





## Convention on Biological Diversity

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COMPLIANCE COMMITTEE UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY
Thirteenth meeting

Thirteenth meeting Montreal, Canada, 24-26 February 2016

### REPORT OF THE COMPLIANCE COMMITTEE UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY ON THE WORK OF ITS THIRTEENTH MEETING

#### **INTRODUCTION**

- 1. The thirteenth meeting of the Compliance Committee was held on the premises of the Secretariat in Montreal, Canada, from 24 to 26 February 2016.
- 2. The following members of the Committee were present:

#### Africa:

Ms. Kaouthar Tliche Aloui Ms. Martha Kandawa-Schulz

Mr. Johansen Voker

Latin America and the Caribbean:

Mr. Héctor Conde Almeida Ms. Jimena Nieto Carrasco Ms. Sol Ortiz García

#### Asia and the Pacific:

Mr. Seung-Hwan Choi Mr. Banpot Napompeth

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#### Western Europe and Others:

Mr. Ruben Dekker Mrs. Clare Hamilton

#### **Central and Eastern Europe:**

Mr. Martin Batic Ms. Angela Lozan Ms. Dubravka Stepic

#### ITEM 1. OPENING OF THE MEETING

- 3. Ms. Jimena Nieto Carrasco, Chair of the Committee, opened the meeting at 9.30 a.m. on 24 February 2016. She welcomed the participants and thanked the Secretariat for facilitating the organization of the meeting.
- 4. On behalf of the Executive Secretary, the Principal Officer for Biosafety welcomed members and introduced the new Legal Officer, who had joined the Biosafety unit in September 2015. He also paid tribute to the Senior Legal Officer, Mr. Worku Yifru, who had served the Compliance Committee since its inception with great distinction. In his remarks, the Principal Officer noted that the Committee had a substantial number of items on the agenda for its current meeting, and he drew particular attention to the importance of the Committee's input to the third assessment and review of the Protocol and mid-term evaluation of the Strategic Plan.

- 5. The representative of the Secretariat reported that two members of the Committee, Mr. Rai Rana from the Asia-Pacific region and Mr. Geoff Ridley from WEOG, were not able to attend the meeting. He confirmed that, with 13 members present, there was a quorum for the meeting to proceed in accordance with rule 16 of the Committee's rules of procedure.
- 6. The Secretariat recalled that the Committee had previously decided to hold its thirteenth meeting in conjunction with the meeting of the Liaison Group on Capacity-building in order to achieve consistency in the contributions of the Group and the input of the Committee to be forwarded to the Subsidiary Body on Implementation (SBI) in the context of the third assessment and review and the mid-term evaluation of the Strategic Plan. Ultimately, however, it had not been possible due to the need to postpone the meeting of the Liaison Group to allow sufficient time to prepare the analysis to be considered by the Group for their contribution to the third assessment and review and mid-term evaluation of the Strategic Plan.

#### ITEM 2. ORGANIZATIONAL MATTERS

#### 2.1. Adoption of the agenda

- 7. The Committee adopted the following agenda on the basis of the provisional agenda (UNEP/CBD/BS/CC/13/1) prepared by the Secretariat:
  - 1. Opening of the meeting.
  - 2. Organizational matters:
    - 2.1 Adoption of the agenda;
    - 2.2 Organization of work.
  - 3. Review of compliance with the obligation to submit national reports and whether the information in the reports is complete.
  - 4. Evaluation of the status of implementation of the Protocol in meeting its objectives: input to the third assessment and review and the mid-term evaluation of the Strategic Plan.
  - 5. Review of general issues of compliance.
  - 6. Clarifications on what constitutes unintentional transboundary movement in contrast with illegal transboundary movement.
  - 7. Report and recommendations of the Committee to the Conference of the Parties serving as the meeting of the Parties to the Protocol at its eighth meeting.
  - 8. Other matters.
  - 9. Adoption of the report.
  - 10. Closure of the meeting.

#### 2.2. Organization of work

8. The Committee agreed on the organization of its work as proposed by the Secretariat, as specified in annex I to the annotations to the provisional agenda (<u>UNEP/CBD/BS/CC/13/1/Add.1</u>). The Committee agreed to consider the information documents prepared for this meeting under the agenda item "other matters" if possible before agenda item 7, to allow any outcomes of the discussion to be included in the report of the Committee to be submitted to the Conference of the Parties serving as the meeting of the Parties to the Protocol at its eighth meeting.

## ITEM 3. REVIEW OF COMPLIANCE WITH THE OBLIGATION TO SUBMIT NATIONAL REPORTS AND WHETHER THE INFORMATION IN THE REPORTS IS COMPLETE

- 9. Introducing the item, the representative of the Secretariat outlined the structure and content of the note by the Executive Secretary (<u>UNEP/CBD/BS/CC/13/2</u>). He noted that, following the preparation of the document, additional third national reports had been received, raising the total to 112. He informed the Committee that the Secretariat was in communication with Parties that had submitted incomplete national reports. He drew the attention of the Committee to the suggestions contained in section III of the document.
- 10. The Chair invited members to provide comments on the document, in particular the suggestions submitted for the consideration of the Committee. The Committee:
- (a) Expressed concern about the lower rate of submission of the third national reports in comparison with the previous reporting cycle;
- (b) Welcomed the funds that had once again been made available by GEF to a number of eligible Parties to support the preparation of their national reports but noted with concern that 39 Parties that were eligible for GEF funding to complete their national reports either had not applied for those funds or were unable to access them;
- (c) Noted with regret that administrative changes within the United Nations had created systems challenges that had resulted in delays for a number of eligible Parties in accessing funding, and also noted that the issue had caused difficulties for a number of Parties in fulfilling their obligations under the Protocol, for example as regards submission of their third national reports;
- (d) Noted with concern that third national reports were still due from 58 Parties, including 12 Parties that had accessed GEF funds for the preparation of their third national reports;
- (e) Recognized that the efforts of the Committee and individual members had contributed positively to the high rate of submission of second national reports as well as reports that were long overdue:
- (f) Welcomed the efforts made by the Secretariat in assisting Parties in submitting national reports and ensuring their completeness;
- (g) Expressed profound concern, however, that Luxembourg, the Marshall Islands and Nicaragua had not submitted an interim, first, second or third report to date.

#### 11. The Committee:

- (a) Requested the Secretariat to follow up with the Parties that had not submitted a third national report;
- (b) Noted that there had been some anomalies in the ability of Parties to access the available GEF funds for the preparation of third national reports and requested the Secretariat to contact GEF and explore the reasons for this along with the possibility of extending the deadline;
- (c) Requested the Secretariat to keep the Committee informed of any issue with access to GEF funds that could adversely affect the ability of Parties to comply with their obligations under the Protocol:
- (d) Also requested the Secretariat to continue to liaise with the Parties that had submitted incomplete reports in order to draw their attention to the information gap in their reports and seek the necessary information;
- (e) Agreed that the Chair of the Committee would send a follow-up letter to the Foreign Ministries of Luxembourg, the Marshall Islands and Nicaragua, with a copy to their national focal points, with a view to seeking an explanation of the situation that has prevented them from submitting their interim, first, second or third report to date and informing them that the Committee would recommend to

the Conference of the Parties serving as the meeting of the Parties at its eighth meeting that it issue a caution to those Parties as provided for in section VI, paragraph 2(b), of the Procedures and Mechanisms on Compliance under the Cartagena Protocol on Biosafety as contained in the annex to decision BS-I/7, unless a response is received before the eighth meeting of the Conference of the Parties serving as the meeting of the Parties.

- 12. The Committee decided to recommend that, at its eighth meeting, the Conference of the Parties serving as the meeting of the Parties should:
- (a) Express concern about the lower rate of submission of third national reports in comparison with the previous reporting cycle, and note with concern that third national reports are still due from 58 Parties, including 12 Parties that have accessed GEF funds for the preparation of their third national reports;
- (b) Welcome the funds that have once again been made available by GEF to eligible Parties to support the preparation of their national reports but note with concern that 39 Parties that were eligible for GEF funding to complete their national reports either did not apply for those funds or were unable to access them;
- (c) Note with regret that administrative changes within the United Nations created systems challenges that resulted in delays for a number of eligible Parties in accessing funding, and further note that this has caused difficulties for a number of Parties in fulfilling their obligations under the Protocol, for example as regards submission of their third national reports;
- (d) Welcome the efforts made by the Secretariat in assisting Parties in submitting national reports and ensuring their completeness;
- (e) Urge the Parties that have not yet submitted their third national report to do so as soon as possible;<sup>1</sup>
- (f) Also urge the Parties that have not submitted a complete third national report to do so as soon as possible;
- (g) Issue a caution, in accordance with section VI, paragraph 2(b) of the Procedures and Mechanisms on Compliance under the Cartagena Protocol on Biosafety as contained in the annex to decision BS-I/7, to Luxembourg, the Marshall Islands and Nicaragua for their failure to submit an interim, first, second and third national report, in compliance with Article 33, as provided in annex I.

# ITEM 4. EVALUATION OF THE STATUS OF IMPLEMENTATION OF THE PROTOCOL IN MEETING ITS OBJECTIVES: INPUT TO THE THIRD ASSESSMENT AND REVIEW AND THE MID-TERM EVALUATION OF THE STRATEGIC PLAN

13. The Secretariat drew the attention of the Committee to the note by the Executive Secretary on the subject (<u>UNEP/CBD/BS/CC/13/3</u>), which analysed the responses from the third national reports and other appropriate sources against the baseline set in the second reporting cycle, provided an overview of the extent to which the information in the Biosafety Clearing-House (BCH) is reliable and up-to-date, and described the experience gained by the Committee in implementing its supportive role, within the scope decided on by the Committee at its previous meeting.

<sup>&</sup>lt;sup>1</sup> Afghanistan, Algeria, Angola, Antigua and Barbuda, Armenia, Azerbaijan, Bahrain, Barbados, Belize, Botswana, Cape Verde, Central African Republic, Comoros, Côte d'Ivoire, Democratic People's Republic of Korea, Djibouti, Ethiopia, El Salvador, Fiji, Greece, Guinea, Guyana, Jamaica, Jordan, Kiribati, Lebanon, Libya, Luxembourg, Malta, Marshall Islands, Mauritius, Montenegro, Mozambique, Myanmar, Nauru, Nicaragua, Niue, Oman, Pakistan, Palau, Papua New Guinea, Paraguay, Philippines, Qatar, Saint Vincent and the Grenadines, Samoa, Saudi Arabia, Serbia, Seychelles, Solomon Islands, Somalia, State of Palestine, Syrian Arab Republic, The Former Yugoslav Republic of Macedonia, Tonga, Trinidad and Tobago, Turkmenistan, Venezuela.

14. The Committee extensively discussed the information in the document, on the basis of which the Committee prepared its input to the third assessment and review and the mid-term evaluation of the Strategic Plan, which would be conducted by SBI. The input is contained in annex II to the present report. The Committee requested the Secretariat to finalize the input, including by adding relevant graphs, and to submit it to SBI for its consideration.

#### 15. The Committee:

- (a) Expressed appreciation for the comprehensive analysis provided in the document but noted that a few questions in the reporting format could be interpreted in different ways and that, as a result, the data per se might not always provide an accurate reflection of the state of implementation of the Protocol:
- (b) Acknowledged the lack of clear linkages between some outcomes and indicators in operational objective 3.1 of the Strategic Plan;
- (c) Expressed grave concern that, more than 12 years after the entry into force of the Protocol, only 51 per cent of Parties report having fully put in place national legal, administrative and other measures to implement the Protocol;
- (d) Recognized that there is a link between compliance and the availability of resources, and recognized the importance of availability of funding dedicated to biosafety and the need to ensure that GEF funds are made available for biosafety activities and capacity-building;
- (e) Noted the low number of Parties having made available to the BCH details of their national point of contact as required under Article 17 and recognized that Parties should be reminded of that obligation.
- 16. The Committee welcomed that some of its members would be present at the eleventh meeting of the Liaison Group on Capacity-building and at the first meeting of SBI to inform those bodies, where required and possible, of the Committee's input to the third assessment and review and mid-term evaluation of the Strategic Plan.
- 17. The Committee decided to recommend that, at its eighth meeting, the Conference of the Parties serving as the meeting of the Parties should:
- (a) Welcome progress made by Parties in complying with their obligations under the Protocol, yet note with concern that, 13 years after the entry into force of the Protocol, a number of Parties are not in full compliance in relation to most obligations under the Protocol;
- (b) Urge Parties that have not yet completely done so to put in place legal, administrative and other measures to implement their obligations under the Protocol, paying particular attention to the importance of putting in place monitoring systems as a prerequisite for effective reporting;
- (c) Also urge Parties that have not yet completely done so to make all required information available to the BCH and keep the records up-to-date, focusing in particular on information related to: (a) national biosafety frameworks, legislation, regulations and guidelines; (b) summaries of risk assessments; (c) final decisions regarding living modified organisms (LMOs) and living modified organisms intended for direct use as food or feed, or for processing (LMOs-FFP); (d) national focal points and national points of contact; (e) information on bilateral, regional or multilateral agreements or arrangements they have entered into with relevance for biosafety;
- (d) Recommend that the Conference of the Parties, in adopting its guidance to the financial mechanism, with respect to support for the implementation of the Cartagena Protocol on Biosafety, invite the Global Environment Facility to make specific funding available to eligible Parties to put in place their national biosafety frameworks;
- (e) Welcome the Committee's input to the assessment and review and mid-term evaluation, and request the Committee to continue providing inputs to the final evaluation of the Strategic Plan;

- (f) Welcome the Committee's supportive role, carried out pursuant to <u>decision BS-V/1</u>, as a contribution to the progress reported and request the Committee to continue carrying out its mandate accordingly;
- (g) Request the Secretariat, as appropriate and following guidance provided by the Committee, to continue following up with Parties that have not yet fully complied with their obligations under the Protocol, and to request Parties to collaborate fully in this regard.

## ITEM 5. REVIEW OF GENERAL ISSUES OF COMPLIANCE BASED ON THE ANALYSIS OF INFORMATION CONTAINED IN THE THIRD NATIONAL REPORTS

- 18. The Secretariat introduced the review of general issues of compliance based on the analysis of information contained in the third national reports (<u>UNEP/CBD/BS/CC/13/4</u>), in which four general issues of compliance were suggested on the basis of the analysis prepared for the Committee's input to the third assessment and review and mid-term evaluation of the Strategic Plan. Those general issues of compliance related to the obligations to: put in place legal, administrative and other measures necessary for the implementation of the Protocol; submit information to the BCH; monitor the implementation of obligations under the Protocol; and report on measures taken to implement the Protocol.
- 19. Committee members noted the overlap between the general issues of compliance and the input that the Committee was providing to the assessment and review and mid-term evaluation of the Strategic Plan. The Committee agreed that the general issues identified in the document for this agenda item had already been considered in the analysis for the input to SBI and addressed in associated recommendations to the Conference of the Parties serving as the meeting of the Parties under agenda item 4.
- 20. With regard to the information submitted to the BCH, the Committee requested the Secretariat to continue liaising with Parties to encourage them to update and complete the information they are obliged to make available through the Biosafety Clearing-House, focusing in particular on information related to: (a) national biosafety frameworks, legislation, regulations and guidelines; (b) summaries of risk assessments; (c) final decisions regarding LMOs and LMOs-FFP; (d) national focal points and national points of contact; (e) information on bilateral, regional or multilateral agreements or arrangements they have entered into with relevance for biosafety; and to report on the outcome of its efforts to the Committee.
- 21. The Committee decided to review any updates in the rate of reporting at its next meeting in its consideration of general issues of compliance.
- 22. The Committee also decided to raise the importance of timely submission of complete fourth national reports in its recommendations to the Conference of the Parties serving as the meeting of the Parties at its ninth meeting, in view of their importance as a primary source of information for the final evaluation of the Strategic Plan.
- 23. Members noted that, in accordance with the organization of work agreed at the eighth meeting of the Committee, a review of compliance on the basis of the third national reports, focusing on priority issues identified by the Conference of the Parties serving as the meeting of the Parties, was expected at its next meeting.

## ITEM 6. CLARIFICATIONS ON WHAT CONSTITUTES UNINTENTIONAL TRANSBOUNDARY MOVEMENT IN CONTRAST WITH ILLEGAL TRANSBOUNDARY MOVEMENT

24. The Secretariat introduced the note by the Executive Secretary providing a synthesis of the views submitted and an overview of the outcome of the discussions held by the Network of Laboratories for the Detection and Identification of Living Modified Organisms on the issue of the distinction between unintentional and illegal transboundary movements (<u>UNEP/CBD/BS/CC/13/5</u>). To facilitate the consideration by the Compliance Committee of a possible way forward, the Secretariat drew the attention

of the Committee to the section containing suggested clarifications on what constitutes an unintentional transboundary movement in contrast with an illegal transboundary movement, including draft operational definitions.

- 25. Some members described challenges at the national level in regulating unintentional and illegal transboundary movements.
- 26. The Committee noted that an operational definition could provide Parties with useful guidance and, in that regard, decided to recommend that the Conference of the Parties serving as the meeting of the Parties at its eighth meeting adopt the operational definitions of the terms "unintentional transboundary movement" and "illegal transboundary movement", with a corresponding explanatory note, as follows:
- (a) "Illegal transboundary movement" is a transboundary movement carried out in contravention of the domestic measures to implement the Protocol that have been adopted by the affected Party;
- (b) "Unintentional transboundary movement" is a transboundary movement of a living modified organism that has inadvertently crossed the national borders of a Party whereby the living modified organism was released either deliberately or accidentally.

#### Explanatory note:

An illegal transboundary movement may include transboundary movements of living modified organisms that have not been approved for a particular use in the jurisdiction of the affected Party;

A transboundary movement can still be considered illegal if it results in a contravention of the affected Party's domestic measures to implement the Protocol, even if the transboundary movement is unintentional.

27. The Committee recommended that the information presented in document <u>UNEP/CBD/BS/CC/13/5</u> also be submitted to the Conference of the Parties serving as the meeting of the Parties alongside the operational definitions, as it provides the necessary context.

### ITEM 7. REPORT AND RECOMMENDATIONS OF THE COMMITTEE TO THE CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THE PROTOCOL AT ITS EIGHTH MEETING

28. The Committee considered and adopted a consolidated report (to be issued as UNEP/CBD/BS/COP-MOP/8/2) on the work of its two intersessional meetings, including recommendations for consideration and adoption, as appropriate, by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its eighth meeting.

#### Item 8. Other matters

- 29. The Chair reminded members of the discussions held during the last meeting of the Committee regarding what assistance the Committee could provide to Parties and of its request to the Secretariat for the preparation of information documents to support further consideration of the issue.
- 30. The Secretariat introduced the two information documents: a compilation of information on any assistance provided by the Committee in its previous work both before and after the adoption of <u>decision BS-V/1</u>, broadening the scope for intervention by the Committee (<u>UNEP/CBD/BS/CC/13/INF/1</u>); and an update of the information that the Secretariat had previously compiled on the experience of the compliance mechanisms under other multilateral environmental agreements (<u>UNEP/CBD/BS/CC/13/INF/2</u>).
- 31. The Committee welcomed the documents and suggested that, in the future, the Secretariat could make the information documents available to new members of the Committee.

- 32. The Secretariat informed the Committee that the terms of 10 of its members would end on 31 December 2016 and that, therefore, the Conference of the Parties serving as the meeting of the Parties to the Protocol would be invited to elect 10 members at its eighth meeting. The members of the Committee whose terms will end at the end of the year are: (a) *Africa*: Johansen Voker and Kaouthar Tliche Aloui; (b) *Latin America and the Caribbean*: Héctor Conde Almeida and Jimena Nieto Carrasco; (c) *Western Europe and Others Group*: Ruben Dekker (has served two terms) and Geoff Ridley; (d) *Central and Eastern Europe*: Angela Lozan (has served two terms) and Dubravka Stepic; (e) *Asia and the Pacific*: Banpot Napompeth (has served two terms) and Rai Rana (has served two terms).
- 33. The Chair thanked the members who had served the Committee for two terms for their contribution to the Committee and also thanked the other members for their contribution. Members also thanked the Chair for her guidance over the preceding four years.

#### ITEM 9. ADOPTION OF THE REPORT

34. The Chair introduced the draft report of the Committee, which was adopted as orally amended.

#### ITEM 10. CLOSURE OF THE MEETING

35. The Chair declared the meeting closed at 3 p.m. on Friday, 26 February 2016.

#### Annex I

#### **Draft caution**

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

Recalling Article 33 of the Protocol,

Further recalling section VI, paragraph 2 (b) of the Procedures and Mechanisms on Compliance under the Cartagena Protocol on Biosafety as contained in the annex to decision BS-I/7,

*Noting* with regret that Luxembourg, the Marshall Islands and Nicaragua<sup>2</sup> have not submitted their interim, first, second or third national reports,

Further noting that the Compliance Committee and the Executive Secretary have contacted Luxembourg, the Marshall Islands and Nicaragua on numerous occasions, in accordance with <u>decision BS-V/1</u>, including by offering support to these Parties to prepare their reports,

- 1. Cautions Luxembourg, the Marshall Islands and Nicaragua for failure to fulfil their obligations;
- 2. Requests Luxembourg, the Marshall Islands and Nicaragua, as a matter of urgency, to submit their third national reports;
- 3. *Encourages* Luxembourg, the Marshall Islands and Nicaragua to seek the assistance of the Compliance Committee in accordance with <u>decision BS-V/1</u>, should they require support in preparing their reports.

 $<sup>^{\</sup>rm 2}$  On 4 April 2016, Nicaragua submitted its national report.

#### Annex II

### INPUT TO THE THIRD ASSESSMENT AND REVIEW AND MID-TERM EVALUATION OF THE STRATEGIC PLAN

- 1. When preparing its findings on the assessment and review and the mid-term evaluation of the Strategic Plan, the SBI should take into account the following elements identified by the Committee in the field of compliance with the Protocol:
- (a) Although the Committee has reported consistently on general issues of non-compliance to date, no Party has submitted information on compliance issues to the Committee. Following decision BS-V/I, the Committee has engaged proactively with Parties to support them in meeting their obligations. This has contributed to an increase in submission rates for, and completeness of, national reports. (indicator 3.1.1.)
- (b) The Committee noted with concern that 13 years after the entry into force of the Protocol, about half of Parties still do not have national biosafety frameworks (NBFs) fully in place. About one third of Parties are taking decisions on both LMOs and LMO-FFP through their NBFs. Specific financing through the Global Environment Facility (GEF) in a similar manner to the funds available for national reporting and for the production of NBSAPs under the Convention could help the remaining Parties to establish their NBFs and facilitate further implementation of the Protocol. (indicator 3.1.2)
- (c) Almost all Parties have notified their national focal points and BCH focal points to the BCH. Fewer Parties have notified contact points for unintentional transboundary movements, although this could be due to a lack of appreciation of the need to notify a specific contact point in addition to the national focal point. Progress has also been made, following efforts by the Secretariat, in providing other mandatory information to the BCH, in particular as regards Risk Assessments. However, inconsistency and incompleteness of information still occurs. (indicator 3.1.3 and 3.1.5)
- (d) Monitoring and enforcement systems have been put in place in two-thirds of Parties, with progress being much slower in one region. (indicator 3.1.6)
- (e) It is evident from the national reports that some of the questions in the national reporting format are ambiguous and could be interpreted in different ways. This should be addressed when the reporting format is developed for the fourth national report to ensure that Parties are reporting in a consistent way and fully understand the questions that have been asked. The Committee has identified a number of specific questions that need to be reconsidered for this reason. (indicator 3.1.7)
- (f) Provision of funds through the GEF for reporting purposes contributed to the significant increase in the reporting rate for the second national reports. The decline noted in respect of the third national report is, at least partially, linked to issues with obtaining timely financing following the introduction of the new United Nations administrative system. In addition, 39 Parties that were eligible for GEF funding to complete their national reports, either did not apply for those funds or were unable to access them. (indicator 3.1.7)
- (g) Parties continue to struggle to secure the financial and political support needed to fulfill all requirements of the Protocol. Amongst other challenges, assuring adequate human and financial resources remains difficult and seems to be in decline in recent years, possibly due, at least in part, to the global economic situation. (indicator 3.1.8)
- (h) Because no separate focal area exists for Biosafety within GEF, in practice biosafety projects have to compete with biodiversity projects when eligible Parties set priorities in their national allocations. Furthermore, poor coordination within and between government authorities and lack of awareness and capacities hamper accessing of GEF funds. Together, these issues have led to a relatively low uptake of available GEF funds for implementing the Cartagena Protocol. (indicator 3.1.8)
- (i) In conducting its review, the Committee noted that it would have been helpful to have a more specific link between the indicators and outcomes in the Strategic Plan. This should be considered when developing the next Strategic Plan.

2. These elements should be taken into account in the findings of the Subsidiary Body on Implementation for the Conference of the Parties serving as the meeting of the Parties. Below is an explanation of methodology and underlying data that led the Committee to above elements.

#### **METHODOLOGY**

- 3. Operational objective 3.1 of the Strategic Plan is related to Compliance with the Protocol. Under Operational Objective 3.1, a number of outcomes are provided, as well as indicators to measure the extent to which the outcomes have been achieved.
- 4. For the preparation of the present document, an analysis of information available in the third national reports has been carried out for each indicator of operational objective 3.1.<sup>3</sup> Where needed and available, additional sources of information have been used, including the Biosafety Clearing-House (BCH).<sup>4</sup>
- 5. The information provided in the second assessment and review has served as a baseline for measuring progress, pursuant to decision BS VI/15. Where the second national reporting format did not include a similar question, information provided through the "dedicated survey to gather information corresponding to indicators in the Strategic Plan that could not be obtained from the second national reports or through other existing mechanisms" (Survey) has been used.<sup>5</sup>
- 6. In addition, the "possible elements and corresponding core set of identified information needs for the third assessment and review in conjunction with the mid-term evaluation of the strategic plan" have been used to identify information needs to measure progress and have been linked to the indicators of operational objective 3.1. These "possible elements" were adopted in decision BS-VII/3, related to assessment and review of the effectiveness of the Protocol, in which the Conference of the Parties serving as the meeting of the Parties requested SBI to undertake the third assessment and review of the Protocol and the mid-term evaluation of the Strategic Plan.
- 7. Only those third national reports that were received by 31 December 2015 have been included in the analysis. Furthermore, for the purpose of measuring progress against the baseline, only responses from those Parties that answered the specific question or its equivalent in both the third and second national reports or Survey, have been taken into account.<sup>8</sup> References to increases or decreases at the regional level are based on the aggregate regional result.<sup>9</sup> The wording of the indicator (percentage of Parties/number of Parties) determines whether information is presented as a percentage or as the number of Parties.
- 8. The Compliance Committee noted that a number of questions in the reporting format could be subject to different interpretations, in particular questions 14, 17 and 126(d). This may have affected the responses and as a consequence, the analysis provided in this document.
- 9. The analysis per indicator is provided below. Indicators have been numbered for ease of reference.

<sup>4</sup> A matrix detailing the source of information for each indicator has been made available at <a href="https://bch.cbd.int/protocol/issues/mid-term\_evaluation">https://bch.cbd.int/protocol/issues/mid-term\_evaluation</a>. This matrix also shows the linkages between the indicators and the various outcomes under Operational Objective 3.1.

<sup>7</sup> See Appendix B for a list of "possible elements".

<sup>&</sup>lt;sup>3</sup> See Appendix A for a list of questions.

<sup>&</sup>lt;sup>5</sup> The Survey results were issued as <u>UNEP/CBD/BS/COP-MOP/7/INF/10</u> and online at: http://bch.cbd.int/database/reports/surveyonindicators.shtml

<sup>&</sup>lt;sup>6</sup> See <u>decision BS-VII/3</u>, annex.

<sup>&</sup>lt;sup>8</sup> An analyser tool to compare the third national reports with the second national reports and survey results is available at: <a href="http://bch.cbd.int/database/reports/analyzer?type=nr-cpb-3&date=2015-12-31">http://bch.cbd.int/database/reports/analyzer?type=nr-cpb-3&date=2015-12-31</a>

<sup>&</sup>lt;sup>9</sup> Where, for example, an increase in respect of the second national report is reported by four Parties within one region, and a decrease by one Party within the same region, the overall regional difference is three.

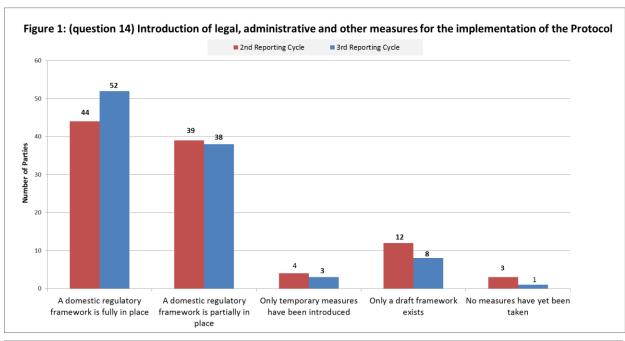
#### **ANALYSIS**

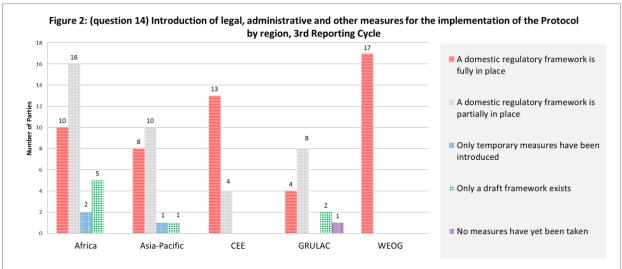
Indicator 3.1.1: Number of Parties that have identified and addressed their non-compliance issues

- 10. The Compliance Committee reviews compliance by the Parties with their obligations. Its proceedings constitute an appropriate source of information for identifying cases of non-compliance. In addition, Element 14 of the "possible elements" is related to this indicator. Element 14 identifies the following information needs: (a) Parties raise issues with the Compliance Committee concerning their own compliance; (b) Compliance Committee has decision-making rules of procedure in place.
- 11. Pursuant to the Procedures and Mechanisms on Compliance under the Cartagena Protocol on Biosafety, as contained in the annex of decision BS-I/7, the Compliance Committee may carry out functions in relation to promoting compliance and addressing cases of non-compliance. A Party may submit to the Committee issues relating to compliance with respect to the Party itself. In addition, a Party, which is affected or likely to be affected, may submit to the Committee issues relating to compliance with respect to another Party.
- 12. In the current reporting period, Parties have not submitted information on compliance issues to the Compliance Committee. However, the Committee has started the substantive implementation of its extended mandate, as given in decision BS-V/1, in particular by taking the initiative to approach individual Parties facing difficulties with their compliance.
- 13. In this context, the Committee has taken action in relation to the submission and completeness of the second national reports and in relation to issues identified from a review of information provided in the second national reports and the BCH.
- 14. The supportive role of the Committee has contributed to the high submission rates and completeness of the second national reports and to the consistency of information provided in the second national reports and in the BCH. In this respect, Parties have made progress in addressing compliance issues.

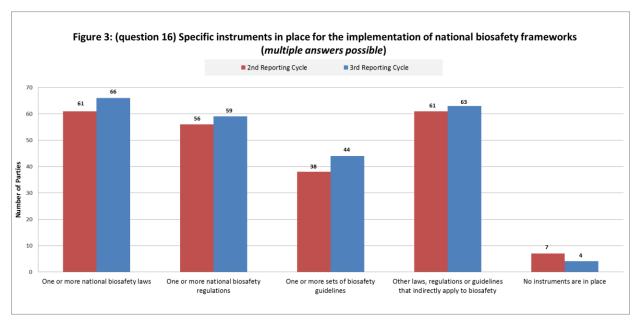
Indicator 3.1.2: Number of Parties having approved and functional national legal, administrative and other measures to implement the Protocol

- 15. Questions 14, 15 and 16 of the format for the third national report are related to this indicator. Under Elements 2 and 3 of the "possible elements", a number of information needs relate to the issue of biosafety frameworks, which is closely related to this indicator. Elements 2(c), 3(b) and 3(c) relate to information needs for this indicator and questions 124, 17 and 18 of the third national report format respectively are relevant.
- 16. A total of 52 Parties (51 per cent) report that they have fully introduced the necessary legal, administrative and other measures for the implementation of the Protocol, which represents an increase of eight Parties (+8 per cent) (see figure 1 and 2). Most growth is reported in Africa, followed by Latin America and the Caribbean.





The number of Parties reporting that their biosafety framework has become operational within the current reporting period has continued to increase (+9 Parties). Parties report progress in adopting biosafety-specific and non-specific instruments, with 101 Parties (98 per cent) reporting that at least some kind of instrument is in place, which represents an increase of 3 Parties (see figure 3).



- 17. Some Parties indicate in their free-text submissions that further measures are under development or that their adoption is pending, although other Parties report that the measures have been awaiting adoption for many years. In this respect, some Parties indicate that awareness at the political and decision-making level is insufficient and that this results in a lack of priority being accorded to the strengthening of national biosafety frameworks. A considerable number of Parties that indicate that legislation, regulations and administrative measures are not yet fully in place, report that to some extent such measures have been adopted (38 Parties) (see figure 1). Some Parties that report having specific instruments in place indicate in their free-text submission that these instruments are still to be adopted.
- 18. In their free text submission, Parties indicate that the slow rate of adoption of legal, administrative and other measures continues to be one of the main obstacles to implementing the obligations under the Protocol, despite the progress reported in the third national report.
- 19. In relation to administrative structures, in their free text submissions Parties report that insufficient human and financial resources are available. Parties report a considerable decrease (-11 per cent) in the establishment of mechanisms that ensure budgetary allocations for the operation of their national biosafety framework, with just over half of the Parties (53 Parties) reporting that such mechanisms have been established. A slight increase (+2 Parties, or +2 per cent) is reported in having permanent staff to administer functions directly related to the national biosafety framework, with a global total of 87 Parties (85 per cent), indicating accordingly. In their free text submissions, some Parties that report having permanent staff dedicated to biosafety, specify that staff work on a part-time basis on biosafety.
- 20. Progress is reported, especially in Africa, in the establishment of institutional capacity to enable competent national authorities to perform the administrative functions required under the Protocol, with 48 Parties (48 per cent) reporting having done so, which represents an increase of 5 Parties (5 per cent). Despite making progress in establishing institutional capacities to some extent, in the GRULAC region, the number of Parties reporting that they had fully established adequate institutional capacities has decreased (1 Party), with a total of 2 out of 15 Parties reporting to have done so fully.
- 21. In their free-text submissions, some Parties, including some of those that indicate that capacities have been established to some extent, report that more capacity-building is required. Some report that the legal framework providing the basis for the establishment and functioning of the competent national authorities has not been adopted.
- 22. In relation to administrative structures, some Parties report in their free-text submissions that institutional changes are being implemented or are about to be implemented. In examining this issue, the

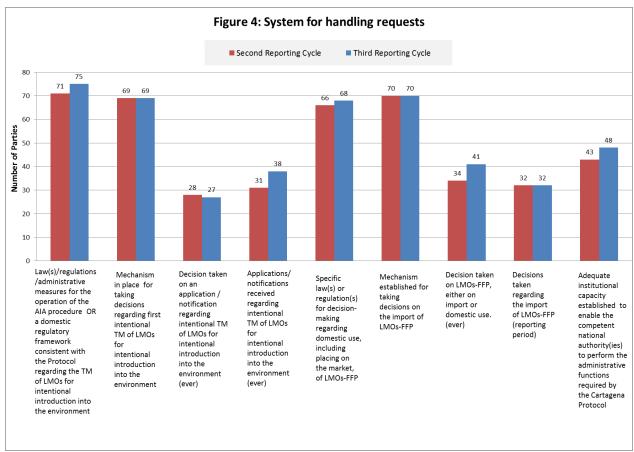
Compliance Committee recognized that many Parties face substantial budget reductions at the domestic level, which may negatively affect their administrative structures.

Indicator 3.1.3: Percentage of Parties that designated all national focal points

- 23. The information relevant to this indicator is drawn from the BCH.
- 24. All but two Parties have notified the Secretariat of their national focal point, in accordance with Article 19 of the Protocol (99 per cent). This is the same percentage as reported in the baseline. Furthermore, all but two Parties have notified the Secretariat of their BCH national focal point, in accordance with decision BS-I/3 and decision BS-II/2 (99 per cent), which represents an increase of 1 per cent. Out of 170 Parties, 101 Parties (59 per cent) have made available to the BCH the relevant details regarding the national point of contact, in accordance with Article 17, related to unintentional transboundary movements.<sup>10</sup>

Indicator 3.1.4: Number of Parties having in place a system for handling requests including for Advance Informed Agreement

25. Questions 29, 30, 34, 35, 47, 50, 52, 54 and 55 of the third national report format relate to this indicator. Under Element 2, 3 and 4 of the "possible elements", a number of information needs relate to the issue of biosafety frameworks, which is closely related to this indicator. Elements 2(a) and 2(b) relate to question 29 of the third national report format. Element 3(a) relates to question 30. Element 3(d) relates to questions 35 of the third national report format. Element 4(a) relates to questions 52 and 54 of the third national report format and Element 4(b) relates to question 50 of the third national report format. Figure 4 shows the information provided by Parties in the second and third reporting cycles.



<sup>&</sup>lt;sup>10</sup> Based on data available in the BCH on 31 December 2015.

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- 26. A total of 75 Parties (71 per cent) report having adopted laws, regulations or administrative measures for the operation of the AIA procedure, or have a domestic regulatory framework that is consistent with the Protocol, which is an increase of 4 Parties. A total of 69 Parties report that a mechanism for taking decisions regarding first intentional introduction into the environment has been established, which is the same result as in the second national report. Regional differences are noted, with the proportion of Parties within each region reporting that mechanisms are fully in place varying between 47 per cent (GRULAC) and 100 per cent (WEOG). Most Parties that report having laws, regulations or administrative measures also report having mechanisms for taking decisions in place (or in place to some extent) for taking decisions regarding first intentional introduction into the environment.
- 27. The number of Parties that report having taken a decision on an application/notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment has remained stable with 27 Parties indicating that they had taken such decisions (31 per cent), which is one Party less than in the second national report, on a total of 38 Parties reporting that they have received applications/notifications, compared to 31 in the second reporting cycle. All Parties that indicate having taken a decision report having legislation in place for taking such decisions. Most of these Parties also report having mechanisms in place for taking decisions, although one Party reports not having such a mechanism in place, and two report having such mechanisms in place to some extent.
- 28. In their free-text submissions, some Parties indicate that reviews of applications are currently being carried out. Others indicate that, pending the entry into force of legislation, applications cannot be processed.
- 29. Most Parties that indicate having laws, regulations and administrative measures related to decision-making for intentional introduction into the environment also indicate having such laws and regulations for decision-making regarding domestic use, including placement on the market of LMOs-FFP. A total of 68 Parties, (67 per cent) report having such laws and regulations for LMOs-FFP, which constitutes an increase of 2 Parties (or 2 per cent) in respect of the second national report. A similar number of Parties (70) report having a mechanism in place for taking decisions on the import of LMOs-FFP, the same result as reported in the second national reports. Despite regional differences, the global figures remain the same as that reported in the second national report in relation to the establishment of mechanisms for taking decisions on LMOs-FFP. Regional differences show that a majority of Parties in GRULAC and Africa report having neither instruments nor mechanisms for taking decisions.
- 30. In their free text submissions, some Parties indicate that, despite the absence of specific legal instruments related to AIA and LMOs-FFP, the general biosafety framework addresses these issues. Some Parties that report the existence of a legal framework indicate that the legislation has not yet been adopted or that informal procedures are being applied.
- 31. A total of 41 Parties indicate having taken a decision on LMOs-FFP, which represents an increase of 7 Parties (+7 per cent), and 32 Parties report having taken a decision on the import of LMOs-FFP in the current reporting period. A total of 28 Parties report having taken a decision on domestic use, including placement on the market of LMOs-FFP. Most Parties that indicate having taken a decision report having legislation and a mechanism in place for taking such decisions. However, five Parties report having neither a mechanism nor specific legislation in place, although one of them clarifies that informal arrangements have been established and another indicates that, on the occasion when a decision was taken, the imports were rejected.

#### Indicator 3.1.5: Percentage of Parties that published all mandatory information via the BCH

- 32. Information for this indicator has been drawn from Questions 20, 43, 56, 57, 74, 91, 126(h) of the third national reports. The data show that Parties, overall, have made progress in submitting information to the BCH.
- 33. In relation to the submission to the BCH of mandatory information, Parties have reported progress on most types of information. The overall number of Parties that report having submitted information on national legislation, regulations and guidelines to the BCH increased (+12 per cent),

although the percentage of Parties that report having submitted complete information on their frameworks remains just below two thirds (65 per cent). The largest regional increases were reported in Africa (+19 per cent) and GRULAC (+14 per cent). Almost all Parties (96 per cent) reported having submitted at least some information on their frameworks.

- 34. Despite reported progress (+10 per cent) on submitting to the BCH summaries of any type of risk assessments, only about a third of Parties (38 per cent) report having done so in all cases. In one region, Africa, none of the Parties reports having submitted such summaries in all cases. Considerable regional progress is reported in Asia and the Pacific (+27 per cent) and GRULAC (+28 per cent). When considering the number of Parties that indicate having submitted summaries in some cases only, overall figures rise to just over two thirds (70 per cent), which is a considerable increase in respect of the second national report (16 per cent).
- 35. About two thirds of Parties (64 per cent) report having submitted information on final decisions regarding LMOs for intentional introduction into the environment, which constitutes a considerable increase (+21 per cent). Progress is attributable to GRULAC (+50 per cent) and WEOG (+34 per cent). Overall figures are similar in relation to submission of information regarding final decisions on import of LMOs-FFP (65 per cent). A total of 14 Parties responded by providing information on decisions relating to LMOs for intentional introduction into the environment, and 23 Parties in relation to final decisions on import of LMOs-FFP. Information provided in response to different questions relating to submission of decisions on LMOs-FFP was found to be inconsistent.
- 36. Of the 23 Parties having provided such information in their second and third national reports, 48 per cent report having always informed Parties through the BCH of decisions regarding domestic use of LMOs-FFP within 15 days. This represents a 9 per cent decrease. Regional differences are noted with decreases reported in Africa (-25 per cent) and WEOG (-13 per cent). A total of 26 per cent of Parties report having always informed Parties through the BCH of decisions regarding domestic use of LMOs-FFP beyond the delay of 15 days, which represents an increase in respect of the second reporting cycle of (+17 per cent).
- 37. In addition, the Secretariat reviewed information on decisions and risk assessments, as referred to in paragraph 1 of decision BS-V/2, in order to strive for completeness of information on decisions regarding LMOs. In this regard, the Secretariat compared the information available in the BCH with information available through other channels and databases. <sup>11</sup> It also reviewed BCH records on decisions for which mandatory risk assessments have not been submitted.
- 38. In this context, the Secretariat has contacted Parties to draw their attention to inconsistencies and have invited them to submit the relevant decisions that they have taken regarding LMOs and the corresponding risk assessments as required under Article 20 of the Protocol and subsequent Conference of the Parties serving as the meeting of the Parties decisions, or to provide clarification of the apparently incomplete data. This has resulted in an increase from 83 per cent to 95 per cent in the rate of completeness of risk assessment reports in the BCH. The Secretariat has been in contact with Parties in relation to decisions available in the BCH, and has noted progress by Parties in addressing this issue.
- 39. Out of 11 Parties that indicated that they have entered bilateral, regional or multilateral agreements or arrangements, 45 per cent indicate having always submitted related information to the BCH. This figure rises to just over 50 per cent, when taking into consideration those Parties that have

<sup>&</sup>lt;sup>11</sup> The Biotradestatus database (www.biotradestatus.com), but also the databases of: (i) the Organization for Economic Cooperation and Development (OECD) (http://www2.oecd.org/biotech/); the International Portal on Food Safety, Animal and Plant Health (IPFSAPH) (http://www.ipfsaph.org/En/default.jsp); (ii) the European Food Safety Authority (EFSA) (http://registerofquestions.efsa.europa.eu/roqFrontend/login); and national biosafety clearing-houses, where applicable, have been used as references to identify gaps in the decisions published. The International Service for the Acquisition of Agri-biotech Applications (ISAAA) database is now also consulted.

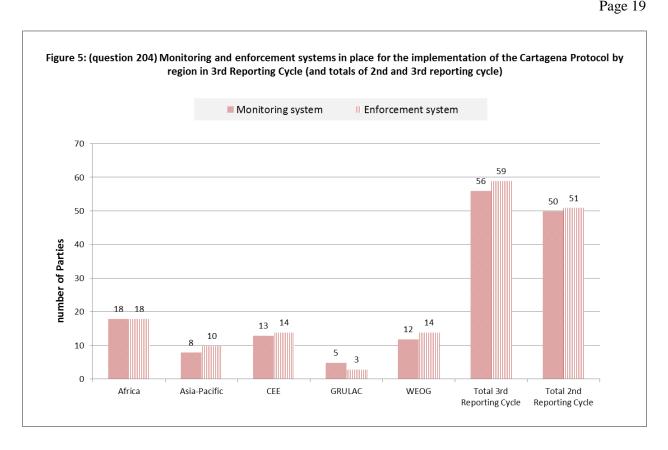
<sup>&</sup>lt;sup>12</sup> Data for the second reporting cycle was drawn from the review by the Ad Hoc Technical Expert Group Meeting on the Second Assessment and Review of the Cartagena Protocol on Biosafety, held in June 2012 (UNEP/CBD/BS/A&R/1/INF/1).

submitted such information in some cases only. Information on the same matter provided under different questions varies slightly.

- 40. Of the Parties that have received information concerning cases of illegal transboundary movements of an LMO in the current reporting period, only 4 Parties (44 per cent) reported submitting complete information to the BCH on these movements, which is the same result as reported in the second national report. Only nine Parties report that such information is available.
- 41. In their free text submissions, Parties report that, at the national level, information on field trials is not made available and therefore cannot be submitted. Some Parties indicate that information is available but not centrally stored and, therefore, not all information is made available through the BCH. Some Parties report that agencies, policymakers and legislators need to be made aware of the BCH and its functioning. Many Parties indicate that they lack the information and data altogether.
- 42. In their free-text submissions, some Parties indicate that, where data exist, they are not always made available due to lack of capacity. Parties report that human capacities and financial resources are insufficient for keeping the information in the BCH up to date. Some Parties report on the beneficial effect of capacity-building activities offered through the UNEP/GEF in this respect. Parties report a number of challenges in relation to making information available in full to the BCH, including: lack of permanent and full-time staff, rotation of staff, insufficient coordination in the collection of information at the national level, and insufficient awareness on need to submit certain types of information to the BCH. Some Parties indicate that there is a continuing need for training of officers in the use of the BCH. Some Parties indicate that, due to changes in personnel, acquired skills have been lost.

Indicator 3.1.6: Number of Parties having in place a monitoring and enforcement system

- 43. Question 204 of the third national reporting format is related to this indicator. Figure 5 shows the information provided by Parties in the second and third reporting cycles.
- 44. Out of 78 Parties responding to the related question in the second and third reporting cycle, about two thirds of Parties (56 Parties or 72 per cent) report having a monitoring system in place, which is in increase of 6 Parties (8 per cent). Within the regions, differences are noted: within GRULAC, fewer Parties report having monitoring systems (42 per cent) than in CEE (93 per cent), WEOG (80 per cent), Africa (78 per cent) and Asia and the Pacific (57 per cent). Out of 78 Parties responding to the related question in the second and third reporting cycle, a slightly higher number of Parties (59 Parties or 76 per cent) report having an enforcement system in place, with similar but slightly more pronounced regional differences (CEE 100 per cent; WEOG 88 per cent; Africa 78 per cent; Asia and the Pacific 77 per cent; GRULAC 25 per cent).



Indicator 3.1.7: Number of national reports received under each reporting cycle

- 45. The information related to this indicator has been drawn from the BCH and from Question 205 and Question 206 of the third national reporting format.
- 46. As of 31 December 2015, 105 Parties had submitted their third national report out of the 170 Parties to the Protocol that had the obligation to do so (62 per cent). At a comparable point in time after the submission deadline for the second national reports, the submission rate was higher (89 per cent). It is however difficult to compare these figures, due to delays in disbursing the available funding to Parties to support the completion of their third national report, related to the implementation of the Enterprise Resource Planning system (Umoja) by UNEP.
- 47. With regard to previous reporting cycles, Parties reported as reasons for not having submitted one or more national reports the lack of financial resources, lack of relevant information at the national level and difficulty in compiling information from different sectors. These factors may have affected current submission rates.

Indicator 3.1.8: Number of Parties able to access financial resources to fulfil their obligations under the Protocol

- 48. Questions 139, related to funding for capacity building for implementation of the Protocol, and 203, related to funding for implementation of the Protocol in general, are related to this indicator.
- 49. About a third of 80 Parties responding to the related questions in the second and third reporting cycle, (26 Parties or 33 per cent) indicate that they dispose of predictable and reliable funding for capacity-building for the effective implementation of the Protocol, with the lowest results reported in GRULAC and Africa. Considerable regional differences are noted. Within Africa and GRULAC, 4 (17 per cent) and 2 (17 per cent) Parties respectively report having such resources. In Asia and the Pacific, WEOG and CEE respectively 6 (43 per cent), 7 (44 per cent) and 7 (50 per cent) Parties report having such funding. In the second reporting cycle, a total of 37 out of 80 Parties (46 per cent) indicated having predictable and reliable funding for capacity-building for the implementation of the Protocol. Both overall and regional scores were higher in the Survey.

- 50. About two thirds of Parties (68 Parties or 65 per cent) indicate that they have received additional funding for implementation of the Protocol, which is similar to what was reported in the second reporting cycle, where 50 out of 80 Parties reported having received such funding (63 per cent), although larger amounts (more than US\$ 50,000) are reported than previously. The Global Environment Facility has continued to make available funding to support the implementation of the Protocol. On 31 December 2015, 17 national and 1 regional projects were under implementation. Despite the availability of the additional resources, many Parties indicate that the lack of sufficient funding is one of the main obstacles to full implementation of the Protocol at the national level. Because no separate focal area exists for Biosafety within GEF, in practice biosafety projects have to compete with biodiversity projects when eligible Parties set priorities in their national allocations. Furthermore, poor coordination within and between government authorities and lack of awareness and capacities hamper accessing of GEF funds. Together, these issues have led to a relatively low uptake of available GEF funds for implementing the Cartagena Protocol.
- 51. In addition, GEF/UNEP has made available funding for 82 Parties for completing their third national reports. In addition, 39 Parties that were eligible for GEF funding to complete their national reports, either did not apply for those funds or were unable to access them.

#### Appendix A

#### Third Reporting Format questions considered in the analysis of Indicator 3.1 of the Strategic Plan

#### Question 14:

Has your country introduced the necessary legal, administrative and other measures for the implementation of the Protocol?

#### Ouestion 15:

If you indicated that a national biosafety framework exists in the above question, when did it become operational?

#### Ouestion 16:

Which specific instruments are in place for the implementation of your national biosafety framework?

#### Ouestion 17:

Has your country established a mechanism for the budgetary allocations of funds for the operation of its national biosafety framework?

#### Ouestion 18:

Does your country have permanent staff to administer functions directly related to the national biosafety framework?

#### Ouestion 20:

Has your country's biosafety framework / laws / regulations / guidelines been submitted to the Biosafety Clearing-House (BCH)?

#### Ouestion 29:

Has your country adopted law(s) / regulations / administrative measures for the operation of the AIA procedure of the Protocol OR a domestic regulatory framework consistent with the Protocol regarding the transboundary movement of LMOs for intentional introduction into the environment?

#### Ouestion 30:

Has your country established a mechanism for taking decisions regarding first intentional transboundary movements of LMOs for intentional introduction into the environment?

#### Question 35:

Has your country ever taken a decision on an application / notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment?

#### Ouestion 43:

Has your country informed the notifier(s) and the BCH of its decision(s)?

#### Ouestion 45:

In cases where your country approved an import with conditions or prohibited an import, did it provide reasons on which its decisions were based to the notifier and the BCH?

#### Ouestion 47:

Has your country adopted specific law(s) or regulation(s) for decision-making regarding domestic use, including placing on the market, of LMOs-FFP?

#### Question 50:

Has your country established a mechanism for taking decisions on the import of LMOs-FFP?

#### Question 52:

Has your country ever taken a decision on LMOs-FFP (either on import or domestic use)?

#### Question 54:

In the current reporting period, how many decisions has your country taken regarding the import of LMOs-FFP?

#### Ouestion 56:

Has your country informed the Parties through the BCH of its decision(s) regarding import, of LMOs-FFP?

Page 22

#### Question 57:

Has your country informed the Parties through the BCH of its decision(s) regarding domestic use, including placing on the market, of LMOs-FFP within 15 days?

#### Question 74:

If you answered Yes to question 72, has your country informed the Parties through the BCH of the agreements or arrangements?

(Question 72: Has your country entered into any bilateral, regional or multilateral agreements or arrangements?)

#### Question 91:

If you answered Yes to question 89, were the summary reports of the risk assessments submitted to the BCH?

(Question 89: Has your country ever conducted a risk assessment of an LMO including any type of risk assessment of LMOs, e.g. for contained use, field trials, commercial purposes, direct use as food, feed, or for processing?)

#### Ouestion 124:

Has your country established adequate institutional capacity to enable the competent national authority(ies) to perform the administrative functions required by the Cartagena Protocol on Biosafety?

#### Question 126:

Please provide an overview of the status of the mandatory information provided by your country to the BCH by specifying for each category of information whether it is available and whether it has been submitted to the BCH.

- (a) Existing national legislation, regulations and guidelines for implementing the Protocol, as well as information required by Parties for the advance informed agreement procedure (Article 20, paragraph 3 (a))
- (b) National laws, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing (Article 11, paragraph 5)
- (c) Bilateral, multilateral and regional agreements and arrangements (Articles 14, paragraph 2 and 20, paragraph 3 (b))
- (d) Contact details for competent national authorities (Article 19, paragraphs 2 and 3), national focal points (Article 19, paragraphs 1 and 3), and emergency contacts (Article 17, paragraph 3 (e))
- (e) Reports submitted by the Parties on the operation of the Protocol (Article 20, paragraph 3 (e))
- (f) Decisions by a Party on regulating the transit of specific living modified organisms (LMOs) (Article 6, paragraph 1)
- (g) Occurrence of unintentional transboundary movements that are likely to have significant adverse effects on biological diversity (Article 17, paragraph 1)
- (h) Illegal transboundary movements of LMOs (Article 25, paragraph 3)
- (i) Final decisions regarding the importation or release of LMOs (i.e. approval or prohibition, any conditions, requests for further information, extensions granted, reasons for decision) (Articles 10, paragraph 3 and 20, paragraph 3(d))
- (j) Information on the application of domestic regulations to specific imports of LMOs (Article 14, paragraph 4)
- (k) Final decisions regarding the domestic use of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing (Article 11, paragraph 1)
- (1) Final decisions regarding the import of LMOs intended for direct use as food or feed, or for processing that are taken under domestic regulatory frameworks (Article 11, paragraph 4) or in accordance with annex III (Article 11, paragraph 6) (requirement of Article 20, paragraph 3(d))
- (m) Declarations regarding the framework to be used for LMOs intended for direct use as food or feed, or for processing (Article 11, paragraph 6)

- (n) Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12, paragraph 1)
- (o) LMOs granted exemption status by each Party (Article 13, paragraph 1)
- (p) Cases where intentional transboundary movement may take place at the same time as the movement is notified to the Party of import (Article 13, paragraph 1)
- (q) Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and relevant information regarding products thereof (Article 20, paragraph 3 (c))

#### Ouestion 139:

Does your country have predictable and reliable funding for building capacity for the effective implementation of the Protocol?

#### Ouestion 187:

If your country received information concerning cases of illegal transboundary movements of an LMO in the current reporting period, has your country informed the BCH and the other Party(ies) involved?

#### Ouestion 203:

How much additional funding (in the equivalent of US dollars) has your country mobilized in the last four years to support implementation of the Biosafety Protocol, beyond the regular national budgetary allocation?

#### Question 204(a):

Does your country have in place a monitoring and/or an enforcement system for the implementation of the Cartagena Protocol? Monitoring system?

#### Question 204 (b):

Does your country have in place a monitoring and/or an enforcement system for the implementation of the Cartagena Protocol? Enforcement system?

#### Question 205:

Has your country submitted all the previous due National Reports?

#### Question 206:

If you answered No to question 205, indicate the main challenges that hindered the submission.

#### Appendix B

# Possible Elements and Corresponding Core Set of Identified Information Needs for the Third Assessment and Review in conjunction with the mid-term Evaluation of the Strategic Plan from the annex to decision BS-VII/3, considered in the analysis of Indicator 3.1 of the Strategic Plan

- *Element 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/or administrative measures for operation of the AIA procedure;
- (b) Number of Parties that have adopted a domestic regulatory framework consistent with the Protocol as regards the transboundary movement of LMOs for intentional introduction into the environment;
- (c) Number of Parties that have designated competent national authorities;
- *Element 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;
- *Element 4.* Procedures for decision-making in relation to transboundary movements of living modified organisms intended for direct use as food or feed, or for processing (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.

*Element 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;

*Element 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.

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