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COMPLIANCE COMMITTEE UNDER THE
CARTAGENA PROTOCOL ON BIOSAFETY
Eleventh meeting
Montreal, 28–30 May 2014
Item 3 of the provisional agenda*

STATUS OF COMPLIANCE WITH RESPECT TO CASES REVIEWED AT THE PREVIOUS MEETING

INTRODUCTION

1. At its tenth meeting in May 2013, the Compliance Committee considered a report of the activities undertaken by the Secretariat since the ninth meeting of the Committee with regard to the compliance of Parties' with their obligation to: (a) submit a second national report; (b) put in place national biosafety frameworks; and (c) make information available to the Biosafety Clearing-House (BCH) as required under the various provisions of the Protocol. The Committee decided on further actions that the Secretariat and the Committee itself may undertake to assist relevant Parties to comply with requirements in these areas.

2. This document provides a report on the further activities carried out by the Secretariat and the Chair of the Compliance Committee on behalf of the Committee, following the tenth meeting of the Committee and their outcomes as regards the compliance of Parties with these obligations.

I. STATUS OF SUBMISSION OF SECOND NATIONAL REPORTS

3. At its tenth meeting, the Committee was informed that, despite letters sent by the Secretariat and the Compliance Committee to relevant national focal points regarding outstanding reports, second national reports were still due from 13 Parties.[1] The Committee, therefore, decided to send an additional letter to these Parties urging them to submit their report as soon as possible. The letters would also be copied to the head of the institution where the national focal point was located and the ministry of foreign affairs where that ministry was not the national focal point. The letters would make reference to the availability of the Committee to provide support with any advice and appropriate assistance, as indicated in decision BS-V/1.

4. In September 2013, a letter signed by the Chair of the Committee, was sent to 12 Parties that had not submitted their second national report.[2] Consequently, second national reports were received from

[1] The Bahamas, Barbados, Belize, Georgia, Greece, Luxembourg, the Marshall Islands, Montenegro, Nicaragua, Pakistan, Palau, Trinidad and Tobago and Turkmenistan

[2] Palau submitted its report in June 2013.

/…

Trinidad and Tobago and Georgia in September and November of 2013, respectively. Submission of a second national report is still due from 10 Parties.

II. PUTTING IN PLACE LEGAL AND ADMINISTRATIVE BIOSAFETY FRAMEWORKS

5. Decision BS-VI/1 recognized the task of putting operational biosafety frameworks in place as the top most priority for Parties. Parties were called upon to expedite their efforts to take legal, administrative and other measures necessary for the implementation of the Protocol. Parties that had not yet put in place operational biosafety frameworks were requested to submit information on the challenges they were faced with in this regard, and the plans and timelines, as appropriate, that they envisaged for the purpose of taking the necessary measures.

6. At the last Committee meeting, the Secretariat indicated that 38 Parties were identified, based on the responses they had provided through their second national reports, for follow-up pursuant to the decision of the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety. The Secretariat also informed the Committee that letters were sent to the 38 Parties and responses were received from 13 of them. The Committee agreed that the Secretariat send another letter to the 25 Parties that did not respond to the first letter. If no response was received to the second letter from the Secretariat, the Chair of the Committee would send an additional letter to the national focal points of the Parties with a copy to their respective ministry of foreign affairs inquiring as to why they had been unable to fulfil their obligation and offering the assistance of the Compliance Committee.

7. Accordingly, the Secretariat sent letters, in June 2013, to each of the 25 Parties identified for follow-up action. Responses were received from 5 Parties only.[3] The Secretariat consulted with the Chair of the Committee on the next steps. In November 2013, the Chair of the Committee sent, in accordance with the Committee's guidance agreed at its tenth meeting, a letter to each of the remaining twenty Parties that had not responded to the second letter from the Secretariat. Responses were received from 4 Parties[4]. The comments received from the nine Parties are summarized in the table annexed to this document (annex I).

8. The responses show that most of the concerned Parties have draft national biosafety frameworks and that they are making efforts to update, officially adopt and implement them. However, multifaceted challenges still remain.

III. MAKING INFORMATION AVAILABLE IN THE BIOSAFETY CLEARING-HOUSE

9. At its tenth meeting, the Committee continued its discussion concerning the importance of making available, by Parties, complete and up-to-date information to the Biosafety Clearing-House (BCH) in general, and information on decisions and risk assessments in particular, as referred to in Paragraph 1 of decision BS-V/2, and initially discussed by the Committee at its ninth meeting. The Secretariat reported that it had identified 19 Parties which had not made available to the BCH all the decisions on living modified organisms taken by their regulatory bodies,[5] and/or had not provided the risk assessments that had to accompany such decisions. The Secretariat also reported that it had contacted these 19 Parties to draw their attention to the apparent gaps and the need to submit the relevant decisions and risk assessments, or any other relevant and mandatory information, and that a few of them had taken appropriate action. The Committee considered the issue and requested the Secretariat to send another reminder to the Parties from which no action had been taken towards providing the missing information.

[3] The Gambia, Maldives, Niger, Saint Lucia and Saudi Arabia.

[4] Antigua and Barbuda, Guatemala, Saint Vincent and the Grenadines, and Serbia.

[5] The Secretariat used the Biotradestatus database (www.biotradestatus.com) as reference to identify gaps in this regard.

10. The issue of completeness of information in the BCH is an ever evolving one where some Parties take action to update their information others fall short. The Secretariat follows up with Parties in this regard as part of its overall periodic tasks and surveys. Accordingly, it conducted a new survey in October 2013 using, once again, the Biotradestatus database (www.biotradestatus.com), but also the databases of: (i) the Organization for Economic Co-operation and Development (OECD) (http://www2.oecd.org/biotech/); the International Portal on Food Safety, Animal and Plant Health (IPFSAPH) (http://www.ipfsaph.org/En/default.jsp); (iii) the European Food Safety Authority (EFSA) (http://registerofquestions.efsa.europa.eu/roqFrontend/login); and national biosafety clearing-houses, where applicable, as references to identify gaps in the decisions published.

11. The Secretariat contacted 15[6] Parties identified as having missing decisions or accompanying risk assessments at that time. A sample of the communication sent to Biosafety Clearing-House national focal points and Cartagena Protocol national focal points is annexed to this document (annex II). It shows the detail of the guidance provided to Parties to assist them in accessing a list of all national records for their country that are currently missing mandatory information, and how to go about updating or completing such required information. Two[7] of the Parties contacted by the Secretariat have updated records since they were contacted. The Secretariat continues its periodic follow-up and verification of information in this regard.

IV. SUGGESTION

12. The Committee may wish to:

(a) Make recommendation to the seventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to follow up, through its Bureau, with the 10 Parties that still need to submit a second national report;

(b) Request the Secretariat to follow up, in consultation with the Chair of the Committee, with those Parties that are still behind in putting in place their national biosafety framework, and making complete and up-to-date information available to the Biosafety Clearing-House; and report the progress to the twelfth meeting of the Committee.

[6] Burkina Faso, China, Colombia, Egypt, EU, Honduras, India, Indonesia, Japan, Mexico, Norway, Paraguay, Philippines, Republic of Korea and South Africa.

[7] Colombia and the Republic of Korea

***Annex* I**

Party	Response received from the national focal point (unless specified otherwise)
Antigua and Barbuda	*We are working on a national response and will get back to you.*
Gambia	*The NBF is yet to be ratified by the Parliament.* ***Challenges cited:*** *1. The funds were exhausted while the activities not completed during project implementation.* *2. Inadequate capacity (human and material) at the Focal Point department.* *3. The awareness and understanding of the general public and decision makers is very low.* ***Support needed:*** *1. Revitalization of National Task Force members on biosafety for the implementation* *2. Capacity building for the focal institution and other relevant sectors* *3. Preparation and submission of the legal instrument for its ratification by the National Assembly* *4. General public sensitization on biosafety.*
Guatemala	(Courtesy translation from Spanish by Secretariat) *1. Progress towards the Implementation of the Cartagena Protocol on Guatemala* *The development of the proposed biosafety policy was initiated in 2011 involving different relevant sectors of society (government, academia, private sector, civil society). After 11 months of work, it was submitted to the authorities of the National Council of Protected Areas (Focal Point for the Cartagena Protocol), who requested that discussion continue for final approval by the relevant authorities of the sectors represented in the group. In early November 2013, it was finally passed by the National Council of Protected Areas and forwarded for approval by government authorities. It is expected that this process will be completed by the first quarter of next year (2014).* *For policy implementation, a national biosafety system needs to be developed. This system would include a legal framework, administrative and technical measures describing the obligations of each National Competent Authority. To date, a first proposal of a legal framework for the future National Biosafety System has been developed and is currently being discussed with different relevant sectors so as to be submitted for approval by government authorities and subsequent implementation. The administrative and technical measures are being developed with the expectation that the legal and administrative framework to implement the Cartagena Protocol in Guatemala will be achieved by mid-2014.* *In addition to these efforts, we have developed parallel activities to train staff (workshops, post graduate courses) and laboratories to enable the development of science-based risk assessment. A national strategy for public awareness of biotechnology and biosafety has been developed, including its initial implementation through workshops with identified priority sectors identified (journalists, social communicators, staff of Competent national Authorities). We continue to implement the national BCH.*

	2. Challenges and difficulties encountered in trying to implement the legal and administrative measures that will form the National Biosafety System. *Due to the fact that Guatemala, to date, has not officially nominated its National Competent Authorities, it does not have complete clarity from Ministries regarding its obligations towards the Cartagena Protocol. As a result, there isn't sufficient responsible staff to deal with the issue. In addition, there are continuous changes in the staff of the institutions that make up the ANC, including both technical staff and those that can take decisions. Also, the subject of LMOs is very controversial because of conflicting views held on the topic by the general population, especially some public servants; this is mainly due to ignorance of the subject. Finally, the development of administrative and technical mechanisms is complicated because there are not many Guatemalan professionals who are specialists in the field of biotechnology and biosafety of LMOs.* *3. Support requested* *Support is necessary in the field of technical capacity-building, especially the training of legal professionals to thoroughly understand relevant international treaties, particularly the Convention on Biological Diversity and the Cartagena Protocol. In addition, remote or face-to-face learning courses should be continued for technicians responsible for developing risk assessment, and teaching material on the subject needs to be developed aimed at different target audiences.* *I want to mention my appreciation for the financial support that my country is currently receiving through the GFL - 2238-2716 - 4C03 project entitled "Implementation of the Cartagena Protocol in Guatemala.*
Maldives	*Please note the following points:* *1. To strengthen implementation of CPB and National Biosafety Framework, we conducted a National Training Workshop on Biosafety to all relevant stakeholders last year with the assistance from a consultant Ms Rachel Shabrila.* *2. One of the outcomes of the above workshop was the development of an Action Plan for Biosafety.* *3. As per implementation of the NBF and the Action Plan for Biosafety we are currently translating the drafted regulation on biosafety to be gazetted.* *Also note that I will write a formal communication from the Maldives with the details requested in the attached letter."* *The NFP provided a copy of the report of the National Training Workshop on Biosafety which include an Action Plan and the way forward in implementing the Biosafety Protocol in Maldives.* *Relevant excerpts:* *(a) It was agreed that the Ministry of Environment would take the lead in the implementation of the action plan, but would involve relevant stakeholders including the agencies in the implementation.* *(b) It was also agreed that the Ministry would consider developing a MSP and collaborate with the UNEP in seeking for funding of the activities under the MSP* *(c) It was also agreed that the Ministry would carry out a stock-taking activity so as to determine the needs/gaps and the existing infrastructure necessary for the implementation of the CPB.*

	OBJECTIVE	ACTIVITY	LEAD AGANCY	TIME	Priority
	Educate public	1. Policy dialogue 2. Awareness criteria and area 3. Awareness material to be produced 4. Media awareness 5. Identification of stakeholders 6. Training	MEE	2013 -2014	5
	Strengthening the legal framework on biosafety	1. Make a Dhivehi draft by end of March 2013 2. Stakeholder consultation by end of June 2013 3. Review, consult stakeholders and Finalize the regulation by August 2013 4. Awareness among politicians, public etc by end of October 5. Gazette by end of Dec 2013	MEE	By end of 2013	4
	Collaborative and informed decision making	Include the National Technical Committee, their responsibilities, constitution …etc in the regulation Representation from all different stakeholders should be there in the NTC			4&5
	Contingency planning	Develop SOPs	MEE, MNDF, FDA, NDMC		6
	Cost benefit analysis	- Analysis on cost benefit of a national laboratory on biosafety	Economic development		3
	Improving technology and capacity needs	Do a capacity and technology need assessment.	MEE	February 2013	2
	Gap analysis/Stock taking				1
Niger	*- Niger has elaborated its National Biosafety Framework since December 2005;* *- Niger has elaborated Biosafety law project* *- Niger has taken administrative measures including:* • *Ministry in charge of Environment as National Competent Authority* • *Nomination of Biosafety and BCH Focal National Point* • *Establishment of National Biosafety Committee including government institutio institutes, University, Civil Society and NGOs.* *Challenges and difficulties:* *- Many administrative procedures for Biosafety law project adoption by the parliament* *- Lack of financial means for the functionality of the National Biosafety Committee.* *Support requirement:* *Financial assistance to organize workshops of information and awareness on Biosafety*				

	law Project for parliament members and deciders to facilitate adoption process.
Saint Lucia	*Saint Lucia is currently undertaking the project on the implementation of biosafety systems in the country. The legal and administrative measures are two of the systems actively being pursued and the country is also in the process of hiring a legislative drafter to finalize its draft legislation. It is also working on establishing the administrative measures.* *The legislation should be finished by the end of October 2013. It is hoped that soon afterwards the Cabinet of Ministers will endorse this legislation with a view to enacting it in Parliament at the earliest opportunity. The administrative measures should be in place by the end of the project in 2015…."*
Saint Vincent and the Grenadines	Letter from the Permanent Secretary of the Ministry of Health, Wellness and the Environment: *"I wish to inform that draft legislation on biosafety was developed after the successful completion of the Biosafety Frameworks Project. Currently, we have initiated an implementation project for Biosafety, which is part of a wider Caribbean project. As a component of this project, a review of this draft legislation will be undertaken to ensure that the Nagoya Protocol on Biosafety is adequately covered in the draft and relevant update.* *A draft policy has also been developed and was presented to the Honourable Minister of Health, Wellness and the Environment on February 12th, 2013. It is anticipated that during this year much progress will be made in advancing the legal and administrative processes to implement the biosafety frameworks to meet our obligation under the protocol."*
Saudi Arabia	*The operational biosafety framework is being worked out in Saudi Arabia before being implemented.* *The responses to the points raised in your letter are as follows:* *i) Saudi National Biosafety Law as well as National Biosafety Framework have been drafted and were submitted to the concerned ministries for proper review.* *(ii) The measures/framework were then transferred to Saudi Food and Drug Authority (SFDA) for the review and it will be there responsibility to implement those. They are reviewing it and might ask for explanations from us before the approval and to take necessary measures to implement the obligations under the Protocol;* *(iii) Currently we do not need support for the purpose of adopting the necessary legal and administrative measures.*
Serbia	*In the Republic of Serbia, the use of GMOs is regulated since 2001 when was adopted the Law on Genetically Modified Organisms ("Official Gazette of FRY", No. 21/2001). This law had regulated the conditions for contained use, deliberate release into the environment, and placing on the market of GMOs and products of GMOs, as well as the conditions and measures for the prevention and elimination of adverse effects occurring on the occasion of contained use, production of and trade of GMOs and products of GMOs.* *National Assembly of the Republic of Serbia adopted a new Law on Genetically Modified Organisms ("Official Gazette RS", No. 41/2009).* *This law regulates: "... the procedure for issuing approvals for use in closed systems and for deliberate release into the environment of GMOs and products of GMOs, conditions for use in closed systems and for deliberate release into the environment of GMOs, handling, packaging and transport of GMOs and products of GMOs, as well as other issues of importance for GMOs and products of GMOs".* *The Law on Genetically Modified Organisms ("Official Gazette RS", No. 41/2009),*

	Article 2 provides for the prohibition of placing on the market of GMOs and products of GMOs, as well as prohibition of commercial growing of GMOs: "No genetically modified organisms or product containing genetically modified organisms can be traded or grown for commercial use at the territory of the Republic of Serbia". *The ban was not considered to be in compliance with EU legislation in this area, as well as with Cartagena Protocol on Biosafety, therefore, the Ministry of Agriculture, Forestry and Water Management of Republic of Serbia as competent authority prepared the draft of a new Law on genetically modified organisms, in order to harmonize it with the following EU Directive and Regulations: Directive 2001/18, Regulation 1829/2003, Regulation 1830/2003 , Regulation 1831/2003, Regulation 1946 / 2003, Regulation 65/2004 and Cartagena Protocol on Biosafety.* *The Ministry of Agriculture is expected that the Draft law on genetically modified organisms to be adopted in 2014. We are currently in the process of gathering positive opinions from other relevant ministries, after which the draft law will be submitted to Parliament for approval.*

Annex II

SAMPLE E-MAIL SENT TO NATIONAL FOCAL POINTS REGARDING THE COMPLETENESS OF THEIR RECORDS/INFORMATION IN THE BIOSAFETY CLEARING-HOUSE

Dear XXXX

As a follow up to our correspondence regarding the process of ensuring the completeness and accuracy of records in the Biosafety Clearing-House (BCH) of the Cartagena Protocol on Biosafety, we would like to remind you that you can access all of your national records through the country profile menu on the right side of the green horizontal navigation bar at the top of all BCH web pages.

We would like to advise you that your country has missing or incomplete records in the BCH as follows:

- **Incomplete records (missing one or more mandatory fields)**

  - **Biosafety Expert**: 11 records
  - **Country's Decision or any other Communication**: 46 records
  - **Law, Regulation or Guideline**: 9 records

A list of all your national records that are currently missing some of the mandatory information is available at http://bch.cbd.int/managementcentre/record-completeness/.

In order to review the missing information, please select any record that is flagged as incomplete, click on the 'Edit record' button and then on the 'Review' button – the 'Errors' section that precedes the record contains the incomplete information. Note that, as a result of a recent meeting of the Informal Advisory Committee of the BCH, it is now possible for you to update your incomplete records and republish them **even if you are unable to complete *all* of the mandatory fields**.

In particular, we would like to draw your attention to the information, pertaining to decisions regarding the first intentional transboundary movements of LMOs for intentional introduction into the environment and the risk assessments associated with such decisions, registered in the BCH as mandated by Article 20 of the Protocol and subsequent COP-MOP decisions.

- **Decisions registered by your country under Articles 10 and 11 that require an accompanying risk assessment :**

  1. http://bch.cbd.int/database/record.shtml?documentid=XXXX
  2. http://bch.cbd.int/database/record.shtml?documentid=XXXX
  3. Etc..

Please note that the Risk Assessments that must accompany Decisions are separate BCH records that are linked to Decision records. Both Common Formats for 'Country's Decision or any other Communication' and 'Risk Assessment' are attached to this message for your ease of reference.

- **Decisions listed by the Biotradestatus database**

We have noted that the following LMOs, which are listed as commercialized in your country by the Biotradestatus database, maintained by the Biotechnology Industry Organization (BIO at http://www.biotradestatus.com/), are not listed in your national BCH records (please note that the LMOs highlighted in yellow are ones we have previously brought to your attention):

  - MON-XXXXXXXXXXXXXXXXXXXXX
  - MON-XXXXXXXXXXXXXXXXXXXXXX

- ACS-XXXXXXXXXXXXXXXXXXXXXXX
- ACS-XXXXXXXXXXXXXXXXXXXXXXX

We would be grateful if you could take steps toward providing the necessary information through the BCH regarding the relevant national decisions on the status of these products in your country.

- **Decisions and/or risk assessments listed by the Organisation for Economic Co-operation and Development (OECD) database**

We have noted that the following LMOs, for which information has been listed in the OECD database (http://www2.oecd.org/biotech/), are not listed in your national BCH records:

- ACS-XXXXXXXXXXXXXXX
- BPS-XXXXXXXXXXXXXXX
- DAS-XXXXXXXXXXXXXXX
- DP-XXXXXXXXXXXXXX
- MON-XXXXXXXXXXXXX

We would be grateful if you could make this information available through the BCH or let us know if there is a reason for its exclusion.

Finally, we would like to remind you that, in your capacity as BCH-NFP, you may assign any number of National Authorized Users (NAU) to assist you in creating and maintaining national records in the BCH. For a detailed explanation on the role of NAUs see our FAQ at http://bch.cbd.int/help/faq/#NAU.

Either you or your NAUs may access all of the common formats for registering information at http://bch.cbd.int/resources/common-formats/. While we encourage Parties to enter their information directly online through the Management Centre, in cases of limited Internet connectivity, you may fill out the offline common formats and send them to the Secretariat to register on your behalf.

It would be appreciated if you would kindly update these records at your earliest convenience, but no later than **31 December 2013**.

Please do not hesitate to contact us if we can be of any further assistance regarding the accuracy and completeness of your country's records registered in the BCH.

Best regards.
