



**Convention on
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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

Fifth meeting

Nagoya, Japan, 11-15 October 2010

Item 16 of the provisional agenda*

ASSESSMENT AND REVIEW (ARTICLE 35): APPROACH AND CRITERIA

A proposed framework for the second assessment and review

Note by the Executive Secretary

I. INTRODUCTION

1. Article 35 of the Cartagena Protocol on Biosafety requires the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) to undertake, five years after the entry into force of the Protocol, and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.
2. In accordance with the terms of Article 35, the first evaluation was due to be conducted in 2008. At their fourth meeting, in May 2008, the Parties had before them a synthesis of submissions (UNEP/CBD/BS/COP-MOP/4/14) from Parties and Governments made in response to a questionnaire circulated by the Secretariat related to assessment and review. The Parties adopted decision BS-IV/15 wherein they noted that the limited experience gained by Parties in the implementation of the Protocol, as reflected in the first national reports, and the lack of operational experience did not provide a good basis for an effective assessment and review of the Protocol.
3. In the decision, the Parties, *inter alia*, requested the Executive Secretary to develop: (i) a sound methodological approach to contribute to an effective second assessment and review of the Protocol, its annexes, procedures and mechanisms, on the basis of the information contained in the first national reports, answers to the "effectiveness questionnaire", the reports of the Compliance Committee, information available in the Biosafety Clearing-House (BCH) and any other relevant documents; and (ii) draft criteria or indicators that could apply in the evaluation of the effectiveness of the Protocol and provide an indication of the utility.

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4. Decision BS-IV/15 also invited Parties to make submissions on a Strategic Plan for the Protocol and requested the Executive Secretary to present a draft Strategic Plan for consideration at the fifth meeting of the Parties. The draft of a Strategic Plan developed on the basis of submissions from Parties and inputs from a number of consultative processes is presented to the present meeting in a separate document (UNEP/CBD/BS/COP-MOP/5/16) for consideration and possible adoption under agenda item 17.

5. The present note is prepared in response to the request for a proposal on possible methodology for the second evaluation of the effectiveness of the Protocol and sets out suggestions for the consideration of the Parties. It seeks solely to consider a possible methodology for the conduct of the second assessment and review. It is neither intended to conduct the evaluation of the effectiveness of the Protocol nor to prejudge the outcome of such an evaluation nor does it seek to establish a baseline of the status of implementation of the Protocol against which future evaluations might be measured.

6. While Article 35 requires periodic evaluations of the effectiveness of the Protocol, it does not provide guidance as to how such evaluations should be conducted nor does it specify the nature or scope of the evaluation beyond indicating that it should encompass an assessment of the Protocol's procedures and annexes. There are a number of generic challenges associated with designing and conducting an evaluation of the effectiveness of a multilateral environmental agreement (MEA). As a study conducted for the United Nations Environment Programme (UNEP) in 2001 has highlighted, "[e]ffectiveness is a concept that can be defined in various ways: as the degree to which a given rule induces changes in behaviour that further the goals of the rule; the degree to which a rules improves the state of the underlying problem; or the degree to which a rule achieves its inherent policy objectives."¹

7. There are a number of approaches that might be taken to reviewing the effectiveness of the Cartagena Protocol on Biosafety. The review might focus on the degree to which the Protocol's provisions have been implemented by Parties; it might examine the establishment and functioning of procedures and mechanisms at both the national and international levels; and/or it might examine the extent to which the adoption and implementation of the Protocol has contributed to the achievement of the overall objective of the Protocol. The review might also be directed towards assessment of the adequacy and scope of the Protocol's procedures and annexes in light of evolving scientific and technical knowledge about any risks that may be posed to biological diversity by living modified organisms, taking also into account risks to human health.²

8. In general terms, for the reasons highlighted in section V below, it is recommended that the second evaluation of effectiveness focus primarily on ascertaining the overall level of domestic implementation of the Protocol; i.e. the extent to which the Protocol has led to date to the establishment and operation of functioning domestic regulatory systems for biosafety. It is also acknowledged that the focus of the evaluation of effectiveness might change over time as subsequent Article 35 assessments are conducted.

9. The present document is structured as follows: section II briefly reviews progress in implementation of the Protocol since its entry into force in 2003; section III highlights approaches to effectiveness evaluation taken in three relevant multilateral environmental agreements; section IV refers to developments in relation to the Strategic Plan of the Convention on Biological Diversity (CBD); and section V addresses considerations relating to the scope of the second evaluation of effectiveness under Article 35 of the Protocol. Section VI sets out suggestions for the possible methodology for the conduct of the second evaluation of effectiveness and makes some brief observations on possible steps towards

¹ K. Raustiala, *Reporting and Review Institutions in 10 Multilateral Environmental Agreements*, UNEP 2001, at 6.

² See paragraph 5 of the note prepared by the Executive Secretary for the third meeting of the Parties on initiating a process of evaluation of the effectiveness of the Protocol (UNEP/CBD/BS/COP-MOP/3/13). See also Articles 7, paragraph 4, and 16, paragraph 5. of the Protocol.

future evaluations of effectiveness of the Protocol. Section VII summarizes conclusions and recommendations, and section VIII presents possible elements of a decision. The annex to the document sets out a number of draft indicators for consideration as the basis for the second evaluation of effectiveness. It is noted that these indicators have been taken into consideration in the drafting of indicators for the proposed Strategic Plan and also in the design of the proposed format for the second national reports (see UNEP/CBD/BS/COP-MOP/5/14).

II. PROGRESS IN IMPLEMENTATION OF THE PROTOCOL SINCE ITS ENTRY INTO FORCE

A. Domestic implementation by Parties

10. The Protocol relies principally, for its effective implementation, on the domestic implementation by Parties of procedures to regulate, *inter alia*, the transboundary movement of living modified organisms (LMOs) for intentional release into the environment and of living modified organisms intended for direct use as food or feed, or for processing (LMO-FFPs).

11. It was apparent at the time of the Protocol's adoption that while some Parties already had relevant domestic regulatory procedures in place, there would be many Parties that were not immediately in a position to implement the Protocol's central regulatory mechanism, the advance informed agreement (AIA) procedure. Hence, even before the Protocol entered into force, mechanisms were established to promote the further development of capacity at the domestic level for implementation of the Protocol's procedures. In particular, many eligible countries have received support through the Global Environmental Facility (GEF) to develop national biosafety frameworks (NBFs).

12. By July 2009, 111 countries had finalized their draft national biosafety frameworks under the UNEP-GEF project.³ Nonetheless, it is evident that a country that has completed the NBF process is not necessarily in a position to implement the Protocol in terms, for example, of dealing with an application for the first import of an LMO for intentional introduction into the environment. In some cases, while draft legislation may have been prepared, it has not been enacted;⁴ and in others, secondary regulations that form an integral component of an operational regulatory system have not been finalized and adopted. In numerous cases, it is suggested, even though a regulatory framework has been put in place, Parties may not be in a position to process an application due to a lack of sufficient technical or other capacity. The Capacity-Building Action Plan adopted by the Parties is designed to address the capacity deficit that still hampers full implementation of the Protocol.⁵ This is discussed in paragraph 22 below.

13. Notwithstanding the significant activity and effort that has been devoted to the Protocol's implementation since its adoption, there remain gaps and deficiencies in implementation. The 2008 revised analysis by the Secretariat of information contained in the first national reports noted that in most regions, significant gaps were acknowledged regarding the introduction of the necessary legal, administrative and other measures required to implement the Protocol.⁶ In particular, the revised analysis concluded that implementation of the AIA procedure was generally low and that the full application of the procedure had not yet been fully realized.⁷ It also noted that the slow pace of implementation of requirements relating to Article 18 remained of utmost concern to Parties of import of LMOs.⁸ A number

³ <http://www.unep.org/biosafety/>.

⁴ A search for national laws and regulations on the BCH reveals that a number of NBFs remain on the BCH in draft form.

⁵ Decision BS-I/5; decision BS-III/3; decision BS-IV/3.

⁶ UNEP/CBD/BS/CC/5/2, para. 21.

⁷ *Ibid*, para. 98.

⁸ *Ibid*.

of countries, it was noted, had not yet provided information to the Biosafety Clearing-House as required under Article 20 of the Protocol, again in many cases reportedly due to the fact that draft legislation contained in NBFs had not yet been implemented or applied in practice.⁹

14. In its review of general issues of compliance, on the basis of the analysis of national reports, the Compliance Committee has noted the continued existence of significant gaps in relation to the obligation to put in place at the national level the necessary legal, administrative and other measures. The Committee has further noted that compliance with the obligation to promote public awareness and participation is not at a satisfactory level. It has also identified gaps with respect to implementing the requirement to adopt national measures addressing illegal transboundary movements of LMOs and reporting occurrences of such movements to the Biosafety Clearing-House.¹⁰

15. As discussed further in section V below, the status of implementation of the Protocol and gaps in knowledge about the extent to which it is implemented in Parties have implications for the consideration of the scope of the effectiveness evaluation under Article 35.

B. Action taken by the meeting of the Parties

16. The Protocol directed or enabled a number of additional steps to be taken by the meeting of the Parties after the Protocol's entry into force to "complete" the regime established in the Protocol and its institutional mechanisms. These included the establishment of compliance procedures and mechanisms (Article 34); the consideration of the modalities of the Biosafety Clearing-House established by Article 20 of the Protocol; the consideration of rules and procedures on liability and redress (Article 27); and the consideration of further rules under Article 18, paragraph 2 (a) on documentation accompanying living modified organisms for direct use as food or feed, or for processing (LMO-FFPs). Over their first four meetings, the Parties have made progress on each of these issues and on other aspects related to the elaboration of common understandings and guidance relating to the Protocol's provisions.

17. In terms of institutional arrangements, the compliance procedures and mechanisms were addressed at the first meeting of the Parties, and a Compliance Committee was established.¹¹ The Committee has met regularly and is functioning but it has yet to receive any admissible communications relating to instances of possible non-compliance with the Protocol.¹²

18. In terms of mechanisms for information-sharing, the Biosafety Clearing-House has been established and is operational.¹³ Much work has gone in to developing the BCH as an accessible and functional tool. The Protocol's procedures for LMOs rely significantly on the BCH as an effective information-sharing mechanism. Nonetheless, it has been noted that there remain some significant gaps in the information available through the BCH particularly in terms of the apparently limited notifications made to the BCH to date.¹⁴ For example, a search for "decisions on LMOs for intentional introduction into the environment" on the BCH reveals that 14 Parties and four non-Parties appear to have notified such decisions to the BCH. For LMO-FFPs, decisions by 16 Parties and four non-Parties can be found on

⁹ *Ibid.*

¹⁰ UNEP, CBD/BS/COP-MOP/4/2, *Report of the Compliance Committee*, 5 December 2007, paras. 16-18. UNEP/CBD/BS/CC/5/4, *Report of the Compliance Committee under the CPB on the Work of its Fifth Meeting*, 21 November 2008, para. 19

¹¹ Decision BS-I/7.

¹² UNEP/CBD/BS/COP-MOP/4/2, 5 December 2007, para. 21; UNEP/CBD/BS/CC/5/4, 21 November 2008, paras. 24-25.

¹³ Decision BS-I/3.

¹⁴ One analysis of impediments to the provision of information to the BCH is contained in A. Gupta, *Effective Participation in the Biosafety Clearing House: Participation Options and impediments to information provisions*, An academic report prepared for the UNEP-GEF BCH Project, May 2008, at 18-24. See also UNEP/CBD/BS/CC/6/3, 30 September 2009, para.7.

the BCH.¹⁵ This suggests either that such decisions are not being made by many Parties or that they are being made but are not being notified to the BCH. The Secretariat produced a summary of records available through the BCH for the sixth meeting of the Compliance Committee in 2009. The report notes that while there has been a general increase in the amount of information reported to the BCH over the years for all the main categories of data, there still remain important gaps.¹⁶ The ongoing development of the BCH is informed by the BCH Informal Advisory Committee established pursuant to decision BS-I/3.

19. The national reporting cycle commenced upon the entry into force of the Protocol, and the third meeting of the Parties adopted a format for the first national reports,¹⁷ which were due in September 2007. At their fourth meeting, the Parties requested the Executive Secretary to suggest improvements to the reporting format for their fifth meeting.¹⁸ By June 2010, 89 national reports had been received indicating that a significant number of Parties have not yet submitted their first national reports.

20. In terms of the elaboration of additional rules, procedures and requirements under the Protocol, the Parties have also, *inter alia*, adopted a decision containing more detailed requirements for the purpose of Article 18, paragraph 2 (a).¹⁹ Experience in implementation of this decision is due to be reviewed at the fifth meeting of the Parties with a view to consideration of adoption of a further decision on Article 18, paragraph 2 (a), at the sixth meeting of the Parties.²⁰ At their fifth meeting, the Parties will also consider the possible adoption of rules and procedures on liability and redress pursuant to Article 27 of the Protocol.²¹

21. The Parties have also adopted numerous decisions that contain certain additional common understandings or guidance designed to guide Parties' implementation of the Protocol. Of particular interest for the assessment and review process, the Parties have put in place a process for the further consideration of the guidance on risk assessment in Annex III to the Protocol by establishing an Ad Hoc Technical Expert Group on Risk Assessment and Risk Management.²² The Group has developed a roadmap for risk assessment, including a flowchart, and guidance on risk assessment on specific types of LMOs or traits. The Group's report is to be submitted to the Parties at their fifth meeting with recommendations for their consideration.

22. The meeting of the Parties has devoted significant attention to capacity-building for implementation of the Protocol. At their first meeting, the Parties adopted an Action Plan on capacity-building and established a coordination mechanism for implementation of the Action Plan. They also adopted a set of indicators for monitoring the implementation of the Action Plan.²³ An updated Action Plan was adopted at third meeting of the Parties and the indicators were revised at the fourth meeting.²⁴ The updated Action Plan requires that it be reviewed every five years by the meeting of the Parties "based on an independent evaluation of the effectiveness and outcomes of capacity-building

¹⁵ As at November 2009.

¹⁶ UNEP/CBD/BS/CC/6/3, para. 8.

¹⁷ Decision BS-III/14.

¹⁸ Decision BS-IV/14. Note that the suggestions made in section VI below, and the annex, imply certain adjustments to the reporting format for second national reports in order to generate data for the effectiveness evaluation.

¹⁹ Decision BS-III/10.

²⁰ *Ibid.*, para. 7. The Secretariat suggests, based on the submissions it received which showed limited experience, that such consideration take place at the eighth meeting of the Parties. See document UNEP/CBD/BS./COP-MOP/5/8

²¹ Decision BS-IV/12, UNEP/CBD/BS/COP-MOP/4/18.

²² The establishment of the Ad Hoc Technical Experts Group and its terms of reference can be found in decision BS-IV/11.

²³ Decision BS-I/5.

²⁴ Decisions BS-III/3 and BS-IV/3.

initiatives implemented in support of the Action Plan.”²⁵ The first review of the updated Action Plan is due to be undertaken in 2011. At their fifth meeting, the Parties will have before them a note by the Executive Secretary on the implementation of the Action Plan (UNEP/CBD/BS/COP-MOP/5/4). In order to facilitate the review of the Action Plan, the Parties will also be invited to consider draft terms of reference for the independent evaluation of the effectiveness and outcomes of capacity-building initiatives implemented in support of the Action Plan.

23. The meeting of the Parties has also regularly considered reports on the status of bilateral, regional and multilateral capacity-building activities. In addition, a number of coordination meetings have been held for governments and organisations implementing or funding biosafety-related activities and the Liaison Group on Capacity-Building for Biosafety has met seven times. These activities have generated a large amount of information about biosafety training and capacity-building opportunities. They have also provided an opportunity for developing country Parties to identify and notify their priority capacity needs. Nonetheless, it is widely recognised that a significant capacity gap remains.²⁶

24. At its most recent meeting, the Liaison Group on Capacity-Building for Biosafety considered, *inter alia*, the capacity-building component of the proposed Strategic Plan for the Cartagena Protocol on Biosafety. In this context, the Group gave further consideration to indicators for monitoring the implementation of the Action Plan and it was suggested that such indicators should be incorporated into the broader set of indicators for assessing implementation of the Protocol.²⁷

25. The Parties have also initiated some work on public awareness and participation. They have agreed to review at their fifth meeting progress in the implementation of the obligation in paragraph 1 (a) of Article 23 to promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs. Furthermore, at their fourth meeting, the Parties agreed to develop a programme of work on public awareness, education and participation which is to be considered at their fifth meeting (see document UNEP/CBD/BS/COP-MOP/5/13).

III. EVALUATION OF EFFECTIVENESS IN OTHER MULTILATERAL ENVIRONMENTAL AGREEMENTS

26. The Cartagena Protocol on Biosafety is relatively unusual among multilateral environmental agreements (MEAs) in containing a specific provision, in Article 35, requiring periodic evaluations of effectiveness. This section briefly reviews approaches developed in some other MEAs that have undertaken some form of assessment and review. In a few cases such reviews have been conducted because, like the Protocol, the MEA in question contains a specific provision requiring an evaluation of effectiveness or a similar form of assessment.²⁸ Such reviews are sometimes specifically focused on adaptation of the agreement to technical progress and evolving scientific knowledge. In other MEAs, mechanisms for evaluating effectiveness, in terms of progress towards specific goals, have been developed in the context of strategic planning processes, with a view to monitoring implementation of a strategic plan and assessing progress towards goals and objectives established in the plan. In some MEAs, the governing body, such as the conference of the parties, is accorded the general responsibility of

²⁵ Decision BS-III/3, annex, para. 9.

²⁶ See generally, S. Johnston, C. Monagle, J. Green and R. Mackenzie, *Internationally Funded Training in Biotechnology and Biosafety: Is it Bridging the Biotech Divide*, UNU 2008.

²⁷ Report of the sixth meeting of the liaison group on capacity-building for biosafety (UNEP/CBD/BS/LG-CB/6/3), para. 12.

²⁸ See for example, the discussion of the Basel and Stockholm Conventions. Of ten agreements reviewed in 2001, Raustiala found that three (Basel Convention, Montreal Protocol and CITES) had some process for effectiveness review and that additionally, such a process was envisaged in the Ramsar Convention's Strategic Plan. His review did not include the Stockholm Convention. Raustiala, note 1 above, appendix 2.

keeping under review the implementation of the agreement without specific provisions on effectiveness evaluation.

A. *Stockholm Convention on Persistent Organic Pollutants*

27. The 2001 Convention on Persistent Organic Pollutants (Stockholm Convention) requires Parties to, *inter alia*, reduce or eliminate releases from the production and use of certain persistent organic pollutants. Article 16 provides for the evaluation of the effectiveness of the Convention commencing four years after entry into force and periodically thereafter at intervals to be decided by the Conference of the Parties (COP). Article 16 requires the Conference of the Parties to the Stockholm Convention to set in motion a process to facilitate this evaluation by initiating arrangements to provide comparable monitoring data on the presence of certain chemicals and their regional and global environmental transport. The evaluation of effectiveness is to be conducted on the basis of available scientific, environmental, technical and economic information including: the monitoring information derived from the process initiated under Article 16; national reports submitted by Parties to the Stockholm Convention; and information provided pursuant to the Stockholm Convention's non-compliance procedure under Article 17.²⁹

28. Although still at an early stage of evolution, the Stockholm Convention offers a developing model of organising a process of evaluation of effectiveness. The Secretariat of the Stockholm Convention noted that the evaluation would "assist the Parties to determine whether the Convention's provisions are sufficient to meet its objective or whether they need to be modified or additional measures adopted, or whether additional activities or projects should be undertaken to complement or improve the Convention's implementation to meet the objective."³⁰ It also noted that evaluation of a programme or activity requires comparison of the situation before and after the action is taken.

29. For the first evaluation, the Secretariat sought to produce a baseline evaluation report, taking into account the available sources of information identified in Article 16 of the Convention. This included data from 44 national reports received by the Secretariat by the end of 2008.³¹ The evaluation was based, *inter alia*, upon indicators identified for specific articles of the Convention, including the objective, and incorporated outcome indicators relating to the objective as well as process indicators to reflect measures or actions taken.³² The Secretariat noted that the compilation of data was constrained by a number of factors including the small number of national reports received, differences in the way Parties provided information, lack of specific information provided through the national reporting format, and the fact that not all Parties submitting reports had done so through the electronic reporting system.³³

30. The Conference of the Parties to the Stockholm Convention completed the first effectiveness evaluation at its fourth meeting in May 2009. It acknowledged that the Secretariat's document prepared for that meeting comprised the first evaluation under Article 16 and that the information compiled on environmental monitoring and from the national reports submitted by Parties could be used as a baseline for comparative purposes in future evaluations. The Conference of the Parties noted that procedures for the evaluation stage of the effectiveness evaluation had not yet been defined. It established an Ad Hoc Working Group on Effectiveness Evaluation consisting of ten experts in programme evaluation nominated by Parties (two from each United Nations region) to develop proposals for future evaluations, including how available information should be evaluated, data requirements and suggested changes to national reporting formats, and indicators. The Conference of the Parties set out a time frame for this

²⁹ It should be noted that the Stockholm Convention's non-compliance procedure has not yet been finalised. See COP decision SC-4/33, on procedures and mechanisms on compliance with the Stockholm Convention (UNEP/POPS/COP.4/38).

³⁰ Note by the Secretariat on effectiveness evaluation (UNEP/POPS/COP.4/30), para. 2.

³¹ *Ibid*, paras 7-9.

³² *Ibid*, para 10.

³³ *Ibid*, para 92.

process and will consider the proposed procedures for future evaluations at its fifth meeting in 2011.³⁴ The Ad Hoc Working Group on Effectiveness Evaluation held its first meeting in November 2009.

B. Basel Convention on the Control of the Transboundary Movement of Hazardous Wastes and their Disposal

31. The 1989 Basel Convention regulates the transboundary movement of hazardous wastes. Article 15(7) of the Convention provides that the Conference of the Parties shall undertake, three years after entry into force of the Convention and at least every six years thereafter, an evaluation of the Convention's effectiveness. Specifically, Article 15(7) requires consideration of the need for a complete or partial ban on transboundary movements of hazardous wastes and other wastes in the light of latest scientific, environmental, technical and economic information. It has been noted that the first evaluation of effectiveness was prepared by a consultant in 1995 and focused on whether implementation of the Convention was on the "right track",³⁵ it being considered premature at that stage to evaluate effectiveness in terms of the Convention's objectives.³⁶

32. Consideration of effectiveness evaluation of the Basel Convention now seems to be incorporated with the Convention's evolving strategic framework.³⁷ The Conference of the Parties adopted a Strategic Plan for the period 2002-2010,³⁸ and a new strategic framework is currently under discussion for the post-2010 phase with a view to adoption by the Conference of the Parties at their tenth meeting, in 2011. A recent draft discussion paper on the new strategic framework notes that "20 years after the adoption of the Convention, Parties continue to experience difficulties in evaluating its effectiveness. The principal source of such handicap emanates from the data collection and reporting shortcomings and the absence of agreed indicators to evaluate its effectiveness."³⁹ The discussion paper recognizes the need for an improved framework for assessing the effectiveness of the Convention and reviewing implementation. Within the proposed elements of the new draft strategic framework, it proposes specific goals, objectives and actions, together with related indicators.⁴⁰

C. Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

33. CITES does not contain a specific provision requiring an effectiveness evaluation. Nonetheless, Article XI.3 requires the Conference of the Parties at its meetings to review the implementation of CITES and indicates in subparagraph (e) that the Conference of the Parties may, "where appropriate, make recommendations for improving the effectiveness of the Convention."

34. In 1996, in accordance with a decision of the ninth meeting of the Conference of the Parties directed to the CITES Standing Committee, a study on improving the effectiveness of the Convention was

³⁴ COP Decision SC-4/32, UNEP/POPS/COP.4/38, 8 May 2009. To facilitate effectiveness evaluation, as required under Article 16, the POPs COP has also adopted a global monitoring plan for POPs. Decisions SC-2/13 and SC-3/19.

³⁵ K. Raustiala, *Reporting and Review Institutions in 10 Multilateral Environmental Agreements*, UNEP 2001, at 41.

³⁶ Raustiala reports, *ibid*, note 100, that the evaluation was made available in document UNEP/CHW.3/Inf.7. This document was not available for the purposes of the preparation of the present report and had not been reviewed.

³⁷ E-mail communication with the Secretariat of the Basel Convention.

³⁸ Decision VI/1, UNEP/CHW.6/40, 10 February 2003.

³⁹ *New strategic framework for the implementation of the Basel Convention 2011-2020*, Draft 2 Discussion Paper, 10 November 2009, available at <http://www.basel.int/stratplan/index.html>. It should be emphasized that, as indicated in its title, the document is a discussion draft only and is open for comments by Parties and stakeholders. It forms an element of the consultation process towards the development of the new 2011-2020 strategic framework.

⁴⁰ *Ibid*, p.10 et seq.

conducted by a consultant.⁴¹ The principal purposes of the review were to evaluate the extent to which the Convention had achieved its objectives and the progress made since CITES came into being and, most importantly, to identify deficiencies and requirements necessary to strengthen the Convention and help plan for the future.⁴² Among the recommendations of the report was that a strategic plan should be prepared for CITES. Accordingly, a “Strategic Vision through 2005” and an Action Plan were adopted at the eleventh meeting of the Conference of the Parties to CITES, in 2000. The validity of this Strategic Vision was subsequently extended to 2007. The 2008-2013 Strategic Vision sets out goals and objectives for CITES and indicators of progress in relation to the various objectives were subsequently developed.⁴³ In line with the strategic objectives, the indicators are largely process-oriented focusing on the steps taken by Parties to implement the Convention and related CITES resolutions and decisions.

D. Observations

35. It is apparent from the brief review of the above three MEAs that there is some variety of experience with effectiveness evaluations and strategic plan reviews in other MEAs upon which future assessment and review processes under Article 35 of the Cartagena Protocol on Biosafety might draw. In some instances, however, such procedures and mechanisms remain at a relatively early stage of existence or are still under development. It is also important to keep in mind that the MEAs referred to above differ in significant respects from the Protocol in terms of their objectives and the regulatory techniques that they employ.⁴⁴ Thus, the specific processes for evaluation of effectiveness or assessment of implementation may well not be directly transferable or appropriate to the Protocol. Nonetheless it is considered instructive to consider whether elements of such approaches might yield useful insights into the assessment and review process of the Protocol. As a general point, it is noteworthy that 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 sets of dedicated data upon which such evaluations can be based.⁴⁵

IV. STRATEGIC PLAN OF THE CONVENTION ON BIOLOGICAL DIVERSITY

36. In addition to the processes surveyed above, the Convention on Biological Diversity has adopted a Strategic Plan and developed a framework for reviewing progress towards the goals of that Plan, specifically the 2010 target.⁴⁶ The Convention on Biological Diversity’s Strategic Plan was adopted by

⁴¹ CITES Doc. 10.20, *Evolution of the Convention: How to Improve the Effectiveness of the Convention, Comments from Parties and Organizations on the Study*, and Doc 10.21 *Evolution of the Convention: How to Improve the Effectiveness of the CITES, Consideration of the Recommendations arising from the Study*.

⁴² CITES Resolution Conf. 14.2, *CITES Strategic Vision 2008-13*, Annex, General Introduction.

⁴³ CITES, *Indicators for Objectives contained in the CITES Strategic Vision: 2008-2013*, available at <http://www.cites.org/eng/news/E-SV-indicators.pdf>. See also CITES Doc. SC57 Doc. 9.

⁴⁴ For example, while a number of them, like the Biosafety Protocol, seek to control in some manner the transboundary movement of certain products in order to prevent adverse effects on the environment, some of them also explicitly provide for reducing or phasing out the production and/or consumption of certain substances. Measuring changes in, for example, the manufacture, import and export of persistent organic pollutants will inevitably pose different methodological challenges to measuring the impact of LMOs on the conservation and sustainable use of biological diversity.

⁴⁵ UNEP has also undertaken work on the effectiveness of MEAs, with particular focus on compliance and enforcement issues. See, for example, E. Mrema and C. Bruch, *Manual on Compliance with and Enforcement of Multilateral Environmental Agreements* (2006).

⁴⁶ The Parties to the Convention committed themselves to achieve by 2010 a significant reduction of the current rate of biodiversity loss at the global, regional and national level as a contribution to poverty alleviation and to the benefit of all life on Earth. This is known as the 2010 target.

the Conference of the Parties in 2002⁴⁷ and an updated and revised Plan for the period 2011-2020 is due for consideration and possible adoption at the tenth meeting of the Conference of the Parties, in October 2010. In 2004, the Conference of the Parties developed a framework of goals and targets, identifying provisional indicators in seven focal areas for evaluating status and trends of biodiversity and assessing progress towards the 2010 target.⁴⁸ The indicators were further considered and refined at the eighth meeting of the Conference of the Parties.⁴⁹ The 2010 Biodiversity Indicator Partnership⁵⁰ is working on indicator development and generating information on biodiversity trends to assess progress regarding the 2010 target.

37. As attention focuses on the revision of the Convention's Strategic Plan for the post-2010 phase, further consideration is being given to the development and use of biodiversity indicators and the question whether modified or new indicators may be required. An expert workshop in July 2009 recommended, *inter alia*, the modification and simplification of the current set of global indicators and the development of some additional measures on threats to biodiversity.⁵¹ The Strategic Plan as being developed includes 20 headline targets for 2020 organized under five strategic goals. The goals and targets comprise both aspirations for achievement at the global level and a flexible framework for the establishment of national or regional targets. Parties are expected to set their own targets within the global framework, taking into account national needs and priorities. Parties are also called upon to monitor and review the implementation of their national biodiversity strategies and action plans in accordance with the 2011-2020 Strategic Plan and their national targets, making use of the set of indicators developed for the Strategic Plan and to report to the Conference of the Parties through their fifth and sixth national reports and any other means to be decided by the Conference of the Parties.⁵²

V. EVALUATING THE EFFECTIVENESS OF THE PROTOCOL UNDER ARTICLE 35: NATURE AND SCOPE

38. As noted in the introductory section to the present document, while Article 35 requires periodic evaluations of the effectiveness of the Protocol, it does not provide guidance as to how such evaluations should be conducted nor does it specify the nature or scope of the evaluation beyond indicating that it should encompass an assessment of the Protocol's procedures and annexes. The experience in other MEAs and in the Convention on Biological Diversity indicates that there are different ways in which such evaluations or measures of progress might be organised and conducted and that the practice in this area is evolving.

39. In 2006, prior to the Parties' first consideration of Article 35 at their third meeting, the Secretariat raised the question of "whether there has been enough experience gained by Parties that makes any evaluation of the effectiveness of the Protocol in the next few years appropriate and timely."⁵³ The

⁴⁷ CBD COP Decision VI/26.

⁴⁸ CBD COP Decision VII/30.

⁴⁹ CBD COP Decision VIII/15.

⁵⁰ www.twentyten.net.

⁵¹ UNEP/WCMC/Post2010/0709/10, *UNEP WCMC/CBD International Expert Workshop on the 2010 Biodiversity Indicators and Post-2010 Indicator Development, 6-8 July 2009, Workshop Report*, available at <http://www.cbd.int/doc/meetings/ind/emind-02/official/emind-02-0709-10-workshop-report-en.pdf>.

⁵² Report of the Ad Hoc Open-ended Working Group on Review of Implementation of the Convention on the work of its third meeting (UNEP/CBD/COP/10/4).

⁵³ UNEP/CBD/BS/COP-MOP/3/13, para 10. On the basis of reviews carried out at that time, the document reported that quite a number of Parties were then 'still at different levels of what could be considered as a preparatory phase towards the full implementation of the Protocol.' *Ibid*, para. 7.

Secretariat also noted the difficulties associated with pinpointing and attributing the specific impact of the Protocol in promoting or contributing to the conservation and sustainable use of biological diversity.⁵⁴

40. The submissions of Parties and Governments made prior to the fourth meeting of the Parties revealed some differences of views as to the appropriate nature and scope of the assessment and review under Article 35.⁵⁵ While some seemed to indicate that the review should focus on implementation of the provisions of the Protocol, particularly those provisions that address advance informed agreement, others suggested a deeper focus on the extent to which the objective of the Protocol had been achieved. A number recognized that the Protocol remained in its initial phase, that there was still a low level of implementation, and thus it might be difficult or premature to evaluate fully its effectiveness.⁵⁶ Several referred to capacity impediments hampering implementation of the Protocol.

41. A number of Parties and Governments also made suggestions prior to the fourth meeting of the Parties as to possible indicators and/or criteria for evaluating the effectiveness of the Protocol.⁵⁷ Many of these suggestions focused on implementation of biosafety frameworks at the national level in terms of the existence and implementation of a domestic regulatory framework, including risk assessment and risk management. A number mentioned capacity issues and identification of difficulties in implementation; others highlighted the role of the Biosafety Clearing-House and the number of submissions to it. Some others suggested the development of specific indicators to measure the outcomes of the Protocol in terms of its objective.

42. As noted by the Parties in decision IV/15, the first national reports have shown that in many Parties the Protocol remains in an early stage of implementation. Indeed, in some respects, as the Protocol's Compliance Committee has noted, it remains difficult to ascertain with certainty the status of implementation of the Protocol at the domestic level since a number of Parties are yet to submit their first national reports.⁵⁸

43. To date, it is difficult to conclude that the situation as regards implementation of the Protocol has changed from the status as captured in the first national report. Many of the national laws available on the Biosafety Clearing-House are still in the form of draft biosafety frameworks. Without further detailed Party-by-Party research, it is not possible to state with any certainty how many Parties have finalized, adopted and/or implemented their national biosafety frameworks since the fourth meeting of the Parties when the analysis of the first national reports was considered, or how many are in a position to implement them in practice. While there have undoubtedly been developments in terms of domestic implementation, the dearth of detailed data in this respect and the continued expressions of concern about the capacity deficit at the national level suggest that there has likely not been a significant improvement in the level of implementation of the Protocol since 2008.

44. In the light of the foregoing, it may be concluded that, in principle, an evaluation of the effectiveness of the Protocol should assess whether or to what extent the Protocol has achieved its objective; however, in practice, the second evaluation of effectiveness should primarily serve to secure a global picture of the state of implementation of the Protocol and its impact to date in establishing a

⁵⁴ *Ibid*, paras 11-12.

⁵⁵ See the compilation of submissions of views on assessment and review (Article 35) (UNEP/CBD/BS/COP-MOP/4/INF/10) prepared for the fourth meeting of the Parties.

⁵⁶ See the SCBD synthesis of the submissions prepared for the fourth meeting of the Parties (UNEP/CBD/BS/COP-MOP/4/14).

⁵⁷ See the compilation of submissions of views on assessment and review (Article 35) (UNEP/CBD/BS/COP-MOP/4/INF/10) prepared for the fourth meeting of the Parties at 19-25.

⁵⁸ The deadline for submission of the first regular national reports under the Protocol was 11 September 2007. By that date only 50 first national reports were submitted from among 141 Parties to the Protocol as at September 2007. To date total of 89 first national reports have been received from among 159 Parties to date.

framework for information exchange, risk assessment and decision-making procedures in relation to the transboundary movement of LMOs. This could serve as a baseline against which future improvements in implementation could be measured and upon which might be built future evaluations of the effectiveness of the Protocol in achieving its objective.

45. It may be argued that such an approach risks duplicating the function of the existing system of monitoring implementation through the national reporting process. Indeed, it is suggested in section VI below that national reports form the key data gathering mechanisms for the evaluation. However, it seems premature to attempt to evaluate the Protocol's effectiveness in terms of outcome, i.e. its impact on conservation and sustainable use of biodiversity, taking also into account risks to human health, when it seems evident that in many respects the regulatory procedures and mechanisms required under the Protocol have not yet been put into effect. In such circumstances, it may well not be possible reasonably to attribute to the Protocol impacts or the avoidance of impacts of LMOs on the conservation and sustainable use of biodiversity.⁵⁹

46. The approach proposed does not disregard the fact that there may, and indeed should, be further improvements in the overall picture of implementation of the Protocol by 2010-2012, the period in which it is envisaged the second evaluation would take place. Notwithstanding the proposal that the second evaluation focus primarily on assessing the status of implementation, some suggested options are put forward in the remainder of this working document for the development of a process to move towards more outcome-oriented evaluation in the future. Should it be considered timely and appropriate by the Parties at their fifth meeting, some of these elements could be integrated into the second evaluation process.

VI. POSSIBLE ELEMENTS OF A METHODOLOGY FOR THE SECOND EVALUATION OF EFFECTIVENESS

47. On the basis of the review above, this section sets out possible elements for the methodology for the second evaluation of effectiveness under Article 35. It considers: the timing of the assessment; its scope; a range of possible indicators that might be utilized as the basis for the evaluation; and mechanisms for gathering data for the assessment and for data analysis.

A. *Timing*

48. The first assessment under Article 35 was considered at the meeting of the Parties in 2008, five years after the Protocol entered into force, although, as noted in paragraph 2 above, it was considered that there did not then exist sufficient operational experience on which to base an effective assessment and review of the Protocol. In accordance with the terms of Article 35, future evaluations of effectiveness must be held at least every five years. Thus the next assessment should be conducted by 2013. Assuming that the current sequencing of meetings of the Parties is maintained, the sixth meeting might be held in 2012 and the seventh in 2014. This suggests that the second evaluation of effectiveness should be conducted by the Parties at their sixth meeting, in 2012.

49. As discussed in more detail below, it is suggested that data for the evaluation be collected primarily through the second national reports submitted by Parties to the Protocol. In decision BS-I/9, the Parties decided that national reports should be submitted every four years and that they should be submitted 12 months before the meeting of the Parties at which they will be considered. Since the first national reports were submitted in September 2007 for consideration at the fourth meeting of the Parties,

⁵⁹ This is not to imply that an evaluation of progress in relation to Article 1 could only be undertaken once every Party has realised the full implementation of its obligations under the Protocol but rather that, as in any MEA, evaluation of implementation is always likely to be a component of an effectiveness evaluation and, at this stage in the Protocol's evolution, seems to be the most significant component.

in 2008, if the approach of decision BS-I/9 is followed, the second national reports would be due in 2011 for consideration by the Parties at their meeting in 2012.

50. While this national reporting timeframe in principle corresponds with that suggested for the second evaluation of effectiveness, it should be acknowledged that it could impose difficulties on Parties in terms of timely submission of reports,⁶⁰ and on the Secretariat or such other entity that might be charged with compiling and analysing relevant evaluation data for consideration by the Parties.

B. Scope

52. For the reasons discussed in section V above, it is suggested that the second evaluation of effectiveness focus primarily on assessing the status of implementation of key provisions, procedures and mechanisms of the Protocol. In this way, the second evaluation should establish a set of baseline data not only against which future progress in the Protocol's implementation and effectiveness can be more reliably measured but also against which progress for the implementation of the proposed Strategic Plan of the Protocol can be measured. Therefore, in developing a preliminary list of draft indicators for consideration, an attempt has been made to focus on domestic implementation of certain core elements of the Protocol (see the annex to the present document). The preliminary list of draft indicators in the annex has also been used as the basis for developing the core set of outcome indicators for the proposed strategic plan and is also reflected in the proposed format for the second national reports. The second evaluation, apart from establishing the global picture of implementation, also provides a platform for the possible development of a set of outcome indicators with which to begin to assess the effectiveness of the Protocol in achieving the objective set out in Article 1.

C. Data-gathering/sources of information

53. The methodology proposed for the second evaluation of effectiveness relies primarily on gathering information through the second national reports (see figure 1 below). This would require that the second national reporting format to be adopted by the Parties at their fifth meeting incorporates indicators relevant to the assessment.

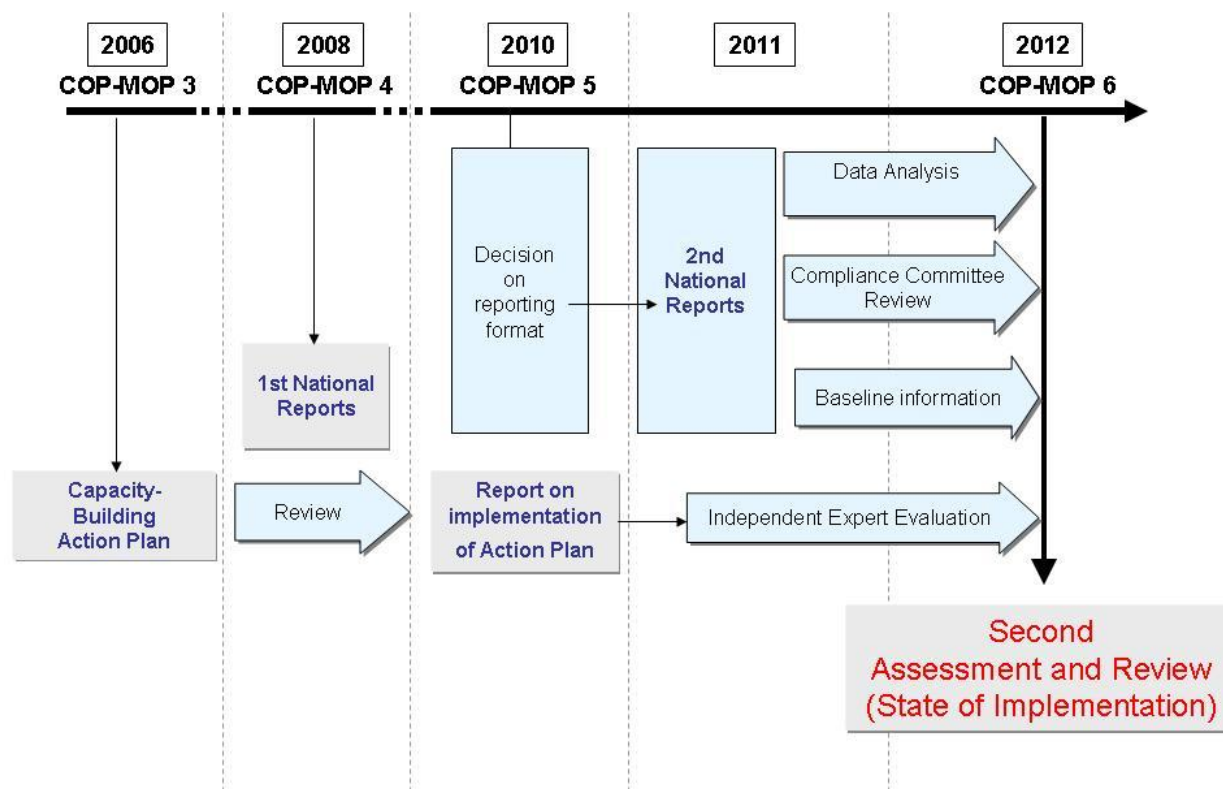
54. Reliance on national reports as the primary data source does entail, however, that the second evaluation of effectiveness will rely in large part upon the timely and complete submission of second national reports by Parties. On the basis of experience with the submission of first national reports, it should be acknowledged that difficulties in conducting the evaluation would be encountered if second national reports are submitted late or not at all.

55. Other sources of information are likely to include the Biosafety Clearing-House and other relevant biosafety databases, the reports of the Compliance Committee, the Capacity-Building Coordination Mechanism, and other international and regional organisations that address biosafety issues.

56. Data gathering and compilation might be undertaken by the Secretariat.

⁶⁰ Document UNEP/CBD/BS/CC/5/2, the revised analysis of information contained in first national reports, prepared by the Executive Secretary for the fifth meeting of the Compliance Committee notes that, taking into account the rate of timely submission of first national reports, Parties may wish to review the current reporting interval in decision BS-I/9 (para. 98 (o)).

Fig.1 Second Assessment and Review Process
Establishing a Global Picture for the State of Implementation of the Protocol



D. Data analysis

57. There are a number of options that might be considered for the conduct of the data analysis phase of the evaluation. As noted in section III above, some MEAs have relied upon their secretariats to compile and analyse data for the purposes of effectiveness evaluations and related exercises; others have established expert panels or ad hoc expert groups; and in some cases external consultants have been commissioned to conduct the evaluation. Each of these options might be considered for the Protocol evaluation. Another option might be to delegate the evaluation of effectiveness to the Compliance Committee which already reviews general issues of compliance at its meetings.

58. The Secretariat might be charged with conducting the initial analysis of information gathered through the evaluation process. Nonetheless, it is submitted that it would be desirable at an early stage to establish a small ad hoc group of experts to participate in the evaluation, and, in due course, to begin to review and ensure consistency and usefulness among the set of indicators for the second national reports and the strategic plan for purposes of the third and subsequent evaluations of effectiveness.

59. Given that the Compliance Committee also considers general issues of compliance at its meetings,⁶¹ some consideration might be given to whether the Compliance Committee should be asked to assume responsibility for the conduct of the evaluation of effectiveness of the Protocol. The mandate of the Compliance Committee under decision BS-I/7 indicates that, in addition to the specific functions laid down in that decision, the Committee shall carry out any other functions as may be assigned to it by the Parties. However, it might be argued that this may not be an appropriate role for the Committee since it is

⁶¹ Decision BS-I/7, annex, section III, para. 1 (d).

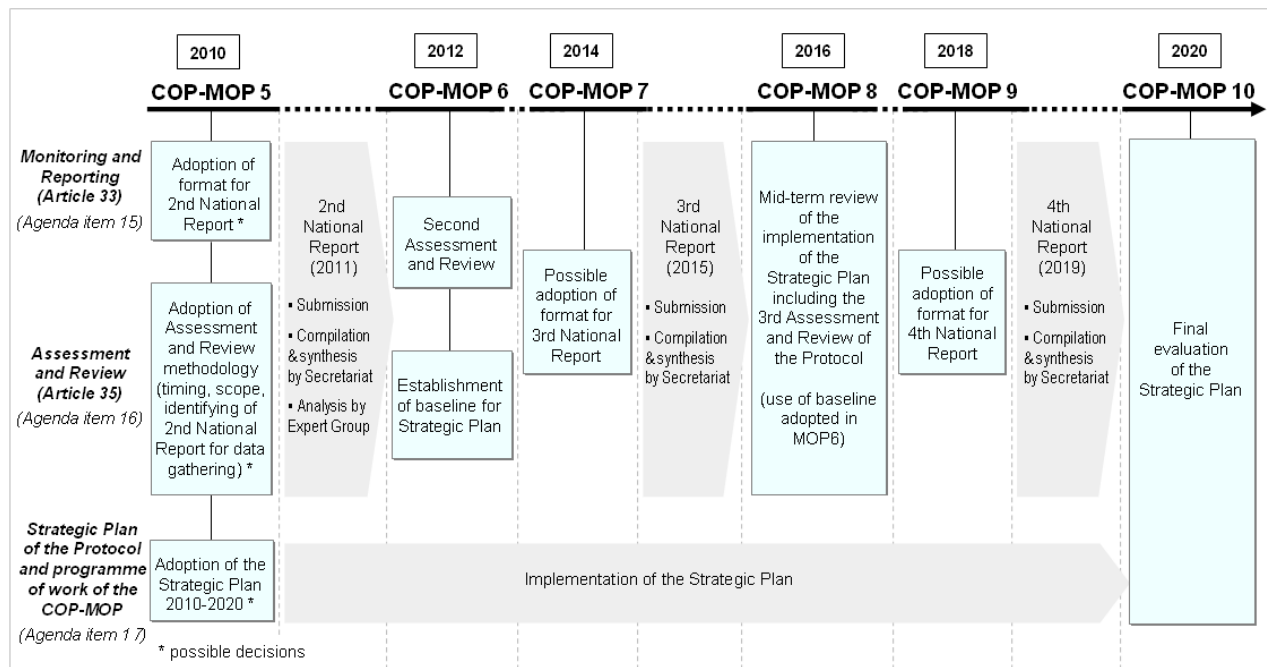
also mandated to review individual cases of non-compliance. The effectiveness evaluation is not concerned with compliance by individual Parties, but rather with the overall implementation and effect of the Protocol. Assuming that in the future, individual cases of non-compliance might come before the Committee, it might be considered more appropriate to separate the functions of compliance review and effectiveness evaluation.

E. Integrating reporting, effectiveness evaluation and the strategic planning process in the Protocol

60. It is envisaged that the Parties at their fifth meeting may consider and adopt a Strategic Plan for the Protocol with specific indicators to monitor progress. If this is the case, consideration might usefully be given to the integration of future evaluations of effectiveness into any monitoring and review processes established for the strategic plan. Subject, of course, to the final content of the strategic plan, such an approach would appear *prima facie* to satisfy the requirements of Article 35. Such an approach would also entail tailoring aspects of the content of national reporting requirements as well as the timing of national reports to the evaluation and monitoring process. In practical terms, it might offer an opportunity to achieve economies in data collection and analysis and serve to lessen the reporting burden on Parties.

61. The proposed format for the second national reports (see document UNEP/CBD/BS/COP-MOP/5/14) already initiates this process by incorporating broader questions on national implementation. This is intended to serve both as a good source of information for the assessment and review process and also to lessen the burden on Parties by endeavouring to avoid the need for other separate data collection requirements in the future. Figure 2 below, presents the possible interrelationship among the national reporting process, the assessment and review process and the Strategic Plan from the fifth to tenth meetings of the Parties.

Figure 2. Possible linkages among national reports, assessment and review and Strategic Plan



F. Indicators

62. The annex to the present document sets out a draft core set of indicators for the second evaluation of effectiveness of the Protocol. As noted previously, this is based on the approach that the second evaluation should focus primarily on evaluating overall domestic implementation of the Protocol's provisions. The purpose of setting out the draft indicators at this stage is to generate discussion as to whether this is an appropriate and useful approach.

63. A number of principles and assumptions have informed the development of the annex. First, as noted in section V above, it is assumed that the effectiveness of the substantive provisions and annexes of the Protocol in achieving the objective in Article 1 can be assessed only once the core procedures and mechanisms for implementation of the Protocol are in place hence the focus on national implementation at this stage.

64. Second, it is emphasized that the aim of the assessment and review process is not to evaluate the implementation of the Protocol by any individual Party or region or to duplicate the work of the Compliance Committee in relation to possible instances of non-compliance. Rather the goal of the assessment and review is to ascertain the overall status of implementation, i.e. to what extent procedures necessary to implement the Protocol's core elements have been put in place.

65. Third, the assessment and review is not intended to duplicate the review of national reports. The latter review will contain information on a broader range of issues and activities.

66. Fourth, in drawing up the annex, one principal consideration was the need to focus on a limited number of indicators for which information should be readily available and measurable through the reporting process or other available sources of information. This takes into account the need to draw on existing sources of information and not to overburden Parties with reporting requirements. That said, in relation to some of the proposed indicators, some further thought may be required as to available sources of reliable data.

67. Fifth, in order to limit the number of indicators to a manageable number, the annex focuses on certain core obligations contained in the Protocol and thus at this stage excludes others. There may well be differences of view as to which elements of the Protocol might most usefully be subject to evaluation at this stage and the list contained in the annex may need to be revised to take into account such views. The framework in the annex focuses on the following aspects:

(a) The establishment of AIA procedures (or domestic regulatory frameworks consistent with the Protocol) for the transboundary movement of LMOs for intentional introduction into the environment;

(b) The operationalization and functioning of AIA procedures (or domestic regulatory frameworks consistent with the Protocol) for the transboundary movement of LMOs for intentional introduction into the environment;

(c) The existence and operationalization of procedures for risk assessment;

(d) The existence and operationalisation of procedures for appropriate risk management measures and monitoring;

(e) Procedures and capacities for identifying and addressing illegal transboundary movements of LMOs;

(f) Procedures and capacities for avoiding and addressing unintentional transboundary movements of LMOs, including notification procedures and emergency measures;

(g) Appropriate implementation of the Protocol's requirements on the handling, transport, packaging and identification of LMOs;

- (h) Procedures and capacity for information-sharing through the Biosafety Clearing-House;
and
(i) Procedures and measures for promoting public awareness.

68. A further assumption is that in order to achieve the desired objective of the Protocol, the geographic coverage of the Protocol should be as comprehensive as possible. If a significant number of States remain outside the Protocol, it is likely to impact the potential for the Protocol's objective to be achieved. However this remains outside the control of Parties.

VII. CONCLUSIONS AND RECOMMENDATIONS

69. The following conclusions and recommendations are offered as to the methodology for the second assessment and review:

(a) The second evaluation should focus primarily on ascertaining and reviewing the status of implementation of core elements of the Protocol;

(b) A set of indicators based on the draft indicators contained in the Annex to this document might inform the evaluation process for the purposes of the second evaluation of effectiveness;

(c) Given the proposed focus of the evaluation, data for the evaluation should be gathered primarily through the Protocol's national reporting process. This may require some adjustments to the formats of national reports and some consideration of the timing of second national reports. The proposed format for the second national reports reflects this consideration;

(d) The evaluation should also draw upon available information from other sources including the Biosafety Clearing-House, the Capacity-Building Coordination Mechanism and other relevant organizations;

(e) The effectiveness evaluation process should be linked to, or integrated with, the process for the monitoring and review of the Protocol's Strategic Plan. This may impact upon the selection of indicators utilised. Such an integrated approach might also incorporate the review of national reports and the monitoring of implementation of the capacity-building action plan. In drawing the set of indicators for the strategic plan, linkages were established between the questions for the proposed national reporting format and the indicators for the proposed strategic plan of the Protocol to ensure consistency;

(f) In order to comply with the requirements of Article 35, the second evaluation of effectiveness should be completed at the sixth meeting of the Parties. At their fifth meeting, the Parties should therefore establish the basis for data gathering, including the determination of appropriate indicators and guidance on appropriate reporting formats, and allocate responsibilities for the review and analysis of data and the preparation of a report for the sixth meeting;

(g) The Secretariat might be charged with conducting the data-gathering phase of the evaluation and the initial compilation and analysis of data;

(h) An ad hoc technical expert group might be established before the sixth meeting of the Parties to: (i) advise on and/or participate in or conduct the review and analysis of data; and (ii) advise on the modification of indicators and the development of further or alternative indicators as the basis for future evaluations of effectiveness under Article 35. Such indicators should include appropriate "outcome-oriented" indicators to evaluate progress towards the objective of the Protocol. As an alternative to the establishment of an ad hoc technical expert group, part or all of these tasks might be mandated to the Compliance Committee;

(i) The Compliance Committee, in its review of general issues of compliance, should have input into the effectiveness evaluation, and submit comments or recommendations thereon to the Parties at their sixth meeting;

(j) The effectiveness-evaluation process should incorporate forward-looking elements so as to consider whether there are new or emerging aspects of biosafety that might require attention under the Protocol;

(k) Consideration should be given to the development of one or more Protocol-relevant indicators in the wider context of the post-2010 Strategic Plan of the Convention on Biological Diversity, for example through the Biodiversity Indicators Partnership;

(l) The Protocol might usefully seek to share information and experience with other multilateral environmental agreements on effectiveness evaluation processes.

VIII. SUGGESTED ELEMENTS OF A DRAFT DECISION

70. On the basis of the information provided in this note, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to:

1. Decide that the scope of the second assessment and review primarily focus on ascertaining and reviewing the status of implementation of core elements (key provisions, procedures and mechanisms) of the Protocol;

2. Request the Executive Secretary to collect, compile and analyse information on the implementation of the Protocol using the second national reports as a primary source, with a view to contributing to the second assessment and review of the Protocol;

3. Decide that the evaluation should also draw upon available information from other sources, including the Biosafety Clearing-House, the Capacity-Building Coordination Mechanism and other relevant processes and organizations;

4. Urge Parties and other Governments to contribute effectively to the data collection process by timely completion and submission of their national reports in accordance with the relevant decisions on national reporting, and by providing adequate and complete information in their reports;

5. Decide to establish an ad hoc technical expert group on assessment and review to: (i) review the information gathered and analysed by the Executive Secretary with a view to contributing to the second assessment and review of the Protocol; (ii) undertake the second assessment and review of the effectiveness of the Protocol using the indicators in the annex to this decision as adjusted by the group as necessary; and (iii) submit its findings and recommendations to the sixth meeting of the Conference of the Parties serving as the meeting of the Parties for its consideration;

6. Request the Compliance Committee, in its review of general issues of compliance, to provide input into the effectiveness evaluation and submit comments or recommendations thereon to the Parties at their sixth meeting;

7. Decide to conduct the third assessment and review of the Protocol in conjunction with the mid-term review of the implementation of the Strategic Plan at the eighth meeting of the Parties, using, among other things, information collected through the third national reports.

Annex

POSSIBLE INDICATORS FOR SECOND ASSESSMENT AND REVIEW

A. Coverage

1. Geographic coverage of the Protocol and Protocol's coverage of transboundary movements of LMOs:

- (a) Number of Parties to the Protocol;
- (b) Number of Parties that have designated national focal points;
- (c) Number of Parties submitting timely national reports on their implementation of the Protocol;
- (d) Number of Parties importing LMOs from non-Parties;
- (e) Number of Parties exporting LMOs to non-Parties.

B. Domestic implementation of core procedures and annexes

2. AIA procedures (or domestic regulatory frameworks consistent with the Protocol), in accordance with the Protocol, are established for the transboundary movement of LMOs for intentional introduction into the environment:

- (a) Number of Parties that have put in place laws and regulations and administrative measures for operation of the AIA procedure or adopted a domestic regulatory framework consistent with the Protocol as regards the transboundary movement of LMOs for intentional introduction into the environment;
- (b) Number of Parties that have designated competent national authorities;
- (c) Number of Parties importing or exporting LMOs that do not have relevant laws and regulations in place governing transboundary movements of LMOs for intentional introduction into the environment;
- (d) Regional trends in adopting AIA procedures or domestic regulatory frameworks consistent with the Protocol.

3. AIA procedures (or domestic regulatory framework consistent with the Protocol) for the transboundary movement of LMOs for intentional introduction into the environment are operational and functioning:

- (a) Number of Parties with domestic institutional and administrative (decision-making) arrangements in place to deal with AIA applications;
- (b) Number of Parties with a budgetary allocation for the operation of their national biosafety framework;
- (c) Number of Parties with permanent staff in place to administer their national biosafety frameworks (including AIA applications);
- (d) Number of Parties that have processed AIA applications and reached decisions on import;

/...

- (e) Regional trends in operation and functioning of AIA procedures.
4. Procedures for decision-making in relation to transboundary movements of LMO-FFPs are established and operational:
- (a) Number of Parties that have taken final decisions regarding domestic use, including placing on the market, of LMO-FFPs that may be subject to transboundary movement;
 - (b) Number of Parties with a decision-making procedure specific to the import of LMO-FFPs.
5. Risk assessment procedures for LMOs are established and operational:
- (a) Number of Parties with risk assessment guidance in place for LMOs;
 - (b) Number of Parties that have conducted risk assessments as part of a decision-making process regarding an LMO;
 - (c) Number of Parties with an advisory committee or other arrangements in place for conducting or reviewing risk assessment;
 - (d) Number of decisions in the Biosafety Clearing-House accompanied by a summary of the risk assessment of the LMO;
 - (e) Number of Parties with the necessary domestic capacity to conduct risk assessment;
 - (f) Number of Parties reporting having used Annex III of the Protocol or any other guidance on risk assessment agreed by the Conference of the Parties serving as the meeting of the Parties to the Protocol;
 - (g) Regional trends in relation to risk assessment capacity.
6. Procedures for the establishment of appropriate LMO risk management measures and monitoring are established and operational:
- (a) Number of Parties that have authorized introductions of LMOs into the environment and that have requirements and/or procedures in place and enforced to regulate, manage and control risks identified in risk assessments;
 - (b) Number of Parties with capacity to detect and identify the presence of LMOs;
 - (c) Regional trends in relation to risk-management capacity.
7. Procedures for identifying and addressing illegal transboundary movements of LMOs are in place and operational:
- (a) Number of Parties with domestic measures to prevent and penalize illegal transboundary movements, including through the regulation of transit and contained use;
 - (b) Number of Parties reporting having received information concerning cases of illegal transboundary movements of an LMO to or from territories under its jurisdiction;
 - (c) Number of Parties with capacity to detect illegal transboundary movements of LMOs (e.g. personnel, technical capacity).
8. Procedures for preventing, identifying and addressing unintentional transboundary movements of the LMOs are established and operational, including notification procedures and emergency measures:

(a) Number of Parties having notified to the Biosafety Clearing-House their contact points regarding unintentional transboundary movement of LMOs in accordance with Article 17;

(b) Number of Parties with a mechanism in place for notifying potentially affected States of actual or potential unintentional transboundary movements of LMOs;

(c) Number of instances of unintentional transboundary movements identified;

(d) Number of Parties with a mechanism to identify and determine significant adverse effects on biological diversity of any unintentional transboundary movements of LMOs;

9. Appropriate requirements are established and implemented in relation to the Protocol's requirements on the handling, transport, packaging and identification of LMOs:

(a) Number of Parties with requirements for handling, transport, packaging and identification of LMOs in place consistent with Article 18 of the Protocol and relevant subsequent decisions of the Conference of the Parties serving as the meeting of the Parties to the Protocol for:

(i) Contained use;

(ii) Intentional introduction into the environment;

(iii) LMO-FFPs.

10. Procedures for notification of required information to Biosafety Clearing-House are established and operational:

(a) Number of Parties that have allocated responsibilities for notification of information to the Biosafety Clearing-House;

(b) Number of Parties that have in place systems for the management of biosafety information necessary for the implementation of the Protocol

11. Procedures and measures for promoting public awareness are being implemented:

(a) Number of Parties implementing public-awareness programmes or activities;

(b) Number of Parties providing for some level of public participation in decision-making processes on LMOs.

C. International level procedures and mechanisms

12. BCH is operational and accessible:

(a) Number of Parties accessing the Biosafety Clearing-House on a regular basis, i.e. at least once a month;

(b) Number of Parties reporting difficulties accessing or using the Biosafety Clearing-House;

(c) Extent to which information on the Biosafety Clearing-House is reliable and up to date.

13. Capacity-building Action Plan being effectively implemented:

(a) Amount of funding provided or received for supporting biosafety capacity-building activities;

(b) Number of Parties seeking assistance to be able to use experts from the roster of experts and number of Parties actually receiving such assistance;

(c) Number of Parties reporting using local expertise to undertake or review risk assessments and other activities relating to the implementation of the Protocol.

14. Compliance Committee is functioning:

(a) Parties raise issues with the Compliance Committee concerning their own compliance with Protocol obligations;

(b) Compliance Committee has decision-making rules of procedure in place.

D. Impacts of transboundary movements of LMOs on biological diversity, taking into account risks to human health

15. Consideration should be given to the work on biodiversity indicators in the context of the Convention on Biological Diversity.
