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**N O T I F I C A T I O N**

**Testing of the "Guidance on Risk Assessment of Living Modified Organisms" in actual cases of risk assessment**

Dear Madam/Sir,

In its decision BS-VI/12, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) commended the progress made on the Guidance on Risk Assessment of Living Modified Organisms (hereinafter "the Guidance"), clearly understanding that:

(a) The Guidance is not prescriptive and does not impose any obligations on Parties;

(b) The Guidance will be tested nationally and regionally for further improvement in actual cases of risk assessment and in the context of the Cartagena Protocol on Biosafety.

Further, with regard to the testing of the Guidance, the COP-MOP:

(a) *Encourages* Parties, other Governments and relevant organizations, as appropriate, to translate the Guidance into national languages and to make such translated versions available through the Biosafety Clearing-House for wide dissemination, in order to facilitate the testing of the Guidance at national, regional and subregional levels;

(b) *Also encourages* Parties, other Governments and relevant organizations, through their risk assessors and other experts who are actively involved in risk assessment, to test the Guidance in actual cases of risk assessment and share their experiences through the Biosafety Clearing-House and the open-ended online forum;

(c) *Invites* Parties, other Governments and relevant organizations to provide financial and technical assistance to developing country Parties and Parties with economies in transition to undertake, as appropriate, the testing activities referred to above.

In that same decision, the COP-MOP requested the Executive Secretary to:

(a) Develop appropriate tools to structure and focus the testing of the Guidance;

(b) Gather and analyse, in a transparent manner, feedback provided as a result of testing on the practicality, usefulness and utility of the Guidance, (i) with respect to

To: BCH Focal Points, National Focal Points of the Cartagena Protocol on Biosafety (CBD when no CPB designated), Relevant Organizations

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consistency with the Cartagena Protocol on Biosafety; and (ii) taking into account past and present experiences with living modified organisms; and

(c) Provide a report on possible improvements to the Guidance for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its seventh meeting.

Furthermore, the COP-MOP also mandated the Open-Ended Online Forum and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management to, provide input, *inter alia*, to assist the Executive Secretary in his task to structure and focus the process of testing the Guidance, and in the analysis of the results gathered from the testing.

In response to the above, the Secretariat, in collaboration with the Open-Ended Online Forum and the AHTEG on Risk Assessment and Risk Management developed a concept note (annexed hereto) and a questionnaire to structure and focus the testing of the Guidance, which are available through the Biosafety Clearing-House at http://bch.cbd.int/protocol/testing_guidance_RA.shtml.

Accordingly, I am pleased to invite Parties, other Governments and relevant organizations to undertake the testing of the Guidance through their risk assessors and other experts who are actively involved in risk assessment. To facilitate the process of the testing and the submission of the feedback, technical information is hereby provided as Annex 2.

The feedback from the testing on the practicality, usefulness and utility of the Guidance is to be submitted through the Biosafety Clearing-House (BCH) through the above link. **The questionnaire for the reporting of the results of the testing initiatives by Parties and other Governments is to be submitted by their respective BCH Focal Points. The Head Offices of organizations are invited to contact the Secretariat at secretariat@cbd.int to indicate a contact person who will submit the questionnaire on their behalf.** Organizations wishing to submit the result of their testing initiatives must be registered in the BCH.

In order to enable the Open-Ended Online Forum and the AHTEG on Risk Assessment and Risk Management to assist the Executive Secretary in the analysis of the results of the testing, the completed online questionnaire is to be submitted through the above BCH link as soon as possible but no later than **31 December 2013.** Parties, other Governments and relevant organizations are to submit one completed questionnaire each as the result of their testing initiatives.

Please accept, Madam/Sir, the assurances of my highest consideration.

Braulio Ferreira de Souza Dias
Executive Secretary

*Annex 1*

**Concept note regarding the testing of the Guidance on Risk Assessment of LMOs**

In decision BS-VI/12[1], the Conference of the Parties serving as the meeting of Parties to the Cartagena Protocol on Biosafety (COP-MOP) commended the progress made on the Guidance on Risk Assessment of Living Modified Organisms, clearly understanding that:

(a) The Guidance is not prescriptive and does not impose any obligations on Parties;

(b) The Guidance will be tested nationally and regionally for further improvement in actual cases of risk assessment and in the context of the Cartagena Protocol on Biosafety.

Furthermore, with regard to the testing of the Guidance, the COP-MOP:

(a) Encouraged Parties, other Governments and relevant organizations, as appropriate, to translate the Guidance into national languages and to make such translated versions available through the Biosafety Clearing-House for wide dissemination, in order to facilitate the testing of the Guidance at national, regional and subregional levels;

(b) Also encouraged Parties, other Governments and relevant organizations, through their risk assessors and other experts who are actively involved in risk assessment, to test the Guidance in actual cases of risk assessment and share their experiences through the Biosafety Clearing-House and the open-ended online forum;

(c) Invited Parties, other Governments and relevant organizations to provide financial and technical assistance to developing country Parties and Parties with economies in transition to undertake, as appropriate, the testing activities referred to above.

In that same decision, the COP-MOP requested the Executive Secretary to:

(a) Develop appropriate tools to structure and focus the testing of the Guidance;

(b) Gather and analyse, in a transparent manner, feedback provided as a result of testing on the practicality, usefulness and utility of the Guidance, (i) with respect to consistency with the Cartagena Protocol on Biosafety; and (ii) taking into account past and present experiences with living modified organisms; and

(c) Provide a report on possible improvements to the Guidance for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its seventh meeting.

Furthermore, the COP-MOP also mandated the Open-Ended Online Forum and the AHTEG on Risk Assessment and Risk Management to, provide input, *inter alia*, to assist the Executive Secretary in his task to structure and focus the process of testing the guidance, and in the analysis of the results gathered from the testing.

Accordingly, the Secretariat is setting up the process of testing the Guidance as follows:

*Testing process:*

(a) The objective of the testing is to evaluate the practicality, usefulness and utility of the Guidance on Risk Assessment of Living Modified Organisms with respect to consistency with the Cartagena Protocol on Biosafety, in particular Article 15 and Annex III, and taking into account past and present experiences with living modified organisms;

(b) The testing may be conducted by Parties, other Governments and relevant organizations through their risk assessors and other experts who are actively involved in risk assessment;

(c) The testing may be conducted by individuals or as a group initiative (e.g. workshops);

[1] Available at http://bch.cbd.int/database/attachment/?id=13599.

(d) The Guidance is to be tested using actual cases of risk assessment conducted in accordance with Annex III of the Cartagena Protocol, noting that the actual case of risk assessment itself is not the subject of the testing;

*Actual cases of risk assessment:*

(e) The technical and scientific data of actual cases of risk assessment used in the testing may originate from various sources. These sources may include application dossiers, and previous or ongoing risk assessment processes. Alternatively, the summaries of notifications may also be used;

(f) Irrespective of the source of the technical and scientific data in (e) above, the actual cases of risk assessment used in the testing must be clearly identified either through references to Risk Assessment Records in the Biosafety Clearing House (BCH), or hyperlinks to their original source;

(g) The BCH Risk Assessment Records referring to the actual cases of risk assessment used in the testing may be generated either through the regulatory process of a country or through an independent or non-regulatory process;[2]

*Reporting the results of the testing:*

(h) The results of the testing are to be submitted through the BCH using the questionnaire common format that is made available for this purpose;

(i) The BCH Risk Assessment Records or hyperlinks to webpages containing information on the actual cases of risk assessment used in the testing are to be linked to the questionnaire;

(j) The results of the testing conducted by Parties and other Governments are to be submitted by their respective BCH National Focal Points and those by relevant organizations through their head offices;

(k) Each Party, other Government or relevant organization may test the Guidance with as many actual cases of risk assessment available but may only complete and submit one questionnaire reporting their results.

[2] The BCH contains two broad categories of records: "National Records" and "Reference Records". Risk assessment records generated through a regulatory process are "National Records" created and maintained by the country submitting the record, as per Article 20 paragraph 3 ( c ) of the Cartagena Protocol on Biosafety. Risk assessment records generated through a non-regulatory or independent process are "Reference Records", which are created through means other than a country's regulatory processes, e.g. a risk assessment conducted by a relevant organization, such as a business, non-governmental or academic organization, including risk assessments that may trigger the regulatory process of a country. BCH Risk Assessment Records may be searched at http://bch.cbd.int/database/riskassessments/.

*Annex 2*

**Technical information on the testing of the Guidance on Risk Assessment of Living Modified Organisms and the submission of feedback**

The following technical information is aimed at facilitating the testing of the Guidance and the submission of feedback as a result of the testing initiatives.

The tools to structure the process of testing the Guidance are available in the six official UN languages through the Biosafety Clearing-House at http://bch.cbd.int/protocol/testing_guidance_RA.shtml. These include:

(a) An offline questionnaire available to download. It is recommended that the offline questionnaire be used in the testing phase for gathering the results from risk assessors and other experts prior to the final online submission.

(b) The version of the Guidance to be used in the testing available to download. Furthermore, as per decision BS-VI/12 the COP-MOP "*Encourages Parties, other Governments and relevant organizations, as appropriate, to translate the Guidance into national languages and to make such translated versions available through the Biosafety Clearing-House for wide dissemination, in order to facilitate the testing of the Guidance at national, regional and subregional levels".*

(c) The online questionnaire for reporting feedback as a result of the testing. Access to the online questionnaire through the link above is limited to BCH Focal Points and persons appointed by organizations for the submission of the results of the testing. On an exceptional basis, countries and organizations with limited internet connectivity may submit the completed offline questionnaire reporting the results of their testing initiatives to secretariat@cbd.int.

Examples of actual cases of risk assessment containing the full sets of technical and scientific information as submitted by the notifier include those available through the BCH at: http://bch.cbd.int/database/record.shtml?documentid=104904 and http://bch.cbd.int/database/record.shtml?documentid=104905 or in other websites such as: http://www.efsa.europa.eu/en/press/news/130114.htm.

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