Biosafety Clearing-House (BCH)

FOURTH NATIONAL REPORT ON THE IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY (NR4)

General Information

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Country

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

Contact person submitting the report

- Person: Stephanie Langerock

PERSON

Stephanie Langerock
Federal Public Service Health, Food Chain Security and Environment
Directorate-General for Environment (DG5)
Brussels
1060,
Belgium
Phone: +32 2 524 92 96
Email: stephanie.langerock@health.fgov.be

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

Sciensano, Authorities of the different regions (Flanders, Wallonia, Brussels-Captial Region), Federal authorities, European Union EN

10. Time period covered by this report

From

31 Oct 2015

To

31 Jul 2019

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

Article 2 requires each Party to take the necessary and appropriate legal, administrative and other measures to implement its obligations under the Protocol

14. Has your country introduced the necessary national measures for the implementation of the Protocol?

National measures are fully in place EN

15. Which specific instruments are in place for the implementation of national biosafety measures? (select all that apply)

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

16. Has your country undertaken initiatives to mainstream biosafety into national biodiversity strategies and action plans, other policies, or legislation?

Yes EN

Additional Information

The EU has a comprehensive science-based legal framework on LMOs, where biosafety is an essential element to take decisions on the development, use and transfer of GMOs (please see Q20). Furthermore biosafety is considered in Belgium's National Strategy for Biodiversity. EN

17. Has your country established a mechanism for budget allocations for the operation of its national biosafety measures?

Yes EN

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

Yes EN

19. If you answered *Yes* to question 18, how many permanent staff members are in place whose functions are directly related to biosafety ?

10 or more	EN

Is this number adequate

Yes	EN

20. 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 commercialization), 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 the three Regions, a cooperation agreement between all the competent entities has been established since 1997 to manage in an harmonized 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 Service Biosafety and Biotechnology (SBB) of Sciensano (formerly 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.	EN

Article 5 - Pharmaceuticals

21. Does your country regulate the transboundary movement, handling or use of living modified organisms (LMOs) which are pharmaceuticals to humans?

Yes	EN

22. 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

23. Does your country regulate the transit of LMOs?

Yes EN

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

Yes EN

25. Has your country taken a decision concerning the import of LMOs for contained use?

No EN

26. 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 Service Biosafety and Biotechnology (SBB) of Sciensano, 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

27. Has your country established legal requirements for exporters under its jurisdiction to notify in writing the competent national authority of the Party of import prior to the intentional transboundary movement of an LMO that falls within the scope of the AIA procedure?

Yes EN

28. When acting as the Party of export, has your country established legal requirements for the accuracy of information contained in the notification provided by the exporter?

Yes EN

29. In the current reporting period, has your country received a notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment?

No EN

30. If you answered *Yes* to question 29, did the notification(s) contain complete information (at a minimum the information specified in Annex I to the Cartagena Protocol on Biosafety)?

31. If you answered *Yes* to question 29, has your country acknowledged receipt of the notification(s) to the notifier within ninety days of receipt?

32. If you answered *Yes* to question 29, has your country informed of its decision(s)

a. The notifier?

b. The Biosafety Clearing-House (BCH)?

33. In the current reporting period, has your country taken a decision in response to the notification(s) regarding intentional transboundary movements of LMOs for intentional introduction into the environment?

No EN

34. If you answered *Yes* to question 33, how many LMOs has your country approved for import for intentional introduction into the environment?

35. If you answered *under question 34* that *LMOs were approved*, have all these LMOs actually been

imported into your country?

36. If you answered *Yes* to question 33, what percentage of your country's decisions fall into the following categories? (select all that apply)

37. If you answered *under question 36* that your country has taken a decision to *approve the import with conditions* or to *prohibit the import*, were the reasons provided?

38. Here you may provide further details on the implementation of Articles 7 to 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)

39. Does your country have law(s), regulation(s) or administrative measures for decision-making regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing?

Yes	EN

40. Has your country established legal requirements for the accuracy of information to be provided by the applicant regarding the domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing?

Yes	EN

41. In the current reporting period, how many decisions has your country taken regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing?

10 or more EN

42. Does your country have law(s), regulation(s) or administrative measures for decision-making regarding the import of LMOs for direct use as food or feed, or for processing?

Yes EN

43. In the current reporting period, how many decisions has your country taken regarding the import of LMOs for direct use as food or feed, or for processing?

10 or more EN

44. 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 that may be subject to transboundary movement for direct use as food or feed, or for processing

Please refer to the report submitted by the European Union. EN

Article 12 – Review of decision

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

Yes EN

46. In the current reporting period, has your country reviewed and/or changed a decision regarding an intentional transboundary movement of an LMO?

No EN

47. If you answered *Yes* to question 46, how many decisions were reviewed and/or changed?

48. If you answered *Yes* to question 46, were any of the reviews triggered by a request from the Party of export or the notifier?

49. If you answered *Yes* to question 48, did your country provide a response within ninety days setting out the reasons for the decision?

50. If you answered *Yes* to question 46, were any of the reviews initiated by your country as the Party of import?

51. If you answered *Yes* to question 50, did your country, within thirty days, set out the reasons for the decision and inform

a. The notifier

b. The BCH?

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

Article 13 – Simplified procedure

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

No EN

54. In the current reporting period, has your country applied the simplified procedure?

No EN

55. If you answered *Yes* to question 54, for how many LMOs has your country applied the simplified procedure?

56. If you answered *Yes* to question 54, has your country informed the Parties through the BCH of the cases where the simplified procedure was applied?

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

BE has not made use of the simplified procedure for imports of LMOs as specified in Article 13. EN

Article 14 – Bilateral, regional and multilateral agreements and arrangements

58. How many bilateral, regional or multilateral agreements or arrangements relevant to biosafety has your country established with other Parties/non-Parties?

None EN

59. If you answered *under question 58* that *agreements or arrangements were established*, please provide a brief description of their scope and objective

60. 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).
Please also refer to the report submitted by the European Union.

EN

Articles 15 & 16 – Risk Assessment and Risk Management

61. Does the domestic regulatory framework of your country require risk assessments of LMOs to be conducted?

Yes

EN

62. If you answered *Yes* to question 61, with regard to which LMOs does the requirement apply (select all that apply)?

For imports of LMOs for intentional introduction into the environment
For imports of LMOs intended for direct use as food or feed, or for processing
For decisions regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movements for direct use as food or feed, or for processing
For imports of LMOs for contained use

63. Has your country established a mechanism to conduct risk assessments prior to taking decisions regarding LMOs?

Yes

EN

64. If you answered *Yes* to question 63, does the mechanism include procedures to identify and/or train national experts to conduct risk assessments?

Yes

EN

Capacity-building in risk assessment or risk management

65. How many people in your country have been trained in risk assessment, risk management and monitoring of LMOs?

a. Risk assessment

100 or more

EN

Is this number adequate

Yes EN

b. Risk management

50 to 99 EN

Is this number adequate

Yes EN

c. Monitoring

1 to 9 EN

Is this number adequate

Yes EN

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

Yes EN

67. If you answered *Yes* to question 66, is your country using the “Manual on Risk Assessment of LMOs” (developed by the CBD Secretariat) for training in risk assessment?

No EN

68. If you answered *Yes* to question 66, is your country using the “Guidance on Risk Assessment of LMOs” (developed by the Online Forum and the AHTEG on Risk Assessment and Risk Management) for training in risk assessment?

Yes EN

69. Does your country have specific needs for further guidance on specific topics of risk assessment of LMOs?

No EN

70. Does your country have the capacity to detect, identify, assess the risk of 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?

a. Detect

Yes EN

b. Identify

Yes EN

c. Assess the risk

Yes EN

d. Monitor

Yes EN

Conducting risk assessment or risk management

71. 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?

a. Risk assessment

Yes EN

b. Risk management

Yes EN

72. If you answered *Yes* to question 71, is your country using the “Guidance on Risk Assessment of LMOs” (developed by the Online Forum and the AHTEG on Risk Assessment and Risk Management) for conducting risk assessment or risk management, or for evaluating risk assessment reports submitted by notifiers?

No EN

73. Has your country adopted common approaches or methodologies to risk assessment in coordination with other countries?

Yes EN

74. Has your country cooperated with other Parties with a view to identifying LMOs or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity?

Yes EN

75. In the current reporting period, has your country conducted any kind of risk assessment of LMOs, including for contained use, field trials, commercial purposes, direct use as food, feed, or for processing?

Yes EN

76. If you answered *Yes* to question 75, how many risk assessments were conducted?

100 or more EN

77. If you answered *Yes* to question 75, please indicate the scope of the risk assessments (select all that apply)

- LMOs for contained use (in accordance with Article 3)
- LMOs for intentional introduction into the environment for experimental testing or field trials
- LMOs for intentional introduction into the environment for commercial purposes
- LMOs for direct use as food
- LMOs for direct use as feed
- LMOs for processing

78. If you answered *Yes* to question 75, were risk assessments conducted for all decisions taken on LMOs for intentional introduction into the environment or on domestic use of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing?

Yes, always EN

79. Has your country established appropriate mechanisms, measures and strategies to regulate and manage risks identified in the risk assessment of LMOs?

Yes EN

80. Has your country taken appropriate measures to prevent unintentional transboundary movements of LMOs, including such measures as requiring a risk assessment to be carried out prior to the first release of

a LMO?

Yes	EN

81. Has your country taken measures to ensure that any LMO, whether imported or locally developed, undergoes an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use?

Yes	EN

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

Yes	EN

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

Yes	EN

84. 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 Serice for Biosafety and Biotechnology (SBB) of Sciensano. The BAC advises the authorities for all regulatory dossiers related 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 use 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[2] and emergency measures

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

85. Has your country established measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations in case of a release under its jurisdiction that leads, or may lead, to an unintentional transboundary movement?

Yes EN

86. In the current reporting period, how many releases of LMOs occurred under your country's jurisdiction that led, or may have led, to an unintentional transboundary movement?

None EN

87. If you answered *under question 86* that a *release occurred*, has your country notified affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations?

88. Does your country have the capacity to take appropriate response measures in response to unintentional transboundary movements?

Yes EN

89. In the current reporting period, how many times has your country become aware of an unintentional transboundary movement into its territory?

None EN

90. 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

91. 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

92. Has your country taken measures to require that documentation accompanying LMOs-FFP, *in cases where the identity of the LMOs is not known*, clearly identifies that they *may contain LMOs* and are not intended for intentional introduction into the environment, as well as a contact point for further information?

Yes EN

93. Has your country taken measures to require that documentation accompanying LMOs-FFP, *in cases where the identity of the LMOs is known*, clearly identifies that they *contain LMOs* and are not intended for intentional introduction into the environment, as well as a contact point for further information?

Yes EN

94. If you answered *Yes* to question(s) 91, 92 and/or 93, what type of documentation accompanying LMOs does your country require?

Documentation specific for LMOs EN

95. Has your country taken measures to require that documentation accompanying *LMOs that are*

destined for contained use clearly identifies them as *LMOs* 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

96. If you answered *Yes* to question 95, what type of documentation does your country require for the identification of LMOs that are destined for contained use?

Documentation specific for LMOs EN

97. Has your country taken measures to require that documentation accompanying *LMOs that are intended for intentional introduction into the environment of the Party of import* clearly identifies them as *living modified organisms*; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter?

Yes EN

98. If you answered *Yes* to question 97, what type of documentation does your country require for the identification of LMOs that are intended for intentional introduction into the environment?

Documentation specific for LMOs EN

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

Yes EN

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

Yes EN

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

None EN

Is this number adequate

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

Yes EN

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

10 to 49 EN

Is this number adequate

Yes EN

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

Yes EN

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

5 to 9 EN

106. If you answered *under question 105* that *certified laboratories exist in your country*, how many of them are currently operating in the detection of LMOs?

5 to 9 EN

107. 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 Sciensano (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 Sciensano. 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

EN

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 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

108. In case your country has designated more than one competent national authority, has your country established a mechanism for the coordination of their actions prior to taking decisions regarding LMOs?

Yes	EN

109. Has your country established adequate institutional capacity to enable the competent national authority(ies) to perform the administrative functions required by the Cartagena Protocol on Biosafety?

Yes	EN

110. Has your country undertaken initiatives to strengthen collaboration among national focal points, competent national authority(ies) and other institutions on biosafety-related matters?

Yes	EN

Additional Information

Biosafety-related matters are implemented at the regulatory and scientific levels in Belgium in a harmonized and collaborative way thanks to a cooperation agreement between all the competent entities. In addition several fora exist where entities involved in biosafety-related matters can exchange and coordinate.	EN

111. 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	EN

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.

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

112. 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.

a. Existing legislation, regulations and guidelines for implementing the Protocol, as well as information required by Parties for the advance informed agreement procedure (Article 20, paragraph 3 (a))

Information available and in the BCH | EN

b. Legislation, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing (Article 11, paragraph 5)

Information available and in the BCH | EN

c. Bilateral, multilateral and regional agreements and arrangements (Articles 14, paragraph 2 and 20, paragraph 3 (b))

Information not available | EN

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 | EN

e. Decisions by a Party regarding transit of LMOs (Article 6, paragraph 1)

Information not available | EN

f. Decisions by a Party regarding import of LMOs for contained use (Article 6, paragraph 2)

Information not available | EN

g. Notifications regarding the release under your country’s jurisdiction that leads, or may lead, to an unintentional transboundary movement of a LMO that is likely to have significant adverse effects on biological diversity (Article 17, paragraph 1)

Information not available	EN

h. Information concerning cases of illegal transboundary movements of LMOs (Article 25, paragraph 3)

Information not available	EN

i. Decisions regarding the importation of LMOs for intentional introduction into the environment (Article 10, paragraph 3)

Information available and in the BCH	EN

j. Information on the application of domestic regulations to specific imports of LMOs (Article 14, paragraph 4)

Information available and in the BCH	EN

k. Decisions regarding the domestic use of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing (Article 11, paragraph 1)

Information available and in the BCH	EN

l. Decisions regarding the import of LMOs intended for direct use as food or feed, or for processing that are taken under domestic regulatory frameworks (Article 11, paragraph 4) or in accordance with Annex III to the Protocol (Article 11, paragraph 6)

Information available and in the BCH	EN

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 not available	EN

n. Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12, paragraph 1)

Information not available	EN

o. Cases where intentional transboundary movement may take place at the same time as the movement is notified to the Party of import (Article 13, paragraph 1 (a))

Information not available EN

p. LMOs granted exemption status by each Party (Article 13, paragraph 1 (b))

Information not available EN

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 EN

113. Please provide a brief explanation if you answered that the information is available *but not in the BCH or only partially available in the BCH* to any item under question 112

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

No EN

115. 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

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

Yes, in some cases EN

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

No EN

118. In the current reporting period, how many biosafety-related events (e.g. seminars, workshops, press conferences, educational events) has your country organized?

5 to 9 EN

119. In the current reporting period, how many biosafety-related publications has your country published?

10 to 49 EN

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

Article 21 – Confidential information

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

Yes EN

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

Yes, always EN

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

Article 22 – Capacity-building

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

No EN

125. Has your country received external support or benefited from collaborative activities with other Parties in the development and/or strengthening of human resources and institutional capacities in biosafety?

No EN

126. If you answered *Yes* to question 125, how were these resources made available? (select all that apply)

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

No EN

128. If you answered *Yes* to question 127, how were these resources made available? (select all that

apply)

129. In the reporting period, has your country initiated a process to access funds from the Global Environment Facility (GEF) for building capacity in biosafety?

No EN

130. If you answered *Yes* to question 129, how would you characterize the process?

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

No EN

132. If you answered *Yes* to question 131, in which of the following areas were these activities undertaken (select all that apply)?

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

No EN

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

No EN

135. If you answered *Yes* to question 134, which of the following areas still need capacity-building (select all that apply)?

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

No EN

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

No EN

138. 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

139. Is biosafety public awareness, education and/or participation addressed in legislation or policy in your country?

Yes, to some extent EN

140. In the current reporting period, has your country cooperated with other States and international bodies in relation to public awareness, education and participation?

Yes EN

141. Has your country established a mechanism to ensure public access to information on LMOs?

Yes EN

142. Does your country have in place a national communication strategy on biosafety?

Yes EN

Additional Information

Please refer to the report submitted by the European Union. EN

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

No EN

144. Does your country currently have a national biosafety website?

Yes EN

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

1 to 4 EN

Is this number adequate

Yes EN

146. How many educational materials and/or online modules on biosafety are available and accessible to the public in your country?

10 to 24 EN

Is this number adequate

Yes EN

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

Yes EN

148. Has your country informed the public about existing modalities for public participation in the decision-making process regarding LMOs?

Yes EN

149. If you answered *Yes* to question 148, please indicate the modalities used to inform the public: (select all that apply)

National websites

150. In the current reporting period, how many times has your country consulted the public in the decision-making process regarding LMOs?

5 or more EN

151. Has your country informed the public about the means to access the Biosafety Clearing-House?

No EN

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

Article 24 – Non-Parties

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

No EN

154. In the current reporting period, has your country imported LMOs from a non-Party?

Yes EN

155. In the current reporting period, has your country exported LMOs to a non-Party?

Yes EN

156. If you answered *Yes* to question 154 and/or 155, were the transboundary movements of LMOs consistent with the objective of the Cartagena Protocol on Biosafety?

Yes, always EN

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

Article 25 – Illegal transboundary movements[3]

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

158. Has your country adopted domestic measures aimed at preventing and/or penalizing transboundary movements of LMOs carried out in contravention of its domestic measures to implement the Cartagena Protocol?

Yes EN

159. In the current reporting period, how many cases of illegal transboundary movements of LMOs has your country become aware of?

10 or more EN

160. If you indicated *under question 159* that *your country became aware of cases of illegal transboundary movements*, has the origin of the LMO(s) been established?

Yes EN

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

Article 26 – Socio-economic considerations

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

No EN

163. In the current reporting period, have socioeconomic considerations arising from the impact of LMOs been taken into account in decision-making?

No EN

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

None EN

Is this number adequate

165. Has your country cooperated with other Parties on research and information exchange on any socioeconomic impacts of LMOs?

Yes EN

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

Article 28 – Financial Mechanism and Resources

167. In the current reporting period, how much funding (in the equivalent of US dollars) has your country mobilized to support implementation of the Cartagena Protocol beyond the regular national budgetary allocation?

Nothing EN

Article 33 – Monitoring and reporting

Article 33 requires Parties to monitor the implementation of its obligations under the Cartagena Protocol and to report to the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on measures taken to implement the Protocol

168. Does your country have in place a system to monitor and enforce the implementation of the Cartagena Protocol?

Yes EN

Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress

Parties to the Cartagena Protocol that are not yet Party to the Supplementary Protocol are also invited to respond to the questions below

169. Is your country a Party to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress?

No EN

170. If you answered *No* to question 169, is there any national process in place towards becoming a Party to the Supplementary Protocol?

Yes	EN

171. Has your country introduced the necessary measures for the implementation of the Supplementary Protocol?

National measures are fully in place	EN

172. Which instruments are in place for the implementation of the Supplementary Protocol?

One or more national laws	EN

Additional Information

Walloon Region: - 22 novembre 2007 Décret modifiant le Livre Ier du Code de l'Environnement en ce qui concerne la prévention et la réparation des dommages environnementaux - 3 juin 2016. — Décret modifiant le Code de l'Environnement, le Code de l'Eau et divers décrets en matière de déchets et de permis d'environnement Flanders Region: Decreet van 5 april 1995 houdende algemene bepalingen inzake milieubeleid, titel XV Milieuschade. Brussels Capital Region - 25 MARS 1999. - Code de l'inspection, la prévention, la constatation et la répression des infractions en matière d'environnement et de la responsabilité environnementale, (art. 4 ; 20 ; 21, § 1, 6 ; 24-30 ; 57) - 19 MARS 2009. - Arrêté du Gouvernement de la Région de Bruxelles-Capitale précisant certaines dispositions de l'ordonnance du 13 novembre 2008 relative à la responsabilité environnementale en ce qui concerne la prévention et la réparation des dommages environnementaux. Federal level : - Koninklijk besluit betreffende de preventie en het herstel van milieuschade bij het in de handel brengen van genetisch gemodificeerde organismen of van producten die er bevatten - 8 NOVEMBER 2007. - Koninklijk besluit betreffende de preventie en het herstel van milieuschade tengevolge van het vervoer over de weg, per spoor, over de binnenwateren of in de lucht van : uitheemse plantensoorten evenals van uitheemse diersoorten en hun krengen, naar aanleiding van de in-, de uit- en de doorvoer ervan; alsook van afvalstoffen bij hun doorvoer	EN

173. Does your country have administrative or legal instruments that require response measures to be

taken

a. In case of damage resulting from LMOs?

Yes EN

b. In case there is sufficient likelihood that damage will result if response measures are not taken?

Yes EN

174. If you answered *Yes* to question 173a, do these instruments impose requirements on an operator (select all that apply)?

Yes, the operator must inform the competent authority of the damage
Yes, the operator must evaluate the damage
Yes, the operator must take response measures
Yes, other requirements (The operator must take preventive measures.)

175. If you answered *Yes* to question 173a, do these instruments require the operator to take response measures to avoid damage?

Yes EN

176. If you answered *Yes* to question 173a or 173b, do these instruments provide for a definition of “operator”?

Yes EN

177. If you answered *Yes* to question 176, which of the following could be an ‘operator’ (select all that apply)?

Permit holder
Person who placed the LMO on the market
Developer
Producer
Notifier
Exporter
Importer
Carrier
Supplier

178. Has a competent authority been identified for carrying out the functions set out in the

Supplementary Protocol?

Yes EN

179. If you answered *Yes* to question 178, what measures may the competent authority take (select all that apply)?

Identify the operator that caused the damage
Evaluate the damage
Determine response measures to be taken by operator
Implement response measures
Recover costs and expenses of the evaluation of the damage and the implementation of any response measures from the operator

180. Does your country have measures in place to provide for financial security for damage resulting from LMOs?

Yes EN

Additional Information

Walloon Region: it is a possibility on a case by case basis
Flemish Region: Yes, for the recovery of costs made by the competent authority, the competent authority can impose a collateral/ security in rem or other type of security. EN

181. If you answered *Yes* to question 180, what type of financial security measures are in place (select all that apply)?

Requirement to provide evidence for secure source of funding
Mandatory insurance
Government schemes, including funds
Other (Flemish Region: for the recovery of costs made by the competent authority, the competent authority can impose a collateral/ security in rem or other type of security)

182. Does your country have rules and procedures on civil liability that address damage resulting from LMOs, or has such damage been recognized in court rulings (select all that apply)?

No

183. Have there been any occurrences of damage resulting from LMOs in your country?

No EN

184. If you answered *Yes* to question 183, have response measures been taken?

185. 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

Walloon region: awareness raising, guidance document, and conferences EN

Other information

186. 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

187. 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.

Secretariat of the Convention
on Biological Diversity
413 rue Saint-Jacques, suite 800
Montreal, Québec, H2Y 1N9
Canada
Fax: +1 514 288-6588
Email: secretariat@cbd.int