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COMPLIANCE COMMITTEE UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY

Second meeting

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Item 4 of the provisional agenda*

REVIEW OF GENERAL ISSUES OF COMPLIANCE

Analysis of interim national reports and information in the Biosafety Clearing House

Note by the Executive Secretary

INTRODUCTION

1. The Compliance Committee under the Cartagena Protocol on Biosafety held its first meeting from 14 to 16 March 2005 in Montreal. At that meeting, the Committee developed its rules of procedure and adopted a work plan for the period up to the time of review of the procedures and mechanisms on compliance under the Protocol is carried out by the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP). It was also understood that the work plan would be subject to review at each meeting of the Committee in light of new developments.
2. The Committee further agreed to consider, at its second meeting, general issues of compliance that may arise from interim national reports, which were due not later than the end of the first two years after the date of entry into force of the Protocol. Review of general issues of compliance is one of the functions of the Committee stipulated in paragraph 1(d), section III of the Procedures and Mechanisms on Compliance adopted under the Protocol in the annex to decision BS-I/7 of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. The Committee also considered that information in the Biosafety Clearing-House (BCH) would also be taken into account in its consideration of general issues of compliance. In this regard, the Committee asked the Secretariat to prepare necessary documentation. Accordingly, the Secretariat prepared the present document to facilitate the work of the Committee in its consideration of general issues of compliance.
3. The present document contains, in section II, the summary of some general compliance related issues as identified through the analysis of interim national reports, on the one hand and the review of information in the BCH, on the other. Section III of the note presents, for the consideration of the Committee, possible elements for draft recommendations that it may wish to submit to the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol as regards addressing

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the general issues emerged from the review, and promoting compliance in the implementation of the Protocol.

II. GENERAL ISSUES OF COMPLIANCE

A. *Analysis of interim national reports*

4. Interim national reports were due to be submitted by 11 September 2005. By 11 October 2005, the Secretariat received interim national reports from 44 Parties to the Protocol. The submissions were made in accordance with decision BS-I/9 of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. The reports include: 7 from Africa; 4 from Asia & Pacific; 5 from Latin America and the Caribbean; 12 from Central and Eastern Europe; and 16 from Western Europe and Other States Group. The Secretariat has prepared an analysis of these reports for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol. The statistical summary of the information provided in the interim national reports is presented in an information document (UNEP/CBD/BS/COP-MOP/3/INF/8). The analysis of the reports is available to the present meeting in a note by the Executive Secretary (UNEP/CBD/BS/COP-MOP/3/12). The full text of each report is available through the BCH at: <http://bch.biodiv.org/protocolreports/>

5 For the purpose of this document, 'general issues of compliance' may be understood to mean 'issues relating to the problems of several Parties to fully and effectively implement the Protocol, and that may require a concerted action or cooperation by all Parties in order to overcome them and ensure compliance'.

6. Based on the analysis of the interim national reports, the following major issues of a general nature affecting several Parties with respect to their compliance to the Protocol may be derived*:

(i) ***Legal and administrative measures necessary to implement the Protocol (paragraph 1, Article 2):***

Several reports recognize that there is a time lag in taking, at national level, legal and administrative measures that are necessary to implement the Protocol. In case of a number of developing country Parties respondents, national biosafety frameworks are either absent, or are still under preparation, or even if they exist in draft or planning form, their Governments have not yet adopted them. In other cases, even if the national biosafety frameworks exist, they are not fully operational or they lack the tools and the mechanisms necessary for implementing them.

The existence of other competing priorities at the national level, and time-taking administrative procedures in processing projects by the implementing/funding agencies, in the case of some Parties that rely on international assistance for developing their national biosafety frameworks, are noted as contributing factors to the delay in putting the necessary legal and administrative frameworks in place. Lack or low level of institutional, financial, human resources, and technical capacities, as well as lack of actual experience in implementing biosafety frameworks, are also indicated as possible reasons for hindering some of the biosafety frameworks that already exist from becoming fully operational.

(ii) ***Risk assessment and risk management (Articles 15 and 16):***

It is acknowledged that there are weaknesses in carrying out sound risk assessment, risk management, and monitoring as regards the long-term effects of living modified organisms.

* The Secretariat would like to point out that the general issues of compliance identified herein on the basis of the analysis of the interim national reports are simply generalizations that should be understood within the limitations of the analysis itself as pointed out in document UNEP/CBD/BS/COP-MOP/3/12.

The possible causes of these weaknesses are noted to be absence or low level of institutional, financial, human resources and technical capacities.

(iii) ***Handling, packaging, transport and identification (Article 18):***

Several reports indicate that there are limitations in knowing about incoming shipments that may contain living modified organisms, and taking the necessary handling measures.

The possible causes attributed to these limitations are the absence or low level of technical and technological capacities necessary for testing and identifying such shipments on the one hand, and the delay in finalizing, at the international level, the detailed identification and documentation requirements for living modified organisms that are intended for direct use as food or feed, or for processing, on the other.

(iv) ***Public awareness and participation (Article 23):***

As it can be seen from some of the reports, there is little or no work undertaken in promoting and facilitating public awareness and participation concerning the safe transfer, handling and use of living modified organisms, as well as facilitating public access to the Biosafety Clearing-House.

Some have acknowledged that this was due to, mainly, lack of enabling legislation and limitations in technical as well as financial capacities to design and implement public awareness and consultation programmes.

B. Review of information available in the Biosafety Clearing-House

7. The Biosafety Clearing-House (BCH) has also been considered as another source of information that could possibly show the extent to which Parties are or are not fulfilling their obligations under the Protocol and consequently helping to identify general issues of compliance.

8. In order to facilitate the review of general issues of compliance by the Compliance Committee based on information available in the BCH, the Secretariat has prepared a summary table on the records in the BCH as submitted by Parties. The statistics compiled in the summary table are based on website analytics carried out as at 10 November 2005. The purpose is to provide a general picture of what percentage of Parties are complying with the requirements of the Protocol to make a variety of information available to the BCH. The summary table is annexed to the present document. For further information on the status of operation and activities of the BCH, document UNEP/CBD/BS/COP-MOP/3/3 is also available.

9. Some of the general issues of compliance that one might derive from the BCH central portal website analytics and from the response that Parties included in their interim national reports under the questions relevant to the provision of information to the BCH, include the following:

(v) ***Information sharing (paragraph 3, Article 20 and other relevant provisions)***

(a) *Several Parties are still behind in fulfilling the requirements to make information available at the date of entry into force of the Protocol to them (such as information on national focal points, national competent authorities), or after, as and when the information exists at the national level (such as national laws, information regarding import requirements, decisions relating to the importation of living modified organisms);*

There are a number of possible reasons explaining this difficulty facing Parties, in particular developing country Parties. These include:

- ❑ Lack of capacity in terms of expertise, infrastructure and predictable funding to cover running cost necessary to gather relevant information available at the national level, which may sometimes be in the hands of multiple national competent authorities, and to provide such information to the BCH;

/...

- ❑ Lack of capacity in terms of expertise, infrastructure and predictable funding to cover running cost necessary to create and maintain a national biosafety database, including getting such database interoperable with the central portal, as appropriate, and keeping it well updated, despite the fact that there is no provision in the Protocol that requires Parties to have a national database or website, and that information can be provided to the BCH via other means;
- ❑ Lack of resources, time as well as financial, to get the necessary information available at national level in local languages translated into English or one of the official United Nations languages before submission to the BCH;
- ❑ Lack of clarity on whether there is a need to make information available to the BCH central portal in cases where there are biosafety or BCH websites, nodes or database at national level.

(b) *It is also indicated that the BCH lacks information regarding living modified organisms, which are currently subject to transboundary movement.*

Several Parties have indicated that this information, which presumably exists at national level, was necessary to undertake risk assessment, monitor the effects of living modified organisms, possibly identify shipments of living modified organisms, and to determine import conditions.

The lack of adequate information in the BCH regarding all living modified organisms that are currently subject to transboundary movement could possibly be explained by the fact that most or all of these organisms have their origin in one or more of the non-Parties to the Protocol that are providing information to the BCH on voluntary basis.

On the other hand, there are situations where the living modified organisms that are currently subject to transboundary movement were approved for use, including placing on the market prior to the entry into force of the Protocol, in which case making available information about these living modified organisms retroactively is not a requirement under the Protocol.

C. Other possible general issue of compliance

(vi) Monitoring and reporting (Article 33)

10. Only 35 percent of Parties to the Protocol submitted their interim national reports fulfilling their obligation under Article 33 of the Protocol and decision BS-I/9 of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. This may also cause a concern in relation to the consideration of general issues of compliance. Reporting by each Party is essential not merely because it has been required under Article 33, but it is also a critical input for the effective implementation of other provisions of the Protocol. For example, national reports serve as important sources of information for the Conference of the Parties serving as the meeting of the Parties to the Protocol to appropriately discharge its functions such as the one described under paragraph 4(a), Article 29, which requires the Conference of the Parties serving as the meeting of the Parties to the Protocol, as one of its functions, to make recommendations on any matters necessary for the implementation of the Protocol.

11. As mentioned in paragraph 2 of this document above, reviewing general issues of compliance is one of the functions of the Compliance Committee as stipulated in paragraph 1 (d), section III of the Procedures and Mechanisms on Compliance adopted under the Protocol in the annex to decision BS-I/7 of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. In this regard, the Committee is required, as it is currently doing, to take into account national reports communicated in accordance with Article 33 of the Protocol. Furthermore, the process and the outcome of an evaluation of the effectiveness of the Protocol every five years in accordance with Article 35 would

also be influenced by the information that would be communicated by each Party through its national report.

12. The Compliance Committee may, therefore, wish to take up the matter as regards failure by a large number of Parties to communicate their interim national reports with a view to identifying constraints and developing suggestions that may, in the future, improve the situation in monitoring implementation of obligations and reporting under Article 33 of the Protocol.

III. ELEMENTS OF DRAFT RECOMMENDATIONS

13. The Compliance Committee may wish to consider the following elements for draft recommendations for possible submission for the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol:

Delay in putting in place the necessary regulatory and administrative measures/frameworks to implement the Protocol, and making such measures/frameworks operational

(a) Call upon Parties to give appropriate attention to the development of these enabling frameworks and urge those Parties that have duly completed the development of their national biosafety frameworks to take measures necessary to make these frameworks effective;

(b) Call upon Parties to allocate the resources necessary to make the frameworks operational;

(c) Request GEF to expedite support to eligible Parties for the implementation of their national biosafety frameworks;

(d) Invite those with a well developed and functional biosafety frameworks or systems to cooperate and share their practical experiences with those Parties that have a demand in this regard.

Lack of adequate institutional, human resources and technical capacities:

(e) Call upon Governments and intergovernmental organizations, as well as the private sector to further cooperate with developing countries with a view to strengthening their biosafety capacity building programmes taking into account Article 22 of the Protocol on capacity building, and the Action Plan for Building Capacities for effective Implementation of the Protocol adopted in decision BS-I/5 of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, or any new or revised action plan that may be adopted in the future.

(f) Invite eligible Parties to make use of the biosafety Roster of Experts, and call upon donors to make financial contribution to the appropriate fund under the Protocol in order to cover the cost of using experts from the Roster of Experts.

Lack of capacity in developing and maintaining information-sharing systems:

(g) Call upon UNEP/GEF to further enhance its BCH related capacity-building activities, including the provision of support in putting in place appropriate public awareness and participation policies and action plans.

Translation cost holding back Parties from making their information available to the BCH:

(h) Find ways to cover costs that may be needed for translation of the elements of national relevant documents or information from local languages into English or into one of the official United Nations languages that is necessary for submission to the BCH by some Parties that may have difficulties in this regard, on the basis of their demand and eligibility.

Lack of clarity on whether there is a need to make information available to the BCH in cases where there are biosafety or BCH websites, nodes or database at the national level:

(i) Request the Secretariat, as the administrator of the central portal of the BCH, to issue or provide clarification confirming that simply having a biosafety website, node, a database or a biosafety /...

clearing-house at the national level does not exonerate a Party from its obligation to make information available to the BCH-central portal.

Lack of sufficient information on living modified organisms that are subject to transboundary movements:

(j) Urge those that have access to information regarding living modified organisms that are currently subject to transboundary movements to make such information available to the BCH, taking into account the minimum information requirement described in annex I, and annex II of the Protocol.

Reporting obligation

(k) Urge Parties to fulfil their reporting obligations and to invite eligible Parties that may face difficulties in the preparation of their national reports to make these difficulties known, through the Secretariat, and seek assistance from any available opportunities such as the Roster of Experts.

Annex

SUMMARY OF RECORDS IN THE BCH SUBMITTED BY PARTIES

As at 10 November 2005

Category of Information	Time-frame for implementation	Number of Parties reporting (percentage of total in brackets)			
		Developing countries <u>1/</u>	Countries with economies in transition <u>2/</u>	Developed countries <u>3/</u>	Total <u>4/</u>
National Contacts					
CPB National Focal Points	At entry into force	72 (84%)	20 (95%)	18 (90%)	110 (87%)
Emergency Measures (Article 17) Contact Point	At entry into force	23 (27%)	12 (57%)	10 (50%)	45 (35%)
Competent National Authorities (CNAs) <u>5/</u>	At entry into force	60 (70%)	17 (81%)	18 (90%)	95 (75%)
Laws and regulations					
National Laws	When applicable	31 (36%)	14 (67%)	13 (65%)	58 (46%)
National laws (outlining full information)		15 (17%)	11 (52%)	9 (45%)	35 (28%)
National laws (not outlining full information)		16 (19%)	3 (14%)	4 (20%)	23 (18%)

1/ Total number of developing countries Parties = 86

2/ Total number of Parties with economies in transition = 21

3/ Total number of developed country Parties = 20

4/ Total number of Parties = 127

5/ In one case, although multiple CNAs have been designated, the responsibilities of each has not been conveyed to the Secretariat (as required by Article 19, paragraph 2).

Bilateral, multilateral & regional agreements	If applicable	3 (3%)	0 (0%)	2 (9%)	5 (4%)
Decisions and Declarations					
Decisions under AIA (introduction into the environment)	Within 270 days of taking decision	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Decisions under Article 11.1 (LMOs-FFP)	Within 15 days of taking decision	1 (1%)	2 (9%)	5 (25%)	8 (6%)
Article 11.6 Declaration (LMO-FFP import without domestic framework)	If applicable	1 (1%)	0 (0%)	0 (0%)	1 (1%)
Article 13.1(a) (Simplified procedure - import at same time as notification)	If applicable	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Article 13.1(b) (Simplified procedure - imports exempt from AIA)	If applicable	2 (2%)	0 (0%)	0 (0%)	2 (2%)
Article 14.4 (domestic regulations that apply with respect to specific imports)	If applicable	0 (0%)	0 (0%)	3 (15%)	3 (2%)
Article 17.1 Notification (unintentional transboundary movement)	When applicable (as soon as Party knows of the situation)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Article 25.3 notification (illegal transboundary movements)	When applicable	0 (0%)	0 (0%)	0 (0%)	0 (0%)
