





Convention on Biological Diversity

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

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

ASSESSMENT AND REVIEW (ARTICLE 35): COMPILATION OF SUBMISSIONS OF VIEWS

Note by the Executive Secretary

- 1. In its decision BS-III/15, the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) invited, in paragraph 1 of decision BS-III/15, Parties, other Governments as well relevant intergovernmental and non-governmental organizations and other stakeholders to submit to the Secretariat their views, which should: (i) evaluate the effectiveness of the Protocol, including an assessment of procedures and annexes, taking into account the items specified in paragraph 6 (b) of the medium-term programme of work contained in the annex to decision BS-I/12; and (ii) assess the procedures and annexes under the Protocol, with a view to identifying difficulties arising from implementation as well as suggestions for appropriate indicators and/or criteria for evaluating effectiveness and ideas on the modalities of the evaluation.
- 2. Below is a compilation of responses to the questionnaire that the Secretariat had formulated and circulated on the basis of the above decisions relevant to assessment and review submitted by Parties, other Governments and relevant international organizations.

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^{*} UNEP/CBD/BS/COP-MOP/4/1

Question 1

Please evaluate the effectiveness of the Protocol. Include an assessment of the Protocol's procedures (e.g. the advance informed agreement (AIA) procedure (Articles 7-10), the procedure for LMOs intended for direct use food or feed, or for processing (Article 11), mechanisms (e.g. the compliance mechanism), and annexes (Annexes I, II and III of the Protocol). (paragraph 1(a), decision BS-III/15)

Armenia

The effectiveness of the Protocol is highly evaluated, as there are involved all the procedures concerning to LMOs, safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures.

Austria

The effectiveness of the Cartagena Protocol, including its procedures, mechanisms and annexes, depends not only on whether and how it is implemented in the national legislation of the Parties, but also to a large extent on whether and how the Protocol and its implementing legislation is applied. Each Party's capacity and capacity building measures, in particular in relation to risk assessment, risk management and sampling and detection, are crucial and may take some time to develop. As the Cartagena Protocol entered into force on 11 September 2003 and therefore still is in its implementation phase, it may present some difficulties to fully evaluate its effectiveness at this stage.

Implementation measures are described in the national reports of the Parties provided pursuant to Article 33 of the Protocol. The scope of an evaluation of the Protocol's effectiveness is however wider than this factual description. It encompasses an assessment of the ability to achieve the objectives of the Protocol as set out in Article 1 of the Protocol, through its procedures, mechanisms and annexes.

Barbados

The Government of Barbados is not in a position to assess the effectiveness of the Protocol since we have not established a functional National Biosafety Framework (NBF) to gain experience related to the implementation of the various procedures and mechanisms of the Protocol.

Belize

Belize has not really had an opportunity to base its assessment of the Cartagena protocol on practical experience of imports of GMO to Belize because no such importation has occurred. There has been a request to import corn from the USA for animal feed. When the competent authority in Belize requested from the importer (and subsequent supplier) of the nature of the corn, information received was that the product may contain a mixture of GMO and non GMO corn and there was no way in determining its true nature as the elevator that the product was purchased from did not practice any segregation of GMO from Non GMO crops. The product, (cracked corn) was allowed in following information being provided from the importer and the provision of regulatory oversight to ensure that the product was truly destined for animal feed and not to be allowed in the food chain. In reviewing this case, trading with a non party can be problematic in that the nonparty may be reluctant to provide information to the importer particularly if the amount of import is relatively small and the request require "extra effort" on part of the exporter. It is our opinion that a specific document that contains all the relevant information about the commodity of import should accompany the shipment and presented for review and assessment as part of the risk assessment process by the competent authority in the country of import.

Bhutan

The Royal Government of Bhutan has not engaged itself either in the export or import of LMOs. The awareness on the LMOs is very low. During drafting of the National Biosafety Framework few awareness workshops among relevant government agencies were conducted. Since Bhutan has no experience in this area, no evaluation of the effective of the protocol could be conducted.

Bulgaria

Bulgaria has no experience with the procedures, listed in this question due to the fact of not being a country of import/export in the context of Biosafety Protocol during the reported period.

Cambodia

Regarding AIA procedure (Articles 7-10), Cambodia has developed into a national law on biosafety required all parties of import or notifiers, or applicants to inform and submit related applications to the competent authorities. Insofar, only one applicant has approached the Ministry of Environment to conduct the assessment for Vanila plant before allowing for planting in Cambodia. However, this plant is not genetically modified organism, therefore, we did not process. This indicated that at least information on the CPB has been disseminated among private companies. At presence, there are no LMOs plants or animals have been allowed to plant or to raise in the country.

Regarding for LMOs intended for direct use for food, feed or for processing (Article 11): Cambodia has incorporated this chapter into the context of the national law on biosafety. Up to date, no encountering any application for direct use as for FFP yet. The law on biosafety has been at the parliament since 2005.

In implementing the annexes I, II and III of the protocol, all have been addressed in the national law on biosafety and the draft sub-decree on control and management of the transboundary movement of LMOs. Cambodia through Ministry of Environment has been implementing the Capacity Building project to implement the national biosafety framework including capacity for Risk Assessment and Risk Management resulting from LMOs. Cambodia is in the process of developing application form for import and export of LMOs for FFP, contained use and field trials.

Cameroon

Evaluation is limited to our experiences:

- AIA procedure: Individuals importing GMOs did not inform Competent Authority hence there
 was no AIA when GM maize was imported. However, documents related to the procedure of
 notification are elaborated but not validated.
- Mechanisms: the compliance mechanisms appear to have failed in the case just cited.
- First import of GMO (GM maize) from Argentina had no AIA and so an action in respect of annexes I, II and III of the Protocol could not be planned/Implemented.
- Long delay (4 years) between regulatory framework (law) and its text/instrument of application.
- Immense capacity building needs and inability of the country to cope with.

Canada

Although, as a non-Party, Canada has not implemented the Protocol's procedures per se, Canada has developed a product- and science-based approach to regulating products of biotechnology, and our regulatory system seeks to achieve the same objective as the Cartagena Protocol on Biosafety, that is, the protection of biodiversity.

It has been noted, however, that the report by the compliance committee at its second meeting on general/systemic issues of non-compliance (UNEP/CBD/BS/COP-MOP/3/2) revealed undesirably low levels of implementation of Protocol obligations among Parties. Without Parties' full compliance with the Protocol's obligations, including its procedures, it is very difficult to properly assess the Protocol's effectiveness on a comprehensive basis.

Canada believes that the Biosafety Clearing-House (BCH) has the potential to be an effective means by which both Parties and non-Parties can share information about Living Modified Organisms (LMOs). Thus, a high level of compliance and timely compliance with the BCH notification requirements by Parties would be one measure of the Protocol's effectiveness. The BCH provides a unique venue through

which to inform other countries of changes to regulations, newly approved LMOs, and government departments responsible for providing regulatory oversight of LMOs. Canada continues to support the BCH by posting such information for the benefit of other countries on the Canadian Node of the BCH (www.bch.gc.ca) and the BCH central portal (http://bch.biodiv.org/default.aspx).

Colombia

En Colombia, el Protocolo de Cartagena ha venido siendo implementado de manera adecuada y conforme a las directrices y obligaciones derivadas de las Reuniones de las Partes (MOP). El Protocolo se ha constituido en un instrumento importante para regular el movimiento transfronterizo, el tránsito, la manipulación y la utilización de los OVM. El procedimiento de Acuerdo Fundamentado Previo ha sido reglamentado en el país a través del Decreto 4525 de 2005, el cual establece que la Autorización otorgada por una de las tres (3) Autoridades Nacionales Competentes (Ministerio de la Protección Social; Ministerio de Ambiente, Vivienda y Desarrollo Territorial y Ministerio de Agricultura y Desarrollo Rural) para el movimiento transfronterizo de los OVM de su competencia, equivale al AFP establecido en el Protocolo. En este mismo sentido, el procedimiento establecido para el movimiento transfronterizo de OVM destinado al uso directo como alimentación humana o animal o para procesamiento se ha venido aplicando adecuadamente.

En cuanto al Mecanismo de Cumplimiento, de acuerdo a lo discutido y aprobado en MOP 3, Colombia considera que debido a la reciente entrada en vigencia del Prtocolo de Cartagena, no ha trascurrido el tiempo suficiente para evaluar su efectividad, pues las Partes aún se encuentran en proceso de implementación y no se han evidenciado, al menos para Colombia, casos de incumplimiento y se debe seguir consolidando la información necesaria para abordar su efectividad.

Para los OVM hasta la fecha autorizados en Colombia, no ha sido necesario para el país requerir información adicional a la estipulada en los Anexos I, II y III pues la misma provee un suficiente nivel de información técnica y científica para adelantar el proceso de Evaluación de Riesgos. No obstante, se considera que a futuro la información requerida deberá ser complementada o presentada con un mayor nivel de especificidad para el caso de nuevos desarrollos de la biotecnología moderna como pudieran ser los microorganismos, insectos, peces o árboles genéticamente modificados o para el caso de plantas vivas modificadas con finalidades diferentes a la alimentación y agricultura, como es el caso de productos fitofármacos, nutraceúticos o con usos industriales (bio polímeros, biocombustibles, etc.).

Costa Rica

Artículos 7-10

El Acuerdo Fundamentado Previo (AFP) se ejecuta de manera similar en la legislación costarricense, en su Ley N°7664 y su Reglamento N°26921-MAG.

El análisis del riesgo se realiza caso por caso, por lo cual el estudio de cada aplicación de proyecto, aún teniendo el mismo Organismo Vivo Modificado (OVM), son tratados de acuerdo con la información que acompaña al OVM, siguiendo la legislación nacional vigente.

El proceso se encuentra en concordancia con e l primer movimiento transfronterizo de un OVM para solicitudes presentadas por solicitante. Cada OVM es regulado y monitoreado desde su introducción al país.

Además, los períodos o tiempos de análisis y respuesta están acorde con lo establecido con el Protocolo de Cartagena sobre Seguridad de la Biotecnología (PCSB).

El país considera que la aplicación de los artículos 7 al 10 se ha ejecutado de manera concordante con lo establecido en el PCSB, en las actividades relacionadas con OVMs de uso agrícola desde hace más de 15 años con base en la legislación nacional vigente.

Artículo 11

Como se concluye en la elaboración del Proyecto UNEP-GEF "Desarrollo de un Marco Nacional en Bioseguridad para Costa Rica", el país necesita establecer una política en Biotecnología y Bioseguridad, particularmente en lo que refiere a OVMs utilizados para consumo humano, animal o para su procesamiento, debido a que hay una ausencia de legislación relacionada con ese tema. El PCSB brinda las bases para generar el cumplimiento de lo descrito anteriormente, pero el país necesita desarrollar legislación, estructuras, herramientas y protocolos para poder implementar el Artículo 11 de dicha legislación a nivel nacional.

Mecanismos

El país está brindando las bases y realizando esfuerzos para generar el cumplimiento del Artículo 20 del PCSB, con lo que, se va a dar la plataforma para la toma de decisiones y cumplimiento de otros artículos de dicho Protocolo.

Costa Rica en este momento está utilizando el Portal Central para el registro de información acorde con el PCSB, y se está desarrollando una aplicación nacional con la información exclusiva de país relacionada con el Centro de Intercambio de Información sobre Seguridad de la Biotecnología (CIISB).

Anexos

Los anexos del PCSB están siendo utilizados como elementos comparativos en la línea base de la información que se solicita para los artículos 7-10, especialmente, van a servir para registrar la información respectiva en el CIISB y dar cumplimiento del Artículo 20 del PCSB.

En virtud de lo anteriormente descrito el Anexo II no se está aplicando ni utilizando actualmente.

Croatia

Cartagena Protocol on Biosafety as a globally accepted set of rules on GMOs, important in particular to ensure transparency in the transboundary movement of GMOs and application of the advance informed agreement (AIA) procedure regarding imports has been very effective in the recent years i.e. from the entry into force in 2003.

Provisions of the Protocol on AIA procedure (Art. 7-10), the procedure for LMOs intended for direct use for food or feed, or processing (Art.11), compliance mechanism and Protocol's Annexes (Annex I on Information required in Notifications under articles 8,10 and 13; Annex II on Information required concerning LMOs intended for direct use as food or feed, or for processing under Article 11 and Annex III on Risk Assessment) were of invaluable help to many countries in the world, Parties to the Protocol in the times when they were not in a position and ready to deal with GMOs and biosafety issues internally.

All the procedures, mechanisms and annexes covered under the Protocol, Parties were able to use as a valuable guidance and a tool in the period while developing their own national biosafety legislation.

Cartagena Protocol on Biosafety offered to its Parties significant benefits and at the same time, set in place an institutional mechanism through which implementation can be fostered and a continued dialogue and cooperation can be affected.

European Community

In general, an effective national implementation of the Protocol's procedures, mechanisms and Annexes depends on fundamental capacities of Parties particularly in relation to risk assessment and risk management as well as sampling and detection of LMOs. Establishing such capacities is a major task for many Parties. The Cartagena Protocol only entered into force on 11 September 2003 and is therefore still in its early phase of implementation. This makes a full-scale assessment of its effectiveness particularly challenging.

Adding to these more general considerations, the European Community and its Member States see some difficulties in responding to Question 1.

An evaluation of the effectiveness according to Article 35 of the Cartagena Protocol goes significantly beyond a mere description of national measures taken by Parties in order to ensure the Protocol's implementation. The latter information is already included in national reports provided by Parties in accordance with Article 33 of the Cartagena Protocol. An evaluation of the Protocol's effectiveness, however, should rather identify the extent to which the procedures and mechanisms established by the Protocol are effective in achieving the objectives set out in Article 1 of the Cartagena Protocol.

The European Community and its Member States have put in place a comprehensive legal framework for ensuring safety in the development, use and transfer of GMOs. This framework is in full compliance with the Protocol but more detailed and elaborated. Therefore, the European Community and its Member States to a very large extent do not rely exclusively on the procedures and mechanisms established by the Protocol in order to achieve its objectives. Evaluations of the EU-framework indicate that it is effective overall in achieving its objectives and thereby the objectives of the Protocol.

In the view of the European Community and its Member States discussion on the effectiveness of the Protocol should be supported by an expert study on this subject. Such study should develop a sound methodological approach to evaluate the effectiveness of the Protocol, its procedures and mechanisms and apply this suggested approach drawing from information provided by Parties in their national reports, views expressed in responding to this questionnaire, the report of the Compliance Committee, and further information gathered from relevant stakeholders.

India

Presently, India is neither an importer nor exporter of LMOs except for the purpose of research and contained use. India is relying on its domestic legislative framework for import/export of LMOs. Therefore in the absence of experience in implementing the AIA procedure (Articles 7-10), the procedure for LMOs intended for direct use food or feed, or for processing (Article 11), mechanisms (e.g. the compliance mechanism), and annexes (Annexes I, II and III of the Protocol), effectiveness of the Protocol cannot be assessed at this stage.

Japan

Japan has its domestic law implementing the Protocol, with the following provisions:

- A person who produces or imports LMOs for intended use of Type 1 (the Use of LMOs without preventive measures against their dispersal into the environment) shall submit the Use Regulations (the way of using the LMOs such as food, feed, industrial material etc. including FFP) and obtain the approval from the competent minister. In order to apply for the approval, a Biological Diversity Risk Assessment Report needs to be attached. (Article 4.1 and 4.2 of the domestic law)
- The competent minister must, when recognizing that no Adverse Effect on Biological Diversity would arise, give approval for the Type 1 Use Regulations. (Article 4.5 of the domestic law)
- When the approval is given based on Article 4, the competent minister shall announce to that effect and the approved Type 1 Use Regulations. (Article 8, 1(i) of the domestic law)

When the Japanese government makes decision or approves the use of LMOs, the Japanese government submits the relevant information to the Biosafety Clearing-House (BCH) within fifteen days based on Article 11.1 of the Protocol.

The fact that major LMO exporting countries are non-Parties to the Protocol makes the evaluation of the effectiveness of the Protocol difficult for Japan, as almost all LMOs are imported from those non-Parties. At present, Japan does not export LMOs for release into the environment or direct use as FFP.

Lithuania

No experience

Madagascar

Jusqu'à présent, le Protocole de Cartagena pour Madagascar n'est pas encore effectif dans la mesure où la législation nationale sur la biosécurité n'est pas en vigueur. Néanmoins, il n'y a pas encore de demande d'importation ni d'exportation d'Organismes génétiquement modifiés à Madagascar.

Malaysia

Malaysia has limited experience in implementing the Protocol due to the absence of a regulatory framework in place (during the reporting period). During the reporting period, Biosafety measures were done administratively with the assistance of GMAC.

With the passing of the Biosafety law in July 2007, it is envisaged Malaysia will be able to enhance the implementation of the Protocol and would then be in a better position to comment on the effectiveness of the Protocol. Furthermore Malaysia has just started the UNDP/GEF Capacity Building Project on Biosafety which will complement national efforts in implementing the National Biosafety Framework and the Protocol.

Norway

The Cartagena Protocol on Biosafety is implemented in Norway through several legislative measures applying to the production and use of LMOs, including transport, import and marketing. These measures are described in Norway's First Regular National Report. They are in compliance with, but more detailed than the Protocol. Norway relies largely on these national legislative measures and not primarily on the Protocol's procedures in relation to LMOs. There has been no field trials of LMOs in Norway, no export of LMOs from Norway, no import of LMOs for release into the environment or for direct use as food, feed or for processing, and only very limited import of LMOs destined for contained use since the Protocol entered into force. Norway therefore has limited possibility to evaluate the effectiveness of the Protocol.

Answers to questions concerning the effectiveness of the Protocol may differ significantly due to different ways of implementing and applying the Protocol, different levels of activities covered by the Protocol and different levels of experiences. The answers therefore may not be directly comparable and allow for sound conclusions to be drawn on the effectiveness of the Protocol.

A study conducted by experts could therefore provide valuable input to the discussion on the effectiveness of the Protocol. The study should include the development of an appropriate methodology in order to obtain informative and generalized results. The study should also make use of the information submitted by the Parties in the First Regular National Reports and the answers to this questionnaire. The report of the Compliance Committee could also provide information useful for the study.

Given the crucial importance of risk assessment as pointed out by COP-MOP1 and 2 in decisions BS-I/5 and BS-II/9 and above, Norway would nevertheless like to stress the need for additional guidance on risk assessment and risk management that was identified by COP-MOP3 in its decision BS-III/11, based on the report of the Ad Hoc Technical Expert Group on Risk Assessment that met in Rome in November 2005, and the Workshop organized by Canada and Norway in June 2007.

The Workshop focused on emerging applications of modern biotechnology in trees, fish, veterinary applications and specific plant varieties, and addressed available guidance on risk assessment for, identification of gaps in information or science that could impact on appropriate risk assessments and appropriateness of current models for risk assessment applied to these applications. The workshop concluded that the general principles and methodologies for risk assessment contained in Annex III to the Cartagena Protocol also apply to transgenic fish, trees, viruses and pharmaplants, but that there is a need for further guidance on how to perform risk assessment for GM fish and viruses. The workshop also concluded that there may be a need to develop specific methodologies and specific protocols for generating data necessary to conduct risk assessments for the applications of modern biotechnology covered by the workshop. Furthermore, the experts agreed that there is a need for additional data on several elements necessary to conduct risk assessments for all four types of transgenic organisms and that

further research is recommended to fill the knowledge gaps, inter alia the specific gaps identified during the workshop. The report is available on http://www.regjeringen.no/Upload/MD/Vedlegg/Naturmangfold/Fremmede%20arter/Risk%20Assessmen t_Workshop_rapport%20FINAL_juli07.pdf

We would also like to recall that Norway, in the answer to questions 28 and 35 of the first regular national report from Norway, favored to appoint a scientific committee with the task of providing scientific and technical guidance on risk assessment guidelines, and other tasks that might also be considered important for the fulfillment of the objectives of the Protocol, such as a standardized format for documentation and identification requirements for inclusion in a stand-alone document, and sampling and detection methods.

Republic of Moldova

In our opinion some procedural prescriptions of the text of the Protocol should be clarified I a more explicit manner in order to avoid double understanding and confusions.

For example we could address to the Art 9, p1 and p.4 of the Protocol. Thus, Art.9 p.1 required the following: "The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt". P.4 of the same article stipulates: "A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement." We consider that is contradictory and could provide some misunderstanding regarding the obligation of Parties to provide the notifier with an aknowlegement that should be issued by ninety days of its receipt. The Party of import must provide the notifier with acknowledgement in accordance with the CP procedures, indifferent of the fact if the Party of import wants to approve or refuse this LMOs import. In the actual redaction of the text of the Protocol, p.4 allows that Party could avoid its obligations to acknowledge the notifier. That fact would provoke unjustified obstacles for the LMOs transboundery movements.

New Zealand

At the time of writing, New Zealand has not granted regulatory approval for any intentional transboundary movement of living modified organisms (LMOs) intended for introduction into the environment of the Party of import, nor for import for introduction into the New Zealand environment.

Similarly, regulatory approval has not been granted for any intentional transboundary movement of LMOs intended for use as food, feed or for processing in the Party of import, nor for import for use as food, feed or for processing in New Zealand. We therefore have no practical experience in implementing Articles 7 through 12 of the Protocol, or in application of the information requirements under Annex I or Annex II.

New Zealand's regulatory framework does, however, provide for decision-making consistent with the obligations on Parties as prescribed in those articles. The New Zealand regulatory systems applies equally to Parties and non-Parties alike, both for importation and for export, with no distinction in the way the legislation applies.

All decisions on the importation and domestic use in New Zealand of LMOs that are genetically modified organisms are made by the Environmental Risk Management Authority on the basis of a thorough assessment of the potential risks posed by the organism, under the stringent requirements of the Hazardous Substances and New Organisms Act 1996. Such risk assessment requirements are fully consistent with the requirements under the Protocol, particularly in relation to Annex III.

(Please refer to National Report for more detail if required.)

Nigeria

The AIA procedure is very adequate particularly for those countries without law . It serves as a major clause in the regulation of LMOs. There should be a mechanism for applicants to inform the public of applications made and their status of approval in the BCH , to check level of compliance .

Norway

The effectiveness of the Cartagena Protocol, including its procedures, mechanisms and annexes, depends not only on whether and how it is implemented in the national legislation of the Parties, but also to a large extent on whether and how the Protocol and its implementing legislation is applied. Each Party's capacity and capacity building measures, in particular in relation to risk assessment, risk management and sampling and detection, are crucial and may take some time to develop. As the Cartagena Protocol entered into force on 11 September 2003 and therefore still is in its implementation phase, it may present some difficulties to fully evaluate its effectiveness at this stage.

Implementation measures are described in the national reports of the Parties provided pursuant to Article 33 of the Protocol. The scope of an evaluation of the Protocol's effectiveness is however wider than this factual description. It encompasses an assessment of the ability to achieve the objectives of the Protocol as set out in Article 1 of the Protocol, through its procedures, mechanisms and annexes.

The Cartagena Protocol on Biosafety is implemented in Norway through several legislative measures applying to the production and use of LMOs, including transport, import and marketing. These measures are described in Norway's First Regular National Report. They are in compliance with, but more detailed than the Protocol. Norway relies largely on these national legislative measures and not primarily on the Protocol's procedures in relation to LMOs. There has been no field trials of LMOs in Norway, no export of LMOs from Norway, no import of LMOs for release into the environment or for direct use as food, feed or for processing, and only very limited import of LMOs destined for contained use since the Protocol entered into force. Norway therefore has limited possibility to evaluate the effectiveness of the Protocol.

Answers to questions concerning the effectiveness of the Protocol may differ significantly due to different ways of implementing and applying the Protocol, different levels of activities covered by the Protocol and different levels of experiences. The answers therefore may not be directly comparable and allow for sound conclusions to be drawn on the effectiveness of the Protocol.

A study conducted by experts could therefore provide valuable input to the discussion on the effectiveness of the Protocol. The study should include the development of an appropriate methodology in order to obtain informative and generalized results. The study should also make use of the information submitted by the Parties in the First Regular National Reports and the answers to this questionnaire. The report of the Compliance Committee could also provide information useful for the study.

Given the crucial importance of risk assessment as pointed out by COP-MOP1 and 2 in decisions BS-I/5 and BS-II/9 and above, Norway would nevertheless like to stress the need for additional guidance on risk assessment and risk management that was identified by COP-MOP3 in its decision BS-III/11, based on the report of the Ad Hoc Technical Expert Group on Risk Assessment that met in Rome in November 2005, and the Workshop organized by Canada and Norway in June 2007.

The Workshop focused on emerging applications of modern biotechnology in trees, fish, veterinary applications and specific plant varieties, and addressed available guidance on risk assessment for, identification of gaps in information or science that could impact on appropriate risk assessments and appropriateness of current models for risk assessment applied to these applications. The workshop concluded that the general principles and methodologies for risk assessment contained in Annex III to the Cartagena Protocol also apply to transgenic fish, trees, viruses and pharmaplants, but that there is a need for further guidance on how to perform risk assessment for GM fish and viruses. The workshop also concluded that there may be a need to develop specific methodologies and specific protocols for generating data necessary to conduct risk assessments for the applications of modern biotechnology covered by the workshop. Furthermore, the experts agreed that there is a need for additional data on several elements necessary to conduct risk assessments for all four types of transgenic organisms and that further research is recommended to fill the knowledge gaps, inter alia the specific gaps identified during the workshop. The report is available on

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We would also like to recall that Norway, in the answer to questions 28 and 35 of the first regular national report from Norway, favored to appoint a scientific committee with the task of providing scientific and technical guidance on risk assessment guidelines, and other tasks that might also be considered important for the fulfillment of the objectives of the Protocol, such as a standardized format for documentation and identification requirements for inclusion in a stand-alone document, and sampling and detection methods.

Poland

The advance informed agreement (AIA) – still is questionable interpretation of wording "**intentional** transboundary movement of living modified organisms" (Article 7.1). Thus, what does **unintentional** transboundary movement mean? Does it mean only non-caused by human activity transboundary movement, for example movement through transboundary rivers or also movement carried out by unaware exporter? This problem has significant practical meaning and needs more discussion.

Article 9.3 - concept of consistance of the domestic regulatory framework with the Protocol is not defined. It seems that consistance concerns the basic law institutions provided for in the Protocol which allows certain discrepancies between detailed solutions but without infingement of the principals of this Protocol.

Information in Annexes I, II and III of the Protocol were used by us to prepare the Polish national law in the field of GMO. The Polish administration and GMO users still take advantage of it.

Switzerland

Article 7: Application of the advanced informed agreement procedure

Since the entry into force of the Cartagena Protocol, no transboundary movement (import or export) of LMOs intended for intentional use in the environment have taken place in Switzerland. The main reason is that there is currently a five-year moratorium banning the dissemination of LMOs in Swiss agriculture which started in November 2005 and will end in November 2010. This moratorium does not concern the dissemination of LMOs for research purposes, which is allowed after approval of the application from the competent authorities (Federal Office for the Environment, FOEN).

Articles 8, 9 and 10:

See comments on article 7.

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

According to art. 11.4 of the Cartagena Protocol, a Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol. This is the case for Switzerland, where the AIA procedure does not apply in the Swiss regulation regarding LMOs.

Currently in Switzerland four types of LMOs are authorized for import as food or feed (three maize lines and one soybean line). However, no commercialization of these LMOs have yet taken place, essentially due to the strong consumer resistance to GM derived food products.

Ten additional applications (9 maize lines and one colza line) are currently under review for use as food, feed or for processing.

Annexes I, II and III

The annexes were not used because there was no transboundary movements of LMOs.

Tanzania

Not Applicable – To-date the United Republic of Tanzania has no practical experience on the export or import of LMOs. It is therefore, difficult to assess its effectiveness.

Thailand

The Protocol's procedures and annexes are fairly effective to be applied for the country. They guide and align with in-country procedures without any major difficulties and impracticalities. In comparison, Protocol's mechanisms (e.g. the compliance mechanism) do not clarify how to implement and set-up to achieve its objectives.

Togo

Aux points 5, 6, 15 et 16 du rapport (premier rapport national régulier sur la mise en œuvre du Protocole de Cartagena sur la prévention des risques biotechnologiques), nous avons indiqué que le Togo n'a été, ni Partie importatrice, ni Partie exportatrice d'organismes vivants modifiés destinés à être introduits dans l'environnement ou à être utilisés directement pour l'alimentation humaine et animale.

Par ailleurs, le processus de mise en place de la réglementation nationale de biosécurité n'a pas encore abouti. En conséquence, notre pays le Togo n'a pas encore d'expériences à communiquer ou à partager en matière d'évaluation des procédures prévues par le Protocole

USA

The United States welcomes the opportunity to provide views on the assessment and review, as invited by the Secretariat, to assist with the evaluation of the effectiveness of the Protocol in accordance with Article 35.

The United States recognizes that further information regarding the status of implementation of the Protocol is currently being collected through the Parties' submission of First Regular National Reports. However, available information and experience indicate that a considerable number of Parties are still at the early stages of developing and implementing their national biosafety frameworks. Approximately half of the Parties have yet to post information on their national biosafety frameworks to the Biosafety Clearing House (BCH). The BCH shows only two records of decisions made under the Advance Informed Agreement. We also note that 31 Parties and other governments have posted over 500 decisions on LMO/FFP's. This record of decisions represents only a portion of the Parties to the Protocol, suggesting that many Parties have not implemented their obligations under the Protocol. At this time, we concur with the Parties' conclusion at MOP-3 (BS-III/15), that the lack of implementation may not be due to inherent problems with the Protocol, but with a lack of capacity to implement the Protocol.

It is worth noting that the adequacy of Annex III was affirmed at the recent Canada Norway Expert Workshop on Risk Assessment for Emerging Applications of Living Modified Organisms, held in Montreal on June 4-6, 2007, which concluded that "[t]he general principles and methodologies for risk assessment contained in Annex III to the Cartagena Protocol also apply to transgenic fish, trees, viruses and pharmaplants." Further, work related to risk assessment of emerging technologies such as genetically engineered fish is under development in fora such as OECD.

We believe the existing compliance procedures and mechanisms are sufficient to promote compliance by Parties and do not consider it beneficial, or consistent with Article 34, to add new more punitive measures in cases of repeated non compliance.

Regarding the decision-making procedures and mechanisms of the Protocol, the United States observes that the overwhelming number of decisions that have been reported to the BCH are related to LMO/FFP's, as opposed to decisions related to LMO's intended for environmental release or contained use. This record indicates a focus on commodity trade that underscores the importance implementing the Protocol in a way that is not unnecessarily disruptive to trade.

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The United States would like to note our contribution to the development of the BCH through both financial and technical assistance and our provision of information to the BCH. We continue to believe that the success of the BCH is a critical element for the successful implementation of the Protocol. The United States continues to be committed to sharing our experience in regulating LMO's, to facilitate transboundary movement of LMO's and to support science-based decision-making.

Venezuela

In Venezuela the Protocol has not been implemented yet. We have already established the National Biosafety Commission, through a Presidential Decree. The commission already proposed the internal regulation for the fulfillment of provisions of the Biosafety protocol. Such internal regulation has been submitted for the consideration of the National Competent Authority of Biosafety (The Biological Diversity Office of the Ministry of the Popular Power for the Environment) and it is currently analyzed by the legal department of the Office.

Since Venezuela ratified the protocol in 2003, it is conscious that the Protocol establishes a procedure for the regulation of any LMOs transboundary movement, and it is working toward having the national regulation needed to complement the effectiveness of the Protocol in the national territory. Being a party of the Protocol, even though Venezuela does not have a national biosafety regulation, any transboundary movement of LMOs is subjected to the Protocol regulations. So that, any party of export must fulfill Protocol obligations, such as those referred in articles 6 to 11. Also, Venezuelan authorities acknowledge the importance of annexes I, II and III for any LMO transboundary movement application.

The appointment of the National Biosafety Commission (NBC) is an important step for the implementation of the Protocol, since any application can be received by the National Competent Authority and Analyzed by the NBC.

Question 2

Please identify any difficulties arising from the implementation of the procedures, mechanisms and annexes under the Protocol. (paragraph 1(b), decision BS-III/15)

Armenia

Armenia is in the early stage of developing and implementing its national biosafety legislative and regulatory regimes.

As well as there is not enough information and operational experience with the implementation of the Protocol.

Austria

As mentioned above, Norway's legislative measures implementing the Cartagena Protocol are more detailed than the Protocol, and Norway therefore largely relies on these national legislative measures and not primarily on the Protocol's procedures, mechanisms and annexes. Our possibility to identify any difficulties arising from the implementation of these procedures, mechanisms and annexes is therefore limited.

Norway is however in the process of considering a response to Notification 2006-53 of 1 June 2006, inviting Governments to submit views on difficulties with, and suggestions for improvements of the Biosafety Clearing House.

Barbados

See Question 1.

Belize

Applying the procedures associated with import of LMOs may be problematic for small developing states in that the expertise for a sound decision based on risk assessment (Annex III) may not be available. Performing the risk assessment in itself is a difficult task especially when the party of export is reluctant to provide "additional" information on the commodity of import. Of course, difficulty will also arise if the country does not yet have a sound policy or a well defined policy on GMOs. This is the current case for Belize who is still in the process of developing its Policy based on input following extensive consultation with a wide array of individuals organizations, institutions, regulatory agencies and the general public. Perhaps when this policy is in place the implementation of the Cartagena procedures will be better defined.

Bhutan

Bhutan has not implemented any procedures or mechanisms and annexes under the protocol.

Bulgaria

Bulgaria has no experience with the procedures, listed in this question due to the fact of not being a country of import/export in the context of Biosafety Protocol during the reported period.

Cambodia

Difficulties implementing the procedures, mechanisms and annexes under the protocol are mainly coming from the lacking of capacity in terms of human expertise, lab facilities on LMOs detection and coordination among line agencies.

Capacity for detecting and LMOs identification is necessary for Cambodia to be preparedness when encountering transboundary movement of LMOs.

The country is awaiting the national law to be passed by the parliament for implementation. The draft law is at the third committee dealing with trade, agriculture, rural development and environment of the Parliament.

Cameroon

- The difficulty from our experience is importations unknown to the Competent Authority (hence procedures mechanisms and annexes to the Protocol could not be respected as already indicated in (1) above)
- The institutional and regulatory frameworks were not fully functional (inadequate resources human, financial and material).
- Poor execution of instructions from the Competent Authority

Canada

While, as a non-Party, Canada is not obligated to implement the Protocol's procedures, Canada believes that clarification of the implementation procedures for various provisions of the BSP is important for both Parties and non-Parties.

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

Colombia

Como se manifestó en la pregunta precedente, para Colombia los procedimientos, mecanismos y anexos establecidos en el Protocolo de Cartagena, hasta la fecha han sido funcionales y adecuados para la evaluación y gestión de los riesgos que para la conservación y uso sostenible de la biodiversidad, teniendo también en cuenta los riesgos para la salud humana, puedan derivarse del desarrollo de actividades con Organismos Vivos Modificados.

No obstante, Colombia considera importante que en el contexto de la revisión de eventuales dificultades y retos para fortalecer la implementación de los procedimientos y mecanismos bajo el Protocolo, se pueda avanzar en la definición de instrumentos y metodologías para la evaluación de las consideraciones socio económicas, de conformidad con lo establecido en el Artículo 26 del Protocolo, pues este ha sido un aspecto de difícil implementación y desarrollo.

De igual manera, Colombia se encuentra adelantando el proceso de consolidación de acciones que permitan integrar de manera más dinámica y efectiva a sectores de la sociedad civil, como es el caso de comunidades indígenas, afrodescendientes y locales, ONG, sectores de aduanas y comercio entre otros. Así mismo, de acuerdo con la normatividad nacional en materia de participación pública el país se encuentra en el proceso de definir los mecanismos e instrumentos para garantizar la participación del público en el proceso de adopción de decisiones en materia de Bioseguridad y OVM, de acuerdo con lo establecido en el Artículo 23 del Protocolo de Cartagena.

Costa Rica

El procedimiento aplicado de manera específica, indicado en el articulo 7 del Protocolo de cartagena de un primer movimiento transfronterizo de un evento, crea una dificultad de interpretación, ya que en el desarrollo de esta tecnología pueden presentarse muchos movimientos transfronterizos de un OVM de diferentes aplicantes que se refieren a un mismo constructo en diferentes variedades o germoplasmas, por lo que Costa Rica evalúa los movimientos caso por caso para cada solicitante

Actualmente, el país tiene deficiencia de herramientas para la gestión de los riesgos. Sin embargo, se están generando esfuerzos para el desarrollo de guías, protocolos de bioseguridad y diferentes herramientas con el fin de garantizar la mejor gestión de los riesgos que se identifiquen en la toma de decisiones, mediante la cooperación y participación en proyectos regionales y proyectos nacionales que van a satisfacer estas necesidades.

En el tema de la aplicación de los artículos relacionados con monitoreo y seguimiento, una de las dificultades del país para el buen cumplimiento del PCSB, es que no existen sistemas de detección de OVMs.

Asimismo, y aún cuando Costa Rica cuenta con experiencia acumulada en la liberación de OVMs de uso agrícola, especialmente en liberaciones experimentales y servicios de contraestación de plantas modificadas genéticamente, regulados en Costa Rica, el sistema todavía tiene poca capacidad para:

- Analizar OVMs diferentes de plantas que puedan ser liberados al ambiente, tales como insectos, animales, microorganismos, etc.
- Estudios y análisis de nuevos rasgos que no han sido estudiados en el campo como biofarmacéuticos, biocomponentes, biorremediación y algunos otros productos de las nuevas generaciones de la biotecnología.
- Estandarizar la información para publicar, debido a que se consume mucho tiempo en resumir la información que fue utilizada para cada decisión, basada en estudios de caso y porque alguna de la información se clasifica como confidencial por los aplicantes.

Por otra parte, con respecto al Artículo 11, Costa Rica debe de armonizar la legislación nacional vigente o crear nueva, conforme al PCSB. Actualmente, el Artículo 11 no puede ser adecuadamente aplicado en el país, debido a que la autoridad nacional competente que debe tomar la decisiones no cuenta con la capacidad técnica y administrativa en el ámbito de su competencias ni una claridad extrema de sus obligaciones, por lo que es fundamental el desarrollo y apoyo en este tema.

Croatia

Since capacity building is an essential element and avails countries to implement provisions, procedures, mechanisms and annexes of the Protocol in order to comply with their obligations under the Protocol, Republic of Croatia is facing the same difficulties as so many other countries. For more details, please refer to the First National Report, questions under Art. 22 (capacity building).

In addition to lack of human, technical and financial capacities of Republic of Croatia to implement provisions of the Protocol in full, another difficulty is poor flow of information, complex channels of communication, inadequate information sharing among competent national authorities (various ministries) as well as absence of coordination and cooperation on problematic scientific issues between administrative officials/regulators and research institutions (universities and institutes).

European Community

As mentioned above, to a very large extent the European Community and its Member States do not rely exclusively on the procedures and mechanisms established by the Protocol in order to achieve its objectives. This makes it hard to identify if specific issues arising in the implementation of the EU regulatory framework will also be relevant for the implementation of the procedures, mechanisms and annexes of the Protocol.

One mechanism used by the European Community and its Member States is, however, the Protocol's Biosafety Clearing House. The European Community and its Member States are currently working on a submission that identifies difficulties and suggestions for improvements of the BCH.

India

Though presently India is neither an importer nor exporter of LMOs except for the purpose of research and contained use, various private and public institutions are in the process of developing several GM crops and other biotech products. All decisions on the domestic use of living modified organisms are made by the Genetic Engineering Approval Committee (GEAC) on the basis of thorough assessment of the potential risks posed by the organism, under stringent requirements of the Rules, 1989 and Biosafety Guidelines of 1994 and 1998. Risk assessment requirements under the Rules, 1989 are consistent with the requirements under the Protocol, and as are provided for in Annex III.

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In the absence of experience in implementing the various procedures, mechanisms and annexes under the Protocol, the constraints or difficulties arising in the implementation of the Protocol cannot be assessed at this stage.

However, India is aware of its obligation and measures that need to be taken if India becomes a major exporter/importer of LMOs in future. Initiatives taken by India to meet its obligations include strengthening the institutional capabilities, development of infrastructure and enhancing core competence of the personnel.

Japan

There were cases that GM aquarium fishes were imported into Japan without following the AIA procedure. The effective implementation of the Protocol requires the compliance of the Protocol, including the implementation of appropriate AIA procedures, not only by the importing countries but also by producing or exporting countries.

Therefore, Japan considers that the conclusion of and accession to the Protocol by major LMO producing and exporting countries is important. In addition, the Parties need to control the domestic use of LMOs and to inform their developers and exporters to take appropriate measures required under the Protocol for the export of LMOs.

Lithuania

No experience

Madagascar

Jusqu'à présent, Madagascar n'a pas rencontré de difficulté dans l'application de procédures, de mécanismes et annexe du Protocole en ce sens où il n' y a pas encore eu de mouvement d'organismes génétiquement modifiés

Malaysia

See question 1.

Republic of Moldova

Moldova has not been a party of LMOs imports/export, there is no any country experience for implementation of procedures, mechanisms and annexes under the Protocol.

New Zealand

As noted in the response to question 1 of this questionnaire, New Zealand to date has no practical experience in implementing Articles 7 through 12 of the Protocol, or in application of the information requirements under Annex I or Annex II.

We consider that analysis of the First Regular National Reports on Implementation of the Protocol, in combination with an assessment of the information provided by Parties to the Biosafety Clearing House, will provide information valuable in identifying any difficulties arising from the implementation of the procedures, mechanisms and annexes under the Protocol.

From New Zealand's perspective, some difficulty was encountered in interpreting the extent of information and domestic decisions appropriate for notification to the Biosafety Clearing House. A comprehensive approach has been taken whereby all decisions relating to the regulatory approval of any LMOs for domestic use have been notified to the BCH. Access to associated information regarding assessment of risk has also been provided where appropriate.

The area we have found most problematic concerns practical limitations in relation to the resources required to provide information to the Biosafety Clearing House. Populating the BCH has not in itself proved troublesome, however, resource constraints effectively limit the ability of officials to proactively

back-capture information generated through domestic decision-making processes before entry into force of the Protocol for New Zealand.

In this regard we note particularly Decision BS-I/3, relating to Information-sharing and the Biosafety Clearing-House (Article 20): modalities of operation of the Biosafety Clearing-House.

Parties to the Protocol recognised in Decision BS-I/3 that

"some developing countries, in particular the least developed and small island developing states among them, either do not have access to the Internet, or experience periodically unreliable telecommunication networks, and/or unaffordably high cost of access to the Internet, as well as inadequate information technology and competent human resources capacity to access and manage Internet-based information."

Given the above noted constraints New Zealand has experienced in populating the Biosafety Clearing House, and taking into account the special needs of some Parties, we are concerned that there may increasingly be potential for the effectiveness of the BCH as a mechanism to facilitate the exchange of information on, and experience with, LMOs for the purposes of assisting Parties to implement the Protocol may be undermined, on the basis that a surplus of information may hamper Parties' abilities to extract the particular information of value for their own specific needs.

Nigeria

N/A

Norway

As mentioned above, Norway's legislative measures implementing the Cartagena Protocol are more detailed than the Protocol, and Norway therefore largely relies on these national legislative measures and not primarily on the Protocol's procedures, mechanisms and annexes. Our possibility to identify any difficulties arising from the implementation of these procedures, mechanisms and annexes is therefore limited.

Norway is however in the process of considering a response to Notification 2006-53 of 1 June 2006, inviting Governments to submit views on difficulties with, and suggestions for improvements of the Biosafety Clearing House.

Poland

Poland as the Party and the UE Member State has to comply with both the Protocol and the Community law. Some difficulties arising from the division of competences between the Member States and the European Commission in relation to provision of information to the BCH (EU Regulation No 1946/2003). However it constitutes no risk for the function of the BCH and exerts insignificant influence on timely transfer of information between the Polish focal point and BCH.

Switzerland

Switzerland has very little experience with the import and export of LMOs for intentional use in the environment, as well as for LMOs intended for direct use as food or feed, or for processing, whereas the import and export of LMOs for contained use are more frequent.

Therefore there were no particular difficulties arising from the implementation of the procedures mechanisms and annexes.

Tanzania

Not Applicable – To-date the United Republic of Tanzania has no practical experience on the export or import of LMOs. It is difficult to assess its effectiveness as long as we don't have experience on export or import of LMOs.

Thailand

National legislation is needed to effectively implement of the procedures, mechanisms and annexes under the Protocol, Those under the Protocol shall not prejudice with domestic rules, regulation and procedures.

Togo

En l'absence de requêtes d'autorisation d'introduction d'OVMs sur le territoire togolais adressées à l'autorité nationale compétente, et pour les raisons précédemment évoquées, l'application des procédures, mécanismes et annexes du Protocole n'a pas encore été testée. Il n'est donc pas possible, pour le moment, d'identifier les difficultés réelles qui en sont liées.

USA

Despite the fact that the Protocol entered into force nearly four years ago, the United States believes that many countries continue to face significant challenges regarding implementation. We believe that the focus should continue to be on assisting developing country Parties to put in place appropriate systems for making science-based decisions related to the transboundary movement of LMO's.

The United States recognizes that further information regarding the status of implementation of the Protocol is currently being collected through the Parties' submission of First Regular National Reports. However, available information and experience indicate that a considerable number of Parties are still at the early stages of developing and implementing their national biosafety frameworks. Approximately half of the Parties have yet to post information on their national biosafety frameworks to the Biosafety Clearing House (BCH). The BCH shows only two records of decisions made under the Advance Informed Agreement. We also note that 31 Parties and other governments have posted over 500 decisions on LMO/FFP's. This record of decisions represents only a portion of the Parties to the Protocol, suggesting that many Parties have not implemented their obligations under the Protocol. At this time, we concur with the Parties' conclusion at MOP-3 (BS-III/15), that the lack of implementation may not be due to inherent problems with the Protocol, but with a lack of capacity to implement the Protocol.

The United States would like to note our contribution to the development of the BCH through both financial and technical assistance and our provision of information to the BCH. We continue to believe that the success of the BCH is a critical element for the successful implementation of the Protocol.

The United States continues to be committed to sharing our experience in regulating LMO's, to facilitate transboundary movement of LMO's, and to support science-based decision-making.

Venezuela

Since we have not implemented the protocol yet, Venezuela has not had any difficulty with these aspects.

Question 3

Please provide any suggestions for appropriate indicators and/or criteria for evaluating the effectiveness of the Protocol and ideas on the modalities of the evaluation. (paragraph 1(b), decision BS-III/15)

Armenia

There may be different indicators and criteria for evaluating the effectiveness of the Protocol. But they must be edited and make more concrete in order the use of Protocol become more practice.

Austria

The study conducted by experts proposed in the answer to Question 1 above should include development of proposals for indicators and/or criteria for evaluating the effectiveness of the Protocol to be considered by the Parties to the Protocol.

Barbados

See Question 1.

Belize

I believe some of the more important indicators for evaluating the effectiveness of the Protocol include:

An increase in the information provided to the BCH in a transparent manner

Surveys/reports requested from parties on the difficulties encountered in implementing the Protocol

Evaluation of Country legislation that deal with the regulation of LMOs to assess its compatibility with the tenets of the protocol.

Wide adoption (where appropriate) of the Protocol procedures, annexes by international standard setting bodies

Bhutan

No information.

Bulgaria

Bulgaria has no experience with the procedures, listed in this question due to the fact of not being a country of import/export in the context of Biosafety Protocol during the reported period.

Cambodia

The criteria for evaluating the effectiveness of the protocol under decisionBS-III/15 paragraph 1(b) should cover:

- Existing domestic regulation on biosafety;
- Supportive mechanism in place;
- Capacity Development to tackle RA and RM in the country;
- Simplicity of the procedure for LMOs release in the environment; and
- Cooperative

Cameroon

- Existence of comprehensive and functional legal and regulatory framework;
- Existence of adequate and stable resources (human, financial, material);
- Existence of effective institutional framework.

Canada

With 142 Parties to the BSP, Canada believes the Protocol is now at a stage where it needs to begin focusing on quantitative performance measurements. Such indicators should focus on the impact of transboundary movement of LMOs on biodiversity, before and after implementation of the Protocol by Parties. In evaluating the effectiveness of the Protocol, as contributing to an adequate level of protection of biodiversity, indicators could include:

- a) Ecological baseline data;
- b) Level of compliance of submissions to the BCH, for example,
 - Number of AIA and FFP submissions and decisions (pre and post Protocol),
 - Availability of information on risk assessment, management and decisions, and
 - Notifications of unintentional transboundary movements;
- c) Incorporation of indicators from Capacity Building Action Plan, including establishment of Competent National Authorities and Focal Points, Risk Assessment/Risk Management procedures, operational BCH, and incorporation of biosafety into national agendas; and
- d) Detailed Party reports on application of the documentation provisions.

On modality of evaluation, the most effective process would be data gathering through a detailed questionnaire on each indicator, followed by a detailed analysis.

Colombia

Como criterios e indicadores para evaluar la efectividad del Protocolo se consideran:

- Numero de Partes con marcos normativos nacionales en Bioseguridad.
- Número de Informes de Implementación reportados por las Partes.
- Numero de Estados Parte del Protocolo frente a números de Estados Parte del Convenio de Diversidad Biológica.
- Número de iniciativas de cooperación y de acuerdos entre Partes para la implementación del Protocolo, con especial referencia a Partes que se consideren Economías en desarrollo.
- Número de sinergias entre el Protocolo de Cartagena y otros acuerdos multilaterales en medio ambiente, comercio y sanidad.

Como sugerencias de modalidades de evaluación se presentan las siguientes:

- Diseño y distribución a los Estados Parte de una serie de encuestas direccionadas a recopilar información relevante relacionada con los indicadores referidos.
- Sistematización, análisis y puesta a disposicición entre las Partes de la información compilada.
- Determinación de aspectos críticos y cuellos de botella relevantes para la efectividad e implementación del Protocolo y formulación de sugerencias y alternativas para su solución.

Costa Rica

Algunos criterios apropiados para la evaluación serían:

- La aplicación de regulaciones nacionales o regionales paralelas para la implementación conjunta de normativas relacionadas con los Organismos Vivos Modificados.
- El grado de desarrollo de la industria biotecnológica y su nivel de comercio internacional.
- Los índices de exportación de los países productores de OVMs en comparación con los índices de comercio internacional e importación de países parte del PCSB.

• Cantidad y calidad de los registros dentro del CIISB/BCH.

Croatia

Procedures, mechanisms and annexes under the Protocol have been of a great value as a guidance and tool to Parties in their process of development of national biosafety legislations.

Indicators/criteria for evaluating the effectiveness of the Protocol might be the same as for assessing the results and success of the implementation of the Protocol and they might be the following:

- 1. Information submitted in the National Reports is a good indicator for evaluating the effectiveness of the Protocol.
- 2. State of the BCH Records:
- For example, the Secretariat might monitor the BCH records and review data every 3-6 months to see substantive activity of a particular Party (ies) and change of information in provision of their substantive records, e.g. national legislation, risk assessment reports, etc.
- Roster of Experts should be completely revised and more operational in order to improve effectiveness of the Protocol. Working experience(s) and expertise in particular areas should be clearly indicated and such information reviewed by the national competent authorities, Cartagena NFP on Biosafety and the Secretariat before listing it on the BCH. Roster of experts should be efficient tool for implementation of the provisions under the Protocol and its effectiveness. At the moment, Roster is rarely utilized and inadequate. High quality Roster of experts and the efficiency of experts in providing advice to Parties upon requests might be an indicator of the effectiveness of the Protocol.
- Increase in number of Parties capable of performing independently scientifically sound risk assessment and risk management and accordingly, increase of risk assessment reports on the BCH. At the moment, only few Parties were able to conduct such assessments and accordingly, in the position to submit their risk assessment reports/summaries.
- Absence of any difficulties, obstacles and problems on the ground in each country Party to the Protocol in implementation of any of its provisions might be an indicator that the Protocol is completely effective. Such information is evident from the national reports.
- 3. Increase in sub-regional, regional, bilateral and multilateral cooperation concerning the biosafety and GMO issues.
- 4. Increase in number of fully developed national biosafety frameworks that are operational in all segments (mainly evident through the BCH records of Parties and their National Reports).
- 5. Absence of any case of non-compliance might be an immediate and direct indicator that Parties have no difficulties in implementing provisions of the Protocol, and as such, might be an indicator of the effectiveness of the Protocol.

European Community

The EU favours developing and testing a small pilot set of meaningful indicators as part of the suggested expert study on the effectiveness of the Protocol to enable Parties to better consider appropriate indicators.

India

Some of the indicators and/or criteria for evaluating the effectiveness of the Protocol are suggested below:

• Whether Parties have put in place the required domestic, legal and administrative measures consistent with the procedures, mechanisms and annexes under the Protocol.

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- Whether a Party is an importer and/or exporter of LMOs. Effectiveness of the Protocol can be evaluated only when a country has enough experience of importing and exporting LMOs. There should be separate proforma for the countries having experience as importer or exporter.
- Capacity and financial resources required for implementing the legal and administrative measures.
- Whether BCH is serving its intended purpose in providing enough information
- Whether there is a technical competence to certify the presence of LMOs in transboundary movement.

The effectiveness of the protocol may be evaluated in terms of time viz. short term, medium term and long term.

Japan

No particular comment. Check list for evaluation could be an option.

Lithuania

No experience

Madagascar

Actuellement, nous n'avons pas de suggestions d'indicateurs parce qu' il n'y a pas encore de cas qui se présente à Madagascar.

Malaysia

See question 1.

Republic of Moldova

We consider that indicators and criteria of evaluation of the Protocol should reflect the grade of realization of the main objective of the Protocol, i.e. ,... to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements".

The important criteria of evaluation of the effectiveness of the Protocol should be axed to the operational security with LMOs in the following cases:

- Safe transfer of LMOs
- Handling of LMOs
- LMOs use;
- Effects on the conservation and sustainable use of biological diversity
- Adverse risks to human health
- Transboundary movements

Some of the following indicators could be used during the evaluation of the effectiveness of the Protocol:

- 1. Institutional setting-up in place (i.e. amount of countries Part of the Protocol/all countries Part of the Protocol)
- 2. Administrative systems in place
- 3. Regulatory system in place

- 4. Procedural requirements in place Art. 7-13
- 5. Decisions according the CP requirements / all amount of LMOs approvals.
- 6. Effectiveness of the implementation of the following articles of the Protocol:
 - Art. 6 transit and contained use
 - Art. 11 procedure for living modified organisms intended for direct use as food or feed, or for processing
 - Art. 14 bilateral, regional and multilateral agreements and arrangements
 - Art. 15 risk assessment
 - Art. 16 risk management
 - Art. 17 unintentional transboundary movements and emergency measures
 - Art. 18 handling, transport, packaging and identification
 - Art. 20 information sharing and the biosafety clearing-house
 - Art. 19 competent national authorities and national focal points
 - Art. 21 confidential information
 - Art. 22 capacity-building
 - Art. 23 public awareness and participation
 - Art. 24 non-parties
 - Art. 25 illegal transboundary movements
 - Art. 26 socio-economic considerations
 - Art. 27 liability and redress
 - Art. 28 financial mechanism and resources

New Zealand

Decision BS-I/3

Urges all Parties, governments and other users to provide relevant information to the Biosafety Clearing-House as soon as possible, including information pertaining to decisions on the release or import of living modified organisms taken prior to entry into force of the Protocol.

However, if information is provided in a manner that is not readily accessible or applicable to Parties seeking to retrieve and utilize that information in their decision-making, the BCH may in practice not be meeting its purpose or objective.

In as much as the operation of the Biosafety Clearing-House is a Standing Issue under the *Medium-Term Programme of Work of The Conference of The Parties Serving as The Meeting of The Parties to The Protocol* (as provided for in the annex to decision BS-I/12), New Zealand considers it may be appropriate for Parties to evaluate, the effectiveness of the Biosafety Clearing House (as it currently operates) as a tool for assisting Parties to implement the Protocol.

Nigeria

There should be indicators on the nos. of applications withdrawn and reason for withdrawal.

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Norway

The study conducted by experts proposed in the answer to Question 1 above should include development of proposals for indicators and/or criteria for evaluating the effectiveness of the Protocol to be considered by the Parties to the Protocol.

Poland

The objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements. Full implementation of the Protocol should lead to the utter elimination of disputes and cases of non-compliance. Therefore in our view the most reliable indicator for evaluating the effectiveness of the Protocol could be a quantity of conflicts between Parties, resulting from illegal transboundary movements of LMOs, contravention of principals on handling and use of LMOs for experimental and commercial purposes *et cetera*. Such cases are more visible in comparison with other cases of non-compliance. They could be subject to monitoring and remain under the scrutiny of Secretariat or other competent authorities.

Any cases of illegal transboundary movements of LMOs should be put in BCH as soon as possible (the name of user, the name of product being the subject of illegal transboundary movement, scale of infringement).

Switzerland

N/A

Tanzania

Not Applicable – To-date the United Republic of Tanzania has no practical experience on the export or import of LMOs. It is difficult to make any suggestion as we don't have any practical experience on used indicators.

Thailand

- 1. Suggestions for Indicators:
- Number of AIAs procedures accomplished by the Party of Import and Export of LMOs
- A decreased number of non-compliances to the Protocol with respect to number of LMOs transboundary movements, region or year.
- 2. Modalities of the evaluation
- Survey an increase of national implementations of the protocol by categories of procedures/mechanisms.

Togo

Sans objet

USA

Given the current state of implementation, the United States believes that it is still too early to try to measure the effectiveness of the Protocol in a meaningful way. In response to the Secretariat's request for suggestions for appropriate indicators for evaluating the effectiveness of the Protocol, we would emphasize that indicators should be restricted to those that measure impacts to biodiversity related to the transboundary movement, transit, handling and use of LMOs, which is the scope of the Protocol.

Venezuela

In Venezuela there is insufficient information and operational experience with the implementation of the Protocol. However, the implementation of the protocol is feasible in the country, since Venezuela has the

appropriate legal framework, infrastructure and competent professionals for the proper analysis of any application regarding LMOs. In this regard, it is important to emphasize that even though Venezuela does not have a specific regulation for Biosafety issues, it does have a legal framework that would allow to make decisions on this subject.

Question 4

Within the framework of your overall evaluation of the effectiveness of the Protocol above, please assess the effectiveness of the procedures and mechanisms on compliance under the Protocol as provided for in the annex to decision BS-I/7 (available at http://www.biodiv.org/biosafety/cop-mop/result.aspx?id=8289). Please include your views on measures concerning cases of repeated non-compliance and on rule 18 of the rules of procedure of the Copmpliance Committee regarding voting. (paragraph 1, decision BS-III/1)

Armenia

Within the framework of your overall evaluation of the effectiveness of the Protocol, it is too early to undertake the review of the effectiveness of the compliance procedures and mechanisms. Armenia has no appropriate legal and administrative measures at the national level to implement the necessary activities.

Austria

Norway fully supports the procedures and mechanisms on compliance established under the Cartagena Protocol and consider them to be an important element in order to secure the effectiveness of the Protocol. The Compliance Committee has so far reviewed general issues of compliance by Parties with their obligations under the Protocol. The Committee has not considered any specific cases of non-compliance by individual Parties to the Protocol. Norway is currently considering its position on measures concerning cases of repeated non-compliance and rule 18 of the rules of procedure of the Compliance Committee regarding voting.

Barbados

See Question 1.

Belize

Non compliance that occurs repeatedly even after determination of the cause of noncompliance and the provision of support to the party to address the issues resulting in noncompliance should be referred to the non compliance committee for action through voting by a majority vote.

Bhutan

No information

Bulgaria

Bulgaria has no experience with the procedures, listed in this question due to the fact of not being a country of import/export in the context of Biosafety Protocol during the reported period.

Cambodia

With regard to the rule 18 of the rules of procedure of the Compliance Committee regarding voting, Cambodia viewed that it is necessary to apply the rule shall be enforced and especially on the non-compliance of repeated cases to ensure improvement of the compliance cases and the effectiveness of the Protocol implementation.

Cameroon

- The first import of GMO between Cameroon as a party and a non-party (Argentina) was illegal because the National Competent Authority was not notified of the transboundry movement by the importer, thus Cameroon was not in a position to ensure compliance to the Protocol.
- Cameroon does not have experience with repeated cases of non-compliance

Canada

As there have been no individual cases of non-compliance referred to the Committee to date for consideration, there consequently have not been any "cases of repeated non-compliance". Therefore, the adequacy of the current rules cannot be assessed.

As regards Rule 18, there has been no evidence brought forward by the Committee that this rule has hindered its deliberations to date on general issues of compliance. As no individual cases of non-compliance have been referred to the Committee, the rule cannot currently be assessed. As the overall decision-making rule for the Meeting of the Parties is consensus, we consider that a similar rule for a subsidiary body such as the Compliance Committee is most appropriate.

Therefore there would not appear to be any basis on which to assess the compliance procedures or Rule 18 or the need to revise it at this time.

Colombia

El Protocolo se encuentra en una etapa temprana de implementación para evaluar la efectividad de los mecanismos de cumplimiento de acuerdo a la Decisión BS-I/7, en razón de lo cual se considera que conforme fue aprobado en MOP 3, los eventuales casos de incumplimiento o casos reiterados de incumplimiento y el sistema de voto en el Comité de Cumplimiento debe ser revisado en el contexto del Artículo 35 del Protocolo, adicional al fortalecimiento que debería darse al Comité de Cumplimiento y a la evaluación de la posibilidad de propiciar reuniones con mayor periodicidad de los Grupos Regionales.

Colombia no ha evidenciado casos de incumplimiento y menos aun de reiterado incumplimiento del Protocolo. No obstante, en la legislación nacional en el Código Penal Colombiano (Ley 599 de 2002), ha sido incorporada regulación relacionada con cel incumplimiento por parte de nacionales de los requerimientos y procedimientos establecidos para la importación y desarrollo de actividades con OVM. Esta norma establece que aquel que con incumplimiento de la normatividad existente realice actividades de modificación genética o introduzca ilegalmente al país organismos modificados genéticamente, con peligro para la salud o la existencia de los recursos faunísticos, florísticos o hidrobiológicos, o que alteren perjudicialmente sus poblaciones, incurrirá en prisión de dos (2) a seis (6) años y multa de trescientos (300) a diez mil (10.000) salarios mínimos legales mensuales vigentes. Si se produce enfermedad, plaga o erosión genética de las especies, la pena se aumentará en una tercera parte

Costa Rica

El artículo 18.2b y el 18.2c son requerimientos establecidos en la legislación nacional de Costa Rica. Cada aplicante además, debe desarrollar protocolos de transporte, manipulación, envase e identificación de OVMs en Costa Rica. Cada solicitante tiene que tener protocolos de transporte y todos los OVMs deben estar bien identificados.

El artículo 18.2a, en el que se indica la premisa de "puede llegar a contener" y la respectiva documentación que acompaña el OVM para consumo humano, animal o para procesamiento, se debe implementar y establecer los acuerdos relacionados con los niveles de OVM; como se describió previamente la Autoridad Nacional Competente debe hacer cumplir lo indicado en la legislación vigente, como es el PCSB y llegar a un consenso sobre la manera de implementar esta parte de la legislación.

Croatia

a) Effectiveness of the procedure and mechanisms on compliance:

Objective, nature and underlying principles of the compliance procedures and mechanisms as well as the functions of the Compliance Committee under the Protocol, as listed in Annex to decision BS-I/7 are well laid down and clearly defined.

Taking into account different financial and technical capacities of the Parties, it is important and unavoidable that the Compliance Committee in cases of non-compliance first considers the facilitation procedure to help the Party concerned.

In the case of its recommendation to develop a compliance action plan and/or strategy, it is important that financial resources are defined and secured in advance through some type of the financial assistance.

b) Views on measures concerning cases of non-compliance:

Measures should be taken only in cases when facilitation procedures, advice, assistance, public notification of non-compliance and compliance action plan/strategy have failed. The cause, type, degree and frequencies of compliance difficulties, including financial and technical capacities of the Parties should be taken into account.

When deciding on measures to take to achieve compliance, there has to be range of sequential and graduated responses/actions to cases of non-compliance.

- 1. Restriction of the right to vote at one or more meetings of the COP-MOP.
- 2. Ineligibility of a Party to have a member in any future subsidiary body under the Protocol and/or part of any current legal, scientific, administrative forum/body under the Protocol and/or under the Convention on Biological Diversity (e.g. COP Bureau member).
- 3. Financial penalties:
- Ineligibility of a Party to have its participation in a meeting of the COP-MOP or any other intersessional meeting(s) funded by the Secretariat of the CBD.
- Ineligibility to receive any other financial assistance from available fund(s) under the Protocol, the Convention and/or UNEP-GEF.
- 4. Declaration of a Party to be a "non Party" in cases of persistent non-compliance.

c) Views on Rule 18 regarding voting:

For taking decision on matters of substance, Republic of Croatia is favoring a two third majority voting in case where all efforts to reach consensus have been exhausted.

European Community

The European Community and its Member States find that only part of this question can be answered at this stage, since so far the compliance mechanism has not been used to support compliance and address cases of non-compliance of individual Parties.

However, considering some of the first national implementation reports submitted by Parties, it seems evident that many countries are still struggling to fully implement the Cartagena Protocol. The European Community and its Member States therefore strongly appreciate the regular review undertaken by the Compliance Committee of general issues of compliance by Parties with their obligations under the Protocol (see Section III.1 (d) of the Annex to Decision BS-I/7). As part of these reviews the Committee might also include assessing why so far the compliance procedures and mechanisms established under the Cartagena Protocol have not been used for providing advice or assistance to Parties that continue to struggle with national implementation.

Furthermore and in line with previous positions, the European Community and its Member States strongly support the removal of brackets around Rule 18 paragraph 1 of the Rules of Procedure of the Compliance Committee adopted by Decision BS-II/1. Not allowing for majority voting in matters of substance once all efforts to reach consensus within the Compliance Committee have been exhausted is at odds with the compliance mechanisms of all other multilateral environmental agreements. It also ignores the fact that members of the Compliance Committee serve objectively and in a personal capacity (see section II.3 of the annex to dec. BS-I/7).

As regards repeated cases of non-compliance, the European Community and its Member States wish to recall that they have argued in the past for a suspension of rights and privileges of Parties that are persistently or wilfully in non-compliance with obligations established under the Protocol. Under current circumstances, however, it does not seem a priority to address this issue. The EU will re-consider the

issue of repeated cases of non-compliance in future effectiveness evaluations undertaken in accordance with Article 35 Cartagena Protocol.

India

Views on measures concerning cases of repeated non-compliance:

The analysis of information provided through the national interim reports indicates the following:-

- 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 country has reported on decisions taken
 under the advance informed agreement procedure for importing living modified organisms for
 intentional introduction into the environment:
- Mechanisms and measures to implement the Protocol provisions are largely operational and are being implemented in developed country Parties however, in many developing country Parties, national legislative frameworks for biosafety are still at drafting stage, and therefore cannot be implemented as yet;
- Although in many cases a lot of information is available at the 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;
- 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 legislative frameworks;
- There are a number of capacity-building initiatives in place, and the donor institutions are working together to implement the same. However, finances available to meet the capacity building needs are not adequate.

India is of the view that measures recommended by the Compliance Committee for non-compliance should be non-punitive and suggestive in nature (taking into consideration lack of capacity among the developing countries). Since measures against cases of repeated non—compliance come into picture only after all options and measures recommended by the Compliance Committee to facilitate compliances are exhausted, decision on measures concerning cases of non-compliance may be taken after more experience is gained.

Views on rule 18 of the rules of procedure of the Compliance Committee regarding voting

The mandate of the Compliance Committee is to report cases of non-compliance and recommend measures to facilitate compliance taking into consideration the capacity of the Party. Therefore two-thirds majority is acceptable, as the final decision will be taken by COP-MOP by consensus.

Japan

Japan considers it is still too early to assess and evaluate the performance of the Compliance Committee established by BS-I/7. The lack of any submission of specific cases to the Committee does not itself reflect its ineffectiveness. It requires certain time for the Committee to garner trust among the Parties so as that the mechanism would indeed function to assist the Parties to comply with the Protocol, rather than to punish or blame them.

The compliance mechanism, being cooperative in nature (Section I, Paragraph 2), should work on the basis of consensus. If there are divisions among the members of the Committee, it would be difficult to cultivate trust and authority which are necessary for the Compliance Committee.

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Lithuania

No experience

Madagascar

N/A

Malaysia

See question 1.

Republic of Moldova

We consider the effectiveness of the procedures and mechanisms on compliance under the Protocol as provided for in the annex to decision BS-I/7 at a good level.

The measures concerning cases of non-compliance and on rule 18 of the rules of procedures of the Compliance Committee regarding voting are effective and satisfactory.

New Zealand

New Zealand has no specific comment to make at this time in relation to the effectiveness of the procedures and mechanisms on compliance under the Protocol as provided for in the annex to decision BS-1/7.

Nigeria

There should be a mechanism for applicants to inform the public of applications made and their status of approval in the BCH, to check level of compliance.

Norway

Norway fully supports the procedures and mechanisms on compliance established under the Cartagena Protocol and consider them to be an important element in order to secure the effectiveness of the Protocol. The Compliance Committee has so far reviewed general issues of compliance by Parties with their obligations under the Protocol. The Committee has not considered any specific cases of non-compliance by individual Parties to the Protocol. Norway is currently considering its position on measures concerning cases of repeated non-compliance and rule 18 of the rules of procedure of the Compliance Committee regarding voting.

Poland

It seems that only possible and right measure to solve all disputes between Parties including those which concern cases of repeated non-compliance should remain bilateral and multilateral negotiations. Some cases of non-compliance can result from a shortage in the field of capacity building. Therefore Mechanism on compliance under the Protocol shall take into consideration various reasons which are sometimes entirely independent from a Party. Too strict measures would be harmful especially for developing countries Parties and Parties with economies in transition.

Switzerland

Concerning the effectiveness of the procedures and mechanisms on compliance it has to be pointed out that no individual case of non-compliance had been submitted to the Compliance Committee so far. In addition the Committee could up to now not review as mandated general issues of compliance because the deadline for submitting national reports had not been expired yet.

Concerning cases of repeated non-compliance we can not give you our view as long as not one single individual case of non compliance had been reported yet.

Tanzania

Not Applicable – To-date the United Republic of Tanzania has no practical experience on the export or import of LMOs. Therefore, we are not in a position to assess its effectiveness.

Thailand

No comments

Togo

Sans objet

USA

The United States believes the existing compliance procedures and mechanisms are sufficient to promote compliance by Parties and do not consider it beneficial, or consistent with Article 34, to add new more punitive measures in cases of repeated non compliance.

With regard to rule 18, it continues to be the position of the United States that it is vital to the successful operation

Venezuela

Since in Venezuela there is insufficient information and operational experience with the implementation of the Protocol. There is no mechanism or procedure established on compliance.

However, Venezuela agrees that compliance procedures and mechanisms shall be simple, facilitative, non-adversarial and cooperative in nature, as stated in decision BSI-7. Also, the operation of compliance procedures and mechanisms, in Venezuela, will be guided by the principles of transparency, fairness, expedition and predictability.
