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CONFERENCE OF THE PARTIES TO THE CONVENTION
ON BIOLOGICAL DIVERSITY SERVING AS THE
MEETING OF THE PARTIES TO THE CARTAGENA
PROTOCOL ON BIOSAFETY

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Item 18 of the provisional agenda

SECOND ASSESSMENT AND REVIEW OF THE EFFECTIVENESS OF THE PROTOCOL (ARTICLE 35)

Note by the Executive Secretary

I. INTRODUCTION

1. The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) is required, under Article 35 of the Cartagena Protocol on Biosafety, to undertake an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes, at least every five years. The first review was considered in 2008 by the fourth meeting of the Parties to the Protocol. In that review, it was noted that due to the limited operational experience gained by Parties in the implementation of the Protocol, there was insufficient basis for effective assessment and review of the Protocol.

2. Accordingly, in decision BS-IV/15, the Parties requested the Executive Secretary to: (i) develop a sound methodological approach to contribute to an effective second assessment and review of the Protocol; and (ii) draft criteria or indicators that could apply in the evaluation of the effectiveness of the Protocol.

3. At their fifth meeting, the Parties to the Protocol decided that: (i) the scope of the second assessment and review of the effectiveness of the Protocol focus primarily on evaluating the status of implementation of core elements of the Protocol with identified elements and indicators; and (ii) the evaluation should be based on information on the implementation of the Protocol gathered through the second national reports, the Biosafety Clearing-House, information that might be made available through the Compliance Committee in relation to its functions to review general issues of compliance, the capacity-building coordination mechanism and other relevant processes and organizations.

4. The Parties to the Protocol in decision BS-V/15 also requested the Executive Secretary to collect and compile information on the implementation of the Protocol and to commission the analysis of such compilation of information with a view to facilitating the second assessment and review of the effectiveness of the Protocol. The Parties also decided to establish a regionally balanced ad hoc technical

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expert group, to: (i) review the analysis of information gathered; and (ii) submit its recommendations to the sixth meeting of the Conference of the Parties serving as the meeting of the Parties for its consideration. .

5. The Parties to the protocol also adopted, at its fifth meeting, decision BS-V/16, on a strategic plan for the Protocol for the period 2011-2020. The decision provides for, among other things, a midterm evaluation of the Strategic Plan to be carried out five years after its adoption. Furthermore, paragraph 4(a) of decision BS-V/16 and paragraph 3(b) of decision BS-V/15, state that the midterm evaluation will take place at the eighth meeting of the Parties in conjunction with the third assessment and review of the effectiveness of the Protocol. The evaluation process is to use the indicators set out in the Strategic Plan to assess the extent to which the strategic objectives are being achieved (paragraph 11 of annex I to decision BS-V/16). Information for the evaluation is to be drawn mainly from the national reports submitted by Parties and from other sources that are relevant and available to generate the data necessary for the analysis.

6. In paragraph 4 (b) of decision BS-V/16, the Parties to the Protocol also decided that the midterm evaluation would use appropriate evaluation criteria to be proposed by the Executive Secretary at the seventh meeting of the Parties to the Protocol. As a starting point, decision BS-V/16 states the assumption that *“a baseline of the status of implementation of the Protocol and global indicators will be established after the second assessment and review at the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol to establish a global picture”* (paragraph 13 of annex I to decision BS-V/16). The decision further notes that the indicators in the Strategic Plan have been drafted in such a way that they would facilitate measurement of progress against this baseline. The present meeting of the Parties to the Protocol is expected to consider such a baseline on the basis of the conclusions and recommendation of the Ad Hoc Technical Experts Group on the Second Assessment and Review.

7. The present document is structured as follows: section II briefly reviews sources of information, collection and compilation of information on the implementation of the Protocol that were used for the second assessment and review; section III introduces the report, commissioned by the Secretariat, which analysed the information on the status of implementation of the Protocol,¹ section IV presents a preliminary outline of a suggested process towards conducting the third assessment and review of the effectiveness of the Protocol in conjunction with the midterm evaluation of the Strategic Plan at the eighth meeting of the Parties to the Protocol; and section V suggests some elements for a draft decision for consideration by the Parties to the Protocol .

II. COLLECTION AND COMPILATION OF INFORMATION ON THE IMPLEMENTATION OF THE PROTOCOL

8. The second national reports submitted to the Secretariat as at 31 December 2011, by 143 Parties to the Protocol served as the primary source of information utilized for the analysis of the status of implementation of the Protocol for the purpose of the second assessment and review of the effectiveness of the Protocol. The second national reports provide information on measures that each Party has taken to implement the Protocol. The information provides some indication of the extent to which domestic procedures and mechanisms are working in practice in order to fulfil obligations under the Protocol. A separate document (UNEP/CBD/BS/COP-MOP/6/16) on monitoring and reporting summarizes and analyses the information contained in the national reports in relation to each article of the Protocol. The information is also analysed in the form of histograms in document UNEP/CBD/BS/COP-

¹ The full report of the analysis is made available separately as document UNEP/CBD/BS/COP-MOP/6/17/Add.1.

MOP/6/INF/21. Additional information given by Parties in the text field of the second national report format, at the end of the set of questions pertinent to each Article of the Protocol, provide further information into trends and challenges in the implementation of the Protocol.

9. The Biosafety Clearing-House (BCH) provided significant amount of information particularly in relation to the records on national laws and regulations, and national decisions and communications on transboundary movements of living modified organisms (LMOs) for intentional introduction into the environment and on LMOs for direct use as food or feed, or for processing. Reports of the Compliance Committee also served as sources for information in particular in relation to its review of general issues of compliance. The Capacity-building Coordination Mechanism provided some general information on national level implementation, as well as insights and observations into difficulties in implementation and ways to address those challenges. The coordination meetings for governments and organisations implementing and/or funding biosafety capacity-building activities under the Coordination Mechanism, was also reviewed to identify areas where critical capacity-building needs have been identified as well as measures taken to date to address those needs.

10. Information from other sources including both official documents, academic and grey literature, and relevant websites such as material on the existence and status of projects funded through the Global Environment Facility also provided data for the second assessment and review of the Protocol.

11. The available material from the second national reports which forms the main source of data for the second assessment and review for the effectiveness of the Protocol comes with some limitations identified as follows:

(a) The variation in the details of information provided by Parties in their second national reports. For example, some Parties provided quite detailed information on current or evolving national laws and regulations, or on particular regulatory decisions, while others did not respond to specific questions or provide details in the text entry field;

(b) Parties may have adopted differing interpretations to questions posed in the second national report questionnaire, and used different processes to gather the information provided in the reports. It was noted however that the purpose of analysis is not to verify information contained in national reports, and in that sense the report can only be as accurate as the data upon which it is based;

(c) The report is based on the assumption that the information provided in national reports is accurate and up-to-date;

(d) There appear to be some inconsistencies between information made available in national reports, and the corresponding information available in BCH or through other sources. Of the 143 Parties that have submitted second national reports by 31 December 2011, 67 reported that the information they have submitted to the BCH was not complete or up to date. Some apparent discrepancies are highlighted in general terms in the report, where appropriate;

(e) The second national reports do not expressly address all of the specific elements and indicators listed set out in the annex to decision BS-V/15. Where this was the case, an attempt was made as much as possible to interpret the data provided in the context of the specific element or indicator concerned, or to find relevant information through the BCH or another source;

(f) In a number of respects, the national reports tend to focus on measures developed or under development by Parties for the purpose of implementing the Protocol rather than on the implementation and enforcement of these measures in practice, and/or their impact and success in terms

of outcomes. To a significant extent, this is due to the fact that many Parties remain at an early stage of implementing their national biosafety frameworks;

(g) No additional formal surveys, interviews and consultations were conducted specifically for the purposes of preparing the report on analysis of the status of implementation of the Protocol.

III. ANALYSIS OF THE STATUS OF IMPLEMENTATION OF THE PROTOCOL

12. The report on the status of implementation of the Protocol, document UNEP/CBD/BS/COP-MOP/6/17/Add.1, contains an analysis of the information on implementation from the various sources identified in decision BS-V/15 and listed in section II above, with a view to facilitate the second assessment and review of the effectiveness of the Protocol. The analysis addresses the following principal areas as identified in the decision: (a) Coverage of the Protocol; (b) Domestic implementation of core procedures and other requirements of the Cartagena Protocol including its annexes (c) International level procedures and mechanisms. The assessment is based upon a review of the elements and indicators set out in the annex to decision BS-V/15. The report however does not cover the area (d) on: *The impact of transboundary movements of living modified organisms (LMOs) on biological diversity, taking also into account risk to human health*; since the information available on the current state of implementation does not at this stage permit a detailed analysis of this element.

13. Furthermore, as specified in paragraph 3 of decision BS-V/16, the report also aims to assist in establishing a baseline of the status of implementation of the Protocol for the COP-MOP in the context of the second assessment and review of the Protocol, as well as in relation to the implementation of the Strategic Plan for the Cartagena Protocol on Biosafety for the period 2011-2020. It also highlights some trends in and reasons for the current status of implementation.

14. The analysis was reviewed by the Ad hoc Technical Expert Group on the second assessment and review of the Cartagena Protocol on Biosafety (AHTEG) at its meeting on 14 – 16 May 2012, in Vienna, Austria. The Group, made up of fifteen experts, nominated by Governments from 13 Parties, namely Antigua and Barbuda, Belarus, Burkina Faso, Denmark, Ecuador, India, Japan, Liberia, Malaysia, Mexico, Norway, Slovenia and Uganda. The chairpersons of two subsidiary bodies under the Protocol, namely the AHTEG on Risk Assessment and Risk Management and the Compliance Committee also attended the meeting. Observers from the United States of America, the United Nations Environment Programme, Asociación Desarrollo Medio Ambiental Sustentable, Public Research and Regulation Initiative and Third World Network also attended.

15. The Group, after reviewing the analysis of the status of implementation of the Protocol, made, for the purposes of the second assessment and review, its recommendations contained in annex I to this document for the consideration of the Parties to the protocol. The full report of the AHTEG including its conclusions and recommendations is made available in document UNEP/CBD/BS/COP-MOP/6/INF/21.

IV. PRELIMINARY OUTLINE OF A PROCESS TOWARDS CONDUCTING THE MIDTERM EVALUATION OF THE STRATEGIC PLAN IN CONJUNCTION WITH THE THIRD ASSESSMENT AND REVIEW OF EFFECTIVENESS

16. The midterm evaluation of the Strategic Plan and the third assessment and review of the effectiveness of the Protocol are both scheduled for consideration at the eighth meeting of the Parties to the Protocol.

17. The analysis of the status of implementation of the Protocol in document UNEP/CBD/BS/COP-MOP/6/17/Add1 indicates that many developing country Parties, in particular, remain at a relatively early stage of implementing their national biosafety frameworks (NBFs). A number of Parties are presently undertaking or initiating projects funded by the Global Environment Facility (GEF) on implementation of their NBFs. In addition to finalizing legal and regulatory frameworks, such projects often appear to address capacity development in areas identified as priorities by the Parties concerned, such as risk assessment and management, and/or sampling and detection of LMOs. Within this context, the third assessment and review of effectiveness is likely to devote significant attention to consideration of the extent to which the overall status of implementation of the Protocol by Parties has progressed since the establishment of a baseline of the status of implementation after the second assessment and review of effectiveness² at the sixth meeting of the Parties.

18. The midterm evaluation of the Strategic Plan is intended to review progress in respects of all focal areas and operational objectives under the Plan. Such an evaluation will normally be based upon an analysis of the eighty-one (81) indicators set out in the Strategic Plan (annex I to decision BS-V/16). Recent preliminary assessment of the status of implementation of the Protocol based on the eighty-one (81) indicators of the Strategic Plan against information from the second national reports has identified the lack of a mechanism for gathering data for approximately 25% of the indicators (UNEP/CBD/BS/COP-MOP/6/INF/22). There is, therefore, a need for the collection of the data through a dedicated survey as soon as possible to complement the baseline of the status of implementation resulting from the second assessment and review of effectiveness.

19. In addition, several processes developed under the Protocol provide for measurement of progress by reference to indicators.³ To a significant extent, such measurement depends upon the provision of information by Parties through their national reports, or potentially through dedicated surveys.

20. As indicated in paragraph 17 above, it would seem that the third evaluation of effectiveness should, *inter alia*, assess what further progress has been made in domestic implementation of core elements of the Protocol. It is also noted that in their comments prior to the second evaluation of effectiveness of the Protocol, a number of Parties expressed the view that evaluations under Article 35 should address the effectiveness of the Protocol in achieving its objective.⁴ Article 1 of the Protocol states that:

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

² Paragraph 13 of annex I to decision BS-V/16. See the indicators of the Strategic Plan specified in relation to operational objectives 1.1, 1.3, 1.4, 1.6, 1.8, 2.1, 2.2, 2.5, 2.6, 3.1, 4.1 and 5.3.

³ In addition to the Strategic Plan, these include the Article 35 assessment and review process itself, the implementation of the Action Plan on capacity-building (decision BS-IV/3) and the programme of work on public awareness, education and participation (decision BS-V/13). The independent evaluation of the Action Plan for Capacity-building, UNEP/CBD/BS/COP-MOP/6/INF/2, suggests that linkages be made between a new results-based Action Plan for capacity-building and the Strategic Plan (see recommendations 1 and 2 of the independent evaluation).

⁴ UNEP/CBD/BS/COP-MOP/4/INF/10, 3 April 2008, *Assessment and Review (Article 35): Compilation of Submissions of Views*.

21. Within the context of assessment and review of the effectiveness of the Protocol, the wording of Article 1, particularly the phrase “*to contribute to ensuring an adequate level of protection*”, raises the question whether an evaluation of effectiveness of the Protocol requires primarily an evaluation of whether appropriate procedural mechanisms have been adopted and applied in order to ensure the safe transfer, handling and use of living modified organisms. Alternatively, or in addition, this wording could be interpreted to imply that there should be an evaluation as to whether the procedures and mechanisms put in place pursuant to the Protocol have had the effect of identifying and managing any risks associated with the transfer, handling and use of living modified organisms such that adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, have not occurred.

22. It is proposed that both of these elements form part of the objective of the Protocol, and that the reference to the evaluation of “effectiveness” in Article 35 indicates that future evaluations should encompass consideration of substantive outcomes arising from the application of the procedures and mechanisms that the Protocol provides. The questions that then arise include: how might this be achieved; what data would be required in order to make such an evaluation (and are such data available); and upon what criteria or indicators should such an evaluation be based. The scope of and process for the third evaluation of effectiveness will need to be determined by the seventh meeting of the Parties, so as to enable data gathering and analysis before the eighth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

23. As far as possible, these processes i.e. third evaluation of effectiveness and the Strategic Plan review could be combined, both in terms of procedure and in terms of substantive analysis. Combining evaluation under Article 35 and the Strategic Plan review process at the eighth meeting of the of the Parties would simplify and streamline the evaluation process, particularly at the information-gathering stage. This would have implications for the design of the format for the third national reports to be submitted by Parties. The two processes could benefit from further deliberation in a regionally balanced forum: these are, first, the possible consolidation of indicators for the evaluation of effectiveness and the midterm evaluation of the Strategic Plan, and, second, the development of indicators concerning the substantive outcomes of the application of the procedures and mechanisms of the Protocol.

24. As noted in document UNEP/CBD/BS/COP-MOP/5/15 which was placed before the Parties at their last meeting other multilateral environmental agreements (MEAs) , for which evaluation processes have been put in place differ in significant respects from the Cartagena Protocol on Biosafety in terms of their objectives and the regulatory techniques that they employ. Thus, the specific processes for evaluation of effectiveness or assessment of implementation may well not be directly transferable or appropriate to the Cartagena Protocol on Biosafety. As a general point, it is noteworthy, however, that a number of other MEAs are grappling with the challenge of evaluating their effectiveness, often in the context of limited resources and national capacity of Parties, a lack of a prior common understanding of or framework for assessing effectiveness, and inadequate or incomplete existing dedicated data sets upon which such evaluations can be based.

25. For the reasons above, it is proposed that an Ad Hoc Technical Expert Group on the Strategic Plan and the Evaluation of the Effectiveness of the Cartagena Protocol be established by the sixth meeting of the Parties to the Protocol, in order to prepare for the evaluations to be undertaken by the eighth meeting of the Parties. In order to facilitate the discussions on this proposal the Secretariat has developed, for the consideration of the Parties to the Protocol, draft terms of reference for the proposed Ad Hoc Technical Expert Group on the Strategic Plan and the Evaluation of the Effectiveness of the Cartagena Protocol, as contained in annex II below.

V. SUGGESTED ELEMENTS FOR A DRAFT DECISION

The Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to:

1. Welcome the work of the Ad hoc Technical Expert Group on the second assessment and review of the Cartagena Protocol on Biosafety and its recommendations;
2. Consider and, as appropriate, adopt the recommendations of the AHTEG in annex I to this document;
3. Note that the information provided in the second national reports and analysed in UNEP/CBD/BS/COP-MOP/6/17/Add1 establishes the baseline for measuring progress of implementation of the Protocol for subsequent assessment and review processes and evaluation of the implementation of the Strategic Plan;
4. Request the Secretariat to undertake a dedicated survey to gather the necessary information in response to the remaining indicators of the Strategic Plan that currently lack mechanism for data gathering, to complement the baseline established at the present meeting and make the results available to the Parties before their seventh meeting;
5. Request Parties to provide the necessary data during any dedicated survey to complement the baseline as established;
6. Decide to establish Ad Hoc Technical expert Group on the Strategic Plan and the Evaluation of the Effectiveness of the Cartagena Protocol to undertake the tasks described in annex II to this document;
7. Consider the following recommendations submitted by the Compliance Committee as specified in paragraphs 16 and 17 of the annex to document UNEP/CBD/BS/COP-MOP/6/2, which suggest for the Parties to the Protocol to:
 - (a) Decide that, in the process of preparing for the third assessment and review of the Protocol, the experiences of the Parties in complying with the Protocol, including submission of national reports, are taken into account, along with the input of, inter alia, the Compliance Committee;
 - (b) Request the Compliance Committee, in light of the conclusions and recommendation of the Ad Hoc Technical Experts Group on the Second Assessment and Review of the Cartagena Protocol on Biosafety, to evaluate the status of implementation of the Protocol as a contribution to the third evaluation of the effectiveness in meeting the objective of the Protocol in accordance with Article 35 of the Protocol.

Annex I

RECOMMENDATIONS OF THE AD HOC TECHNICAL EXPERT GROUP ON THE SECOND ASSESSMENT AND REVIEW OF THE CARTAGENA PROTOCOL ON BIOSAFETY TO THE SIXTH MEETING OF THE CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THE PROTOCOL

The Ad Hoc Technical Expert Group on Assessment and Review, having reviewed the information contained in the second national reports, the synthesis in document UNEP/CBD/BS/COP-MOP/6/16, the analysis on the status of implementation as contained in document UNEP/CBD/BS/COP-MOP/6/17/Add. 1 and information provided through the presentations by the Secretariat made the following recommendations for consideration by COP-MOP at its sixth meeting:

1. Coverage

(a) Welcomes the valuable information concerning the status of implementation contained in the second national reports;

(b) Requests the Executive Secretary to seek information from Parties to the Convention on Biological Diversity that are non-Parties to the Protocol to identify constraints to ratification of or accession to the Protocol with a view to increasing the geographic coverage of the Protocol;

(c) Reminds Parties that under Article 24 of the Protocol, transboundary movements of living modified organisms between Parties and non-Parties are required to be consistent with the objective of the Protocol.

2. Domestic implementation of core procedures and annexes

(a) Encourages Parties to address biosafety as part of the national development agenda and prioritize biosafety activities at the national level;

(b) Urges Parties to continue promoting public awareness concerning the safe transfer, handling and use of LMOs among policy-makers and the public, including through the programme of work adopted in decision BS-V/13;

(c) Urges those Parties that have not yet done so to designate competent national authorities and make the information available to the BCH as soon as possible in accordance with Article 19 of the Protocol.

3. Capacity-building and resource mobilization

(a) Requests the Conference of the Parties in its guidance to the financial mechanism to request the GEF to:

(i) Provide support to all eligible Parties that have not yet done so to initiate implementation of their legal, administrative and other measures for the implementation of the Protocol;

(ii) Define specific quotas for biosafety for each country during the GEF-6 programming period;

- (iii) Set aside more resources for thematic and regional capacity-building projects;
- (iv) Allow for more flexibility in the utilization of funds provided for capacity-building to address emerging needs within the overall framework of the approved projects
- (v) Provide support to eligible Parties for preparation of their national reports on a regular basis.

(b) Urges Parties to mobilize new financial resources from other sources, including relevant international and regional organizations, to support implementation of the Protocol, and to provide for budgetary allocations for biosafety at the domestic level;

(c) Encourages Parties to address sustainability in building capacities for domestic implementation of the Protocol.

4. Regional approaches

(a) Encourages Parties to explore and utilize, as appropriate, existing regional and subregional arrangements and initiatives for information-sharing and for cooperation in facilitating the implementation of the Protocol in areas such as risk assessment, risk management, promoting public awareness, and sampling, detection and identification of living modified organisms.

5. Information Sharing and BCH

(a) Requests the Executive Secretary to draw the attention of relevant Parties to any missing or incomplete information in the BCH;

(b) Reiterates the need for Parties to cooperate fully with the Secretariat in the effort to maintain complete, accurate and up-to-date information in the BCH;

(c) Reminds Parties of their obligations and invites governments, to include in the BCH information on domestic approvals of small and large-scale field trials, if such trials involve any introduction of LMOs into the environment, as specified in paragraphs 3(c) and (d) of Article 20 of the Protocol and paragraph 1(a) of decision BS-V/2;

(d) Encourages Parties to establish or maintain effective coordination mechanisms between the BCH national focal points and competent national authorities to ensure that relevant information is made available to the BCH in a timely manner, for example by appointing national authorised users in all competent national authorities;

(e) Requests the Executive Secretary to continue to explore and establish, as appropriate, linkages between the BCH and other international and national databases containing information relevant to biosafety and biotechnology.

6. Compliance mechanisms and procedures

(a) Requests the Compliance Committee to support implementation in the manner envisaged in decision BS-V/1, and encourage Parties to make submissions to, and to cooperate with, the Compliance Committee where they face difficulties complying with their obligations.

7. Subsequent Assessment and Review of the Cartagena Protocol on Biosafety

(a) Considers putting in place, at its sixth meeting, a process to prepare for the third assessment and review of effectiveness of the Protocol and the mid-term evaluation of the Strategic Plan, which will take place at the eighth meeting of the Parties to the Protocol, in light of experience gained in relation to the second assessment and review of the effectiveness of the Protocol, particularly the availability and coherence of data.

In this context, the Parties to the Protocol may wish to consider, *inter alia*, the following elements:

- (i) Whether, in addition to evaluating the status of implementation of the Protocol, the scope of the third assessment and review of effectiveness of the Protocol should include evaluation of its effectiveness in meeting the objective of the Protocol;
- (ii) The identification, development or consolidation of indicators for the third assessment and review and the mid-term evaluation of the Strategic Plan;
- (iii) The types of information required as the basis for the third assessment and review of effectiveness and the mid-term review of the Strategic Plan, and the corresponding arrangements and format for the third national reports;
- (iv) The need for a mechanism for the preparation and conduct of the third assessment and review and the mid-term evaluation of the Strategic Plan, including the possible establishment of an ad hoc technical expert group on the Strategic Plan and assessment and the review of effectiveness of the Protocol to prepare recommendations.

Annex II

**PROPOSED TERMS OF REFERENCE OF THE AD HOC TECHNICAL EXPERT GROUP ON
THE STRATEGIC PLAN AND THE EVALUATION OF THE EFFECTIVENESS OF THE
CARTAGENA PROTOCOL**

1. At its fifth meeting, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) adopted, in decision BS-V/16, a Strategic Plan for the Protocol for the period 2011-2020. In this decision, the Parties to the Protocol provided for a midterm evaluation of the Strategic Plan to be carried out five years after its adoption. In paragraph 4(a) of the decision and paragraph 3(b) of decision BS-V/15 on Assessment and Review, it is stated that the midterm evaluation will take place at the eighth meeting of the Parties in conjunction with the third assessment and review of the effectiveness of the Protocol. The evaluation process is to use the indicators set out in the Strategic Plan to assess the extent to which the strategic objectives are being achieved (paragraph 11 of annex I to decision BS V/16). Information for the evaluation is to be drawn mainly from national reports submitted by Parties and from other sources that are relevant and available to generate the data necessary for the analysis. The Parties to the Protocol also decided that the midterm evaluation would use appropriate evaluation criteria to be proposed to the Parties at their seventh meeting for their consideration.
2. The second assessment and review of the Protocol which primarily focused on evaluating the status of implementation of core elements of the Protocol with identified elements and indicators has been completed at the sixth meeting of the Parties to the Protocol. The analysis of the status of implementation of the Protocol, contained in document UNEP/CBD/BS/COP-MOP/6/17/Add.1, indicates that many developing country Parties, in particular, remain at a relatively early stage of implementing national biosafety frameworks (NBFs). Against this context, it is found appropriate that the third assessment and review of effectiveness devote further significant attention to consideration of the extent to which the overall status of implementation of the Protocol by Parties has progressed since 2012. At the same time, the Strategic Plan contains a number of indicators which are designed to facilitate measurement of progress against the baseline of the status of implementation established by the second assessment and review of effectiveness.
3. Several processes such as the implementation of the Action Plan on capacity-building (decision BS-IV/3) and the programme of work on public awareness, education and participation (decision BS-V/13), have now been developed under the Protocol which provide for measurement of progress by reference to indicators. The independent evaluation of the Action Plan for Capacity-building, UNEP/CBD/BS/COP-MOP/6/INF/2, suggests that linkages be made between a new results-based Action Plan for capacity-building and the Strategic Plan.
4. Such measurement depends upon the provision of information by Parties through their national reports, or through dedicated surveys, as appropriate. Combining evaluation under Article 35 and the Strategic Plan review process at the eighth meeting of the Conference of the Parties serving as the meeting of the Parties would simplify and streamline the evaluation process, particularly at the information-gathering stage. This will also have implications for the design of the format for the third national reports to be submitted by Parties.
5. It is also noted that in their comments prior to the second evaluation of effectiveness of the Protocol, a number of Parties expressed the view that evaluations under Article 35 should address the effectiveness of the Protocol in achieving its objective (UNEP/CBD/BS/COP-MOP/4/INF/10). For the purposes of the Article 35 assessment and review process, the wording of Article 1, particularly the

phrase “to contribute to ensuring an adequate level of protection”, may be interpreted to mean an evaluation of whether appropriate *procedural* mechanisms have been adopted and applied by each Party in order to ensure the safe transfer, handling and use of living modified organisms, on the one hand and an evaluation as to whether the procedures and mechanisms put in place pursuant to the Protocol have had the *effect* of identifying and managing any risks associated with the transfer, handling and use of living modified organisms such that adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, have not occurred, on the other. It is suggested that both of these elements form part of the objective of the Protocol, and that the reference to the evaluation of “effectiveness” in Article 35 indicates that future evaluations should encompass consideration of substantive outcomes arising from the application of the procedures and mechanisms that the Protocol provides.

6. In the context of the above, the Ad Hoc Technical expert Group on the Strategic Plan and the Evaluation of the Effectiveness of the Cartagena Protocol should:

(a) Overall task:

Undertake, in a coherent manner, preparatory work necessary for the third assessment and review of effectiveness of the Protocol and the mid-term evaluation of the Strategic Plan in light of experience gained in relation to the second assessment and review of the effectiveness of the Protocol.

(b) Specific tasks:

- (i) Review the information that may be gathered through a dedicated survey by the Secretariat in response to some of the indicators of the Strategic Plan to complement the baseline on the status of implementation of the Protocol established at the sixth meeting of the Parties;
- (ii) Develop consolidated indicators for the third evaluation of effectiveness of the Protocol and the midterm evaluation of the Strategic Plan, taking into account the indicators of the Strategic Plan (annex I, BS-V/16), and other existing indicators adopted in the context of specific work programmes and action plans;
- (iii) Develop indicators concerning the substantive outcomes of the application of the procedures and mechanisms of the Protocol;
- (iv) Develop, or review the draft of, a third national report format that facilitate the gathering of information on the implementation of Protocol in general (consistent with any priority areas that may be identified) and the Strategic Plan in particular;
- (v) Analyse information on the implementation of the Protocol provided through third national reports using consolidated indicators with a view to facilitate the third assessment and review of the effectiveness of the Protocol and the midterm evaluation of the Strategic Plan; and
- (vi) Submit report(s) and recommendations as appropriate in accordance with the schedule indicated in (c) below.

(c) Expected outcomes:

- (i) Consolidated indicators for the evaluation of effectiveness of the Protocol and the midterm evaluation of the Strategic Plan, including indicators on the substantive outcomes of the application of the procedures and mechanisms of the Protocol (for submission to the seventh meeting of the Parties to the Protocol);
- (ii) A draft third national report format on the implementation of the Protocol (for submission to the seventh meeting of the Parties to the Protocol);
- (iii) Analysis of information that form the basis for the third assessment and review of the effectiveness of the Protocol and the midterm evaluation of the Strategic Plan (for submission to the eighth meeting of the Parties to the protocol).
