**FIRST REGULAR NATIONAL REPORT ON THE IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY**

*Origin of report*

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| Party: | Brazil |
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| *Submission* | |
| Signature of officer responsible for submitting report: | |
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| Time period covered by this report: | From february 2006 (entry into force of the Protocol in Brazil) to august 2008. |

Please provide summary information on the process by which this report has been prepared, including information on the types of stakeholders who have been actively involved in its preparation and on material which was used as a basis for the report:

This report has been prepared with the involvement of the eleven Ministries which compose the National Biosafety Council, responsible for the issue of biosafety under the Brazilian legislation.

*Obligations for provision of information to the Biosafety Clearing-House*

1. Several articles of the Protocol require that information be provided to the Biosafety Clearing-House (see the list below). For your Government, if there are cases where relevant information exists but has not been provided to the Biosafety Clearing-House (BCH), describe any obstacles or impediments encountered regarding provision of that information (note: To answer this question, please check the BCH to determine the current status of your country's information submissions relative to the list of required information below. If you do not have access to the BCH, contact the Secretariat for a summary):

The Biosafety Clearing House (BCH) is a key element in ensuring the adequate implementation of the Cartagena Protocol on Biosafety. Brazil is committed to providing all relevant information on its activities involving living modified organisms. Brazil does not currently face technical impediments for the provision of information to the BCH. The need for coordination of information among competent agencies, as well as human resource and language limitations, may contribute to delays in provision of information.

The approval, in March 2005, of new Biosafety Legislation (Law No. 11.105/2005), regulated by Decree 5591/2005, has led to important changes in the national biosafety framework. For the purpose of reformulating information to be provided to the BCH, the Brazilian Ministry of External Relations, as the institution currently charged with the responsibilities of National Focal Point and Competent National Authority, has been coordinating with the technical Government agencies with responsibilities in the area of living modified organisms, such as the Presidential Staff Office, the Ministries of Agriculture; Development Industry and Trade; Environment; Health; and Science and Technology, as well as the National Technical Biosafety Commission (CTNBio). This process is ongoing, as implementation of the new legislation is gradually achieved. Among important steps taken pursuant to the new Biosafety Law are the establishment of a reformulated CTNBio, charged with approving activities related to GMOs, and the implementation of the Information System on Biosafety, which will be an important element for information sharing and for promoting public awareness.

Legal regulations concerning LMOs related to the environment, health and agriculture are in force in Brazil. With respect to the environment, the most relevant regulations are:

**i) Federal Constitution - Articles 196 and 225:**

Article 196. Everyone has the right to health, and health is a duty of the State and shall be guaranteed by social and economic policies aimed at reducing the risk of disease and other hazards and at ensuring universal and equal access to actions and services for its promotion, protection and recovery.

Article 225. Everyone has the right to an ecologically balanced environment, which is an asset for common use and essential to a healthy quality of life, and both the Government and the community have the duty to protect and preserve it for present and future generations.

Paragraph 1 - In order to ensure the effectiveness of this right, it is incumbent upon the Government to:

I – Preserve and restore the essential ecological processes and provide for the ecological treatment of species and ecosystems;

II – Preserve the diversity and integrity of the genetic heritage of the country and to control entities engaged in research and manipulation of genetic material;

III – Define, in all states, territorial spaces and their components to receive special protection. All alterations and suppressions will only be allowed through law, and any use which may harm the integrity of the attributes that justify their protection is forbidden;

IV – Require, in the manner prescribed by law, a prior environmental impact study for the installation of works and activities that may potentially cause significant degradation of the environment. This study shall be made public;

V – Control the production, sale and use of techniques, methods or substances that represent a risk to life, the quality of life and the environment;

VII – Protect fauna and flora, prohibiting, in the manner prescribed by law, all practices which represent a risk to their ecological function, cause the extinction of species or subject animals to cruelty.

ii) Law No 6,938 (08/31/1981), which establishes the National Environment Policy;

iii) Resolutions of the National Environment Council (CONAMA) No 001/86 (01/23/1986), 237/97 (12/19/1997), and 305/02 (07/04/2002), which establish the requirements for environmental licensing of GMOs, including the need for Environmental Impact Studies and the Report of Impacts of Activities and Enterprises on the Environment from Genetically Modified Organisms and their derivatives. These Resolutions have force of law in Brazilian legislation.

iv) Law No 7,802/89 regulates research, experiments, production, packaging, labeling, transport, storage, commercialization, marketing, use, import and export, registration, final destination of waste packaging of pesticides and their components, in the cases where LMOs are used as raw material for a pesticide.

v) Decree No 4,074/02 implements Law No 7,802/89 and states:
Article 1
III – Biological control agent: live organism, occurring naturally or obtained by genetic manipulation, introduced in the environment to control a population or biological activities of other living organisms considered harmful.

vi) Law No 7,802/89 and Decree No 4,074/02 must be complied with when GMOs are used as raw materials for producing pesticides and the like, and they must be submitted to an assessment of agricultural, toxicological and environmental efficiency at Ministry of Agriculture, Ministry of Health and at the Ministry of the Environment;

In cases where CTNBio (National Technical Commission on Biosafety) determines, as provided for in Law No 11,105/05, that the GMO can potentially cause significant damage to the environment, the same environmental requirements will be applied as for commercial and research activities. For field research of agricultural activities, IBAMA Regulatory Instruction No 11, dated December 5, 2003 is also applicable.

vii) Legislative Decree No 908 (10/31/03) approves the text of the Cartagena Protocol on Biosafety.

viii) Law No 11,105/05 implements Article 225 of the Federal Constitution and defines safety

rules and oversight mechanisms for the construction, cultivation, manipulation, transport, transfer, import and export, storage, research, release into the environment of GMOs and their derivatives. These rules must take into account scientific advances, protection of life, of human, animal and plant health, and also observe the precautionary principle for the protection of the environment. This legislation is included in the BCH.

ix) Decree No 5,591/05: implements Law Nr 11,105/05 (above). The activities referred to by the decree must be authorized by the National Technical Commission on Biosafety (CTNBio). The Commission, among other responsibilities, will carry out the risk analysis with respect to activities and projects that involve GMOs. It will issue a technical decision on the biosafety of the GMO and its derivatives, within the scope of research activities and commercial use, including the classification as to the biosafety level required and degree of risk, as well as required safety measures and use restrictions. The decree also defines the competency of the National Biosafety Council, associated to the Presidency of the Republic, which will analyze the requests for commercial use of GMOs and their derivatives with respect to socioeconomic opportunity and convenience and to national interest, and it may take the final decision with respect to the processes related to activities that involve the commercial use of GMOs and their derivatives. This legislation is included in the BCH.

x) Law No 8078/90: defines the mandatory provision of clear and precise information to the end consumer on labeling of products and services that are placed in the market or otherwise made available, reporting on their inherent risk. The Law expressly forbids the supplier to expose the consumer to danger, requiring safety and protection of human health.

xi) Law No 11,105/2005 (03/24/2005) – Biosafety Law and implementing Decree No 5,591/2005; Law No 7,802/89 and Decree No 4,074/02 are applicable to GMO imports for use as raw materials in the production of pesticides and the like.

xii) The Brazilian Consumer Code and Decree No 4,680/03 establish rules that mandate detailed information on GMOs labeling contained in foodstuffs.

xiii) Decree No 5,705 (02/16/2006): promulgates the Cartagena Protocol on Biosafety.
Brazil is advanced in building its National BCH and it is planned to be operative by the end of 2007.

2. Please provide an overview of information that is required to be provided to the Biosafety Clearing-House:

| *Type of information* | *Information exists and is being provided to the Biosafety Clearing-House* | *Information exists but is not yet provided to the Biosafety Clearing-House* | *Information does not exist /not applicable* |
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| 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 20.3(a)) | X | | |

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| b) National laws, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing (Article 11.5); | X | | |
| c) Bilateral, multilateral and regional agreements and arrangements (Articles 14.2, 20.3(b), and 24.1); | | | X |
| d) Contact details for competent national authorities (Articles 19.2 and 19.3), national focal points (Articles 19.1 and 19.3), and emergency contacts (Article 17.2 and 17.3(e)); | X | | |
| e) In cases of multiple competent national authorities, responsibilities for each (Articles 19.2 and 19.3); | | X | |
| f) Reports submitted by the Parties on the operation of the Protocol (Article 20.3(e)); | | | X |
| g) Occurrence of unintentional transboundary movements that are likely to have significant adverse effects on biological diversity (Article 17.1); | | | X |
| *Type of information* | *Information exists and is being provided to the Biosafety Clearing-House* | *Information exists but is not yet provided to the Biosafety Clearing-House* | *Information does not exist /not applicable* |
| h) Illegal transboundary movements of LMOs (Article 25.3); | | | X |
| 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 10.3 and 20.3(d)); | | | X |
| j) Information on the application of domestic regulations to specific imports of LMOs (Article 14.4); | | | X |
| 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 11.1); | X | | |
| 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 11.4) or in accordance with annex III (Article 11.6) (requirement of Article 20.3(d)) | | X | |

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| m) Declarations regarding the framework to be used for LMOs intended for direct use as food or feed, or for processing (Article 11.6) | X | | |
| n) Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12.1); | | | X |
| o) LMOs granted exemption status by each Party (Article 13.1) | | | X |
| p) Cases where intentional transboundary movement may take place at the same time as the movement is notified to the Party of import (Article 13.1); | | | X |
| q) Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and relevant information regarding products thereof (Article 20.3(c)). | X | | |

*Article 2 – General provisions*

| 3. Has your country introduced the necessary legal, administrative and other measures for implementation of the Protocol? (Article 2.1) | |
|---|---|
| a) full domestic regulatory framework in place (please give details below) | |
| b) some measures introduced (please give details below) | X |
| c) no measures yet taken | |
| 4. Please provide further details about your response to the above question, as well as description of your country's experiences and progress in implementing Article 2, including any obstacles or impediments encountered: | |
| The National Congress published Legislative Decree No. 908, on October 31, 2003, approving the text of the Cartagena Protocol on Biosafety. An Executive Decree promulgating the Protocol – the final stage in internalizing the Protocol – was published on February 16, 2006. The new National Biosafety Law (Law 11,105/2005) establishes norms and mechanisms for oversight of activities with GMOs, having as guidelines the promotion of scientific advancement in the area of biosafety and biotechnology, the protection of human, animal and plant life and health, and the observance of the precautionary principle in the protection of the environment. Decree 5,591/2005 contains complementary regulations related to the implementation of the new Biosafety Law, including the functioning of the National Technical Biosafety Commission (CTNBio). Other regulations for implementing the Protocol are yet to be implemented. The Ministry of External Relations has been designated as the National Focal Point and, temporarily, as Competent National Authority for the Protocol. | |

*Articles 7 to 10 and 12: The advance informed agreement procedure*

See question 1 regarding provision of information to the Biosafety Clearing-House.

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| 5. Were you a Party of import during this reporting period? | |
| a) yes | |
| b) no | X |
| 6. Were you a Party of export during this reporting period? | |
| a) yes | |
| b) no | X |
| 7. Is there a legal requirement for the accuracy of information provided by exporters 1/ under the jurisdiction of your country? (Article 8.2) | |
| a) yes | |
| b) not yet, but under development | |
| c) no | |
| d) not applicable – not a Party of export | X |
| 8. If you were a Party of export during this reporting period, did you request any Party of import to review a decision it had made under Article 10 on the grounds specified in Article 12.2? | |
| a) yes (please give details below) | |
| b) not yet, but under development | |
| c) no | |
| d) not applicable – not a Party of export | X |
| 9. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 9.2(c). | |
| a) yes | X |
| b) no | |
| c) not applicable – no decisions taken during the reporting period | |
| 10. If your country has been a Party of export of LMOs intended for release into the environment during the reporting period, please describe your experiences and progress in implementing Articles 7 to 10 and 12, including any obstacles or impediments encountered: | |
| Brazil did not export LMOs destined for intentional introduction into the environment during the period covered by this report. | |
| 11. If your country has taken decisions on import of LMOs intended for release into the environment during the reporting period, please describe your experiences and progress in implementing Articles 7 to 10 and 12, including any obstacles or impediments encountered: | |
| Brazil imported research material (Bollgard cotton – event 531), in accordance with national legislation, during the reporting period. At a later stage, and in accordance with national law, the product of the research was authorized to be released into the environment. | |

1/ The use of terms in the questions follows the meanings accorded to them under Article 3 of the Protocol.

*Article 11 – Procedure for living modified organisms intended for direct use as food or feed, or for processing*

See question 1 regarding provision of information to the Biosafety Clearing-House.

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| 12. Is there a legal requirement for the accuracy of information provided by the applicant with respect to the domestic use of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing? (Article 11.2) | |
| a) yes | X |
| b) not yet, but under development | |
| c) no | |
| d) not applicable (please give details below) | |
| 13. Has your country indicated its needs for financial and technical assistance and capacity-building in respect of living modified organisms intended for direct use as food or feed, or for processing? (Article 11.9) | |
| a) yes (please give details below) | |
| b) no | X |
| c) not relevant | |
| 14. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 11.4? | |
| a) yes | X |
| b) no | |
| c) not applicable – no decisions taken during the reporting period | |

15. If your country has been a Party of export of LMOs intended for direct use for food or feed, or for processing, during the reporting period, please describe your experiences and progress in implementing Article 11, including any obstacles or impediments encountered:

Brazil has notified through the BCH its final decision to produce genetically modified soybeans derived from the transformation event GTS 40-3-2.

16. If your country has been a Party of import of LMOs intended for direct use for food or feed, or for processing, during the reporting period, please describe your experiences and progress in implementing Article 11, including any obstacles or impediments encountered:

Brazil has imported genetically modified soybeans resistant to gliphosate and five events of genetically modified maize for use as feed, in line with its domestic regulations. In 2005, after a favorable ruling by the National Technical Biosafety Commission (CTNBio), Brazil authorized the importation of 400 thousand tonnes of genetically modified corn from Argentina containing the genes CrylAb, CrylAc, pat and bar, for use exclusively as animal feed. This authorization was based upon the national regulatory framework, as envisaged in Article 11.4 of the Protocol. The importation and utilization of said product are being monitored by the competent Government oversight agencies. By decision of the National Biosafety Council (CNBS), the genetic modification event NK 603 was excluded from the aforementioned import authorization.

*Article 13 – Simplified procedure*

See question 1 regarding provision of information to the Biosafety Clearing-House.

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| 17. Have you applied the simplified procedure during the reporting period? | |
| a) yes | |
| b) no | X |
| 18. If your country has used the simplified procedure during the reporting period, or if you have been unable to do so for some reason, please describe your experiences in implementing Article 13, including any obstacles or impediments encountered: | |
| Brazil has not adopted the simplified procedure envisaged in Article 13. | |

*Article 14 – Bilateral, regional and multilateral agreements and arrangements*

See question 1 regarding provision of information to the Biosafety Clearing-House.

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| 19. Has your country entered into any bilateral, regional or multilateral agreements or arrangements? | |
| a) yes | |
| b) no | X |
| 20. If your country has entered into bilateral, regional or multilateral agreements or arrangements, or if you have been unable to do so for some reason, describe your experiences in implementing Article 14 during the reporting period, including any obstacles or impediments encountered: | |
| Not applicable | |

*Articles 15 and 16 – Risk assessment and risk management*

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| 21. If you were a Party of import during this reporting period, were risk assessments carried out for all decisions taken under Article 10? (Article 15.2) | |
| a) yes | X |
| b) no (please clarify below) | |
| c) not a Party of import / no decisions taken under Article 10 | |
| 22. If yes to question 21, did you require the exporter to carry out the risk assessment? | |
| a) yes – in all cases | |
| b) yes – in some cases (please specify the number and give further details below) | |
| c) no | X |
| d) not a Party of import / no decisions taken under Article 10 | |
| 23. If you took a decision under Article 10 during the reporting period, did you require the notifier to bear the cost of the risk assessment? (Article 15.3) | |
| a) yes – in all cases | |
| b) yes – in some cases (please specify the number and give further details | |

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| below) | |
| c) no | X |
| d) not a Party of import / no decisions taken under Article 10 | |
| 24. Has your country established and maintained appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol? (Article 16.1) | |
| a) yes – fully established | X |
| b) not yet, but under development or partially established (please give further details below) | |
| c) no | |
| 25. Has your country adopted appropriate measures to prevent unintentional transboundary movements of living modified organisms? (Article 16.3) | |
| a) yes – fully adopted | X |
| b) not yet, but under development or partially adopted (please give further details below) | |
| c) no | |
| 26. Does your country endeavour to ensure that any living modified organism, whether imported or locally developed, undergoes an appropriate period of observation commensurate with its life-cycle or generation time before it is put to its intended use? (Article 16.4) | |
| a) yes – in all cases | X |
| b) yes – in some cases (please give further details below) | |
| c) no (please give further details below) | |
| d) not applicable (please give further details below) | |
| 27. Has your country cooperated with others for the purposes specified in Article 16.5? | |
| a) yes (please give further details below) | |
| b) no (please give further details below) | X |
| 28. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Articles 15 and 16, including any obstacles or impediments encountered: | |
| In accordance with Brazilian Biosafety Law (Law 11,105/2005), for all activities involving genetically modified organisms (GMOs), including those related to import and export, a prior risk analysis must be carried out by the National Technical Biosafety Commission (CTNBio), on a case by case basis, which may determine risk management measures for the activity involving GMOs or for its proposed use. In the case of the import of genetically modified corn from Argentina in 2005, destined for use exclusively as animal feed, the internment, transport and processing of the product was monitored by Federal Government oversight agencies.<br><br>The process of risk assessment has been receiving special attention from the Brazilian Government, due to its complexity. To fulfill the requirements established by the Cartagena | |

Protocol on Biosafety, Brazil has taken efforts to improve its capacity to conduct risk assessments, within the framework of the Brazilian Biosafety Law. The CTNBio has emitted technical opinion favorable to the import of genetically modified corn for the specific use as feed, taking into account risk assessments made by other Parties and countries that are not Parties to the Protocol. Nevertheless, in case of LMO for intentional introduction into the environment, Brazil is aware of the need to consider assessments which shall focus on the interactions with Brazilian ecosystems.

*Article 17 – Unintentional transboundary movements and emergency measures*

See question 1 regarding provision of information to the Biosafety Clearing-House.

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| 29. During the reporting period, if there were any occurrences under your jurisdiction that led, or could have led, to an unintentional transboundary movement of a living modified organism that had, or could have had, significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States, did you immediately consult the affected or potentially affected States for the purposes specified in Article 17.4? | |
| a) yes – all relevant States immediately | |
| b) yes – partially consulted, or consultations were delayed (please clarify below) | |
| c) no – did not consult immediately (please clarify below) | |
| d) not applicable (no such occurrences) | X |
| 30. Please provide further details about your response to the above question, as well as description of your country's experiences in implementing Article 17, including any obstacles or impediments encountered: | |
| There were no such occurrences during the reporting period. | |

*Article 18 – Handling, transport, packaging and identification*

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| 31. Has your country taken measures to require that living modified organisms that are subject to transboundary movement within the scope of the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards? (Article 18.1) | |
| a) yes (please give details below) | X |
| b) not yet, but under development | |
| c) no | |
| d) not applicable (please clarify below) | |
| 32. Has your country taken measures to require that documentation accompanying living modified organisms for direct use as food or feed, or for processing, clearly identifies that they 'may contain' living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for information? (Article 18.2(a)) | |
| a) yes | |
| b) not yet, but under development | X |
| c) no | |

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| 33. Has your country taken measures to require that documentation accompanying living modified organisms 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 living modified organisms are consigned? (Article 18.2(b)) | |
| a) yes | |
| b) not yet, but under development | X |
| c) no | |
| 34. Has your country adopted measures to require that documentation accompanying living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, 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? (Article 18.2(c)) | |
| a) yes | |
| b) not yet, but under development | X |
| c) no | |
| 35. Please provide further details about your responses to the above questions, as well as a description of your country's experiences and progress in implementing Article 18, including any obstacles or impediments encountered: | |
| Regulations for implementing the requirements of Article 18 are currently under development. The import of micro-organisms remains under consideration by the Government of Brazil, in order to identify adequate measures to fully implement Article 18.1. | |

*Article 19 – Competent national authorities and national focal points*

See question 1 regarding provision of information to the Biosafety Clearing-House.

*Article 20 – Information-sharing and the Biosafety Clearing-House*

See question 1 regarding provision of information to the Biosafety Clearing-House.

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| 36. In addition to the response to question 1, please describe any further details regarding your country's experiences and progress in implementing Article 20, including any obstacles or impediments encountered: | |
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*Article 21 – Confidential information*

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| 37. Does your country have procedures to protect confidential information received under the Protocol and that protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms? (Article 21.3) | |
| a) yes | X |
| b) not yet, but under development | |

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| c) no | |
| 38. If you were a Party of import during this reporting period, did you permit any notifier to identify information submitted under the procedures of the Protocol or required by the Party of import as part of the advance informed agreement procedure that was to be treated as confidential? (Article 21.1) | |
| a) yes | X |
| If yes, please give number of cases | |
| b) no | |
| c) not applicable – not a Party of import / no such requests received | |
| 39. If you answered yes to the previous question, please provide information on your experience including description of any impediments or difficulties encountered: | |
| | |
| 40. If you were a Party of export during this reporting period, please describe any impediments or difficulties encountered by you, or by exporters under your jurisdiction if information is available, in the implementation of the requirements of Article 21: | |
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*Article 22 – Capacity-building*

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| 41. If a developed country Party, during this reporting period has your country cooperated in the development and/or strengthening of human resources and institutional capacities in biosafety for the purposes of the effective implementation of the Protocol in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition? | |
| a) yes (please give details below) | |
| b) no | |
| c) not applicable – not a developed country Party | X |
| 42. If yes to question 41, how has such cooperation taken place: | |
| | |
| 43. If a developing country Party, or Party with an economy in transition, during this reporting period has your country contributed to the development and/or strengthening of human resources and institutional capacities in biosafety for the purposes of the effective implementation of the Protocol in another developing country Party or Party with an economy in transition? | |
| a) yes (please give details below) | |
| b) no | X |
| c) not applicable – not a developing country Party | |
| 44. If yes to question 43, how has such cooperation taken place: | |
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| 45. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training in the proper and safe management of biotechnology to the extent that it is required for biosafety? | |

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| a) yes – capacity-building needs fully met (please give details below) | |
| b) yes – capacity-building needs partially met (please give details below) | X |
| c) no – capacity-building needs remain unmet (please give details below) | |
| d) no – we have no unmet capacity-building needs in this area | |
| e) not applicable – not a developing country Party or a Party with an economy in transition | |
| 46. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training in the use of risk assessment and risk management for biosafety? | |
| a) yes – capacity-building needs fully met (please give details below) | |
| b) yes – capacity-building needs partially met (please give details below) | X |
| c) no – capacity-building needs remain unmet (please give details below) | |
| d) no – we have no unmet capacity-building needs in this area | |
| e) not applicable – not a developing country Party or a Party with an economy in transition | |
| 47. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training for enhancement of technological and institutional capacities in biosafety? | |
| a) yes – capacity-building needs fully met (please give details below) | |
| b) yes – capacity-building needs partially met (please give details below) | X |
| c) no – capacity-building needs remain unmet (please give details below) | |
| d) no – we have no unmet capacity-building needs in this area | |
| e) not applicable – not a developing country Party or a Party with an economy in transition | |
| 48. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 22, including any obstacles or impediments encountered: | |
| Brazil has benefited from some capacity-building initiatives. Brazil participates in the UNEP-GEF "Biosafety Clearing-House" (BCH) Project, coordinated by the Ministry of Science and Technology, which aims at enabiling Parties to develop their national biosafety clearing-house, as well as build the capacity of relevant stakeholders in the use of the Central BCH Portal. Brazil also participates in the GEF Project "Multi-country Capacity-building for Compliance with the Cartagena Protocol on Biosafety" (Brazil, Colombia, Costa Rica and Peru).<br><br>Brazil, as a member of the International Center for Genetic Engineering and Biotechnology (ICGEB), through the Ministry of Science and Technology, has participated in training activities on GMO risk assessment provided by that Center. It is worth noting, however, that there are few organized courses offered. Participation from different countries is limited but to a few individuals. The need for capacity-building therefore remains, particularly for analysts and | |

enforcement agents.

Internally, the Ministry of the Environment has held three capacity-building courses in GMO biosafety. These courses aimed to train analysts and inspectors involved in licensing and inspection of GMOs and their derivatives. They took place in the states of Paraná, Santa Catarina and Mato Grosso do Sul. Experts in various areas from universities and government agencies were invited to lecture at these courses. The Brazilian Agricultural Research Corporation (EMBRAPA) has also promoted courses on the ecological impact of genetically modified organisms and on risk assessment for these organisms. The Santa Catarina Federal University (Florianópolis/SC) has a one year graduate course on biosafety. Fiocruz, a Governmental Health Institute, also offers courses on biosafety.

For a megadiverse country such as Brazil, a very important gap remains in the area of capacity-building in risk analysis. On the one hand, environmental impact studies are few and have generally been produced in temperate climate countries. There is little experience and scientific results in tropical countries, such as Brazil, on risk analysis and management relating to LMOs.

*Article 23 – Public awareness and participation*

| | |
|---|---|
| 49. Does your country promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health? (Article 23.1(a)) | |
| a) yes – significant extent | |
| b) yes – limited extent | X |
| c) no | |
| 50. If yes, do you cooperate with other States and international bodies? | |
| a) yes – significant extent | |
| b) yes – limited extent | |
| c) no | X |
| 51. Does your country endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with the Protocol that may be imported? (Article 23.1(b)) | |
| a) yes – fully | |
| b) yes – limited extent | X |
| c) no | |
| 52. Does your country, in accordance with its respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and make the results of such decisions available to the public? (Article 23.2) | |
| a) yes – fully | |
| b) yes – limited extent | X |
| c) no | |

| 53. Has your country informed its public about the means of public access to the Biosafety Clearing-House? (Article 23.3) | |
|---|---|
| a) yes – fully | |
| b) yes – limited extent | X |
| c) no | |

54. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 23, including any obstacles or impediments encountered:

The Brazilian Constitution establishes the principle of publicity that mandates public officials to work under transparency rules. Moreover, Federal Law No. 10,650/2003 mandates public officials, on request by a consumer, to supply information on documents, proceedings and records in its custody that involve environmental quality, environmental impacts and other issues, such as biosafety and GMOs. Also, since 1997, several events related to GMOs have been held in Brazil with participation from various stakeholders, in response to public concerns about biotechnology products. These events helped to increase public awareness. However, despite the level of perception and awareness, further participation by civil society in the decision-making process needs to be promoted, especially through the new Biosafety Law (Law No. 11,105/2005), which provides for:

- The establishment, within the Ministry of Science and Technology, of the Information System on Biosafety (SIB), in order to manage information resulting from the analysis, authorization, registration and monitoring of activities involving GMOs and products derived therefrom (art. 19);

- Mandatory adoption of means necessary to fully inform the National Technical Biosafety Commission (CTNBio), health, environmental and plant and animal health authorities, the general population and other workers in an institution or company on the risks which they may be subjected to, as well as the procedures to be adopted in case of accidents with LMOs (art. 7.III);

- Ample publicity of CTNBio acts through the Information System on Biosafety (SIB) (art. 14.XIX);

- The holding of public hearings by CTNBio, with the participation of civil society. In cases of commercial release, the public hearing may be requested by interested parties, including civil society organizations with a proven interest on the matter (art. 15);

- Publication, including in the SIB, of registrations and authorizations given by registration and oversight agencies (art.16.V);

- The creation of an Internal Biosafety Commission (CIBio) by any institution utilizing techniques and methods of genetic engineering or conducting research with GMOs and products derived from GMOs to, among others, maintain workers and the population as a whole duly informed as to questions related to health and safety, as well as to procedures in case of accident, when they may be affected by a given activity (art. 18.I).

Brazilian Government websites, such as those for the Ministry of the Environment (www.mma.gov.br) and the Ministry of Science and Technology (www.mct.gov.br) contain links to the BCH. The future SIB will also be developed with a view to greater inter-operability

with the BCH.

Brazil is also finalizing the "Brazilian BCH Portal", which is due to be launched until the end of this year (2008). The "Brazilian BCH Portal" will be an important tool in promoting public awareness on activities related to the implementation of the Cartagena Protocol on Biosafety.

*Article 24 – Non-Parties*

See question 1 regarding provision of information to the Biosafety Clearing-House**.**

| 55. Have there been any transboundary movements of living modified organisms between your country and a non-Party during the reporting period? | |
|---|---|
| a) yes | X |
| b) no | |

56. If there have been transboundary movements of living modified organisms between your country and a non-Party, please provide information on your experience, including description of any impediments or difficulties encountered:

Brazil has imported genetically modified maize from Argentina for use as feed. The importation was authorized based on national legislation – i.e. a favorable technical decision on biosafety by the National Technical Biosafety Commission (CTNBio). The Ministry of Agriculture, Livestock and Supply (MAPA) and by the Brazilian Institute for the Environment and Renewable Natural Resources (IBAMA), an agency linked to the Ministry of the Environment, are involved in the monitoring of these imports.

*Article 25 – Illegal transboundary movements*

See question 1 regarding provision of information to the Biosafety Clearing-House.

| 57. Has your country adopted appropriate domestic measures to prevent and penalize, as appropriate, transboundary movements of living modified organisms carried out in contravention of its domestic measures? (Article 25.1) | |
|---|---|
| a) yes | X |
| b) no | |
| 58. Have there been any illegal transboundary movements of living modified organisms into your country during the reporting period? | |
| a) yes | |
| b) no | X |

59. Please provide further details about your response to the above question, as well as description of your country's experiences in implementing Article 25, including any obstacles or impediments encountered:

Law 11,105/2005 (Biosafety Law) establishes that all activities related to GMOs, including those related to import and export, must be submitted to prior risk analysis by the National Technical Biosafety Commission (CTNBio). Violation of this stipulation exposes violators to penalties and administrative sanctions established in the Law. Nonetheless, in light of its extensive land border with other countries, Brazil may still eventually register occurrences of cultivation of GMOs

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| authorized in other countries, but not authorized in its territory. Those occurrences are investigated by competent Government oversight agencies. |

*Article 26 – Socio-economic considerations*

| 60. If during this reporting period your country has taken a decision on import, did it take into account socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities? (Article 26.1) | |
|---|---|
| a) yes – significant extent | |
| b) yes – limited extent | |
| c) no | X |
| d) not a Party of import | |

| 61. Has your country cooperated with other Parties on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities? (Article 26.2) | |
|---|---|
| a) yes – significant extent | |
| b) yes – limited extent | |
| c) no | X |

| 62. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 26, including any obstacles or impediments encountered: |
|---|
| In analyzing the request for importation of corn containing the genetic transformation events derived from the genes CrylAb, Cryl Ac, pat/bar, for example, the National Technical Biosafety Commission (CTNBio) took into account, among other arguments, the shortage of corn in the Northeastern region of the country, which compromised the activity of numerous poultry producers.<br><br>The approval of the new Biosafety Law has led to the creation of the National Biosafety Council (CNBS), composed of 11 Cabinet Ministers, which will be responsible for analyzing the convenience and opportunity of releasing GMOs for commercial purposes, taking into account, among others, socio-economic considerations. This will contribute to strengthening of rules, strategies and guidelines for assessing socioeconomic impacts of LMOs in the decision making process. |

*Article 28 – Financial mechanism and resources*

| 63. Please indicate if, during the reporting period, your Government made financial resources available to other Parties or received financial resources from other Parties or financial institutions, for the purposes of implementation of the Protocol. | |
|---|---|
| a) yes – made financial resources available to other Parties | |
| b) yes – received financial resources from other Parties or financial institutions | X |
| c) both | |
| d) neither | |

| 64. Please provide further details about your response to the above question, as well as description of your country's experiences, including any obstacles or impediments encountered: |
| --- |
| Brazil has received funding from the GEF, under the UNEP-GEF "BCH Project", in order to set up the national BCH. Brazil also participates in the GEF Project "Multi-country Capacity-building for Compliance with the Cartagena Protocol on Biosafety" (Brazil, Colombia, Costa Rica and Peru). |

*Other information*

| 65. Please use this box to provide any other information related to articles of the Protocol, questions in the reporting format, or other issues related to national implementation of the Protocol: |
| --- |
| |

*Comments on reporting format*

The wording of these questions is based on the Articles of the Protocol. Please provide information on any difficulties that you have encountered in interpreting the wording of these questions:

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