Biosafety Clearing-House (BCH)

SECOND NATIONAL REPORT ON THE IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY (NR2)

General Information

PUBLISHED: 07 OCT 2011

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 of the Scientific Institute of Public Health). Secretariat of the national Biosafety Advisory Council.] EN

10. Time period covered by this report

From

01 Oct 2007

To

30 Sep 2011

Party to the Cartagena Protocol on Biosafety

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

13. If you answered No to question 12, is there any national process in place towards becoming a Party?

14. Here you may provide further details

Article 2 – General provisions

15. Has your country introduced the necessary legal, administrative and other measures for the implementation of the Protocol?

A domestic regulatory framework is fully in place | 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:

As a member of the European Union, Belgium has to apply the EU legislation on GMOs (see report of the European Commission), that is based on the precautionary principle (cf. EU' s report).
Regulations of the EU are directly applicable by Member States. Some requirements of the regulations have been included in Belgian federal laws (for punishment in case of no respect of the regulations: in program law of 20 July 1992, modified by program law of 1 March 2007).
A Cooperation Agreement concerning Biosafety determines the repartition of competences relative to GMOs between the federal and regional levels. This cooperation agreement establishes a common structure for the Federal State and the Regions for the scientific assessment of GMOs, consisting in the Biosafety Advisory Council (BAC) and the Biosafety and Biotechnology Unit (SBB) of the | EN

Scientific Institute of Public Health (linked to the Federal public Service for Health, Food Chain Safety and Environment). The BAC is composed of administrative and academic representatives appointed by the federal and regional competent authorities. It is assisted by external academic experts. The BAC advises the competent authorities about the safety for human health and the environment of any activities using GMOs, in particular the environmental release and the commercialisation of GMOs. The SBB is composed of a group of scientists with expertise in biosafety. It is in charge of the secretariat of the BAC. The SBB takes over the risk assessment of contained use activities, and offers scientific support to the BAC and to the federal and regional authorities in the field of GMO risk assessment.
Directives of the EU have been transposed respectively in federal and regional decrees, since different uses of GMOs are under different competences in Belgium: contained use is under regional competence (decree of the Brussels Region of 8 november 2001, of the Flemish Region of 6 February 2004, of Walloon Region of 4 July 2002, amended by decrees of 5 June 2008), deliberate release (Royal Decree of 21 February 2005) and placing on the market for direct food, feed or transformation are under federal competence (shared with regional competence for field trials for other purposes than placing on the market - part B of directive 2001/18/CE).
Guidances for coexistence have been established by the regional governments (decree of the Walloon Region of 27 March 2009, and of the Flemish Region of 3 April 2009), since agriculture is mainly under regional competence in Belgium.
Competent Authorities have been designated respectively for implementation of directive 2001/18/CE (deliberate release of GMOs), of regulation CE/1829/2003 (import and placing on the market for direct use as food/feed/tranformation), for regulation CE/1946/2003 (export of GMOs), for contained use of GMOs. National focal point for the Protocol and national focal point for the BCH have been designated. Have also been designated: - Federal controlers of field trials; - Federal controlers of content and labelling of products; - Regional Administrative staffs for the implementation of agriculture coexistence rules.

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:

As all clinical trials, clinical research in gene therapy using living modified organisms falls under the scope of the Belgian law of 7 mai 2004 on experimentation on human beings implementing Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. Such research activities also fall under the scope of Belgian biosafety regulation. In all cases, an authorisation must be obtained according to the Belgian regulations on contained use of GMOs and/or pathogen organisms which implement Directive 2009/41/EC. In the case of multicentre trials and/or for trials involving ambulatory medicine or the risk of shedding of GMOs by the patient into the environment, the Belgian regulation on the deliberate release of GMOs which implements Directive 2001/18/EC must also be applied. To be placed on the market, all medicinal products derived from biotechnology (and therefore also medicinal products containing or consisting of GMOs) must obtain an authorisation issued by the European Commission upon advice of the European Medicines Agency (EMA). Access to the Community market for GMO medicinal products is subject to the centralised procedure laid down in Regulation (EEC) no. 2309/93, as amended by Regulation (EC) no. 726/2004. If authorisation is granted, it is automatically valid for all Member States of the European Union. Please refer to the European Commission report for more information.	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 (this Directive repeals Directive 90/219/EEC and its successive amendments). These Community measures ask for Member States to regulate the contained use of genetically	EN

modified micro-organisms 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.
cf. EU' s report for transit.

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

29. Has your country adopted law(s) / regulations / administrative measures for the operation of the AIA procedure of the Protocol?

Yes | EN

30. Has your country adopted a domestic regulatory framework consistent with the Protocol regarding the transboundary movement of LMOs for intentional introduction into the environment?

Yes | EN

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

Yes | EN

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

Yes | EN

33. Has your country established a mechanism for monitoring potential effects of LMOs that are released

into the environment?

Yes EN

34. Does your country have the capacity to detect and identify LMOs?

Yes EN

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

Yes EN

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

Yes EN

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

Yes EN

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

Yes EN

39. If you answered Yes to question 38, how many LMOs has your country approved to date for import for intentional introduction into the environment?

Less than 5 EN

40. If you answered Yes to question 38, how many LMOs, not imported, has your country approved to date for intentional introduction into the environment?

Less than 5 EN

41. In the current reporting period, how many applications/notifications has your country received regarding intentional transboundary movements of LMOs for intentional introduction into the environment?

Less than 5 EN

42. In the current reporting period, how many decisions has your country taken regarding intentional transboundary movements of LMOs for intentional introduction into the environment?

Less than 5 EN

43. With reference to the decisions taken on intentional transboundary movements of LMOs for intentional introduction into the environment, has your country received a notification from the Party(ies) of export or from the exporter(s) prior to the transboundary movement?

Yes, always EN

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

Yes, always EN

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

n/a EN

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

n/a EN

47. Has your country informed the notifier(s) and the BCH of its decision(s) in due time (within 270 days or the period specified in your communication to the notifier)?

n/a EN

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

49. In cases where your country approved an import with conditions or prohibited an import, did it provide reasons on which its decisions were based to the notifier and the BCH?

n/a EN

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

introduction to the environment:

cf. EU' s report. As a Member State of the EU, Belgium participates in the authorisation procedure for the placing of the market of GMOs intended for intentional introduction into the environment. There were less than 5 GMOs in that case during the reporting period, and none of them is presently cultivated in Belgium for commercial purpose. The placing on the BCH of the decision concerning an authorisation on the EU market is made by the European Commission. During the reporting period, there was no application to a competent national authority in Belgium from a person or company out of the EU to obtain authorisation for the introduction of GMOs into the environment for experimental purposes, 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)

51. Has your country adopted specific law(s) or regulation(s) for decision-making regarding domestic use, including placing on the market, of LMOs-FFP?

Yes	EN

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

Yes	EN

53. Has your country established a mechanism to ensure that decisions regarding LMOs-FFP that may be subject to transboundary movement will be communicated to the Parties through the BCH?

Yes	EN

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

Yes	EN

55. Has your country declared through the BCH that in the absence of a regulatory framework its decisions prior to the first import of an LMO-FFP will be taken according to Article 11.6 of the Cartagena Protocol on Biosafety?

No	EN

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

No EN

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

Yes EN

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

More than 10 EN

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

More than 10 EN

60. 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

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

Yes, always EN

62. Has your country informed the Parties through the BCH of its decision(s) regarding domestic use, including placing on the market, of LMOs-FFP within 15 days?

Yes, always EN

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

cf EU's report. EN

Article 12 – Review of decision

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

Yes EN

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

No EN

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

No EN

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

None EN

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

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

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

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

Article 13 – Simplified procedure

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

No EN

73. Has your country ever applied the simplified procedure?

No EN

74. If you answered Yes to question 73, has your country informed the Parties through the BCH of the cases where the simplified procedure applies?

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

None EN

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

cf EU's report. EN

Article 14 – Bilateral, regional and multilateral agreements and arrangements

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

No EN

78. If you answered Yes to question 77, has your country informed the Parties through the BCH of the agreements or arrangements?

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

80. 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).
cf. EU' s report. EN

Article 15 – Risk assessment

81. Has your country established a mechanism for conducting risk assessments prior to taking decisions regarding LMOs?

Yes EN

82. If you answered Yes to question 81, does this mechanism include procedures for identifying experts to conduct the risk assessments?

Yes EN

83. Has your country established guidelines for how to conduct risk assessments prior to taking decisions regarding LMOs?

Yes EN

84. Has your country acquired the necessary domestic capacity to conduct risk assessment?

Yes EN

85. Has your country established a mechanism for training national experts to conduct risk assessments?

No EN

86. Has your country ever conducted a risk assessment of an LMO for intentional introduction into the environment?

Yes EN

87. Has your country ever conducted a risk assessment of an LMO intended for direct use as food or feed, or for processing?

Yes EN

88. If your country has taken decision(s) on LMOs for intentional introduction into the environment or on domestic use of LMOs-FFP, were risk assessments conducted for all decisions taken?

Yes, always EN

89. Has your country submitted summary reports of the risk assessments to the BCH?

Yes, always EN

90. In the current reporting period, if your country has taken decisions regarding LMOs, how many risk assessments were conducted in the context of these decisions?

More than 10 EN

91. Has your country ever required the exporter to conduct the risk assessment(s)?

Yes, always EN

92. Has your country ever required the notifier to bear the cost of the risk assessment(s) of LMOs?

Yes, always EN

93. Here you may provide further details on the implementation of Article 15 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 competent authorities about the safety for human health and the environment (including genetic and ecological aspects related to biodiversity) of any activities using LMOs. In particular, it provides advices for all applications regarding the deliberate release of LMOs in the environment and the placing on the market of LMOs for cultivation, for food use, for feed use or for processing. The Council 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 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, 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 spectific 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.	EN

Article 16 – Risk management

94.1. LMOs for intentional introduction into the environment?

Yes, to some extent	EN

94.2. LMOs intended for direct use as food or feed, or for processing?

Yes, to some extent	EN

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

Yes	EN

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

Yes	EN

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

Yes	EN

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

Yes	EN

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

cf. EU' s report Some precisions on Monitoring: the EU distinguishes a specific post-marketing monitoring (for risks identified during the risk assessment procedure) from a general post-marketing monitoring (for unforeseen adverse effects). Till now, the notifiers and concerned GMOs operators are in charge of these 2 types of monitoring, that is mainly limited to the elements observable by these operators. The European Commission envisages to more implicate the Member States, and national public networks on health and environmental monitoring in this GMO monitoring. In Belgium in particular, a study financed by the budget for the Federal public Service Health, Food Chain Safety & Environment has shown that an adaptation of existing networks would be necessary to involve these networks in the monitoring of potential GMOs adverse effects. Concerning the spatially and timely more limited monitoring of GMOs field trials not intended for placing on the market, a more accurate and operational	EN

mechanisme can already operate, accompanied by post-trials controls.

Article 17 – Unintentional transboundary movements and emergency measures

100. Has your country made available to the BCH the relevant details setting out its point of contact for the purposes of receiving notifications under Article 17?

Yes EN

101. Has your country established a mechanism for addressing emergency measures in case of unintentional transboundary movements of LMOs that are likely to have significant adverse effect on biological diversity?

Yes EN

102. Has your country implemented emergency measures in response to information about releases that led, or may have led, to unintentional transboundary movements of LMOs?

No EN

103. In the current reporting period, how many times has your country received information concerning occurrences that led, or may have led, to unintentional transboundary movement(s) of one or more LMOs to or from territories under its jurisdiction?

Never EN

104. Has your country notified affected or potentially affected States, the BCH and, where appropriate, relevant international organizations, of the above release?

105. If you answered Yes to question 104, who did your country notify?

106. Has your country immediately consulted the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures?

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

cf. EU' s report.
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. Anyway, some precisions on information EN

transmission and eventual emergency measures still have to be defined.

Article 18 – Handling, transport, packaging and identification

108. Has your country taken measures to require that LMOs that are subject to transboundary movement are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards?

Yes EN

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

Yes EN

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

Yes EN

111. Has your country taken measures to require that documentation accompanying LMOs that are destined for contained use clearly identifies them as living modified organisms and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the LMO are consigned?

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

Yes	EN

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

Yes	EN

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

cf. EU' s report : EU legislation for GMOs is consistent with Article 18 Belgian customers have been informed on the requirements of Art. 18 and related COP-MOP decisions. Concerned customers have followed Workshops organized by the Green Customs However, in face of poorly sufficient custom' s staff, GMOs control is not always considered as a priority. Custom' s responsable staff especially deplore the absence of methods to distinguish, generally speaking, GMOs from non-GMOs; they consider that the availability of such methods would make their job relative to GMOs controlling more efficient. In order to control the application of Art. 18 and its implementation through the EU legislation, the Belgian Federal Agency for Food Chain Safety is in charge of controlling the content and labelling (following the EU legislation)of food and feed products sold in shops and restaurants in Belgium and to control imported products considered as dubious by customers.	EN

Article 19 – Competent National Authorities and National Focal Points

116. Has your country designated one national focal point for the Cartagena Protocol to be responsible for liaison with the Secretariat?

Yes	EN

117. Has your country designated one national focal point for the Biosafety Clearing-House to liaise with the Secretariat regarding issues of relevance to the development and implementation of the BCH?

Yes	EN

118. Has your country designated one or more competent national authorities, which are responsible for performing the administrative functions required by the Cartagena Protocol on Biosafety and are authorized to act on your country’s behalf with respect to those functions?

Yes, more than one	EN

119. In case your country designated more than one competent national authority, has your country

conveyed to the Secretariat the respective responsibilities of those authorities?

Yes	EN

120. Has your country made available the required information referred in questions 116-119 to the BCH?

Yes, all information	EN

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

Yes	EN

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

Yes	EN

123. 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 Administrative staffs for the implementation of agriculture coexistence rules...	EN

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

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

Information available and in the BCH	EN

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

Information available and in the BCH	EN

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

Information not available	EN

124.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

124.e. Reports submitted by the Parties on the operation of the Protocol (Article 20, paragraph 3 (e))

Information available and in the BCH	EN

124.f. Decisions by a Party on regulating the transit of specific living modified organisms (LMOs) (Article 6, paragraph 1)

Information not available	EN

124.g. Occurrence of unintentional transboundary movements that are likely to have significant adverse effects on biological diversity (Article 17, paragraph 1)

Information not available	EN

124.h. Illegal transboundary movements of LMOs (Article 25, paragraph 3)

Information not available	EN

124.i. Final decisions regarding the importation or release of LMOs (i.e. approval or prohibition, any conditions, requests for further information, extensions granted, reasons for decision) (Articles 10, paragraph 3 and 20, paragraph 3(d))

Information available and in the BCH	EN

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

Information not available	EN

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

Information available and in the BCH	EN

124.l. Final decisions regarding the import of LMOs intended for direct use as food or feed, or for processing that are taken under domestic regulatory frameworks (Article 11, paragraph 4) or in accordance with annex III (Article 11, paragraph 6) (requirement of Article 20, paragraph 3(d))

Information available and in the BCH	EN

124.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

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

Information not available	EN

124.o. LMOs granted exemption status by each Party (Article 13, paragraph 1)

Information not available	EN

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

Information not available	EN

124.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

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

No	EN

126. Has your country established a mechanism for the coordination among the BCH National Focal Point, the Cartagena Protocol focal point, and the competent national authority(ies) for making information available to the BCH?

Yes	EN

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

Yes, in some cases	EN

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

Yes	EN

129. If you answered Yes to question 128, has your country reported these problems to the BCH or the Secretariat?

Yes	EN

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

Yes	EN

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

Belgium has provided all the required information directly in the BCH Central Portal. In addition, Belgium is running since 2001 a BCH national node, the "Belgian Biosafety Clearing-House" (BBCH - http://www.biosafetyprotocol.be). This site is a basic website providing general information about the Cartagena Protocol and serving as a entry point for national information required under the Protocol. Detailed information on biosafety and LMOs is available on other national websites, in particular the "Belgian Biosafety Server" (BBS - http://www.biosafety.be - runned by the SBB since March 1996) and the GMO portal of the FPS Health Food Chain Safety and Environment (http://www.ogm-ggo.be) set up in 2005. Concerning answers to questions 124 j and m, Belgium did not furnish itself the information on the BCH: the European Commission furnishes to the BCH the answers that are also applicable for Belgium.	EN

Article 21 – Confidential information

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

Yes	EN

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

Yes, always EN

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

cf. EU's report. EN

Article 22 – Capacity-building

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

No EN

136. If you answered Yes to question 135, how were these resources made available?

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

Yes EN

138. If you answered Yes to question 137, how were these resources made available?

Bilateral channels EN

139. Is your country eligible to receive funding from the Global Environment Facility (GEF)?

No EN

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

141. If you answered Yes to question 140, how would you characterize the process?

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

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

No EN

144. If you answered Yes to question 143, in which of the following areas were these activities undertaken?

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

No	EN

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

Yes, a few	EN

147. If you answered Yes to question 146, indicate which of the following areas still need capacity-building.

5B6177DD-5E5E-434E-8CB7-D63D67D5EBED (See answer to Q150)

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

No	EN

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

No	EN

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

Belgium is not a Party eligible to benefit from exterior funding for capacity-building, but would still need to develop its own capacities in various of the areas mentionned in question 147, for the purpose of an effective implementation of the Protocol, and more specifically in the areas mentionned in places 4, 5, 10, 11, 13 of question 147.	EN

Article 23 – Public awareness and participation

151. Has your country established a strategy or put in place legislation for promoting and facilitating public awareness, education and participation concerning the safe transfer, handling and use of LMOs?

Yes, to some extent	EN

152. Has your country established a biosafety website?

Yes EN

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

Yes EN

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

Yes EN

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

Yes EN

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

No EN

157. In the current reporting period, has your country promoted and facilitated public awareness, education and participation concerning the safe transfer, handling and use of LMOs?

Yes, to a limited extent EN

158. If you answered Yes to question 157, has your country cooperated with other States and international bodies?

No EN

159. In the current reporting period, how many times has your country consulted the public in the decision-making process regarding LMOs and made the results of such decisions available to the public?

Less than 5 EN

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

Following the EU legislation, BE, as a Member State of the EU, is in charge of consulting the public in the case of field trials of LMOs asked by notifiers to be EN

undertaken in Belgium.
Besides, the Federal public service for Health, Food Chain Safety and Environment, that houses the national focal point of the Protocol and the federal competent authorities for the implementation of the EU legislation, has developped a website informative for the general public, on basic knowledge, legislations, activities and news around GMOs in BE and in the EU.

Article 24 – Non-Parties

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

No EN

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

Yes EN

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

Yes EN

164. If you answered Yes to questions 162 or 163, were the transboundary movements of LMOs consistent with the objective of the Cartagena Protocol on Biosafety?

Yes, always EN

165. If you answered Yes to questions 162 or 163, was information about these transboundary movements submitted to the BCH?

In some cases only EN

166. If your country is not a Party to the Cartagena Protocol, has it contributed information to the BCH on LMOs released in, or moved into, or out of, areas within its national jurisdiction?

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

cf. EU' s report
Following our knowledge, transboundary movements of LMOs from Belgium to third countries concern mainly LMOs developped in contained use in Belgium and intended for field trials in non Parties (mainly USA). EN

Article 25 – Illegal transboundary movements

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

Yes EN

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

Yes EN

170. In the current reporting period, how many times has your country received information concerning cases of illegal transboundary movements of an LMO to or from territories under its jurisdiction?

Less than 5 EN

171. Has your country informed the BCH and the other Party(ies) involved?

n/a EN

172. Has your country established the origin of the LMO(s)?

Yes EN

173. Has your country established the nature of the LMO(s)?

Yes EN

174. Has your country established the circumstances of the illegal transboundary movement(s)?

Yes, some cases EN

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

cf EU's report. EN

Article 26 – Socio-economic considerations

176. If your country has taken a decision on import, has it ever taken into account socio-economic considerations arising from the impact of the LMO on the conservation and sustainable use of biological diversity?

No | EN

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

Yes, to a limited extent | EN

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

Belgium has participated through its contributions of informations and opinions to the recent European Commission report on socio-economic implications of GMOs cultivation.
Belgium has participated through its National focal Point in the recent online forum of discussions and conference on this subject organized by the Secretariat of the Protocol. | EN

Article 27 – Liability and Redress

179. Has your country signed the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress?

Yes | EN

180. Has your country initiated steps towards ratification, acceptance or approval of the Nagoya-Kuala Lumpur Supplementary Protocol?

Yes | EN

181. Here you may provide further details on any activities undertaken in your country towards the implementation of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress:

Belgium has signed the Supplementary Protocol in NY on September 20 at a ceremony taking place during the high-level event on desertification of the 66th session of the UN assembly.
cf. EU' s report: since the adopted Supplementary Protocol is fully consistent with the EU legislation, no further action at the European Union level and its Member States seems necessary to ratify this agreement. | EN

Article 33 – Monitoring and reporting

182. Has your country submitted the previous national reports (Interim and First National Reports)?

Yes EN

183. If your country did not submit previous reports, indicate the main challenges that hindered the submission

Other information

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

Comments on reporting format

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

Survey on indicators of the Strategic Plan (2014)

3. When did your national biosafety framework become operational?

2001 or earlier EN

Additional Information

No governmental additional funding has been mobilized in the last four years in favor of less developed countries for the implementation of the Cartagena Protocol (see answer to question 5). We have no precise knowledge of funds eventually mobilized individually by academic institutions or the private sector in this direction.. For the implementation of the Protocol inside Belgium, the Biosafety Cooperation Agreement (cf. answer to question 5) foresees the financing of the activities of the BAC by the federal and regional governments (50%/50%). In the last 4 years, this financing (having a complex repartition for various specific activities) allows: 1) the payment of 9 members of the personnel of the SBB (scientific secretariat of the BAC) for their secretariat, expertise and data collection activities.; 2) the payment of external experts supporting activities; 3) the administrative functioning of the BAC activities . EN

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

1 per year or more EN

Additional Information

Biosafety courses are offered in several academic institutions in Belgium (especially those offering training in agronomical sciences). Part of these general courses is taught by SBB experts. The Biosafety and Biotechnology Unit (SBB) of the Scientific Institute of Public Health also offers training modules in biosafety, currently primarily aimed at those involved in the contained use of GMOs and pathogenic organisms, combining theoretical descriptions, examples of activities concerned and practical exercises, adapted to the needs of the users each time. In particular, training sessions are regularly delivered to staff of the inspection departments of Belgium’s Regions, and since 2009 to State scientific personnel which focuses on laboratory biosafety . (Between 2003 and 2006, the SBB also contributed to the organization and implementation of a project in partnership with developing countries to train delegates from those countries in the use of the BCH . This training was conducted in collaboration with the Belgian Royal Institute of Natural Sciences , the national focal point of the CBD.)	EN

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

Yes	EN

Additional Information

There is no national mechanism for coordinating biosafety capacity-building initiatives in favor of less developed countries, despite efforts of the national focal point towards this .(No priority devoted towards this issue since several years by the federal ministry of development cooperation that should officially be the main supporter of such coordination mechanism; no incentive till biosafety is not a specific demand from developing countries in bilateral cooperation agreements). Concerning capacity-building initiatives to implement the Cartagena Protocol inside Belgium, a Biosafety Cooperation Agreement has been signed in 1997 between the federal and the regional governments for the sharing of official competences relative to GMOs (briefly, placing on the market is under federal competence; GMOs in confined use is under regional competence; GMOs field trials is under mixed competence) and for the establishment of a common scientific risk assessment process of the GMOs to be released in the environment or directly aimed at food/feed on the EU market, and for field trials of GMOs in Belgium. This Agreement should presently be revised and actualized. A national Biosafety Advisory Council (BAC) has been established in the framework of this Agreement; it is composed of members nominated by several competent federal and regional ministers, working as volunteers, and by a scientific secretariat which is part of the SBB (Biosafety and Biotechnology Unit of the Scientific Institute of Public Health); a list of external experts , mainly academicians and experts of the SBB, may help the Council in its task. The SBB is also in charge of scientific expertise for the risk assessment of GMOs to be developed in contained use, which are under exclusive regional competence	EN

6. 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?

n/a EN

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

Yes EN

Additional Information

The budget allocated for the activities of the national Biosafety Advisory Council and the related activities of the SBB is predictable and defined by official documents . EN

8. How many LMO-related collaborative bilateral/multilateral arrangements has your country established with other Parties/non-Parties?

One or more EN

Additional Information

Belgium is a Member State of the European Union EN

9.a. Has your country adopted or used any guidance documents for the purpose of conducting risk assessment and/or risk management? Risk assessment

Yes EN

9.b. Has your country adopted or used any guidance documents for the purpose of conducting risk assessment and/or risk management? Risk management

Yes EN

10. Has your country adopted or used any guidance documents for the purpose of evaluating risk assessment reports submitted by notifiers?

Yes EN

Additional Information

For details, please refer to the European Commission survey report. EN

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

Yes	EN

Additional Information

As a EU Member State, Belgium applies approaches to risk assessment that have been harmonized at the EU level. Belgium is also a partner in the discussions under the Codex Alimentarius and the Organization for Economic Co-operation Development (OECD) The Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology developed several documents regarding the safety assessment of genetically modified foods. The OECD's Working Group on the Harmonization of Regulatory Oversight in Biotechnology and the Task Force for the safety of Novel Foods and Feeds developed conceptual and technical documents relative to the environmental risk/safety assessment of LMOs.	EN

12. Has your country ever conducted a risk assessment of an LMO?

Yes	EN

Additional Information

The advices of the national Biosafety Advisory Council on the risk assessment of LMOs (aimed directly at food/feed or transformation, aimed at deliberate release into the environment on the EU market or at field trials) are available on the website: www.bio-council.be/bac_advices . The SBB (Biosafety and Biotechnology Unit of the Scientific Institute of Public Health) also reviews the risk assessment of contained use activities, under regional competence.	EN

13.a. Does your country have the capacity to 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

13.b. Does your country have the capacity to 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

13.c. Does your country have the capacity to 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

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

Yes	EN

Additional Information

For details, please refer to the European Commission survey report The EU regulation EC/1946/2003 implements the requirements of the Cartagena Protocol relatively to the export of LMOs. The national Competent Authority for implementation of EU regulation 1946/2003 (requirements for export of GMOs) has established specific requirements details for exporters to implement their duty towards the Competent Authority .	EN

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

Yes	EN

Additional Information

Socio-economic considerations are relevant for the question of co-existence of non-GM cultures with cultures of GM seeds authorized on the EU market. The EU Commission has developed recommendations but no precise guidance on co-existence. In Belgium, where agriculture is mainly under regional competence, the regional governments have established guidance for coexistence through respective regional decrees.(Note that the guidance in Walloon and Flemish Regions are different in some technical terms, in particular in terms of distances to respect between GM – and non-GM fields.) Concerning the question of SEC that could be taken into account in the authorization process of GMOs at the EU level , there is some consensual view at the Belgian level, despite some disparities on views till now in the relevancy of ex ante SEC and on the composition of a body that would evaluate the SEC. There is some common agreement that, if SEC were taken into account in the authorization process, SEC should be considered by a body separate from the present Biosafety Advisory Council; and no consensual advice but rather a compilation/summary of different opinions of experts/ stakeholders should be communicated with their arguments to competent ministers. For the current debate on SEC at the EU level, please refer to the European Commission survey report.	EN

16. 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

Additional Information

This question is not relevant till now for Belgium since no precise official	EN

consensual national actions have been elaborated till now regarding SEC.

17. What is your country's experience, if any, in taking socio-economic considerations into account in LMO decision making?

Socio-economic considerations were taken into account for national approvals for 2 field trials of GM trees in Belgium. One for apple trees, before 2004. The Minister for public health and environment established a provisional committee, giving an opinion based on ethical and socio-economic considerations, in addition to the usual biosafety concerns considered by the Biosafety Belgian Advisory Council. The opinion of that committee was unfavorable, and so was the final decision for the field trial. More recently, the federal Ministers for health and environment took a negative decision for field trials of poplar trees, after a positive advice submitted to risk management conditions of the Biosafety Belgian Advisory Committee. The negative decision was based a.o. on public concerns and on doubts about the societal benefit and therefore the sustainability of the GM poplars (developed for biofuels to be used in transportation). The applicant went to the administrative Court. The State Council gave reason to the applicant, considering that the arguments for a negative decision were not justified enough and should have been based according to the legislation derived from EU law only on risk concerns, especially for a field trial level of dissemination in the environment.	EN

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

Yes	EN

Additional Information

For details, please refer to the European Commission survey report	EN

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

10 or more	EN

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

None	EN

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

10 or more | EN

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

Yes | EN

Additional Information

The Scientific Institute of Public Health coordinates the Belgian National Reference Laboratory for GMOs (NRL-GMO) which provides a laboratory research and analysis mission centered on the detection, identification and quantification of GMOs, in particular in food and feed . It is also member of the “ European Network of GMO Laboratories “ (ENGL), and supports the “ European Union Reference Laboratory for GM Food and Feed” (EU-RL GMFF) which is responsible for the scientific assessment and validation of detection methods for GM Food and Feed as part of the EU authorization procedure. Both organizations are hosted by the Joint Research Center of the European Union . In addition, the Federal Agency for the Safety of the Food Chain (FASFC) which represents the competent authorities in Belgium possesses laboratory facilities and is also a member of the ENGL . | EN

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

Yes | EN

Additional Information

See answer to question 10. | EN

22.a. Are the available training materials and technical guidance on risk assessment and risk management of LMOs sufficient and effective? Sufficient

Yes | EN

22.b. Are the available training materials and technical guidance on risk assessment and risk management of LMOs sufficient and effective? Effective

Yes | EN

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

None | EN

Additional Information

Customs officers already took benefit of international initiatives of the Green Customs. EN

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

10 or more EN

Additional Information

The Belgian National Reference Laboratory for GMOs (NRL-GMO)is composed of 3 laboratories involving, together with the FASFC, between 10 and 50 staff members. EN

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

Yes EN

Additional Information

See answer to question 20. EN

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

One or more EN

Additional Information

The 3 Belgian National Reference Laboratories for GMOs (NRL-GMO) and the FASFC laboratory are accredited laboratories. EN

27. How many of the certified laboratories in the previous question are operational?

One or more EN

Additional Information

All abovementioned laboratories are operational. EN

28. 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

Additional Information

Not relevant for Belgium. EN

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

Yes	EN

Additional Information

Please refer to the European Commission survey report. In addition, the European regulation 2004/35/EC relative to environmental responsibility in case of environmental damage also applies to potential damages caused by GMOs and has been transposed in the Belgian legislation.	EN

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

Yes	EN

Additional Information

For the decision process at the EU level, please refer to the European Commission survey report. In addition, during the authorization process for field trials with LMOs, there is always a public consultation phase The public is informed about this possibility by internet. For Belgium, this public consultation is organized in accordance with the provisions in the Royal Decree of 21 February 2005. The consultation is made at 2 levels: at the city/town where the field trial will take place, and through an online consultation on the website of the Federal Public Service Health, Food Chain Safety & Environment: www.ogm-ggo.be.	EN

31. If you answered yes to the previous question, please indicate the modalities used to inform the public?

National website
Mailing lists
5B6177DD-5E5E-434E-8CB7-D63D67D5EBED (A notice of the public consultation is placed at the city hall of the place where the field trial will take place. In addition, there is the online consultation through the website of the FPS announced by a NEWS message published on the webpage.)

32. If you indicated multiple modalities for public participation in the question above, which one was most used?

National website	EN

Additional Information

Most (almost 100%) of the reactions during the public consultation are received through the online consultation.	EN

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

5 or more	EN

34. How many biosafety training materials and/or online modules are available in your country?

5 or more	EN

Additional Information

Each academic institution offering biosafety training course has its own training material. The Ghent University also offers a Postgraduate Certificate in Biosafety in Plant Biotechnology by Distance Learning. This international e-learning course is aimed at training scientists and law specialists in biosafety expertise and evaluation both at governmental and industrial levels. The course combines distance learning with on campus training.	EN

35.a. Does your country have in place a monitoring and/or an enforcement system? Monitoring system

Yes	EN

35.b. Does your country have in place a monitoring and/or an enforcement system? Enforcement system

Yes	EN

36. 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.

One or more	EN

Additional Information

The Biosafety and Biotechnology Unit (SBB) of the Scientific Institute of Public Health (Belgium) has co-organized in 2012, with 3 other national biosafety advisory bodies (the French High Council for Biotechnology, the German Central Committee on Biological Safety, the Netherlands Commission on Genetic Modification) an international scientific workshop to review some of the latest scientific insights and look into possible challenges in the risk assessment of Synthetic Biology. The SynBio Workshop – Risk assessment challenges of Synthetic Biology , took place in Paris on the 12th of December 2012. See outcome at http://rd.springer.com/article/10.1007%2Fs00003-013-0829-9 The national focal point (from the Federla public Service Health, Food Chain Safety & Environment) made a presentation in a side-event during COP-MOP6 of the Cartagena Protocol, relative to the history of the discussions and meetings on SEC (socio-economic considerations) in the context of the Protocol NB: A meeting on	EN

issues regarding the Cartagena Protocol and the BCH , with the participation of European concerned focal points and competent authorities, is organized in Brussels by the SBB assisted by the national focal point on the 11 and 12 September 2013 (10th anniversary of the coming into force of the Protocol)	

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

One or more	EN

Additional Information

The Biosafety and Biotechnology Unit (SBB) of the Scientific Institute of Public Health regularly publishes or contributes to biosafety-related publications. The full list is available at http;//www.biosafety.be/SBB/SBB_3.html. The DG Environment of the Federal Public Service Health, Food Chain Safety and Environment (which is the national focal point of the Cartagena Protocol) has written a chapter in the book “Ecosystem Services: global Issues, local practices “; this book is a compilation of various Belgian authors working in relation with the ecosystem services concept, to be published soon by Elsevier. The concerned chapter is briefly tackling the notion of ecosystem services in relation with biosafety assessment and socio-economic considerations linked to LMOs, and underlines the opportunities and challenges (and threats) brought by the ecosystem services concept and especially by the economic valuation of ecosystems.	EN

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

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39. 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?

None	EN

Additional Information

The national focal point of the Cartagena Protocol has recently established an unformal contact group with Belgian experts involved in the BEES network (Belgian Economy of Economy Services) that implements in Belgium the TEEB (The Economy of Ecosystems and Biodiversity) international concept – , with a view on reflections and suggestions on indicators and methods for SEC (socio-economic considerations) related to LMOs	EN

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

No	EN

41. If you answered yes to the question above, please indicate what entity is responsible for carrying out the programmes and/or services and at which level the programmes take place.

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

Yes	EN

Additional Information

If official websites may be considered as communication strategy, see answer to question 43 Moreover, the DG Environment of the Federal Public Service Health, Food Chain Safety & Environment (that is the focal point of the Cartagena Protocol) is organizing every 6 months a “Stakeholders dialogue” for information sharing on the evolution of files dealt with by this DG; this involves biosafety, whereas it is not restricted to this. Stakeholders are welcome to take this opportunity to raise questions.	EN

43. Please indicate the number of educational materials on biosafety that are available and accessible to the public.

One or more	EN

Additional Information

The website dedicated to GMOs of the Federal Public Service Health, Food Chain Safety & Environment: www.ogm-ggo.be, and the Belgian Biosafety Server of the SBB: www.biosafety.be.	EN

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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