Biosafety Clearing-House (BCH)

THIRD NATIONAL REPORT ON THE IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY (NR3)

General Information

PUBLISHED: 28 OCT 2015

Country

Belgium **PARTY TO THE CARTAGENA PROTOCOL ON BIOSAFETY** **ENTRY INTO FORCE: 14 JUL 2004**

9. Organizations/stakeholders who were consulted or participated in the preparation of this report

Competent authorities at the federal and regional levels. SBB (Biosafety and Biotechnoly Unit), acting as a Unit of the Scientific Institute of Public Health and as Secretariat of the Belgian Biosafety Advisory Council. EN

10. Time period covered by this report

From

01 Oct 2011

To

30 Sep 2015

Party to the Cartagena Protocol on Biosafety

11. Is your country a Party to the Cartagena Protocol on Biosafety (CPB)?

Yes EN

Article 2 – General provisions

14. 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 EN

15. If you indicated that a national biosafety framework exists in the above question, when did it become operational?

2001 or earlier | EN

16. Which specific instruments are in place for the implementation of your national biosafety framework?

One or more national biosafety laws
One or more sets of biosafety guidelines
Other laws, regulations or guidelines that indirectly apply to biosafety

17. Has your country established a mechanism for the budgetary allocations of funds for the operation of its national biosafety framework?

Yes | EN

18. Does your country have permanent staff to administer functions directly related to the national biosafety framework?

Yes | EN

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?

More than 10 | EN

20. Has your country's biosafety framework / laws / regulations / guidelines been submitted to the Biosafety Clearing-House (BCH)?

Yes | EN

21. Here you may provide further details on the implementation of Article 2 in your country

The implementation of the Cartagena Protocol in Belgium is ensured through a set of regulatory instruments, most of which corresponding to the direct application or the transposition in Belgian law of EU legal provisions. Many of these legal instruments were also in place largely before the adoption of the Cartagena Protocol.
These regulatory instruments cover in particular the contained use of GMOs, their environmental release (for R&D and for commercialisation), their use as food or feed, their transboundary movements, and their coexistence with non-GM and organic agricultural products.
Since competencies on GMO matters are shared between the Federal State and

EN

the three Regions, a cooperation agreement between all the competent entities has been established since 1997 to manage in an harmonised way the administrative and scientific implementation of the Belgian GMO regulatory framework. As a result, decisions by different administrative bodies representing different institutional levels are based on a single science-based biosafety advisory system, composed of the Belgian Biosafety Advisory Council (BAC) and the Biosafety and Biotechnology Unit (SBB) of the Scientific Institute of Public Health. In this system, all regulatory-related aspects of the uses of GMOs and pathogens are assessed altogether in a coordinated way, independently of the specific regulation(s) involved.
Competent Authorities (supported by permanent and temporary experienced staff) have been appointed for all regulatory matters related to the implementation (including control) of the Cartagena Protocol. This implementation is also supported by guidelines developed at Belgian or EU level. National focal points for the Protocol and for the BCH have also been designated. For more information about the Belgian biosafety framework, please refer to the BCH.

Article 5 - Pharmaceuticals

22. Does your country regulate the transboundary movement, handling and use of living modified organisms (LMOs) which are pharmaceuticals?

Yes EN

23. If you answered Yes to question 22, has this information been submitted to the BCH?

Yes EN

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

No further information since the 2nd NR. EN

Article 6 – Transit and Contained use

25. Does your country regulate the transit of LMOs?

Yes EN

26. Does your country regulate the contained use of LMOs?

Yes EN

27. If you answered Yes to questions 25 or 26, has this information been submitted to the BCH?

Yes	EN

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

The contained use of genetically modified micro-organisms (GMMs) or organisms (GMOs) and/or pathogens is regulated in Belgium at the regional level and is based on the implementation of European Directive 2009/41/EC. These Community measures ask for Member States to regulate the contained use of GMMs in order to minimise their potential adverse effects on human health and the environment. Although the EU regulatory framework only covers genetically modified micro-organisms, the scope of the Belgian regional legislations has been extended to genetically modified organisms and pathogenic organisms for humans, animals and plants. The three Regions (Flanders, Wallonia and Brussels-Capital) have implemented the above-mentioned EU legislation as part of their Environmental laws for classified installations. In such a general context, biosafety is just one of the safety issues covered by the environmental permit. All activities in laboratories, animal houses, greenhouses, hospital rooms and large-scale production facilities involving genetically modified and/or pathogenic organisms are subject to a preliminary written authorisation from the relevant regional competent authorities on the basis of a specific notification and decision procedure. During the procedure, the risk assessment is submitted for advice to the Biosafety and Biotechnology Unit (SBB), who acts as technical expert for the Regions. The full text of the three regional legislation is available from the BCH. See EU' s report for transit.	EN

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 OR a domestic regulatory framework consistent with the Protocol regarding the transboundary movement of LMOs for intentional introduction into the environment?

Yes	EN

30. Has your country established a mechanism for taking decisions regarding first intentional transboundary movements of LMOs for intentional introduction into the environment?

Yes	EN

31. If you answered Yes to question 30, does the mechanism also apply to cases of intentional introduction of LMOs into the environment that were not subject to transboundary movement?

Yes EN

32. 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 EN

33. Has your country established legal requirements for the accuracy of information contained in the notification?

Yes EN

34. Has your country ever received an application / notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment?

Yes EN

35. Has your country ever taken a decision on an application / notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment?

Yes EN

36. If you answered Yes to question 35, how many LMOs has your country approved to date for import for intentional introduction into the environment?

Less than 5 EN

37. If you answered Yes to question 35, how many LMOs, not imported, has your country approved to date for intentional introduction into the environment?

Less than 5 EN

38. 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?

Less than 5 EN

39. 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	EN

40. 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?

41. Did the notifications contain complete information (at a minimum the information specified in Annex I of the Cartagena Protocol on Biosafety)?

42. Has your country acknowledged receipt of the notifications to the notifier within ninety days of receipt?

43. Has your country informed the notifier(s) and the BCH of its decision(s)?

44. What percentage of your country’s decisions fall into the following categories?

45. 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?

46. 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

Notifications related to the transboundary movement of LMOs for intentional introduction into the environment for commercial purpose are managed at EU level. Final decisions are also adopted at EU level with all EU Member States contributing. To date, two GMOs have been approved at EU level for intentional introduction into the environment for commercial purpose. None of them are actually cultivated in Belgium. Please refer to the EU' s report for further information. During the reporting period, there was no notification in Belgium related to the transboundary movement of LMOs for intentional introduction into the environment for experimental testing or field trials (not intended for placing on the market).	EN

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

47. 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 EN

48. Has your country established legal requirements for the accuracy of information to be provided by the applicant?

Yes EN

49. 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 EN

50. Has your country established a mechanism for taking decisions on the import of LMOs-FFP?

Yes EN

51. Has your country indicated its needs for financial and technical assistance and capacity-building in respect of LMOs-FFP?

No EN

52. Has your country ever taken a decision on LMOs-FFP (either on import or domestic use)?

Yes EN

53. How many LMOs-FFP has your country approved to date?

More than 10 EN

54. In the current reporting period, how many decisions has your country taken regarding the import of LMOs-FFP?

More than 10 EN

55. In the current reporting period, how many decisions has your country taken regarding domestic use, including placing on the market, of LMOs-FFP?

More than 10 EN

56. Has your country informed the Parties through the BCH of its decision(s) regarding import, of LMOs-FFP?

Yes, always EN

57. 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 EN

58. 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

cf EU's report EN

Article 12 – Review of decision

59. Has your country established a mechanism for the review and change of a decision regarding an intentional transboundary movement of LMOs?

Yes EN

60. Has your country ever received a request for a review of a decision?

No EN

61. Has your country ever reviewed / changed a decision regarding an intentional transboundary movement of LMOs?

No EN

62. In the current reporting period, how many decisions were reviewed and/or changed regarding an intentional transboundary movement of an LMO?

None EN

63. Has your country informed both the notifier and the BCH of the review and/or changes in the decision?

64. Has your country informed both the notifier and the BCH of the review and changes in the decision within thirty days?

65. Has your country provided reasons to both the notifier and the BCH for the review and/or changes in the decision?

66. Here you may provide further details on the implementation of Article 12 in your country

Article 13 – Simplified procedure

67. Has your country established a system for the application of the simplified procedure regarding an intentional transboundary movement of LMOs?

No EN

68. Has your country ever applied the simplified procedure?

No EN

69. If you answered Yes to question 68, has your country informed the Parties through the BCH of the cases where the simplified procedure applies?

70. In the current reporting period, how many LMOs has your country applied the simplified procedure to?

None EN

71. Here you may provide further details on the implementation of Article 13 in your country

Article 14 – Bilateral, regional and multilateral agreements and arrangements

72. Has your country entered into any bilateral, regional or multilateral agreements or arrangements?

No EN

73. If you answered Yes to question 72, how many LMO-related collaborative bilateral/multilateral arrangements has your country established with other Parties/non-Parties?

74. If you answered Yes to question 72, has your country informed the Parties through the BCH of the agreements or arrangements?

75. If you answered Yes to question 72, please provide a brief description of the scope and objective of the agreements or arrangements entered into

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

BE, part of the EU, has not entered into any bilateral, regional or multilateral agreements or arrangements as per Article 14(1). EN

cf. EU' s report.

Articles 15 & 16 – Risk Assessment and Risk Management

77. Has your country established a national framework for conducting risk assessments prior to taking decisions regarding LMOs?

Yes EN

78. If you answered Yes to question 77, does this framework include procedures for identifying and/or training national experts to conduct risk assessments?

Yes EN

79 a. How many people in your country have been trained in risk assessment, monitoring, management and control of LMOs? Risk assessment:

100 or more EN

79 b. How many people in your country have been trained in risk assessment, monitoring, management and control of LMOs? Management / Control:

50 or more EN

79 c. How many people in your country have been trained in risk assessment, monitoring, management and control of LMOs? Monitoring:

One or more EN

80. Is your country using training material and/or technical guidance for training in risk assessment and risk management of LMOs?

Yes EN

81. Is your country using the "Manual on Risk Assessment of LMOs" (developed by CBD Secretariat) for training in risk assessment?

No EN

82. 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 EN

83. Are the currently available training materials or technical guidance on risk assessment and/or risk management of LMOs sufficient?

Yes EN

84 a. Does your country have the capacity to detect, identify, assess and/or monitor living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health? Detect:

Yes EN

84 b. Does your country have the capacity to detect, identify, assess and/or monitor living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health? Identify:

Yes EN

84 c. Does your country have the capacity to detect, identify, assess and/or monitor living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health? Assess:

Yes EN

84 d. Does your country have the capacity to detect, identify, assess and/or monitor living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health? Monitor:

Yes EN

85 a. Has your country adopted or used any guidance documents for the purpose of conducting risk assessment or risk management, or for evaluating risk assessment reports submitted by notifiers? Risk assessment:

Yes EN

85 b. Has your country adopted or used any guidance documents for the purpose of conducting risk assessment or risk management, or for evaluating risk assessment reports submitted by notifiers? Risk management:

Yes EN

86. 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?

No EN

87. Has your country adopted any common approaches to risk assessment with other countries?

Yes EN

88. 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 EN

89. Has your country ever conducted a risk assessment of an LMO including any type of risk assessment of LMOs, e.g. for contained use, field trials, commercial purposes, direct use as food, feed, or for processing?

Yes EN

90. If you answered Yes to question 89, please indicate the scope of the risk assessments (select all that apply):

Commercial production
Field trial
LMOs for Contained use
LMOs for direct use as food
LMOs for direct use as feed
LMOs for processing

91. If you answered Yes to question 89, were the summary reports of the risk assessments submitted to the BCH?

In some cases only EN

92. If you answered Yes to question 89, were risk assessments conducted for all decisions taken on LMOs for intentional introduction into the environment or on domestic use of LMOs for direct use as food, feed, or for processing?

Yes, always EN

93. If you answered Yes to question 89, how many risk assessments were conducted in the current

reporting period?

More than 10	EN

94. 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	EN

95. Has your country established a mechanism for monitoring potential effects of LMOs that are released into the environment?

Yes	EN

96. Does your country have the infrastructure (e.g. laboratory facilities) for monitoring or managing LMOs?

Yes	EN

97. Here you may provide further details on the implementation of Articles 15 and 16 in your country

Belgium has implemented a comprehensive system for risk assessment dealing with all uses of LMOs. Accordingly, all regulatory-related aspects of the uses of LMOs are assessed altogether in a coordinated way, independently of the specific concerned regulation(s). The main legal basis is the "Cooperation Agreement between the Federal State and the Regions on the administrative and scientific coordination concerning Biosafety" (1997). This cooperation agreement establishes a common scientific evaluation system for the Federal State and the Regions, consisting in the Biosafety Advisory Council (BAC) and the Biosafety and Biotechnology Unit (SBB) of the Scientific Institute of Public Health. The BAC advises the authorities for all regulatory dossiers related to to the placing on the market of products consisting of or containing GMOs, for applications for field trials of transgenic plants, and for applications relating to clinical trials in which a release of GMO into the environment is possible. The Council can be consulted by the Regions for contained activities involving GMOs. The BAC is composed of academic and administrative representatives appointed by the Regional and Federal competent authorities. The SBB is in charge of the secretariat of the Biosafety Council. It is composed of an administrative secretariat and a multidisciplinary group of scientists. The SBB advises the regional authorities in relation to the use of pathogens and GMOs under contained conditions. It provides permanent scientific support to the BAC and to the competent Federal and Regional authorities in the field of risk assessment of LMOs, including in official fora at EU (Council, Commission, EFSA,	EN

EMA) and international (OECD, UN) level.
In the framework of the scientific evaluation of regulatory dossiers and other biosafety-related matters, the BAC and the SBB frequently call for the scientific support of external experts coming from Belgian (and sometimes foreign) academic institutions. For this purpose, a list of experts has been compiled in a Database. Experts are consulted on a case by case basis, depending of the specific expertise needed in the frame of the evaluation of a dossier. The expertise is most of the cases done according to a written procedure. The experts are entitled to receive a financial allowance for their scientific work. This cooperation with scientific experts is very important to deliver scientifically sound advices to the competent authorities. It also makes it possible to involve Belgium's academic community in biosafety matters. Furthermore, many scientists see an increase in the value of their research work due to their contributions to the BAC and SBB expertise.

Article 17 – Unintentional transboundary movements and emergency measures

98. Has your country established and maintained appropriate measures to prevent unintentional transboundary movements of LMOs?

Yes | EN

99. 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 | EN

100. Does your country have the capacity to take appropriate measures in the event that an LMO is unintentionally released?

Yes | EN

101. 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 | EN

102. If you answered Yes to question 101, has your country notified affected or potentially affected States, the BCH and, where appropriate, relevant international organizations, of the above release?

103. If you answered Yes to question 101, who did your country notify?

104. If you answered Yes to question 101, 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?

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

Article 14 of EU Regulation 1946/2003 provides for measures to prevent unintentional transboundary movement of GMOs and appropriate responses, including emergency measures Belgium has a "Crisis cell" in its Federal public Service Health, Food Chain Safety & Environment, where unintentional transboundary movements of LMOs likely to have significant adverse effects on biological biodiversity, including human health, should be communicated.	EN

Article 18 – Handling, transport, packaging and identification

106. 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	EN

107. 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	EN

108. 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	EN

109. If you answered Yes or Yes, to some extent to question(s) 107 and/or 108, what type of documentation does your country require for the identification of LMOs-FFP?

Existing types of documentation	EN

110. 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 EN

111. If you answered Yes or Yes, to some extent to question 110, what type of documentation does your country require for the identification of LMOs that are destined for contained?

Existing types of documentation EN

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 EN

113. If you answered Yes or Yes, to some extent to question 112, what type of documentation does your country require for the identification of LMOs that are intended for intentional introduction into the environment?

Existing types of documentation EN

114. Does your country have available any guidance for the purpose of ensuring the safe handling, transport, and packaging of living modified organisms?

Yes EN

115. Does your country have the capacity to enforce the requirements of identification and documentation of LMOs?

Yes EN

116. How many customs officers in your country have received training in the identification of LMOs?

None EN

117. Has your country established procedures for the sampling and detection of LMOs?

Yes	EN

118. How many laboratory personnel in your country have received training in detection of LMOs?

10 or more	EN

119. Does your country have reliable access to laboratory facilities for the detection of LMOs?

Yes	EN

120. How many laboratories in your country are certified for LMO detection?

One or more	EN

121. How many of the certified laboratories in the previous question are currently operating in the detection of LMOs?

One or more	EN

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

With regards to GMO detection and identification, Belgian is part of the European Network of GMO Laboratories (ENGL). The main missions of the ENGL are the development, harmonisation and standardisation of sampling, detection, identification and quantification methods for GMOs or GMO-derived products from a wide variety of matrices, covering seeds, cereals, foodstuffs, animal feed and environmental samples. The Belgian component of the ENGL, namely the National Reference Laboratory for Genetically Modified Organisms (NRL-GMO), was officially set up in 2006. It is made up of the WIV-ISP (the federal laboratory for the GMO detection), the ILVO (Flemish Institute for Agricultural and Fisheries Research) and the CRA-W (Walloon Agricultural Research Centre). The NRL-GMO is coordinated by the WIV-ISP. It works to support the Belgian Federal Agency for the Safety of the Food Chain (FASFC) within the context of implementing Regulation (EC) 1830/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMos. In particular, it has the task of promoting the application and development of new GMO detection, identification and quantification methods in food matrices. The European consortium ENGL, including the Belgian NRL-GMO, works to support the European Union Reference Laboratory for GM Food and Feed (EURL-GMFF, formerly the Community Reference Laboratory), which was established in accordance with the provisions of Regulation (EC) 1829/2003 on GM Food and Feed. The main task of the EURL-GMFF is the scientific assessment and validation	EN

of detection methods supplied by notifiers within the framework of marketing authorisation applications for GMO food or feed.

Article 19 – Competent National Authorities and National Focal Points

123. 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 EN

124. 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 EN

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

Permanent staff members have been designated respectively as:
- National focal Point of the Protocol
- National focal point of the BCH
- Federal Competent Authority for the placing on the market and import of GMOs intended for deliberate release into the environment.
- Federal Competent Authority for the import of GMOs directly intended for food and feed.
- Federal Competent Authority for the export of GMOs

Are also designated as permanent staff:
- National Secretariat of the Biosafety Advisory Council (the members of this last organ can be renewed every 4 years)
- Regional Competent Authorities for the contained use of GMOs (responsible for the follow-up of administrative procedures, for authorisations and for inspections)
- Regional Competent Authorities for the implementation of agriculture coexistence rules.

EN

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

126 a. Please provide an overview of the status of the mandatory 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. 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 EN

126 b. Please provide an overview of the status of the mandatory 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. 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	EN

126 c. Please provide an overview of the status of the mandatory 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. Bilateral, multilateral and regional agreements and arrangements (Articles 14, paragraph 2 and 20, paragraph 3 (b))

Information not available	EN

126 d. Please provide an overview of the status of the mandatory 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. 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	EN

126 e. Please provide an overview of the status of the mandatory 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. Reports submitted by the Parties on the operation of the Protocol (Article 20, paragraph 3 (e))

Information available and in the BCH	EN

126 f. Please provide an overview of the status of the mandatory 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. Decisions by a Party on regulating the transit of specific living modified organisms (LMOs) (Article 6, paragraph 1)

Information not available	EN

126 g. Please provide an overview of the status of the mandatory 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. Occurrence of unintentional transboundary movements that are likely to have significant adverse effects on biological diversity (Article 17, paragraph 1)

Information not available	EN

126 h. Please provide an overview of the status of the mandatory 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. Illegal transboundary movements of LMOs (Article 25, paragraph 3)

Information not available	EN

126 i. Please provide an overview of the status of the mandatory 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. 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	EN

126 j. Please provide an overview of the status of the mandatory 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. Information on the application of domestic regulations to specific imports of LMOs (Article 14, paragraph 4)

Information not available	EN

126 k. Please provide an overview of the status of the mandatory 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. 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	EN

126 l. Please provide an overview of the status of the mandatory 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. 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	EN

126 m. Please provide an overview of the status of the mandatory 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. 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 not available	EN

126 n. Please provide an overview of the status of the mandatory 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. Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12, paragraph 1)

Information not available	EN

126 o. Please provide an overview of the status of the mandatory 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. LMOs granted exemption status by each Party (Article 13, paragraph 1)

Information not available	EN

126 p. Please provide an overview of the status of the mandatory 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. 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 not available	EN

126 q. Please provide an overview of the status of the mandatory 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. 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	EN

127. Has your country established a mechanism for strengthening the capacity of the BCH National Focal Point to perform its administrative functions?

No	EN

128. 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	EN

129. Does your country use the information available in the BCH in its decision making processes on LMOs?

Yes, in some cases	EN

130. Has your country experienced difficulties accessing or using the BCH?

Yes EN

Additional Information

These difficulties have been discussed with the SCBD during a meeting of the EU NFP in December 2013 (Brussels) EN

131. Is the information submitted by your country to the BCH complete and up-to date?

Yes EN

132. Please indicate the number of regional, national and international events organized in relation to biosafety (e.g. seminars, workshops, press conferences, educational events, etc.,) in the last 2 years:

5 or more EN

133. Please indicate the number of biosafety related publications that has been made available in your country in the last year:

10 or more EN

134. If biosafety related publications were made available (see question above), please indicate which modalities were preferred:

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

Article 21 – Confidential information

136. Has your country established procedures to protect confidential information received under the Protocol?

Yes EN

137. Does your country allow the notifier to identify information that is to be treated as confidential?

Yes, always EN

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

Article 22 – Capacity-building

139. Does your country have predictable and reliable funding for building capacity for the effective implementation of the Protocol?

No EN

140. 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?

No EN

141. If you answered Yes to question 140, how were these resources made available?

142. Has your country provided support to other Parties in the development and/or strengthening of human resources and institutional capacities in biosafety?

No EN

143. If you answered Yes to question 142, how were these resources made available?

144. Has your country ever initiated a process to access GEF funds for building capacity in biosafety?

No EN

145. If you answered Yes to question 144, how would you characterize the process?

146. Has your country ever received funding from the GEF for building capacity in biosafety?

147. During the current reporting period, has your country undertaken activities for the development and/or strengthening of human resources and institutional capacities in biosafety?

No EN

148. If you answered Yes to question 147, in which of the following areas were these activities undertaken?

149. During the current reporting period, has your country carried out a capacity-building needs assessment?

No EN

150. If you answered Yes to question 149, has this information been submitted to the BCH?

151. Does your country still have capacity-building needs?

Yes, a few EN

152. If you answered Yes to question 151, indicate which of the following areas still need capacity-building.

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153. Has your country developed a capacity-building strategy or action plan?

No EN

154. Does your country have in place a functional national mechanism for coordinating biosafety capacity-building initiatives?

No EN

155. How many biosafety short-term training programmes and/or academic courses are offered annually in your country?

10 per year or more EN

156. Has your country submitted the details of national biosafety experts to the Roster of Experts in the BCH?

No EN

157. 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

Article 23 – Public awareness and participation

158. 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, to some extent EN

159. Has your country designed and/or implemented an outreach/communication strategy on biosafety?

No EN

160. Does your country have any awareness and outreach programmes on biosafety?

No EN

161. If you answered Yes to question 160, please indicate what entity is responsible for carrying out the programmes and/or services and at which level the programmes take place (e.g. local, national, etc.):

162. Has your country established a biosafety website searchable archives, national resource centres or sections in existing national libraries dedicated to biosafety educational materials?

Yes EN

163. How many collaborative initiatives (including joint activities) on the Cartagena Protocol and other Conventions and processes has your government established in the last 4 years?

One or more EN

164. Has your country established a mechanism to ensure public access to information on living modified organisms that may be imported?

Yes EN

165. Has your country established a mechanism to consult the public in the decision-making process regarding LMOs?

Yes EN

166. Has your country established a mechanism to make available to the public the results of decisions taken on LMOs?

Yes EN

167. Has your country informed the public about existing modalities for public participation in the decision-making process regarding living modified organisms?

Yes EN

168. If you answered Yes to question 167, please indicate the modalities used to inform the public:

National website

169. If you indicated more than one modality for public participation in question 168, which one was most

used?

National website EN

170. Has your country taken any initiative to inform its public about the means of public access to the Biosafety Clearing-House?

No EN

171. How many academic institutions in your country are offering biosafety education and training courses and programmes?

10 or more EN

172. Please indicate the number of educational materials and/or online modules on biosafety that are available and accessible to the public in your country:

None EN

173. 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?

No EN

174. If you answered Yes to question 173, has your country cooperated with other States and international bodies?

175. 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?

More than 5 EN

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

Article 24 – Non-Parties

177. Has your country entered into any bilateral, regional, or multilateral agreement with non-Parties regarding transboundary movements of LMOs?

No EN

178. Has your country ever imported LMOs from a non-Party?

Yes EN

179. Has your country ever exported LMOs to a non-Party?

Yes EN

180. If you answered Yes to questions 178 or 179, were the transboundary movements of LMOs consistent with the objective of the Cartagena Protocol on Biosafety?

Yes EN

181. If you answered Yes to questions 178 or 179, was information about these transboundary movements submitted to the BCH?

In some cases only EN

182. 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?

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

Article 25 – Illegal transboundary movements

184. 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 EN

185. Has your country established a strategy for detecting illegal transboundary movements of LMOs?

Yes EN

186. 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?

More than 10 EN

187. If your country received information concerning cases of illegal transboundary movements of an LMO in the current reporting period, has your country informed the BCH and the other Party(ies) involved?

Only in some cases EN

188. If your country received information concerning cases of illegal transboundary movements of an LMO in the current reporting period, has your country established the origin of the LMO(s)?

Yes EN

189. If your country received information concerning cases of illegal transboundary movements of an LMO in the current reporting period, has your country established the nature of the LMO(s)?

Yes EN

190. If your country received information concerning cases of illegal transboundary movements of an LMO in the current reporting period, has your country established the circumstances of the illegal transboundary movement(s)?

Yes EN

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

Article 26 – Socio-economic considerations

192. Does your country have any specific approaches or requirements that facilitate how socio-economic considerations should be taken into account in LMO decision making?

No EN

193. 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?

No EN

194. How many peer-reviewed published materials has your country used for the purpose of elaborating or determining national actions with regard to socio-economic considerations?

None EN

195. What is your country's experience, if any, in taking socio-economic considerations into account in LMO decision making? Please give details:

196. Has your country cooperated with other Parties on research and information exchange on any socio-economic impacts of LMOs?

Yes, to some extent EN

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

Article 27 – Liability and Redress

198. Has your country ratified or acceded to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress?

No EN

199. If you answered No to question 198, is there any national process in place towards becoming a Party?

Yes EN

200. Has your country received any financial and/or technical assistance for capacity-building in the area of liability and redress relating to living modified organisms?

No EN

201. Does your country have administrative or legal instrument that provide for response measures for damage to biodiversity resulting from living modified organisms?

Yes EN

202. 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

Article 28 – Financial Mechanism and Resources

203. How much additional funding (in the equivalent of US dollars) has your country mobilized in the last four years to support implementation of the Biosafety Protocol, beyond the regular national budgetary allocation?

100,000 USD or more EN

Article 33 – Monitoring and reporting

204 a. Does your country have in place a monitoring and/or an enforcement system for the implementation of the Cartagena Protocol? Monitoring system:

No EN

204 b. Does your country have in place a monitoring and/or an enforcement system for the implementation of the Cartagena Protocol? Enforcement system:

Yes EN

205. Has your country submitted all the previous due National Reports?

Yes EN

206. If you answered No to question 205, indicate the main challenges that hindered the submission:

Other information

207. Please use this field to provide any other information on issues related to national implementation of the Protocol, including any obstacles or impediments encountered.

Comments on reporting format

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

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Further Information

Questions about the Nagoya Protocol on Access and Benefit-sharing or the operation of the Access and Benefit-sharing Clearing-House may be directed to the Secretariat of the Convention on Biological Diversity.

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