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Second Regular National Report on the Implementation of the Cartagena Protocol on Biosafety

Origin of report

1.	Country:	[Type here your text]
Con	ntact officer for report			
2.	Name of contact officer:	[Type here your text]
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Sub	mission			
8.	Date of submission:	[Type here your text]
9.	Time period covered by this report:	[Type here your text]
Sigi	nature of the reporting officer 1			
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To facilitate the analysis of the reports, please $\underline{\text{do not}}$ send this report via fax or postal mail or in electronic formats other than MS Word.

Note: Questions highlighted in light-grey may not reflect obligations derived by the Cartagena Protocol on Biosafety and are introduced in this report format only to help drawing a baseline for the future assessment and review process due by COP-MOP 6.

Article 2 – General provisions

10.	Is your country a Party to the Cartagena Protocol on Biosafety (CPB)?	Yes No
11.	If you answered <i>No</i> to question 10, is there any national process in place towards becoming a Party?	Yes No Not applicable
12.	Has your country introduced the necessary legal, administrative and other measures for the implementation of the Protocol?	A domestic regulatory framework is in place Only some measures have been introduced Only ad interim measures have been introduced Only a draft framework exists No measures has yet been taken
13.	Which specific instruments are in place for the implementation of your National Biosafety Framework?	One or more national biosafety laws. One or more national biosafety by-laws or regulations. One or more sets of biosafety guidelines. Other laws, by-laws, regulations or guidelines not specifically addressing biosafety. None of the above.
14.	Has your country established a mechanism for budgetary allocation for the operation of national biosafety framework	Yes No

15.	Does your country have any permanent staff in place to administer functions directly related to the national biosafety framework?		Yes No	
16.	If you answered <i>Yes</i> to question 15, how many permanent staff members are in place whose functions are directly related to the national biosafety framework?		One Less than 5 Less than 10 More than 10 Not applicable	
17.	Has your country's legislative framework/law/guidelines been submitted to the Biosafety Clearing-House (BCH)?		Yes Partially No	
18.	3. Here you may provide further details on the implementation of the above article in your country: [Type here your text]			
	Article 5 – Pharmaceuticals			
19.	Has your country introduced specific measures on living modified organisms (LMOs) which are pharmaceuticals?		Yes No	
20.	If you answered <i>Yes</i> to question 19, was this information submitted to the BCH?		Yes Partially No Not applicable	
21.	Here you may provide further details on the implement country: [Type here your t		of the above article in your]	
	Article 6 – Transit and Con	tained u	ise	
22.	Has your country introduced specific measures regarding the transit of LMOs?		Yes No	
23.	Has your country introduced specific measures regarding the contained use of LMOs?		Yes No	

	2 nd National Report on the Implementation o	f the Cartage	ena Protocol on Biosafety – Page 4		
24.	If you answered <i>Yes</i> to questions 22 or 23, was this information submitted to the BCH?		Yes Partially No Not applicable		
25.	5. Here you may provide further details on the implementation of the above article in your country: [Type here your text]				
	Articles 7 to 10: Advance Informed Agreement LMOs into the envi		intentional introduction of		
26.	Has your country adopted law(s) or regulations and administrative measures for operation of the AIA procedure (or consistent domestic regulatory framework)		Yes No		
27.	Has your country established a mechanism for taking decisions regarding first intentional transboundary movements for intentional introduction of LMOs into the environment?		Yes No		
28.	If you answered <i>Yes</i> to question 27, are intentional introduction of LMOs into the environment, non-related to transboundary movements, addressed by the same mechanism?		Yes No Not applicable		
29.	Has your country established a mechanism for monitoring potential effects of LMOs that are released in the environment?		Yes No		
30.	Has your country developed some capacity in the detection and identification of LMOs?		Yes No		
31.	Has your country established legal requirements to ensure that national exporters notify in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of an LMO that falls within the scope of the AIA?		Yes No		
32.	Has your country established legal requirements for the accuracy of information contained in the polification?		Yes No		

33.	Has your country ever receive an application regarding intentional transboundary movements of LMOs for intentional introduction into the environment?		Yes No
34.	Has your country ever take a decision on an application regarding intentional transboundary movements of LMOs for intentional introduction into the environment?		Yes No Not applicable
35.	If you answered <i>Yes</i> to question 34, how many transboundary movements of LMOs has your country approved to date for intentional introduction into the environment?		None Less than 5 Less than 10 More than 10 Not applicable
36.	How many LMOs has your country approved to date for intentional introduction into the environment non-related to transboundary movements?		None Less than 5 Less than 10 More than 10
37.	In the current reporting period, how many applications has your country received regarding intentional transboundary movements of LMOs for intentional introduction into the environment?		None Less than 5 Less than 10 More than 10
38.	In the current reporting period, how many decisions has your country taken regarding intentional transboundary movements of LMOs for intentional introduction into the environment?		None Less than 5 Less than 10 More than 10
If yo	u replied <u>None</u> to the previous question please go	to question	XX
39.	With reference to the decisions taken on intentional transboundary movements of LMOs for intentional introduction into the environment, has your country received a notification from the Party(ies) of export or from the exporter(s)?		Yes, always In some cases only No

	2 nd National Report on the Implementation of	the Cartagena Protocol on Biosafety – Page 6
40.	Have the notifications contained complete information (at a minimum the information specified in Annex I of the CPB)?	☐ Yes, always☐ In some cases only☐ No
41.	Has your country acknowledged receipt of the notifications to the notifier within ninety days of its receipt?	☐ Yes, always☐ In some cases only☐ No
42.	Has your country informed the notifier(s) and the BCH of its decision(s)?	 Yes, always In some cases only In some cases only the notifier In some cases only the BCH No
43.	Has your country informed the notifier(s) and the BCH of its decision(s) in due time (within 270 days or the period specified in your acknowledgement to the notifications)?	☐ Yes, always☐ In some cases only☐ No
44.	Which percentage of your country's decisions applies to the following categories:	 Approving the import without conditions [%] Approving the import with conditions [%] Prohibiting the import [%] Requesting additional information [%] Extending the period for the communication of the decision [%]
45.	In cases where your country's decision(s) were not of unconditional consent (<i>Approving the import with conditions</i> or <i>Prohibiting the import</i>), did your country provide, to the notifier and the BCH, reasons on which they were based?	 Yes, always In some cases only In some cases only the notifier In some cases only the BCH No

2nd National Report on the Implementation of the Cartagena Protocol on Biosafety – Page 7

55.	In the current reporting period, how many decisions has your country taken regarding the import of LMOs-FFP?		None Less than 5 Less than 10 More than 10		
56.	In the current reporting period, how many decisions has your country taken regarding domestic use, including placing on the market, of LMOs-FFPs?		None Less than 5 Less than 10 More than 10		
If yo	u replied <u>None</u> to the previous question please go	to question	XX		
57.	Has your country informed the Parties through the BCH of its decision(s)?		Yes, always In some cases only No		
58.	Has your country informed the Parties through the BCH within 15 days?		Yes, always In some cases only No		
59.	59. Here you may provide further details on the implementation of the above article in your country: [Type here your text]				
	Article 12 – Review o	of decision			
60.	Has your country established a mechanism for the review/change in a decision regarding an intentional transboundary movement of LMOs?		Yes No		
61.	Has your country ever reviewed/changed a decision regarding an intentional transboundary movement of LMOs?		Yes No		
62.	In the current reporting period, how many decisions were reviewed/changed regarding an intentional transboundary movement of LMO?		None Less than 5 More than 5		
It vo	ou replied None to the previous question please go	to auestion	XX		

 2^{nd} National Report on the Implementation of the Cartagena Protocol on Biosafety – Page 8

63.	Has your country informed the notifier and the BCH of the review/change in the decision?		Yes, always In some cases only In some cases only the notifier In some cases only the BCH No		
64.	Has your country informed the notifier and the BCH of the review/change in the decision within thirty days?		Yes, always In some cases only No		
65.	Has your country provided reasons to the notifier and the BCH for the review/change in the decision?		Yes, always In some cases only In some cases only the notifier In some cases only the BCH No		
66.	66. Here you may provide further details on the implementation of the above article in your country: [Type here your text]				
	country: [Type nere your	text			
	Article 13 – Simplified p		e e		
67.			Yes No		
67.	Has your country established a mechanism for the application of a simplified procedure regarding an intentional transboundary		Yes		
	Article 13 – Simplified p Has your country established a mechanism for the application of a simplified procedure regarding an intentional transboundary movement of LMOs? Has your country ever applied simplified		Yes No Yes		

 2^{nd} National Report on the Implementation of the Cartagena Protocol on Biosafety – Page 9

If you replied <u>None</u> to the previous question please go to question <u>XX</u>				
71.	How many times has the simplified procedure been applied to cases in which intentional transboundary movement may take place at the same time as the movement is notified?		Never Less than 5 More than 5	
72.	How many times has your country applied the simplified procedure to imports of LMOs to be exempted from the AIA procedure?		Never Less than 5 More than 5	
73.	73. Here you may provide further details on the implementation of the above article in your country: [Type here your text]			
	Article 14 – Bilateral, regional and multilateral	agreem	ents and arrangements	
74.	Has your country entered into any bilateral, regional or multilateral agreements or arrangements?		Yes No	
75.	If you answered <i>Yes</i> to question 74, has your country informed the Parties through the BCH of the agreements or arrangements?		Yes, always In some cases only No Not applicable	
76.	76. Here you may provide further details on the implementation of the above article in your country: [Type here your text]			
	Articles 15 – Risk asses	sment		
77.	Has your country established a mechanism for conducting risk assessments prior to taking decisions regarding LMOs?		Yes No	
78.	Has your country established a mechanism for identifying experts to conduct risk assessments?		Yes No	
79.	Has your country submitted the details of national experts to the Roster of Expert in the BCH?		Yes No	

80.	Has your country established a mechanism for training among your national experts to conduct risk assessments?	Yes No
81.	Has your country established guidelines to conduct risk assessments prior to taking decisions regarding LMOs?	Yes No
82.	Has your country attained the necessary domestic capacity to conduct risk assessment?	Yes No
83.	Has your country ever conducted a risk assessment regarding an intentional introduction of LMOs into the environment?	Yes No
84.	Has your country ever conducted a risk assessment of LMOs-FFP?	Yes No
85.	In the current reporting period, how many risk assessment of LMOs has your country conducted?	None Less than 5 Less than 10 More than 10
86.	If your country conducted risk assessments, were the summary reports submitted to the BCH?	Yes, always In some cases only No Not applicable
87.	If your country took decision(s) on intentional introduction(s) into the environment or on domestic use of LMOs, were risk assessments conducted for all decisions taken?	Yes, always In some cases only No Not applicable
88.	Has your country ever required the exporters to conduct the risk assessment(s) of LMOs?	Yes, always In some cases only No Not applicable

	2 nd National Report on the Implementation of	the Cartagen	a Protocol on Biosafety – Page 12
89.	Has your country ever required the exporters to bear the cost of the risk assessment(s) of LMOs?		Yes, always In some cases only No Not applicable
90.	Here you may provide further details on the imple country: [Type here yo		of the above article in your
	Articles 16 – Risk ma	nagement	
91.	Has your country established and maintained appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol?		Yes, always In some cases only No
92.	Has your country established and maintained appropriate mechanisms to prevent unintentional transboundary movements of LMO?		Yes No
93.	Has your country taken measures to ensure that any LMO, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use?		Yes No
94.	Has your country cooperated with other Parties with a view to a) identifying LMOs or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity and b) taking measures regarding the treatment of such LMOs or specific traits?		Yes, always In some cases only No
95.	Here you may provide further details on the imple country: [Type here you		of the above article in your
	Article 17 – Unintentional transboundary mo	vements aı	nd emergency measures
96.	Has your country made available to the BCH the relevant details setting out its point of contact for the purposes of receiving notifications under Article 17?		Yes No

97.	Has your country establish a mechanism for managing emergency measures in case of unintentional transboundary movements of LMOs?		Yes No	
98.	In the current reporting period, how many times has your country received information concerning cases that lead, or may have lead, to unintentional transboundary movement(s) of one or more LMOs to or from territories under its jurisdiction?		Never Less than 5 Less than 10 More than 10	
If yo	u replied <u>Never</u> to the previous question please go to	question	$\imath \frac{XX}{}$	
99.	Has your country taken measures to notify affected or potentially affected States, the BCH and, where appropriate, relevant international organizations, of the above release? Has your country immediately consulted the		Yes Only in some cases Only the affected or potentially affected State Only the BCH No	
	affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures?		Yes, always In some cases only No	
101.	01. Here you may provide further details on the implementation of the above article in your country: [Type here your text]			
	Article 18 – Handling, transport, packa	aging an	d identification	
102.	Has your country taken measures to require that LMOs that are subject to transboundary movement are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards?		Yes, always In some cases only No	

2nd National Report on the Implementation of the Cartagena Protocol on Biosafety – Page 14

Article 19 – Competent National Authorities (CNAs) and National Focal Points (NFPs)		
108. Has your country designated one <i>national</i> focal point for the Cartagena Protocol (CPB-NFP) to be responsible on its behalf for liaison with the Secretariat?	☐ Yes ☐ No	
109. Has your country designated one <i>national</i> focal point for the Biosafety Clearing-House (BCH-NFP) to liaise with the Secretariat regarding issues of relevance to the development and implementation of the BCH?	☐ Yes ☐ No	
110. Has your country designate one or more competent national authorities (CNAs), which are responsible for performing the administrative functions required by the CPB and is/are authorized to act on its behalf with respect to those functions?	☐ Yes ☐ No	
111. In case your country designated more than one CNA, has your country provided relevant information on the respective responsibilities of those authorities?	☐ Yes ☐ No	
112. Has your country made available the above information to the BCH?	☐ Yes ☐ No	
113. In case your country has designated more than one CNA, has your country established a mechanism for the coordination of their actions prior to taking decisions regarding LMOs?	☐ Yes☐ No☐ Not applicable	
114. Has your country established a mechanism for training of staff of CNA(s) to perform the administrative functions required by the CPB?	☐ Yes ☐ No	
115. Here you may provide further details on the implementation of the above article in your country: [Type here your text]		
Article 20 – Information Sharing and the Biosafety Clearing-House (BCH)		
116. Please provide an overview of the status of the specifying for each category of information who been submitted to the BCH.	<u> </u>	

2nd National Report on the Implementation of the Cartagena Protocol on Biosafety – Page 16

		Available and in the BCH
m.	Declarations regarding the framework to be	Available but not in the BCH
	used for LMOs-FFP, or for processing (Article 11 paragraph 6);	Available but only partially available in the BCH
		Not available
		Available and in the BCH
n.	Review and change of decisions regarding	Available but not in the BCH
	intentional transboundary movements of LMOs (Article 12 paragraph 1);	Available but only partially available in the BCH
		Not available
		Available and in the BCH
0	LMOs granted exemption status by each Party (Article 13 paragraph 1);	Available but not in the BCH
0.		Available but only partially available in the BCH
		Not available
	Cases where intentional transboundary movement may take place at the same time as the movement is notified to the Party of import (Article 13 paragraph 1);	Available and in the BCH
p.		Available but not in the BCH
		Available but only partially available in the BCH
		Not available
	Summaries of risk assessments or environmental reviews of LMOs generated by	Available and in the BCH
q.		Available but not in the BCH
regulatory processes and relevant in		Available but only partially available in the BCH
	paragraph 3 I).	Not available
117.	Has your country established a mechanism for	Yes
	training the BCH-NFP to perform the administrative functions required by its role?	No
118.	Has your country established a mechanism for	Yes
	coordinating the actions among the BCH-NFP and the NCAs?	No

 2^{nd} National Report on the Implementation of the Cartagena Protocol on Biosafety – Page 18

119. Has your country experienced difficulties accessing or using the BCH?	☐ Yes☐ No		
120. If you answered <i>Yes</i> to question 119, has your country reported these problems to the BCH or the Secretariat?	☐ Yes☐ No☐ Not applicable		
121. Is the information submitted by your country to the BCH reliable and up-to date?	☐ Yes☐ No		
122. Here you may provide further details on the implem country: [Type here your	•		
Article 21 – Confidential information			
123. Has your country established procedures to protect confidential information received under the Protocol?	☐ Yes ☐ No		
124. Does your country allow the notifier to identify information that is to be treated as confidential?	☐ Yes, always☐ In some cases only☐ No		
125. Here you may provide further details on the implementation of the above article in your country: [Type here your text]			
Article 22 – Capacity-b	ouilding		
126. Has your country benefited from cooperation in the development and/or strengthening of human resources and institutional capacities in biosafety?	☐ Yes ☐ No		
127. Has your country cooperated in the development and/or strengthening of human resources and institutional capacities in biosafety in developing country Parties and in Parties with economies in transition?	☐ Yes ☐ No		

		Pilot Project
		Development of National Biosafety Frameworks
		Implementation of National Biosafety Frameworks
128.	Has your country taken part in any project funded by the Global Environment Facility (GEF) for building capacity in biosafety?	Building Capacity for Effective Participation in the BCH (Phase I)
		Building Capacity for Effective Participation in the BCH (Phase II)
		None of the above
129.	Has your country taken part in any other internationally funded project for Building	Yes (please specify): <text entry=""></text>
	Capacity in biosafety?	No
130.	During the current reporting period has your country carried on activities for the development and/or strengthening of human resources and institutional capacities in biosafety?	Yes No
the	If you answered <i>Yes</i> to question 130, which of the following areas were covered by these activities?	Biosafety policy and regulation
		LMO use and transboundary movement
		Scientific and technical issues
		Public awareness, education and participation
		Socio-economic and trade issues
		Information sharing and management
		Other (please specify): <text entry=""></text>
		Not applicable

	2 nd National Report on the Implementation of the Cartagena Protocol on Biosafety – Page 21		
132. Are there still capacity building needs in you country?	Are there still capacity building needs in your		Yes
	country?		No
			Biosafety policy and regulation
			LMO use and transboundary movement
			Scientific and technical issues
133.	If you answered <i>Yes</i> to question 132, which of the following areas need to be further covered		Public awareness, education and participation
	by capacity building activities?		Socio-economic and trade issues
		Information sharing and management	
			Other (please specify): <text entry=""></text>
			Not applicable
134.	Here you may provide further details on the implem country: [Type here your		of the above article in your
	Article 23 – Public awareness an	d parti	cipation
135.	Has your country established a strategy for promoting and facilitating public awareness, education and participation concerning the safe transfer, handling and use of LMOs?		Yes No
136.	Has your country established a national node of the BCH?		Yes No
137.	Has your country established a mechanism to ensure public access to the BCH and to information on LMO that may be imported?		Yes No
138.	Has your country established a mechanism to consult the public in the decision-making process regarding LMO?		Yes No

139. Has your country established a mechanism to make available to the public the results of decisions taken on LMOs?		Yes No	
140. In the current reporting period, has your country promoted and facilitated public awareness, education and participation concerning the safe transfer, handling and use of LMOs?		Yes No	
141. If you answered <i>Yes</i> to question 140, has your country cooperated with other States and international bodies?		Yes No Not applicable	
142. In the current reporting period, how many times has your country consulted the public in the decision-making process regarding LMOs and make the results of such decisions available to the public?		Never Less than 5 More than 5	
143. In the current reporting period, has your country taken any initiative on promoting public access to the BCH?		Yes No	
144. Here you may provide further details on the implementation of the above article in your country: [Type here your text]			
Article 24 – Non-Parties			
145. Has your country entered into any bilateral regional, or multilateral agreement with non-Parties regarding transboundary movements of LMOs non-Party?		Yes No	
146. In the current reporting period, has your country imported LMOs from a non-Party?		Yes No	
147. Has your country exported LMOs to a non- Party?		Yes No	

 2^{nd} National Report on the Implementation of the Cartagena Protocol on Biosafety – Page 22

2 nd National Report on the Implementation of the Cartagena Protocol on Biosafety – Page 23			
148. If you answered <i>Yes</i> to questions 146 or 147, were the transboundary movements of LMOs consistent with the objective of the CPB?	☐ Yes, always☐ In some cases only☐ No☐ Not applicable		
149. If you answered <i>Yes</i> to questions 146 or 147 under this Article, have you submitted this information to the BCH?	☐ Yes, always☐ In some cases only☐ No☐ Not applicable		
150. Here you may provide further details on the implementation of the above article in your country: [Type here your text]			
Article 25 – Illegal transboundary movements			
151. Has your country provided a definition of <i>illegal transboundary movement</i> in its domestic regulatory framework?	☐ Yes ☐ No		
152. Has your country adopted domestic measures aimed at preventing and/or penalizing transboundary movements of LMOs carried out in contravention of its domestic measures to implement this Protocol?	☐ Yes ☐ No		
153. Has your country established a strategy for enhancing capacity to detect illegal transboundary movements of LMOs?	☐ Yes ☐ No		

2 nd National Report on the Implementation of the Cartagena Protocol on Biosafety – Page 24			
155. If your country received information concerning cases of illegal transboundary movements of an LMO, has your country informed the BCH and the other Party(ies) involved?	 ☐ Yes ☐ Only in some cases ☐ Only the other Party(ies) involved ☐ Only the BCH ☐ No ☐ Not applicable 		
156. Here you may provide further details on the implementation of the above article in your country: [Type here your text]			
Article 26 – Socio-economic considerations			
157. If during the current reporting period your country has taken a decision on import, has it taken into account socio-economic considerations arising from the impact of LMO on the conservation and sustainable use of biological diversity?	☐ Yes☐ Only in some cases☐ No☐ Not applicable		
158. Has your country cooperated with other Parties on research and information exchange on any socio-economic impacts of LMOs?	☐ Yes ☐ No		
159. Here you may provide further details on the implementation of the above article in your country: [Type here your text]			
Article 28 – Financial mechanism and resources			
160. In the current reporting period, has your country benefited from financial and/or technological resources for the implementation of the provisions of the CPB?	☐ Yes ☐ No		
161. If you answered <i>Yes</i> to question 160, how were these resources made available?	☐ Bilateral channels☐ Regional channels☐ Multilateral channels☐ Not applicable		

162. In the current reporting period, has your country provided financial and/or technological resources for the implementation of the provisions of the CPB to developing country Parties or Parties with economies in transition?	☐ Yes ☐ No		
163. If you answered <i>Yes</i> to question 162, how were these resources made available?	☐ Bilateral channels☐ Regional channels☐ Multilateral channels☐ Not applicable		
164. Here you may provide further details on the implementation of the above article in your country: [Type here your text]			
Other information			
165. Please use this field to provide any other information on issues related to national implementation of the Protocol, including any obstacles or impediments encountered.			
[Type here your text]			
Comments on reporting format			
166. Please use this field to provide any other information on difficulties that you have encountered in filling in this report.			
[Type here your to	ext]		

 2^{nd} National Report on the Implementation of the Cartagena Protocol on Biosafety – Page 25