Convention on Biological Diversity

2010 International Year of Biodiversity

Format for the Second National Report on the implementation of the Cartagena Protocol on Biosafety

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GUIDELINES FOR USE OF THE REPORTING FORMAT

The following format for preparation of the second national report on implementation of the Cartagena Protocol on Biosafety called for under Article 33 of the Protocol is a series of questions based on those requirements of the Protocol as well as questions that relate to indicators of the Strategic Plan.

Responses to these questions will help Parties to review the extent to which they are successfully implementing the provisions of the Protocol and will assist the Conference of the Parties serving as the meeting of the Parties to the Protocol to assess the overall status of implementation of the Protocol.

Questions highlighted in grey may not strictly be based on provisions of the Cartagena Protocol on Biosafety or the decisions of the Parties to the Protocol. They are included in this reporting format only to help draw a baseline for the assessment and review of the Protocol in the context of Article 35 and to help measure progress in the implementation of the Strategic Plan of the Protocol.

The deadline for submission of the second national report is no less than 12 months prior to the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. It is intended to cover activities undertaken between the presentation of the first national report (or the entry into force of the Protocol for reporting Parties that ratified or acceded to the Protocol after 11 September 2007) and the date of reporting for the second national report.

For subsequent national reports, the format is expected to evolve, as questions that are no longer relevant may be deleted, questions that are relevant to ongoing progress in implementation will be retained, and additional questions will be formulated pursuant to future decisions of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

The wording of questions follows the wording of the relevant articles of the Protocol as closely as possible. The use of terms in the questions follows the meanings accorded to them under Article 3 of the Protocol.

The format tries to minimize the reporting burden on Parties, while eliciting the important information regarding implementation of the provisions of the Protocol. Most of the questions asked require only a tick in one or more boxes and for each article, a text field allows the provision of further details on its implementation. Although there is no set limit on the length of text, in order to assist with the review and synthesis of the information in the reports, respondents are asked to ensure that answers are as relevant and as succinct as possible.

The Executive Secretary welcomes any comments on the adequacy of the questions, and difficulties in completing the questions, and any further recommendations on how these reporting guidelines could be improved. Space is provided for such comments at the end of the report.

It is recommended that Parties involve all relevant stakeholders in the preparation of the report, in order to ensure a participatory and transparent approach to its development and the accuracy of the information requested.

The form is also available on the BCH for completion electronically at the following address: http://bch.cbd.int/managementcentre/edit/CPBnationalreport2.shtml

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

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

Origin of report

1.	**Country:**	**Sweden**

Contact officer for report

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9. Organizations/stakeholders who were consulted or participated in the preparation of this report:	**Swedish Environmental Protection Agency** **Swedish Work Environment Authority** **Swedish Board of Fisheries** **Formas** **Swedish Gene Technology Advisory Board** **Swedish Board of Agriculture** **Swedish Chemical Agency** **Swedish National Board of Trade** **Swedish National Food Agency** **Swedish Medical Products Agency** **Swedish Civil Contingencies Service** **Swedish International Development Cooperation Agency** **Swedish Board of Forestry** **Swedish Customs Agency** **Swedish Ecological Farmers** **Greenpeace** **Federation of Swedish Farmers** **Plant Science Sweden AB** **SW Seed** **SwedBio** **Swedish Society for Nature Conservation** **Syngenta Seeds AB**

Submission

10. Date of submission:	**[Type your text here]**
11. Time period covered by this report:	**2006-2011**

Signature of the reporting officer[1] _____

[1] This document is made available as a protected form in MS Word format for further processing of the information contained therein by the CBD Secretariat. Only text entries and checkboxes are changeable. Once the document is filled in, please save it and print this first page for signature. The form is also available on the BCH for completion electronically at: http://bch.cbd.int/managementcentre/edit/CPBnationalreport2.shtml

IMPORTANT: To facilitate the analysis of the information contained in this reports, please send the report to the Secretariat via e-mail at secretariat@cbd.int as attachment in MS Word format, together with a scanned copy of the first signed page; please *do not* send this report via fax or postal mail or in electronic formats other than MS Word.

12. Is your country a Party to the Cartagena Protocol on Biosafety (CPB)?	☒	Yes
	☐	No
13. If you answered *No* to question 12, is there any national process in place towards becoming a Party?	☐	Yes
	☒	No
	☐	Not applicable
14. Here you may provide further details: [Type your text here]		
Article 2 – General provisions		
15. Has your country introduced the necessary legal, administrative and other measures for the implementation of the Protocol?	☒	A domestic regulatory framework is fully in place
	☐	A domestic regulatory framework is partially in place
	☐	Only temporary measures have been introduced
	☐	Only a draft framework exists
	☐	No measures have yet been taken
16. 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 regulations
	☐	One or more sets of biosafety guidelines
	☐	Other laws, regulations or guidelines that indirectly apply to biosafety
	☐	No instruments are in place

17. Has your country established a mechanism for the budgetary allocations of funds for the operation of its national biosafety framework?	☒ Yes ☐ No	
18. Does your country have permanent staff to administer functions directly related to the national biosafety framework?	☒ Yes ☐ No	
19. If you answered *Yes* to question 18, 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	
20. Has your country's biosafety framework / laws / regulations / guidelines been submitted to the Biosafety Clearing-House (BCH)?	☒ Yes ☐ Partially ☐ No	
21. Here you may provide further details on the implementation of Article 2 in your country: We refer to the EU's Second National Report on the Implementation of the Cartegena Protocol on Biosafety		
Article 5 – Pharmaceuticals		
22. Does your country regulate the transboundary movement, handling and use of living modified organisms (LMOs) which are pharmaceuticals?	☒ Yes ☐ Yes, to some extent ☐ No	
23. If you answered *Yes* to question 22, has this information been submitted to the BCH?	☒ Yes ☐ Partially ☐ No ☐ Not applicable	

24. Here you may provide further details on the implementation of Article 5 in your country:

    Pharmaceuticals are regulated under EU-law as other LMOs

Article 6 – Transit and Contained use

25. Does your country regulate the transit of LMOs?	☒	Yes
	☐	No
26. Does your country regulate the contained use of LMOs?	☒	Yes
	☐	No
27. If you answered *Yes* to questions 25 or 26, has this information been submitted to the BCH?	☒	Yes
	☐	Partially
	☐	No
	☐	Not applicable

28. Here you may provide further details on the implementation of Article 6 in your country:

    Regarding 25: Transit is not specifically regulated in Swedish or EU-law, but the rules for traceability and labelling provides for a transparent system if LMOs were to be in transit via Sweden. Regarding 26: Decisions on LMO that are micro-organisms in risk class 3 or 4 (high risk human pathogens) are routinely sent to the Swedish Focal Point for submission to the BCH mechanism, as we cannot exclude export of such LMOs (all are used in research). We also refer to the EU's Second National Report on the Implementation of the Cartegena Protocol on Biosafety.

Articles 7 to 10: Advance Informed Agreement (AIA) and intentional introduction of LMOs into the environment

29. Has your country adopted law(s) / regulations / administrative measures for the operation of the AIA procedure of the Protocol?	☒	Yes
	☐	No
30. Has your country adopted a domestic regulatory framework consistent with the Protocol regarding the transboundary movement of LMOs for intentional introduction into the environment?	☒	Yes
	☐	No

31. Has your country established a mechanism for taking decisions regarding first intentional transboundary movements of LMOs for intentional introduction into the environment?	☒ Yes ☐ No
32. If you answered *Yes* to question 31, does the mechanism also apply to cases of intentional introduction of LMOs into the environment that were not subject to transboundary movement?	☒ Yes ☐ No ☐ Not applicable
33. Has your country established a mechanism for monitoring potential effects of LMOs that are released into the environment?	☒ Yes ☐ No

34. Does your country have the capacity to detect and identify LMOs?	☒ Yes ☐ Yes, to some extent ☐ No
35. 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 ☐ No
36. Has your country established legal requirements for the accuracy of information contained in the notification?	☒ Yes ☐ No
37. Has your country ever received an application / notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment?	☐ Yes ☒ No
38. Has your country ever taken a decision on an application / notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment?	☐ Yes ☒ No ☐ Not applicable
39. If you answered *Yes* to question 38, how many LMOs has your country approved to date for import for intentional introduction into the environment?	☐ None ☐ Less than 5 ☐ Less than 10 ☐ More than 10 ☐ Not applicable
40. If you answered *Yes* to question 38, how many LMOs, not imported, has your country approved to date for intentional introduction into the environment?	☐ None ☐ Less than 5 ☐ Less than 10 ☒ More than 10 ☐ Not applicable

41. In the current reporting period, how many applications/notifications 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
42. 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 you replied <u>None</u> to question 42 please go to question 50		
43. 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) prior to the transboundary movement?	☐	Yes, always
	☐	In some cases only
	☐	No
44. Did the notifications contain complete information (at a minimum the information specified in Annex I of the Cartagena Protocol on Biosafety)?	☐	Yes, always
	☐	In some cases only
	☐	No
	☐	Not applicable
45. Has your country acknowledged receipt of the notifications to the notifier within ninety days of receipt?	☐	Yes, always
	☐	In some cases only
	☐	No
	☐	Not applicable

46. 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 ☐ Not applicable
47. 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 communication to the notifier)?	☐ Yes, always ☐ In some cases only ☐ No ☐ Not applicable
48. What percentage of your country's decisions fall into 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 ☐ Not applicable
49. In cases where your country approved an import with conditions or prohibited an import, did it provide reasons on which its decisions were based to the notifier and the BCH?	☐ Yes, always ☐ In some cases only ☐ In some cases only to the notifier ☐ In some cases only to the BCH ☐ No ☐ Not applicable

50. Here you may provide further details on the implementation of Articles 7-10 in your country, including measures in case of lack of scientific certainty on potential adverse effects of LMOs for intentional introduction to the environment:

Article 7 – 10 for release on the market is implemented in legislation at the EU level and these answers will be provided by the Member States and the European Commission (Dir. 2001/18, Reg, 1829/2003 and Reg. 1830/2003).

Directive 2001/18/EC is implemented in Swedish Ordinance (2002:1086). Decisions on intentional introduction to the environment as field trials are however made at national level. This procedure is also regulated in Ordinance (2002:1086) and is in compliance with the provisions of the Biosafety protocol. The regulation for authorisation of LMO is based on the use of a LMO, not the transboundary movement in itself even though import might be one of the areas of use.

30-32. Decisions on field trials are always based on an application that corresponds with the provisions of articles 7-10 and 12. Permission must be given by proper authority before a release into the environment. There is no difference if the LMO is produced within the country or imported.

33. Monitoring is required by EU Dir. 2001/18 and the Swedish Ordinance (2002:1086) on the Deliberate Release of Genetically Modified Organisms in the Environment.

35. According to EU legislation, the export of GMOs is primarily an issue between the exporter and the Party of import. Swedish authorities are responsible for supervising the exporter's compliance with the rules i.e. Reg. (EU) 1946/2003.

36. Regarding exports, the EU legislation (Reg. no 1946/2003) doesn't specifically address the accuracy of the information provided by the exporter. But the penalties laid down in the Swedish Environmental Code Chapter 29 Section 9.7-8 lay down the penalty for violation articles 6, 12 and 13 of Reg. (EU) 1946/2003.

38-42. One of the European authorisation process for release on the market of an LMO (Dir. 2001/18) include that the competent authority that first received a notification shall also write the decision. This was done in by a Swedish authority in 2010. The authorisation is though applicable in all of the European community. Decisions on field trials are taken nationally. Since 2006, 23 applications have been submitted and all have received permission (5 year permits).

We also refer to the EU's Second National Report on the Implementation of the Cartegena Protocol on Biosafety

Article 11 – Procedure for living modified organisms intended for direct use as food or feed, or for processing (LMOs-FFP)

51. Has your country adopted specific law(s) or regulation(s) for decision-making regarding domestic use, including placing on the market, of LMOs-FFP?	☒ Yes ☐ No	
52. Has your country established legal requirements for the accuracy of information to be provided by the applicant?	☒ Yes ☐ No	
53. Has your country established a mechanism to ensure that decisions regarding LMOs-FFP that may be subject to transboundary movement will be communicated to the Parties through the BCH?	☒ Yes ☐ No	
54. Has your country established a mechanism for taking decisions on the import of LMOs-FFP?	☒ Yes ☐ No	
55. Has your country declared through the BCH that in the absence of a regulatory framework its decisions prior to the first import of an LMO-FFP will be taken according to Article 11.6 of the Cartagena Protocol on Biosafety?	☐ Yes ☒ No	
56. Has your country indicated its needs for financial and technical assistance and capacity-building in respect of LMOs-FFP?	☐ Yes ☒ No	
57. Has your country ever taken a decision on LMOs-FFP (either on import or domestic use)?	☒ Yes ☐ No	
If you replied <u>No</u> to question 57 please go to question 63		
58. How many LMOs-FFP has your country approved to date?	☐ None ☐ Less than 5 ☐ Less than 10 ☒ More than 10 ☐ Not applicable	

59. 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
60. In the current reporting period, how many decisions has your country taken regarding domestic use, including placing on the market, of LMOs-FFP?	☐	None
	☐	Less than 5
	☐	Less than 10
	☒	More than 10

If you replied <u>None</u> to both questions 59 and 60 please go to question 63

61. Has your country informed the Parties through the BCH of its decision(s) regarding import, of LMOs-FFP?	☒	Yes, always
	☐	In some cases only
	☐	No
62. Has your country informed the Parties through the BCH of its decision(s) regarding domestic use, including placing on the market, of LMOs-FFP within 15 days?	☒	Yes, always
	☐	In some cases only
	☐	Yes, but with delays (i.e. longer than 15 days)
	☐	No

63. Here you may provide further details on the implementation of Article 11 in your country, including measures in case of lack of scientific certainty on potential adverse effects of LMOs-FFP:

Article 11 is implemented in legislation at EU level and Sweden has answered questions 51-63 according to the European Commission's Second National Report on the Implementation of the Cartegena Protocol on Biosafety .

Article 12 – Review of decision

64. Has your country established a mechanism for the review and change of a decision regarding an intentional transboundary movement of LMOs?	☒	Yes
	☐	No

65. Has your country ever received a request for a review of a decision?	☐	Yes
	☒	No
66. Has your country ever reviewed / changed a decision regarding an intentional transboundary movement of LMOs?	☐	Yes, decision reviewed
	☐	Yes, decision reviewed and changed
	☒	No
67. In the current reporting period, how many decisions were reviewed and/or changed regarding an intentional transboundary movement of an LMO?	☒	None
	☐	Less than 5
	☐	More than 5
If you replied <u>None</u> to the question 67 please go to question 71		
68. Has your country informed the notifier and the BCH of the review and/or changes in the decision?	☐	Yes, always
	☐	In some cases only
	☐	In some cases only the notifier
	☐	In some cases only the BCH
	☒	No
69. Has your country informed the notifier and the BCH of the review and changes in the decision within thirty days?	☐	Yes, always
	☐	In some cases only
	☐	Yes, but with delays (i.e. longer than 30 days)
	☐	No
70. Has your country provided reasons to the notifier and the BCH for the review and/or changes in the decision?	☐	Yes, always
	☐	In some cases only
	☐	In some cases only the notifier
	☐	In some cases only the BCH
	☐	No

71. Here you may provide further details on the implementation of Article 12 in your country: Article 12 is implemented in legislation at EU level. Sweden has followed the answers as provided by the European Commission for questions 64-70. We also refer to the EU's Second National Report on the Implementation of the Cartegena Protocol on Biosafety	

Article 13 – Simplified procedure

72. Has your country established a system for the application of the simplified procedure regarding an intentional transboundary movement of LMOs?	☐ Yes ☒ No
73. Has your country ever applied the simplified procedure?	☐ Yes ☒ No
74. If you answered *Yes* to question 73, has your country informed the Parties through the BCH of the cases where the simplified procedure applies?	☐ Yes, always ☐ In some cases only ☐ No ☒ Not applicable
75. In the current reporting period, how many LMOs has your country applied the simplified procedure to?	☒ None ☐ Less than 5 ☐ More than 5
76. Here you may provide further details on the implementation of Article 13 in your country: Article 13 is implemented in legislation at EU level. Sweden has followed the answers as provided by the European Commission for questions 72-75.	

Article 14 – Bilateral, regional and multilateral agreements and arrangements

77. Has your country entered into any bilateral, regional or multilateral agreements or arrangements?	☒ Yes ☐ No

78. If you answered *Yes* to question 77, has your country informed the Parties through the BCH of the agreements or arrangements?	☒	Yes, always
	☐	In some cases only
	☐	No
	☐	Not applicable

79. If you answered Yes to question 77, please provide a brief description of the scope and objective of the agreements or arrangements entered into:

Sweden is a Member State of the European Union. In the European Union the main part of issues covered by the Cartagena Protocol is totally harmonised legislation.

80. Here you may provide further details on the implementation of Article 14 in your country:

[Type your text here]

Articles 15 – Risk assessment

81. Has your country established a mechanism for conducting risk assessments prior to taking decisions regarding LMOs?	☒	Yes
	☒	No
82. If you answered *Yes* to question 81, does this mechanism include procedures for identifying experts to conduct the risk assessments?	☒	Yes
	☐	No
83. Has your country established guidelines for how to conduct risk assessments prior to taking decisions regarding LMOs?	☒	Yes
	☐	No
84. Has your country acquired the necessary domestic capacity to conduct risk assessment?	☒	Yes
	☐	No
85. Has your country established a mechanism for training national experts to conduct risk assessments?	☒	Yes
	☐	No
86. Has your country ever conducted a risk assessment of an LMO for intentional introduction into the environment?	☒	Yes
	☐	No

87. Has your country ever conducted a risk assessment of an LMO intended for direct use as food or feed, or for processing?	☒	Yes
	☐	No
88. If your country has taken decision(s) on LMOs for intentional introduction into the environment or on domestic use of LMOs-FFP, were risk assessments conducted for all decisions taken?	☒	Yes, always
	☐	In some cases only
	☐	No
	☐	Not applicable
89. Has your country submitted summary reports of the risk assessments to the BCH?	☐	Yes, always
	☒	In some cases only
	☐	No
	☐	Not applicable
90. In the current reporting period, if your country has taken decisions regarding LMOs, how many risk assessments were conducted in the context of these decisions?	☐	None
	☐	5 or less
	☐	10 or less
	☒	More than 10
91. Has your country ever required the exporter to conduct the risk assessment(s)?	☒	Yes, always
	☐	In some cases only
	☐	No
	☐	Not applicable
92. Has your country ever required the notifier to bear the cost of the risk assessment(s) of LMOs?	☒	Yes, always
	☐	In some cases only
	☐	No
	☐	Not applicable

93. Here you may provide further details on the implementation of Article 15 in your country:

Regarding question 82-85 Sweden does not have a special mechanism for training experts, but the staff involved in assessing risk assessment is well educated.

88, 91. The legislation requires the notifier to perform a risk assessment. Risk assessments are to be evaluated by all member-states. Risk assessments contained in notifications made under EU Reg. 1829/2003 are evaluated by the European Food Safety Authority and the competent authorities of the member-states. Field trials are assessed nationally.

92.There is a fee for submitting a notification to Swedish authorities.

Laws states that all risk assessment shall be done by the notifier and for contained use of LMOs that are micro-organisms, the risk assessment must be done according to the EU-directive 2009/41/EC on the contained use of genetically modified micro-organisms and the workers protection EU-directive 2000/54/EC on biological agents.

We also refer to the EU's Second National Report on the Implementation of the Cartegena Protocol on Biosafety.

Article 16 – Risk management

94. Has your country established and maintained appropriate and operational mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessments for:

(i) LMOs for intentional introduction into the environment?	☒	Yes
	☐	Yes, to some extent
	☐	No
(ii) LMOs intended for direct use as food or feed, or for processing?	☒	Yes
	☐	Yes, to some extent
	☐	No

95. Has your country established and maintained appropriate measures to prevent unintentional transboundary movements of LMOs?	☒ Yes ☐ Yes, to some extent ☐ No
96. 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 ☐ No
97. 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
98. Has your country cooperated with other Parties with a view to taking measures regarding the treatment of LMOs or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity?	☐ Yes ☒ No

99. Here you may provide further details on the implementation of Article 16 in your country, including any details regarding risk management strategies, also in case of lack of scientific certainty on potential adverse effects of LMOs:

Regarding question 96, the EU legislation stipulates that a step-wise introduction into the environment. A thorough risk assessment must be done prior to commercialisation but this does not necessarily include field trials in all Member States where the GMO will be released.

Concerning 94: Respective Swedish authorities are responsible for supervising, through inspections, all activity with LMOs.

Concerning 98: A case-by-case risk assessment must be done prior to commercialisation.

We also refer to the EU's Second National Report on the Implementation of the Cartegena Protocol on Biosafety.

Article 17 – Unintentional transboundary movements and emergency measures

100. 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
101. Has your country established a mechanism for addressing emergency measures in case of unintentional transboundary movements of LMOs that are likely to have significant adverse effect on biological diversity?	☒	Yes
	☐	No
102. Has your country implemented emergency measures in response to information about releases that led, or may have led, to unintentional transboundary movements of LMOs?	☒	Yes
	☐	No
103. In the current reporting period, how many times has your country received information concerning occurrences that led, or may have led, 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 you replied Never to question 103 please go to question 107		
104. Has your country notified affected or potentially affected States, the BCH and, where appropriate, relevant international organizations, of the above release?	☒	Yes, for every occurrence
	☐	Yes, for some occurrences
	☐	No
105. If you answered *Yes* to question 104, who did your country notify?	☒	The affected or potentially affected State
	☐	The BCH
	☒	Relevant international organizations
	☐	Not applicable

106. Has your country immediately consulted the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures?	☒	Yes, always
	☐	Yes, in some cases
	☐	No, consultation was made but not immediately
	☐	No, consultation was never made

107. Here you may provide further details on the implementation of Article 17 in your country:

Concerning 101. The Swedish Board of Agriculture has an organisation for handling of crisis that would deal with such measures.

Concerning 102. In 2010 there was an incident in Sweden where a GM-potato authorised only for field trials was discovered in plantings with a GM-potato that was authorised for commercial cultivation. This co-mingling was not considered as an environmental risk. The Member States that also cultivated this potato were immediately notified. Since there was no risk for transboundary movement, the BCH or others outside of the European Community were not informed.

Article 18 – Handling, transport, packaging and identification

108. 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
	☐	Yes, to some extent
	☐	No
109. Has your country taken measures to require that documentation accompanying LMOs-FFP clearly identifies that, in cases where the identity of the LMOs is *not known* through means such as identity preservation systems, they *may contain* living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information?	☒	Yes
	☐	Yes, to some extent
	☐	No

110. Has your country taken measures to require that documentation accompanying LMOs-FFP clearly identifies that, in cases where the identity of the LMOs *is known* through means such as identity preservation systems, they *contain* living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information?	☒ Yes ☐ Yes, to some extent ☐ No
111. Has your country taken measures to require that documentation accompanying LMOs that are destined for *contained use* clearly identifies them as *living modified organisms* 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 ☐ No
112. 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 ☐ No
113. Does your country have the capacity to enforce the requirements of identification and documentation of LMOs?	☒ Yes ☐ Yes, to some extent ☐ No
114. Has your country established procedures for the sampling and detection of LMOs?	☒ Yes ☐ Yes, to some extent ☐ No

115. Here you may provide further details on the implementation of Article 18 in your country:

Article 18 is implemented in legislation at EU level and Sweden has followed the answers provided by the European Commission for questions 108-114. Regarding 109, the EU legislation does not accept a "may contain" labelling, but it is mandatory to label if a product contains GMOs.

Regarding 11: Sweden is furthermore a Contracting Party to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). EU Council Directive 94/55/EC on the Approximation of the Laws of the Member-States with regard to the Transport of Dangerous Goods stipulates that the ADR rules shall be extended to cover national traffic, as well. Even Dir 96/49/EC on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail applies. Accordingly, GMO:s classified as dangerous goods are transported according to the ADR rules. This involves requirements for packaging, labelling and accompanying documentation.

We also refer to the EU's Second National Report on the Implementation of the Cartegena Protocol on Biosafety.

Article 19 – Competent National Authorities and National Focal Points

116. Has your country designated one *national focal point for the Cartagena Protocol* to be responsible for liaison with the Secretariat?	☒	Yes
	☐	No
117. Has your country designated one *national focal point for the Biosafety Clearing-House* to liaise with the Secretariat regarding issues of relevance to the development and implementation of the BCH?	☒	Yes
	☐	No
118. Has your country designated one or more *competent national authorities*, which are responsible for performing the administrative functions required by the Cartagena Protocol on Biosafety and are authorized to act on your country's behalf with respect to those functions?	☐	Yes, one
	☒	Yes, more than one
	☐	No
119. In case your country designated more than one *competent national authority*, has your country conveyed to the Secretariat the respective responsibilities of those authorities?	☒	Yes
	☐	No
	☐	Not applicable

120. Has your country made available the required information referred in questions 116-119 to the BCH?	☒	Yes, all information
	☐	Yes, some information
	☐	No
121. 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
122. 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
	☐	No

123. Here you may provide further details on the implementation of Article 19 in your country:

The responsibility for administrating and handling GMOs in Sweden is shared by several central authorities depending on type of organisms. The Swedish Board of Agriculture takes a large part because most GMOs so far have been agricultural crops.

Article 20 – Information Sharing and the Biosafety Clearing-House (BCH)

124. Please provide an overview of the status of the information provided by your country to the BCH by specifying for each category of information whether it is available and whether it has been submitted to the BCH.

a. Existing national 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.	National laws, 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 (Articles 14, paragraph 2 and 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.	Reports submitted by the Parties on the operation of the Protocol (Article 20, 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

f. Decisions by a Party on regulating the transit of specific living modified organisms (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
g. Occurrence of unintentional transboundary movements that are 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. 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. Final decisions regarding the importation or release of LMOs (i.e. approval or prohibition, any conditions, requests for further information, extensions granted, reasons for decision) (Articles 10, paragraph 3 and 20, paragraph 3(d))	☐ 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.	Final 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
l.	Final 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 (Article 11, paragraph 6) (requirement of Article 20, paragraph 3(d))	☒ 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. LMOs granted exemption status by each Party (Article 13, 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
p. 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)	☐ 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
125. Has your country established a mechanism for strengthening the capacity of the BCH National Focal Point to perform its administrative functions?	☐ Yes ☒ No

126. Has your country established a mechanism for the coordination among the BCH National Focal Point, the Cartagena Protocol focal point, and the competent national authority(ies) for making information available to the BCH?	☒ Yes ☐ No
127. Does your country use the information available in the BCH in its decision making processes on LMOs?	☐ Yes, always ☒ Yes, in some cases ☐ No
128. Has your country experienced difficulties accessing or using the BCH?	☐ Yes ☒ No
129. If you answered *Yes* to question 128, has your country reported these problems to the BCH or the Secretariat?	☐ Yes ☐ No ☐ Not applicable
130. Is the information submitted by your country to the BCH complete and up-to date?	☐ Yes ☒ No

131. Here you may provide further details on the implementation of Article 20 in your country:

We also refer to the EU's Second National Report on the Implementation of the Cartegena Protocol on Biosafety

Article 21 – Confidential information

132. Has your country established procedures to protect confidential information received under the Protocol?	☒ Yes ☐ No
133. Does your country allow the notifier to identify information that is to be treated as confidential?	☒ Yes, always ☐ In some cases only ☐ No

134. Here you may provide further details on the implementation of Article 21 in your country:

Regarding question 132. Article 25 in directive 2001/18/EC and article 30 in 1829/2003 implements article 21 of the protocol. This is further implemented in the Swedish Public Access to Information and Secrecy Act 2009:400 and the Public access to information and Secrecy ordinance 2009:641.

Regarding question 133. The notifier is allowed to identify what information it wants to keep confidential. However, the decision on what information to be considered confidential has to be assessed by for the Swedish authority. We also refer to the EU's Second National Report on the Implementation of the Cartegena Protocol on Biosafety

Article 22 – Capacity-building

135. 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
	☒	No
136. If you answered *Yes* to question 135, how were these resources made available?	☐	Bilateral channels
	☐	Regional channels
	☐	Multilateral channels
	☐	Not applicable
137. Has your country provided support to other Parties in the development and/or strengthening of human resources and institutional capacities in biosafety?	☒	Yes
	☐	No
138. If you answered *Yes* to question 137, how were these resources made available?	☒	Bilateral channels
	☐	Regional channels
	☒	Multilateral channels
	☐	Not applicable
139. Is your country eligible to receive funding from the Global Environment Facility (GEF)?	☐	Yes
	☒	No

If you replied No to question 139 please go to question 143

140. Has your country ever initiated a process to access GEF funds for building capacity in biosafety?	☐	Yes
	☐	No
141. If you answered *Yes* to question 140, how would you characterize the process? *Please add further details about your experience in accessing GEF funds under question 150.*	☐	Very easy
	☐	Easy
	☐	Average
	☐	Difficult
	☐	Very difficult
142. Has your country ever received funding from the GEF for building capacity in biosafety?	☐	Pilot Biosafety Enabling Activity
	☐	Development of National Biosafety Frameworks
	☐	Implementation of National Biosafety Frameworks
	☐	Building Capacity for Effective Participation in the BCH (Phase I)
	☐	Building Capacity for Effective Participation in the BCH (Phase II)
	☐	None of the above
143. During the current reporting period, has your country undertaken activities for the development and/or strengthening of human resources and institutional capacities in biosafety?	☒	Yes
	☐	No

144. If you answered *Yes* to question 143, in which of the following areas were these activities undertaken?	☒ Institutional capacity ☐ Human resources capacity development and training ☐ 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 ☐ Identification of LMOs, including their detection ☐ Socio-economic 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 ☐ Other: <Text entry> ☐ Not applicable

145. During the current reporting period, has your country carried out a capacity-building needs assessment?	☒	Yes
	☐	No
146. Does your country still have capacity-building needs?	☐	Yes
	☒	Yes, a few
	☐	No

147. If you answered *Yes* to question 146, indicate which of the following areas still need capacity-building.	☐ Institutional capacity ☐ Human resources capacity development and training ☐ 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 ☐ Identification of LMOs, including their detection ☐ Socio-economic 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 ☐ Other: <Text entry> ☐ Not applicable

148. Has your country developed a capacity-building strategy or action plan?	☐ Yes ☒ No
149. Has your country submitted the details of national biosafety experts to the Roster of Experts in the BCH?	☐ Yes ☐ No

150. Here you may provide further details on the implementation of Article 22 in your country, including further details about your experience in accessing GEF funds:

[Type your text here]

Article 23 – Public awareness and participation

151. Has your country established a strategy or put in place legislation for promoting and facilitating public awareness, education and participation concerning the safe transfer, handling and use of LMOs?	☒ Yes ☐ Yes, to some extent ☐ No
152. Has your country established a biosafety website?	☐ Yes ☒ No
153. Has your country established a mechanism to ensure public access to information on living modified organisms that may be imported?	☒ Yes ☐ Yes, to a limited extent ☐ No
154. Has your country established a mechanism to consult the public in the decision-making process regarding LMOs?	☒ Yes ☐ Yes, to a limited extent ☐ No
155. Has your country established a mechanism to make available to the public the results of decisions taken on LMOs?	☒ Yes ☐ Yes, to a limited extent ☐ No
156. Has your country taken any initiative to inform its public about the means of public access to the Biosafety Clearing-House?	☐ Yes ☒ No

157. 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
	☐	Yes, to a limited extent
	☐	No
158. If you answered *Yes* to question 157, has your country cooperated with other States and international bodies?	☐	Yes
	☒	No
	☐	Not applicable
159. In the current reporting period, how many times has your country consulted the public in the decision-making process regarding LMOs and made the results of such decisions available to the public?	☐	Never
	☐	Less than 5
	☒	More than 5

160. Here you may provide further details on the implementation of Article 23 in your country:

151. Swedish GMO authorities have a joint website (www.gmo.nu) for information on GMO regulations, including a link to the BCH website. All authorities have specific information on GMOs in relation to their competence on their website. The designated function of the Swedish Gene Technology Advisory Board is to promote, by means of consultation, uses of gene technology which are ethically defensible from the standpoint of human and animal health. That task includes dissemination of knowledge concerning the development of gene technology. The public should be informed in such a way that its interests in ethical and safety issues are safeguarded, while public debate on such issues is stimulated.

153. In Sweden the principle of public access to official documents is applied. All Swedish citizens are entitled to read the documents held by public authorities. This means that documents received as well as dispatched letters, decisions and reports are in principle official documents and must be made available for anyone to read. Access to official documents may however be restricted if they may be kept secret in order to protect specified interests, namely:

• the security of the Realm or its relations with another state or international organization;

• the central fiscal, monetary or currency policies of the Realm;

• the inspection, control or other supervisory activities of a public authority;

• the interest of preventing or prosecuting crime;

• the public economic interest;

• the protection of the personal or economic circumstances of private subjects; or

• the preservation of animal or plant species.

154. The responsible authorities have information on their web sites on every notification. The public can read summaries of the notifications and is also given the opportunity to send in any comments to the authorities. Depending on the scope of the application and what legislation it is notified within, the public can also submit comments via the Joint Research Centre website, the EC commission or the competent authorities web-sites.

155. The website of the Swedish Board of Agriculture (www.jordbruksverket.se) contains information about which GM crops have been approved for import and/or cultivation within the EU and decisions on field trials in Sweden.

Article 24 – Non-Parties

161. Has your country entered into any bilateral, regional, or multilateral agreement with non-Parties regarding transboundary movements of LMOs?	☐ Yes ☒ No
162. Has your country ever imported LMOs from a non-Party?	☐ Yes ☒ No
163. Has your country ever exported LMOs to a non-Party?	☐ Yes ☒ No
164. If you answered *Yes* to questions 162 or 163, were the transboundary movements of LMOs consistent with the objective of the Cartagena Protocol on Biosafety?	☐ Yes, always ☐ In some cases only ☒ No ☐ Not applicable
165. If you answered *Yes* to questions 162 or 163, was information about these transboundary movements submitted to the BCH?	☐ Yes, always ☐ In some cases only ☐ No ☐ Not applicable
166. If your country is not a Party to the Cartagena Protocol, has it contributed information to the BCH on LMOs released in, or moved into, or out of, areas within its national jurisdiction?	☐ Yes, always ☐ In some cases only ☐ No ☐ Not applicable

167. Here you may provide further details on the implementation of Article 24 in your country:

[Type your text here]

Article 25 – Illegal transboundary movements

168. 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

169. Has your country established a strategy for detecting illegal transboundary movements of LMOs?	☐	Yes
	☒	No
170. In the current reporting period, how many times has your country received information concerning cases of illegal transboundary movements of an LMO to or from territories under its jurisdiction?	☒	Never
	☐	Less than 5
	☐	Less than 10
	☐	More than 10
If you replied Never to question 170 please go to question 175		
171. 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
172. Has your country established the origin of the LMO(s)?	☐	Yes
	☐	Yes, some cases
	☐	No
173. Has your country established the nature of the LMO(s)?	☐	Yes
	☐	Yes, some cases
	☐	No
174. Has your country established the circumstances of the illegal transboundary movement(s)?	☐	Yes
	☐	Yes, some cases
	☐	No

175. Here you may provide further details on the implementation of Article 25 in your country:

Regarding question 168. Infringement of EU Reg. no 1946/2003 will in Sweden be regarded as an infringement of the Environmental Code and the penalties laid down in the Code will apply.

Article 26 – Socio-economic considerations

176. If your country has taken a decision on import, has it ever taken into account socio-economic considerations arising from the impact of the LMO on the conservation and sustainable use of biological diversity?	☐	Yes
	☐	Only in some cases
	☐	No
	☒	Not applicable
177. Has your country cooperated with other Parties on research and information exchange on any socio-economic impacts of LMOs?	☐	Yes
	☒	Yes, to a limited extent
	☐	No

178. Here you may provide further details on the implementation of Article 26 in your country:

Sweden has submitted a report (2010 Feb) to the EU Commission on expected socio-economic consequences of the use of GMOs in Sweden. The EU has published "Report from the Commission to the European Parliament and the COuncil on socio-economic implications of the GMO cultivation on the basis of Member States contributions SEC (2011) 481 final.

Article 27 – Liability and Redress

179. Has your country signed the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress?	☒	Yes
	☐	No
180. Has your country initiated steps towards ratification, acceptance or approval of the Nagoya-Kuala Lumpur Supplementary Protocol?	☒	Yes
	☐	No

181. 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]

Article 33 – Monitoring and reporting

182. Has your country submitted the previous national reports (Interim and First National Reports)?	☒	Yes
	☐	Yes, Interim report only
	☐	Yes, First report only
	☐	No
	☐	Not applicable
183. If your country did not submit previous reports, indicate the main challenges that hindered the submission	☐	Lack of financial resources to gather the necessary information
	☐	Lack of relevant information at the national level
	☐	Difficulty in compiling the information from various sectors
	☐	No obligation to submit (e.g. country was not a Party at the time)
	☐	Other, please specify [Type your text here]
	☒	Not applicable

Other information

184. 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 your text here]

Comments on reporting format

185. Please use this field to provide any other information on difficulties that you have encountered in filling in this report.

[Type your text here]