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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
Fourth meeting
Bonn, 12 -16 May 2008
Item 15 of the provisional agenda*

ASSESSMENT AND REVIEW (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, to undertake an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes, five years after the entry into force of the Protocol and at least every five years thereafter. The Protocol entered into force on 11 September 2003 and the first review of the effectiveness of the Protocol is due in September 2008.

2. The first meeting of the Parties to the Protocol in its adoption of the medium-term programme of work (decision BS-I/12), set up a programme for the process for the review and assessment to be initiated at its third meeting, including an assessment of the Protocol's procedures and annexes.

3. In initiating the review and assessment process, the third meeting of Parties to the Protocol, in paragraph 1 of decision BS-III/15, invited Parties, other Governments as well as relevant intergovernmental and non-governmental organizations and other stakeholders to submit their views to the Secretariat. These views were required to: (a) evaluate the effectiveness of the Protocol, including an assessment of procedures and annexes, taking into account the items specified in paragraph 6 (b) of the medium-term programme of work contained in the annex to decision BS-I/12; (b) assess the procedures and annexes under the Protocol, with a view to identifying difficulties arising from implementation as well as suggestions for appropriate indicators and/or criteria for evaluating effectiveness and ideas on the modalities of the evaluation.

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4. Paragraph 2 of decision BS-III/15 requested the Executive Secretary, under the guidance of the Bureau, to prepare a synthesis of the views submitted in accordance with paragraph 1 of the same decision as well as information contained in the first national reports submitted by Parties, and make it available to the fourth meeting of the Parties to the Protocol.

5. In paragraph 1 of decision BS-III/8 on Article 18.2(b) and (c) (handling, transport, packaging and identification), the Parties requested Parties and invited other Governments and relevant international organizations to submit to the Executive Secretary further information on experience gained with the use of a commercial invoice or other documents required or utilized by existing documentation systems, or pursuant to national requirements with a view to future consideration of a stand-alone document. In paragraph 2 of this decision, the Parties requested the Executive Secretary to compile the information received and to prepare a synthesis report for consideration in the context of the process of review of the implementation of the Protocol as provided for under Article 35 of the Protocol.

6. Furthermore, in paragraph 1 of decision BS-III/1, the Parties decided to undertake the review of the effectiveness of the procedures and mechanisms on compliance as provided for in section VII of decision BS-I/7, including addressing the issue of measures concerning repeated cases of non-compliance as well as rule 18 of the rules of procedure of the Compliance Committee, at their fourth meeting within the framework of the overall evaluation of the effectiveness of the Protocol under Article 35 and in accordance with the modalities established in decision BS-III/15.

7. Accordingly, the Executive Secretary, under the guidance of the Bureau, has prepared the present document. Section II contains the synthesis of views submitted in accordance with paragraph 1 of decision BS-III/15. Section III presents a summary of observations based on information from the first national reports received by the Secretariat pertaining to the specific areas referred to in decision BS-III/15. Section IV contains information on the review of the effectiveness of the procedures and mechanisms on compliance pursuant to paragraph 1 of decision BS-III/1. Section V contains a synthesis of views received pursuant to decision BS-III/8 on paragraphs 2(b) (and 2(c) of Article 18 with respect to documentation accompanying shipments of living modified organisms destined for contained use and those for intentional introduction into the environment, respectively. Section VI attempts to identify possible modalities that the Parties to the Protocol may wish to take into account in establishing the process to undertake the evaluation of the Protocol among which are the development and use of indicators and/or criteria for evaluating effectiveness. Finally, section VII submits suggestions of elements of a draft decision that the Parties to the Protocol may wish to consider. The complete text of all the submissions received pursuant to the items referred to above can be found in document UNEP/CBD/BS/COP-MOP/4/INF/10.

8. Lastly, it might be mentioned that in paragraph 3 of decision BS-III/15, the Parties requested the Compliance Committee to prepare a report on general issues of compliance by Parties with their obligations under the Protocol, in accordance with paragraph 1 (d) of section III of the Compliance Procedures and Mechanisms contained in the annex to decision BS-I/7. This report has been prepared by the Compliance Committee and is submitted along with its main report to the fourth meeting of the Parties to the Protocol in document UNEP/CBD/BS/COP-MOP/4/2/Add.1.

9. The present note is intended to assist the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol in its consideration of the item on ‘assessment and review of the Protocol’, with a view to fulfilling the requirement under Article 35.

II. SYNTHESIS OF VIEWS FROM RESPONDENTS TO THE QUESTIONNAIRE ON ASSESSMENT AND REVIEW OF THE PROTOCOL

10. By 22 February 2008, the Secretariat had received a total of 27 responses to the questionnaire that it had formulated and circulated on the basis of the decisions relevant to assessment and review. These consisted of responses from 25 Parties: Armenia, Austria, Belize, Bhutan, Bulgaria, Cambodia, Cameroon, China, Colombia, Costa Rica, Croatia, the European Community, India, Lithuania, Madagascar, Malaysia, Moldova, New Zealand, Nigeria, Poland, Switzerland, United Republic of Tanzania, Thailand, Togo, and Venezuela, and from two other Governments namely, Canada and the United States of America. The full text of the submissions has been compiled and made available in an information document (UNEP/CBD/BS/COP MOP/4/INF/10).

11. In all the submissions, Parties indicated that there has not been much practical experience in implementation of the Protocol in general and more particularly in the use of Articles 7 through 12, (the advance informed agreement procedure and the procedure for living modified organisms for direct use as food or feed, or for processing) or in the application of the respective information requirements under annex I or annex II. In light of this lack of practical experience, various submissions seem to imply that there exists no or little possibility to evaluate the effectiveness of the Protocol at this moment in its evolution. In addition, answers to questions concerning the effectiveness of the Protocol may differ significantly due to the different approaches to implementing and applying the Protocol, and further, due to the varying levels of capacity among Parties.

12. Belize stated in its submission that even though it has no practical experience in applying the processes and procedures under the Protocol, their application in small-island developing states may be problematic due to the lack of expertise in areas such as risk assessment and risk management. Belize suggested some indicators for evaluating the effectiveness of the implementation of such processes and procedures such as the following: an increase in the information provided to the Biosafety Clearing-House (BCH) in a transparent manner; surveys/reports requested from Parties on the difficulties encountered in implementing the Protocol; evaluation of country legislation that deals with the regulation of living modified organisms (LMOs) to assess its compatibility with the tenets of the Protocol; and widespread adoption (where appropriate) of the Protocol procedures, annexes by international standard setting bodies.

13. Cameroon stated that there is little experience in applying the processes under the Protocol due to the fact that the institutional and regulatory frameworks are not fully functional. Cameroon, however, suggested the following indicators for evaluating the effectiveness of the Protocol: a comprehensive and functional legal and regulatory framework; adequate and stable resources (human, financial, material); and an effective institutional framework.

14. China indicated that public awareness is a key to the implementation of the Protocol. China stated that the advance informed agreement (AIA) procedure, the LMOs-FFP procedure and annexes I, II and III of the Protocol have played very positive roles in providing guidance in China's safety administration of LMOs and helped achieved good results. China indicated that its main challenge has been the incompatibility of biosafety capacity-building with the development of the technology. China suggested that the Secretariat set up a support system for Parties to build their capacities for Protocol public awareness and mechanisms for public participation. China further suggested that an in-depth analysis of the first national reports could be a good measure of effectiveness of the Protocol and could bring out issues that need to be addressed.

15. Croatia noted its challenge of developing its technical and human resources for the implementation of the Protocol but suggested some indicators for the evaluation of the Protocol, including, *inter alia*: information submitted in the national reports; state of the BCH reports; increase in

subregional, regional, bilateral and multilateral cooperation concerning biosafety and genetically modified organism (GMO) issues; an increase in the number of fully developed national biosafety frameworks that are operational and absence of any cases of non-compliance.

16. The European Community (EC) also stated that a full-scale assessment of the Protocol for its effectiveness is particularly challenging at this time due to the fact that Parties are in an early phase of implementation. The EC further stated that an effective national implementation of the Protocol's procedures, mechanisms and annexes depends on fundamental capacities of Parties particularly in relation to risk assessment, risk management and sampling and detection. The EC noted that an evaluation of the Protocol's effectiveness should rather identify the extent to which the procedures and mechanisms established by the Protocol are effective in achieving the objectives set out in the Article 1 of the Protocol. It is also the view of the European Commission that discussions on the effectiveness of the Protocol should be supported by an expert study. Such a study should develop a sound methodological approach to evaluate the effectiveness of the Protocol and its processes. On the question of indicators, the EC supports developing and testing a small pilot set of meaningful indicators as part of the suggested study so as to enable Parties to better consider appropriate indicators.

17. In its submission, India stated that currently it is neither an importer nor an exporter of LMOs except for the purposes of research and contained use. India noted that in the absence of experience in the application of the advance informed agreement (AIA) procedure and the procedure for LMOs intended for direct use for food, feed and processing (LMOs-FFP), the effectiveness of the Protocol cannot be assessed at this stage. India noted that it is, however, aware of its obligations should it become an importer or exporter and, therefore, is taking the necessary measures to strengthen its institutional capabilities, develop its infrastructure and enhance the core competence of personnel. India suggested some indicators/criteria that could be used in evaluating the effectiveness of the Protocol such as: (a) whether Parties have put in place the required domestic, legal and administrative measures consistent with the procedures, mechanisms under the Protocol; (b) whether a Party is an exporter/importer of LMOs (effectiveness of the Protocol can be evaluated only when a country has enough experience of importing or exporting LMOs; there should be a separate pro forma for countries having experience as importers or exporters); (c) capacity and financial resources required for implementing the legal and administrative measures; (d) whether BCH is serving its intended purpose in providing enough information; (e) whether there is a technical competence to certify the presence of LMOs in transboundary movement. India concluded that the effectiveness of the Protocol may be evaluated in terms of time vis-à-vis short term, medium term and long term.

18. New Zealand, in its submission, stated that it has not granted regulatory approval for any intentional transboundary movement of LMOs intended for introduction into the environment of the Party of import, nor for import for introduction into its own environment. Similarly, regulatory approval has not been granted for any intentional transboundary movement of LMOs intended for use as food, feed or for processing in the Party of import, nor for import for use as food, feed or for processing in New Zealand. New Zealand, therefore, has no practical experience in implementing Articles 7 through 12 of the Protocol, or in the application of the information requirements under annex I or annex II. New Zealand noted, however, that its regulatory framework provides for decision making consistent with the obligations of Parties under the Protocol. The regulatory systems apply equally to Parties and non-Parties alike, both for import and for export, with no distinction in the way in which the legislation applies. All import and domestic use decisions regarding LMOs are made on the basis of risk-assessment principles that are fully consistent with the requirements under the Protocol, particularly in relation to annex III.

19. A particular challenge in implementing the Protocol for New Zealand is the back-capturing of information on decisions with their associated risk-assessment reports for populating the BCH. In New Zealand's experience in adopting a comprehensive approach to capturing the necessary information,

populating the BCH has not in itself proved troublesome; however, resource constraints effectively limit the ability of officials to proactively back-capture information generated through domestic decision-making processes before the entry into force of the Protocol. Further, New Zealand noted that since some Parties are constrained in accessing the information on the BCH as noted in decision BS-I/3 and also in their interpretation, the situation has the potential to undermine the BCH as a mechanism to facilitate the exchange of information on, and experience with, LMOs for the purposes of assisting Parties to implement the Protocol. New Zealand is of the view that a surplus of information may hamper the ability of Parties to extract the particular information of value for their own specific needs, which may in turn undermine the effective implementation of the Protocol.

20. New Zealand considers evaluation of the BCH by Parties as it currently operates as a tool for assessing the effectiveness of the Protocol since information provided in a manner that is not readily accessible or applicable to Parties seeking to retrieve and utilize that information in their decision making, may in practice not make the BCH meet its envisaged purpose or objective.

21. In its submission, Norway indicated that the effectiveness of the Protocol does not only depend on whether and how it is implemented in national legislation but to a large extent on how the legislation is applied. It was further stated that the capacity and capacity-building measures – in particular risk assessment, risk management and sampling and detection – are crucial and may take time to develop. Norway is of the view that since the Protocol is still in its initial implementation phase, it may be difficult to assess its effectiveness. It is the view of Norway that even though the implementation measures are reported by Parties in their first national reports, the scope of evaluation of the Protocol is wider than the factual description of measures. Norway, therefore, indicates that it has limited possibility to evaluate the effectiveness of the Protocol because there has neither been field trial of LMOs in Norway, nor export of LMOs from Norway, nor import of LMOs for release into the environment or for direct use as food, feed or for processing. It indicates that it has limited experience in importing LMOs for contained use.

22. Norway, therefore, advocates a study by experts in order to thoroughly assess the effectiveness of the Protocol and to provide valuable inputs to discussions in this regard. The study, it is recommended, should include the development of an appropriate methodology in order to obtain information and general results. Norway, however, expresses its recognition of the adequacy of the general principles and methodologies for risk assessment as contained in annex III to the Protocol for emerging applications of modern biotechnology such as transgenic fish, trees, viruses and pharmaplants as pointed out recently at a workshop on risk assessment, sponsored and conducted by Canada and Norway. (The report of the workshop is made available in document UNEP/CBD/BS/COP-MOP/4/INF/13.)

23. Canada, in its submission, admitted that it has not implemented the processes and procedures of the Protocol but has a regulatory system that seeks to achieve the same objective as the Cartagena Protocol on Biosafety, that is, the protection of biodiversity. It noted, however, that with the undesirably low levels of implementation of Protocol obligations among Parties, it is very difficult to properly assess the Protocol's effectiveness on a comprehensive basis. Canada believes that the Biosafety Clearing-House has the potential to be an effective means by which both Parties and non-Parties can share information about LMOs. Thus, a high level of compliance and timely compliance with the BCH notification requirements by Parties would be one measure of the Protocol's effectiveness.

24. Canada believes that the Protocol's success in protecting global biodiversity is dependent on the development of clear, consistent implementation procedures for the provisions of the Protocol. The overarching consideration being to provide predictability and certainty.

25. The United States of America also acknowledges that information and experience available indicate that many Parties are still at the early stages of developing and implementing their national biosafety frameworks. The United States noted that the BCH shows only two records of decisions made

under the advance informed agreement (AIA) procedure and that 31 Parties and other Governments have posted over 500 decisions on LMOs-FFP, indicating that many Parties have not implemented their obligations under the Protocol. The United States, therefore, agrees with the Parties' conclusion in decision BS-III/15 that the lack of implementation may not be due to inherent problems with the Protocol, but with a lack of capacity to implement the Protocol.

26. The United States further observes that under the decision-making procedures and mechanisms of the Protocol, the overwhelming majority of decisions that have been reported to the BCH are related to LMOs-FFP, as opposed to decisions related to LMOs intended for environmental release or contained use. In its view, this record indicates a focus on commodity trade that underscores the importance of implementing the Protocol in a way that is not unnecessarily disruptive to trade.

III. EXPERIENCES ON THE IMPLEMENTATION OF THE PROTOCOL AS DERIVED FROM THE REVIEW OF THE FIRST NATIONAL REPORTS

A. Implementation of the Protocol in general

27. Practical experiences of Parties in the implementation of the Protocol form the primary basis for evaluating the effectiveness of the Protocol. Biosafety-related systems and procedures are still evolving in the national jurisdiction of several of the Parties to the Protocol, especially in developing country Parties. The Secretariat has received and analyzed reports on the implementation of the Protocol from some 50 Parties and two non-Parties (the full analysis of the national reports is made available in document UNEP/CBD/BS/COP-MOP/4/13).

28. As a first step towards implementing any international legal instrument, Parties need to put in place their domestic administrative and legislative arrangements, which are expected to be in compliance with the international legal instrument, in this case, the Cartagena Protocol on Biosafety. A review of the first national reports indicates that quite a number of Parties, especially developing country Parties are still at various levels of implementation that could be considered a preparatory phase towards the full implementation of the Protocol.

29. The analysis of the first national reports, with the sample size of only 50 respondent Parties and 2 other Governments, i.e. 35 per cent of the Parties to the Protocol, shows that at the global level, 57 per cent have indicated having a full domestic regulatory framework in place. Out of the remaining 43 per cent of respondent Parties, 28 per cent reported having in place a limited level of measures, and 15 per cent none at all as at the time of the report.

30. The first national reports analysed on a regional basis indicated that with the exception of the Western Europe and Others Group (WEOG), in which 100 per cent of respondents reported having a full domestic regulatory framework in place, all the other regional groups acknowledged significant gaps regarding the introduction of the necessary legal, administrative and other measures required to implement the Protocol. In particular, no respondent from the GRULAC region reported having a full domestic regulatory framework in place. In all of the developing country groups, between 17 and 22 per cent of respondents indicated that no measures have as yet been instituted. Many countries from Africa and Asia-Pacific reported that draft biosafety laws and regulations are currently emerging under their national biosafety frameworks supported by the United Nations Environment Programme and the Global Environment Facility (UNEP-GEF) projects.

31. The low level of both administrative and institutional structures in place in developing country Parties suggests a lack of effective implementation of the Protocol due to lack of capacity rather than an inherent weakness in the Protocol itself.

B. The decision-making procedures and mechanisms adopted in accordance with paragraph 7 of Article 10: the advance informed agreement procedure

32. The advance informed agreement procedure applies to the first intentional transboundary movement of a specific LMO into the jurisdiction of a Party of import for intentional introduction into the environment. The procedure allows for the Party of import to decide whether or not it will authorize the import or impose any conditions. Approximately 37 per cent of the respondent Parties identified themselves as Parties of import while only 10 per cent of the respondent Parties considered themselves as Parties of export.

33. In finding out the level of application of the AIA procedure regarding imports under domestic regulatory frameworks as allowed by Article 9.2 (c), only twenty-two percent (22 per cent) of respondent Parties indicated that they have made such decisions. Of these, 50 per cent were from WEOG, 20 per cent from Asia-Pacific, 20 per cent from GRULAC, 9 per cent from CEE and 6 per cent from Africa, indicating a low level of application of the procedure.

34. In the category of Parties that have been exporters of LMOs intended for release into the environment and asked to describe their experiences and progress in implementing Articles 7 to 10 and Article 12 of the Protocol, including any obstacles or impediments encountered, none of the countries reporting from Africa, Asia-Pacific, and CEE have been Parties of export in the reporting period. One Party from GRULAC reported exporting to a non-Party. One Party from WEOG indicated that difficulties arose "in the semantic interpretation of some requirements of the Protocol", particularly with respect to annex I, which specifies information required in notifications under Articles 8, 10 and 13. Another WEOG country reported that consent for import and release into the environment for the purpose of field trials has been granted for 6 notifications (and that no obstacles were reported in the process).

35. On the question of experiences and progress in implementing Articles 7 to 10 and Article 12 for imports of LMOs intended for release into the environment, again, no African countries reported having taken decisions on import and one Party reported having received "several requests for confined field trials of LMOs", but in all occasions they "had to request for more information from the applicant as the first submissions were deemed insufficient". As a result, two confined field trials were approved with conditions, one rejected and the other is still under review. Some Parties from GRULAC reported going through decision processes consistent with both the objective of the Protocol and their national legislation for importation from non-Parties. There were no decisions reported from Asia-Pacific but one Party reported that obstacles faced "include inadequate information sharing of imported LMOs, shortage of testing technical standards, reference standards and reference materials". Most Parties from the CEE and WEOG reported that these decisions are taken at the EU level (i.e., under the EU's domestic regulatory framework and in place of the advance informed agreement procedure) and that only decisions relating to LMOs that are not for the purpose of placing on the market are taken at the national level. One of the Parties from the CEE reported that between 2004-2007 "14 written authorizations have been issued by the national competent authority for import of GM maize, barley and tobacco seeds for experimental release".

36. Overall, the experience with the advance informed agreement procedure as stipulated in the Protocol or with a comparative procedure provided for under domestic regulatory frameworks has generally been minimal. This in turn, shows the non-application of the guidelines, mechanisms and the additional procedures specified in the annex to decision BS-I/2 adopted in order to facilitate decision making by Parties of import in the context of paragraph 7 of Article 10 of the Protocol.

C. Procedure for living modified organisms intended for direct use as food or feed, or for processing (LMOs-FFP)

37. Article 11 of the Protocol establishes a specific procedure for the transboundary movement of LMOs-FFP whereby a Party must inform other Parties through the Biosafety Clearing-House, within fifteen days, of its final decision regarding domestic use of LMOs that may be subject to transboundary movement. The majority of respondents (63 per cent) indicated in their first national reports that there is a legal requirement for the accuracy of information provided by the applicant with respect to the domestic use of an LMO that may be subject to transboundary movement for direct use as food or feed, or for processing (FFP) (paragraph 2, Article 11).

38. With the exception of WEOG countries, all groups reported having indicated their needs for financial and technical assistance and capacity-building in respect of LMOs-FFP (Article 11, paragraph 9). Approximately 25 per cent of the respondent Parties indicated taking decisions regarding import under domestic regulatory frameworks (Article 11, paragraph 4) while another 25 per cent of respondents reported not taking any decision. A significant group of respondent Parties (49 per cent) reported that the question was not applicable or that no decisions were taken during the reporting period with the Africa region having the highest percentage (71 per cent).

39. When the respondent countries were asked if they have been a Party of export of LMOs intended for direct use for FFP and to describe their experiences and progress in implementing Article 11, including any obstacles or impediments encountered, none of the countries from any of the regions reported having been such a Party of export. On the question of being a Party of import of LMOs intended for direct use for FFP and to comment on their experiences and progress in implementing Article 11, including any obstacles or impediments encountered, most reporting countries from Africa indicated that they have not been Parties of import during the period under review. One African country highlighted the following obstacles: "(i) information/documents accompanying import contradictory (LMO and not LMO); (ii) non compliance by importers of the existing regulations due to ignorance; (iii) decision taking on the matter across at least two ministries delays work; (iv) payment for laboratory analysis delayed due to lack of funding; and (v) confidentiality of opinions by officials was not guaranteed". Another reported that LMO-FFPs were being imported in violation of Article 11 of the Protocol because the provision has not yet been implemented.

40. Two Parties in GRULAC reported LMO imports for FFP and one stated that the mechanism for enforcing and monitoring the implementation of the national legislation for this type of import is still under development and not yet in force. One Party from Asia-Pacific reported that it had imported "annually scores of million tons of genetically modified soybean and corn for processing and for animal feed" in accordance with regulations and statutes requiring "detailed and accurate information". The same country identified technical problems related to "risk assessment, defining threshold for limit, effective identification and traceability". One Party from CEE that acceded to the EU reported it had "imported approximately 8 million tons of soybeans as a feed component that may have contained GMOs".

D. Information sharing through the Biosafety Clearing-House

41. The mechanism of information sharing through the Biosafety Clearing-House is crucial for the effective implementation of the Protocol. The analysis revealed that many countries are in the process of developing their national biosafety frameworks and biosafety databases and websites and hope that upon completion of those projects, they would be in a better position to provide all necessary information required under the Protocol to the Biosafety Clearing-House. The lack of in-country mechanisms for gathering the necessary information coupled with the lack of both financial and technical resources have also been identified as contributory factors to the low level of information available in the Biosafety

Clearing-House. However, as indicated by New Zealand (see para. 19 above), concerns exist about how Parties can effectively use the data available in the Biosafety Clearing-House.

42. According to the analysis of the first national reports, at the global level, only 28 per cent of the information required under the Protocol is reported to exist and has been provided to the Biosafety Clearing-House. Furthermore, 64 per cent of the information either does not exist or is inapplicable. However, only 8 per cent of the respondents indicated that the information exists but has not yet been provided.

IV. VIEWS REGARDING THE REVIEW OF THE EFFECTIVENESS OF THE PROCEDURES AND MECHANISMS FOR COMPLIANCE

43. Parties were of the view that since there have been no individual cases of non-compliance referred to the Compliance Committee to date for consideration, and consequently, there have not been any "cases of repeated non-compliance", the adequacy of the current rules cannot be assessed.

44. As regards rule 18 of the rules of procedure of the Compliance Committee, a responding Party was of the view that, in the same vein, since no individual cases of non-compliance have been referred to the Compliance Committee, the rule cannot currently be assessed either. In the Party's opinion, since the overall decision-making rule for the meeting of the Parties is by consensus, a similar rule is most appropriate for a subsidiary body such as the Compliance Committee.

45. The Compliance Committee considered the question of evaluation of effectiveness of the compliance procedures and mechanisms at its third and fourth meetings. The Committee noted that no cases of non-compliance had been submitted to it regardless of the fact that several Parties are still facing difficulties in implementing their obligations under the Protocol. In the opinion of the Committee, this lack of submissions could be attributed to the procedure for triggering the compliance procedures (decision BS-I/7, annex, section IV). In that context, the Committee agreed at its fourth meeting to recommend to the fourth meeting of the Parties to the Protocol that the latter request Parties and other Governments to submit views and information on the lack of submissions by Parties with respect to themselves under section IV of the annex to decision BS-I/7, and to request the Committee to make observations and suggestions, on the basis of these views and information, on how to make better use of the compliance procedures with a view towards improving the implementation of the Protocol, taking also into account experiences of compliance mechanisms under other multilateral environmental agreements.

V. SYNTHESIS OF FURTHER INFORMATION ON EXPERIENCE GAINED WITH THE USE OF EXISTING DOCUMENTATION TO FULFIL THE IDENTIFICATION REQUIREMENTS OF PARAGRAPHS 2(b) AND 2(c) OF ARTICLE 18

46. At their third meeting, the Parties to the Protocol considered a synthesis document on experience gained with the use of documentation to fulfil the identification requirements of paragraphs 2(b) and 2(c) of Article 18 as prepared by the Executive Secretary on the basis of submissions received from Parties, other Governments and relevant international organizations. In decision BS-III/8, the Parties requested Parties and invited other Governments and relevant international organizations to submit further information on experience gained with the use of a commercial invoice or other documents required or utilized by existing documentation systems, or pursuant to national requirements with a view to future consideration of a stand-alone document. The Executive Secretary was requested to compile the information received and prepare a synthesis report for consideration in the context of the process of review of the implementation of the Protocol as provided for in Article 35.

47. By 18 December 2007, submissions had been received from China, Colombia, Lithuania, Norway, and South Africa, and from the Governments of Canada and the United States of America. The Global Industry Coalition and the Public Research and Regulation Initiative also made submissions. Any submissions received after this date are not considered in the synthesis below but are contained in the compilation of submissions which is made available as an information document (UNEP/CBD/BS/COP MOP/4/INF/10/Add.1).

48. As outlined above, there has been a previous request and invitation for the submission of information related to paragraphs 2(b) and 2(c) of Article 18 and so some of the submissions received are similar to earlier submissions on this subject.

49. In its submission, China stated that it has followed all relevant standards and technical specifications of the International Organization for Standardization (ISO) and the Codex Alimentarius Commission in the process of managing the safety of the transboundary movements of living modified organisms. The Regulations on Risk Management of Living Modified Organisms, the Regulations on Labelling of Agricultural Living Modified Organisms, and the Measures for Inspection and Quarantine of the Import and Export of Living Modified Organisms have all served to regulate the transportation, packaging and labelling of living modified organisms.

50. Colombia's submission spoke to its experience with documentation for the importation of material intended for direct use as food or feed, or for processing. This information has been included in this synthesis given its relevance to paragraphs 2(b) and 2(c) of Article 18 as well. Colombia indicated that officials from the *Instituto Nacional de Vigilancia de Medicamentos y Alimentos* of the *Ministerio de la Protección Social* (INVIMA) verify commercial invoices and import documentation when necessary as part of the process for importing food and raw materials for the food industry into the country. INVIMA officials are located at points of entry to Colombia and their verification of commercial invoices takes place after the health inspection of the certificate for nationalization.

51. Colombia also stated that with regard to LMOs for direct use as food or feed, or for processing under Article 11 of the Protocol, the country has not to date been verifying commercial invoices at the point of first entry. However, the country is in the process of adopting rules for the implementation of paragraph 2(a) of Article 18, which will be followed up by a procedure to be used by INVIMA officials.

52. Lithuania stated that in implementing Article 18 in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, it has a requirement for exporters and importers to inform the competent authority in transport documentation of living modified organisms. At the same time, however, Lithuania has not yet gained any experience with the use of a commercial invoice or other documents required or utilized by the existing documentation system.

53. Norway referred to its first regular national report on the implementation of the Protocol and the description contained therein of the country's requirements regarding the documentation that accompanies living modified organisms destined for contained use or for intentional introduction into the environment. Norway also stated that its experience with activities involving the transport, import and export of living modified organisms for contained use or intentional introduction into the environment and the documentation accompanying such living modified organisms is limited. The country has, for the time being, chosen not to establish a standard format for transport documents accompanying living modified organisms for intentional introduction into the environment in the form of marketing.

54. Norway's submission also referred to its two submissions on this issue for previous meetings of the Parties, stating that the country's position has consistently been that the identification and documentation requirements under paragraph 2 of Article 18 of the Protocol should be that such

identification and documentation should be as detailed, clear and informative as possible and be conveyed in a manner that is easy to find and understand, both in relation to the content of the information and the way it is presented, in order to allow importing countries to verify that the imported living modified organisms are those they agreed to import. Norway reiterated its view that the Parties to the Protocol should establish a standard format for transport documents, preferably in the form of a stand-alone document, to fulfil the requirements of paragraphs 2(b) and 2(c) of Article 18. It was stated that a standard format would make it easier for traders in living modified organisms to fulfil the information requirements of the Protocol. Norway's submission included examples of templates for transport documentation in accordance with paragraphs 2(a), (b) and (c) of Article 18 of the Protocol.

55. In its submission, South Africa stated that it makes use of existing documentation for living modified organisms intended for contained use or intentional introduction into the environment. This documentation takes the form of a permit, which, according to South Africa, is intended to limit the burden of additional bureaucracy that could negatively impact on trade. Permits are issued under South African legislation (the Genetically Modified Organisms Act) and accompany consignments of living modified organisms for contained use and intentional introduction into the environment. South Africa indicated that all requirements pertaining to the safe handling, transport, packaging and identification of living modified organisms have been incorporated into existing permits in the form of permit conditions.

56. Canada indicated that, in its experience, most countries have either not implemented documentation requirements under paragraphs 2(b) and 2(c) of Articles 18 or have only recently implemented them. Canadian regulatory requirements for living modified organisms vary according to the product and the end use and are implemented in accordance with Canada's domestic regulatory framework. Canada felt that it was difficult to provide views or relate experience on the use of a commercial invoice or other documents as there has been little practical application of the documentation requirements. It stated that it would welcome a further opportunity to provide feedback on the implementation of the requirements under paragraph 2 of Article 18 and suggested that Parties and non-Parties be given further opportunity to comment on the requirements of this paragraph at the fifth meeting of the Parties to the Protocol.

57. The United States of America expressed its belief that the documentation in common commercial practices for living modified organisms for contained use or intentional introduction into the environment is sufficient to ensure the safety of the environment and the protection of biodiversity. These practices, according to the submission, are well established and recognized by both public and private sectors involved in the transboundary movement of the LMOs in question. The submission further pointed out that invoices that contain information concerning the cargo and handling procedures have functioned well and have not led to any reported adverse incidents. Therefore, no additional requirement is justified as it would have the potential to create a needless burden and would likely compromise existing and well functioning procedures that are already Protocol-compliant.

58. The submission also emphasized the importance of good communications between the import and export communities as well as between these two communities and national authorities. In this regard, the submission indicated that communication between national authorities and those entities that are shipping living modified materials would greatly be facilitated by taking full advantage of the Biosafety Clearing-House to make available national laws, regulations and guidelines concerning requirements for living modified organisms destined for contained use and for intentional introduction into the environment.

59. The submission from the Global Industry Coalition (GIC) stated that users and developers of biotechnology include the information required to identify shipments of living modified organisms for contained use and living modified organisms for intentional introduction into the environment on existing shipping documents such as commercial or pro forma invoices and avoid unnecessary duplication of

information. The submission indicates that commercial or pro forma invoices have been used by the private and public sector to move biological material for many years and, therefore, are well recognized by customs officials. It argued that since the existing documents such as the invoices already contain most of the information required by paragraphs 2(b) and 2(c) of Article 18, the adjustments that are needed to comply with the Protocol are minimal and can be done through the addition of only a small amount of text. Indeed, the submission referred to efforts by the GIC to develop guidance for implementation of the documentation requirements, which led to the necessary modifications being made to the existing documents since the time of the entry into force of the Protocol. Furthermore, the submission also contains, as an annex, examples of how the language required by paragraphs 2(b) and 2(c) of Article 18 of the Protocol can be included in existing shipping documentation.

60. The GIC submission pointed out that a survey of its members and those of the International Seed Federation found that the members have been applying the GIC guidance developed for the purpose of documentation to accompany shipments of living modified organisms for contained use and living modified organisms for intentional introduction into the environment. Shipments using the guidance are taking place regularly and without incident. GIC believes that the use of a stand-alone document would result in duplication of information that already exists on commercial and pro forma invoices.

61. The submission recommended that Parties to the Protocol continue to accept shipments of living modified organisms for contained use and living modified organisms for intentional introduction into the environment that are accompanied by existing documentation as long as such documentation includes the additional requirements of paragraphs 2(b) and 2(c) of Article 18 as indicated in the guidance document developed by the GIC. This approach, according to the submission, avoids potential delays and allows for the continued transboundary movement of living modified organisms. The GIC, therefore, is of the view that there is no need for a stand-alone document and calls upon Parties to rather focus on clarifying national requirements for the import of living modified organisms by posting clear information on the Biosafety Clearing-House and to engage in outreach and education efforts to ensure awareness of and compliance with Protocol documentation and identification requirements.

62. The Public Research and Regulation Initiative (PRRI) highlights that biotechnology researchers are accustomed to taking care of the handling, transport, packaging and identification of all kinds of organisms, including living modified organisms, as part of their work. The submission stated that packaging, handling and labelling must frequently take into account requirements from different regulations and guidelines as well as the need to carefully protect the organisms concerned from outside influences and contamination. PRRI believes that existing documentation systems in combination with the guidance provided by the Conference of the Parties serving as the meeting of the Parties to the Protocol, at its first meeting, are sufficient and that further documentation requirements are not necessary at this stage.

VI. POSSIBLE MODALITIES FOR PURSUING FURTHER THE CURRENT PROCESS TO UNDERTAKE AN EVALUATION OF THE EFFECTIVENESS OF THE PROTOCOL

63. Analysis of the first national reports and information received from Parties and other Governments through the questionnaire indicates the complexity of the issues involved in the process and the contents of evaluating the effectiveness of the Protocol. The complexity is further deepened by the various stages of implementation of the Protocol by Parties. Notwithstanding the divergent issues involved in such an evaluation, the meeting of the Parties to the Protocol is required by Article 35 of the Protocol to conduct an evaluation of the effectiveness of the Protocol in contributing to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs 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.

64. Some suggestions made by the respondent Parties and other Governments to the questionnaire point to the development of possible indicators that could be applied to evaluating the effectiveness of the Protocol, including: information provided to the BCH; surveys/reports requested from Parties on the difficulties encountered in implementing the Protocol; compatibility of country legislation with the tenets of the Protocol; and level of institutional support mechanisms for the Protocol within Parties.

65. One Government suggested, in its response, that the indicators for evaluating effectiveness of the Protocol should focus on the impact of transboundary movements of LMOs on biodiversity, before and after implementation of the Protocol by Parties. The suggestion of the Government on the modality of the evaluation is that it could take the form of data gathering through a detailed questionnaire on each agreed indicator followed by a detailed analysis. Some indicators suggested by the Government include: ecological data, level of compliance of submission to the BCH (e.g., number of AIA and FFP submissions and decisions [pre- and post-Protocol], availability of information on risk assessment, management and decisions, notifications of unintentional transboundary movements); incorporation of indicators from the Action Plan for Building Capacities for the Effective Implementation of the Protocol (including establishment of national competent authorities and focal points, risk-assessment/risk-management procedures, operational BCH and incorporation of biosafety into national agenda); detailed Party reports on applications of the documentation provisions.

66. On the modalities of evaluation, it was suggested by a Party that a study by experts could give a real insight into the issue of measuring effectiveness of the Protocol. It was recommended that such a study develop the methodology that could obtain factual and general results. Such a study should develop a sound methodological approach to evaluate the effectiveness of the Protocol, its procedures and mechanisms and apply this suggested approach drawing from information provided by Parties in their national reports; views expressed in responding to this questionnaire; the report of the Compliance Committee; and further information gathered from relevant stakeholders.

67. Alternatively, the Parties to the Protocol may consider the establishment of an ad hoc technical expert group on assessment and review that would be convened by the Executive Secretary to assess the Protocol, on the basis of the synthesis of views prepared by the Secretariat, and other relevant sources of information in order to meet the obligations of Parties under Article 35 for a realistic and useful outcome.

68. While the assessment and review process is set up, the Parties to the Protocol may wish to integrate in the process the overall review of the medium-term programme of work and the development of a long-term strategic plan for the Protocol, which will have built-in milestones for effective implementation and which could be adopted at the Parties' fifth meeting, in 2010.

69. Therefore, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety may wish to proceed with fulfilling the task set out in Article 35 by establishing a process on the basis of a clear understanding of the issues involved and a modality that would facilitate the achievement of a realistic and useful outcome.

VII. ELEMENTS OF A DRAFT DECISION

70. The Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider the following elements in developing and adopting its decision under this agenda item:

(a) On possible modalities for undertaking the evaluation of the Protocol

(i) Take note of the considerations highlighted in the views on assessment and review of the Protocol by the Parties and other Governments in the present document that may be taken into account in initiating a process of evaluation of the effectiveness of the Protocol;

(ii) Consider the suggestions on the experiences from the implementation of the Protocol as reviewed from the first national reports as reviewed above, with a view to determining the most appropriate modality of a process to undertake the evaluation of the effectiveness of the Protocol, its annexes, procedures and mechanisms as required by Article 35;

(iii) Consider to engage or assign: (i) an independent consultant; or (ii) an ad hoc technical expert group to assess and review the effectiveness of the Protocol on the basis of the information contained in this document and specific criteria or indicators that need to be developed or adopted.

(b) Regarding compliance procedures and mechanisms

Consider and adopt, as appropriate, the following recommendation of the Compliance Committee:

"Request Parties to submit views and information on the lack of submissions relating to compliance by Parties with respect to themselves under section IV of the procedures and mechanisms on compliance under the Protocol (decision BS-I/7, annex) and to *further request* the Committee to make observations and suggestions, on the basis of these views and information, on how to make better use of the compliance procedures with a view towards improving the implementation of the Protocol, taking also into account experiences of the compliance mechanisms under other multilateral environmental agreements" (paragraph 5, annex, Report of the Compliance Committee Under the Cartagena Protocol on Biosafety, document UNEP/CBD/BS/COP-MOP/4/2).

(c) Concerning experience in the use of existing documentation accompanying living modified organisms for contained use and those for intentional introduction into the environment (paragraphs 2(b) and 2(c) of Article 18)

Considering the synthesis in section V above, determine whether the experience gained so far in the use of existing documents such as commercial invoices provides sufficient basis to take a decision on the need for a stand-alone document; or alternatively request Parties and encourage other Governments and relevant international organizations to continue to implement the requirements under paragraphs 2(b) and 2(c) of Article 18 and associated decisions by the Conference of the Parties serving as the meeting of the Parties to the Protocol, and defer any further discussion on the matter until the review of experience based on analysis of second national reports.
