat could compile these points and that could be the basis for the discussion during the next meeting of AHTEG.

Concerning the road map we could follow a similar procedure taking into account the proposal by Philippe to have a parallel process

Helmut Gaugitsch - Austria - Chairperson **12:46 GMT/UTC**

Thank you Beatrix! Does any other Party wish to make additional concrete proposals before I give the floor to Non-Parties and observers?

Jaroslava Ovesna - Czech Republic - Party **12:47 GMT/UTC**

It would be difficult to revise existing guidelines. Priorities should be based by ATHEG base on on-line discussion. More precise methodology, data filtering and sorting for available resources should be identified prior the work will start

Maria Antonietta Toscano - Italy - Party **12:47 GMT/UTC**

For my opinion, it is necessary that roadmap is linear, simply to read and opened to the different ways to approach all the focal points of RA, as suggested. For every step, may be present an annex, based upon scientific notices in that point.

Helmut Gaugitsch - Austria - Chairperson **12:48 GMT/UTC**

OK, I give the floor to David Heron from the US. Welcome!

David Heron - United States of America - Non-Party **12:48 GMT/UTC**

Thank you, Helmut, and good morning/afternoon to all. The discussions have been fascinating, and I appreciate the free flow of ideas to forward for the consideration of the AHTEG. Before we move on in the discussions, I would also like to add a quick note in support of the many comments this morning that stressed the importance of hazard identification as an early, crucial step. As part of hazard identification,

we know that it is important that a risk assessor identify a logical, scientifically valid mechanism by which a particular hazard might arise.

I would also like to make a brief comment on the interventions that raised the issue of monitoring. It may be useful for the AHTEG to ways to distinguish monitoring for potential impacts on biodiversity from the notion of monitoring for the presence of an LMO.

I look forward to the discussions during the second half of our session.

Jaroslava Ovesna - Czech Republic - Party **12:49 GMT/UTC**

Perhaps a kind of decision tree or decision support system would be appropriate as well.

David Quist - Norway - Party **12:50 GMT/UTC**

I would like to offer an alternative to Marias point that a road map be linear. It seems that what is necessary is better feedback, between risk assessors, risk managers that facilitate risk communication. I see it more like a circle than a line or a tree. So now we have lines, circles and trees!

Helmut Gaugitsch - Austria - Chairperson **12:52 GMT/UTC**

Dear colleagues, just to clarify the guiding question. This is more on procedure - not what the AHTEG should be discussing - we have dealt with that to some extent before our break. Here I would be interested more in your procedural suggestions, on HOW the AHTEG should perform its task? How an ACTION PLAN should look like? Thank you! Beatrix you have the floor!

Beatrix Tappeser - Germany - Party **12:52 GMT/UTC**

Problem formulation or hazard identification is a crucial step as already mentioned. May be a matrix can be helpful to identify and frame the cases an assessor has to deal with because there will be quite a number of dimensions in different receiving environments.

Helmut Gaugitsch - Austria - Chairperson **12:53 GMT/UTC**

Just to add: The points you have made are very valid and will be submitted to the AHTEG as well. But as I said, in addition to that you are also welcome to provide procedural suggestions. Thank you!

Hans Bergmans - Netherlands - Party **12:54 GMT/UTC**

During this discussion we have already had quite some good ideas on the table for development of the road map. You will get more, no doubt, in the next real time discussions. The AHTEG should focus on the structured approach to risk assessment first, so on the road map, taking into account suggestions made. Probably after that you need an overarching discussion on guidance materials - what type of documents we need etc. - we have also mentioned the points of discussion already. Then prioritization should be looked into, and finally the details of guidance materials. Remember that the first AHTEG has to be clear on what has to be done in the intersessional period! To me it is not clear who is going to do the work in that period - I guess there will be a role for AHTEG participants too there? Anyhow, clearly the intersessional work should be very focussed, which means that there should be clearly defined tasks there.

Philippe Baret - Belgium - Party **12:55 GMT/UTC**

I'd like to have a precision on the intervention of David. "we know that it is important that a risk assessor identify a logical, scientifically valid mechanism by which a particular hazard might arise." For some

hazards, we don't know the scientific mechanism but we know that they constitute an hazard. In the past, it was the case for AIDS and prion diseases. They were identified and risk management was put in place before we fully understood the scientific background. For some environmental aspects of transgenic plants, such as fitness in the wild, we don't know all the scientific dimensions. All hazards are not logical, unfortunately. Concerning roadmaps, I prefer circles to lines. In fact, we need circles leading to (guide)lines.

Helmut Gaugitsch - Austria - Chairperson **12:57 GMT/UTC**

Thank you colleagues. I just would like to state that Hans` intervention just before very well touches on the issues this guiding question is aiming at. So if you could add to those ideas, this would be very helpful. Thank you!

Jaroslava Ovesna - Czech Republic - Party **12:57 GMT/UTC**

Anyway we need a workable system. It would be great to identify existing gaps - is it possible to use a kind of questionnaire of expertise for specific topic? The experience will be useful in drawing other documents and suggestions. To formulate, how to identify hazard especially for long-term effect and continuously changing environment by many factor, is key issue. It can not be streamline like in case of toxic compound where immediate effect is apparent. Does scientific publications on that exist?

Maria Antonietta Toscano - Italy - Party **12:57 GMT/UTC**

Yes David Quist, perhaps I was not enough clear, and I excuse myself. I agree. But in the sense of linear I see not a simple line, but a simple way to go on, without possibility of too much alternatives. Simple to read and easy to apply. May be a circle, indeed, or a tree, but the important is a facility to read and to apply.

David Quist - Norway - Party **13:00 GMT/UTC**

Some thoughts for an action plan: 1) Defining roles of various actors along the roadmap, 2) Defining relevant analytical metrics applied in the road map that strengthen the technical and analytical aspects of the risk assessment, 3) Identify the obstacles, and the means to remove them, to improving the efficacy, relevance and usefulness of a risk assessments for management decisions and risk communication. This third part obviously necessitates dialogue with other actors, defined in #1 including risk managers (who should be separate people as pointed out by Philippe) and other stakeholders.

Jaroslava Ovesna - Czech Republic - Party **13:00 GMT/UTC**

Agree with Maria Antonietta It could be a PC tool, easy to handle, answering as much questions as possible.

Helmut Gaugitsch - Austria - Chairperson **13:01 GMT/UTC**

Thank you, I will now give the floor to observers. Tom please!

Thomas Nickson - Monsanto Company - Observer **13:01 GMT/UTC**

Thank you Helmut. I will need to go back and explore the point that Hans made in the earlier online forum. But the idea of asking the AHTEG to start organizing the information as a goal of the road map seems appropriate. A roadmap based on Annex III and integrating existing information in an organized manner seems like a worthwhile exercise. I also agree with Philippe and others immediately before that break that proceeding down parallel paths is essential. There is a body of knowledge already in the

literature that needs to be organized in a manner to make it readily extractable and understood by all interested parties, especially developing nations. As we learned from Marvier et al and Duan et al, this literature can lead us to a greater understanding of GMOs broadly. However, organizing the literature at the AHTEG also could reveal a path to knowledge gaps that are both critical for risk assessment and interesting from the perspective of basic science. Also, problem formulation helps us identify information that is relevant for the risk assessment (need to know). The process would be complex, but the discussion would be worthwhile. I'm not sure how to state this better as a process for the AHTEG.

Helmut Gaugitsch - Austria - Chairperson **13:02 GMT/UTC**

Thank you colleagues, these are very valuable contributions, both procedurally and with respect to contents. Any more requests for the floor at this stage?

David Heron - United States of America - Non-Party **13:05 GMT/UTC**

Considering the preceding interventions, I wonder if it might be useful for the AHTEG to consider an approach that would examine extant risk assessments in order to discern cases in which risk assessors have used similar methodologies or reached similar conclusions on particular cases.

Helmut Gaugitsch - Austria - Chairperson **13:07 GMT/UTC**

Thank you colleagues. I would just like to ask you if you have additional thoughts on how the important intersessional period between the 2 AHTEGs could be organized. We do not know the outcome of the first AHTEG of course, but still it might be worth considering on how to organize the work in preparation for the second AHTEG. What do you think?

Beatrix Tappeser - Germany - Party **13:10 GMT/UTC**

I think we should plan to have for example some real time online conferences to concrete questions as it seems that is a very targeted tool to discuss different aspects and views.

Helmut Gaugitsch - Austria - Chairperson **13:12 GMT/UTC**

Thank you Beatrix, your suggestion is very concrete and specific and it also shows that this instrument seems to work very well!

Marja Ruohonen-Lehto - Finland - Party **13:12 GMT/UTC**

I support that idea because we are indeed talking about concrete issues here.

Hans Bergmans - Netherlands - Party **13:12 GMT/UTC**

David: there might be merit in that approach, as a refinement of the methodology that is already presented in Annex III. I think it would be hard to come up with a completely new methodology, ut that is probably not what you mean. In the intersessional period you will need a few task forces that tackle problems identified and defined by the first AHTEG. Clearly, these tasks might be quite large - probably larger than the CBD Secretariat or participants of the AHTEG can tackle. Real time conferences could be a way, but then still that would require a lot of preparation. It also implies that specific tasks have to be given to people in one region, if we want to be efficient.

Helmut Gaugitsch - Austria - Chairperson **13:13 GMT/UTC**

Dear colleagues, thank you for the interventions.

I would now like to proceed to the second and last guiding question under the Item 3.3.:

(b) Would you be available, and on which topic, to offer assistance to the AHTEG in case it decides to establish working groups for the development of guidance materials and the roadmap?

I will now open the floor for your reactions.

Philippe Baret - Belgium - Party **13:14 GMT/UTC**

I agree with Beatrix on real time conference but we have not to forget that scientists need also blackboard and powerpoint. We will probably need a mix of plenary session (like this one) and expert group session on a more "videoconference" mode or at least with an online diffusion of images.

Beatrix Tappeser - Germany - Party **13:15 GMT/UTC**

In addition we should perhaps form small working groups which can be supported by those who participated in the discussion forums. The outcome can then be discussed as a first step in an online forum - that would cover some how the preparation which is addressed by Hans and can be complemented by the suggestions by Philippe

Helmut Gaugitsch - Austria - Chairperson **13:15 GMT/UTC**

Thank you Philippe and Beatrix for your suggestions on applying a "technology mix". Any further suggestions or offers?

Hans Bergmans - Netherlands - Party **13:16 GMT/UTC**

I am quite sure that the Netherlands, probably meaning me with the help of my colleagues, will be available for further development of the idea of the road map, based on all the input that we are getting. That does not exclude help on other issues.

Helmut Gaugitsch - Austria - Chairperson **13:16 GMT/UTC**

Thank you Hans for your generous offer! Jaroslava you have the floor.

Jaroslava Ovesna - Czech Republic - Party **13:17 GMT/UTC**

The first ATHEG meeting will select specific issue, will made list of priorities. Probably, after the round of on-line real-time conferences the secretariat should assess the impact. The on-line conferences are O.K More specific materials will be probably to discuss. So a general pre-discussion via e-mail may be appropriate as well. Also e-mail discussion would be O.K. Specialised questionnaires may be O.K. as well to get info how to formulate questions for the on line discussion.

Marja Ruohonen-Lehto - Finland - Party **13:17 GMT/UTC**

Yes, I and my colleague Katileena Lohtander-Buckbee would certainly be available. More specifically, on monitoring issues and structural improvement of risk assessment. Also, on structuring the roadmap.

Helmut Gaugitsch - Austria - Chairperson **13:18 GMT/UTC**

Thank you Marja for your nice offer and support. Any other interventions?

Thomas Nickson - Monsanto Company - Observer **13:18 GMT/UTC**

How would the Secretariat like to engage the support and help of observers and non-parties? We have much expertise to offer on the topics being discussed?

Jaroslava Ovesna - Czech Republic - Party **13:19 GMT/UTC**

It takes me longer time to write a message. In fact I would be available for scientific issues (plant interactions), data analysis. We should define the topics

David Quist - Norway - Party **13:20 GMT/UTC**

An enthusiastic yes from Norway! These are central issues we are also facing, along with our EU friends to the south. We here at GenØk (during our abundantly long and dark winters) have been working on a guidance document that outlays some of these ideas in a Norwegian context. These are set in a series of modules that relate primarily to the Evidence based risk assessment ideas, and the latter focus on risk management inputs.

"Evidence based guidance: A systematic approach to strengthen the scientific assessment of GM crops and foster innovation, safety and sustainability in technology development"

In summation, an EBRA approach can:

- Strengthen the scientific basis of risk assessments

- Improve transparency and efficiency of risk assessments

- Identify the most relevant evidence needs through structured question framing

- Ensure the use of the most advance, highest quality research and methodologies

- Provide a means for a comprehensive assessment by identifying gaps in needed evidence

- Foster scientific innovation by identifying safety and knowledge gaps/needs

- Bring needed changes on how error and uncertainty are addressed

Helmut Gaugitsch - Austria - Chairperson **13:21 GMT/UTC**

Thank you Jaroslava and David, very nice! I will give the floor to the Secretariat for an answer to Tom`s question.

Manoela Miranda - UNEP/SCBD/Biosafety - Moderator **13:21 GMT/UTC**

Tom, the AHTEG would be the one to decide who would be involved and how this involvement would be. For this reason, it is very important to give the AHTEG an indication of who would be willing to be part of the process and what the contribution may be.

Beatrix Tappeser - Germany - Party **13:22 GMT/UTC**

Thank you Hans and others, we can also offer support for developing the road map e.g. with respect to the improvement of RA , knowledge gaps, methodologies to be developed or discussed, including monitoring

methodologies. As I indicated in the discussion forum we have some projects underway dealing with these questions.

Helmut Gaugitsch - Austria - Chairperson **13:22 GMT/UTC**

Thank you Manoela and Beatrix! Maria Antonietta you have the floor.

Maria Antonietta Toscano - Italy - Party **13:22 GMT/UTC**

Also my availability is sure, about questions regarding biological aspects of RA.

Helmut Gaugitsch - Austria - Chairperson **13:23 GMT/UTC**

Thank you, that is highly appreciated!

Jaroslava Ovesna - Czech Republic - Party **13:23 GMT/UTC**

Also availability depends on how the work will be organized. Does ATHEC plan a conference or discussion forum for individual regions on a certain topic(s)? Could perhaps help to strengthen discussion.

Philippe Baret - Belgium - Party **13:23 GMT/UTC**

I may help on systemic aspects of ecology and genetics.

Helmut Gaugitsch - Austria - Chairperson **13:25 GMT/UTC**

Thank you colleagues. You may recommend issues the AHTEG should deal with. What the AHTEG is going to do, depends on these types of suggestions you and others make!

Jaroslava Ovesna - Czech Republic - Party **13:25 GMT/UTC**

I can also help with molecular characterisation/employment of bioinformatics and related aspects

Helmut Gaugitsch - Austria - Chairperson **13:28 GMT/UTC**

Thank you colleagues for your excellent suggestions and generous offers and support. This is highly appreciated and will facilitate the work in front of us. All this will be taken into account in the next steps and by the AHTEG. In the interest of time and keeping the work programme that we agreed at the beginning of the conference, I will now close the discussion on item 3.

Thank you all for your interventions.

Hans Bergmans - Netherlands - Party **13:29 GMT/UTC**

Just another comment. I think we (or anyhow the AHTEG) should give some thought to the process for getting input on any and all of the subjects. In OECD we have the experience that you need some form of consensus on documents that we are producing, to strengthen their impact. Clearly, this can be a tedious process, still, the value of documents is greatly improved if there is a form of consensus process involved.

Helmut Gaugitsch - Austria - Chairperson **13:31 GMT/UTC**

Thank you Hans for your comment which surely will be taken into account. We will now move to

ITEM 4. OTHER MATTERS

I will open the floor for about 5 minutes for any suggestions, comments etc that you may wish to make that are relevant to the mandate of this conference.

The floor is now open.

Helmut Gaugitsch - Austria - Chairperson **13:33 GMT/UTC**

Dear colleagues, any comments from your side under other matters before we move to the closure of this Online Conference?

David Quist - Norway - Party **13:34 GMT/UTC**

Perhaps one of the mandates would be a synthesis documents that distils the key points and concrete recommendations to be provided to the AHTEG. Will this be performed by someone?

Jaroslava Ovesna - Czech Republic - Party **13:35 GMT/UTC**

O.K. Conference was interesting, perhaps, if found appropriate, the mandate of on line conference should be available written somewhere in the window during the whole course of such conference to clarify exactly the topic and aim,

Beatrix Tappeser - Germany - Party **13:36 GMT/UTC**

I think these real time online conference is a valuable tool to compile the important aspects of a given question and I like to thank the secretariat and the chairperson for their support

Thomas Nickson - Monsanto Company - Observer **13:36 GMT/UTC**

As I must leave now (our day is beginning with 10 cm of new snow and -10 degrees C), I wish to express my sincere thanks to the Secretariat for organizing this forum. It has worked very well. I thank Helmut for his outstanding job chairing this session and keeping things on track. Finally, I thank all the other participants for sharing their ideas and suggestions on this important topic.

Manoela Miranda - UNEP/SCBD/Biosafety - Moderator **13:36 GMT/UTC**

David, the COP-MOP has requested the Secretariat to prepare a synthesis document of all regional conferences to be submitted to the AHTEG.

Maria Antonietta Toscano - Italy - Party **13:37 GMT/UTC**

For me this on-line conference was the first experience, but very exciting! I hope to repeat this experience and I thank for attention! My best regards to whole virtual forum.

Hans Bergmans - Netherlands - Party **13:37 GMT/UTC**

I want to thank you all very much for this experience; it exceeded my best expectations! This is very useful indeed. And thank you, Helmut for the way you chaired this.

David Quist - Norway - Party **13:38 GMT/UTC**

Helmut, Manoela, Giovanni, others, Thank you for your energy and excellent work in facilitating this important dialogue!

Helmut Gaugitsch - Austria - Chairperson **13:39 GMT/UTC**

Thank you colleagues for your very nice feedback, we are soon closing. We are approaching the end of our conference, but before I move on to the next agenda item, I would like to invite the Secretariat to make some final remarks.

Secretariat, you have the floor.

Manoela Miranda - UNEP/SCBD/Biosafety - Moderator **13:39 GMT/UTC**

Thank you all for a very fruitful and exciting conference. We, at the Secretariat, are extremely pleased with the level of interaction and relevance of the discussion.

The full transcript of the conference will be posted online and sent to the other participants so that we can also have some continuity between the regional real-time conferences.

We are very grateful to all the participants. I would like to give special thanks to Helmut for chairing this conference in an incredibly skilful manner.

Our work continues until COP-MOP5. Thank you all, have a good afternoon, and we are looking forward to upcoming discussions!

Helmut Gaugitsch - Austria - Chairperson **13:40 GMT/UTC**

Thank you secretariat, before closing I give the floor to a few other colleagues!

Jaroslava Ovesna - Czech Republic - Party **13:40 GMT/UTC**

Thanks the secretariat for the help (especially Manoela) and chairman for guiding the whole tour !

Marja Ruohonen-Lehto - Finland - Party **13:40 GMT/UTC**

Thank you Helmut, thank you the Secretariat, thank you all! Very interesting and useful!

David Heron - United States of America - Non-Party **13:40 GMT/UTC**

Thanks to all for a very interesting experience today. I look forward to our next meeting and discussion, whether virtual or actual. Best to all.

Philippe Baret - Belgium - Party **13:41 GMT/UTC**

Thank for all for this very interesting discussion.

Helmut Gaugitsch - Austria - Chairperson **13:42 GMT/UTC**

Thank you, dear colleagues and dear Secretariat!

I would like also to thank all the participants and guests who have joined today for making this groundbreaking initiative a success. I would also like to thank the colleagues in the Secretariat very much for their tireless efforts and extremely valuable assistance in making this Conference possible. It was my pleasure to be part of this and chair this online Conference! I am also looking forward to meeting you virtually and in person soon again!

With that, I now declare the First Regional Real-time Online Conference on Risk Assessment and Risk Management: Europe, closed.

Thank you.

Annex II

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