



## Convention on Biological Diversity

Distr.  
GENERAL

UNEP/CBD/BS/A&R/1/2  
30 April 2012

ORIGINAL: ENGLISH

### AD HOC TECHNICAL EXPERT GROUP MEETING ON THE SECOND ASSESSMENT AND REVIEW OF THE CARTAGENA PROTOCOL ON BIOSAFETY

Vienna, 14–16 May 2012

Item 5 of the provisional agenda\*

### SECOND ASSESSMENT AND REVIEW OF THE EFFECTIVENESS OF THE CARTAGENA PROTOCOL ON BIOSAFETY (ARTICLE 35)

#### I. SCOPE AND METHODOLOGY

##### A. Background

1. Article 35 of the Cartagena Protocol on Biosafety requires the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol (COP-MOP) to undertake, at least every five years, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes. In accordance with the terms of Article 35, the first evaluation was to be conducted in 2008.

2. At their fourth meeting, in May 2008, the Parties, in decision BS-IV/15, on assessment and review, noted the limited experience gained by Parties in the implementation of the Protocol, as reflected in the first national reports, and recognised that the lack of operational experience did not provide a good basis for an effective assessment and review of the Protocol.

##### B. *The second assessment and review of the effectiveness of the Protocol*

3. In decision BS-IV/15, the Parties to the Protocol, *inter alia*, requested the Executive Secretary to develop a sound methodological approach to contribute to an effective second assessment and review of the Protocol, its annexes, procedures and mechanisms. The approach was to be developed on the basis of the information contained in the first national reports, answers to the “effectiveness questionnaire” submitted by Parties prior to their fourth meeting, the reports of the Compliance Committee, information on the Biosafety Clearing-House and any other relevant documents. The Executive Secretary was also requested to develop draft criteria or indicators that could apply in the evaluation of the effectiveness of the Protocol and provide an indication of the utility.

4. At their fifth meeting, held in 2010, the Parties to the Protocol considered a note by the Executive Secretary (UNEP/CBD/BS/COP-MOP/5/15) containing, *inter alia*, elements of a possible methodology for the conduct of the second assessment and review proposed by the Executive Secretary, and adopted decision BS-V/15 on *Assessment and Review*. The decision provided that the scope of the second assessment and review of the effectiveness of the Protocol would focus primarily on *evaluating the status of implementation of core elements of the Protocol*, identified in an annex to

\* UNEP/CBD/BS/A&R/1/1.

the decision. The annex identified certain criteria by which the status of implementation should be addressed.

5. Decision BS-V/15 also provided that the evaluation should be based on the following sources of information:

- (a) Second national reports of Parties;
- (b) The Biosafety Clearing House (BCH);
- (c) Information that might be made available through the Compliance Committee in relation to its functions to review general issues of compliance;
- (d) The capacity-building coordination mechanism; and
- (e) Other relevant processes and organizations.

The decision envisages three stages to the second assessment and review process: (i) the collection and compilation of information on the implementation of the Protocol by the Executive Secretary; (ii) the analysis of the information compiled; and (iii) the review of the analysis of information by a regionally balanced ad hoc technical expert group.

6. Accordingly, this report attempts to analyse information from the various sources identified in decision BS-V/15, with a view to facilitating the second assessment and review of the effectiveness of the Protocol. For reasons explained in section 4 below, the primary information source has been the 143 second national reports submitted by Parties by 31 December 2011. The report has been prepared in accordance with terms of reference issued by the Executive Secretary in November 2011. At the beginning of the preparation of this report no formal compilation of information from the various sources was available for analysis. However, copies of the second national reports as well as the national reports 'analyser' tool were available on the BCH. Other relevant information was also identified and provided by the Secretariat of the Convention on Biological Diversity (SCBD) on an ongoing basis. In March 2012, a compilation of responses to the second national report questionnaire<sup>1</sup> was made available by the SCBD. Documentation related to the capacity-building Coordination Mechanism and the Compliance Committee was available through the Protocol website. Other resources were accessed through the internet and through web-based databases.

7. In accordance with the Annex to decision BS-V/15, the principal areas addressed in this report are:

- (a) Coverage of the Protocol
- (b) Domestic implementation of core procedures and other requirements of the Cartagena Protocol including its annexes
- (c) International level procedures and mechanisms
- (d) The impact of transboundary movements of living modified organisms (LMOs) on biological diversity, taking also into account risk to human health.

In relation to each of these areas, the assessment is based upon a review of the elements and indicators set out in the annex to decision BS-V/15. As will be discussed further below, the information available on the current state of implementation does not at this stage permit a detailed analysis of item (d).

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<sup>1</sup> A preliminary draft of document UNEP/CBD/BS/COP-MOP/6/16.

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

**C. *The context of the second assessment and review of effectiveness***

9. By the time the COP-MOP considers the second assessment and review in October 2012, the Protocol will have been in force for nine years. Since the Protocol entered into force in 2003, many decisions have been adopted to facilitate its implementation. The Biosafety Clearing House has become fully operational. More than 120 countries have received capacity-building assistance in support of their efforts to develop initial drafts of their national biosafety legal and administrative frameworks, but a significantly lower number, to date, has been granted support for the implementation of these frameworks.<sup>2</sup> At present, ‘significant challenges remain as regards the implementation of the Protocol’.<sup>3</sup>

10. The Strategic Plan for the Cartagena Protocol on Biosafety for the Period 2011-2020 assumes that a baseline of the status of implementation of the Protocol and global indicators will be established after the second assessment and review at COP-MOP 6 ‘to establish a global picture’ in terms of the achievement of the objectives of the Strategic Plan.<sup>4</sup>

11. As noted above, the second assessment and review focuses on evaluating the extent to which Parties have implemented core mechanisms of the Protocol, such as the advance informed agreement procedure or consistent domestic measures, and the extent to which they are in a position to implement those procedures. According to the information provided in second national reports and other available materials, there remain clear variations both among and within regions in the overall implementation picture.

12. It is evident that at this stage the exercise of assessment and review of the Protocol is inextricably linked with the review of the status and effectiveness of capacity-building efforts related to the Protocol. It is also apparent that the second and future assessments and reviews need to be closely linked to relevant objectives, outcomes and indicators set out in the Strategic Plan.<sup>5</sup>

13. More broadly, the assessment and review of the status of implementation of the Protocol should be considered in the context of developments concerning the status, use and transboundary movement of LMOs since the Protocol entered into force. Parties are clearly at different stages not only in their implementation of the Protocol, but also in their research on and utilization of LMOs whether in contained use, for introduction into the environment (principally in agriculture), or as food or feed or for processing. The level of interest and activity in the field of modern biotechnology in a Party would seem, *prima facie*, to be a significant factor affecting the priority that a Party attaches to the adoption and implementation of its regulatory framework for biosafety.

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<sup>2</sup> Strategic Plan for the Cartagena Protocol on Biosafety for the Period 2011-2020, Decision BS-V/16, Annex I, para. 2.

<sup>3</sup> *Ibid.*, para. 5.

<sup>4</sup> *Ibid.*, para. 13.

<sup>5</sup> The COP-MOP has already decided that the third assessment and review of effectiveness should be conducted alongside the mid-term evaluation of the Strategic Plan at COP-MOP8. Decision BS-V/16, para. 4(a). See also document UNEP/CBD/BS/A&R/1/3.

### *D. Methodology and sources of information*

14. This report is based on a review of information from the sources identified in paragraph 1(b) of decision BS-V/15.

#### *Second national reports*

15. The second national reports submitted by Parties to the Protocol are the primary source of information utilized in this report. While there are some challenges (noted in paragraph 25 below) associated with using the information in the national reports as the basis for comparison and assessment of trends, the second national reports provide a rich and unparalleled source of up-to-date information about the status of domestic implementation of the Protocol by Parties. There were 161 Parties to the Protocol on 30 September 2011 (the due date for the second national reports) and by 31 December 2011, 143 Parties had submitted their second national reports. This level of compliance with reporting requirements is impressive, and reflects the efforts made by the COP-MOP to provide a user-friendly reporting format,<sup>6</sup> as well as the support provided for the preparation of national reports.<sup>7</sup> The Secretariat has produced a separate document (UNEP/CBD/BS/COP-MOP/6/16) that summarizes and analyses the information contained in the national reports in relation to each article of the Protocol.

16. The regional breakdown of the second national reports received is as follows:

- Africa: 49 reports (100% of the Parties in the region);
- Asia-Pacific: 35 reports (85% of the Parties in the region);
- Central and Eastern Europe (CEE): 19 reports (86% of the Parties in the region);
- Latin America and the Caribbean (GRULAC): 21 reports (75% of the Parties in the region);
- Western Europe and Others Group (WEOG): 19 reports (90% of the Parties in the region).

For the WEOG, of the 19 reports submitted, 15 were from the European Union (EU) and individual member states of the EU. Of the reports submitted by CEE Parties, ten were submitted by Parties that are members of the EU.<sup>8</sup> For Least Developed Countries and Small Island Developing States,<sup>9</sup> the breakdown was as follows:

- Least developed countries (LDCs): 39 reports (100% of the Parties in the group) and
- Small island developing States (SIDS): 22 reports (76% of the Parties in the group).<sup>10</sup>

17. In accordance with the format of second national reports decided by the COP-MOP,<sup>11</sup> Parties were requested to respond to questions relating to specific articles of the Protocol. Most of the questions required Parties only to tick one or more boxes so as to indicate the current status of domestic

<sup>6</sup> Decision BS-V/14.

<sup>7</sup> See Decision BS-V/5, para. 4(c), and Decision X/25 of the Conference of the Parties to the Convention on Biological Diversity, para. 20(c).

<sup>8</sup> One report from a Party in the Asia-Pacific group was also from a member state of the EU.

<sup>9</sup> This breakdown is drawn from the SCBD document UNEP/CBD/BS/COP-MOP/6/16.

<sup>10</sup> The current list of LDCs includes 48 UN Members (33 in Africa, 14 in Asia and the Pacific and 1 in the Caribbean). The current list of SIDS includes 38 UN Members (6 in Africa, 16 in Asia and the Pacific and 16 in Latin America and the Caribbean) and 14 Non-UN Members/Associate Members of the Regional Commissions. The two groups (LDCs and SIDS) have ten UN Members in common. More information about LDCs and SIDS is available on the website of the UN Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and Small Island Developing States (UN-OHRLLS) at <http://www.unohrrls.org/en/home/>.

<sup>11</sup> Decision BS-V/14.

implementation, but for each article a text field in the reporting format also allowed Parties to provide further details on implementation. Parties were asked to ensure that answers were as relevant and succinct as possible. For the purpose of the analysis in this report, the additional information given by Parties in the text field provided insights into trends and challenges in implementation.

### *Biosafety Clearing-House*

18. There is a significant amount of information available on the Biosafety Clearing-House (BCH).<sup>12</sup> A survey of information available in the BCH was undertaken as part of this study, particularly in relation to the records on national laws and regulations, and national decisions and communications on transboundary movement of LMOs for intentional introduction into the environment and on LMOs for direct use as food or feed, or for processing. However, no comprehensive exercise has been undertaken to cross-check data contained in national reports with that available in the BCH.<sup>13</sup> All categories of information in the BCH are open to, and contain submissions from non-Parties.

### *Compliance Committee*

19. Reports and documentation of the Compliance Committee in relation to its review of general issues of compliance have been taken into account.<sup>14</sup> On the basis of the analysis of first national reports, the Compliance Committee noted, at its third, fourth and fifth meetings held in 2007 and 2008, the continued existence of significant gaps in relation to the obligation to put in place at the national level the necessary legal, administrative and other measures. The Committee further noted that compliance with the obligation to promote public awareness and participation is not at a satisfactory level. It also identified gaps with respect to implementing the requirement to adopt national measures addressing illegal transboundary movements of LMOs and reporting such occurrences to the BCH.<sup>15</sup> At its sixth and seventh meetings in 2009 and 2010, the Compliance Committee made recommendations to the COP-MOP concerning the provision of information to the BCH on domestic decisions approving LMOs and risk assessment reports associated with such decisions.<sup>16</sup>

### *Capacity-building Coordination Mechanism*

20. The Coordination Mechanism for the Implementation of the Action Plan on Building Capacities for the Effective Implementation of the Protocol was established under decision BS-I/5. The Coordination Mechanism comprises a number of elements, including coordination meetings for

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<sup>12</sup> For example, as at 30 March 2012, there are 709 records on the BCH relating to national laws, regulations and guidelines; 479 records relating to decisions on transboundary movement of LMOs for international introduction to the environment; and 649 records relating to decisions on LMOs for food or feed, or for processing. Some non-Parties have made a significant amount of information available on the BCH.

<sup>13</sup> While that task is beyond the scope of this report, it should be noted that currently there do appear to be some inconsistencies between the data available in national reports and certain other sources, and data available in their BCH. Some Parties explained in their national reports that they were in the process of collating and/or reviewing information with a view to providing it to the BCH. Document UNEP/CBD/BS/COP-MOP/6/16 does include some comparison of information provided in the second national reports and that available in the BCH.

<sup>14</sup> The Compliance Committee decided, at its fifth meeting, to have a standing agenda item on 'review of general issues of compliance'. UNEP/CBD/BS/CC/5/4, para. 23.

<sup>15</sup> UNEP, CBD/BS/COP-MOP/4/2, *Report of the Compliance Committee*, 5 December 2007, paras. 16-18. UNEP/CBD/BS/CC/5/4, *Report of the Compliance Committee under the Cartagena Protocol Biosafety on the Work of its Fifth Meeting*, 21 November 2008, para. 19.

<sup>16</sup> UNEP/CBD/BS/CC/7/3, *Report of the Compliance Committee under the Cartagena Protocol Biosafety on the Work of its Seventh Meeting*, 23 September 2010, para. 24.

governments and organisations implementing and/or funding biosafety capacity-building activities. The Coordination Mechanism provides an opportunity for Parties to exchange information and share experiences on their ongoing initiatives, identify their capacity-building needs and emerging issues in relation to biosafety and consider ways to address such needs and issues; and identify opportunities for collaboration.

21. Eight coordination meetings for governments and organisations implementing or funding biosafety capacity-building activities have been held to date, most recently in March 2012. The meetings have played a role in identifying capacity-building needs, measures and approaches in relation to specific aspects of implementation of the Protocol identified by the Parties.

22. Nine meetings of the Liaison Group on Capacity-Building for Biosafety have also been held. Through those meetings, the Liaison Group has provided advice to the Executive Secretary on a number of capacity-building issues relating to the implementation of various elements of the Protocol, including advice on the draft Strategic Plan for the Protocol; the draft programme of work on public awareness, education and participation; and measures for improvement of the roster of experts on biosafety.

23. For the purposes of the present report, the work carried out under the Coordination Mechanism was reviewed to identify areas where critical capacity-building needs have been identified as well as measures taken to date to address those needs. A separate independent evaluation of the Action Plan on Capacity-Building has been undertaken for consideration by COP-MOP6.<sup>17</sup>

#### *Other processes and organisations*

24. A review of information from other sources was undertaken, including both official documents, academic and grey literature, and relevant websites. These materials are referred to in footnotes, as appropriate, and in the bibliography. Most specifically, information was obtained concerning the existence and status of projects funded through the Global Environment Facility, as well as other organisations involved in capacity-building.<sup>18</sup>

#### *Issues relating to data*

25. The information made available through both the second national reports and the BCH provide a general overview of what Parties have done, and are doing, to implement the Protocol. They also provide some indication of the extent to which domestic procedures and mechanisms are working in practice. Reports on the work of the Compliance Committee and Capacity-building Coordination Mechanism also provide some general information on national level implementation, as well as insights and observations into difficulties in implementation and ways to address those difficulties. Assessing the overall status of implementation of the Protocol is challenging for a number of reasons, including the following:

(a) Parties are clearly at different stages of implementation of the Protocol.<sup>19</sup> Some Parties had existing regulatory frameworks for biosafety in place when the Protocol entered into force, and

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<sup>17</sup> See document UNEP/CBD/BS/COP-MOP/6/INF/2.

<sup>18</sup> This category of information was obtained from compilation reports prepared for the capacity-building Co-ordination meetings and for the COP-MOP, as well as directly from the websites of the organisations concerned.

<sup>19</sup> As many Parties are in the process of implementing recently developed National Biosafety Frameworks, the status of implementation is also a 'work in progress'. For example, while this report was under preparation, it was reported that

may have made adjustments to these to take into account specific Protocol requirements on transboundary movements of LMOs. Other Parties have, in many respects, ‘started from scratch’ in developing a new regulatory framework for biosafety, albeit that they may have some sectoral laws and regulations that are applicable, or potentially applicable, to issues addressed in the Protocol.

(b) The report is intended to provide an assessment of the *overall* status of implementation of the Protocol. It is *not* a review of implementation or of compliance by *individual* Parties. Parties have adopted different approaches to implementing the Protocol. However, the diversity of Parties’ starting points, policy contexts and regulatory approaches raises challenges for any overall analysis of trends.

(c) The amount of information provided by Parties in their national reports varies. For example, some Parties provided quite detailed information on current or evolving national legislation and regulations, or on particular regulatory decisions, while others did not respond to specific questions or provide details in the text option.

(d) Parties may have adopted differing interpretations to questions posed in the second national report questionnaire, and used different processes to gather the information provided in the reports. It is not the purpose of this study to verify information contained in national reports, and in that sense the report can only be as accurate as the data upon which it is based. The report is based on the assumption that the information provided in national reports is accurate and up-to-date.

(e) As noted earlier, there appear to be some inconsistencies between information made available in national reports, and the corresponding information available in the BCH or through other sources. Of the 143 Parties that have submitted second national reports, 67 reported that the information they have submitted to the BCH was not complete or up to date. Some apparent discrepancies are highlighted in general terms in this report, where appropriate.

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

(g) In a number of respects, the national reports tend to focus on measures developed or under development by Parties for the purpose of implementing the Protocol (“*implementation on paper*”) rather than on the implementation and enforcement of these measures *in practice*, and/or their impact and success in terms of outcomes. To a significant extent, this is due to the fact that many Parties remain at an early stage of implementing their national biosafety frameworks.

26. Additional formal surveys, interviews and consultations were not conducted specifically for the purposes of the preparation of this report. Given the extent of the up-to-date and regionally-balanced information from Parties available in documentary sources, particularly the national reports, it was considered that reliance on such sources might yield a more balanced and reliable overview, particularly since resources would not have allowed for a large sample of interviewees. However, input and comment from country and regional perspectives, and from the perspectives of different stakeholders in the process, would be of great assistance in finalising conclusions as to the present status of implementation and the recommendations emerging therefrom. In this regard, the COP-MOP provided for such input through the opportunity for review and discussion of the assessment report by a regionally balanced ad hoc technical expert group. The report could also perhaps usefully be considered by the Compliance Committee in relation to its consideration of general issues of compliance. Ongoing work on the assessment was also presented informally to the eighth meeting of governments and

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Ghana’s Biosafety Act had received Presidential Assent after some years of discussion. (Meridian Institute, *Food Security and AgBiotech News*, 17 February 2012).

organisations implementing or funding biosafety capacity-building activities, held in Prague from 12 to 14 March 2012.

## II. REVIEW OF STATUS OF IMPLEMENTATION OF THE PROTOCOL

### A. *Coverage of the Protocol*

#### **Element 1 Geographic coverage of the Protocol and Protocol's coverage of transboundary movements of LMOs**

##### *Parties to the Protocol*

27. As of 31 December 2011, the Cartagena Protocol had 161 Parties.<sup>20</sup> The regional breakdown of the Parties was as follows:

- Africa: 49 Parties (91% of the countries in the regional group);
- Asia-Pacific: 41 Parties (75% of the countries in the regional group);
- Central and Eastern Europe: 22 Parties (96% of the countries in the regional group);
- Latin America and the Caribbean: 28 Parties (85% of the countries in the regional group);
- Western Europe and Others Group (WEOG): 20 Parties (69% of the countries in the regional group).

##### *National focal points*

28. Information in the BCH suggests that 182 national focal points (NFPs) for the Protocol have been designated in total: 163 by Parties (four Parties have designated two NFPs) and 19 by non-Parties (two non-Parties having designated two NFPs).<sup>21</sup> All 143 Parties that had submitted their national reports by 31 December 2011 have designated one or more national focal points.

##### *Submission of national reports*

29. As previously noted, a large number of Parties submitted their second national reports in a timely manner. By 31 December 2011, 143 Parties (88% of all the Parties to the Protocol) had submitted their reports. The regional breakdown of the reports is as follows:

- Africa: 49 reports (100% of the Parties in the region);
- Asia-Pacific: 35 reports (85% of the Parties in the region);
- Central and Eastern Europe (CEE): 19 reports (86% of the Parties in the region);
- Latin America and the Caribbean (GRULAC): 21 reports (75% of the Parties in the region);
- Western Europe and Others Group (WEOG): 19 reports (90% of the Parties in the region).

<sup>20</sup> Uruguay became the 162nd Party on 31 January 2012, and Bahrain the 163rd Party on 7 May 2012.

<sup>21</sup> According to a document issued by the Secretariat on 30 March 2012, 182 States have designated focal points for the Protocol (including some non-Parties to the Protocol and one non-Party to the Convention on Biological Diversity).

*Parties exporting and importing LMOs to and from non-Parties*

30. It is evident that a number of States involved to a significant degree in the transboundary movement of LMOs are non-Parties to the Protocol. In their second national reports, 37 Parties<sup>22</sup> reported importing LMOs from non-Parties, while seven reported exporting LMOs to non-Parties.<sup>23</sup> Of those importing from non-Parties, 13 were from the WEOG region, seven from GRULAC, nine from Asia and the Pacific, four from CEE and four from Africa. Of those exporting to non-Parties, four were from WEOG, two from GRULAC and one from Africa.

31. Of the 37 Parties reporting transboundary movements of LMOs involving non-Parties, 31 indicated that such transboundary movements were always consistent with the objective of the Protocol.<sup>24</sup> Some of these Parties noted that their domestic regulatory framework applied in the same manner to imports of LMOs from Parties and non-Parties; some reported importing only LMOs for direct use as food, feed, or for processing (LMOs-FFP) from non-Parties; some reported having imported or exported LMOs for contained use or small- or large-scale field trials. Some other Parties reported that, since they lacked capacity to monitor and detect imports of LMOs, they could not confirm whether LMOs had been imported from non-Parties. One reported an instance of a transboundary movement of a LMO from a non-Party, which had been unintentional and thus not in conformity with the Protocol.

32. A number of non-Parties have approved LMOs for intentional introduction into the environment and/or for food, feed and/or processing. Several such states have made information on these approvals available on the BCH. Indeed, a significant number of the decisions on the BCH have been recorded by non-Parties. For example, of the 649 records on LMO-FFP decisions on the BCH, at least 223 (more than one-third) have been recorded by four non-Parties. Of 479 decisions concerning transboundary movement of LMOs for intentional introduction into the environment, 155 are recorded by four non-Parties. A recent report published by the International Service for the Acquisition of Agri-biotech Applications (ISAAA) suggests that 29 states cultivated LMO crops in 2011. Of the 29 states mentioned in that report, six were non-Parties to the Protocol in 2011.<sup>25</sup>

***B. Domestic implementation of core procedures and other requirements of the Cartagena Protocol including its annexes.***

33. This issue lies at the heart of the review of status of implementation of the Protocol. In accordance with the annex to decision BS-V/15, key elements in assessing the status of domestic implementation of core procedures and other requirements of the Protocol include that:

- Advance informed agreement (AIA) procedures or domestic regulatory frameworks consistent with the Protocol have been established for the transboundary movement of LMOs for intentional introduction into the environment (Element 2)
- Such procedures and frameworks are operational and functioning (Element 3)
- Procedures for decision-making in relation to transboundary movement of LMOs-FFP are established and operational (Element 4)

<sup>22</sup> Note that the European Union, comprising 27 member states, was one of the Parties reporting imports from non-Parties. Some individual EU member states also reported imports from non-Parties, while others did not.

<sup>23</sup> Questions 162 and 163. The question numbers referred to in the footnotes in this document are those in the format for second national reports set out in Decision BS-V/14.

<sup>24</sup> Question 164.

<sup>25</sup> C. James, *Global Status of Commercialized Biotech/GM Crops: 2011*, ISAAA Brief 43, 2011, Executive Summary, p.2. One of the states referred to became a Party to the Protocol in January 2012.

- Risk assessment procedures for LMOs are established and operational (Element 5)
- Procedures for establishment of appropriate LMO risk management measures and monitoring are established and operational (Element 6)
- Procedures for identifying and addressing illegal transboundary movements of LMOs are in place and operational (Element 7)
- Procedures for preventing, identifying and addressing unintentional transboundary movements of LMOs are established and operational, including notification and emergency measures (Element 8)
- Appropriate requirements are established and implemented in relation to the Protocol's requirements on the handling, transport, packaging and identification of LMOs (Element 9)
- Procedures for notification of required information to the BCH are established and operational (Element 10)
- Procedures and measures for promoting public awareness are being implemented (Element 11).

34. These elements are reviewed in turn below in light of the specific indicators identified in decision BS-V/15.<sup>26</sup> Overall, it is clear that some significant progress has been made in the establishment and operationalization of the procedures and mechanisms identified above. However, the picture remains uneven. As would be expected, there remains quite substantial variation among regions at this stage in terms of the extent to which functioning administrative systems for decision-making on transboundary movement of LMOs are in place. In particular, while in most Parties national biosafety frameworks (NBFs) have been developed, in a significant number of Parties relevant laws have not yet been enacted and remain in draft form, or regulatory and administrative systems have not been put in place or are not yet functional.

**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**

35. 83 Parties reported that they had put in place laws and regulations for the operation of the advance informed agreement procedure or a domestic regulatory framework consistent with the Protocol. 60 reported that they had not yet done so. As might be expected at this stage, there are clear regional differences in this respect. Almost half of the Asia-Pacific and African group Parties that submitted national reports reported that they had not yet put in place laws and regulations for the AIA procedure. For at least 38 Parties, the only national law or regulation available on the BCH is the National Biosafety Framework in final or draft form.

*Table 1: Parties that have put in place laws and regulations and/or administrative measures for operation of the AIA procedure<sup>27</sup>*

<b>Region</b>	<b>Yes</b>	<b>No</b>
Africa	22	27
Asia-Pacific	19	16
CEE	15	4

<sup>26</sup> The information contained in the Tables in this section is drawn from the Second National Reports 'analyser' tool, available on the Protocol website as at 31 December 2011.

<sup>27</sup> Question 29.

GRULAC	8	13
WEOG	19	0
<b>Total</b>	<b>83</b>	<b>60</b>

36. *Many Parties reported that they had drafted but not yet adopted, or were in the process of drafting, relevant laws and regulations.* It is noteworthy that by the end of 2011, some 123 states had implemented projects for the development of draft NBFs with the support of the Global Environment Facility (GEF) through the United Nations Environment Programme (UNEP). Of these, 117 states had completed drafting their national biosafety frameworks under the UNEP-GEF project, including 39 in Africa, 34 in Asia and the Pacific, 18 in Central and Eastern Europe and 26 in Latin America and the Caribbean.<sup>28</sup> Most NBFs include, as appropriate, draft biosafety laws. It is evident from the second national reports that these frameworks have in many instances yet to be fully implemented: either because relevant draft national laws have yet to be enacted, or because administrative systems necessary for implementation of the biosafety system have not yet been adopted.<sup>29</sup>

37. Further implementation efforts are underway in many Parties. In particular, the GEF has supported a number of projects on implementation of NBFs, and further such projects are ongoing or in the pipeline. In addition to the 12 NBF implementation projects approved by the GEF Council in November 2001, another 41 national GEF-supported NBF implementation projects have been approved, but very few have already started.<sup>30</sup> In addition, four regional projects and two global thematic projects (BCH I and II) addressing aspects of implementation have also been approved<sup>31</sup>. Other national, regional and thematic projects are under development both in the context of GEF support and through other bilateral, regional and multilateral initiatives.<sup>32</sup> Implementation projects allow eligible Parties to seek support for developing specific capacities or approaches relating to NBF implementation. For example, at least one Party has developed a project aimed at building capacity in detection and monitoring of LMOs; another is undertaking a project to develop and institute a national monitoring and control system for LMOs and alien invasive species.

38. Where Parties reported that no domestic AIA or other regulatory framework to govern transboundary movement of LMOs was in place, then as would be expected they also reported that they had not yet implemented other elements of the Protocol. It should be noted, however, that numerous Parties reported that some sectoral laws, measures and institutional arrangements existed relevant to LMOs, for example in relation to plant protection and quarantine procedures, food safety, public health and more generally on environmental protection.

39. A number of Parties provided explanations for the delay in putting in place the basic regulatory framework for biosafety. In the majority of cases, these related to a lack of human, financial and technical resources. Other reasons included a lack of priority given to the issue of biosafety; a continuing lack of awareness of the issue among the public and policymakers; a need to revise and update the national biosafety frameworks that had been prepared; staff turnover; changing sectoral

<sup>28</sup> <http://www.unep.org/biosafety/National%20Biosafety%20frameworks.aspx>, site accessed 27 January 2012.

<sup>29</sup> Further detail is provided in relation, in particular, to element 3 below.

<sup>30</sup> GEF Project Database, <http://www.gefonline.org/projectListSQL.cfm>, site last accessed 30 March 2012; and information provided by UNEP March 2012.

<sup>31</sup> Of the four approved regional projects only one has started. Of the thematic projects, BCH I has completed its support for 120 countries while BCH II will complete its support for 50 Parties in 2012.

<sup>32</sup> See, for example, Document UNEP/CBD/BS/CM-CB/8/INF/1, *Capacity-building projects/initiatives: Update on the Ongoing Biosafety Capacity-Building Projects and Other Initiatives: A compilation of submissions from Governments and Organizations*, 9 March 2012

responsibilities in government; and wider political instability or economic upheaval. Thus some of the barriers to implementation of the Protocol are specific to biosafety regulation, while others relate to the wider political, economic and/or institutional context of each Party.

*Competent national authorities*

40. 134 Parties reported having designated competent national authorities, with 92 having designated one and 42 having designated more than one. Nine Parties reported that they had not yet designated a competent national authority. Designation of a competent national authority does not indicate that that authority necessarily has the legal and technical capacity to take a decision on proposed imports of LMOs in the manner required under the Protocol.

**Element 3 AIA procedures (or domestic regulatory frameworks consistent with the Protocol) for the transboundary movement of LMOs for intentional introduction in the environment are operational and functioning**

*Table 2. Parties that have introduced necessary legal, administrative and other measures for implementation of Protocol<sup>33</sup>*

<b>Region</b>	<b>Fully</b>	<b>Partially</b>	<b>Temporary measures</b>	<b>Draft framework</b>	<b>No measures in Place</b>
Africa	9	23	5	10	2
Asia-Pacific	11	14	3	7	0
CEE	12	6	0	1	0
GRULAC	2	12	1	6	0
WEOG	18	1	0	0	0
<b>Total</b>	<b>52</b>	<b>56</b>	<b>9</b>	<b>24</b>	<b>2</b>

41. As noted above, implementation of NBFs is by no means accomplished, particularly in developing country Parties. In their national reports, many Parties report that they have not fully established the laws and regulations necessary for the operation of their NBF. For example 23 Parties in Africa, 14 in Asia-Pacific, 12 in GRULAC, 6 in CEE and 1 in WEOG reported that their domestic regulatory frameworks were 'partially' in place. In 10 African Parties, 7 in Asia-Pacific, 6 in GRULAC, and 1 in CEE only a draft framework is reported to exist. In addition, 5 Parties in Africa, 3 in Asia-Pacific and 1 in GRULAC have reported that only temporary measures were in place. On the other hand, only 2 Parties report that to date no progress has been made in establishing laws and regulations for the implementation of the Protocol.

<sup>33</sup> Question 15. Note that in the national reports format, this question relates to Article 2 of the Protocol, and thus goes beyond the implementation of AIA procedures in respect of the intentional introduction of LMOs into the environment. See also Table 3.

*Table 3. Parties with domestic institutional and administrative (decision-making) arrangements in place to deal with AIA applications (transboundary movement of LMOs for intentional introduction into the environment)<sup>34</sup>*

<b>Region</b>	<b>Yes</b>	<b>No</b>
Africa	25	24
Asia-Pacific	16	18
CEE	14	5
GRULAC	9	12
WEOG	19	0
<b>Total</b>	<b>83</b>	<b>59</b>

42. Eighty-three Parties reported that they had established a mechanism for taking decisions regarding the first intentional transboundary movement of LMOs for intentional introduction into the environment, while 59 had not yet done so. Of those that had yet to establish such mechanisms, 18 were in Asia-Pacific, 12 in GRULAC, 5 in CEE and 24 in Africa. Administrative systems for handling applications and enabling decision-making on transboundary movement of LMOs are widely recognised as a critical component in the effective implementation of the Protocol.<sup>35</sup> Of the 83 Parties reporting that they had put in place such mechanisms, 79 reported that they apply the same mechanism to cases of intentional introduction of LMOs to the environment that were not subject to transboundary movement.

43. In terms of actual experience of implementation of the AIA procedure, 36 Parties reported that they had taken a decision on an application/notification of intentional transboundary movement of LMOs for intentional introduction into the environment, with 26 of those Parties indicating that they had approved at least one such import.<sup>36</sup> Among those Parties reporting that no decisions on imports had been taken. Some noted that with no applicable legal framework in place, no decisions could be taken. Others noted that no notifications or applications had been received in the reporting period. In fact, 103 Parties stated that they had never received an application/notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment.<sup>37</sup> One Party reported taking decisions on domestic LMOs but not on imports.

44. The developments in relation to GEF-supported NBF implementation projects (see paragraph 37 above) would suggest that further progress on the status of implementation and operationalization of AIA procedures should be made in coming years. However, the results of these projects are likely to take time to materialize. While a number of the projects have been completed recently, others are in their preliminary stages and will be of three or four year duration. In 2008, UNEP observed in relation to the initial demonstration projects on implementation of NBFs (2002-2006) that it would be 'premature to assess the workability and effectiveness of the still evolving national biosafety frameworks' and that the NBFs resulting from the projects had not yet been seriously tested in terms of receiving actual applications.<sup>38</sup>

<sup>34</sup> Question 31.

<sup>35</sup> See, SCBD, *Biosafety Protocol News: National Administrative Systems for Biosafety*, Issue 9, July 2011.

<sup>36</sup> Question 38 and 39. Only 19 Parties appear to have registered information on the BCH concerning decisions on transboundary movement of LMOs for introduction into the environment.

<sup>37</sup> Question 37. 40 Parties reported having received such notifications or applications.

<sup>38</sup> UNEP, *Guidance Towards the Implementation of National Biosafety Frameworks: Lessons Learned from the UNEP Demonstration Projects*, Prepared by UNEP-GEF Biosafety Unit as of April 2008, p.2.

*Funding and staffing**Table 4. Parties with mechanism for budgetary allocations of funds for operation of their NBF<sup>39</sup>*

<b>Region</b>	<b>Yes</b>	<b>No</b>
Africa	23	26
Asia	15	19
CEE	10	9
GRULAC	12	9
WEOG	18	0
<b>Total</b>	<b>78</b>	<b>63</b>

45. 78 Parties reported that they had established a mechanism for budgetary allocation of funds for the operation of the NBF; while 63 had not. 108 Parties reported having in place permanent staff for the operation of the NBF. However, there are significant variations in the number of staff available: some Parties report having several full-time permanent staff in place; numerous others report that permanent staff from various agencies are involved in the biosafety framework (for example, as members of a National Biosafety Committee), but not on a full-time basis.

**Element 4: Procedures for decision-making in relation to transboundary movement of LMOs-FFP are established and operational**

*Table 5. Mechanism established for taking decisions on imports of LMOs-FFP<sup>40</sup>*

<b>Region</b>	<b>Yes</b>	<b>No</b>
Africa	28	21
Asia-Pacific	15	20
CEE	15	4
GRULAC	9	12
WEOG	17	2
<b>Total</b>	<b>84</b>	<b>59</b>

46. 84 Parties report having established a mechanism for taking decisions on imports of LMOs-FFP; 59 have not. 83 Parties reported that they had adopted specific laws and regulations for decision-making concerning domestic use, including placing on the market of LMO-FFPs. Many Parties again noted that while they did not yet have a decision-making procedure in place, they were in the process of developing such a procedure.

47. 40 Parties reported that they had taken final decisions regarding domestic use of LMOs-FFP that may be subject to transboundary movement.<sup>41</sup> 15 Parties seem to have recorded such decisions on the BCH. As noted earlier, of the 649 records on LMO-FFP decisions on the BCH, at least 223 (more than one-third) have been recorded by four non-Parties.

<sup>39</sup> Question 17.

<sup>40</sup> Question 54.

<sup>41</sup> Question 51 and 57. Note that in relation to the European Union, decisions for placing on the market of LMOs-FFP are taken for the whole EU territory.

### Element 5: Risk assessment procedures for LMOs are established and operational

48. A total of 95 Parties indicated that they have established mechanisms for conducting risk assessment, and 70 have risk assessment guidelines in place for LMOs (see Tables 6 and 7 below).

*Table 6. Mechanisms for risk assessment in place<sup>42</sup>*

Region	Yes	No
Africa	27	21
Asia-Pacific	22	13
CEE	16	3
GRULAC	11	10
WEOG	19	0
<b>Total</b>	<b>95</b>	<b>47</b>

*Table 7. Risk assessment guidance in place for LMOs<sup>43</sup>*

Region	Yes	No
Africa	19	29
Asia-Pacific	16	19
CEE	11	8
GRULAC	8	13
WEOG	16	1
<b>Total</b>	<b>70</b>	<b>70</b>

49. Only 63 Parties reported that they had acquired the necessary capacity to conduct risk assessment (see Table 8 below), including one third of GRULAC Parties reporting, less than one half of the Asia-Pacific Parties, and less than one quarter of the African Parties. Once again, many Parties pointed to the fact that their national biosafety laws and regulations had not yet been brought into law.

*Table 8. Parties that have acquired necessary domestic capacity to conduct risk assessment<sup>44</sup>*

Region	Yes	No
Africa	11	36
Asia-Pacific	14	21
CEE	12	7
GRULAC	7	14
WEOG	19	0
<b>Total</b>	<b>63</b>	<b>78</b>

50. The responses in table 8 highlight the fact that further capacity development is required in relation to risk assessment before the procedures and mechanisms established in accordance with the Protocol can become fully operational in all Parties. Indeed, numerous Parties noted in their national reports the need for further capacity development in this area in their national reports. The issue of risk assessment has also been prominent in the work of the Capacity-Building Coordination Meetings. A

<sup>42</sup> Question 81. In the Annex to Decision BS-V/15, indicator 5(c) addresses the 'Number of Parties with an advisory committee or other arrangements in place for conducting or reviewing risk assessment.'

<sup>43</sup> Question 83.

<sup>44</sup> Question 84.

number of Parties reported some degree of regional cooperation, ongoing or prospective, in relation to risk assessment and post-release monitoring of LMOs. At the global level, the Parties have mandated an Ad Hoc Technical Experts Group on Risk Assessment and Risk Management to develop, *inter alia*, further guidance on risk assessment. The COP-MOP has also mandated regional capacity-building risk assessment workshops, which the SCBD has been conducting.<sup>45</sup>

51. 47 Parties reported having conducted a risk assessment of a LMO for intentional introduction into the environment and 34 had conducted risk assessments for one or more LMOs-FFP.<sup>46</sup> 12 Parties reported that they had submitted summary reports of all risk assessments to the BCH, and 15 had done so ‘in some cases only’.<sup>47</sup> A search for “risk assessment” in the BCH<sup>48</sup> yields 639 records, submitted by 24 Parties<sup>49</sup> and two non-Parties. Almost two-thirds of Parties had not conducted any risk assessments in the latest reporting period; 25 Parties had conducted more than ten; 7 less than ten; and 11 less than five.<sup>50</sup> On the basis of information contained in national reports, it would appear that many Parties have not conducted risk assessments as they have not received applications for approvals of LMOs that would require such assessments to be undertaken.

**Element 6: Procedures for establishment of appropriate LMO risk management measures and monitoring are established and operational**

52. Once again, in responses to questions relevant to this indicator in the national reports questionnaire, a number of Parties noted generally that their biosafety laws and regulations were under development but not yet in place.

*Table 9: Parties that have established and maintained appropriate and operational mechanisms, measures and strategies to regulate manage and control risks identified in risk assessments for LMOs for intentional introduction into the environment<sup>51</sup>*

Region	Yes	To some extent	No
Africa	8	12	29
Asia-Pacific	12	8	15
CEE	12	4	3
GRULAC	7	3	11
WEOG	17	2	0
<b>Total</b>	<b>56</b>	<b>29</b>	<b>58</b>

<sup>45</sup> Decision BS-V/12.

<sup>46</sup> Questions 86 and 87.

<sup>47</sup> In response to this question (Question 89 on the national report questionnaire), 57 Parties responded that they had never submitted a summary report of risk assessment to the BCH. For some of those that gave this response, the explanation would seem to lie in the fact that they have not undertaken risk assessments as yet. The option to respond ‘not applicable’ was not available for this question.

<sup>48</sup> As at 31 March 2012.

<sup>49</sup> 1 Party from Africa; 7 Parties from Asia-Pacific; 2 from CEE; 6 from GRULAC; and 8 from WEOG.

<sup>50</sup> Question 90.

<sup>51</sup> Question 94a).

*Table 10: Parties that have established and maintained mechanisms, measures and strategies to regulate manage and control risks identified in risk assessments for LMOs-FFP<sup>52</sup>*

<b>Region</b>	<b>Yes</b>	<b>To some extent</b>	<b>No</b>
Africa	8	11	30
Asia-Pacific	10	8	17
CEE	12	6	1
GRULAC	3	3	15
WEOG	17	2	0
<b>Total</b>	<b>50</b>	<b>30</b>	<b>63</b>

53. 56 Parties reported that they have established and maintained mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessments for LMOs for intentional introduction into the environment, and 29 have done so ‘to some extent’. 58 Parties reported that they had not yet done so (see Table 9). The latter category includes more than half the African Parties and nearly half of those from Asia-Pacific and GRULAC.

54. Fifty Parties have established similar measures for LMOs-FFP, 30 have done so “to some extent” and 64 Parties had not yet established such measures for LMOs-FFP (see Table 10). The latter category includes more than half of African and GRULAC Parties and almost half of Asia-Pacific Parties. Many Parties have no practical experience implementing such measures.

55. A number of Parties mentioned regional cooperation in relation to risk management (and risk assessment), in a variety of regions and subregions,<sup>53</sup> and others noted the potential for regional cooperation in these fields. Numerous developing country Parties also noted the need to strengthen capacity in relation to risk management.

**Element 7: Procedures for identifying and addressing illegal transboundary movements of LMOs are in place and operational**

56. Eighty-six Parties reported having adopted measures aimed at preventing and penalizing illegal transboundary movements of the LMOs, while 55 have not (Table 11). Most Parties (87) that submitted reports have not established a strategy for detecting illegal transboundary movements.<sup>54</sup> A number of Parties mentioned in their reports provisions of relevant domestic law providing for penalties for illegal transboundary movements of LMOs, and others noted that there were provisions for such penalties in their national biosafety frameworks. In many instances such provisions have not been utilized to date or are not yet in effect.

<sup>52</sup> Question 94b).

<sup>53</sup> These included, for example, reference to relevant activities in SADC, the African Union, and ASEAN.

<sup>54</sup> Question 169.

*Table 11. Parties with domestic measures to prevent and penalize illegal transboundary movement of LMOs<sup>55</sup>*

<b>Region</b>	<b>Yes</b>	<b>No</b>
Africa	27	20
Asia-Pacific	18	17
CEE	13	6
GRULAC	9	12
WEOG	19	0
<b>Total</b>	<b>86</b>	<b>55</b>

57. Few cases of illegal transboundary movements of LMOs appear to have been reported in the period covered by the second national reports.<sup>56</sup> Fifteen Parties reported receiving information on less than five cases of such movements, two reported between five and nine such instances, and one reported more than ten. Only two countries have reported cases of illegal transboundary movements to the BCH.<sup>57</sup> The low number of illegal transboundary movements reported may simply indicate compliance with the procedures of the Protocol, as reflected in national law. At the same time, as noted earlier in this report, it is clear that relevant legal frameworks are not in place or fully operational in many of the Parties. Numerous developing country Parties noted impediments to implementation of provisions on illegal transboundary movements, particularly related to lack of legal provisions on detection and monitoring, as well as lack of technical capacity. In such instances, as some Parties noted in their second national reports, Parties may not be in a position to identify illegal transboundary movements of LMOs where they occur. Lack of public awareness may also contribute either to illegal transboundary movements themselves or to a failure to identify and report such movements. A number of national reports also suggest that some transboundary movements that have taken place in a manner that does not comply with provisions of the Protocol have been unintentional transboundary movements, and thus have not been recorded as illegal in the Biosafety Clearing-House.

58. The Updated Action Plan for Building Capacities for the Effective Implementation of the Protocol adopted by the Parties in decision BS-III/3 includes, as one of the key elements requiring capacity-building support and action, “measures to address unintentional and/or illegal transboundary movements of living modified organisms”. The eighth coordination meeting for governments and organizations implementing and/or funding biosafety capacity-building activities held in March 2012, considered measures to enhance the capacities of Parties in detecting, preventing and managing illegal transboundary movements of living modified organisms.<sup>58</sup>

**Element 8: Procedures for preventing, identifying and addressing unintentional transboundary movements of LMOs are established and operational, including notification and emergency measures**

59. Ninety-three Parties reported that they had notified the Biosafety Clearing-House of contact points regarding unintentional transboundary movements of LMOs in accordance with Article 17.

<sup>55</sup> Question 168.

<sup>56</sup> Question 170.

<sup>57</sup> UNEP/CBD/BS/CM-CB/8/1.Add.1, Annotations to the Provisional Agenda, Eighth Coordination Meeting for Governments and Organizations Implementing or Funding Biosafety Capacity-Building Initiatives, 7 January 2012, para. 11.

<sup>58</sup> The Convention Secretariat issued a note dated 6 April 2012 listing Article 17 national focal points. The note reflects the information available on the Biosafety Clearing-House, and also includes details of the Article 17 national focal point of one Party that is not currently available on the Biosafety Clearing-House.

However, only 83 national focal points for Article 17 are listed in the Biosafety Clearing-House, including eleven notified by one Party and two by another.

*Table 12. Parties have notified the Biosafety Clearing-House of their contact point regarding unintentional transboundary movements of LMOs<sup>59</sup>*

Region	Yes	No
Africa	29	20
Asia-Pacific	19	16
CEE	12	7
GRULAC	15	6
WEOG	18	1
<b>Total</b>	<b>93</b>	<b>50</b>

60. Eighty Parties have established mechanisms for addressing emergency measures in case of unintentional transboundary movements of LMOs.<sup>60</sup> Nine Parties reported receiving information concerning occurrences that led, or may have led, to unintentional transboundary movement in the period covered by the second national report. Of these, two indicated that they had notified affected or potentially affected states of the occurrence, but had not notified the Biosafety Clearing-House.<sup>61</sup>

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

61. In relation to handling, packaging and transport, 61 Parties reported having taken measures to ensure that LMOs subject to transboundary movement are treated under conditions of safety, taking into account relevant international rules and standards. 25 reported having taken such measures 'to some extent'; and 44 had taken no such measures.<sup>62</sup>

62. The indicator in decision BS-V/15 for this element also addresses the number of Parties with requirements for handling, transport, packaging and identification of LMOs in place consistent with Article 18, and relevant subsequent decisions of the COP-MOP, for (i) LMOs destined for contained use; (ii) LMOs intended for intentional introduction into the environment; and (iii) LMOs-FFP. The number of Parties in different regions that have put in place such measures are presented in Table 13-16.

<sup>59</sup> Question 100.

<sup>60</sup> Question 101.

<sup>61</sup> There do not appear to be any records of unintentional transboundary movements in the Biosafety Clearing-House.

<sup>62</sup> Question 108.

*Table 13. Party has taken measures to ensure documentation accompanying LMOs destined for contained use clearly identifies them as LMOs and meets other requirements of Article 18 relating to such LMOs<sup>63</sup>*

<b>Region</b>	<b>Yes</b>	<b>To some extent</b>	<b>No</b>
Africa	15	12	22
Asia-Pacific	10	12	13
CEE	11	5	3
GRULAC	6	3	12
WEOG	19	0	0
<b>Total</b>	<b>61</b>	<b>32</b>	<b>50</b>

*Table 14. Party has taken measures to require that documentation accompanying LMOs intended for intentional introduction into the environment of the Party of import clearly identifies them as LMO, and meets other requirements of Article 18 relating to such LMOs<sup>64</sup>*

<b>Region</b>	<b>Yes</b>	<b>To some extent</b>	<b>No</b>
Africa	14	11	24
Asia-Pacific	11	9	15
CEE	12	3	4
GRULAC	5	2	14
WEOG	18	0	1
<b>Total</b>	<b>60</b>	<b>25</b>	<b>58</b>

*Table 15. Party has taken measures to require that documentation accompanying LMOs-FFP clearly identifies that, in cases where the identity of the LMOs is not known through means such as identity preservation systems, they may contain LMOs and are not intended for intentional introduction into the environment, as well as a contact point for further information<sup>65</sup>*

<b>Region</b>	<b>Yes</b>	<b>To some extent</b>	<b>No</b>
Africa	12	11	26
Asia-Pacific	8	7	20
CEE	12	3	4
GRULAC	0	4	17
WEOG	18	0	1
<b>Total</b>	<b>50</b>	<b>25</b>	<b>68</b>

<sup>63</sup> Question 111.

<sup>64</sup> Question 112.

<sup>65</sup> Question 109.

*Table 16. Party has taken measures to require that documentation accompanying LMOs-FFP clearly identifies that, in cases where the identity of the LMOs is known through means such as identity preservation systems, they contain LMOs and are not intended for intentional introduction into the environment, as well as a contact point for further information<sup>66</sup>*

Region	Yes	To some extent	No
Africa	14	12	23
Asia-Pacific	9	11	14
CEE	12	4	3
GRULAC	0	3	18
WEOG	19	0	0
<b>Total</b>	<b>54</b>	<b>30</b>	<b>58</b>

63. It seems clear from these responses that a significant amount remains to be done in relation to the implementation of Article 18, particularly its provisions relating to documentation requirements. To a certain extent, as in relation to other aspects of the Protocol, deficits in implementation of these provisions reflect the general status of implementation of NBFs discussed above. A number of Parties noted in their national reports that provisions relating to documentation would be included in their national regulatory framework once adopted. Many Parties reported that they have no (42 Parties) or only some (63 Parties) capacity to enforce requirements of identification and documentation of LMOs.<sup>67</sup>

**Element 10: Procedures for notification of required information to the BCH are established and operational**

64. The BCH lists BCH focal points for 191 states and the European Union.<sup>68</sup> Most Parties reported that they had established a mechanism for coordination among their BCH focal point, the national focal point for the Protocol and their competent national authority(ies) with regard to making information available to the BCH.

*Table 17. Coordination mechanism in place between BCH focal point, national focal point and competent national authority(ies)<sup>69</sup>*

Region	Yes	No
Africa	31	16
Asia-Pacific	27	8
CEE	17	2
GRULAC	18	3
WEOG	17	2
<b>Total</b>	<b>110</b>	<b>31</b>

<sup>66</sup> Question 110.

<sup>67</sup> Question 113.

<sup>68</sup> See indicator (a) under Element 10: 'Number of Parties that have allocated responsibilities for notification of information to the BCH'.

<sup>69</sup> Question 126. See indicator (b) under Element 10: 'Number of Parties that have in place systems for the management of biosafety information necessary for the implementation of the Protocol'.

65. As at 30 March 2012, there were 709 records on the BCH relating to national laws, regulations and guidelines; 479 records relating to decisions on transboundary movement of LMOs for intentional introduction to the environment; and 649 records relating to decisions on LMOs for food or feed, or for processing. Some non-Parties have made a significant amount of information available on the BCH. The second national report questionnaire requested Parties to indicate whether they had provided certain categories of information to the BCH and whether such information was available. Reflecting the relatively limited experience to date in many Parties, for several categories of information a significant majority of Parties reported that such information was not available.<sup>70</sup>

66. As noted earlier in this report, 67 Parties reported that information that they had submitted to the BCH was incomplete or required updating. A number reported that they were in the process of collating and updating information for submission to the BCH.

67. Some Parties reported difficulties in relation to the BCH, but these related principally to access to reliable internet access. Some reports indicated difficulties relating to issues of language.

#### **Element 11: Procedures and measures for promoting public awareness are being implemented**

68. In their national reports, 50 Parties reported that they have put in place a strategy or legislation for promoting public awareness, and a further 50 reported that they had done this 'to some extent'. 43 had no such strategies in place (Table 18). Numerous Parties reported on specific public awareness activities, particularly within the context of the NBF development process. Many also reported the establishment of specific websites. Again, however, a significant number of developing country Parties reported obstacles to the development of public awareness and participation mechanisms due to lack of relevant expertise and/or funding.

*Table 18. Strategy or legislation in place to promote public awareness<sup>71</sup>*

<b>Region</b>	<b>Yes</b>	<b>To some extent</b>	<b>No</b>
Africa	14	17	18
Asia-Pacific	8	16	11
CEE	11	3	5
GRULAC	3	10	8
WEOG	14	4	1
<b>Total</b>	<b>50</b>	<b>50</b>	<b>43</b>

69. 64 Parties have established mechanisms to consult the public in decision-making processes on LMOs, and 27 have done so to some extent (Table 19). A significant number of Parties noted that while provisions for public awareness and participation had been included in the NBF, there was no real experience of implementation of such provisions as yet either because the NBF had yet to be put into operation or because they had not yet dealt with an application for transboundary movement of an LMO.

<sup>70</sup> These categories included, for example, decisions on regulating transit of LMOs (107 Parties); occurrences of unintentional transboundary movements (133 Parties); illegal transboundary movements (126 Parties); final decisions on the importation or release of LMOs (80 Parties); final decisions regarding import of LMOs-FFP (93 Parties).

<sup>71</sup> Question 151. See indicator (a) under Element 11: 'Number of Parties implementing public awareness programmes or activities'.

*Table 19. Mechanisms in place to consult the public in decision-making processes on LMOs<sup>72</sup>*

<b>Region</b>	<b>Yes</b>	<b>To some extent</b>	<b>No</b>
Africa	19	9	21
Asia-Pacific	10	9	16
CEE	13	3	3
GRULAC	3	6	12
WEOG	19	0	0
<b>Total</b>	<b>64</b>	<b>27</b>	<b>52</b>

70. Some Parties referred to difficulties with putting public participation provisions into practice due to the complexity of the issue, a lack of appropriate mechanisms and issues of language. A number of Parties described the procedures for public participation they have been put in place including making information available on public websites and the possibility of holding consultation meetings in appropriate circumstances.

### *C. International level procedures and mechanisms*

71. Since the entry into force of the Protocol, significant work has been done to put in place international level procedures and mechanisms to support and review implementation of the Protocol. Decision BS-V/15 identified the Capacity-Building Action Plan, the Compliance Committee and the BCH as elements that should be subject to analysis as part of the second assessment and review of the effectiveness of the Protocol.

#### **Element 12: Capacity-building Action Plan being effectively implemented**

72. At their first meeting, the Parties adopted an Action Plan on capacity-building, and established a coordination mechanism for the implementation of the Action Plan. It also adopted a set of indicators for monitoring implementation of the Action Plan,<sup>73</sup> which were revised at the fourth meeting of the Parties.<sup>74</sup> The Parties have regularly considered reports on the status of capacity-building activities including bilateral, regional and multilateral initiatives.

73. In accordance with decision BS-V/3, the implementation of the capacity-building Action Plan is subject of specific independent evaluation, and is not separately analysed here.<sup>75</sup> The independent evaluation concluded that overall, some progress has been made in building capacity for the effective implementation of the Protocol. There have been a number of initiatives, such as the projects on the development and implementation of NBFs funded by the GEF, which have provided a stepping stone for many Parties to undertake capacity-building for biosafety.

74. The independent evaluation concluded that the Action Plan has been effective to varying degrees in guiding, catalysing and leveraging capacity-building activities at the national, regional, and international level. For the majority of the cases, the Action Plan has served as a useful guidance tool

<sup>72</sup> Question 154. See indicator (b) under Element 11: 'Number of Parties providing for some level of public participation in decision-making processes on LMOs'.

<sup>73</sup> Decision BS-I/5.

<sup>74</sup> Decision BS-IV/3.

<sup>75</sup> See document UNEP/CBD/BS/COP-MOP/6/INF/2 from which paragraphs 74-77 are drawn.

for countries and some organizations. However, it does not seem to have been used as a guide in the design and implementation of some donor initiatives.

75. Although still relevant, it was suggested that the current Action Plan needs to be modified in order to respond to emerging needs of Parties and be in line with the new Strategic Plan of the Cartagena Protocol on Biosafety. There is also a need for the prioritisation and elaboration of its elements to provide a clearer linkage with the main components of national biosafety frameworks and the Strategic Plan for the Protocol and foster a results-based approach. Furthermore, there is a need for a detailed monitoring framework.

76. One of the key challenges for the implementation of the Action Plan is that, overall, funding for capacity-building for biosafety has decreased over the last few years. The funding issue is of grave concern, given the unmet and new emerging needs of developing countries, and particularly in view of the fact that many countries have yet to undertake crucial capacity-building initiatives to meet their obligations under the Cartagena Protocol and the implementation of their national biosafety frameworks. In the context of the financial mechanism for the Protocol, under the current System for Transparent Allocation of Resources (STAR) as well as in the previous Resource Allocation Framework (RAF), in the allocation of funds biosafety activities compete with other biodiversity-related activities. This competitive situation has resulted in the decrease in funding for biosafety activities. The COP-MOP may need to pay special attention to this issue.

77. The role of the Secretariat in capacity-building is still important in complementing the implementation of the Action Plan. There is a need for the Secretariat to continue its work, particularly in conducting training workshops at regional and subregional levels and developing online training tools for use by the Parties.

### **Element 13: Compliance Committee is functioning**

78. The Compliance Committee is fully established and has held regular meetings to discuss issues related to compliance and related to its own functioning. However, to date no specific situation of non-compliance has been brought to the attention of the Committee by any Party with respect to itself or with respect to another Party.<sup>76</sup> In Decision BS-V/1, the COP-MOP addressed the supportive role of the Compliance Committee in relation to the provision of advice and assistance to Parties. According to the decision, the Committee may consider taking measures in a situation where a Party fails to submit its national report, or information has been received through a national report or the Secretariat based on information from the Biosafety Clearing-House that shows the Party being faced with difficulties complying with its obligations under the Protocol. This is expected to give the Committee some room to activate the compliance procedures and to play a more active and supportive role. Previously, the compliance procedures could be triggered only by a Party either with regard to itself or against another Party.

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<sup>76</sup> At its sixth meeting, the Compliance Committee considered whether it had a mandate to receive and consider a submission made by a non-governmental organization alleging non-compliance of a Party with its obligations under the Protocol. It concluded that it had no mandate to consider the submission because section IV of the compliance procedures adopted in the annex to decision BS-I/7 permits only a Party to trigger the procedures with respect to itself or with respect to another Party. UNEP/CBD/BS/CC/6/4, paras. 20 and 21.

79. The rules of procedure of the Committee concerning decision-making have not been finalized, and rule 18 of the Committee's rules of procedure remains in square brackets.<sup>77</sup> Nonetheless, the Committee has been able to function and adopt decisions on the basis of consensus to date.

**Element 14: The BCH is operational and accessible**

80. The Biosafety Clearing House has been established and is operational.<sup>78</sup> Much work has gone into developing the BCH as an accessible and functional tool. Issues related to whether the content of the BCH is reliable and up-to-date have been addressed in the preceding sections of this report. While the BCH is functioning and, for the most part, accessible, there are cases where Parties have not made timely notification of information to the BCH required under the Protocol.

81. Twenty-six Parties reported difficulties accessing or using the BCH, while 113 had experienced no problems. Some Parties reported technical difficulties with the BCH that had been resolved after contact with the SCBD; others cited general difficulties in terms of human, financial and technical capacity; and some referred to specific difficulties concerning language.

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

82. On the basis of information contained in the second national reports, it seems that where LMOs are being moved between Parties, and for the most part between Parties and non-Parties, such movements are taking place in accordance with the Protocol. However, many Parties have not yet used the Protocol's procedures in relation to transboundary movement of LMOs as they are not yet implemented at the domestic level and/or because no notifications or applications have been received. Second national reports reveal continuing concerns on the part of some Parties about possible cases of illegal or unintentional transboundary movements of LMOs, and their capacity to prevent, detect and/or respond to such movements. However, the Protocol has increased awareness of issues associated with transboundary movement of LMOs and triggered significant developments in relation to the drafting and implementation of national biosafety frameworks.

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

83. It does not appear that specific linkages have been drawn between evaluations of the effectiveness of the Cartagena Protocol, under Article 35, and the evaluation of progress in relation to the Strategic Plan for the Convention on Biological Diversity. In decision X/7, the Conference of the Parties to the Convention on Biological Diversity mandated an Ad Hoc Technical Expert Group to work on indicators for the Strategic Plan for Biodiversity 2011-2020. Some consideration might be given as to whether linkages might usefully be drawn between this process and outcome-oriented indicators for the evaluation of the effectiveness of the Cartagena Protocol.

84. A preliminary proposal is made in document UNEP/CBD/BS/A&R/1/3 as to a possible process for the development of outcome-oriented indicators for evaluation of the effectiveness of the Cartagena Protocol in meeting its objective. Parties may wish to consider, in due course, whether and how such a process might be linked to the wider process on indicators in relation to the Strategic Plan of the Convention.

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<sup>77</sup> See Decision BS-II/1 on Rules of Procedure for Meetings of the Compliance Committee.

<sup>78</sup> Decision BS-I/3.

### III. CONCLUSIONS AND RECOMMENDATIONS ON THE STATUS OF IMPLEMENTATION

85. This report has sought to give a general picture of the status of implementation of the Cartagena Protocol in relation to certain core elements, on the basis of the sources of information identified in decision BS-V/15. This section highlights some conclusions and tentative recommendations emerging from this analysis.

86. **Coverage:** While the Protocol has been widely ratified by a large number of states in the various regions, a number of states involved in transboundary movement of LMOs remain non-Parties. All Parties have designated national focal points for the Protocol. The level of timely submission of national reports on implementation of the Protocol is good, but could be further improved.

87. **Regulatory frameworks:** The analysis above clearly indicates that many Parties remain at a relatively early stage of implementation of their national biosafety frameworks, and that many developing country Parties, in particular, are still far from having in place fully established and functioning biosafety regulatory frameworks that meet the requirements of the Protocol. For the next assessment and review period, the significant challenge remains of facilitating the finalization and putting into effect of such frameworks.

88. For the most part, developed country Parties appear to have in place regulatory frameworks for implementation of the Protocol, even though challenges might arise in the application of these frameworks in particular cases. For developing countries Parties, the picture is much more mixed, with implementation in progress and incomplete, and capacity constraints frequently cited in relation to certain aspects of implementation. Nonetheless, almost all Parties have taken *some* steps towards establishing legal, administrative and other measures for the implementation of the Protocol, particularly through the development of national biosafety frameworks.

89. Many Parties have reported no practical experience as yet in decision-making on proposed imports of LMOs for intentional introduction into the environment or for LMOs-FFP. The reasons for this appear to vary. In some cases appropriate legal frameworks and technical capacity for such decision-making are not in place. In a number of Parties, there have been no notifications or applications to consider. In any event, it seems clear that at present a number of Parties would not be in a position to deal with an application for import of LMOs, in accordance with the procedures set out in the Protocol, if they were to receive one. Many do not have in place a mechanism for handling requests and procedures for decision-making in place; and even where such mechanisms and procedures exist on paper, lack of capacity to review applications, including capacity to undertake or review risk assessments prior to making a decision, remains a major challenge.

90. A number of Parties described the barriers that have impeded full implementation of the Protocol to date. In the majority of cases, these related to a lack of human, financial and technical resources. Other reasons included a lack of priority given to the issue of biosafety; a continuing lack of awareness of the issue among the public and policymakers; a need to revise and update the national biosafety frameworks that had been prepared; staff turnover; changing sectoral responsibilities in government; and wider political instability or economic upheaval. Thus some of the barriers to implementation of the Protocol are specific to biosafety regulation, while others relate to the wider political, economic and/or institutional context of each Party. Some of these constraints and challenges seem likely to continue to affect progress in implementation in the next few years.

91. Where developing country Parties have taken up research into and applications of biotechnology, regulatory frameworks seem to have been more fully developed, albeit that capacity needs may remain in some important areas. Some developing countries cited in their reports the need to put regulatory frameworks in place in light of the use of LMOs in neighbouring states or trading partners, and the potential for unintentional as well as intentional transboundary movements of LMOs.

92. **Enforcement of biosafety regulation:** Most Parties that have developed NBFs appear to have addressed in the NBF, or to intend to address in national law, penalties for illegal transboundary movement of LMOs, situations of unintentional transboundary movement of LMOs, and requirements for documentation accompanying transboundary movement of LMOs. However, on the basis of the information in the national reports, relatively few Parties have the systems or capacity to enforce such provisions. In this regard, many developing country Parties cite, in particular, a lack of technical and infrastructure capacity for sampling and detection of LMOs.

93. **Regional approaches:** It is notable in the national reports that regional cooperation forms an important component of the strategy for implementation of the Protocol for many Parties, particularly in relation to risk assessment and risk management. Thus, a number of Parties mentioned in their national reports actual or prospective forms of regional cooperation, whether through existing mechanisms such as regional trade arrangements, or through biosafety-specific projects and arrangements. Regional cooperation also forms a basis for some GEF-funded projects on biosafety, such as those in West Africa and the Caribbean, with more apparently under consideration. In light of experience gained with such models, Parties may wish to consider further opportunities for appropriate regional and subregional cooperation. This is an issue that has been addressed by the COP-MOP, in light of recommendations of the Capacity-Building Coordination Meeting. The independent evaluation of the Capacity-building Action Plan, conducted for consideration by the Parties at their sixth meeting, also recommends an emphasis on regional capacity-building measures.<sup>79</sup>

94. **Information-sharing and the Biosafety Clearing House:** The BCH is fully operational and accessible, but it is not populated with comprehensive and up-to-date information from Parties, including the mandatory information on national biosafety laws, risk assessment summaries or decisions taken on LMOs. Information exchange is a central element in the implementation of the Cartagena Protocol, and thus the Parties need to consider how to improve information exchange through the BCH. This might entail ways to promote the provision to the BCH by Parties of information that is required under the Protocol; and recommendations to Parties to provide additional categories of information to the BCH. It might entail further exploration of linkages between the BCH and other relevant databases of biotechnology and biosafety information. It may be helpful, for example, to undertake a comprehensive review of information on regulatory decisions available in the BCH and elsewhere with a view to promoting consistency and comprehensiveness in the BCH. It might also be useful to invite governments, and remind Parties of their obligations, to include in the BCH information on domestic approvals of small and large-scale field trials, if such trials involve any introduction of LMOs into the environment<sup>80</sup>. Practice among Parties in this regard appears to vary at present. A more comprehensive information base might facilitate future assessments and reviews of effectiveness of the Protocol in terms of the achievement of its objective.

95. **Capacity-building and financial resources:** Significant efforts have been made towards the development of capacity for the implementation of the Protocol, and a significant amount of financial resources provided. However, the national reports make it clear that need for capacity development and

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<sup>79</sup> UNEP/CBD/BS/COP-MOP/6/INF/2.

<sup>80</sup> Articles 10.3 and 20.3(d) of the Cartagena Protocol on Biosafety

financial support for implementation remain critical to achieving further progress. At the same time, the global economic climate means that availability of funds for biosafety is likely to tighten further. As noted above, the Capacity-building Action Plan has been the subject of separate independent evaluation and recommendations, but it would seem essential that any review of the Action Plan considers again how best to leverage and utilize funding for capacity development. The independent evaluation has recommended the development of a new framework for capacity-building and a results-based Action Plan by the meeting of the Parties, setting out prioritised actions, specific targets and a monitoring framework, and including sustainability measures.<sup>81</sup>

#### IV. REVIEW OF THE ANALYSIS

96. The Ad Hoc Technical Expert Group is invited to review the analysis of information contained in this report, in the light of Article 35 of the Protocol and decision BS-V/15, with a view to making appropriate recommendations to the sixth meeting of the Parties on the second assessment and review of the effectiveness of the Protocol, focusing primarily on the status of implementation of core elements of the Protocol, identified in the annex to decision BS-V/15.

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<sup>81</sup> *Ibid.*

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