





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

Ninth meeting Sharm El-Sheikh, Egypt, 17-29 November 2018 Item 10 of the provisional agenda*

MONITORING AND REPORTING (ARTICLE 33): REVISED DRAFT FORMAT FOR THE FOURTH NATIONAL REPORT UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY

Note by the Executive Secretary

I. BACKGROUND

- 1. Article 33 of the Cartagena Protocol on Biosafety requires Parties to monitor the implementation of their obligations under the Protocol and to report, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to the Protocol, on measures taken to implement the Protocol.
- 2. At its eighth meeting, in decision <u>CP-VIII/14</u>, the Conference of the Parties serving as the meeting of the Parties to the Protocol requested the Executive Secretary to develop a revised format for the fourth national report under the Protocol with a view to ensuring that complete and accurate information was captured while striving to ensure the applicability of the baseline information, as established in decision <u>BS-VI/15</u>, for review by the Subsidiary Body on Implementation and for consideration at the ninth meeting of the Parties to the Protocol, in particular by:
- (a) Improving the formulation of questions for their clarity, providing further explanation where necessary;
 - (b) Eliminating the redundancy observed in the questions used for the third national report;
- (c) Adding questions that address mainstreaming biosafety into national biodiversity strategies and action plans, other policies and legislation.
- 3. Furthermore, in decision <u>CP-VIII/16</u>, the Conference of the Parties serving as the meeting of the Parties to the Protocol also requested the Executive Secretary to align the language of the relevant questions in the draft format with the adopted operational definitions of the terms "unintentional transboundary movement" and "illegal transboundary movement".
- 4. At its second meeting, the Subsidiary Body on Implementation considered a draft revised format for the fourth national report that had been prepared by the Secretariat.² In its recommendation 2/13, the Subsidiary Body on Implementation invited Parties to the Cartagena Protocol to provide specific

* CBD/CP/MOP/9/

^{*} CBD/CP/MOP/9/1.

¹ In its decision BS-VI/15, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol decided that the data and information contained in the analysis undertaken in the context of the second assessment and review of the effectiveness of the Protocol would form the baseline for measuring progress in implementing the Protocol, in particular the subsequent evaluation of the effectiveness of the Protocol and the mid-term evaluation of the implementation of the Strategic Plan for the Cartagena Protocol on Biosafety for the period 2011-2020.

² See <u>CBD/SBI/2/13</u>, annex.

comments on the draft format, and requested the Executive Secretary to update the draft format, taking into account the comments received, and to submit it for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, at its ninth meeting, with further clarification on the changes made. In the same recommendation, the Subsidiary Body on Implementation presented a draft decision for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety at its ninth meeting, as reproduced in section II below.

- 5. Accordingly, a notification was issued inviting Parties to provide specific comments on the draft revised format for the fourth national report.³ A total of 11 submissions were received, from Austria, Bulgaria, Cameroon, Czechia, France, India, Iran (Islamic Republic of), Japan, Mexico, United Kingdom of Great Britain and Northern Ireland, and Zimbabwe.
- 6. To give effect to the requests in decision BS-VI/15 as well as the comments received following the second meeting of the Subsidiary Body on Implementation, the Secretariat has prepared an updated draft revised format for the fourth national report, as annexed below. It includes the following main changes:
- (a) The language of the questions was improved where possible and necessary, and was aligned with the wording of the Protocol;
- (b) Questions that were redundant or no longer relevant were removed, in particular duplicate questions;
- (c) References to the indicators in the Strategic Plan for the Protocol, and to question numbers in the second national reporting format, were moved to a reference table that will accompany the format for the fourth national report (similar to the table provided in information document CBD/CP/MOP/9/INF/5);
- (d) The possible responses to some questions were revised to improve the clarity of the answers, in particular where answers that contained interval scales that offered more than one possible option;
- (e) The option to select "No changes since previous report" and to apply the same answer as that provided in the previous report was removed from the offline version of the draft revised format. However, the possibility to visualize and select answers provided in the previous report will be available in the online format (it is intended that the online format for the fourth national reports will be "pre-filled" with the answers submitted by the Party concerned in its last report, as a reference);
- 7. Furthermore, questions related to liability and redress have been included in the proposed draft revised reporting format in the light of the entry into force of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress. The additional questions in the draft revised reporting format would enable Parties to provide information for the review of the effectiveness of the Supplementary Protocol further to its Article 13.
- 8. Further information on the changes to each individual question is available in information document CBD/CP/MOP/9/INF/5 and may be helpful for cross-referencing the questions in the draft revised format for the fourth national report in relation to the format for the third national report.

II. SUGGESTED ELEMENTS FOR A DRAFT DECISION

9. The Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider the updated draft format for the fourth national report, as contained in the annex to the present note, and to adopt a decision along the lines of the draft decision contained in recommendation 2/13 of the Subsidiary Body on Implementation:

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

Recalling decision CP-VIII/14, in which the Executive Secretary was requested to develop a revised format for the fourth national reports with a view to ensuring that complete and accurate

³ Notification 2018-069, issued on 9 August 2018 (Ref. No.: SCBD/SPS/AS/MPM/MW/87584.

information is captured while striving to ensure the applicability of the baseline information, established in decision BS-VI/15,

Welcoming the review by the Subsidiary Body on Implementation, at its second meeting, of the draft revised format for the fourth national report, as proposed by the Executive Secretary,⁴

- 1. Adopts the reporting format annexed hereto, and requests Parties to use it for the fourth national report on the implementation of the Cartagena Protocol on Biosafety;
- 2. *Invites* Parties to prepare their reports through a consultative process involving all relevant national stakeholders, including indigenous peoples and local communities, as appropriate;
- 3. *Encourages* Parties to respond to all questions in the reporting format, and stresses the importance of the timely submission of fourth national reports in order to facilitate the fourth assessment and review of the effectiveness of the Cartagena Protocol and the final evaluation of the Strategic Plan for the Cartagena Protocol on Biosafety for the period 2011-2020;⁵
- 4. *Requests* Parties and *invites* other Governments to submit to the Secretariat their fourth national report on the implementation of the Cartagena Protocol on Biosafety:
 - (a) In an official language of the United Nations;
- (b) Twelve months prior to the tenth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, when the report will be considered;
- (c) Preferably online through the Biosafety Clearing-House, or offline using the appropriate form that will be made available by the Secretariat for this purpose, duly signed by the national focal point for the Cartagena Protocol;
- 5. *Requests* the Executive Secretary to continue making available, in the online reporting tool, the option to view and select the answers provided in the previous national report submitted by the Party concerned;
- 6. Recommends to the Conference of the Parties, in adopting guidance to the financial mechanism, that it invite the Global Environment Facility to make available, in a timely manner, financial resources to eligible Parties to facilitate the preparation and submission of their fourth national reports under the Protocol.

⁴ See Subsidiary Body recommendation <u>2/13</u>.

⁵ Decision <u>BS-V/16</u>, annex I.

Annex

UPDATED DRAFT FORMAT FOR THE FOURTH NATIONAL REPORT UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY

Origin of the report

1.	Country:	[Type your text here]
Сог	ntact person submitting the report			
2.	Name:	[Type your text here]
3.	Title:	[Type your text here]
4.	Organization:	[Type your text here]
5.	Mailing address:	[Type your text here]
6.	Telephone:	[Type your text here]
7.	Fax:	[Type your text here]
8.	E-mail:	[Type your text here]
9.	Organizations/stakeholders who were consulted or participated in the preparation of this report:	[Type your text here]
Sub	omission			
10.	Date of submission:	[day / month / year]
11.	Time period covered by this report:	From	[month / year] to [month / year]
Sig	nature of the reporting officer ⁶			

IMPORTANT: To facilitate the analysis of the information contained in this report, it is recommended that Parties submit the report online through the Biosafety Clearing-House or as an attachment to an e-mail in MS Word format, together with a scanned copy of the signed first page, to the Secretariat at: secretariat@cbd.int.

Please do not send this report via fax or postal mail or in electronic formats other than MS Word.

⁶ This document is a protected form in MS Word format to enable further processing of the information contained therein by the CBD Secretariat. Only text entries and checkboxes may be changed. Once you finish filling in the form, please save it and print this first page for signature. This form is also available in the BCH for electronic submission at: [LINK TO BE ADDED]

12.	If your country is not a Party to the Cartagena Protocol on Biosafety (CPB), is there any national process in place towards becoming a Party?		Yes No
13.	Here you may provide further details:	•	
	[Type your text	t here]
	Article 2 – Gener	al provi	isions
£	Article 2 requires each Party to take the necessary a measures to implement its oblig		
			National measures are fully in place
1.4	TT		National measures are partially in place
14.	Has your country introduced the necessary national measures for the implementation of the Protocol?		Only temporary measures have been introduced
			Only draft measures exist
			No measures have yet been taken
			One or more national biosafety laws
15.	Which specific instruments are in place for the implementation of national biosafety measures?		One or more national biosafety regulations
			One or more sets of biosafety guidelines
			Other laws, regulations or guidelines that indirectly apply to biosafety
			No instruments are in place
16.	Has your country undertaken initiatives to		Yes: [Please specify]
	mainstream biosafety into national biodiversity strategies and action plans,		No
	other policies, or legislation?		Other: [Please specify]
17.	Has your country established a mechanism		Yes
1,,	for budget allocations for the operation of		Yes, to some extent: [Please specify]
	its national biosafety measures?		No
18.	Does your country have permanent staff to administer functions directly related to biosafety?		Yes No
19.	If you answered <i>Yes</i> to question 18, how many permanent staff members are in place whose functions are directly related to biosafety?	☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐	1 to 4 5 to 9 10 or more number adequate: ☐ Yes ☐ No

20.	Here you may provide further details on the implementation of Article 2 in your country:				
	[Type your text]			
	Article 5 – Pharmaceuticals				
21.	Does your country regulate the transboundary movement, handling or use of living modified organisms (LMOs) which are pharmaceuticals to humans?		Yes Yes, to some extent: [Please specify] No		
22.	Here you may provide further details on the imple	ementatio	on of Article 5 in your country:		
	[Type your text	here]		
	Article 6 – Transit ar	ıd conta	ined use		
23.	Does your country regulate the transit of LMOs?		Yes Yes, to some extent: [Please specify] No		
24.	Does your country regulate the contained use of LMOs?		Yes No		
25.	Has your country taken a decision concerning the import of LMOs for contained use?		Yes No		
26.	Here you may provide further details on the implementation of Article 6 in your country: [Type your text here]				
	Articles 7 to 10: Advance infor intentional introduction of LM				
27.	Has your country established legal requirements for exporters under its jurisdiction to 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 procedure?		Yes Yes, to some extent: [Please specify] No		
28.	When acting as the Party of export, has your country established legal requirements for the accuracy of information contained in the notification provided by the exporter?		Yes Yes, to some extent: [Please specify] No Not applicable (Party currently not exporting LMOs)		

29.	In the current reporting period, has your country received a notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment?		Yes No
30.	If you answered <i>Yes</i> to question 29, did the notification(s) contain complete information (at a minimum the information specified in Annex I to the Cartagena Protocol on Biosafety)?		Yes, always In some cases only No
31.	If you answered <i>Yes</i> to question 29, has your country acknowledged receipt of the notification(s) to the notifier within ninety days of receipt?		Yes, always In some cases only No
32.	If you answered Yes to question 29, has your coun	itry infor	rmed of its decision(s):
	a. The notifier?		Yes, always In some cases only No
	b. The Biosafety Clearing-House (BCH)?		Yes, always In some cases only No
33.	In the current reporting period, has your country taken a decision in response to the notification(s) regarding intentional transboundary movements of LMOs for intentional introduction into the environment?		Yes No
34.	If you answered <i>Yes</i> to question 33, how many LMOs has your country approved for import for intentional introduction into the environment?		None 1 to 4 5 to 9 10 or more
35.	If you answered <i>under question 34</i> that <i>LMOs were approved</i> , have all these LMOs actually been imported into your country?		Yes, always In some cases only No

36.	If you answered <i>Yes</i> to question 33, what percentage of your country's decisions fall into the following categories?	[%] [%] [%]	Approval of the import/use of the LMO(s) without conditions Approval of the import/use of the LMO(s) with conditions Prohibition of the import/use of the LMO(s) Request for additional relevant information Inform the notifier that the period for communicating the decision has been extended		
37.	If you answered <i>under question 36</i> that your country has taken a decision to approve the import with conditions or to prohibit the import, were the reasons provided?		Yes, always In some cases only No		
38.	Here you may provide further details on the imple country, including measures in case of lack of sci- of LMOs for intentional introduction to the environment.	entific ce onment:			
	Article 11 – Procedure for living modified organisms intended for direct use as food or feed, or for processing (LMOs-FFP)				
39.	Does your country have law(s), regulation(s) or administrative measures for decision-making regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing?		Yes No		
40.	Has your country established legal requirements for the accuracy of information to be provided by the applicant regarding the domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing?		Yes Yes, to some extent: [Please specify] No		

41.	In the current reporting period, how many decisions has your country taken regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing?		None 1 to 4 5 to 9 10 or more		
42.	Does your country have law(s), regulation(s) or administrative measures for decision-making regarding the import of LMOs for direct use as food or feed, or for processing?		Yes No		
43.	In the current reporting period, how many decisions has your country taken regarding the import of LMOs for direct use as food or feed, or for processing?		None 1 to 4 5 to 9 10 or more		
44.	including measures in case of lack of scientific certainty on potential adverse effects of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing:				
	[Type your text here]				
	Article 12 – Revie	ew of de	cision		
45.	Has your country established a mechanism for the review and change of a decision regarding an intentional transboundary movement of LMOs?	ew of de	Yes Yes, to some extent: [Please specify] No		
45.	Has your country established a mechanism for the review and change of a decision regarding an intentional	ew of de	Yes Yes, to some extent: [Please specify]		
	Has your country established a mechanism for the review and change of a decision regarding an intentional transboundary movement of LMOs? In the current reporting period, has your country reviewed and/or changed a decision regarding an intentional	ew of de	Yes Yes, to some extent: [Please specify] No Yes		
46.	Has your country established a mechanism for the review and change of a decision regarding an intentional transboundary movement of LMOs? In the current reporting period, has your country reviewed and/or changed a decision regarding an intentional transboundary movement of an LMO? If you answered <i>Yes</i> to question 46, how many decisions were reviewed and/or	ew of de	Yes, to some extent: [Please specify] No Yes No 1 to 4 5 to 9		

50.	If you answered <i>Yes</i> to question 46, were any of the reviews initiated by your country as the Party of import?		Yes No		
51.	If you answered <i>Yes</i> to question 50, did your cour the decision and inform:	you answered <i>Yes</i> to question 50, did your country, within thirty days, set out the reasons for e decision and inform:			
	a. The notifier?		Yes, always In some cases only No		
	b. The BCH?		Yes, always In some cases only No		
52.		re you may provide further details on the implementation of Article 12 in your country: Type your text here			
	Article 13 – Simpli	ified pro	ocedure		
53.	Has your country established a mechanism for the application of the simplified procedure regarding an intentional transboundary movement of LMOs?		Yes Yes, to some extent: [Please specify] No		
54.	In the current reporting period, has your country applied the simplified procedure?		Yes No		
55.	If you answered <i>Yes</i> to question 54, for how many LMOs has your country applied the simplified procedure?		None 1 to 5 5 or more		
56.	If you answered <i>Yes</i> to question 54, has your country informed the Parties through the BCH of the cases where the simplified procedure was applied?		Yes, always In some cases only No		
	procedure was appried:				
57.	Here you may provide further details on the impl	ementati			

	Article 14 – Bilateral, regional and multilateral agreements and arrangements				
58.	How many bilateral, regional or multilateral agreements or arrangements relevant to biosafety has your country established with other Parties/non-Parties?		None 1 to 4 5 to 9 10 or more		
59.	59. If you answered <i>under question 58</i> that <i>agreements or arrangements were established</i> , please provide a brief description of their scope and objective: [Type your text here]				
60.		re you may provide further details on the implementation of Arti-			
	Articles 15 & 16 – Risk assessr	nent an	d risk management		
61.	Does the domestic regulatory framework of your country require risk assessments of LMOs to be conducted?		Yes No		
62.	If you answered <i>Yes</i> to question 61, with regard to which LMOs does the requirement apply (select all that apply)?		For imports of LMOs for intentional introduction into the environment For imports of LMOs intended for direct use as food or feed, or for processing For decisions regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movements for direct use as food or feed, or for processing For imports of LMOs for contained use Other: [Please specify]		
63.	Has your country established a mechanism to conduct risk assessments prior to taking decisions regarding LMOs?		Yes Yes, to some extent: [Please specify] No		
64.	If you answered <i>Yes</i> to question 63, does the mechanism include procedures to identify and/or train national experts to conduct risk assessments?		Yes No		

Capacity-building in risk assessment or risk management					
65.	How many people in your country have been trained in risk assessment, risk management and monitoring of LMOs?				
	a. Risk assessment:		None 1 to 9 10 to 49 50 to 99 100 or more		
	b. Risk management:		None 1 to 9 10 to 49 50 to 99 100 or more number adequate: Yes No		
	c. Monitoring:	☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐	None 1 to 9 10 to 49 50 to 99 100 or more number adequate: ☐ Yes ☐ No		
66.	Is your country using training material and/or technical guidance for training in risk assessment and risk management of LMOs?		Yes No		
67.	If you answered <i>Yes</i> to question 66, is your country using the "Manual on Risk Assessment of LMOs" (developed by the CBD Secretariat) for training in risk assessment?		Yes No		
68.	If you answered <i>Yes</i> to question 66, is your country using the "Guidance on Risk Assessment of LMOs" (developed by the Online Forum and the AHTEG on Risk Assessment and Risk Management) for training in risk assessment?		Yes No		

69.	Does your country have specific needs for further guidance on specific topics of risk assessment of LMOs?		Yes: [Please specify] No		
70.	Does your country have the capacity to detect, identify, assess the risk of and/or monitor LMOs or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health?				
	a. Detect:		Yes No		
	b. Identify:		Yes No		
	c. Assess the risk:		Yes No		
	d. Monitor:		Yes No		
Conc	lucting risk assessment or risk management				
71.	Has your country adopted or used any guidance of assessment or risk management, or for evaluating notifiers?				
	a. Risk assessment:		Yes No		
	b. Risk management:		Yes No		
72.	If you answered Yes to question 71, is your country using the "Guidance on Risk Assessment of LMOs" (developed by the Online Forum and the AHTEG on Risk Assessment and Risk Management) for conducting risk assessment or risk management, or for evaluating risk assessment reports submitted by notifiers?		Yes No		
73.	Has your country adopted common approaches or methodologies to risk assessment in coordination with other countries?		Yes No		

74.	Has your country cooperated with other Parties with a view to identifying LMOs or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity?	Yes No
75.	In the current reporting period, has your country conducted any kind of risk assessment of LMOs, including for contained use, field trials, commercial purposes, direct use as food, feed, or for processing?	Yes No
76.	If you answered <i>Yes</i> to question 75, how many risk assessments were conducted?	1 to 9 10 to 49 50 to 99 More than 100
77.	If you answered <i>Yes</i> to question 75, please indicate the scope of the risk assessments (select all that apply):	LMOs for contained use (in accordance with Article 3) LMOs for intentional introduction into the environment for experimental testing or field trials LMOs for intentional introduction into the environment for commercial purposes LMOs for direct use as food LMOs for direct use as feed LMOs for processing Other: [Please specify]
78.	If you answered <i>Yes</i> to question 75, were risk assessments conducted for all decisions taken on LMOs for intentional introduction into the environment or on domestic use of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing?	Yes, always In some cases only No
79.	Has your country established appropriate mechanisms, measures and strategies to regulate and manage risks identified in the risk assessment of LMOs?	Yes No

80.	Has your country taken appropriate measures to prevent unintentional transboundary movements of LMOs, including such measures as requiring a risk assessment to be carried out prior to the first release of a LMO?		Yes No
81.	Has your country taken measures to ensure that any LMO, whether imported or locally developed, undergoes an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use?		Yes Yes, to some extent: [Please specify] No
82.	Has your country established a mechanism for monitoring potential effects of LMOs released into the environment?		Yes Yes, to some extent: [Please specify] No
83.	Does your country have the necessary infrastructure (e.g. laboratory facilities) for monitoring or managing LMOs?		Yes No
84.	Here you may provide further details on the imple country:	ementatio	on of Articles 15 and 16 in your
	[Type your text	t here]
	Article 17 – Unintentional transboundary	moveme	ents ⁷ and emergency measures
85.	Has your country established measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations in case of a release under its jurisdiction that leads, or may lead, to an unintentional transboundary movement?		Yes Yes, to some extent: [Please specify] No
86.	In the current reporting period, how many releases of LMOs occurred under your country's jurisdiction that led, or may have led, to an unintentional transboundary movement?		None 1 to 4 5 to 9 10 or more

⁷ In accordance with the operational definition adopted in decision CP-VIII/16, "'Unintentional transboundary movement' is a transboundary movement of a living modified organism that has inadvertently crossed the national borders of a Party where the living modified organism was released, and the requirements of Article 17 of the Protocol apply to such transboundary movements only if the living modified organism involved is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, in the affected or potentially affected States."

87.	If you answered <i>under question 86</i> that a <i>release occurred</i> , has your country notified affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations?		Yes, always In some cases only No		
88.	Does your country have the capacity to take appropriate response measures in response to unintentional transboundary movements?		Yes No		
89.	In the current reporting period, how many times has your country become aware of an unintentional transboundary movement into its territory?		None 1 to 4 5 to 9 10 or more		
90.	Here you may provide further details on the implementation of Article 17 in your country: Type your text here				
	[Type your tex	Kt Here	J		
	Article 18 – Handling, transport, packaging and identification				
91.	Has your country taken measures to require that <i>LMOs that are subject to transboundary movement</i> are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards?		Yes Yes, to some extent: [Please specify] No		
92.	Has your country taken measures to require that documentation accompanying LMOs-FFP, in cases where the identity of the LMOs is not known, clearly identifies that they may contain LMOs and are not intended for intentional introduction into the environment, as well as a contact point for further information?		Yes Yes, to some extent: [Please specify] No		
93.	Has your country taken measures to require that documentation accompanying LMOs-FFP, in cases where the identity of the LMOs is known, clearly identifies that they contain LMOs and are not intended for intentional introduction into the environment, as well as a contact point for further information?		Yes Yes, to some extent: [Please specify] No		

94.	If you answered <i>Yes</i> to question(s) 91, 92 and/or 93, what type of documentation accompanying LMOs does your country require?	Documentation specific for LMOs As part of other documentation (not specific for LMOs) Other: [Please specify]
95.	Has your country taken measures to require that documentation accompanying <i>LMOs that are destined for contained use</i> clearly identifies them as <i>LMOs</i> and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the LMO are consigned?	Yes Yes, to some extent: [Please specify] No
96.	If you answered <i>Yes</i> to question 95, what type of documentation does your country require for the identification of LMOs that are destined for contained use?	Documentation specific for LMOs As part of other documentation (not specific for LMOs) Other: [Please specify]
97.	Has your country taken measures to require that documentation accompanying LMOs that are intended for intentional introduction into the environment of the Party of import, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter?	Yes Yes, to some extent: [Please specify] No
98.	If you answered <i>Yes</i> to question 97, what type of documentation does your country require for the identification of LMOs that are intended for intentional introduction into the environment?	Documentation specific for LMOs As part of other documentation (not specific for LMOs) Other: [Please specify]
99.	Does your country have available any guidance for the purpose of ensuring the safe handling, transport, and packaging of living modified organisms?	Yes No

100.	Does your country have the capacity to enforce the requirements of identification and documentation of LMOs?	Yes Yes, to some extent: [Please specify] No
101.	How many customs officers in your country have received training in the identification of LMOs?	□ None □ 1 to 9 □ 10 to 49 □ 50 to 99 □ 100 or more Is this number adequate: □ Yes □ No
102.	Has your country established procedures for the sampling and detection of LMOs?	Yes Yes, to some extent: [Please specify] No
103.	How many laboratory personnel in your country have received training in detection of LMOs?	□ None □ 1 to 9 □ 10 to 49 □ 50 to 99 □ 100 or more Is this number adequate: □ Yes □ No
104.	Does your country have reliable access to laboratory facilities for the detection of LMOs?	☐ Yes☐ No
105.	How many laboratories in your country are certified for LMO detection?	□ None □ 1 to 4 □ 5 to 9 □ 10 to 49 □ 50 or more
106.	If you answered <i>under question 105</i> that <i>certified laboratories exist in your country</i> , how many of them are currently operating in the detection of LMOs?	□ None □ 1 to 4 □ 5 to 9 □ 10 to 49 □ 50 or more
107.	Here you may provide further details on the impl	
	[Type your text here]	

	Article 19 – Competent national authorities and national focal points			
108.	In case your country has designated more than one competent national authority, has your country established a mechanism for the coordination of their actions prior to taking decisions regarding LMOs?		Yes No Not applicable (no competent national authority was designated)	
109.	Has your country established adequate institutional capacity to enable the competent national authority(ies) to perform the administrative functions required by the Cartagena Protocol on Biosafety?		Yes Yes, to some extent: [Please specify] No	
110.	Has your country undertaken initiatives to strengthen collaboration among national focal points, competent national authority(ies) and other institutions on biosafety-related matters?		Yes: [Please specify] No	
111.	11. Here you may provide further details on the implementation of Article 19 in your country:			
	[Type your tex	Type your text here		
	Article 20 – Information sharing and th	e Biosa	fety Clearing-House (BCH)	
112.	Please provide an overview of the status of the mountry to the BCH by specifying for each category whether it has been submitted to the BCH.			
a.	Existing legislation, regulations and guidelines for implementing the Protocol, as well as information required by Parties for the advance informed agreement procedure (Article 20, paragraph 3 (a))		Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available	
b.	Legislation, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing (Article 11, paragraph 5)		Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available	

c.	Bilateral, multilateral and regional agreements and arrangements (Article 14, paragraph 2, and Article 20, paragraph 3 (b))	Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available
d.	Contact details for competent national authorities (Article 19, paragraphs 2 and 3), national focal points (Article 19, paragraphs 1 and 3), and emergency contacts (Article 17, paragraph 3 (e))	Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available
e.	Decisions by a Party regarding transit of LMOs (Article 6, paragraph 1)	Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available
f.	Decisions by a Party regarding import of LMOs for contained use (Article 6, paragraph 2)	Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available
g.	Notifications regarding the release under your country's jurisdiction that leads, or may lead, to an unintentional transboundary movement of a LMO that is likely to have significant adverse effects on biological diversity (Article 17, paragraph 1)	Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available

h.	Information concerning cases of illegal transboundary movements of LMOs (Article 25, paragraph 3)	Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available
i.	Decisions regarding the importation of LMOs for intentional introduction into the environment (Article 10, paragraph 3)	Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available
j.	Information on the application of domestic regulations to specific imports of LMOs (Article 14, paragraph 4)	Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available
k.	Decisions regarding the domestic use of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing (Article 11, paragraph 1)	Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available
1.	Decisions regarding the import of LMOs intended for direct use as food or feed, or for processing that are taken under domestic regulatory frameworks (Article 11, paragraph 4) or in accordance with Annex III to the Protocol (Article 11, paragraph 6)	Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available

m.	Declarations regarding the framework to be used for LMOs intended for direct use as food or feed, or for processing (Article 11, paragraph 6)		Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available
n.	Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12, paragraph 1)		Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available
o.	Cases where intentional transboundary movement may take place at the same time as the movement is notified to the Party of import (Article 13, paragraph 1 (a))		Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available
p.	LMOs granted exemption status by each Party (Article 13, paragraph 1 (b))		Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available
q.	Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and relevant information regarding products thereof (Article 20, paragraph 3 (c))		Information available and in the BCH Information available but not in the BCH Information available but only partially available in the BCH Information not available
113.	Please provide a brief explanation if you answere the BCH or only partially available in the BCH t		
	[Type your text here]		

114.	Has your country established a mechanism for strengthening the capacity of the BCH national focal point to perform its administrative functions?	Yes, to some extent: [Please specify] No
115.	Has your country established a mechanism for the coordination among the BCH national focal point, the Cartagena Protocol national focal point, and the competent national authority(ies) for making information available to the BCH?	Yes, to some extent: [Please specify] No
116.	Does your country use the information available in the BCH in its decision-making processes on LMOs?	Yes, always Yes, in some cases No Not applicable (no decisions were taken)
117.	Has your country experienced difficulties accessing or using the BCH?	Yes: [Please specify] No
118.	In the current reporting period, how many biosafety-related events (e.g. seminars, workshops, press conferences, educational events) has your country organized?	None 1 to 4 5 to 9 10 to 24 25 or more
119.	In the current reporting period, how many biosafety-related publications has your country published?	None 1 to 9 10 to 49 50 to 99 100 or more
120.	Here you may provide further details on the impl	
	Type your tex Article 21 – Confiden	rmation
		Yes
121.	Has your country established procedures to protect confidential information received under the Protocol?	Yes, to some extent: [Please specify] No

122.	Does your country allow the notifier to identify information that is to be treated as confidential?		Yes, always In some cases only No
123.	Here you may provide further details on the imple		on of Article 21 in your country:
	[Type your text		
	Article 22 – Capac	city-buil	ding
124.	Does your country have predictable and reliable funding for building capacity for the effective implementation of the Protocol?		Yes, to some extent: [Please specify] No
125.	Has your country received external support or benefited from collaborative activities with other Parties in the development and/or strengthening of human resources and institutional capacities in biosafety?		Yes Yes, to some extent: [Please specify] No
126.	If you answered <i>Yes</i> to question 125, how were these resources made available?		Bilateral channels Regional channels Multilateral channels
127.	Has your country provided support to other Parties in the development and/or strengthening of human resources and institutional capacities in biosafety?		Yes, to some extent: [Please specify] No
128.	If you answered <i>Yes</i> to question 127, how were these resources made available?		Bilateral channels Regional channels Multilateral channels
129.	In the reporting period, has your country initiated a process to access funds from the Global Environment Facility (GEF) for building capacity in biosafety?		Yes: [Please specify] No
130.	If you answered <i>Yes</i> to question 129, how would you characterize the process?		Very easy Easy Average Difficult Very difficult

131.	In the current reporting period, has your country undertaken activities for the development and/or strengthening of human resources and institutional capacities in biosafety?	Yes, to some extent: [Please specify] No
	If you answered <i>Yes</i> to question 131, in which of the following areas were these activities undertaken (select all that apply)?	Institutional capacity and human resources Integration of biosafety in cross-sectoral and sectoral legislation, policies and institutions (mainstreaming biosafety) Risk assessment and other scientific and technical expertise Risk management Public awareness, participation and
		education in biosafety Information exchange and data management, including participation in the Biosafety Clearing-House
132.		Scientific, technical and institutional collaboration at subregional, regional and international levels
132.		Technology transfer Identification of LMOs, including their detection
		Socioeconomic considerations Implementation of the documentation requirements under Article 18.2 of the Protocol
		Handling of confidential information Measures to address unintentional and/or illegal transboundary movements of LMOs
		Scientific biosafety research relating to LMOs
		Taking into account risks to human health
		Liability and redress Other: [Please specify]
133.	In the current reporting period, has your country carried out a capacity-building needs assessment?	Yes No
134.	Does your country still have capacity-building needs?	Yes No

			Institutional capacity and human
			Integration of biosafety in cross-sectoral and sectoral legislation, policies and
			Risk assessment and other scientific and
			_
			•
			education in biosafety
			Information exchange and data management, including participation in the Biosafety Clearing-House
135.	If you answered <i>Yes</i> to question 134,		and sectoral legislation, policies and institutions (mainstreaming biosafety) Risk assessment and other scientific and technical expertise Risk management Public awareness, participation and education in biosafety Information exchange and data management, including participation in the Biosafety Clearing-House Scientific, technical and institutional collaboration at subregional, regional and international levels Technology transfer Sampling, detection and identification of LMOs Socioeconomic considerations Implementation of the documentation requirements for handling, transport, packaging and identification Handling of confidential information Measures to address unintentional and/or illegal transboundary movements of LMOs Scientific biosafety research relating to LMOs Taking into account risks to human health Liability and redress Other: [Please specify] Yes No
	which of the following areas still need capacity-building (select all that apply)?	П	
	capacity-building (select air that appry):		Sampling, detection and identification
			Implementation of the documentation
			_
			and/or illegal transboundary movements
			Scientific biosafety research relating to
			Other: [Please specify]
136.	Has your country developed a capacity-		Yes
	building strategy or action plan?		No
137.	Does your country have in place a functional national mechanism for		Yes
	coordinating biosafety capacity-building initiatives?		No
138.	Here you may provide further details on the imple		
	including further details about your experience in accessing GEF funds:		
	[Type your text here]		

	Article 23 – Public awareness and participation			
139.	Is biosafety public awareness, education and/or participation addressed in legislation or policy in your country?		Yes Yes, to some extent: [Please specify] No	
140.	In the current reporting period, has your country cooperated with other States and international bodies in relation to public awareness, education and participation?		Yes: [Please specify] No	
141.	Has your country established a mechanism to ensure public access to information on LMOs?		Yes, to some extent: [Please specify] No	
142.	Does your country have in place a national communication strategy on biosafety?		Yes: [Please specify] No	
143.	Does your country have any awareness and outreach programmes on biosafety?		Yes: [Please specify] No	
144.	Does your country currently have a national biosafety website?		Yes No	
145.	How many academic institutions in your country are offering biosafety education and training courses and programmes?	☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐	None 1 to 4 5 to 9 10 or more number adequate: Yes No	
146.	How many educational materials and/or online modules on biosafety are available and accessible to the public in your country?	☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐	None 1 to 4 5 to 9 10 to 24 25 to 99 100 or more number adequate: Yes No	
147.	Has your country established a mechanism to consult the public in the decision-making process regarding LMOs?		Yes Yes, to some extent: [Please specify] No	

148.	Has your country informed the public about existing modalities for public participation in the decision-making process regarding LMOs?		Yes, to some extent: [Please specify] No
149.	If you answered <i>Yes</i> to question 148, please indicate the modalities used to inform the public:		National websites Newspapers Forums Mailing lists Public hearings Social media Other: [Please specify]
150.	In the current reporting period, how many times has your country consulted the public in the decision-making process regarding LMOs?		None (decisions taken without consultation) 1 to 4 5 or more Not applicable (no decisions were taken)
151.	Has your country informed the public about the means to access the Biosafety Clearing-House?		Yes No
152.	Here you may provide further details on the imp	lementat	tion of Article 23 in your country:
	[Type your te	xt here]
	Article 24 – N	on-Parti	ies
153.	Has your country entered into any bilateral, regional, or multilateral agreement with non-Parties regarding transboundary movements of LMOs?		Yes No
154.	In the current reporting period, has your country imported LMOs from a non-Party?		Yes No
155.	In the current reporting period, has your country exported LMOs to a non-Party?		Yes No
156.	If you answered <i>Yes</i> to question 154 and/or 155, were the transboundary movements of LMOs consistent with the objective of the Cartagena Protocol on Biosafety?		Yes, always In some cases only No

157.	Here you may provide further details on the implementation of Article 24 in your country:			
	[Type your text here]			
	Article 25 – Illegal transboundary movements ⁸			
	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 the Cartagena Protocol?		Yes, to some extent: [Please specify] No	
	In the current reporting period, how many cases of illegal transboundary movements of LMOs has your country become aware of?		None 1 to 4 5 to 9 10 or more	
	If you indicated <i>under question 159</i> that your country became aware of cases of illegal transboundary movements, has the origin of the LMO(s) been established?		Yes Yes, some cases No	
161.	Here you may provide further details on the implementation of Article 25 in your country: [Type your text here]			
	Article 26 – Socio-economic considerations			
	Does your country have any specific approaches or requirements that facilitate how socioeconomic considerations should be taken into account in LMO decision-making?		Yes No	
	In the current reporting period, have socioeconomic considerations arising from the impact of LMOs been taken into account in decision-making?		Yes, always In some cases only No Not applicable (no decisions were taken)	

⁸ In accordance with the operational definition adopted in decision CP VIII/16, "'Illegal transboundary movement' is a transboundary movement of living modified organisms carried out in contravention of the domestic measures to implement the Protocol that have been adopted by the Party concerned".

164. How many peer-reviewed published materials has your country used for the purpose of elaborating or determining national actions with regard to socioeconomic considerations?	□ None □ 1 to 4 □ 5 to 9 □ 10 to 49 □ 50 or more Is this number adequate: □ Yes □ No		
165. Has your country cooperated with other Parties on research and information exchange on any socioeconomic impacts of LMOs?	☐ Yes ☐ No		
166. Here you may provide further details on the implementation of Article 26 in your country:			
[Type your te	xt here]		
Article 28 – Financial mechanism and resources			
167. In the current reporting period, how much funding (in the equivalent of US dollars) has your country mobilized to support implementation of the Cartagena Protocol beyond the regular national budgetary allocation?	□ Nothing □ 1 to 4,999 USD □ 5,000 to 49,999 USD □ 50,000 to 99,999 USD □ 100,000 to 499,000 USD □ 500,000 USD or more		
Article 33 – Monitori	ing and reporting		
Article 33 requires Parties to monitor the implementation of its obligations under the Cartagena Protocol and to report to the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on measures taken to implement the Protocol			
168. Does your country have in place a system to monitor and enforce the implementation of the Cartagena Protocol?	☐ Yes ☐ No		
Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress			
Parties to the Cartagena Protocol that are not yet Party to the Supplementary Protocol are also invited to respond to the questions below			
169. Is your country a Party to the Nagoya- Kuala Lumpur Supplementary Protocol on Liability and Redress?	☐ Yes ☐ No		
170. If you answered <i>No</i> to question 169, is there any national process in place towards becoming a Party to the Supplementary Protocol?	☐ Yes ☐ No		

171.	Has your country introduced the necessary measures for the implementation of the Supplementary Protocol?	National measures are fully in place National measures are partially in place Only temporary measures have been introduced Only draft measures exist No measures have yet been taken
172.	Which instruments are in place for the implementation of the Supplementary Protocol?	One or more national laws: [Please specify] One or more national regulations: [Please specify] One or more sets of guidelines: [Please specify] No instruments are in place
173.	Does your country have administrative or legal instruments that require response measures to be taken:	
a.	In case of damage resulting from LMOs?	Yes No
b.	In case there is sufficient likelihood that damage will result if response measures are not taken?	Yes No
174.	If you answered <i>Yes</i> to question 173a, do these instruments impose requirements on an operator (select all that apply)?	Yes, the operator must inform the competent authority of the damage Yes, the operator must evaluate the damage Yes, the operator must take response measures Yes, other requirements: [Please specify] No
175.	If you answered <i>Yes</i> to question 173a, do these instruments require the operator to take response measures to avoid damage?	Yes No
176.	If you answered <i>Yes</i> to question 173a or 173b, do these instruments provide for a definition of "operator"?	Yes No

			Permit holder
155	If you answered <i>Yes</i> to question 176, which of the following could be an 'operator' (select all that apply)?		Person who placed the LMO on the market
			Developer
			Producer
177.			Notifier
			Exporter
			Importer
			Carrier
			Supplier
			Other: [Please specify]
178.	Has a competent authority been identified		Yes: [Please specify]
	for carrying out the functions set out in the		No
	Supplementary Protocol?		110
	If you answered <i>Yes</i> to question 178, what measures may the competent authority take (select all that apply)?		Identify the operator that caused the damage
			Evaluate the damage
179.			Determine response measures to be taken by operator
			Implement response measures
			Recover costs and expenses of the evaluation of the damage and the implementation of any response measures from the operator
			Other: [Please specify]
180.	Does your country have measures in place	П	Yes
	to provide for financial security for damage resulting from LMOs?		No
	If you answered <i>Yes</i> to question 180, what type of financial security measures are in place (select all that apply)?		D : 44 :1 :1 0
181.			Requirement to provide evidence for secure source of funding
			Mandatory insurance
			Government schemes, including funds
			Other: [Please specify]

182.	Does your country have rules and procedures on civil liability that address damage resulting from LMOs, or has such damage been recognized in court rulings (select all that apply)?		Yes, in a civil liability instrument Yes, in court rulings Yes, in other instruments: [Please specify] No
183.	Have there been any occurrences of damage resulting from LMOs in your country?		Yes: [Please specify] No
184.	If you answered <i>Yes</i> to question 183, have response measures been taken?		Yes: [Please specify] No
185.	5. Here you may provide further details on any activities undertaken in your country towards the implementation of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress:		
	[Type your text here]
Other information			
186.	Please use this field to provide any other information on issues related to national implementation of the Cartagena Protocol and the Supplementary Protocol, including any obstacles or impediments encountered.		
[Type your text here]
Comments on reporting format			
187.	. Please use this field to provide any other information on difficulties that you have encountered in filling in this report.		
[Type your text here]		