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Item 14 of the provisional agenda*

MONITORING AND REPORTING UNDER THE PROTOCOL (ARTICLE 33)

Analysis of information contained in the interim national reports

Note by the Executive Secretary

I. INTRODUCTION

1. As specified in Article 33 of the Protocol, each Party is required to monitor the implementation of its obligations under the Protocol and to report to the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) on measures taken to implement the Protocol. At the first meeting, the Parties approved a format for the interim national report on implementation of the Protocol, and agreed on the frequency and timing of such reports (decision BS-I/9). National reports are to be submitted 12 months prior to the meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol at which they will be considered, with a general frequency of every four years.

2. It was also agreed that during the initial four-year period an interim report would be submitted two years after the entry into force of the Protocol, and the intervals and formats of the reports should be kept under review, building on the experience of Parties in preparing their reports. The deadline for submission of interim national reports was 11 September 2005. This analysis includes all reports received by 11 October 2005. The list of Parties that submitted reports before this date is provided in annex I.

3. In decision BS-I/12, the Parties agreed to consider the interim national reports at their third meeting. Accordingly, this paper contains an analysis of information contained in the interim national reports to assist Parties in their deliberations for this item. Section II of the paper discusses the methodology of the analysis, including regional distribution of responses, presentation of information, and limitations of the analysis. Section III contains the substance of the analysis, presented according to

* UNEP/CBD/BS/COP-MOP/3/1.

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relevant articles of the Protocol, and section IV contains observations on the reporting process and implications for submission of the first regular national reports. Section V provides some general conclusions, and section VI contains elements of a draft decision on monitoring and reporting under the Protocol for consideration of the Parties. A proposed format for submission of the first regular national report, which is due to be considered at the fourth meeting of the Parties to the Protocol, is contained in annex II.

4. A summary of responses for each question is provided in information document (UNEP/CBD/BS/COP-MOP/3/INF/8). The complete text of the interim reports submitted to the Secretariat can be accessed through the Biosafety Clearing-House at the following address: <http://bch.biodiv.org/protocolreports/>. Electronic facilities intended to assist users to aggregate and analyse data according to selected Parties, geographic area, economic groups and other criteria are also available on the website.

II. METHODOLOGY OF THE ANALYSIS OF INFORMATION

A. Regional breakdown

5. Of 126 Parties as at 11 October 2005, 44 submitted national reports for inclusion in this analysis. This total includes four reports from Asia and the Pacific, seven reports from Africa, twelve reports from the Central and Eastern European, five reports from Latin America and the Caribbean and sixteen reports from Western Europe and Other States Group. Of the 44 reports, 15 were submitted by developing country Parties, including four reports from the least developed Parties and two reports from small island developing Parties.

B. Presentation of information

6. It is intended that this analysis be used to facilitate the related discussions on substantive items at the third meeting of the Parties to the Protocol. Information is therefore presented according to relevant articles of the Protocol. The analysis aims to identify the progress in, and constraints to, the implementation of the Protocol at the national level. Where relevant, implications of the data provided in the interim reports are discussed in more depth in the pre-session papers for the relevant agenda items.

7. Due to the limited number of submissions received from several regions, analysis of the results from a regional perspective is generally not provided since the results from a small sample may not necessarily be predictive of the whole region. Instead, where appropriate, the analysis addresses economic groupings (i.e. developing country Parties, countries with economies in transition and developed country Parties) where differences among the Parties can be identified from that perspective.

8. In many cases, representative comments from as broad a regional base as possible have been excerpted from the reports and provided in the analysis as illustrative examples. 1/ It should be noted that such comments are included only to provide a context for the conclusions drawn in the analysis and should not be interpreted outside the framework of the complete report as submitted by the Party. The full range of comments for each report can be accessed through the website as indicated in paragraph 4 above.

1/ Excerpts are marked by country name and provided in italics. Courtesy translations have been provided where appropriate in the text. The original language of submission is noted beside the country name as follows: [AR] Arabic; [EN] English; [ES] Spanish; [FR] French; [RU] Russian.

C. Limitations

9. The results presented in this paper should be interpreted within the limitations of the analysis. From a statistical point of view, it should be stressed that the analysis and some conclusions drawn here are based on interim reports submitted, which represent only 35 per cent of the current number of Parties to the Protocol, and that for certain regional or economic groupings this percentage is much lower.

10. It is also important to note that reporting countries were self-selecting (i.e. results were analysed only from those Parties that submitted reports). Therefore, results may be biased towards countries that are better able to submit the reports for any reason, such as stronger monitoring and reporting capacities, or language accessibility. Additionally, the reports vary in the amount of information provided, and some reports provided little additional information to explain their answers to each question. Responses also vary regarding duration of the period of reporting, with some providing information only on activities undertaken since entry into force of the Protocol, and others on relevant activities undertaken prior to this date.

11. A close examination of the received submissions also highlights some weaknesses in the interim reporting format that appear to have lead to ambiguous responses (for example, in some cases Parties provided two contradictory responses to the same question) as discussed further in section V below.

III. INFORMATION IN THE INTERIM NATIONAL REPORTS

A. Provision of information to the Biosafety Clearing-House

12. Several articles of the Protocol require that information be provided to the Biosafety Clearing-House. In question 1 of the interim report, Parties were requested to describe any obstacles or impediments encountered regarding provision of such information, in cases where relevant information exists but has not been provided to the Biosafety Clearing-House. In addition, question 31 requested any further details regarding experiences and progress in implementing Article 20 of the Protocol (Information-sharing and Biosafety Clearing-House).

13. In general, most countries reported that they have made at least a core subset of information available to the Biosafety Clearing-House (usually national focal points and competent national authorities). However, in many developing country Parties, it was reported that information relating to national legislation and decisions has not yet been made available because the countries are still in the process of developing their national biosafety frameworks and such information is not yet officially approved for their country. Some illustrative excerpts from the reports are provided in the following paragraphs below.

14. ***Ethiopia*** *[EN]: The draft National Biosafety Framework is still in the draft form and so far no official regulatory measure on activities related to GMOs has been submitted. Thus, there is no official information that has been provided to the BCH.*

15. Only one Party (Switzerland) reported having in place a fully interoperable national clearing-house.

16. ***Switzerland*** *[FR]: All the information which the Cartagena Protocol requests be provided to the Biosafety Clearing-House is presently available on the website of the Swiss Biosafety Clearing-House […] Moreover, the Swiss Clearing-House is entirely interoperable with the website of the international Clearing-House […] In this way, data presented on the CH-BCH website can be transferred automatically to the international Clearing-House.*

17. Several Parties reported that information is being made available at a national level, but that although the information may be available on a national website that has been registered with the Biosafety Clearing-House, the detailed information is not being provided directly to the Central Portal.

18. ***Belgium*** *[EN]: Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes (article 20.3(c)) have not been submitted as such to the BCH but relevant information is available from the BBCH [Belgian Biosafety Clearing-House] in searchable databases providing data about all deliberate releases of LMOs into the environment in Belgium for research and development or for any other purposes than placing on the market.*

19. Cameroon noted that although its national database has been developed, it has not yet linked to the Biosafety Clearing-House Central Portal due to lack of sustainable funding for technical equipment to maintain its database and website.

20. Several Parties noted that they were currently in the process of developing national databases and expect to make these interoperable with the Central Portal of the Biosafety Clearing-House in future.

21. ***Belize*** *[EN]: […] The committee through the Biosafety Focal point and the national Project Coordinator is in the process of developing an official website with pertinent data to be placed and linked to the BCH.*

22. Many submissions noted that the absence of information that was available in an official United Nation language posed an impediment to posting information in the Biosafety Clearing-House.

23. ***Indonesia*** *[EN]: […] Most of these documents are posted in the national BCH in Indonesian. To facilitate data exchange with other CNAs requires their translation from the Indonesian into English as one of the UN languages besides establishing an exchange mechanism.*

24. ***Romania*** *[EN]: The following relevant information which exists at the date and has not been provided yet to the BCH […] is due to the lack of English version of the studies. The studies have been published on the MEWM's [web]site.*

25. ***Sweden*** *[EN]: Sweden has not provided complete information about Swedish laws and regulations, since most have not been translated from Swedish. But all relevant laws are described in both Swedish and English at the website: www.gmo.nu.*

26. Member States of the European Union noted their regional collaboration in providing information through the European Community.

27. South Africa noted that information is lacking in the Biosafety Clearing-House for those risk assessments and decisions that were taken before the Protocol entered into force.

28. Other obstacles and impediments noted included the flow of new information between multiple Competent National Authorities (Indonesia); time constraints faced by national Biosafety Clearing-House focal points (Austria and Cambodia); fast turnover of staff in charge of uploading and validating information (Mexico); delays in approving the organization with appropriate responsibilities (Iran); difficulties in aligning the layout of the central portal of the Biosafety Clearing-House with the appropriate competent national authorities (Mexico); lack of financial resources within the structure of relevant ministries (Ukraine); difficulties in providing information to both national biosafety databases and the Central Portal of the Biosafety Clearing-House (Austria); problems experienced in functionality with non-English language versions of the Biosafety Clearing-House (Mexico); and delays in gathering relevant information (Albania).

29. Under question 56, on other issues related to national implementation of the Protocol, Japan proposed that, in order to enable the Parties to share information on LMOs likely to be distributed internationally, Parties make available to the Biosafety Clearing-House as much information as possible on the following matters on a voluntary basis: Information on LMOs that are at a field experiment stage (limited field testing and large-scale field testing); information on the recipient organism, introduced trait, conductor of the experiment, cultivation area and period of implementation, etc.

B. Article 2 – General provisions

30. Questions 2 and 3 of the interim report addressed whether Parties have introduced the necessary legal, administrative and other measures for implementation of the Protocol, including a description of experiences and progress in implementing Article 2.

31. Globally, 27 Parties (60 per cent) reported having a full domestic regulatory framework in place, 16 Parties that they had introduced some measures, and two Parties reported that they had not yet taken any measures to implement the Protocol. However, if the results are examined along economic groupings, only three developing country Parties (less than 20 per cent of respondents in this group) have a full framework in place, with the majority of these countries having introduced only some measures (11 Parties, or 68 per cent).

32. Under question 3, some Parties noted that their systems were largely in place, but some elements are still outstanding. For example, South Africa reported that although it has implemented its GMO Act, as yet it has no long-term structure for monitoring LMOs in place.

33. ***South Africa*** *[EN]: […] The GMO Act, regulations, guidelines and operating procedures to a large extent, already encompasses many of the provisions of the Protocol. The remaining provisions will be incorporated into the Act during a legislative review of the Act, which is currently being conducted. While South Africa has implemented the GMO Act, as yet South Africa does not have an operational structure for long term monitoring of GMO's. This is being addressed in the National Environmental Management Biodiversity Act 10 of 2004 under the Department of Environmental Affairs and Tourism.*

34. As noted in responses to question 1, many developing countries and some countries with economies in transition reported that they are making progress towards the introduction of legal and administrative measures to implement the Protocol, but noted that there was still a need to build capacities to implement many of the provisions.

35. ***Bulgaria*** *[EN]: The delays observed in taking some measures necessary for the effective implementation of the Protocol are mainly due to the lack of administrative and financial capacity. In order to overcome these obstacles the Bulgarian Government started an enlargement of its administrative capacity in the subsequent areas.*

C. Articles 7 to 10 and 12: The advance informed agreement procedure

36. Questions 4 to 8 of the interim report address the implementation of the advance informed agreement procedure, including experiences of Parties of export, and decisions taken on import of LMOs intended for release into the environment.

37. It should be noted that results for this section are complex to analyse, since it appears that Parties may have interpreted the available responses differently, according to their national situation. There are some inconsistencies in the numbers of respondents that report negatively (i.e. that a certain requirement is not in place, or procedure has not been followed) versus “not applicable” (i.e. the respondent was not a

Party of import or export during the reporting period). It is likely that this reflects the large number of countries that are still in the process of developing their national biosafety frameworks.

38. ***Mexico*** *[ES]: Even though the Biosafety Law has gone into effect, and the text of that Law stipulates a licensing system for transboundary movements of GMOs, the work of establishing regulations for the Law has not been completed, and it has not yet been harmonized with the legal framework in effect in other areas, such as foreign trade. Therefore, although a decision on future procedures does exist, the procedures are not applicable right now, since they must be integrated into national legislation in order to be mandatory.*

39. Under question 4, 31 countries (70 per cent) reported having in place a legal requirement for the accuracy of information provided by exporters under the jurisdiction of the Party. The remaining 30 per cent of countries responded that it was not applicable since they were not Parties of export.

40. Under question 5, one Party (Cambodia) reported making a request to review a decision it had made under Article 10 on the grounds specified in Article 12.2 and three Parties reported not making such a request. Under question 6, eight Parties reported taking a decision regarding import under domestic regulatory frameworks in accordance with Article 9.2 (c).

41. Under question 7, Parties were requested to provide additional details regarding their experience in implementing the exporting provisions of the AIA procedure. South Africa noted that although it had exported LMOs intended for environmental release, this was only for LMOs that had already been granted commercial release status in the Party of import, hence the AIA procedure was not required before consenting to the importation.

42. Belgium considered that some wording in Annex I of the Protocol regarding provision of a risk assessment was confusing:

43. ***Belgium*** *[EN]: […] For example, in the notification addressed to the potentially importing country, the exporter should furnish "a previous and existing risk assessment report consistent with annex III" . Is it to be understood that there is no absolute requirement to furnish a risk assessment in the notification?*

44. Under question 8, Parties provided details of their experiences in taking decisions of import under the AIA procedure. In many cases, Parties reported that no decisions on import had been taken. However, lack of capacity to monitor the occurrence of such imports in Parties where the biosafety regulatory framework was still under development was raised as an issue.

45. ***Cambodia*** *[EN]: […] if such import occurred, there is neither law to regulate this nor capacity to conduct full scale of risk assessment in the country.*

46. Indonesia noted that LMO imports were made during the reporting period for LMOs where the risk assessments had been carried out before entry into force of the Protocol, therefore they were not presented in the appropriate format for reporting through the Biosafety Clearing-House.

D. Article 11 – Procedure for living modified organisms intended for direct use as food or feed, or for processing

47. Questions 9 to 13 of the interim report addressed decisions taken on import of LMOs intended for direct use as food or feed, or for processing, and the experiences of Parties of export and Parties of import in implementing the relevant provisions.

48. In answer to question 9, 36 Parties report having in place a legal requirement for accuracy of information provided by the applicant with respect to the domestic use of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing, representing 100 per cent of developed country Parties, 80 per cent of countries with economies in transition, and 60 per cent of developing country Parties.

49. Of the 24 developing country Parties and Parties with economies in transition that responded to question 10, less than half have indicated their needs for financial and technical assistance and capacity-building to address issues relevant to living modified organisms intended for direct use as food or feed, or for processing. For question 11, although most Parties had not taken a decision during the reporting period, 11 Parties reported taking a decision under their domestic regulatory frameworks as allowed by Article 11.4.

50. Question 12 requested Parties of export for LMO-FFPs to describe their experiences. Although it is not clear if all responses were submitted by Parties that are currently exporting LMOs, many responses again acknowledged that until the existing legislation is approved in their jurisdiction, reporting on such experiences will be difficult.

51. ***Mexico*** *[ES]: […] However, the authorization system will not be mandatory until the regulations have been established and the Law has been harmonized with the national legal framework for international trade.*

52. Algeria reported on the need to strengthen its control capacities, noting that capacity-building is planned for control techniques and standardizations, and that it considers it necessary to acquire analysis instruments (for example, an ELISA (enzyme-linked immunosorbant assay) reader) for risk assessment and management.

53. Question 13 requested Parties of import of living modified organisms intended for direct use as food or feed, or for processing (LMO-FFPs) to describe their experiences. Again, many countries reported that they lacked experience in this regard. As a region, European Union member countries reported that in accordance with the European Union's legislation, all decisions concerning imports for placing on the market, including release into the environment, are made at the European Union's level.

54. South Africa noted difficulties in accessing all required information through the Biosafety Clearing-House. Mexico noted also difficulties in obtaining all the information requested from developers.

55. ***South Africa*** *[EN]: Obstacles experienced are being sure of what LMOs may be in the consignment based on the information available on the BCH. How can a country be absolutely sure that the Party of export has submitted all the required information to the BCH? Bearing this in mind, a Party of export is often required to formally indicate to Party of import what LMOs are commercially available in the country.*

56. ***Mexico*** *[ES]: Recently, developers have been reluctant to provide information on methods of analysis for the development of a monitoring and watch system.*

E. Article 13 – Simplified procedure

57. Question 14 of the interim reports asked Parties that have used the simplified procedure during the reporting period to describe their experiences. The majority of respondents noted in their answer to this question that they have not used the simplified procedure during the reporting period.

58. South Africa noted that the provisions of Article 13 are very useful to prevent unnecessary delays in trade. Indonesia noted that it experienced some obstacles in conducting a risk assessment for enzyme products derived from genetically modified micro-organisms since the available questionnaire for the proponent was not designed for this type of product.

F. Article 14 – Bilateral, regional and multilateral agreements and arrangements

59. Question 15 of the interim reports asked Parties that have entered into bilateral, regional and multilateral agreements and arrangements to describe their experiences.

60. A number of European Union member States reported that their general policies for management of LMOs is common to the European Union policy in this area. Mali reported that the Economic Community of West African States (ECOWAS) is currently in the progress of developing a common approach toward the promotion of biotechnology, biosafety and public awareness raising. Romania reported that it had entered into cooperation with Hungary on data transmission and information exchange.

61. Switzerland reported that it had made use of Article 14.4 (i.e. domestic regulations apply with respect to imports of LMOs), as previously notified through the Biosafety Clearing-House. Norway also reported that it had made use of Article 14.4 (in response to question 13).

G. Articles 15 and 16 – Risk assessment and risk management

62. Questions 16 to 23 of the interim report addressed the process of risk assessment and risk management, including appropriate mechanisms, measures and strategies put in place to regulate, manage and control risks identified in the risk assessment provisions of the Protocol, and cooperation with other Parties.

63. As noted in previous sections, the results for these questions reflect the limited number of reporting countries that have experience in importing living modified organisms for intentional introduction into the environment in accordance with Protocol provisions.

64. ***Egypt*** *[AR]: The instruments referred to have not yet been put into operation in view of the fact that the law has not been promulgated to date and the fact that no licensing applications have been submitted to the competent national authority.*

65. Among those who have imported living modified organisms for intentional introduction into the environment, risk assessments have been carried out in all but one case (Cambodia, who noted that this was because the law is not yet in place to regulate releases). In most of those cases the Party of Import required the exporter to carry out the risk assessment (75 per cent) and required the notifier to pay for the risk assessment, then followed this with an internal review process.

66. ***South Africa*** *[EN]: All applicants (notifiers) are required to conduct risk assessments at their own cost and submit this with any application for contained use, release into the environment or food, feed and processing. This information is reviewed through an extensive process before authorization is approved.*

67. Results for question 19 indicate that many reporting countries have established mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol in accordance with Article 16.1. However, it is important to note that most of the positive responses come from the developed countries, or countries with economies in transition. Only 50 per cent of reporting Parties from developing countries confirmed that they have such procedures in place.

68. As in previous questions, many developing countries indicated in the general comments provided under question 23 that they have draft national regulatory frameworks in place that are intended to provide for risk assessment and risk management measures but that these have not yet been approved and implemented. Others noted that much work was still to be done in this area.

69. ***Belize*** *[EN]: The Government of Belize has a temporary moratorium on any imports of LMOs/GMOs until the National Biosafety Framework is fully established.*

70. ***St. Kitts*** *[EN]: St. Kitts and Nevis have not yet completed its Biosafety Framework Project and as a result have not done any work on risk assessment in relation to Biosafety.*

71. Austria noted that it has objected to nearly all applications of marketing or cultivating genetically modified plants as the environmental and health risk assessments undertaken seem incomplete so far.

72. Results for question 20 indicate that the majority of reporting countries (32 Parties) have adopted measures to prevent unintentional transboundary movements of living modified organisms. However, once again the positive responses come mostly from the developed country Parties or the Parties with economies in transition, with less than 50 per cent of developing country Parties reporting that such measures are in place.

73. Similar proportions are repeated for question 21, in that developed country Parties and Parties with economies in transition indicate that they are endeavouring to ensure that any living modified organism undergoes an appropriate period of observation before it is put to its intended use, with less than half of the developing country Parties being in a position to do so. Several countries also reported on a variety of means that are put in place at a national level to fulfil this requirement.

74. ***Cuba*** *[ES]: Risk management measures are monitored through inspections carried out by the Regulating Body and the territorial biosafety specialists before, during and after the activity is carried out.*

75. ***Ukraine*** *[RU]: Work has started on creating a centre for tracing LMOs.*

76. Question 22 asked whether a country has cooperated with others for the purposes specified in Article 16.5, namely to identify living modified organisms or traits which may have adverse effects on biodiversity, and to take measures to address such living modified organisms or specific traits. Responses indicate that most developed country Parties and Parties with economies in transition have undertaken such cooperation, with only two developing country Parties reporting that they have cooperated in this manner.

77. Many European Union member States noted that they collaborated with other European Union member States for the purposes specified in Articles 16 and 17. The European Commission report also noted that the Commission has cooperated with members of the European Economic Area (Norway, Iceland and Liechtenstein) on the issue of antibiotic resistance markers in risk assessment.

78. Under the general observations provided on this issue through question 23, Indonesia noted that obstacles for implementation include funding for internally conducted assessments, timeframes and enabling public participation. Ukraine noted that work to meet the requirements of the Protocol was being held up by the absence of a special law on the biosafety of LMOs.

79. ***Indonesia*** *[EN]: It has not been decided yet which institution will be responsible for budgeting the mechanism.*

80. The Netherlands noted that although it has not yet had to perform LMO risk assessments under the requirements of the Protocol, it nevertheless has ample experience with the risk assessment procedures required, as these are very similar to risk assessments performed in other contexts.

81. Norway noted its opinion that a scientific committee should be appointed with the task of providing scientific and technical guidance on risk assessment guidelines, antibiotic resistance marker genes in LMOs, and other tasks that might be considered important for the fulfilment of the objectives of the Protocol, in order to ensure a common approach to these issues among Parties.

H. Article 17 – Unintentional transboundary movements and emergency measures

82. Questions 24 and 25 of the interim report asked Parties to report on any occurrences under their jurisdiction that led, or could have led, to an unintentional transboundary movement of a living modified organism that had, or could have had, significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States.

83. Only one Party (Cambodia) reported such an instance, and further details about its response are provided below.

84. ***Cambodia*** *[EN]: Seek for [risk assessment/risk management] expertise to control risks from LMOs; Cooperate to contain risks; Share information as much as possible to minimize [risks] to biodiversity and human health.*

85. Additionally, Mexico reported that it lacked the capacity to monitor LMO imports that potentially led to an unintentional release.

86. ***Mexico*** *[ES]: During the reporting period, Mexico lacked the capacity to monitor shipments of grain that might contain GMOs. An alarm was sounded to this effect when, apparently, seeds from a shipment containing LMOs were possibly planted in Oaxaca.*

I. Article 18 – Handling, transport, packaging and identification

87. Questions 26 to 30 of the interim report addressed measures taken relating to handling, transport, packaging and identification.

88. Responses to question 26 suggest that efforts to put in place measure to require that LMOs are handled, packaged and transported under conditions of safety are being made at a global level (30 countries, or 72 per cent of respondents report having taken such measures); however most of this is taking place in the developed world (the positive response falls to 40 per cent in developing countries, with only six developing country Parties having taken such measures). Similar percentages are reported for questions 27 to 29, regarding how many Parties have taken measures to require that documentation to accompany LMO-FFPs (Article 18.2 (a)), LMOs destined for contained use (Article 18.2 (b)), and LMOs for intentional introduction into the environment (Article 18.2 (c)).

89. In response to question 30 regarding a description of experiences in implementing Article 18, a number of Parties provided a detailed description of their national or regional processes. In several cases, Parties noted that their national provisions require LMO-FFPs to identify that they "contain" rather than "may contain" LMOs.

90. ***Cameroon*** *[EN]: provision in text of application of the law maintains "contain" instead of "may contain".*

91. ***Bulgaria*** *[EN]: […] The "may contain" language is not used.*

92. ***Switzerland*** *[FR]: Swiss legislation is very clear in terms of the accompanying documentation. For transboundary movement of GMOs, it requires the mention "contains GMOs" and not simply "may contain GMOs".*

93. Additionally, several Parties reported that nationally-determined "threshold" levels are in place which impact on documentation requirements.

94. ***Republic of Moldova*** *[RU]: It is obligatory that the words "This product contains genetically modified organisms" appear on both the label and the accompanying documents. Information concerning the presence of genetically modified organisms must take up no less than ten per cent of the surface of the label and/or the accompanying documents. Products that contain genetically modified organisms and/or the products derived thereform which total no less than one per cent of the total weight are recognized as being genetically modified products. For seeds, the percentage is 0.3 per cent of the total weight.*

95. Mexico noted that lack of capacity has hampered the development of experience in this area. It also noted that some of the obstacles to implementing Article 18 arise from the lack of consensus at a national level.

96. Mexico also reported on an agreement reached for the North American region (Mexico, Canada and the United States of America) on the documentation that must accompany living modified organisms for direct use as food or feed, or for processing, which it entered into to clarify the requirements of the documentation required under Article 18.2 (a) of the Protocol itself, without interrupting the grain trade between these three countries unnecessarily. As a Party to the Protocol, Mexico noted that it negotiated the agreement in accordance with Articles 14 and 24 thereof.

97. ***Mexico*** *[ES]: […] By virtue of this agreement, and in compliance with the stipulations of Article 18.2 (a) of the Protocol, all grain exports from the United States of America or Canada to Mexico must carry the label "may contain" LMOs, except in the following cases: when the shipment is at least 95% free of LMOs, or when importing species for which the exporting country has not yet authorized the marketing of LMOs.*

98. *This agreement seeks to ensure the transparency and flow of transboundary trade in LMOs in the region, in addition to giving Mexico access to the other two countries' scientific information on agricultural biotechnology. At the second meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol, held last May-June in Montreal, Mexico promised to present the initial results of this agreement at the second meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol of the Protocol in March 2006.*

99. The European Community provided a comprehensive summary of its legal framework with regard to issues of handling, transport, packaging and identification requirements covered by Article 18 on behalf of the European Union member states. It noted that with regard to the specific requirements contained in EC legislation, the EC considers it appropriate to impose similar requirements on operators exporting GMOs from the EC and on those using GMOs within the EC.

100. ***European Community**** *[EN]: In relation to Article 18(2)(a) […] exporters are required to state in a document accompanying the GMO, which is to be transmitted to the importer receiving the*

* draft report

GMO: that it contains or consists of GMOs; and the unique identification code(s) assigned to those GMOs if such codes exist.

101. *Article 12 further stipulates that for GMOs intended for direct use as food or feed, or for processing, the above information must be supplemented by a declaration by the exporter: stating that the GMOs are intended for direct use as food or feed, or for processing and indicating clearly that they are not intended for deliberate release into the environment; and giving details of the contact point for further information. In the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed, or for processing, the above identification requirements may be replaced by a list of unique identifiers used to constitute the mixture.*

102. *[…] GM food and feed has to be labelled as GM, except if they contain GM material in a proportion no higher than 0.9% and if this presence is adventitious or technically unavoidable.*

103. The European Community also reported on regulations concerning the traceability and labelling of LMOs and the traceability of food and feed products produced from LMOs, which require business operators to transmit and retain information about products that contain or are produced from LMOs at each stage of the placing on the market. In particular, operators are required to have systems and standardized procedures in place to identify to whom and from whom products are made available; and in the case of products consisting of or containing mixtures of LMOs to be used only and directly as food or feed or for processing, written information on the unique identifier(s) assigned to the LMOs of which the product consists or which are contained in it, may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all those LMOs that have been used to constitute the mixture.

104. In addition, the European Community reported on the system is has established for development and assignment of unique identifiers for genetically modified organisms, which adopts the format developed by the OECD for Unique Identifiers for Transgenic Plants, and extends its use to unique identifiers for genetically modified micro-organisms and animals, pending the development and adoption of any other specific format at an international level.

105. Switzerland reported on some difficulties experienced with exports and imports of LMOs destined for contained use.

106. ***Switzerland*** *[FR]: In order to inform the concerned Parties on the procedures to follow when importing or exporting GMOs, an explanatory notice was prepared in the form of a newsletter in December 2004. However, the requirements regarding the accompanying documentation were confusing, in particular concerning the import and export of GMOs destined for contained use. Moreover, these requirements also vary depending on the transporter. Consequently, during the COP-MOP2, Switzerland asked the Secretariat to take the initiative of collaborating with the other competent organizations toward harmonizing practices in regard to transport and packaging. That proposition was taken up with decision BS-II/6 "Cooperation with other Organizations, Conventions and Initiatives".*

J. Article 19 – Competent national authorities and national focal points

107. Comments relevant to competent national authorities and national focal points are included in section A above.

K. Article 20 – Information-sharing and the Biosafety Clearing-House

108. Question 31 addressed experiences and progress in implementing Article 20 of the Protocol. Relevant comments are provided in section A above.

L. Article 21 – Confidential information

109. Questions 32 to 34 of the interim report addressed protection of confidential information received under the Protocol. In response to question 32, six Parties reported that they do not yet have adequate procedures in place to protect confidential information received under the Protocol, with the majority of these in the developing world (five countries). As in previous sections, this result is reflective of a number of countries that have yet to adopt their biosafety legislation.

110. ***Togo*** *[FR]: The draft bills and decrees concerning biosafety establish procedures for protecting confidential information received. However, these provisions have not yet been adopted.*

111. In response to question 33, five Parties noted that they had permitted a notifier to identify information submitted as part of the AIA procedure as confidential and two did not. No specific implementation difficulties or impediments were reported.

112. In question 34, a number of Parties noted that broad legal provisions are in place to protect confidential information. No specific impediments were reported.

113. ***Indonesia*** *[EN]: In the Joint Decree of Four Ministers which was used prior to the issue of government regulation 21, there are clauses on the protection of confidential information on commercial information, intellectual property right and others not related to biosafety.*

M. Article 22 – Capacity-building

114. Questions 36 to 41 of the interim report addressed building capacities in biosafety for the purpose of effective implementation of the Protocol. Under question 36, 18 Parties responded that they had cooperated in the development and/or strengthening of human resources and institutional capacities in biosafety. This includes most developed country Parties as well as a number of countries with economies in transition and developing countries.

115. ***South Africa*** *[EN]: […] South Africa has hosted [experts] from Lesotho, Angola, Zambia, France and the United States Grains Council during this reporting period.*

116. ***Mexico*** *[ES]: Mexico has cooperated by training personnel from developing countries. The training in LMO risk assessment was provided to members of the Biosafety Committee of Nicaragua, Paraguay and Guatemala. There has been cooperation, in biosafety workshops, with technical personnel from the ministries of the Environment and Agriculture of Nicaragua, Paraguay and Peru. Furthermore, Mexican biosafety experts participated in the review of legal documents arising from changes in the country's legal framework, as in the case of Nicaragua.*

117. Many developing country Parties made specific reference to receipt of support from the Global Environment Facility for development of national biosafety frameworks. Several Parties from the Central and Eastern Europe region also reported on participation in European Union twinning projects (under the EU's Phare programme to prepare countries for European Union accession).

118. Other regional activities reported on included: a capacity-building project on biosafety in the Asian region through contributions to the trust fund of the United Nations Food and Agriculture Organization (Japan); training for a number of African countries in capacity-building for the Biosafety Clearing-House (Belgium); Capacity-building for biosafety and ecological impact assessment of transgenic plants in East Africa (Denmark); training courses on detection techniques for GMOs in foods (EC in collaboration with the World Health Organization; the European Network of Genetically Modified Organisms Laboratories (European Community); a Capacity-Building Initiative for the

implementation of the Cartagena Protocol on Biosafety with project elements implemented in China, Algeria, African Union, and Peru (Germany); a biosafety project involving South Asian Countries (IUCN Regional Biodiversity Programme Asia); Latin American Workshop on Biosafety Capacity-building (Spain); BIO-EARN – East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (Sweden); and Baltic Biosafety (Sweden).

119. Many Parties also reported on bilateral partnerships that were entered into to build capacity at national levels.

120. Several developed country Parties also reported on financial support they provided through the trust funds of the Convention on Biological Diversity to host meetings and provide support for developing country participation and non-government organization (NGO) participation in biosafety meetings, as well as on financial contributions made to the GEF. Switzerland reported on an offer for free hosting of biosafety-websites made through the UNEP-GEF project.

121. In answer to questions 38 to 40, one Party responded that its capacity-building needs were fully met through cooperation for technical and scientific training (Slovakia), many that their needs were partially met (14 countries), and three Parties that they had no unmet needs in this area.

122. Most developing countries reported that their capacity-building needs were partially met through participation in the UNEP-GEF national biosafety framework (NBF) project, although a number of needs remain outstanding and will need to be addressed during implementation. Egypt noted that it experienced several delays in setting up the UNEP-GEF project and eventually drafted its law through national efforts without assistance from the project.

123. Belize noted that funds remain limited for getting the necessary expertise for training. Indonesia commented on difficulties in ensuring that all necessary personnel are recipients of international training.

124. A number of Parties noted specific capacity needs in the area of risk assessment and risk management, and improved technological and institutional capacities.

125. ***The Islamic republic of Iran*** *[EN]: Iran has benefited from the first phase of UNEP-GEF capacity-building programme on the development of NBF. However, this project is far from the fulfillment of the requirements for the capacity building needs of our country. In particular Iran has not benefited from technical and scientific assistances in the proper and safe management of biotechnology and the use of risk assessment and risk management for biosafety and for the enhancement of technological and institutional capacities in biosafety.*

126. ***Bulgaria*** *[EN]: Although the Bulgarian GMO Act is in force which is of a great importance as a starting point for further developments, still several modifications have to be done. Some of the provisions of the Act are inconsistent with the Cartagena Protocol's case-by-case approach, EU directives and other relevant international agreements. More technical and scientific training for enhancement of technological and institutional capacities in biosafety still needed.*

127. Mexico noted difficulties in the lack of Government personnel trained for and dedicated to fulfilling international commitments. Particular difficulties were experienced in accessing information and training that was adapted to national needs.

N. Article 23 – Public awareness and participation

128. Questions 42 to 47 of the interim report addressed measures taken to address public awareness and participation. Globally, the majority of Parties are able to promote and facilitate public awareness,

education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health, either to a significant extent (50 per cent) or a more limited extent (50 per cent). However, of developing country Parties, only two reported undertaking such measure at significant levels.

129. Responses to question 43 reveal that seven Parties are undertaking significant collaboration in the area of public awareness and participation, although none of these are developing countries. According to question 44, four Parties are not able to ensure that public awareness and education encompass access to information on living modified organisms that may be imported and seven are not yet consulting the public in their decision-making process. Again, these results reflect a number of countries that have not yet implemented their biosafety frameworks.

130. Responses to question 46 indicate that only nine Parties have fully informed their public about means of public access to the Biosafety Clearing-House. Forty per cent (6 Parties) of the developing country Parties that responded to this question indicated that they have not yet informed their public even to a limited extent.

131. At a regional level, a number of European Union member States referred to participation in the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters.

132. South Africa commented that there were several non-government initiatives in place that were aimed at communicating biotechnology-related issues to the public. These included stakeholder organizations as well as non-governmental organizations and institutions of higher learning.

133. Indonesia noted that Internet access, although an effective means of communication, is not yet widely available.

O. Article 24 – Non-Parties

134. Question 48 related to experiences gained during transboundary movements with non-Parties.

135. Difficulties encountered in transboundary movement with non-Parties generally related to problems with gaining adequate access to information from non-Parties.

136. ***South Africa*** *[EN]: Yes. As an exporter to non-parties during this reporting period, we experienced that the non-parties prefer not to follow the provisions of the Protocol and are very reluctant to adhere to national requirements that are beyond the requirements provided for by the Protocol.*

137. ***Mexico*** *[ES]: Non-parties are reluctant to provide information on cases of transformation cultivated in those countries, to identify cases that may be contained in shipments, and to describe their approximate composition.*

138. Japan reported on measures it took to avoid a potential unapproved transboundary movement from a non-Party.

139. ***Japan*** *[EN]: Japan imports genetically engineered crops and LMOs intended for contained use from Non-Parties. A person who wishes to use LMOs in the environment in Japan (including the distribution of living seeds as food or as feed) must obtain approval under the domestic law for the Protocol. Therefore, any LMO that has not been approved in Japan can not be used in the environment*

even if it is imported from a Non-Party. Having obtained the information that some genetically engineered corns (Bt 10) which were inadvertently cultivated in the United States, a non-Party, were likely to have been exported to Japan, Japanese competent authorities checked the corns being imported into Japan from the US at borders, based on the relevant laws and regulations, and confirmed that Bt 10 were detected from some cargos. Accordingly, measures have been taken to prevent their distribution in Japan.

140. A few Parties reported on instance of imports of unauthorized LMOs from non-Parties.

141. ***Italy*** *[EN]: About the import of LMOs, in the past a non-authorized presence of LMOs has been discovered in non-LMO seeds from non Parties. After a large effort for sampling and analysis of non-LMOs seed lots of certain crops (maize and soybeans) the level of LMO contamination has been greatly reduced. Other cases of presence of non authorized LMOs have been more recently discovered in LMOs-FFP from a non Party. A specific protocol for sampling and analysis is now in place in the European Union.*

142. Spain commented on difficulties and expense involved in monitoring for LMO presence in excess of approved thresholds.

143. ***Spain*** *[EN/ES]: […] Controls are carried out at border inspection facilities, which fall within the competence of Spain's regions and difficulties still persist as regards the interpretation and application of regulations concerning traceability and labelling depending on whether the import is an LMO or a product obtained or derived from an LMO. Samples are taken of animal feed at borders and quantitative and qualitative tests are used to check for the possible adventitious or accidental LMO presence in excess of 0.9% and 0.5% (the thresholds established by European legislation). However, the tests are quite expensive and there are still very few approved laboratories and at times these do not have available validated methods for all LMOs that might be used in feed, whether or not authorized by the European Union.*

144. Several Parties reported little or no difficulties in transboundary movements with non-Parties.

145. ***Romania*** *[EN]: No difficulties encountered.*

146. ***United Kingdom*** *[EN]: There has been a large volume of imports of LMOs from non-parties into the United Kingdom during the reporting period. These have all been in compliance with the authorization procedure introduced in the European Union to implement the protocol. Earlier this year there was one incidence of the suspected import of an unauthorized LMO into the European Union (Bt10 maize). However this was not an LMO in the sense that it was already processed rather than still living; in addition we have no specific evidence that any Bt 10 has actually entered the United Kingdom. Contingency measures were introduced throughout the European Union with the intention of preventing any import of this product.*

P. Article 25 – Illegal transboundary movements

147. Question 49 addresses domestic measures adopted to prevent and penalize, as appropriate, transboundary movements of living modified organisms carried out in contravention of its domestic measures. Globally, the majority of Parties (80 per cent) have such measures in place, although again many developing country Parties await adoption of the domestic regulatory frameworks.

148. Under question 50, Egypt noted difficulties experienced in monitoring LMOs in transit.

149. ***Egypt*** *[AR]: In view of the particular geographic situation of the Arab Republic of Egypt, it is likely that genetically engineered products will be transported through the Suez Canal without informing the competent national authority. However, no cases of unlawful transboundary movement of such products have come to the knowledge of the competent national authority.*

Q. Article 26 – Socio-economic considerations

150. Questions 51 to 53 refer to experiences on taking into account socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities, when taking a decision on import.

151. For question 51, the majority of respondents indicated that they were not Parties of Import during the reporting period; however three Parties reported taking socio-economic considerations into account to a significant extent, six to a limited extent, and eight did not take them into account. For question 52, nine Parties reported cooperating with other Parties on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities to a limited extent, with the remainder (33 countries) reporting that they did not undertaking such cooperation.

152. ***South Africa*** *[EN]: Although socio-economic factors are taken into consideration when taking decisions in South Africa, there is a need for an international framework with regard to the socio-economic factors that should be taken into account during decision-making.*

153. Belgium reported on a research project on socio-economical impacts of GMOs and Norway reported on a discussion paper on sustainability, benefit to the society and ethics in the assessment of genetically modified organisms developed by the Norwegian Biotechnology Advisory Board.

154. The European Commission reported on socio-economic considerations that have been relevant at member State level for the question of co-existence. Finland noted that in risk assessment carried out prior to decisions on import of LMOs, no account is taken of socio-economic considerations. However, these aspects may be considered in such a risk analysis process where issues of coexistence between GM and non-GM agricultural planting are concerned.

R. Article 28 – Financial mechanism and resources

155. Questions 54 and 55 of the interim report pertain to the operation of the financial mechanism and availability of financial resources. Eleven Parties reported making financial resources available to other Parties and twenty Parties reporting having received financial resources.

156. Many Parties referred to provision of funds to, or receipt of technical and financial support from, the GEF for development of national NBFs, as well as support for attending Protocol meetings. Specific capacity-building activities are discussed further in section M above.

S. Other information

157. Comments received under question 56 of the reporting format regarding other information have been incorporated in the relevant thematic section of the analysis.

T. Reporting format

158. In general, respondents reported no difficulties in completing the reporting format.

159. ***Peru*** *[EN]: No problem. The format fulfils to minimize the reporting burden on Parties, while eliciting the important information regarding implementation of the provisions of the Protocol.*

160. However, during the analysis it did become clear that certain questions were open to different interpretation according to the national situation, particularly for those Parties that were still in the process of developing their national biosafety frameworks. In other cases, it was not always clear whether the Parties were responding on obstacles encountered as Parties of import, or Parties of export. To reflect this adequately in the national reporting format, some questions may need to be revised to include information on the development process of the National Biosafety Frameworks, or to provide responses that more accurately reflect the implementation realities.

161. ***Mali*** *[FR]: The difficulty resides in the fact that in most cases the frameworks are in-progress. There has not yet been a practical context of implementation and this makes it difficult to respond to certain questions. To adapt that situation to the report format, some questions should have been posed on the development process of the National Biosafety Frameworks, especially in the case of developing countries, which are mainly affected by this.*

162. ***Sweden*** *[EN]: For a European Union member-state, it can often be difficult to answer the questions, because the European Union legislation and the Protocol deal with the issues in different ways. The EU has rules for handling GMOs within its borders, and rules for relationships with third parties. Movements of GMOs across national borders within the EU are not considered to comprise imports or exports, due to the workings of the internal market. […] Upon re-reading our answers, what clearly emerge are the differences between the rules for contained use of GMOs and those for deliberate release. Several questions seem to call for answers of both "Yes" and "No". This probably complicates the work of the Secretariat of the Protocol when compiling the national reports.*

U. Process by which interim national reports were prepared

163. Several Parties provided summary information on the process by which their interim national reports were prepared. Material that was used as a basis for the interim report was generally national legislation and expertise in relevant ministries. Several countries reported that the report was based on documents generated through participation in the UNEP-GEF project on the development of national biosafety frameworks.

164. Information provided on the types of stakeholders who were actively involved in its preparation ranged from reports that were prepared largely by the relevant competent national authorities, to reports that were prepared through consultation with a wide range of government departments, ministerial committees, advisory bodies, scientific institutions and other stakeholders, including an opportunity for public comment.

IV. SUBMISSION PROCESS FOR THE FIRST REGULAR NATIONAL REPORT

165. Decision BS-I/9 states that reports are to be submitted with a general frequency of four years, and also 12 months prior to the meeting at which they will be considered. In accordance with decision BS-I/12, the first regular national reports are to be considered at the fourth meeting of the Parties to the Protocol.

166. In accordance with Article 35 of the Protocol, the Conference of the Parties serving as the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol will undertake an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes, five years after the entry into force of the Protocol. Given the

importance of having the first regular national reports available for that review, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol may wish to ensure that the first national reports are submitted 12 months prior to the meeting at which this review will take place (i.e. at its fourth meeting).

167. Although the respondents reported no difficulties in completing the interim report, no information is available on the obstacles that prevented those Parties that did not submit from completing the interim report. Funding may be necessary to assist developing country Parties to consult with relevant stakeholders to obtain the information necessary for preparation of their national reports, or to present the available information appropriately in the required reporting format.

168. On a technical note, interim reports were received in five of the six official United Nations languages (English, French, Spanish, Russian and Arabic). For the purposes of this analysis, it was necessary to undertake formal translation of several of the reports, and the budgetary implications of this should be taken into account when preparing for analysis of the first regular national reports.

169. A draft format for the first regular national report is provided in annex II below. Only minor modifications have been made to update the interim national reporting format, and are outlined here using the reference numbers of the interim reporting format for comparison purposes. These include updating the guidelines for use; addition of a question in the section on the origin of the report that provides details on the time period covered by the report; revision of question 1 on the Biosafety Clearing-House to allow Parties to reflect the current state of reporting for each category of information; introduction of two questions under the advance informed agreement procedure to determine which Parties are Parties of import and export; revision of question 14 to determine which Parties have applied the simplified reporting procedure; revision of question 15 to determine which Parties have entered into any bilateral, regional or multilateral agreements or arrangements; revision of question 36 to enable reporting on provision of capacity-building partnerships between developing countries; revision of question 48 to determine if there have been transboundary movements with non-Parties; revision of question 49 to determine if there have been any illegal transboundary movements during the reporting period; and revision of several response options to better reflect the situation of those Parties that are still in the process of developing their national biosafety frameworks.

V. PRELIMINARY CONCLUSIONS

170. Where relevant, the analysis of information that has been provided through the interim reports is considered in more detail in the appropriate pre-sessional documentation for the third meeting of the Parties. However, it is possible to make a few preliminary general conclusions as follows:

(a) The information provided through use of the interim reporting format is very valuable to provide an overview of the state of implementation of the Protocol;

(b) Assessment of the practical elements of implementation of some of the operational provisions of the Protocol is difficult in many cases, since no concrete experience is available on how the frameworks will be operationalized; for example, no countries have reported on decisions taken under the advance informed agreement procedure for importing living modified organisms for intentional introduction into the environment;

(c) Mechanisms and measures to implement the Protocol provisions are largely operational and are being implemented in developed country Parties and Parties with economies in transition; however, in many developing country Parties, national frameworks for biosafety are still at a draft stage, and therefore not yet implemented;

(d) Although in many cases there is a lot of information available at a national level, not all of this is being reported through the Biosafety Clearing-House. Particular obstacles include making information available in an official language of the United Nations, and in finding ways to make national websites and databases interoperable with the Central Portal in order to reduce duplication of work;

(e) There is still a need to address outstanding capacity-building needs, particularly in the areas of risk assessment and risk management, technical and institutional capacities, building and maintaining human expertise, and adapting global experiences to national needs, as part of the ongoing development and implementation of national biosafety frameworks;

(f) There are a number of capacity-building initiatives in place, and the donor institutions are working together to implement many of these. There are also several capacity-building activities that are being taken through partnerships between developing countries to share experience and expertise.

VI. ELEMENTS OF A DRAFT DECISION ON REPORTING AND MONITORING UNDER THE PROTOCOL

171. On the basis of the analysis of the interim reports, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to:

(a) *Take note* of the interim national reports submitted by Parties, and of the analysis thereof prepared by the Secretariat (UNEP/CBD/BS/COP-MOP/3/12);

(b) *Adopt* the national reporting format annexed to this decision;

(c) *Request* Parties to submit their first regular national report, covering the period between entry into force of the Protocol for each Party and the reporting date, no less than 12 months prior to its fourth meeting, to allow consideration of the reports at that meeting; and

(d) *Invite* the GEF to make available financial resources for the preparation of national reports.

Annex I

COUNTRIES THAT SUBMITTED AN INTERIM NATIONAL REPORT BY 11 OCTOBER 2005

Albania
Algeria
Austria
Belize
Belgium
Bulgaria
Cambodia
Cameroon
Cuba
Denmark
Egypt
Estonia
Ethiopia
European Community (draft report)
Finland
France
Germany
Hungary
Indonesia
Ireland
Islamic Republic of Iran
Italy
Japan
Latvia
Lithuania
Mali
Mexico
Netherlands
Norway
Peru
Poland
Portugal
Republic of Moldova
Romania
St. Kitts and Nevis
Slovakia
Slovenia
South Africa
Spain
Sweden
Switzerland
Togo
Ukraine
United Kingdom of Great Britain and Northern Ireland

Annex II

DRAFT FORMAT FOR THE FIRST REGULAR NATIONAL REPORT ON THE IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY

GUIDELINES FOR USE OF THE REPORTING FORMAT

The following format for preparation of the the first regular national report on implementation of the Cartagena Protocol on Biosafety called for under Article 33 of the Protocol is a series of questions based on those elements of the Protocol that establish obligations for Contracting Parties. Responses to these questions will help Parties to review the extent to which they are successfully implementing the provisions of the Protocol and will assist the Conference of the Parties serving as the meeting of the Parties to the Protocol to assess the overall status of implementation of the Convention.

The deadline for submission of the first regular national report is no less than 12 months prior to the fourth meeting of Conference of the Parties serving as the meeting of the Parties to the Protocol. It is intended to cover activities undertaken between entry into force of the Protocol for the reporting Party and the date of reporting.

For subsequent national reports, the format is expected to evolve, as questions that are no longer relevant after the first national report may be deleted, questions that are relevant to ongoing progress in implementation will be retained, and additional questions will be formulated pursuant to future decisions of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

The wording of questions follows the wording of the relevant articles of the Protocol as closely as possible. The use of terms in the questions follows the meanings accorded to them under Article 3 of the Protocol.

The format tries to minimize the reporting burden on Parties, while eliciting the important information regarding implementation of the provisions of the Protocol. Many questions require only a tick in one or more boxes. 1/ Other questions seek a qualitative description of experiences and progress, including obstacles and impediments to the implementation of particular provisions. 2/ Although there is no set limit on length of text, in order to assist with the review and synthesis of the information in the reports, respondents are asked to ensure that answers are as relevant and as succinct as possible.

The information provided by Parties will not be used to rank performance or to otherwise compare implementation between individual Parties.

The Executive Secretary welcomes any comments on the adequacy of the questions, and difficulties in completing the questions, and any further recommendations on how these reporting guidelines could be improved. Space is provided for such comments at the end of the report**.**

It is recommended that Parties involve all relevant stakeholders in the preparation of the report, in order to ensure a participatory and transparent approach to its development and the accuracy of the information requested. A box is provided in which to identify those groups who have been involved.

Parties are requested to submit an original signed copy by post and an electronic copy on diskette or by electronic mail. An electronic version of this document will be sent to all national focal points and this will also be available from the Convention's website at: http://www.biodiv.org

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1/ If you feel that, in order to properly reflect the circumstances, it is necessary to tick more than one box, please do so. In this case, you are encouraged to provide further information in the text answers that follow to enable any analysis of results to appropriately reflect the spirit of your answers.

2/ Please feel free to append to the report further information on any of the questions.

Completed reports and any comments should be sent to:

The Executive Secretary
Secretariat of the Convention on Biological Diversity
World Trade Centre
413 St. Jacques Street West, suite 800
Montreal, Quebec
H2Y 1N9 Canada

Fax: (+1 514) 288 6588
e-mail: secretariat@biodiv.org

Origin of report

Party:	
Contact officer for report	
Name and title of contact officer:	
Mailing address:	
Telephone:	
Fax:	
E-mail:	
Submission	
Signature of officer responsible for submitting report:	
Date of submission:	
Time period covered by this report:	

Please provide summary information on the process by which this report has been prepared, including information on the types of stakeholders who have been actively involved in its preparation and on material which was used as a basis for the report:

Obligations for provision of information to the Biosafety Clearing-House

1. Several articles of the Protocol require that information be provided to the Biosafety Clearing-House (see the list below). For your Government, if there are cases where relevant information exists but has not been provided to the Biosafety Clearing-House (BCH), describe any obstacles or impediments encountered regarding provision of that information (note: To answer this question, please check the BCH to determine the current status of your country's information submissions relative to the list of required information below. If you do not have access to the BCH, contact the Secretariat for a summary):

2. Please provide an overview of information that is required to be provided to the Biosafety Clearing-House:

Type of information	*Information exists and is being provided to the Biosafety Clearing-House*	*Information exists but is not yet provided to the Biosafety Clearing-House*	*Information does not exist /not applicable*
(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 20.3(a))			
(b) National laws, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing (Article 11.5);			
(c) Bilateral, multilateral and regional agreements and arrangements (Articles 14.2, 20.3(b), and 24.1);			
(d) Contact details for competent national authorities (Articles 19.2 and 19.3), national focal points (Articles 19.1 and 19.3), and emergency contacts (Article 17.2 and 17.3(e));			
(e) In cases of multiple competent national authorities, responsibilities for each (Articles 19.2 and 19.3);			
(f) Reports submitted by the Parties on the operation of the Protocol (Article 20.3(e));			
(g) Occurrence of unintentional transboundary movements that are likely to have significant adverse effects on biological diversity (Article 17.1);			
(h) Illegal transboundary movements of LMOs (Article 25.3);			
(i) Final decisions regarding the importation or release of LMOs (i.e. approval or prohibition, any conditions, requests for further information, extensions granted, reasons for decision) (Articles 10.3 and 20.3(d));			
(j) Information on the application of domestic regulations to specific imports of LMOs (Article 14.4);			

Type of information	*Information exists and is being provided to the Biosafety Clearing-House*	*Information exists but is not yet provided to the Biosafety Clearing-House*	*Information does not exist /not applicable*
(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 11.1);			
(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 11.4) or in accordance with annex III (Article 11.6) (requirement of Article 20.3(d))			
(m) Declarations regarding the framework to be used for LMOs intended for direct use as food or feed, or for processing (Article 11.6)			
(n) Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12.1);			
(n) LMOs granted exemption status by each Party (Article 13.1)			
(o) Cases where intentional transboundary movement may take place at the same time as the movement is notified to the Party of import (Article 13.1);			
(p) Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and relevant information regarding products thereof (Article 20.3(c)).			

Article 2 – General provisions

3. Has your country introduced the necessary legal, administrative and other measures for implementation of the Protocol? (Article 2.1)	
a) full domestic regulatory framework in place (please give details below)	
b) some measures introduced (please give details below)	
c) no measures yet taken	
4. Please provide further details about your response to the above question, as well as description of your country's experiences and progress in implementing Article 2, including any obstacles or impediments encountered:	

Articles 7 to 10 and 12: The advance informed agreement procedure

See question 1 regarding provision of information to the Biosafety Clearing-House.

5. Were you a Party of import during this reporting period?	
a) yes	
b) no	
6. Were you a Party of export during this reporting period?	
a) yes	
b) no	
7. Is there a legal requirement for the accuracy of information provided by exporters 2/ under the jurisdiction of your country? (Article 8.2)	
a) yes	
b) not yet, but under development	
c) no	
d) not applicable – not a Party of export	
8. If you were a Party of export during this reporting period, did you request any Party of import to review a decision it had made under Article 10 on the grounds specified in Article 12.2?	
a) yes (please give details below)	
b) not yet, but under development	
c) no	
d) not applicable – not a Party of export	
9. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 9.2(c).	
a) yes	
b) no	
c) not applicable – no decisions taken during the reporting period	

2/ The use of terms in the questions follows the meanings accorded to them under Article 3 of the Protocol.

10. If your country has been a Party of export of LMOs intended for release into the environment during the reporting period, please describe your experiences and progress in implementing Articles 7 to 10 and 12, including any obstacles or impediments encountered:
11. If your country has taken decisions on import of LMOs intended for release into the environment during the reporting period, please describe your experiences and progress in implementing Articles 7 to 10 and 12, including any obstacles or impediments encountered:

Article 11 – Procedure for living modified organisms intended for direct use as food or feed, or for processing

See question 1 regarding provision of information to the Biosafety Clearing-House.

12. Is there a legal requirement for the accuracy of information provided by the applicant with respect to the domestic use of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing? (Article 11.2)	
a) yes	
b) not yet, but under development	
c) no	
d) not applicable (please give details below)	
13. Has your country indicated its needs for financial and technical assistance and capacity-building in respect of living modified organisms intended for direct use as food or feed, or for processing? (Article 11.9)	
a) yes (please give details below)	
b) no	
c) not relevant	
14. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 11.4?	
a) yes	
b) no	
c) not applicable – no decisions taken during the reporting period	
15. If your country has been a Party of export of LMOs intended for direct use for food or feed, or for processing, during the reporting period, please describe your experiences and progress in implementing Article 11, including any obstacles or impediments encountered:	
16. If your country has been a Party of import of LMOs intended for direct use for food or feed, or for processing, during the reporting period, please describe your experiences and progress in implementing Article 11, including any obstacles or impediments encountered:	

Article 13 – Simplified procedure

See question 1 regarding provision of information to the Biosafety Clearing-House.

17. Have you applied the simplified procedure during the reporting period?	
a) yes	
b) no	
18. If your country has used the simplified procedure during the reporting period, or if you have been unable to do so for some reason, please describe your experiences in implementing Article 13, including any obstacles or impediments encountered:	

Article 14 – Bilateral, regional and multilateral agreements and arrangements

See question 1 regarding provision of information to the Biosafety Clearing-House.

19. Has your country entered into any bilateral, regional or multilateral agreements or arrangements?	
a) yes	
b) no	
20. If your country has entered into bilateral, regional or multilateral agreements or arrangements, or if you have been unable to do so for some reason, describe your experiences in implementing Article 14 during the reporting period, including any obstacles or impediments encountered:	

Articles 15 and 16 – Risk assessment and risk management

21. If you were a Party of import during this reporting period, were risk assessments carried out for all decisions taken under Article 10? (Article 15.2)	
a) yes	
b) no (please clarify below)	
c) not a Party of import / no decisions taken under Article 10	
22. If yes to question 21, did you require the exporter to carry out the risk assessment?	
a) yes – in all cases	
b) yes – in some cases (please specify the number and give further details below)	
c) no	
d) not a Party of import / no decisions taken under Article 10	
23. If you took a decision under Article 10 during the reporting period, did you require the notifier to bear the cost of the risk assessment? (Article 15.3)	
a) yes – in all cases	
b) yes – in some cases (please specify the number and give further details below)	
c) no	
d) not a Party of import / no decisions taken under Article 10	
24. Has your country established and maintained appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol? (Article 16.1)	
a) yes – fully established	
b) not yet, but under development or partially established (please give further details below)	
c) no	
25. Has your country adopted appropriate measures to prevent unintentional transboundary movements of living modified organisms? (Article 16.3)	
a) yes – fully adopted	
b) not yet, but under development or partially adopted (please give further details below)	
c) no	
26. Does your country endeavour to ensure that any living modified organism, whether imported or locally developed, undergoes an appropriate period of observation commensurate with its life-cycle or generation time before it is put to its intended use? (Article 16.4)	
a) yes – in all cases	
b) yes – in some cases (please give further details below)	

c) no (please give further details below)	
d) not applicable (please give further details below)	
27. Has your country cooperated with others for the purposes specified in Article 16.5?	
a) yes (please give further details below)	
b) no (please give further details below)	
28. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Articles 15 and 16, including any obstacles or impediments encountered:	

Article 17 – Unintentional transboundary movements and emergency measures

See question 1 regarding provision of information to the Biosafety Clearing-House.

29. During the reporting period, if there were any occurrences under your jurisdiction that led, or could have led, to an unintentional transboundary movement of a living modified organism that had, or could have had, significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States, did you immediately consult the affected or potentially affected States for the purposes specified in Article 17.4?	
a) yes – all relevant States immediately	
b) yes – partially consulted, or consultations were delayed (please clarify below)	
c) no – did not consult immediately (please clarify below)	
d) not applicable (no such occurrences)	
30. Please provide further details about your response to the above question, as well as description of your country's experiences in implementing Article 17, including any obstacles or impediments encountered:	

Article 18 – Handling, transport, packaging and identification

31. Has your country taken measures to require that living modified organisms that are subject to transboundary movement within the scope of the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards? (Article 18.1)	
a) yes (please give details below)	
b) not yet, but under development	
c) no	
d) not applicable (please clarify below)	
32. Has your country taken measures to require that documentation accompanying living modified organisms for direct use as food or feed, or for processing, clearly identifies that they 'may contain' living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for information? (Article 18.2(a))	
a) yes	
b) not yet, but under development	
c) no	
33. Has your country taken measures to require that documentation accompanying living modified organisms 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 living modified organisms are consigned? (Article 18.2(b))	
a) yes	
b) not yet, but under development	
c) no	
34. Has your country adopted measures to require that documentation accompanying living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, 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? (Article 18.2(c))	
a) yes	
b) not yet, but under development	
c) no	
35. Please provide further details about your responses to the above questions, as well as a description of your country's experiences and progress in implementing Article 18, including any obstacles or impediments encountered:	

Article 19 – Competent national authorities and national focal points

See question 1 regarding provision of information to the Biosafety Clearing-House.

Article 20 – Information-sharing and the Biosafety Clearing-House

See question 1 regarding provision of information to the Biosafety Clearing-House.

36. In addition to the response to question 1, please describe any further details regarding your country's experiences and progress in implementing Article 20, including any obstacles or impediments encountered:

Article 21 – Confidential information

37. Does your country have procedures to protect confidential information received under the Protocol and that protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms? (Article 21.3)	
a) yes	
b) not yet, but under development	
c) no	
38. If you were a Party of import during this reporting period, did you permit any notifier to identify information submitted under the procedures of the Protocol or required by the Party of import as part of the advance informed agreement procedure that was to be treated as confidential? (Article 21.1)	
a) yes	
If yes, please give number of cases	
b) no	
c) not applicable – not a Party of import / no such requests received	
39. If you answered yes to the previous question, please provide information on your experience including description of any impediments or difficulties encountered:	
40. If you were a Party of export during this reporting period, please describe any impediments or difficulties encountered by you, or by exporters under your jurisdiction if information is available, in the implementation of the requirements of Article 21:	

Article 22 – Capacity-building

41. If a developed country Party, during this reporting period has your country cooperated in the development and/or strengthening of human resources and institutional capacities in biosafety for the purposes of the effective implementation of the Protocol in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition?	
a) yes (please give details below)	
b) no	
b) not applicable – not a developed country Party	
42. If yes to question 41, how has such cooperation taken place:	
43. If a developing country Party, or Party with an economy in transition, during this reporting period has your country contributed to the development and/or strengthening of human resources and institutional capacities in biosafety for the purposes of the effective implementation of the Protocol in another developing country Party or Party with an economy in transition?	
a) yes (please give details below)	
b) no	
b) not applicable – not a developing country Party	
44. If yes to question 43, how has such cooperation taken place:	
45. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training in the proper and safe management of biotechnology to the extent that it is required for biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	

c) no – capacity-building needs remain unmet (please give details below)	
b) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	
46. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training in the use of risk assessment and risk management for biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	
c) no – capacity-building needs remain unmet (please give details below)	
b) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	

47. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training for enhancement of technological and institutional capacities in biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	
c) no – capacity-building needs remain unmet (please give details below)	
b) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	
48. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 22, including any obstacles or impediments encountered:	

Article 23 – Public awareness and participation

49. Does your country promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health? (Article 23.1(a))	
a) yes – significant extent	
b) yes – limited extent	
c) no	
50. If yes, do you cooperate with other States and international bodies?	
a) yes – significant extent	
b) yes – limited extent	
c) no	
51. Does your country endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with the Protocol that may be imported? (Article 23.1(b))	
a) yes – fully	
b) yes – limited extent	
c) no	
52. Does your country, in accordance with its respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and make the results of such decisions available to the public? (Article 23.2)	
a) yes – fully	
b) yes – limited extent	
c) no	
53. Has your country informed its public about the means of public access to the Biosafety Clearing-House? (Article 23.3)	
a) yes – fully	
b) yes – limited extent	
c) no	
54. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 23, including any obstacles or impediments encountered:	

Article 24 – Non-Parties

See question 1 regarding provision of information to the Biosafety Clearing-House**.**

55. Have there been any transboundary movements of living modified organisms between your country and a non-Party during the reporting period?	
a) yes	
b) no	
56. If there have been transboundary movements of living modified organisms between your country and a non-Party, please provide information on your experience, including description of any impediments or difficulties encountered:	

Article 25 – Illegal transboundary movements

See question 1 regarding provision of information to the Biosafety Clearing-House.

57. Has your country adopted appropriate domestic measures to prevent and penalize, as appropriate, transboundary movements of living modified organisms carried out in contravention of its domestic measures? (Article 25.1)	
a) yes	
b) no	
58. Have there been any illegal transboundary movements of living modified organisms into your country during the reporting period?	
a) yes	
b) no	
59. Please provide further details about your response to the above question, as well as description of your country's experiences in implementing Article 25, including any obstacles or impediments encountered:	

Article 26 – Socio-economic considerations

60. If during this reporting period your country has taken a decision on import, did it take into account socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities? (Article 26.1)	
a) yes – significant extent	
b) yes – limited extent	
c) no	
d) not a Party of import	
61. Has your country cooperated with other Parties on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities? (Article 26.2)	
a) yes – significant extent	
b) yes – limited extent	
c) no	
62. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 26, including any obstacles or impediments encountered:	

Article 28 – Financial mechanism and resources

63. Please indicate if, during the reporting period, your Government made financial resources available to other Parties or received financial resources from other Parties or financial institutions, for the purposes of implementation of the Protocol.	
a) yes – made financial resources available to other Parties	
b) yes – received financial resources from other Parties or financial institutions	
c) both	
d) neither	
64. Please provide further details about your response to the above question, as well as description of your country's experiences, including any obstacles or impediments encountered:	

Other information

65. Please use this box to provide any other information related to articles of the Protocol, questions in the reporting format, or other issues related to national implementation of the Protocol:

Comments on reporting format

The wording of these questions is based on the Articles of the Protocol. Please provide information on any difficulties that you have encountered in interpreting the wording of these questions:
