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

Sixth meeting  
Hyderabad, India, 1-5 October 2012  
Item 17 of the provisional agenda

### MONITORING AND REPORTING (ARTICLE 33): ANALYSIS OF INFORMATION AND TRENDS CONTAINED IN THE SECOND NATIONAL REPORTS

*Note by the Executive Secretary*

#### I. INTRODUCTION

1. Article 33 of the Cartagena Protocol on Biosafety requires Parties to monitor the implementation of their obligations under the Protocol and report, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP), on measures taken to implement the Protocol.
2. In its decision BS-I/9, the COP-MOP requested Parties to submit reports every four years and, in the initial four-year period, to submit an interim report two years after entry into force of the Protocol. Accordingly, Parties were requested to submit their Interim Report on the implementation of the Cartagena Protocol on Biosafety by 11 September 2005 (decision BS-I/9<sup>1</sup>) and their First Regular National Report by 11 September 2007 (decision BS-III/14<sup>2</sup>).
3. In its decision BS-V/14<sup>3</sup> on monitoring and reporting (Article 33), the COP-MOP adopted a new reporting format and requested the Executive Secretary to make it available to Parties online through the Biosafety Clearing-House (BCH).
4. Further, the COP-MOP requested Parties to use the reporting format for the preparation of their Second National Report or, in the case of Parties submitting their national report for the first time, to use it for their First National Report on the implementation of their obligations under the Protocol. The COP-MOP also encouraged Parties to respond to all questions in the reporting format including questions that do not necessarily represent obligations under the Protocol. These questions are considered to be useful in gathering information that facilitates the establishment of a baseline for subsequent assessment and

<sup>1</sup> Decision BS-I/9 at <http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=8291>

<sup>2</sup> Decision BS-III/14 at <http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=11071>

<sup>3</sup> Decision BS-V/14 at <http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=12327>

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review of the effectiveness of the Protocol, as well as to measure progress in the implementation of the Strategic Plan of the Cartagena Protocol on Biosafety.

5. In recognizing the continuing need for financial resources to enable developing country Parties and Parties with economies in transition to fulfil their obligations under the Protocol, the COP-MOP, in its decision BS-V/5 on “Financial mechanism and resources”, urged the Global Environment Facility (GEF) to make available, in a timely manner, financial resources to eligible Parties to facilitate the preparation of their Second National Reports under the Protocol.

6. In May 2011, the Chief Executive Officer and Chairperson of the GEF approved three umbrella projects, implemented by the United Nations Environment Programme (UNEP), to support all eligible Parties to prepare their Second National Reports on the implementation of the Protocol. The Executive Secretary informed all Parties of the approval of GEF funding and urged them to contact UNEP to access the funds<sup>4</sup>.

7. The Executive Secretary reminded Parties to submit their Second Regular National Report on the implementation of the Cartagena Protocol on Biosafety, no later than 30 September 2011, in an official language of the United Nations through the Management Centre of the BCH<sup>5</sup>. In order to allow a maximum number of Parties to submit their reports for the analysis of the Second National Reports, a further extension was announced with a cut-off date of 31 December 2011.

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<sup>4</sup> Notification 2010-101 of 2010-12-13 at <http://www.cbd.int/doc/notifications/2011/ntf-2011-101-bs-nr2-en.pdf>

<sup>5</sup> Notification 2010-215 of 2011-05-19 at <http://www.cbd.int/doc/notifications/2010/ntf-2010-215-bs-en.pdf>

## II. SUMMARY OF THE RESPONSES

8. As of 31 December 2011, the Secretariat had received submissions of Second National Reports from 143 of the 161 Parties to the Protocol. This represents 89% of the Parties. The submissions received were regionally distributed as follows:

- Africa: 49 reports (100% of the Parties in the region);
- Asia-Pacific (AP): 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).

9. Due to the significant differences in the level of implementation among Parties, and in particular the least developed and small island developing States among them, this summary, in addition to providing the breakdown of results at the regional level, also provides, where possible, the aggregated data of the following two groups:

- 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>6</sup>.

10. The first section of the format for the Second National Report (Questions 1-11) addresses the contact details of the national reporting officer, the organizations and/or stakeholders who were consulted or participated in the preparation of the report, the date of submission and the time period covered by the report. The responses provided in this section of the report are not included in this document.

### *Article 2 – General Provisions (questions 15-21)*

11. In *Question 15*, countries were asked whether they had *introduced the necessary legal, administrative and other measures for the implementation of the Protocol*. Out of the 143 Parties that submitted their reports, 52 Parties (36% of the respondents to this question) reported that a *domestic regulatory framework is fully in place* and 56 Parties (39% of the respondents to this question) reported that it is *partially in place*. On the other hand, 36 Parties reported not yet having a regulatory framework in place. Of these, 9 Parties (6% of the respondents to this question) stated that *only temporary measures have been introduced*; 25 Parties (17% of the respondents to this question) stated that *only a draft framework exists* and 2 countries (1% of the respondents to this question) stated that *no measures have yet been taken*. The percentages of respondents within different regions that do not yet have a regulatory framework in place are as follows: 34% of respondents within Africa, 29% in Asia-Pacific, 10% in CEE and 33% in GRULAC. Among economic groupings, 34% of Parties within LDCs and 59% of Parties within SIDS do not yet have a regulatory framework in place.

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<sup>6</sup> The current list of LDCs includes 48 UN Member States (33 in Africa, 14 in Asia and the Pacific and 1 in the Caribbean), of which 39 are Parties to the Protocol. The current list of SIDS includes 38 UN Member States (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, of which 30 are Parties to the Protocol. The two groups (LDCs and SIDS) have ten UN Member States in common of which 5 are Parties to the Protocol. 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-OHRLS) at <http://www.unohrlls.org/en/home/>.

12. In *Question 16*, countries were asked to provide details regarding *which specific instruments are in place for the implementation of their national biosafety framework*. In this regard, 67% of the responses<sup>7</sup> referred to *biosafety laws, regulations or guidelines*, 31% referred to *other laws, regulations or guidelines that indirectly apply to biosafety* and 2% of the responses indicated that *no instruments are in place*. The breakdown by regional and economic group of the Parties indicating that *no instruments are in place* is as follows: 1% of respondents within Africa, 4% in Asia-Pacific, 8% in GRULAC, 5% within LDCs and 10% of the respondents within SIDS.

13. In response to *Question 17*, 78 Parties (55% of the respondents to this question) reported that they have *established a mechanism for the budgetary allocations of funds for the operation of its national biosafety framework*. Furthermore, 111 Parties (78% of the respondents) reported under *Question 18*, that they have *permanent staff to administer functions directly related to the NBF*. Of these, 30% of the respondents reported, under *Question 19*, that they have in place *more than 10 staff members whose functions are directly related to the national biosafety framework*, 15% have *less than 10 staff*, 47% have *less than 5 staff* and 8% have *one staff member*.

14. Under *Question 20*, 72 Parties (51% of the respondents to this question) reported that they have submitted their *country's biosafety framework / laws / regulations / guidelines to the Biosafety Clearing-House*; 48 Parties (34% of the respondents to this question) reported that they submitted it *partially* and 22 Parties (16% of the respondents to this question) reported that they have not submitted it.

15. In *Question 21*, countries were invited to provide further details on the implementation of the *General Provisions*. A number of Parties stated that they have developed National Biosafety Frameworks with support from the United Nations Environment Programme - Global Environment Facility (UNEP-GEF) Project on Development of National Biosafety Frameworks. Many Parties reported that they have developed draft national biosafety legislation and some reported that they have enacted their biosafety laws. One Party reported that, even though a biosafety bill is under preparation, a ban on the import of LMOs has been in place since 2000. One Party from CEE also reported that there are “essentially no activities relating to transboundary movements of LMOs [...] due to a gene technology moratorium on deliberate release of LMOs”. Most countries from GRULAC and Africa reported that their processes for the implementation of the *General Provisions* of the Protocol are still in early stages.

16. Most of the reporting EU Member State Parties stated that they have set up their primary domestic legal instruments that ensure the enforcement and/or transposition of the overarching EU legislation. One Party from the CEE reported the establishment of a National Co-ordination Biosafety Centre as a national centre responsible for liaising with the CBD Secretariat.

#### *Article 5 – Pharmaceuticals (questions 22-24)*

17. In response to *Question 22* on whether countries do *regulate the transboundary movement, handling and use of LMOs which are pharmaceuticals*, 54 Parties (39% of the respondents to this question), including all WEOG Parties, answered *yes*, while 26 Parties (19% of the respondents to this question) reported that they do so *to some extent*. 58 Parties (42% of the respondents to this question) reported that they have no regulations in place for LMOs which are pharmaceuticals. The percentages of respondents within the different regions/economic groups that have no such regulations in place are as follows: 47% of respondents within Africa, 62% in Asia-Pacific, 21% in CEE, 55% in GRULAC, 61% within LDCs and 62% of the respondents within SIDS.

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<sup>7</sup> It is noted that question 16 allows each respondent to provide multiple answers and therefore the results are given as percentages of responses rather than respondents.

18. Under *Question 23*, 31 Parties (40% of the respondents to this question) reported that they have *submitted this information to the BCH*; 12 Parties (16% of the respondents to this question) reported that they submitted it *partially* and 32 Parties (43% of the respondents to this question) reported that they had not submitted it.

19. In *Question 24* countries were invited to provide further details on the implementation of Article 5. Three Parties from Asia reported that there is no comprehensive system in place to regulate pharmaceutical products that contain LMOs in their countries. Other Parties stated that the import of all pharmaceuticals are subject to a regulatory regime and, in cases of pharmaceuticals containing LMOs, risk assessments are required. A Party from GRULAC reported that LMO pharmaceuticals are not regulated; however, recombinant DNA products such as vaccines for animal use are registered but not using the requirements and parameters for risk assessment set up in the Cartagena Protocol. Most Parties from Africa reported that LMO pharmaceutical regulations typically fall under broader general legislation applicable to all LMOs or all pharmaceutical products. One Party from Africa reported that its Biosafety Act excludes LMOs that are pharmaceuticals. Two Parties from Africa reported that they only authorise the use of any drugs that have been approved and certified by the World Health Organization.

20. A Party from CEE reported that, in accordance with its Law on Medicines, “the active material and the modified micro-organisms that are used for the preparation of these medicines through genetic engineering should be mentioned on the medicines”. Another Party reported that imports of unregistered LMOs which are pharmaceuticals and products containing or derived from unregistered LMOs or obtained from their use are allowed only for research purposes.

#### ***Article 6 – Transit and Contained use (Questions 25-28)***

21. Under *Question 25*, 80 Parties (56% of the respondents to this question), including all WEOG Parties, reported that they *regulate the transit* of LMOs and 63 Parties (44% of the respondents to this question) reported that they do not. The percentages of respondents within the different regions/economic groups that reported no regulations on transit are as follows: 49% of respondents within Africa, 68% in Asia-Pacific, 21% in CEE, 52% in GRULAC, 59% within LDCs and 57% of the respondents within SIDS.

22. In *Question 26*, 96 Parties (68% of the respondents to this question), including all responding WEOG Parties, reported that they regulate the *contained use of LMOs* and 46 Parties (32% of the respondents to this question) reported that they do not. The percentages of respondents within the different regions/economic groups that reported no regulations on contained use are as follows: 45% of respondents within Africa, 38% in Asia-Pacific, 11% in CEE, 43% in GRULAC, 54% within LDCs and 55% of the respondents within SIDS.

23. Under *Question 27*, 45 Parties (47% of the respondents to this question) reported that *this information had been submitted to the BCH*; 20 Parties (21% of the respondents to this question) reported that they submitted it *partially* and 29 Parties (31% of the respondents to this question) reported that they had not submitted it<sup>8</sup>.

24. *Question 28* requested further details on the implementation of Article 6. Most of the Parties from Asia, GRULAC, Africa and non-EU Member States from CEE reported that transit and contained use are not currently regulated. Some Parties reported that legislation is at the drafting stage and/or forms

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<sup>8</sup> According to the information available in the BCH, as of the date this report was prepared, 44 Parties (27% of the Parties to the Protocol) had submitted to the BCH at least one record under the category *National Laws, Regulations and Guidelines* and marked it as specifically relevant to the subject area of *Transit*.

part of their draft National Biosafety Framework. Other Parties reported that transit and contained use are regulated under broader LMO legislation as well as under quarantine laws. A Party from GRULAC reported that it has a protocol for the confined use of genetically-modified salmon as well as for the confined use of "pilot experiments" involving genetically-modified hybrids of corn. The same Party further reported that a study on "Transfer and Evaluation of the new alternative to control *Aedes aegypti* via the use of genetically-modified mosquitoes" was underway. A Party from Africa reported that importers of plant material are requested to provide LMO-free status certificates for imported plants and seeds; however, exemptions are given to scientific and research institutions.

25. The EU reported that its transit regulations require that the exporter ensures notification of the transit of LMOs through the territory of EU Member States and also informs the BCH of its decision. One EU Member State Party reported that, although the EU regulatory framework on contained use only covers genetically modified micro-organisms, the scope of the national legislation has been extended to genetically modified organisms and pathogenic organisms for humans, animals and plants.

***Articles 7 to 10 – Advance Informed Agreement (AIA) and intentional introduction of LMOs into the environment (Questions 29-50)***

In Question 29, countries were asked if they have *adopted law(s)/regulations/administrative measures for the operation of the AIA procedure of the Protocol*. 83 Parties (58% of the respondents to this question), including all WEOG Parties, answered "yes" and 60 Parties (42% of the respondents to this question) answered "no". The percentages of respondents within the different regions/economic groups that reported not having adopted law(s)/regulations/administrative measures on this matter are as follows: 55% of respondents within Africa, 46% in Asia-Pacific, 21% in CEE, 62% in GRULAC, 56% within LDCs and 77% of the respondents within SIDS.

26. Similar results are shown in the responses to Question 30 which asked countries if they have *adopted a domestic regulatory framework consistent with the Protocol regarding the transboundary movement of LMOs for intentional introduction into the environment*. 86 Parties (61% of the respondents to this question) answered "yes" to the question, including all responding WEOG Parties. A significant number of Parties in the other regions reported that they have *not* adopted such a framework: 49% of respondents within Africa, 46% in Asia-Pacific, 21% in CEE, 60% in GRULAC, 54% within LDCs and 68% of the respondents within SIDS.

27. Questions 31-32 address the adoption of measures relevant to the implementation of the AIA procedure in more detail. In Question 31, 83 Parties (58% of the respondents to this question) reported that they have *established a mechanism for taking decisions regarding first intentional transboundary movements of LMOs for intentional introduction into the environment*. With the exception of the WEOG Parties, all of whom (100%) reported that they have such a mechanism in place, a significant number of Parties in the other groups reported that they have not established such a mechanism: 49% of respondents within Africa, 53% in Asia-Pacific, 26% in CEE, 57% in GRULAC, 56% within LDCs and 90% of the respondents within SIDS.

28. Out of the 83 Parties which reported that they have established a mechanism for taking decisions in response to Question 32, 78 Parties (96% of the respondents to this question) indicated that *the mechanism also applies to cases of intentional introduction of LMOs into the environment that were not subject to transboundary movement*. Only 3 Parties (4% of the respondents to this question) reported that the mechanisms in place do not address LMOs that are *not subject to transboundary movement*.

29. In response to Question 33, 71 Parties (50% of the respondents to this question) reported that they have *established a mechanism for monitoring potential effects of LMOs that are released into the environment*. The percentages of respondents within the different regions/economic groups that reported

having established such a mechanism are as follows: 42% of respondents within Africa, 34% in Asia-Pacific, 68% in CEE, 33% in GRULAC, 100% in WEOG, 36% within LDCs and 14% of the respondents within SIDS.

30. In response to *Question 34*, 35 Parties (24% of the respondents to this question) reported that they have *the capacity to detect and identify LMOs* and an additional 52% reported that such capacity exists *to some extent*. The percentages of respondents within the different regions/economic groups that reported not having *the capacity to detect and identify LMOs* are as follows: 43% of the respondents within Africa, 20% in Asia-Pacific, 29% in GRULAC, 49% within LDCs and 55% of the respondents within SIDS.

31. Countries were asked in *Question 35* whether they have *established legal requirements for exporters under their jurisdiction to notify in writing the competent national authority of the Party of import prior to the intentional transboundary movement of an LMO that falls within the scope of the AIA procedure*. 76 Parties (53% of the respondents to this question) indicated that they have established such requirements and 67 Parties (57% of the respondents to this question) reported that they have not done so. The percentages of responding Parties within the different regions/economic groups that reported that they have not yet established such requirements are as follows: 53% of the respondents within Africa, 54% in Asia-Pacific, 32% in CEE, 71% in GRULAC, 5% in WEOG, 56% within LDCs and 86% of the respondents within SIDS.

In response to *Question 36*, 84 Parties (59% of the respondents to this question) reported that they have established legal requirements for the *accuracy of information contained in the notification* and 59 Parties (41% of the respondents to this question) reported that they have not done so. The percentages of respondents within the different regions/economic groups which reported that they have not established these requirements are as follows: 47% of respondents within Africa, 54% in Asia-Pacific, 26% in CEE, 57% in GRULAC, 51% within LDCs and 82% of the respondents within SIDS.

32. Under *Question 37*, 40 Parties (28% of the respondents to this question) reported that they have *received an application/notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment*. The percentages of respondents within the different regions/economic groups are as follows: 25% of the respondents within Africa, 20% in Asia-Pacific, 16% in CEE, 38% in GRULAC, 53% in WEOG, 18% within LDCs and 14% of the respondents within SIDS.

33. In *Question 38*, out of these 40 Parties reporting that they have received an application / notification, 35 Parties (29% of the respondents to this question) reported that they have *taken a decision on an application / notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment* and 86 Parties (71% of the respondents to this question) reported that they have not done so. The percentages of respondents within the different regions/economic groups which reported having taken such a decision are as follows: 21% of the respondents within Africa, 23% in Asia-Pacific, 20% in CEE, 44% in GRULAC, 50% in WEOG, 16% within LDCs and 15% of the respondents within SIDS.

34. Out of the 35 Parties which reported having taken a decision:

- (a) 10 Parties (29% of the respondents to *Question 39*) reported that, to date, they have approved importation of *more than 10 LMOs* for intentional introduction into the environment; 4 Parties (11% of the respondents to this question) have approved *less than 10 LMOs*; 12 Parties (34% of the respondents to this question) have approved *less than 5 LMOs*, and 9 Parties (26% of the respondents to this question) have approved *none*.

- (b) 6 Parties (18% of the respondents to *Question 40*) reported that, to date, they have approved *more than 10* non imported LMOs for intentional introduction into the environment; 2 Parties (6% of the respondents to this question) have approved *less than 10* LMOs; 6 Parties (18% of the respondents to this question) have approved *less than 5* LMOs and 20 Parties (59% of the respondents to this question) have approved *none*.

35. In response to *Question 41*, 12 Parties (9% of the respondents to this question) reported that during the current reporting period they have received *more than 10 applications/notifications regarding intentional transboundary movements of LMOs for intentional introduction into the environment*; 2 Parties (1% of the respondents to this question) received *less than 10 applications*; 21 Parties (15% of the respondents to this question) received *less than 5 applications* and 103 Parties (75% of the respondents to this question) reported that they received none.

36. In response to *Question 42*, 10 Parties (7% of the respondents to this question) reported that during current reporting period, they have taken *more than 10 decisions regarding intentional transboundary movements of LMOs for intentional introduction into the environment*; 3 Parties (2% of the respondents to this question) have taken *less than 10 decisions*; 18 Parties (13% of the respondents to this question) have taken *less than 5 decisions* and 112 Parties (78% of the respondents to this question) have taken none.

37. In their responses to *Question 43*, 23 Parties (74% of the respondents to this question) reported that they have *received a notification from the Party(ies) of export or from the exporter(s) prior to the transboundary movement*; 2 Parties (7% of the respondents to this question) reported that they have received notification only in some cases and 6 Parties (20% of the respondents to this question) reported that they have not received a notification.

38. Out of the 25 Parties which reported that they received a notification, either always or in only some cases, prior to the transboundary movement:

- 20 Parties (77% of the respondents to *Question 44*) reported that the notifications always contained *complete information (at a minimum the information specified in Annex I of the Cartagena Protocol on Biosafety)* while 5 Parties (20% of the respondents to this question) reported that the notifications contained complete information *in some cases only*.
- 2 Parties (50% of the respondents to *Question 45*) reported that they *acknowledged receipt of the notifications to the notifier within ninety days of receipt*.

39. In their responses to *Question 46*, 10 Parties (40% of the respondents to this question) stated that they have *always informed the notifier(s) and the BCH of their decision(s)*; 4 Parties (16% of the respondents to this question) have done so *in some cases only*, 8 Parties (32% of the respondents to this question) have done so *in some cases but only to the notifier*; 1 Party (4% of the respondents to this question) has done so *in some cases, only the BCH*; and 2 Parties (8% of the respondents to this question) reported that they have informed neither the notifier(s) nor the BCH of their decisions<sup>9</sup>.

40. Similar answers were received in the responses to *Question 47* where 10 Parties (50% of the respondents to this question) reported that they have *informed the notifier(s) and the BCH of [their] decision(s) in due time (within 270 days or the period specified in their communication to the notifier)*; 8 Parties (40% of the respondents to this question) have done so *in some cases only*; and 2 Parties (10% of

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<sup>9</sup> According to the information available in the BCH as of the date this report was prepared, 19 Parties had submitted information on their decisions related to LMOs for intentional introduction into the environment (<http://bch.cbd.int/database/results/?searchid=520606>).



the respondents to this question) reported that they have not informed the notifier(s) or the BCH in due time.

41. In *Question 48* countries were asked to indicate the *percentage of their decisions* according to different categories. The percentages indicated by the 23 Parties which answered to this question are as follows<sup>10</sup>:

- *Approval of the import of LMO(s) without conditions*: 19 Parties (83% of the respondents to this question) indicated that no decisions fall into this category, 3 Parties (13% of the respondents to this question) indicated less than 50% of their decisions and 1 Party (4% of the respondents to this question) indicated that all of its decisions fall into this category;
- *Approval of the import of LMO(s) with conditions*: 8 Parties (35% of the respondents to this question) indicated that no decisions fall into this category, 3 Parties (13% of the respondents to this question) indicated less than 50% of their decisions, 4 Parties (17% of the respondents to this question) indicated 50% or more and 8 Parties (35% of the respondents to this question) indicated that all of its decisions fall into this category;
- *Prohibition of the import/use of LMOs*: 14 Parties (61% of the respondents to this question) indicated that no decisions fall into this category, 5 Parties (22% of the respondents to this question) indicated less than 50% of their decisions, 1 Party (4% of the respondents to this question) indicated 50% or more and 3 Parties (13% of the respondents to this question) indicated that all of its decisions fall into this category;
- *Request for additional information*: 7 Parties (30% of the respondents to this question) indicated that no decisions fall into this category, 5 Parties (22% of the respondents to this question) indicated less than 50% of their decisions, 6 Parties (26% of the respondents to this question) indicated 50% or more and 5 Parties (22% of the respondents to this question) indicated that all of its decisions fall into this category;
- *Extension of the period for the communication of the decision*: 18 Parties (78% of the respondents to this question) indicated that no decisions fall into this category, 4 Parties (17% of the respondents to this question) indicated less than 50% of their decisions and 1 Party (4% of the respondents to this question) indicated 50% or more of its decisions fall into this category.

42. In *Question 49*, countries were asked to indicate, *in cases where their country approved an import with conditions or prohibited an import, if they provided reasons on which its decisions were based to the notifier and the BCH*. 13 Parties (59% of the respondents to this question) reported that they have *always provided the reasons to the notifier and the BCH*; 2 Parties (9% of the respondents to this question) reported that they have provided reasons *in some cases only*, 6 Parties (27% of the respondents to this question) reported that they have provided reasons *in some cases only to the notifier*; and 1 Party (5% of the respondents to this question) reported that they have not provided reasons.

43. *Question 50* invites further details on the implementation of Articles 7-10, including measures in case of lack of scientific certainty on potential adverse effects of LMOs for intentional introduction to the

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<sup>10</sup> Numbers and percentages indicated in the text may not be reflected in the general overview of the results provided by the BCH analyser because of different approaches used by countries in reporting under question 48. All data reported are visible in the breakdown of all country answers to this question. To access the breakdown of answers click on any of the "All+" in the online report of the BCH analyser.

environment. Most of the Parties from Asia-Pacific reported that their legislative frameworks require that releases are subject to authorizations, some based on risk assessments. Two Parties from Asia-Pacific reported that they have no specific law addressing the issue. Some Parties from Asia reported a lack of scientific certainty on potential adverse effects of LMOs. A Party from GRULAC reported that it received two applications for importation; it also reported the suspicion that LMOs were brought illegally into the country without the knowledge of the relevant agencies. Another Party from GRULAC reported that it has implemented the AIA procedure in an application for the import of LMO corn. Most Parties from Africa reported that they have not yet implemented Articles 7-10 although some provisions for doing so exist in their draft national biosafety frameworks. One Party from Africa reported receiving an application to test a transgenic crop for therapeutic purposes. Although authorization was initially given, this was revoked after an environmental impact assessment was carried out and the plants were ordered destroyed. Two Parties from Africa also reported that a full moratorium on the introduction of LMOs was in place.

44. The EU reported that it “applies its domestic legislative framework (which is compatible with the provisions of the Protocol) instead of the Protocol’s AIA procedure”. Authorization is required to market an LMO for intentional introduction into the environment. This can be acquired through the submission of a “notification” or “application” which must include a full evaluation of potential risks to human and animal health and to the environment. In order to introduce an LMO for experimental purposes, authorization is required from the Competent National Authority of the Member State where the experimental release is to take place. In this case, the authorization procedure is simpler and is given on the basis of a risk assessment. One non-EU Member State Party from WEOG reported that it received only one application from an importer for the release of an LMO into the environment. This application was for the use of an animal vaccine for equine influenza in an emergency situation. The release was approved “with controls”. Another non-EU Member State Party from WEOG reported that it prohibits the intentional introduction of LMO’s into the environment and therefore the Party is solely an importer of LMOs intended for direct use as food or feed, or for processing. One EU Member State Party from CEE reported that it has prohibited cultivation of LMOs, such as MON810 and genetically modified Amflora potato, through safeguard measures.

***Article 11 – Procedure for living modified organisms intended for direct use as food or feed, or for processing (LMOs-FFP)(Questions 51-63)***

45. In their responses to *Question 51*, 81 Parties (57% of the respondents to this question) stated that they have *adopted specific law(s) or regulation(s) for decision-making regarding domestic use, including placing on the market, of LMOs-FFP*. The percentages of respondents within the different regions/economic groups which reported having adopted specific law(s) or regulation(s) on this subject are as follows: 43% of the respondents within Africa, 46% in Asia-Pacific, 84% in CEE, 43% in GRULAC, 100% in WEOG, 36% within LDCs and 18% of the respondents within SIDS.

46. With reference to the *legal requirements for the accuracy of information to be provided by the applicant (Question 52)*, 82 Parties (57% of the respondents to this question) reported that they have established such legal requirements: 55% of the respondents within Africa, 37%, CEE 79%, GRULAC 38%, WEOG 100%, LDCs 51% and SIDS 23%.

47. Similarly, and with reference to *a mechanism to ensure that decisions regarding LMOs-FFP that may be subject to transboundary movement will be communicated to the Parties through the BCH (Question 53)*, 81 Parties (57% of the respondents to this question) reported that they have established the mechanism: 55% of the respondents within Africa, 37%, CEE 74%, GRULAC 38%, WEOG 100%, LDCs 49% and SIDS 27%.

48. In their responses to *Question 54*, 84 Parties (59% of the respondents to this question) reported that they have *established a mechanism for taking decisions on the import of LMOs-FFP*: 57% of the respondents within Africa, 43%, CEE 79%, GRULAC 43%, WEOG 89%, LDCs 51% and SIDS 32%.

49. Under *Question 55*, 15 Parties (11% of the respondents to this question) reported that they have *declared through the BCH that in the absence of a regulatory framework its decisions prior to the first import of an LMO-FFP will be taken according to Article 11.6 of the Cartagena Protocol on Biosafety*<sup>11</sup>: 16% of the respondents within Africa, 3%, CEE 0%, GRULAC 19%, WEOG 11%, LDCs 10% and SIDS 27%.

50. In their responses to *Question 56*, 61 Parties (43% of the respondents to this question) reported that they have indicated *needs for financial and technical assistance and capacity-building in respect of LMOs-FFP*<sup>12</sup>: 49% of the respondents within Africa, 57%, CEE 21%, GRULAC 57%, WEOG 5%, LDCs 49% and SIDS 59%.

51. In their responses to *Question 57*, 40 Parties (28% of the respondents to this question) reported that they have *taken a decision on LMOs-FFP (either on import or domestic use)*: 14% of the respondents within Africa, 34%, CEE 11%, GRULAC 29%, WEOG 68%, LDCs 5% and SIDS 9%.

52. Out of those 40 Parties that reported that they have *taken a decision on LMOs-FFP*:

- In responding to *Question 58*, 20 Parties (51% of the respondents to this question) reported that they have *approved to date more than 10 LMOs-FFP*; 2 Parties (5%) *less than 10*; 10 Parties (26%) *less than 5*; and 7 Parties (18%) *none*.
- In responding to *Question 59*, 18 Parties (46% of the respondents to this question) reported that, *in the current reporting period*, they have *taken more than 10 decisions regarding the import of LMOs-FFP*; 1 Party (3%) *less than 10*; 12 Parties (31%) *less than 5*; and 8 Parties (21%) *none*.
- In responding to *Question 60*, 19 Parties (49% of the respondents to this question) reported that, *in the current reporting period*, they have *taken more than 10 decisions regarding domestic use, including placing on the market, of LMOs-FFP*; 1 Party (3%) *less than 10*; 9 Parties (23%) *less than 5*; and 10 Parties (26%) *none*.
- In responding to *Question 61*, 16 Parties (47% of the respondents to this question) reported that they have *informed the Parties through the BCH of [their] decision(s) regarding import, of LMOs-FFP*; 6 Parties (18%) reported having done so *in some cases only*; and 12 Parties (35%) reported that they have not *informed the Parties through the BCH*<sup>13</sup>.
- In responding to *Question 62*, 16 Parties (47% of the respondents to this question) reported that they have *informed the Parties through the BCH of its decision(s) regarding domestic use, including placing on the market, of LMOs-FFP within 15 days*; 4 Parties (12%) have

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<sup>11</sup> According to the information available in the BCH, as of the date this report was prepared, only 2 Parties had submitted to the BCH a declaration that, in the absence of a domestic regulatory framework, decisions on LMOs-FFPs will be taken according to Article 11.6 (<http://bch.cbd.int/database/results/?searchid=520357>)

<sup>12</sup> According to the information available in the BCH, as of the date this report was prepared, 27 Parties had submitted to the BCH information about their Capacity-Building Needs and Priorities (<http://bch.cbd.int/database/results/?searchid=520609>)

<sup>13</sup> According to the information available in the BCH, as of the date this report was prepared, 10 Parties had submitted to the BCH information regarding their decisions on the import of LMOs for direct use as food or feed, or for processing (<http://bch.cbd.int/database/results/?searchid=520628>).

reported having done it, *but with delays (i.e. longer than 15 days)*; 2 Parties (6%) *in some cases only*; and 12 Parties (35%) reported that they have not done so<sup>14</sup>.

53. *Question 63* invited further details on the implementation of Article 11, including measures in case of lack of scientific certainty on potential adverse effects of LMOs-FFP. A Party from Asia stated that, based on risk assessments, a request was denied to import three LMO maize varieties for making animal feed for poultry. A GRULAC Party reported that commercial approvals included a variety of corn, soybeans, cotton and microorganisms under a regulatory system that is “more specific than the mechanisms proposed in the Protocol.” Another GRULAC Party reported that, with regard to imports, there were two applications for LMO soy beans, one of which was accepted, the other rejected. With regards to locally manufactured LMOs, the same Party reported that only genetically-modified Corn FR-bt1 was approved. Many African Parties referred to their national biosafety frameworks and draft biosafety laws which will address the implementation of Article 11.

54. The EU stated that, with reference to Article 14.4 of the Cartagena Protocol, it relies on its existing legislative framework for intentional movements of LMOs within the EU and for imports of LMOs into the EU. It also reported that with regard to the decisions taken for placing on the market of LMOs-FFP, those decisions are taken for the whole EU and not by the Member States individually. A non-EU Member State WEOG Party reported that it grants only contained use approvals for LMOs. A non-EU Member State CEE Party reported that LMOs-FFP must be marked “genetically modified feed or food additives [...], if its composition in the feed or feed additives is more than 0.9 %”. Another non-EU Member State CEE Party indicated that it has a similar rule.

#### ***Article 12 – Review of decision (Questions 64-71)***

55. In their responses to *Question 64*, 67 Parties (47% of the respondents to this question) reported that they have *established a mechanism for the review and change of a decision regarding an intentional transboundary movement of LMOs*: 43% of the respondents within Africa, 34%, CEE 58%, GRULAC 25%, WEOG 95%, LDCs 33% and SIDS 19%.

56. In their responses to *Question 65*, 7 Parties (5% of the respondents to this question) reported that they have *received a request for a review of a decision*: 2% of the respondents within Africa, 6%, CEE 0%; GRULAC 10%, WEOG 11%, LDCs 0% and SIDS 0%.

57. Similarly, in *Question 66*, 4 Parties (3% of the respondents to this question) reported that they have *reviewed and changed a decision regarding an intentional transboundary movement of LMOs* and 3 Parties (2% of the respondents to this question) reported that have *reviewed* a decision.

58. Out of the 7 Parties that reported having *received a request for a review of a decision*:

- In responding to *Question 67*, 2 Parties (29% of the respondents to this question) reported having *reviewed and/or changed more than 5 decisions regarding an intentional transboundary movement of an LMO*; 4 Parties (57%) *less than 5*; and 1 Party (14%) *none*.
- In responding to *Question 68*, 2 Parties (29% of the respondents to this question) reported that they have *always informed the notifier and the BCH of the review and/or changes in*

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<sup>14</sup> According to the information available in the BCH, as of the date this report was prepared, 12 Parties had submitted to the BCH information regarding their decisions on domestic use, including its placing on the market, of an LMO for direct use as food or feed, or for processing (<http://bch.cbd.int/database/results/?searchid=520635>).

*the decision*; 3 Parties (43%) reported that they have informed *in some cases only the notifier*; and 1 Party (14%) *in some cases only the BCH*<sup>15</sup>.

- In responding to *Question 69*, 3 Parties (43% of the respondents to this question) reported that they have *informed the notifier and the BCH of the review and changes in the decision within thirty days*; 1 Party (14%) *in some cases only*; and 2 Parties (29%) reported not having done so.
- In responding to *Question 70*, 3 Parties (43% of the respondents to this question) reported that they have *provided reasons to the notifier and the BCH for the review and/or changes in the decision*; 1 Party (14%) reported having done it *in some cases only*; and 2 Parties (29%) *in some cases and only the notifier*.

59. *Question 71* invited further details on the implementation of Article 12. Very few Parties reported reviewing decisions. However, a Party from Asia reported a “comprehensive risk assessment on the study [regarding] corn MON 863 conducted by five independent experts vis-a-vis the original submission by Monsanto. Based on their review, no adverse effects were identified on human and animal health or the environment and corn MON863 was confirmed to not adversely affect the health of rats”. One Party from Africa reported that, in the event of the revocation of a decision, the Competent National Authority may order, by any means it deems appropriate, the destruction of any transgenic organism being cultured and/or its derived products or sterilization of the soil on which the LMO was grown (all cost borne by the user).

#### ***Article 13 – Simplified procedure (Questions 72-76)***

60. In their responses to *Question 72*, 27 Parties (19% of the respondents to this question) reported that they have *established a system for the application of the simplified procedure regarding an intentional transboundary movement of LMOs*: 21% of the respondents within Africa, 14%, CEE 16%, GRULAC 19%, WEOG 26%, LDCs 16% and SIDS 19%.

61. In their responses to *Question 73*, only 6 Parties (4% of the respondents to this question) reported that they have *applied the simplified procedure*: 2% of the respondents within Africa, 3%, GRULAC 10%, WEOG 11%.

62. Out of the 6 Parties that reported that they have *applied the simplified procedure*:

- In responding to *Question 74*, 1 Party (17% of the respondents to this question) reported that it has *always informed the Parties through the BCH of the cases where the simplified procedure applies*; 1 Party (17%) reported it had done it *in some cases only*; and 4 Parties (67%) reported that they have not done so<sup>16</sup>.
- In responding to *Question 75*, 3 Parties (50% of the respondent to the question) reported, *in the current reporting period*, that they have *applied the simplified procedure to more than 5 LMOs*; 2 Parties (33%) *to less than 5*; and 1 Party (17%) *to none*.

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<sup>15</sup> The common format currently in use in the BCH for the submission of information on *Country's Decision or any other Communication* does not require the submitter to specify if the document submitted refers to a review of a previous decision or to a new one. It does, however, ask whether the new information is an amendment to a previous decision and/or communication).

<sup>16</sup> According to the information available in the BCH, as of the date this report was prepared, two Parties have applied the simplified procedure. One of those Parties also indicated in its national report that it has applied the simplified procedure and notified the BCH in some cases. The second Party has indicated that it has not applied the simplified procedure. A third Party has indicated that it has applied the simplified procedure and always notified the BCH of the cases where the simplified procedure has applied; however, there are no decisions or communications from this country to this effect in the BCH (<http://bch.cbd.int/database/results/?searchid=520647>).

63. *Question 76* invited further details on the implementation of Article 13. One Party from Asia stated that “for insect-resistant transgenic cotton strains already awarded with Safety Certificate (for commercialization), and for new pest-resistant transgenic cotton strains cultivated by using the former transgenic cotton strains, the simplified procedure will apply.” A Party from Africa reported that, “According to the provisions of the law on biosecurity, all living modified organisms are subject to the prior informed consent procedure”.

***Article 14 – Bilateral, regional and multilateral agreements and arrangements (Questions 77-80)***

64. In their responses to *Question 77*, 23 Parties (16% of the respondents to this question) reported that they have *entered into bilateral, regional or multilateral agreements or arrangements*: 19% of the respondents within Africa, 14%, CEE 11%, GRULAC 19%, WEOG 16%, LDCs 24% and SIDS 18%. Of the 23 Parties that responded, 7 Parties (33% of the respondents to this question), responding to *Question 78*, reported that they have *always informed the Parties through the BCH of the agreements or arrangements*; 3 Parties (14% of the respondents to this question) *in some cases only*; and 11 Parties (52% of the respondents to this question) reported that they have never done so<sup>17</sup>.

65. *Question 79* invited Parties to provide a brief description of the scope and objective of agreements or arrangements entered into, if applicable. A WEOG Party referred to the Agreement on the European Economic Area which brings together the 27 EU Member States and the three EEA EFTA (European Economic Area - European Free Trade Association) States — Iceland, Liechtenstein and Norway — in a single market, referred to as the “Internal Market”. As a consequence of this Agreement, the EEA EFTA States take part in the approval procedure for LMOs in the EU on the same basis as the EU Member States (with the exception of voting procedures).

66. *Question 80* invited further details on the implementation of Article 14. One Party from CEE stated that, although it is not yet an EU Member State, all of the EU’s legislation pertaining to LMOs “has been transposed into the national legislation and has been already posted on the BCH”. Also, a Party from Asia stated that it is working on the initial stages of becoming a Party to the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress. A Party from Africa reported that it is a part of the Common Market for Eastern and Southern Africa (COMESA) and that “a statement of the policies and directives for handling living modified cash crops, the LMO trade, and emergency food aid containing LMOs has been developed.” Another Party from Africa reported that it has signed and ratified several bilateral and multilateral treaties and agreements at the regional level but does not provide any further elaboration.

***Article 15 – Risk assessment (Questions 81-93)***

67. In their responses to *Question 81*, 95 Parties (67% of the respondents to this question) reported that they have *established a mechanism for conducting risk assessments prior to taking decisions regarding LMOs*. The percentages of respondents within the different regions/economic groups are as follows: 56% of respondents within Africa, 63% in Asia-Pacific, 84% in CEE, 52% in GRULAC, 100% in WEOG, 59% within LDCs and 41% of the respondents within SIDS.

68. In *Question 82*, out of those 95 Parties which reported that they have established such a mechanism, 81 Parties (87% of the respondents to this question) reported that *this mechanism includes procedures for identifying experts to conduct the risk assessments*: 89% of the respondents within Africa, 90%, CEE 75%, GRULAC 82%, WEOG 95%, LDCs 91% and SIDS 86%.

<sup>17</sup> According to the information available in the BCH, as of the date this report was prepared, 9 Parties (5% of the Parties to the Protocol) had submitted to the BCH at least one record under the category *Bilateral, Regional or Multilateral Agreement or Arrangement* (<http://bch.cbd.int/database/results/?searchid=521230>).



69. In responding to *Question 83*, 70 Parties (50% of the respondents to this question) reported having *established guidelines for how to conduct risk assessments prior to taking decisions regarding LMOs*: 40% of the respondents within Africa, 46%, CEE 58%, GRULAC 38%, WEOG 94%, LDCs 41% and SIDS 27%.

70. In responding to *Question 84*, 63 Parties (45% of the respondents to this question) reported that they have *acquired the necessary domestic capacity to conduct risk assessment*: 23% of the respondents within Africa, 40%, CEE 63%, GRULAC 33%, WEOG 100%, LDCs 21% and SIDS 14%.

71. In *Question 85*, 56 Parties (39% of the respondents to this question) reported that they have *established a mechanism for training national experts to conduct risk assessments*: 38% of the respondents within Africa, 31%, CEE 32%, GRULAC 14%, WEOG 95%, LDCs 31% and SIDS 18%.

72. In responding to *Question 86*, 46 Parties (32% of the respondents to this question) reported that they have *conducted a risk assessment of an LMO for intentional introduction into the environment*: 12% of the respondents within Africa, 26%, CEE 37%, GRULAC 33%, WEOG 89%, LDCs 8% and SIDS 5%.

73. In responding to *Question 87*, 34 Parties (24% of the respondents to this question) reported that they have *conducted a risk assessment of an LMO intended for direct use as food or feed, or for processing*: 4% of the respondents within Africa, 23%, CEE 22%, GRULAC 24%, WEOG 79%, LDCs 0% and SIDS 5%.

74. In responding to *Question 88*, 39 Parties (53% of the respondents to this question) reported that they have *conducted risk assessments for all decision(s) taken on LMOs for intentional introduction into the environment or on domestic use of LMOs-FFP*; 3 Parties (4% of the respondents to this question) *in some cases only*; and 32 Parties (43% of the respondents to this question) reported having never done so.

75. In *Question 89*, 12 Parties (14% of the respondents to this question) reported that they have *always submitted summary reports of the risk assessments to the BCH*; 15 Parties (18% of the respondents to this question) *in some cases only*; and 57 Parties (68% of the respondents to this question) reported that they have never done so<sup>18</sup>.

76. *Question 90* asked, if the country had taken decisions regarding LMOs, how many risk assessments have been conducted during the reporting period; 25 Parties (18% of the respondents to this question) reported *more than 10 risk assessments*; 7 Parties (5% of the respondents to this question) reported *less than 10*; 11 Parties (8% of the respondents to this question) *less than 5*; and 98 Parties (70% of the respondents to this question) reported *none*.

77. In responding to *Question 91*, 32 Parties (40% of the respondents to this question) reported that they have *always required the exporter to conduct the risk assessment(s)*; 5 Parties (6% of the respondents to this question) *in some cases only*; and 43 Parties (54% of the respondents to this question) reported that they have never done so.

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<sup>18</sup> According to the information available in the BCH as of the date this report was prepared, 24 Parties (15% of the Parties to the Protocol) had submitted to the BCH information regarding risk assessments (<http://bch.cbd.int/database/results/?searchid=520666>). It is also noted that, as of the same date, 158 decisions referring to specific LMOs (22% of the Parties' decisions in this category) had been submitted to the BCH by 16 Parties (10% of the Parties to the Protocol) without an accompanying risk assessment summary or report.

78. Similarly, in *Question 92*, 33 Parties (42% of the respondents to this question) reported that they have *always required the notifier to bear the cost of the risk assessment(s) of LMOs*; 4 Parties (5% of the respondents to this question) *in some cases only*; and 41 Parties (53% of the respondents to this question) reported that they have never done so.

79. *Question 93* invited further details on the implementation of Article 15. Many Parties emphasized that according to the Protocol, risk assessments were undertaken on a case-by-case basis. A Party from Asia reported that under its regulations, the exporter does not conduct the risk assessment – instead it is “conducted by the technology owner, such as Monsanto, Syngenta, and Dupont” and the cost of the risk assessment is borne by the technology owner rather than the notifier. Another Party from Asia reported that it had conducted several risk assessment workshops, training more than 100 researchers and academics, on different types of LMOs. Although some Parties from Africa have implemented biosafety legislation addressing risk assessment, many refer to their draft national biosafety frameworks in relation to the risk assessment process and emphasize the need for capacity-building. Three GRULAC Parties and three other Parties from Africa reported the undertaking of risk assessment training initiatives.

80. The EU reported that the notification provided by a company intending to market an LMO must include a full risk assessment which is assessed by the European Food Safety Authority, with an active involvement of Member States, notably as regards the authorisation of LMOs for cultivation, where they carry out the initial risk assessment. A non-EU CEE Member State reported the lack of a specific mechanism for the selection of experts to conduct risk assessments as well as limited capacities for the training of risk assessment experts.

#### ***Article 16 – Risk management (Questions 94-99)***

81. In responding to *Question 94a*, 56 Parties (39% of the respondents to this question) reported that they have *established and maintained appropriate and operational mechanisms, measures and strategies for this purpose for LMOs for intentional introduction into the environment*; 29 Parties (20% of the respondents to this question) answered *to some extent*; and 58 Parties (41% of the respondents to this question) reported that they have not done so. The percentages of respondents within the different regions/economic groups which have not established and maintained such mechanisms are as follows: 59% of the respondents within Africa, 43% in Asia-Pacific, 16% in CEE, 52% in GRULAC, 0% in WEOG, 67% within LDCs and 64% of the respondents within SIDS.

82. Similarly, under *Question 94b*, 50 Parties (35% of the respondents to this question) reported that they have *established and maintained appropriate and operational mechanisms, measures and strategies for this purpose for LMOs intended for direct use as food or feed, or for processing*; 30 Parties (21% of the respondents to this question) *to some extent*; and 63 Parties (44% of the respondents to this question) reported that they have not done so. The percentages of respondents within the different regions/economic groups which have not established and maintained such mechanisms are as follows: 61% of the respondents within Africa, 49% in Asia-Pacific, 5% in CEE, 71% in GRULAC, 0% in WEOG, 72% within LDCs and 73% of the respondents within SIDS.

83. In responding to *Question 95*, 47 Parties (33% of the respondents) reported having *established and maintained appropriate measures to prevent unintentional transboundary movements of LMOs*; 34 Parties (24% of the respondents to this question) *to some extent*; and 61 Parties (43% of the respondents to this question) of the respondents reported that they have not done so. The percentages of the latter response within the different regions/economic groups are as follows: 54% of the respondents within Africa, 51% in Asia-Pacific, 21% in CEE, 62% in GRULAC, 0% in WEOG, 67% within LDCs and 45% of the respondents within SIDS.



84. In responding to *Question 96*, 65 Parties (46% of the respondents to this question) reported that they have *taken measures to ensure that any LMO, whether imported or locally developed, undergoes an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use*: 31% of the respondents within Africa, 40% in Asia-Pacific, 53% in CEE, 43% in GRULAC, 89% in WEOG, 21% within LDCs and 18% of the respondents within SIDS.

85. With reference to international cooperation, in *Question 97*, 41 Parties (29% of the respondents to this question) reported that they have *cooperated with other Parties with a view to identifying LMOs or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity*: 18% of the respondents within Africa, 11% in Asia-Pacific, 42% in CEE, 24% in GRULAC, 79% in WEOG, 15% within LDCs and 9% of the respondents within SIDS.

86. In responding to *Question 98*, 37 Parties (26% of the respondents to this question) reported that they have *cooperated with other Parties with a view to taking measures regarding the treatment of LMOs or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity*: 16% of the respondents within Africa, 6% in Asia-Pacific, 47% in CEE, 14% in GRULAC, 79% in WEOG, 10% within LDCs and 9% of the respondents within SIDS.

87. *Question 99* invited further details on the implementation of Article 16, including any details regarding risk management strategies, also in case of lack of scientific certainty on potential adverse effects of LMOs. Some Parties from Asia reported that a post release monitoring period may be imposed for the purpose of ensuring that any unintentional adverse effects are addressed. One Party from Asia reports: “In its efforts to build scientific capacity to monitor longer-term impacts on environment, human health and biodiversity through a risk management programme, the Department of Biosafety is planning to develop infrastructure and establish mechanisms to facilitate the coordination, collection and storage of data for the better inter-sectoral information sharing, exchange and data management.” Two Parties from Africa reported having established laboratories in which, amongst other things, risk management strategies will be elaborated. One country from Africa reported that it has developed a manual for risk assessment and risk management and has also undertaken introductory risk assessment and risk management training workshops to biosafety regulators.

88. The EU reported that its legislative framework provides that environmental risk assessments should be conducted with a view to identifying if there is a need for risk management and, if so, the most appropriate methods to be used as well as a risk management strategy to be defined. In cases where data is limited, appropriate risk management has to be considered to prevent adverse effects on human health and the environment. One EU Member State reported that it focuses “mostly on general surveillance of commercial GM crops, using the established surveillance networks and practices such as monitoring of agricultural plants, variety/seed registration, plant health and environmental observations.”

#### ***Article 17 – Unintentional transboundary movements and emergency measures (Questions 100-107)***

89. In their responses to *Question 100*, 93 Parties (65% of the respondents to this question) reported that they have *made available to the BCH the relevant details setting out points of contact for the purposes of receiving notifications under Article 17*<sup>19</sup>. The percentages of respondents within the different regions/economic groups are as follows: 59% of the respondents within Africa, 54% in Asia-Pacific, 63% in CEE, 71% in GRULAC, 95% in WEOG, 51% within LDCs and 59% of the respondents within SIDS.

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<sup>19</sup> According to the information available in the BCH, as of the date this report was prepared, 71 Parties had submitted to the BCH information regarding their contact points for unintentional transboundary movements and emergency measures (<http://bch.cbd.int/database/results/?searchid=520731>).

90. In responding to *Question 101*, 80 Parties (56% of the respondents to this question) reported that they have *established a mechanism for addressing emergency measures in case of unintentional transboundary movements of LMOs that are likely to have significant adverse effect on biological diversity*: 44% of the respondents within Africa, 43% in Asia-Pacific, 74% in CEE, 52% in GRULAC, 100% in WEOG, 38% within LDCs and 32% of the respondents within SIDS.

91. In responding to *Question 102*, 23 Parties (16% of the respondents to this question) reported that they have *implemented emergency measures in response to information about releases that led, or may have led, to unintentional transboundary movements of LMOs*: 12% of the respondents within Africa, 3% in Asia-Pacific, 21% in CEE, 24% in GRULAC, 37% in WEOG, 10% within LDCs and 0% of the respondents within SIDS.

92. In the current reporting period, in responding to *Question 103*, 2 Parties (1% of the respondents to this question) reported that they have *received, more than 10 times, information concerning occurrences that led, or may have led, to unintentional transboundary movement(s) of one or more LMOs to or from territories under their jurisdiction*; 1 Party (1% of the respondents to this question) *less than 10 times*; 6 Parties (4% of the respondents to this question) *less than 5 times*; and 133 Parties (94% of the respondents to this question) reported that they have never received such information.

93. Only 8 Parties responded to questions 104-106: 2 Parties (both from WEOG) reported in responding to *Question 104* that they have *notified, for every occurrence, affected or potentially affected States, the BCH and, where appropriate, relevant international organizations, of the above release*<sup>20</sup>. Six more Parties, from other regional and economic groups, reported that they have not done so. In responding to *Question 105*, 2 WEOG respondents reported that they have notified the *affected or potentially affected State*, but not the BCH. In responding to *Question 106*, 1 Party from WEOG reported that it has *immediately consulted the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures*; 1 Party from Asia-Pacific reported that it has done so *in some cases*; and the remaining 6 respondents (1 Party from Africa, 1 from GRULAC and 4 from WEOG) reported that *consultation was never made*.

94. *Question 107* invited further details on the implementation of Article 17. One Party from Asia reported that Annex 3 of the Codex Alimentarius Plant Guidelines issued in 2009 was adopted as the standard for food safety assessment in situations of low-level presence of recombinant-DNA plant material in food and feed. One GRULAC Party reported that general procedures exist for the illegal importation of products which are applicable to the illegal importation of LMOs.

95. The EU reported that its legislation provides for measures to prevent unintentional transboundary movement of LMOs and appropriate responses, including emergency measures. One EU Member State reported that it has “a ‘Crisis cell’ in its Federal public Service Health, Food Chain Safety & Environment, where unintentional transboundary movements of LMOs likely to have significant adverse effects on biological biodiversity, including human health, should be communicated”.

#### ***Article 18 – Handling, transport, packaging and identification (Questions 108-115).***

96. In responding to *Question 108*, 61 Parties (43% of the respondents to this question) reported that they have *taken measures to require that LMOs that are subject to transboundary movement are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards*; 38 Parties (27% of the respondents to this question) having taken such measures to

<sup>20</sup> According to the information available in the BCH as of the date this report was prepared, no information regarding unintentional transboundary movements and emergency measures has been submitted to the BCH (<http://bch.cbd.int/database/results/?searchid=520795>).

*some extent*; and 44 Parties (31% of the respondents to this question) reported not having taken such measures. The percentages of respondents within the different regions/economic groups which reported not having taken such measures are as follows: 41% of the respondents within Africa, 29% in Asia-Pacific, 5% in CEE, 62% in GRULAC, 0% in WEOG, 44% within LDCs and 59% of the respondents within SIDS.

97. Similar percentages appear in the responses to questions 109-112 of this section. In responding to Question 109, 50 Parties (35% of the respondents to this question) reported that they have *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 living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information*; 25 Parties (17% of the respondents to this question) *to some extent*; and 68 Parties (48% of the respondents to this question) reported not having done it. The percentages of respondents within the different regions/economic groups reporting the latter are as follows: 53% of the respondents within Africa, 57% in Asia-Pacific, 21% in CEE, 81% in GRULAC, 5% in WEOG, 56% within LDCs and 82% of the respondents within SIDS.

98. In responding to Question 110, 54 Parties (38% of the respondents to this question) reported that they have *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 living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information*; 30 Parties (21% of the respondents to this question) *to some extent*; and 58 Parties (41% of the respondents to this question) reported not having done it. The percentages of respondents within the different regions/economic groups reporting the latter are as follows: 47% of the respondents within Africa, 41% in Asia-Pacific, 16% in CEE, 86% in GRULAC, 0% in WEOG, 50% within LDCs and 77% of the respondents within SIDS.

99. In responding to Question 111, 61 Parties (43% of the respondents to this question) reported that they have *taken measures to require that documentation accompanying LMOs that are destined for contained use clearly identifies them as living modified organisms and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the LMO are consigned*; 32 Parties (22% of the respondents to this question) *to some extent*; and 50 Parties (35% of the respondents to this question) reported not having done it. The percentages of respondents within the different regions/economic groups reporting the latter are as follows: 45% of the respondents within Africa, 37% in Asia-Pacific, 16% in CEE, 57% in GRULAC, 0% in WEOG, 46% within LDCs and 77% of the respondents within SIDS.

100. In responding to Question 112, 60 Parties (42% of the respondents to this question) reported that they have *taken measures to require that documentation accompanying LMOs that are intended for intentional introduction into the environment of the Party of import, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter*; 25 Parties (17% of the respondents to this question) reported having taken such measures *to some extent*; and 58 Parties (41% of the respondents to this question) reported not having done it. The percentages of respondents within the different regions/economic groups reporting the latter are as follows: 49% of the respondents within Africa, 43% in Asia-Pacific, 21% in CEE, 67% in GRULAC, 5% in WEOG, 56% within LDCs and 77% of the respondents within SIDS.

101. In responding to *Question 113*, 38 Parties (27% of the respondents to this question) reported that they have *the capacity to enforce the requirements of identification and documentation of LMOs*; 62 Parties (44% of the respondents to this question) *to some extent*; and 42 Parties (30% of the respondents to this question) reported not having this capacity. The percentages of respondents within the different regions/economic groups reporting the latter are as follows: 46% of the respondents within Africa, 31% in Asia-Pacific, 11% in CEE, 33% in GRULAC, 0% in WEOG, 69% within LDCs and 50% of the respondents within SIDS.

102. In responding to *Question 114*, 39 Parties (27% of the respondents to this question) reported that they have *established procedures for the sampling and detection of LMOs*; 40 Parties (28% of the respondents to this question) *to some extent*; and 64 Parties (45% of the respondents to this question) reported not having done so. The percentages of respondents within the different regions/economic groups reporting the latter are as follows: 63% of the respondents within Africa, 51% in Asia-Pacific, 11% in CEE, 57% in GRULAC, 5% in WEOG, 72% within LDCs and 91% of the respondents within SIDS.

103. *Question 115* invited further details on the implementation of Article 18. One Asian Party reported having organized, in January 2010 and in collaboration with the CBD Secretariat, a “Workshop on the Identification and Documentation of Living Modified Organism” for 50 customs and enforcement officers. Three Parties from Africa reported that LMOs must be labeled in such a manner that the identification must specifically list their traits and characteristics in sufficient detail to ensure traceability.

104. The EU reported that the EC has established a system for the development and assignment of unique identifiers, adopting the format developed by the OECD, for the identification of living modified organisms. An EU Member State from WEOG reported that “concerned customers” have followed Workshops organized by the Green Customs. A non-EU Member State from WEOG reported that products consisting of or containing LMOs must be labeled “Contains genetically modified organisms” or, alternatively, “Contains genetically modified (name of organism(s))”. A number of other Parties from WEOG, CEE and Africa reported using similar labelling language.

#### ***Article 19 – Competent National Authorities and National Focal Points (Questions 116-123)***

105. In responding to *Question 116*, 142 Parties (100% of the respondents to this question) reported that they have *designated one national focal point for the Cartagena Protocol to be responsible for liaison with the Secretariat* and under *Question 117*, 140 Parties (98% of the respondents to this question) reported that they have *designated one national focal point for the Biosafety Clearing-House to liaise with the Secretariat regarding issues of relevance to the development and implementation of the BCH*. The percentages of respondents within the different regions/economic groups are as follows: 96% of the respondents within Africa, 97% in Asia-Pacific, 100% in CEE, 100% in GRULAC, 100% in WEOG, 97% within LDCs and 95% of the respondents within SIDS.

106. In responding to *Question 118*, 42 Parties (29% of the respondents to this question) reported that they have *designated more than one competent national authorities, which are responsible for performing the administrative functions required by the Cartagena Protocol on Biosafety and are authorized to act on country’s behalf with respect to those functions*; 92 Parties (64% of the respondents to this question) reported that they have designated *one* competent national authority; and 9 Parties (6% of the respondents to this question) reported that they have not done so<sup>21</sup>. The percentages of respondents

<sup>21</sup> According to the information available in the BCH, as of the date this report was prepared, 70 Parties (43% of the Parties to the Protocol) had submitted to the BCH the contact details of more than one competent national authority, 73 Parties (45%) had submitted one and 19 Parties (12%) none.

within the different regions/economic groups among the latter 9 Parties are as follows: 6% of the respondents within Africa, 9% in Asia-Pacific, 0% in CEE, 10% in GRULAC, 5% in WEOG, 5% within LDCs and 14% of the respondents within SIDS.

107. Out of those 42 Parties which reported that they have designated more than one competent national authority, in responding to *Question 119*, 33 Parties (80% of the respondents to this question), reported that they have *conveyed to the Secretariat the respective responsibilities of those authorities*<sup>22</sup> and 8 Parties (20% of the respondents to this question) reported that they have not done so. The percentages of respondents within the different regions/economic groups of the latter 8 Parties are as follows: 25% of the respondents within Africa, 40% in Asia-Pacific, 20% in CEE, 0% in GRULAC, 14% in WEOG, 67% within LDCs and 25% of the respondents within SIDS.

108. In responding to *Question 120*, 90 Parties (63% of the respondents to this question) reported that they have *made available all the required information referred in questions 116-119 to the BCH*; 39 Parties (27% of the respondents to this question) reported making *some information* available to the BCH; and 13 Parties (9% of the respondents to this question) reported that they have not done so. The percentages of respondents within the different regions/economic groups among the latter 13 Parties are as follows: 14% of the respondents within Africa, 12% in Asia-Pacific, 0% in CEE, 5% in GRULAC, 5% in WEOG, 15% within LDCs and 9% of the respondents within SIDS.

109. Out of those 42 Parties which reported that they have designated more than one competent national authority, 35 Parties (85% of the respondents to this question) reported, under *Question 121*, that they have *established a mechanism for the coordination of their actions prior to taking decisions regarding LMOs*. The percentages of respondents within the different regions/economic groups are as follows: 50% of the respondents within Africa, 90% in Asia-Pacific, 90% in CEE, 80% in GRULAC, 100% in WEOG, 0% within LDCs and 50% of the respondents within SIDS.

110. In responding to *Question 122*, 46 Parties (34% of the respondents to this question) reported that they have *established adequate institutional capacity to enable the competent national authority(ies) to perform the administrative functions required by the Cartagena Protocol on Biosafety*; 66 Parties (48% of the respondents to this question) reported having established adequate institutional capacity *to some extent*; and 25 Parties (18% of the respondents to this question) reported not having done so. The percentages of respondents within the different regions/economic groups among the 25 Parties are as follows: 29% of the respondents within Africa, 19% in Asia-Pacific, 5% in CEE, 20% in GRULAC, 0% in WEOG, 32% within LDCs and 35% of the respondents within SIDS.

111. *Question 123* invited further details on the implementation of Article 19. A number of Parties from GRULAC and Africa emphasized the need for capacity-building in order for competent national authorities and national focal points to function optimally. Some Parties reported a need to combine the roles of CNA and NFP for greater efficiency.

#### ***Article 20 – Information Sharing and the Biosafety Clearing-House (BCH) (Questions 124-131)***

112. *Question 124* focuses on the specific categories of information (a-q) for which Parties must provide information to the BCH, according to the *Modalities of operation of the BCH* (Annex to decision BS-I/3).

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<sup>22</sup> According to the information available in the BCH, as of the date this report was prepared, out of the 70 Parties having submitted to the BCH the contact details of more than one competent national authority (see note above), 24 Parties (15% of the Parties to the Protocol) had submitted information on 52 competent national authorities without specifying their respective responsibilities.



- 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))* are reported to be available and in the BCH by 71 Parties (50% of the respondents to this question); not available by 19 Parties (13%); and available, but not or only partially available<sup>23</sup> in the BCH, by 53 Parties (37%)<sup>24</sup>. The breakdown of the latter is as follows: 45% of the respondents within Africa, 37% in Asia-Pacific, 26% in CEE, 43% in GRULAC, 21% in WEOG, 44% within LDCs and 45% of the respondents within SIDS.
- 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)* are reported to be available and in the BCH by 60 Parties (42% of the respondents to this question); not available by 38 Parties (27%); and available, but not or only partially available in the BCH, by 44 Parties (31%)<sup>25</sup>. The breakdown of the latter is as follows: 38% of the respondents within Africa, 31% in Asia-Pacific, 31% in CEE, 24% in GRULAC, 22% in WEOG, 34% within LDCs and 41% of the respondents within SIDS.
- c. *Bilateral, multilateral and regional agreements and arrangements (Articles 14, paragraph 2 and 20, paragraph 3 (b))* are reported to be available and in the BCH by 11 Parties (8% of the respondents to this question); not available by 107 Parties (76%); and available, but not or only partially available in the BCH, by 22 Parties (16%)<sup>26</sup>. The breakdown of the latter is as follows: 27% of the respondents within Africa, 6% in Asia-Pacific, 5% in CEE, 24% in GRULAC, 5% in WEOG, 27% within LDCs and 14%.
- 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))* are reported to be available and in the BCH by 98 Parties (69% of the respondents to this question); not available by 8 Parties (6%); and available, but not or only partially available in the BCH, by 37 Parties (26%)<sup>27</sup>. The breakdown of the latter is as follows: 32% of the respondents within Africa, 29% in Asia-Pacific, 16% in CEE, 24% in GRULAC, 16% in WEOG, 36% within LDCs and 32% of the respondents within SIDS.
- e. *Reports submitted by the Parties on the operation of the Protocol (Article 20, paragraph 3 (e))* are reported to be available and in the BCH by 81 Parties (57% of the respondents to this question); not available by 37 Parties (26%); and available, but not or only partially available in the BCH, by 25 Parties (17%)<sup>28</sup>. The breakdown of the latter is as follows:

<sup>23</sup> In the analyses of the responses to questions 124 a-q, information that is “available, but not or only partially available in the BCH”, represents those respondents who selected *Information available but only partially available in the BCH* or *Information available but not in the BCH* in their responses to the questions.

<sup>24</sup> According to the information available in the BCH, as of the date this report was prepared, 55 Parties (34 % of the Parties to the Protocol) had submitted to the BCH at least one record under the category *National Laws, Regulations and Guidelines* and marked it as specifically relevant to the subject area *Intentional introduction into the environment (AIA)*.

<sup>25</sup> According to the information available in the BCH, as of the date this report was prepared, 60 Parties (37 % of the Parties to the Protocol) had submitted to the BCH at least one record under the category *National Laws, Regulations and Guidelines* and marked it as specifically relevant to the subject area *LMOs for direct use as food, feed or for processing*.

<sup>26</sup> See note 17 under the section on Article 14.

<sup>27</sup> See notes 21-22 under the section on Article 19.

<sup>28</sup> According to the information available in the BCH, as of the date this report was prepared, 55 Parties (40% of the Parties at 11 September 2005) had submitted the Interim National Report on the Implementation of the Cartagena Protocol on Biosafety (<http://www.cbd.int/reports/biosafety/?report=NR-CPBI>); 87 Parties (62% of the Parties at 11 September 2007) had submitted the First Regular National Report (<http://www.cbd.int/reports/biosafety/?report=NR-CPB-01>); and 143 Parties (89% of the Parties at 30 September 2011) had submitted the Second Regular National Report (<http://bch.cbd.int/database/reports/>).

30% of the respondents within Africa, 20% in Asia-Pacific, 0% in CEE, 15% in GRULAC, 0% in WEOG, 28% within LDCs and 32% of the respondents within SIDS.

- f. *Decisions by a Party on regulating the transit of specific living modified organisms (LMOs) (Article 6, paragraph 1)* are reported to be available and in the BCH by 22 Parties (16% of the respondents to this question)<sup>29</sup>; not available by 107 Parties (76%); and available, but not or only partially available in the BCH, by 12 Parties (8%). The breakdown of the latter is as follows: 8% of the respondents within Africa, 12% in Asia-Pacific, 5% in CEE, 15% in GRULAC, 0% in WEOG, 8% within LDCs and 5% of the respondents within SIDS.
- g. Information on *Occurrences of unintentional transboundary movements that are likely to have significant adverse effects on biological diversity (Article 17, paragraph 1)* is reported to be available and in the BCH by 3 Parties (2% of the respondents to this question); not available by 133 Parties (94%); and available, but not or only partially available in the BCH, by 5 Parties (4%)<sup>30</sup>. The breakdown of the latter is as follows: 4% of the respondents within Africa, 6% in Asia-Pacific, 0% in CEE, 5% in GRULAC, 0% in WEOG, 6% within LDCs and 5% of the respondents within SIDS.
- h. Information on *Illegal transboundary movements of LMOs (Article 25, paragraph 3)* are reported to be available and in the BCH by 5 Parties (4% of the respondents to this question); not available by 126 Parties (90%); and available, but not or only partially available in the BCH, by 9 parties (7%)<sup>31</sup>. The breakdown of the latter is as follows: 4% of the respondents within Africa, 6% in Asia-Pacific, 0% in CEE, 19% in GRULAC, 5% in WEOG, 5% within LDCs and 9% of the respondents within SIDS.
- 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))* are reported to be available and in the BCH by 26 Parties (19% of the respondents to this question); not available by 80 Parties (57%); and available, but not or only partially available in the BCH, by 34 Parties (24%)<sup>32</sup>. The breakdown of the latter is as follows: 19% of the respondents within Africa, 21% in Asia-Pacific, 16% in CEE, 34% in GRULAC, 43% in WEOG, 17% within LDCs and 14% of the respondents within SIDS.
- j. *Information on the application of domestic regulations to specific imports of LMOs (Article 14, paragraph 4)* are reported to be available and in the BCH by 28 Parties (20% of the respondents to this question); not available by 91 Parties (65%); and available, but not or only partially available in the BCH, by 21 Parties (15%)<sup>33</sup>. The breakdown of the latter is as follows: 14% of the respondents within Africa, 12% in Asia-Pacific, 16% in CEE, 29% in GRULAC, 5% in WEOG, 16% within LDCs and 14% of the respondents within SIDS.

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<sup>29</sup> See note 8 under the section on Article 6.

<sup>30</sup> See note 20 under the section on Article 17.

<sup>31</sup> According to the information available in the BCH, as of the date this report was prepared, 2 Parties (1% of the Parties to the Protocol) had submitted to the BCH a *Notification about illegal transboundary movements* of LMOs (<http://bch.cbd.int/database/results/?searchid=521235>).

<sup>32</sup> See note 9 under the section on Articles 7-10.

<sup>33</sup> According to the information available in the BCH, as of the date this report was prepared, 4 Parties (2 % of the Parties to the Protocol) had submitted to the BCH at least one *Notification that domestic regulations shall apply with respect to specific imports of LMOs* (<https://bch.cbd.int/database/results/?searchid=521237>).

- 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)* are reported to be available and in the BCH by 27 Parties (19% of the respondents to this question); not available by 94 Parties (68%); and available, but not or only partially available in the BCH, by 18 Parties (13%)<sup>34</sup>. The breakdown of the latter is as follows: 8% of the respondents within Africa, 15% in Asia-Pacific, 11% in CEE, 25% in GRULAC, 10% in WEOG, 5% within LDCs and 10% of the respondents within SIDS.
- l. *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))* are reported to be available and in the BCH by 26 Parties (19% of the respondents to this question); not available by 93 Parties (66%); and available, but not or only partially available in the BCH, by 21 Parties (15%)<sup>35</sup>. The breakdown of the latter is as follows: 10% of the respondents within Africa, 24% in Asia-Pacific, 11% in CEE, 19% in GRULAC, 10% in WEOG, 10% within LDCs and 9% of the respondents within SIDS.
- 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)* are reported to be available and in the BCH by 33 Parties (24% of the respondents to this question); not available by 89 Parties (64%); and available, but not or only partially available in the BCH, by 17 Parties (13%)<sup>36</sup>. The breakdown of the latter is as follows: 13% of the respondents in the region, Asia-Pacific 18% in Asia-Pacific, 5% in CEE, 14% in GRULAC, 5% in WEOG, 13% within LDCs and 14% of the respondents within SIDS.
- n. *Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12, paragraph 1)* are reported to be available and in the BCH by 6 Parties (4% of the respondents to this question); not available by 127 Parties (91%); and available, but not available in the BCH, by 6 Parties (4%)<sup>37</sup>. The breakdown of the latter is as follows: 0% of the respondents within Africa, 6% in Asia-Pacific, 11% in CEE, 5% in GRULAC, 5% in WEOG, 0% within LDCs and 5% of the respondents within SIDS.
- o. *Information on LMOs granted exemption status by each Party (Article 13, paragraph 1)* are reported to be available and in the BCH by 3 Parties (2% of the respondents to this question); not available by 130 Parties (93%); and available, but not or only partially available in the BCH, by 7 Parties (5%)<sup>38</sup>. The breakdown of the latter is as follows: 6% of the respondents within Africa, 9% in Asia-Pacific, 5% in CEE, 0% in GRULAC, 0% in WEOG, 6% within LDCs and 5% of the respondents within SIDS.
- 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)* are reported to be available and in the BCH by 4 Parties (3% of the respondents to this question); not available by 132 Parties (94%); and available, but not or only partially available in the BCH, by 4 Parties (3%)<sup>39</sup>. The breakdown of the latter is as follows: 0% of the respondents

<sup>34</sup> See note 13 under the section on Article 11.

<sup>35</sup> See note 13 under the section on Article 11.

<sup>36</sup> See note 11 under the section on Article 11.

<sup>37</sup> See note 15 under the section on Article 12.

<sup>38</sup> See note 16 under the section on Article 13.

<sup>39</sup> See note 16 under the section on Article 13.



within Africa, 9% in Asia-Pacific, 5% in CEE, 0% in GRULAC, 0% in WEOG, 0% within LDCs and 5% of the respondents within SIDS.

- 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))* are reported to be available and in the BCH by 19 Parties (13% of the respondents to this question)<sup>40</sup>; not available by 65%; and available, but not or only partially available in the BCH, by 22%. The breakdown of the latter is as follows: 16% of the respondents within Africa, 21% in Asia-Pacific, 16% in CEE, 24% in GRULAC, 37% in WEOG, 11% within LDCs and 10% of the respondents within SIDS.

113. In responding to *Question 125*, 84 Parties (59% of the respondents to this question) reported that they have *established a mechanism for strengthening the capacity of the BCH National Focal Point to perform its administrative functions*: 62% of the respondents within Africa, 43% in Asia-Pacific, 47% in CEE, 52% in GRULAC, 63% in WEOG, 64% within LDCs and 69% of the respondents within SIDS.

114. In responding to *Question 126*, 110 Parties (34% of the respondents to this question) reported that they have *established a mechanism for the coordination among the BCH National Focal Point, the Cartagena Protocol focal point, and the competent national authority(ies) for making information available to the BCH*: 66% of the respondents within Africa, 77% in Asia-Pacific, 89% in CEE, 86% in GRULAC, 89% in WEOG, 72% within LDCs and 82% of the respondents within SIDS.

115. In responding to *Question 127*, 31 Parties (22% of the respondents to this question) reported that they use *the information available in the BCH in their decision making processes on LMOs*; 55 Parties (39% of the respondents to this question) reported doing so *in some cases*; and 55 Parties (39% of the respondents to this question) reported that they do not use it. The percentages of respondents within the different regions/economic groups reporting the latter are as follows: 47% of the respondents within Africa, 40% in Asia-Pacific, 32% in CEE, 48% in GRULAC, 16% in WEOG, 39% within LDCs and 64% of the respondents within SIDS.

116. In their responses to *Question 128*, 26 Parties (19% of the respondents to this question) reported having *experienced difficulties accessing or using the BCH*: 22% of the respondents within Africa, 24% in Asia-Pacific, 16% in CEE, 14% in GRULAC, 11% in WEOG, 29% within LDCs and 19% of the respondents within SIDS.

117. Of those 26 Parties which reported that they have experienced difficulties accessing or using the BCH, 19 Parties (68% of the respondents to this question), under *Question 129*, reported that they have *reported these problems to the BCH or the Secretariat*: 78% of the respondents within Africa, 36% in Asia-Pacific, 100% in CEE, 100% in GRULAC, 100% in WEOG, 73% within LDCs and 40% of the respondents within SIDS.

118. In their responses to *Question 130*, 71 Parties (51% of the respondents to this question) reported that *the information submitted to the BCH is complete and up-to date*<sup>41</sup>: 30% of the respondents within

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<sup>40</sup> See note 18 under the section on Article 15.

<sup>41</sup> According to the information available in the BCH, as of the date this report was prepared, 1031 national records (44% of the information submitted by Parties to the BCH) are complete and only 8 Parties (5% of the Parties to the Protocol) have all of their national records complete. Missing data are those that have not been provided after the implementation of the mandatory minimum information set in each common format for the submission of information. See also note 18 under the section on Article 15 regarding missing risk assessment records. The Secretariat has repeatedly contacted BCH National Focal Points on this subject and indicated the need for them to revise their records accordingly.

Africa, 56% in Asia-Pacific, 79% in CEE, 52% in GRULAC, 68% in WEOG, 33% within LDCs and 41% of the respondents within SIDS.

119. *Question 131* invited further details on the implementation of Article 20. A number of Parties reported that they have established national BCH nodes (based on Hermes or Ajax solutions), some through the UNEP-GEF project on building capacity for effective participation in the BCH. Some Parties reported limited participation in the BCH due to a lack of necessary resources. One Party from GRULAC reported that it regularly updates the BCH regarding legislation, risk assessments and decisions. A number of countries from Africa reported a lack of participation in the BCH due to a need for capacity-building. One Party from Africa reported hosting two workshops.

120. The EU reported that the European Commission database on “GMO detection methods” was interlinked with the BCH (as decided by the meeting of the Informal Advisory Committee on the BCH held in March 2011). An EU Member State reported that it “organized 2 meetings of the National Focal Points and Competent National Authorities of the EU Parties to the Cartagena Protocol to exchange views and experiences with regard to the implementation of the requirements of the Cartagena Protocol and the submission of information to the Biosafety Clearing House data base.”

### *Article 21 – Confidential information*

121. In responding to *Question 132*, 92 Parties (64% of the respondents to this question) reported that they have *established procedures to protect confidential information received under the Protocol*: 57% of the respondents within Africa, 60% in Asia-Pacific, 79% in CEE, 48% in GRULAC, 95% in WEOG, 56% within LDCs and 36% of the respondents within SIDS.

122. In their responses to *Question 133*, 73 Parties (53% of the respondents to this question) reported that they *always allow the notifier to identify information that is to be treated as confidential*: 27 Parties (19% of the respondents to this question) stated that they do so *in some cases only*; and 39 Parties (28% of the respondents to this question) reported not allowing it. The percentages of respondents within the different regions/economic groups reporting the latter are as follows: 36% of the respondents within Africa, 31% in Asia-Pacific, 16% in CEE, 43% in GRULAC, 0% in WEOG, 42% within LDCs and 62% of the respondents within SIDS.

123. *Question 134* invited further details on the implementation of Article 21. While most Parties from Asia have confidentiality rules to varying degrees, one Party reported that under its National Biosafety Framework “there should be no scope for confidential information. All relevant information should be made available for all the parties.” One Party from Africa reported that the Competent National Authority can make confidential information public if it is in the public’s “general interest”.

124. The EU reported the following under its domestic legislative framework:

- Article 25 of Directive 2001/18/EC (article 27 of Legislative Decree 224/2003) on the deliberate release into the environment of GMOs stipulates that the European Commission and the Member States shall not divulge to third parties any confidential information notified or exchanged under this Directive and shall protect intellectual property rights relating to the data received.
- Article 30 of Regulation (EC) No 1829/2003 on genetically modified food and feed allows applicants to indicate which information submitted under the Regulation they wish to be treated as confidential, based on verifiable justification.

- Article 16 of Regulation (EC) No 1946/2003 on transboundary movements of GMOs obliges the European Commission and the Member States not to divulge to third parties any confidential information received or exchanged under this Regulation.

125. A non-EU Member State WEOG Party reported that “information designated as confidential in an application to the EPA will not be released provided that the grounds for confidentiality are sound and there are no outweighing public interest considerations.” A CEE Party reported that information on the potential impact of LMOs on human health or the environment is not recognized as confidential.

### *Article 22 – Capacity-building (Questions 135-150)*

126. In their responses to *Question 135*, 88 Parties (62% of the respondents to this question) reported that they have *received external support or benefited from collaborative activities with other Parties in the development and/or strengthening of human resources and institutional capacities in biosafety*. The percentages of respondents within the different regions/economic groups, in this regard are as follows: 76% of the respondents within Africa, 63%, CEE 37%, GRULAC 95%, WEOG 11%, LDCs 72% and SIDS 82%.

127. In *Question 136*, the above 88 Parties which reported having received external support or benefited from collaborative activities with other Parties, were asked to indicate how the support has been made available. 37% of the responses<sup>42</sup> refer to *bilateral channels*; 23% to *regional channels*; and 40% to *multilateral channels*.

128. In response to *Question 137*, 41 Parties (29% of the respondents to this question) reported that they have *provided support to other Parties in the development and/or strengthening of human resources and institutional capacities in biosafety*. This includes: 14% of the respondents within Africa, 26% in Asia-Pacific, 21% in CEE, 52% in GRULAC, 53% in WEOG, 8% within LDCs and 14% within SIDS.

129. In *Question 138*, the above 41 Parties which reported having provided support to other Parties, were asked to indicate how the support has been made available<sup>43</sup>. 51% of the responses refer to support through *bilateral channels*; 22% to *regional channels*; and 27% to *multilateral channels*.

130. In response to *Question 139*, 112 Parties (79% of the respondents to this question) reported that they are *eligible to receive funding from the Global Environment Facility (GEF)*<sup>44</sup>: This includes 100% of the respondents within Africa, 86% in Asia-Pacific 58% in CEE, 100% in GRULAC, 6% in WEOG, 100% of respondents in both LDCs and SIDS.

131. In response to *Question 140*, 98 Parties (89% of the respondents to this question) reported that they have *initiated a process to access GEF funds for building capacity in biosafety*: 83% of the respondents within Africa, 93% in Asia-Pacific, 91% in CEE, 100% in GRULAC, 50% in WEOG, 87% within LDCs and 86% within SIDS.

132. In *Question 141*, the above 98 Parties which reported having initiated a process to access GEF

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<sup>42</sup> Questions 136, 138 and 142 allow each respondent to provide multiple answers and therefore the results are offered as percentages of responses rather than respondents.

<sup>43</sup> See note 42 above.

<sup>44</sup> According to the information available on the GEF website (at [http://www.thegef.org/gef/STAR/country\\_allocations](http://www.thegef.org/gef/STAR/country_allocations)), as of the date this report was prepared, 125 Parties (77% of the Parties to the Protocol) have received initial indicative allocations for biodiversity under the System for Transparent Allocation of Resources (STAR) of the GEF fifth replenishment period. Specific funds for biosafety may be part of the biodiversity allocation, but are not identified in the STAR envelopes for GEF-5.

funds were asked to characterize the *ease of the process*. No respondent characterized the process as *very easy*; 13 Parties (13% of the respondents to this question) characterised it as *easy*, 60 Parties (61% of the respondents to this question) as *average*; 20 Parties (20% of the respondents to this question) as *difficult* and 5 Parties (5% of the respondents to this question) as *very difficult*. The percentages of respondents within the different regions/economic groups that characterized the process as *difficult* or *very difficult* are as follows: 32% within Africa, 29% in Asia-Pacific, 24% in GRULAC, 36% in LDCs and 10% of Parties within SIDS. No Party in CEE and WEOG characterised the process as *difficult* or *very difficult*.

133. In *Question 142* countries were asked whether they *have ever received funding from the GEF for building capacity in biosafety*. 21 responses referred to receiving funding for a *pilot biosafety enabling activity*; 88 for the *development of national biosafety frameworks*; 43 for the *implementation of national biosafety frameworks*; 81 for *Phase I of the project Building Capacity for Effective Participation in the BCH*; and 43 for *Phase II* of the same project<sup>45</sup>.

134. In response to *Question 143*, 119 Parties (83% of the respondents to this question) reported that, *during the current reporting period*, they have *undertaken activities for the development and/or strengthening of human resources and institutional capacities in biosafety*. The percentages of respondents within the different regions/economic groups that have done so are as follows: 84% of Parties within Africa, 80% in Asia-Pacific, 79% in CEE, 90% in GRULAC, 84% in WEOG, 79% within LDCs and 73% within SIDS.

135. In *Question 144*, the 119 Parties which reported that they have undertaken capacity-building activities were asked to indicate *in which areas those activities were undertaken*. The following are the percentages of the responses<sup>46</sup> relating to the different areas:

- 12% of the responses referred to *Human resources capacity development and training*;
- 12% to *Information exchange and data management including participation in the Biosafety Clearing-House*;
- 11% to *Institutional capacity*;
- 9% to *Risk assessment and other scientific and technical expertise*;
- 8% to *Identification of LMOs, including their detection*;
- 7% to *Scientific, technical and institutional collaboration at subregional, regional and international levels*;
- 6% to *Risk management*;
- 6% to *Public awareness, participation and education in biosafety*;
- 5% to *Scientific biosafety research relating to LMOs*;
- 4% to *Socio-economic considerations*;

<sup>45</sup> According to the information available in the GEF project database (at <http://www.gefonline.org/>), as of the date this report was prepared, 17 Parties (10% of the Parties to the Protocol) received GEF funding under the *Pilot Biosafety Enabling Activity* (1998-2000); 123 Parties (76% of the Parties to the Protocol) under the *Development of national biosafety frameworks* (2001-2007); 67 Parties (41% of the Parties to the Protocol) under the several national and regional projects for *Implementation of national biosafety frameworks* (2002 – present days); 122 Parties (75% of the Parties to the Protocol) under *Phase I of the project Building Capacity for Effective Participation in the BCH* (2004-2008); and 50 Parties (31% of the Parties to the Protocol) under *Phase II* of the same project (2011-present). A list of the capacity-building activities funded by the GEF in biosafety is also available at <http://bch.cbd.int/protocol/gefprojects.shtml>. See also note 43 above.

<sup>46</sup> Question 144 allows each respondent to provide multiple answers and therefore the results are offered as percentages of responses rather than respondents.

- 4% to *Implementation of the documentation requirements under Article 18.2 of the Protocol*;
- 4% to *Taking into account risks to human health*.
- 3% to *Measures to address unintentional and/or illegal transboundary movements of LMOs*;
- 2% to *Technology transfer*; and
- 2% to *Handling of confidential information*;

136. With regards to *Question 145*, 68 Parties (48% of the respondents to this question) reported that they have, *during the current reporting period, carried out a capacity-building needs assessment*. This includes: 51% of the respondents within Africa, 43% in Asia-Pacific, 63% in CEE, 62% in GRULAC, 16% in WEOG, and 38% within LDCs and 41% within SIDS.

137. In their responses to *Question 146*, 114 Parties (80% of the respondents to this question) reported that they *still have capacity-building needs*; 8% have *a few*; and 13% do not have any. The percentages of respondents within the different regions/economic groups that reported having [many] or *a few capacity-building needs* are as follows: 98% of the respondents within Africa, 92% in Asia-Pacific, 27% in WEOG, and 96% of respondents within SIDS. All respondents from CEE, GRULAC and LDCs indicated that they have needs.

138. In *Question 147*, the 114 Parties which reported still having capacity-building needs were asked to indicate *in which areas they still need capacity-building*. The following are the percentages of responses received:

- 7% of the responses<sup>47</sup> referred to *Human resources capacity development and training*;
- 7% to *Institutional capacity*;
- 7% to *Risk assessment and other scientific and technical expertise*;
- 7% to *Identification of LMOs, including their detection*;
- 7% to *Scientific, technical and institutional collaboration at subregional, regional and international levels*;
- 7% to *Risk management*;
- 7% to *Public awareness, participation and education in biosafety*;
- 7% to *Scientific biosafety research relating to LMOs*;
- 7% to *Measures to address unintentional and/or illegal transboundary movements of LMOs*;
- 7% to *Technology transfer*;
- 6% to *Information exchange and data management including participation in the Biosafety Clearing-House*;
- 6% to *Socio-economic considerations*;

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<sup>47</sup> Question 147 allows each respondent to provide multiple answers and therefore the results are offered as percentages of responses rather than respondents.

- 6% to *Implementation of the documentation requirements under Article 18.2 of the Protocol*;
- 6% to *Taking into account risks to human health*; and
- 6% to *Handling of confidential information*.

139. With regards to *Question 148*, 39 Parties (48% of the respondents to this question) reported that they have *developed a capacity-building strategy or action plan* including: 31% of the respondents in Africa, 29% in Asia-Pacific, 32% in CEE, 29% in GRULAC, 11% in WEOG, 28% in LDCs and 27% of the respondents from within SIDS.

140. In response to *Question 149*, 42 Parties (30% of the respondents to this question) reported that they have *submitted the details of their national biosafety experts to the Roster of Experts in the BCH*<sup>48</sup>. This includes: 25% of the respondents within Africa, 26% in Asia-Pacific, 33% in CEE, 38% in GRULAC, 39% in WEOG, 13% within LDCs and 18% within SIDS.

141. *Question 150* invited further details on the implementation of Article 22, including experiences in accessing GEF funds. A number of Parties reported that they have benefited from the UNEP-GEF capacity-building projects. Many Parties also reported participating in and hosting capacity-building workshops and activities. The EU and its Member States reported that they have contributed to capacity-building initiatives in the field of biosafety in a number of developing country Parties as well as in Parties with economies in transition.

142. One Party from Asia reported that it has approved the establishment of a biotechnology laboratory which will have facilities to detect and analyse LMOs. It reported that through an ongoing biosafety project LMO detection equipment along with rapid test kits will be acquired and training of relevant technicians and inspectors will be done. Another Party from Asia reported that it has developed special plans for extensive scientific and technological capacity development in biosafety in the medium and long-term. A Party from GRULAC also reported that three Competent National Authorities have an LMO detection laboratory which supports the LMO surveillance and monitoring activities. Some Parties from Africa reported challenges about accessing GEF funds for capacity-building.

### ***Article 23 – Public awareness and participation (Questions 151-160)***

143. In response to *Question 151*, 50 Parties (35% of the respondents to this question) reported that they have *established a strategy or put in place legislation for promoting and facilitating public awareness, education and participation concerning the safe transfer, handling and use of LMOs*; 50 Parties (35% of the respondents to this question) have done so *to some extent* and 43 Parties (30% of the respondents to this question) reported that they have not established any strategy. The percentages of respondents within the different regions/economic groups that have not yet established any strategy are as follows: 37% of the respondents within Africa, 31% in Asia-Pacific, 26% in CEE, 38% in GRULAC, 5% in WEOG, 36% in LDCs and 32% within SIDS.

144. In response to *Question 152*, 82 Parties (58% of the respondents to this question) reported that they have *established a biosafety website*<sup>49</sup>. This includes: 31% of the respondents within Africa, 66% in

<sup>48</sup> According to the information available in the BCH, as of the date this report was prepared, 36 Parties (30% of the Parties to the Protocol) had submitted at least one CV of a *Biosafety Expert* to the BCH Roster of Experts (<https://bch.cbd.int/database/results/?searchid=521318>).

<sup>49</sup> According to the information available in the BCH, as of the date this report was prepared, 74 Parties (46% of the Parties to the Protocol) had submitted at least one *National Database or Website link* to the BCH (<http://bch.cbd.int/database/results/?searchid=521321>).

Asia-Pacific, 79% in CEE, 57% in GRULAC, 89% in WEOG, 34% within LDCs and 23% within SIDS.

145. With regards to *Question 153*, 56 Parties (39% of the respondents to this question), including all responding Parties from WEOG, reported that they have *established a mechanism to ensure public access to information on living modified organisms that may be imported*; 44 Parties (31% of the respondents to this question) reported having done so *to a limited extent*; and 43 Parties (30% of the respondents to this question) reported that they have not established such a mechanism. The percentages of respondents within the different regions/economic groups that have not established such a mechanism are as follows: 33% of the respondents within in Africa, 37% in Asia-Pacific, 16% in CEE, 52% in GRULAC, 31% within LDCs and 59% within SIDS.

146. In response to *Question 154*, 64 Parties (45% of the respondents to this question), including all responding Parties from WEOG, reported that they have *established a mechanism to consult the public in the decision-making process regarding LMOs*; 27 Parties (19% of the respondents to this question) reported having done so *to a limited extent*; and 52 Parties (36% of the respondents to this question) reported that they have not established such a mechanism. The percentages of respondents within the different regions/economic groups that have not established such a mechanism are as follows: 43% of the respondents within Africa, 46% in Asia-Pacific, 16% in CEE, 57% in GRULAC, 46% in LDCs and 59% in SIDS.

147. In their responses to *Question 155*, 64 Parties (45% of the respondents to this question), including all responding Parties from WEOG, reported that they have *established a mechanism to make available to the public the results of decisions taken on LMOs*; 31 Parties (22% of the respondents to this question) reported that have done so *to a limited extent*; and 48 Parties (34% of the respondents to this question) reported that they have not established such a mechanism. The percentages of respondents within the different regions/economic groups that have not established such a mechanism are as follows: 43% of the respondents within Africa, 40% in Asia-Pacific, 16% in CEE, 48% in GRULAC, 46% in LDCs and 59% within SIDS.

148. With regards to *Question 156*, 89 Parties (63% of the respondents to this question) reported that they have *taken initiatives to inform their public about the means of public access to the Biosafety Clearing-House*. This includes: 54% of the respondents within Africa, 51% in Asia-Pacific, 74% in CEE, 76% in GRULAC, 79% in WEOG, 56% in LDCs and 71% of the respondents within SIDS.

149. In their responses to *Question 157*, 43 Parties (30% of the respondents to this question) reported that *during the current reporting period*, they have *promoted and facilitated public awareness, education and participation concerning the safe transfer, handling and use of LMOs*; 67 Parties (47% of the respondents to this question) reported doing so *to a limited extent*; and 33 Parties (23% of the respondents to this question) reported that they have not done so. The percentages of respondents within the different regions/economic groups that have not yet done so are as follows: 29% of the respondents within Africa, 26% within Asia-Pacific, 21% within CEE, 19% within GRULAC, 11% within WEOG, 28% within LDCs and 36% within SIDS.

150. Furthermore, in response to *Question 158*, out of the 110 Parties which reported that they have promoted and facilitated public awareness, education and participation (either fully or to a limited extent), 61 Parties (61% of the respondents to this question) reported that they have *cooperated with other States and international bodies*. This includes: 69% of the respondents within Africa, 42% within Asia-Pacific, 71% within CEE, 69% within GRULAC, 59% within WEOG, 60% within LDCs and 38% within SIDS.

151. In their responses to *Question 159*, 29 Parties (21% of the respondents to this question) reported that, *during the current reporting period*, they have *consulted the public in the decision-making process regarding LMOs and made the results of such decisions available to the public more than 5 times*; 18 Parties (13% of the respondents to this question) reported that they have done so *less than 5 times*; and 94 Parties (67% of the respondents to this question) reported that they have had no consultations. The percentages of respondents within the different regions/economic groups that have had no consultations are as follows: 81% of the respondents within Africa, 77% within Asia-Pacific, 61% within CEE, 67% within GRULAC, 16% within WEOG, 87% within LDCs and 91% within SIDS.

152. *Question 160* invited further details on the implementation of Article 23. A number of WEOG and CEE Parties reported that they are using national nodes of the BCH and other government-run websites as means of public awareness and participation. The EU reported that, as a Party to the Aarhus Convention and in accordance with the amendment made to the Aarhus Convention, there are specific obligations placed on Parties with regard to public participation in decision-making processes on the deliberate release into the environment and placing on the market of LMOs.

153. Some of the means of public awareness and participation reported by Parties include: workshops, handbooks, consultation committees, lecture courses, symposia, leaflets and brochures, discussion seminars, guidebooks, animated cartoons, bulletins, mass-media, TV and radio broadcasts. One Party from Asia reported that two of its universities offer undergraduate programs in biosafety. A Party from GRULAC reported that it takes into account the views expressed by indigenous people who do not allow the planting of LMOs on their land. Many Parties from Africa also emphasize the importance of public awareness and participation in their biosafety frameworks.

#### ***Article 24 – Non-Parties (Questions 161-167)***

154. In response to *Question 161*, 7 Parties (5% of the respondents to this question) reported that they have *entered into bilateral, regional, or multilateral agreements with non-Parties regarding transboundary movements of LMOs* and 134 Parties (95% of the respondents to this question), including all responding Parties from CEE, reported that they have not done so. The percentages of respondents within the different regions/economic groups that have entered into such agreements are as follows: 4% of the respondents within Africa, 3% in Asia-Pacific, 14% in GRULAC, 5% in WEOG, 5% in LDCs and 5% within SIDS.

155. In response to *Question 162*, 37 Parties (26% of the respondents to this question) reported that they have *imported LMOs from a non-Party*. This includes: 8% of the respondents within Africa, 26% within Asia-Pacific, 21% CEE, 35% in GRULAC, 68% in WEOG, 5% in LDCs and 10% in SIDS.

156. With regards to *Question 163*, 7 Parties (5% of the respondents to this question) reported having *exported LMOs to a non-Party*. This includes: 2% of the respondents within Africa, 10% within GRULAC and 21% within WEOG. All respondents from Asia-Pacific, CEE, LDCs and SIDS reported that they have not exported LMOs to any non-Party.

157. In *Question 164*, countries which reported having imported from, or exported LMOs to, a non-Party were asked to indicate whether such transboundary movements of LMOs were consistent with the objective of the Protocol. 31 Parties (84% of the respondents to this question), including all responding Parties from Africa, Asia-Pacific, CEE and WEOG, reported that *the transboundary movements were always consistent with the objective of the Protocol*; 5 Parties (14% of the respondents to this question) from GRULAC reported that this was so *in some cases only*; and 1 Party (3% of the respondents to this question), also from GRULAC, reported that the movements were not consistent with the objective of the Protocol.



158. With regards to *Question 165*, out of those Parties which reported having imported LMOs from, or exported LMOs to, a non-Party, 11 Parties (32% of the respondents to this question) reported that *information about these transboundary movements was always submitted to the BCH*; 5 Parties (15% of the respondents to this question) reported such information being submitted *in some cases only*; and 18 Parties (53% of the respondents to this question) reported that no such information was submitted to the BCH. The percentages of respondents to this question within the different regions/economic groups which reported that no such information was submitted to the BCH are as follows: 75% of the respondents within Africa, 38% within Asia-Pacific, 71% with GRULAC, 38% with WEOG, and all respondents from CEE, LDCs and SIDS.

159. In *Question 166* countries that were not Parties to the Cartagena Protocol were asked *whether they had contributed information to the BCH on LMOs released in, or moved into, or out of, areas within its national jurisdiction*. All the national reports received were from Parties and therefore no responses were received on this question.

160. *Question 167* invited further details on the implementation of Article 24. A Party from Asia-Pacific reported that it regularly imports various strains of living modified microorganisms, cell lines and other LMOs from non-Parties for purposes of contained use only and that these imports are not made public due to the confidentiality of the information. One GRULAC Party reported one known instance of unintentional importation from a non-Party. The EU reported that, for both imports and exports of LMOs, the legislative framework applies regardless of whether the country of import or export is a Party or non-Party to the Protocol. Since 2003, most notifications for LMOs intended for deliberate release related to export for use in small-scale field trials. A non-EU Member State Party from WEOG reported that imports and exports of LMOs for research purposes to and from non-Parties have taken place without requiring approval.

#### ***Article 25 – Illegal transboundary movements (Questions 168-175)***

161. In response to *Question 168*, 86 Parties (61% of the respondents to this question), including all Parties from WEOG, reported that they have adopted domestic measures aimed at preventing and/or penalizing transboundary movements of LMOs carried out in contravention of its domestic measures to implement the Protocol. This includes: 57% of the respondents within Africa, 51% in Asia-Pacific, 68% in CEE, 43% in GRULAC, 51% within LDCs and 36% within SIDS.

162. Additionally, in response to *Question 169*, 52 Parties (37% of the respondents) reported having *established a strategy for detecting illegal transboundary movements of LMOs*. This includes: 17% of the respondents in Africa, 35% in Asia-Pacific, 58% in CEE, 19% in GRULAC, 89% in WEOG, 14% in LDCs and 9% within SIDS.

163. *Question 170* asked countries to indicate *how many times they received information concerning cases of illegal transboundary movements of an LMO to or from territories under their jurisdiction during the current reporting period*. One Party (1% of the respondents to this question) reported *more than 10* cases; 2 Parties (1% of the respondents to this question) reported *less than 10* cases; 15 Parties (10% of the respondents to this question) reported *less than 5* cases and 124 Parties (87% of the respondents to this question) reported that they never received such information.

164. Questions 171-174 requested further details from the 18 Parties which reported having received information concerning cases of illegal transboundary movements:

- In *Question 171*, no Party reported having *informed the BCH and the other Party(ies) involved*; 2 Parties (12% of the respondents to this question) reported having done so *only in*

*some cases*; 9 Parties (53% of the respondents to this question) reported having informed *only the other Party(ies) involved*; 1 Party (6% of the respondents to this question) *only the BCH*; and 5 Parties reported that they have informed *neither the BCH nor the other Party(ies) involved*<sup>50</sup>. The breakdown by regional and economic group of Parties reporting the latter is as follows: 2 Parties, Asia-Pacific 1, CEE 0, GRULAC 2, WEOG 0, LDCs 2 and SIDS 2.

- In *Question 172*, 14 Parties (82% of the respondents) reported that they have *established the origin of the LMO(s)*; 2 Parties (12% of the respondents to this question) reported that they have done so *in some cases*; and one Party (6% of the respondents to this question) reported that it has not established the origin.
- In *Question 173*, 14 Parties (78% of the respondents) reported that they have *established the nature of the LMO(s)*; 4 Parties (22% of the respondents to this question) reported that they have done so *in some cases*; and no Party reported not having established the nature of the illegal LMO(s).
- In *Question 174*, 6 Parties (33% of the respondents) reported that they have *established the circumstances of the illegal transboundary movement(s)*; 9 Parties (50% of the respondents to this question) have done so *in some cases*; and 3 Parties (17% of the respondents to this question) have not established the circumstances.

165. *Question 175* invited further details on the implementation of Article 25. A Party from Asia-Pacific reported killifish (*Zebra danios*) and LMO corn were illegally imported into its territory because the importer had not recognized that the organisms were genetically modified. Those LMOs were recalled and disposed of. The same Party reported that it is investigating the possible illegal import of papaya and pharmaceuticals for human consumption. A Party from GRULAC reported that it has recorded in the BCH the presence of LMOs in its territory that have not been authorized by national authorities. Many Parties from Africa reported that there are no known cases of illegal transboundary movements. However some reported that they suspected that illegal transboundary movements have occurred.

166. The EU reported that its Member States are obliged to take domestic measures to prevent and penalize illegal transboundary movements of LMOs. The European legislation contains explicit obligations on Member States to lay down rules on penalties applicable to infringements of the provisions of European regulations. It further stated that these penalties shall be effective, proportionate and dissuasive. One EU Member State from CEE reported that, although there were no illegal transboundary movements recorded, the possible occurrence of the non-approved transgenic fish, *Danio rerio* (or, so-called Glow fish) was found and monitored in 2006 and 2007.

#### ***Article 26 – Socio-economic considerations***

167. Questions 176-178 of the report address the implementation of Article 26. In their responses to *Question 176*, 21 Parties (29% of the respondents to this question) reported that, *when taking a decision on import*, they have *taken into account socio-economic considerations arising from the impact of the LMO on the conservation and sustainable use of biological diversity*; 11 Parties (15% of the respondents to this question) reported doing so *only in some cases*; and 40 Parties (56% of the respondents to this question) reported they have not taken socio-economic considerations into account. The percentages of respondents within the different regions/economic groups reporting the latter are as follows: 53% of the respondents within Africa, 63% in Asia-Pacific, 43% in CEE, 50% in GRULAC, 59% in WEOG, 62% within LDCs and 67% of the respondents within SIDS.

<sup>50</sup> See note 31 under the section on Article 20

168. In their responses to *Question 177*, 10 Parties (7% of the respondents to this question) reported that they have *cooperated with other Parties on research and information exchange on any socio-economic impacts of LMOs*; 39 Parties (27% of the respondents to this question) reported doing so *to a limited extent*; and 94 Parties (66% of the respondents to this question) reported that they have not *cooperated with other Parties* in this regard. The percentages of respondents within the different regions/economic groups which reported having cooperated are as follows: 4% of the respondents within Africa, 0% in Asia-Pacific, 5% in CEE, 0% in GRULAC, 37% in WEOG, 3% within LDCs and 0% of the respondents within SIDS.

169. *Question 178* requested further details on the implementation of Article 26. One Party from Asia reported that it has conducted research on the socio-economic impacts of GM cotton, GM rice, GM poplars and GM papaya. Another Party reported hosting a Workshop on Capacity-Building for Research and Information Exchange on Socio-economic Impacts of LMOs under the Cartagena Protocol on Biosafety on November 14-16, 2011. A GRULAC Party reported that it “took part in two workshops that covered key issues such as, recognizing the value and use of biodiversity, as well as the economic, social, cultural, religious, ethical and institutional aspects”. Parties from Africa reported that RAEIN-Africa has been instrumental regarding capacity-building on how to incorporate socio-economic considerations on decisions made for the introduction of LMOs.

170. The EU reported that, based on the contributions of Member States, it recently issued a report on the socio-economic implications of LMO cultivation. This report reveals that “GMO commercial cultivation in Europe is limited to 7 countries and to herbicide-tolerant (HT) soya, insect-resistant (Bt) maize and starch potato in the European Union. Therefore the amount of statistically relevant information on the ex-post socio-economic impacts of GMO cultivation is rather limited. It focuses mainly on impacts at farm level (seed production, farmers).” A non-EU Member State from WEOG reported that socio-economic considerations are a central part of its impact assessment prior to the marketing of LMOs and LMOs-FFP. One EU Member State from the CEE reported it participated in discussions and information exchanges on socio-economic issues at several international meetings, e.g. Network Group for the Exchange and Coordination of Information “COEX-NET” (a working group under the European Commission).

#### ***Article 27 – Liability and Redress***

171. Questions 179-181 of the report address the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress. Under *Question 179*, 33 Parties (23% of the respondents to this question) reported that they have *signed the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress*<sup>51</sup>: 14% of the respondents within Africa, 6% in Asia-Pacific, 37% in CEE, 14% in GRULAC, 74% in WEOG, 15% within LDCs and 5% of the respondents within SIDS.

172. In their responses to *Question 180*, 84 Parties (60% of the respondents to this question) reported that they have *initiated steps towards ratification, acceptance or approval of the Nagoya – Kuala Lumpur Supplementary Protocol*: 66% of the respondents within Africa, 59% in Asia-Pacific, 74% in CEE, 19% in GRULAC, 79% in WEOG, 68% within LDCs and 29% of the respondents within SIDS.

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<sup>51</sup> According to the information available from the Secretary General of the United Nations (the Depository for the Supplementary Protocol), as of the date this report was prepared, 37 Parties (23% of the Parties to the Protocol) had signed the Nagoya – Kuala Lumpur Supplementary Protocol and one had deposited its instrument of ratification of the treaty. A list of the signatures to and ratifications of the Nagoya – Kuala Lumpur Supplementary Protocol is available at <https://bch.cbd.int/protocol/parties/#tab=1>.

173. *Question 181* invited further details on activities undertaken towards the implementation of the Supplementary Protocol. One Party from Asia reported that, prior to ratification, a study has been commissioned for a legal expert to examine the implications of the Supplementary Protocol and suggest whether the existing domestic laws are sufficient to comply with the obligations under the Supplementary Protocol, and indicate relevant provisions and changes, if any, required for ensuring compliance. A number of Parties from GRULAC and Africa reported that their governments are currently in the analysis phase of determining whether or not to sign the Supplementary Protocol.

174. The EU and its Member States reported having undertaken steps and procedures towards a prompt ratification of the Supplementary Protocol. The EU reported its legislation is already fully consistent with the adopted Supplementary Protocol and, accordingly, no legal amendments are necessary. One non-EU Member State from WEOG reported the “ratification procedure of the Nagoya-Kuala Lumpur Protocol is under way, but it is not expected to be achieved before the year 2013.”

### ***Article 33 – Monitoring and reporting***

175. Questions 182-183 of the report focus on previous national reports on the implementation of the Protocol. Under *Question 182*, 59 Parties (42% of the respondents to this question) reported that they have *submitted the previous national reports (Interim and First National Reports)*; 8 Parties (6% of the respondents to this question) *the Interim report only*; 33 Parties (24% of the respondents to this question) *the First report only*; and 39 (28% of the respondents to this question) reported that they have not submitted a previous report<sup>52</sup>. The breakdown by regional and economic group of Parties reporting the latter is as follows: 36% of the respondents within Africa, 38% in Asia-Pacific, 11% in CEE, 29% in GRULAC, 6% in WEOG, 42% within LDCs and 41% of the respondents within SIDS.

176. In their responses to *Question 183*, those 80 Parties which reported that they have not submitted one or both of the previous reports, indicated the *main challenges that hindered the submission*:

- 33% of responses<sup>53</sup> referred to *lack of financial resources to gather the necessary information*;
- 31% to *lack of relevant information at the national level*;
- 20% to *difficulty in compiling the information from various sectors*;
- 16% to *no obligation to submit (e.g. country was not a Party at the time)*.

### ***Other information***

177. *Question 184* requested *any other information on issues related to national implementation of the Protocol, including any obstacles or impediments encountered*. A number of Parties from all regions reiterated their need for capacity-building initiatives in order to better implement the Protocol.

178. A Party from Asia reported that during the reporting period, it “has taken a decision to release two more events of Bt cotton developed in the country. In addition, several transgenic crops such as Brinjal, Rice, Okra, Pigeon pea, Chick pea, Mustard, Potato, Castor, Maize, sorghum, cabbage, cauliflower, cotton, tomato, groundnut, wheat, watermelon, papaya, banana, sugarcane, rubber etc are in different stages of development and field testing.”

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<sup>52</sup> See note 28 under the section on Article 20.

<sup>53</sup> It is noted that Question 183 allows each respondent to provide multiple answers and therefore the results are offered as percentages of responses rather than respondents.

179. A non-EU Member State from CEE reported that a “project on the strengthening of capacities for the implementation of national Biosafety framework funded by GEF has started in May 2011 and will continue until May 2015.”

180. Finally, *Question 185* offered the possibility to provide *any other information on difficulties that Parties may have encountered in filling in this report*.

181. In general, Parties express satisfaction with the reporting format. The EU reported that “the way in which EU legislation in relation to biosafety is structured makes it challenging to always find a correspondence in the reporting format.” An EU Member State from WEOG also stated that “it was sometimes difficult to find the correct answer e.g. when products are regulated at EU level and field trials at national level.” A Party from CEE reported the “format is not fully compatible with open office and might cause problems in filling in to the governments that use open office instead of MS Word.” One Party reported two errors in the translation of the report.

182. A number of Parties reported that more “Not Applicable” options would be appropriate for the multiple choice questions.

#### IV. GENERAL TRENDS

183. In addition to adopting the reporting format for the Second National Reports, the Parties at their fifth meeting also adopted the Strategic Plan for the Cartagena Protocol on Biosafety for the period 2011-2020 as well as a multi-year programme of work for the sixth, seventh and eighth meetings of the COP-MOP. In this context, the Second National Reports provide important baseline data for evaluating progress in the implementation of the Protocol and its Strategic Plan.

184. According to the provisional agenda for COP-MOP 6, the Parties will be invited to consider under item 18 (Assessment and review), the second assessment and review of the effectiveness of the Protocol which primarily focuses on evaluating the status of implementation of core elements of the Protocol.

185. Notwithstanding the more specific considerations to be discussed under the second assessment and review of the Protocol (see document UNEP/CBD/BS/COP-MOP/6/17), some general trends emerging from the Second National Reports have been identified and summarized as follows:

- a) The number of Second National Reports submitted by Parties has greatly increased due to the financial resources made available by the Global Environment Facility to eligible Parties (Fig. 1);
- b) The majority of the Parties reported that they do not have a domestic regulatory framework fully in place (Fig. 2);
- c) A large number of Parties have not established a mechanism for decision-making regarding LMOs, either for their first intentional transboundary movements for intentional introduction into the environment or for domestic use for direct use as food or feed, or for processing (Fig. 3);
- d) A large number of Parties have not established a mechanism for conducting risk assessments prior to taking decisions regarding LMOs (Fig. 3);
- e) A large majority of Parties have not yet developed the capacity to detect and identify LMOs (Fig. 4);

- f) A large portion of the national information that Parties are obliged to make available through the BCH has not yet been provided to the BCH (Fig. 5);
- g) A large majority of Parties have not yet established a strategy or put in place legislation for promoting and facilitating public awareness, education and participation concerning the safe transfer, handling and use of LMOs (Fig. 6);
- h) The largest portion of funds made available to developing countries for capacity-building in biosafety is from sources outside the financial mechanism of the CBD (Fig. 7);
- i) A large majority of Parties still need capacity-building (Fig. 8).

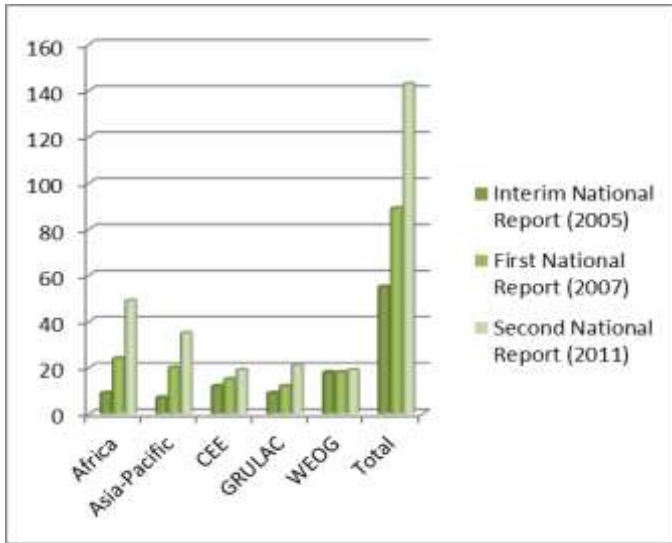


Figure 1: Number of National Reports (2005, 2007 & 2011) submitted per region (source: [http://bch.cbd.int/protocol/cpb\\_natreports.shtml](http://bch.cbd.int/protocol/cpb_natreports.shtml) ).

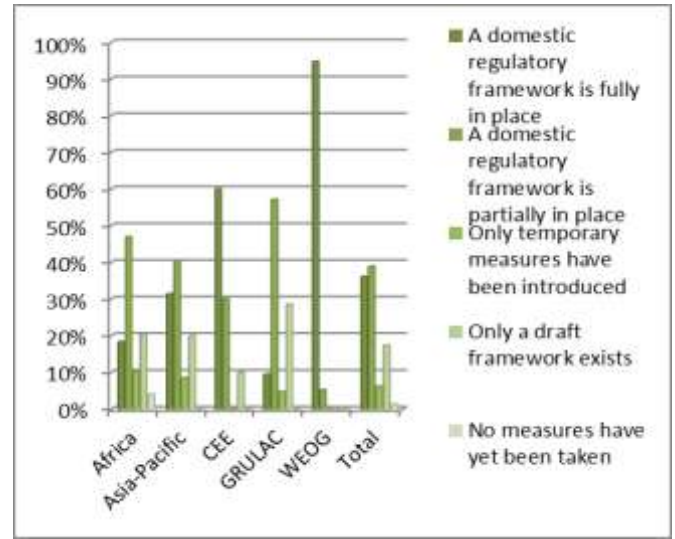


Figure 2: Percentages of Parties per region having introduced the necessary legal, administrative and other measures for the implementation of the Protocol (source: reports on question 15).

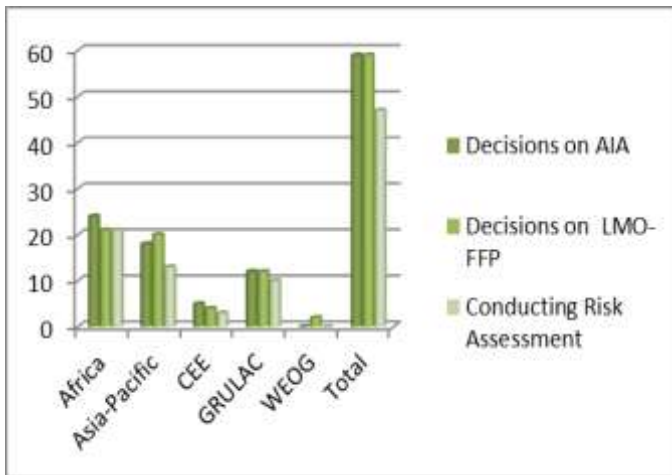


Figure 3: Number of Parties per region that have **not** established mechanisms for decision making regarding LMOs or conducting risk assessment prior to taking decisions regarding LMOs (source: reports on questions 31, 54 and 81).

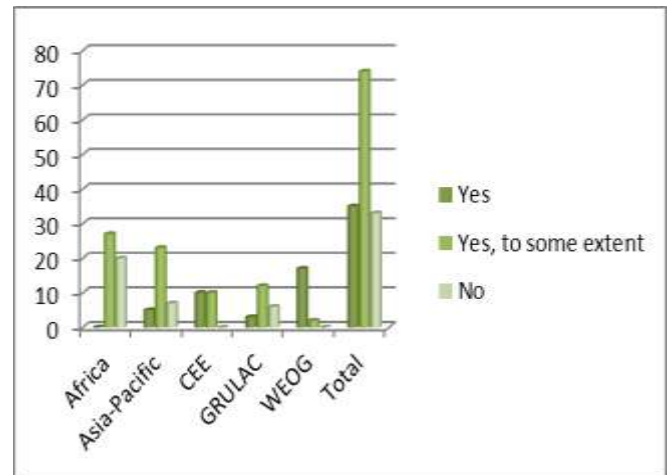


Figure 4: Number of Parties per region with the capacity to detect and identify LMOs (source: reports on question 34).

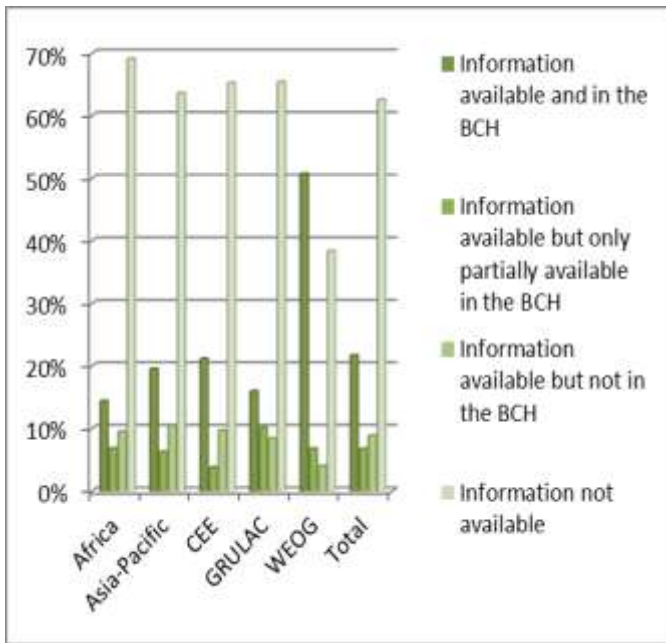


Figure 5: Percentages of Parties per region submitting mandatory information to the BCH (source: reports on question 124).

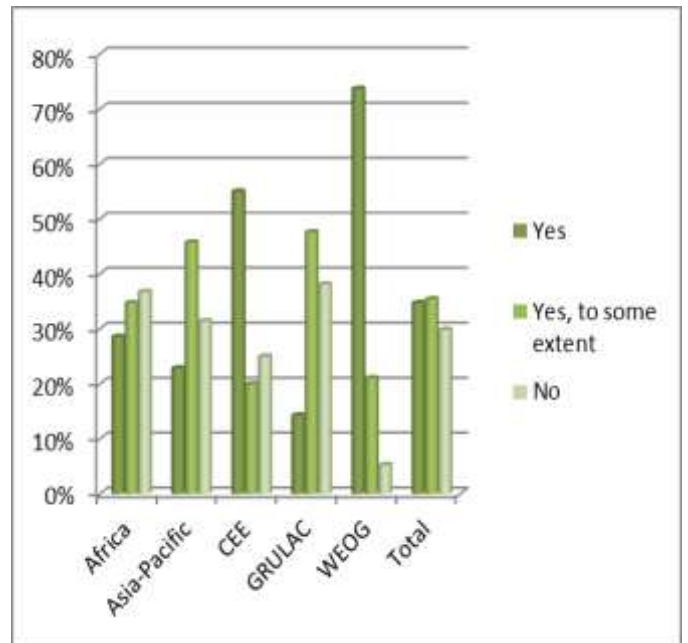


Figure 6: Percentages of Parties per region that have established a strategy or put in place legislation for promoting and facilitating public awareness, education and participation concerning the safe transfer, handling and use of LMOs (source: reports on question 151).

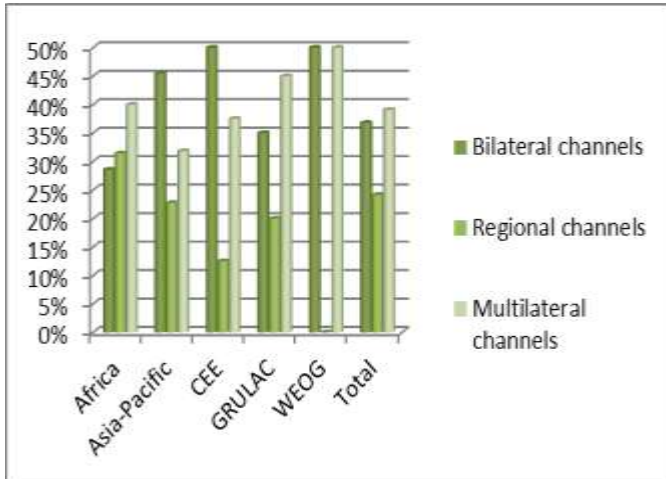


Figure 7: Percentages of Parties per region reporting sources by which financial resources were received for capacity-building (source: reports on question 136).

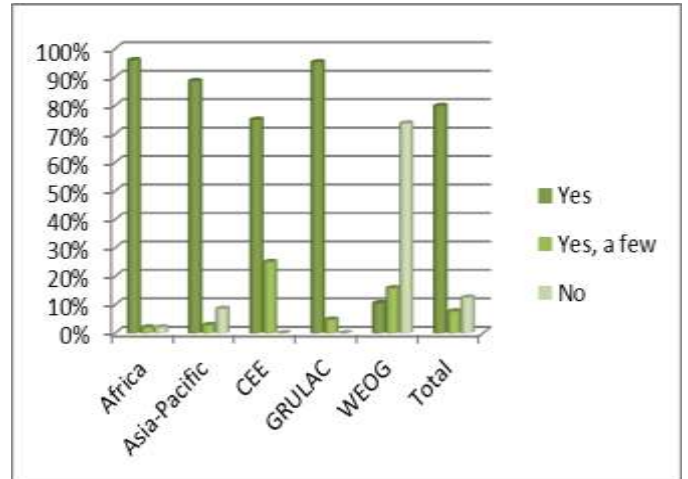


Figure 8: Percentages of Parties per region reporting whether they still have capacity-building needs (source: reports on question 146).



#### IV. ELEMENTS OF A DRAFT DECISION

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

1. *Take note* of the Second National Reports submitted by Parties and of the analysis of the responses prepared by the Secretariat;
2. *Welcome* the financial support provided by the Global Environment Facility to fund all eligible Parties in the preparation of their Second National Reports on the implementation of the Protocol;
3. *Welcome* the high level of submissions of Second National Reports by Parties to the Protocol;
4. *Urge* Parties that have not yet done so to submit, without further delay, their national reports to the Executive Secretary;
5. *Take into account* the recommendation of the Compliance Committee and remind each Party of its obligation to submit national reports in accordance with Article 33 of the Protocol;
6. *Recognize* that the information gathered establishes baselines for subsequent assessment and review processes of the effectiveness of the Protocol as well as for measuring the implementation and achievement of the Strategic Plan of the Protocol;
7. *Note* that there are some discrepancies between the information reported in the Second National Reports and those made available by Parties through the Biosafety Clearing-House and further remind Parties of their obligation to make available to the Biosafety Clearing-House the required information in accordance with article 20 paragraph 3.;
8. *Request* the Executive Secretary to assess, on the basis of the Second National Reports, the gaps in the information made available by Parties to the Biosafety Clearing-House, contact Parties and assist them to submit, without further delay, missing information;
9. *Request* the Executive Secretary to update the reporting format based on experiences gained through the analysis of the Second National Reports the recommendations of the Compliance Committee and the Parties. The updated format, adjusted in accordance with paragraph 8 of decision BS-V/14, is to be submitted to the seventh meeting of Conference of the Parties serving as the meeting of the Parties to the Protocol for its consideration.

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