

*Origin of report*

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Submission	
Signature of officer responsible for submitting report:	
Date of submission:	19 September 2005

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:

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### *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 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):

- (a) The Law on the Biosafety of Genetically Modified Organisms Law must be translated. The entry into effect of the Law changes the procedure for prior informed consent.
- (b) The trilateral arrangement was signed in October 2003 and is valid for two years from the date of signature, with the potential to remain in effect beyond that date with the consent of all parties. This arrangement was signed by the Agriculture authorities of Canada, the United States of America and Mexico.
- (e) The responsibilities of each competent authority are set out in Articles 10 through 18 of the Biosafety Law, since, as they currently appear as is in the BCH, they are not specifically assigned to each authority due to the portal's layout.

Information required to be provided to the Biosafety Clearing-House:

- (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))
- (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);
- (c) Bilateral, multilateral and regional agreements and arrangements (Articles 14.2, 20.3(b), and 24.1);
- (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));
- (e) In cases of multiple competent national authorities, responsibilities for each (Articles 19.2 and 19.3);
- (f) Reports submitted by the Parties on the operation of the Protocol (Article 20.3(e));

- (g) Occurrence of unintentional transboundary movements that are likely to have significant adverse effects on biological diversity (Article 17.1);
- (h) Illegal transboundary movements of LMOs (Article 25.3);
- (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));
- (j) Information on the application of domestic regulations to specific imports of LMOs (Article 14.4);
- (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);
- (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))
- (m) Declarations regarding the framework to be used for LMOs intended for direct use as food or feed, or for processing (Article 11.6)
- (n) Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12.1);
- (o) LMOs granted exemption status by each Party (Article 13.1)
- (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); and
- (q) Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and relevant information regarding products thereof (Article 20.3(c)).

**Article 2 – General provisions**

2. 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	
3. 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:	
<p>In our country, the Law on the Biosafety of Genetically Modified Organisms was proclaimed on 18 March 2005, and went into effect on 4 May 2005. However, the Regulation and various Official Mexican Standards are required for full implementation of the Law.</p> <p>Several factors contribute to the complex situation in our country, which is megadiverse and a center of origin and genetic diversity for over 100 commercially significant species worldwide. Our country is furthermore culturally diverse and territorially vast, and opinions on this issue are polarized.</p>	

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

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

4. Is there a legal requirement for the accuracy of information provided by exporters <u>1/</u> under the jurisdiction of your country? (Article 8.2)	
a) yes In accordance with the Customs Law in effect, a customs document must be filled out by a customs officer for both imports and exports, and the authority has the power to check the truth of what is declared in said document.	x

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

There are also the provisions of the Biosafety Law, in its clauses regarding imports, and NOM-056-FITO-1995.	
b) no	
c) not applicable – not a Party of export	
5. 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) no Even though the Biosafety Law has gone into effect, and the text of that Law stipulates a licensing system for transboundary movements of GMOs, the work of establishing regulations for the Law has not been completed, and it has not yet been harmonized with the legal framework in effect in other areas, such as foreign trade. Therefore, although a decision on future procedures does exist, the procedures are not applicable right now, since they must be integrated into national legislation in order to be mandatory.	X
c) not applicable – not a Party of export	
6. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 9.2(c).	
a) yes	
b) no	X
c) not applicable – no decisions taken during the reporting period	
7. 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:	
We do not have any information on this.	
8. 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:	
According to national legislation.	

***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.

9. 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 As mentioned above, the movement of international trade in our country is subject to	X

a declaration of goods by the importer, and the customs authority has the power to check the truth of what has been declared by the customs officer. Article 92 of the Law on the Biosafety of Genetically Modified Organisms sets out the guidelines, criteria, characteristics and requirements for authorizing these types of organisms, which shall be determined by Official Mexican Standards	
b) no	
c) not applicable (please give details below)	
10. 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	
11. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 11.4?	
a) yes The authorization system set out in the Biosafety Law would also apply to this case. However, the authorization system will not be mandatory until the regulations have been established and the Law has been harmonized with the national legal framework for international trade.	X
b) no	
c) not applicable – no decisions taken during the reporting period	
12. 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:	
Mexico is not a Party of export.	
13. 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:	
Under the General Health Law, permits for LMOs are issued following the risk assessment. The developers must submit documentation supporting the innocuousness of the LMOs. Recently, developers have been reluctant to provide information on methods of analysis for the development of a monitoring and watch system.	

***Article 13 – Simplified procedure***

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

14. If your country has used the simplified procedure during the reporting period, please describe your experiences in implementing Article 13, including any obstacles or impediments encountered:
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It has not been used.
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***Article 14 – Bilateral, regional and multilateral agreements and arrangements***

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

15. If your country has entered into bilateral, regional or multilateral agreements or arrangements, describe your experiences in implementing Article 14 during the reporting period, including any obstacles or impediments encountered:
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No information available.
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**Articles 15 and 16 – Risk assessment and risk management**

16. 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 – Please see commentary under Question 23
b) no (please clarify below)	
c) not a Party of import	
17. If yes, 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 – Please see commentary under Question 56
d) not a Party of import	
18. 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 below)	
c) no	X – Please see commentary under Question 56
19. 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	X – Please see commentary under Question 56
b) no	
20. Has your country adopted appropriate measures to prevent unintentional transboundary movements of living modified organisms? (Article 16.3)	
a) yes	
b) no	X – Please see commentary under Question 56

21. 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)	
22. 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
23. 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:	
<p>One of the more decisive obstacles is the lack of information to conduct the best possible risk assessments and analyses; since the interested parties are not always willing to provide all of the information.</p> <p>In answer to Question 16(a):</p> <p>Risk assessments prior to the Biosafety Law (BL) were conducted according to the provisions of NOM 056-FITO 1995. The published text of the Biosafety Law (DOF 18 March 2005) stipulates that imports of GMOs are subject to the phytosanitary or aquatic regime established in the corresponding legislation. However, the BL (Federal Law that deals specifically with biosafety) determines that, for imports, the importer must provide the following annexes to his application:</p> <ul style="list-style-type: none"> <li>• A characterization of the GMO, taking into consideration the stipulations of the Official Mexican Standards derived from the Law in each case.</li> <li>• An identification of the area where the GMO is intended to be released experimentally, including the specific surface area over which the release will take place;</li> <li>• A study of the possible risks that the release of the GMOs could represent for the environment and biological diversity.</li> </ul> <p>For cases that fall under the jurisdiction of SEMARNAT (Ministry of the Environment and Natural Resources), it has the following powers with respect to activities involving all GMOs, except for those that fall under the authority of SAGARPA (Ministry of Agriculture, Livestock Raising, Rural Development, Fisheries and Food):</p> <ol style="list-style-type: none"> <li>I. To participate in the drafting and implementation of the general biosafety policy;</li> <li>II. To analyze and evaluate, on a case-by-case basis, the possible risks that activities involving GMOs could create for the environment and biological diversity, based on the risk analyses and reports on findings drafted and submitted by the interested parties, as set out in the present Law;</li> <li>III. To decide on and issue permits for activities to release GMOs into the environment, and to establish and follow up on the conditions and measures to which such activities should be subject, in accordance with the provisions of the present order, including the release of GMOs for bioremediation.</li> <li>IV. To monitor the potential effects of the permitted or accidental release of GMOs on the environment and biological diversity, according to the provisions of the present Law and the Official Mexican Standards arising therefrom.</li> <li>V. To participate in the drafting and issuing of the lists referred to in this Law.</li> </ol>	

VI. To suspend the effects of permits, based on scientific and technical information from which it can be deduced that the permitted activity implies greater risks than foreseen, and could have a potentially negative effect on the environment, biological diversity, human health, or animal, plant or aquatic health. In the last two cases, suspension is at the request of SAGARPA or SSA, according to their authority under the present Law, based on technical and scientific elements.

VII. Order and apply the relevant safety or emergency measures, based on scientific and technical information and the precautionary approach, according to the terms of the present Law.

VIII. To inspect and watch over compliance with the present Law, its regulations and the Official Mexican Standards arising therefrom.

IX. To impose administrative sanctions on those who violate the precepts of the present Law, its regulations and derived Official Mexican Standards, without prejudice, as the case may be, to the corresponding sentences in the event that their acts or omissions constituting infractions of the present order also constitute crimes, nor to the civil and environmental liability that could result, and

X. To exercise all other powers attributed by the present Law (Article 11, LBGMOs)

SAGARPA has the authority to exercise the powers attributed by the present Law in the following cases of activities involving GMOs:

I. Plants that are considered to be agricultural species, including seeds, and any other organism or product considered within the scope of application of the Federal Phytosanitary Law, except for the wild and forest species regulated by the Wildlife Law and the Sustainable Forest Development Law, respectively, and those covered by a protection regime under Official Mexican Standards arising from those laws;

II. Animals that are considered to be livestock species, and any other type of animal included within the scope of application of the Federal Law on Animal Health, except for wild species regulated by the Wildlife Law and those covered by a protection regime under Official Mexican Standards arising from those laws;

III. Phytozoosanitary and animal and plant feed inputs;

IV. Fish and aquatic species, except for those covered by a protection regime under Official Mexican Standards;

V. GMOs used for immunization purposes to protect and avoid the dissemination of animal diseases;

VI. GMOs that are fungus, bacteria, protozoa, viruses, viroids, espiroplasm, phytoplasm and other microorganisms that are used for agricultural, fishing, aquatic or phytosanitary production purposes, and;

VII. The other organisms and products determined by the regulation of the present Law (Article 12, LBGMOs)

In the cases set out in the article above, it falls to SAGARPA to exercise the following powers:

I. To participate in the drafting and implementation of the general biosafety policy;

II. To analyze and evaluate, on a case-by-case basis, the possible risks that activities involving GMOs could create for animal, plant and aquatic health, as well as for the environment and biological diversity, based on the risk analyses and reports on findings drafted and submitted by the interested parties, as set out in the present Law;

III. To decide on and issue permits to carry out activities involving GMOs, and to establish and follow up on the conditions and measures to which such activities should be subject, in accordance with the provisions of the present order;

IV. To monitor the potential effects of the permitted or accidental release of GMOs on animal, plant and aquatic health, and on the environment and biological diversity, according to the provisions of the present Law and the Official Mexican Standards arising therefrom.

V. To participate in the drafting and issuing of the lists referred to in this Law.

VI. To suspend the effects of permits, based on newly arising scientific and technical information from which it can be deduced that the permitted activity implies greater risks than foreseen, which could have a potentially negative effect on animal, plant or aquatic health, biological diversity, or human health. In the last two cases, suspension is at the request of SEMARNAT or SSA, according to their authority under the present Law, based on technical and scientific elements.

VII. Order and apply the relevant safety or emergency measures, based on scientific and technical information and the precautionary approach, according to the terms of the present Law.

VIII. To inspect and watch over compliance with the present Law, its regulations and the Official Mexican Standards arising therefrom.

IX. To impose administrative sanctions on those who violate the precepts of the present Law, its regulations and derived Official Mexican Standards, without prejudice, as the case may be, to the corresponding sentences in the event that their acts or omissions constituting infractions of the present order also constitute crimes, nor to the civil and environmental liability that could result, and

X. To exercise all other powers attributed by the present Law (Article 13, LBGMOs)

In cases where SEMARNAT is informed of and asked to process and decide upon a permit application involving wild and forest species, it must send the file in question to SAGARPA so that it may issue the appropriate decision (Article 14, LBGMOs).

In cases that are under SAGARPA's authority, SEMARNAT shall do the following:

I. Issue the appropriate biosafety ruling, before SAGARPA makes its decision, as a result of its analysis and risk assessment based on the study drafted and presented by the interested parties, on the possible risks that the activity involving GMOs could cause for the environment and biological diversity, in cases where the permit applications are for the release of said organisms, or based on the reports of findings and the information that the interested parties annex to their permit applications for release as part of a pilot program, and for commercial release;

II. Require SAGARPA to suspend the effects of permits issued by that Ministry, based on scientific and technical information from which it can be deduced that the permitted activity implies greater risks than foreseen, which could have a potentially negative effect on the environment and biological diversity, and

III. Exercise the powers established in subparagraphs I, II, III, V, VII and VIII of article 11 of this Law.

The biosafety ruling referred to in subparagraph I of the present article shall be binding, prior to the granting of the permits to be issued by SAGARPA, and shall be handed down according to the terms of article 66 of the present Law (Article 15, LBGMOs).

### ***Article 17 – Unintentional transboundary movements and emergency measures***

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

24. 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) partially (please clarify below)

c) no (please clarify below)

X

25. 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:

During the reporting period, Mexico lacked the capacity to monitor shipments of grain that might contain GMOs. An alarm was sounded to this effect when, apparently, seeds from a shipment containing LMOs were possibly planted in Oaxaca.

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

26. 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)	
b) no	X
c) not applicable (please clarify below)	
27. 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	X
b) no	
28. 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) no	X
29. 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) no	X
30. 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 18, including any obstacles or impediments encountered:	
<p>Due to lack of capacity, the Ministry of Health has not developed experience. Some of the obstacles to implementing Article 18 arise from the lack of consensus among certain areas of the Federal Government.</p> <p>With the Protocol’s entry into effect in Mexico, the country must demand that all grain imports for food or feed, or for processing, including from countries that are non-parties to the Protocol, such as Canada or the United States, carry the label “may contain” LMOs in cases where shipments may include transgenic products or their derivatives.</p> <p>Given the importance of the grain trade for the North American region, as well as the significance of this issue in the context of the North American Free Trade Agreement, the agricultural authorities of all three countries, Mexico, Canada and the United States of America (SAGARPA, Agriculture and Agri-food</p>	

Canada and USDA) have reached an agreement on the documentation that must accompany living modified organisms for direct use as food or feed, or for processing. Specifically, the objective of this agreement is to clarify the requirements of the documentation required under Article 18.2 A of the Protocol itself, without interrupting the grain trade between these three countries unnecessarily.

As a Party to the Protocol, Mexico negotiated the agreement in accordance with Articles 14 and 24 thereof. Article 14 stipulates that Parties to the Protocol may enter into regional agreements regarding intentional transboundary movements of living modified organisms, and Article 24 allows transboundary movements of living modified organisms between Parties and non-Parties of the Protocol. It is worth mentioning that the only condition for these agreements, and for the transboundary movements themselves, is that they be consistent with the objective of the Protocol.

By virtue of this agreement, and in compliance with the stipulations of Article 18.2a of the Protocol, all grain exports from the United States of America or Canada to Mexico must carry the label "may contain" LMOs, except in the following cases: when the shipment is at least 95% free of LMOs, or when importing species for which the exporting country has not yet authorized the marketing of LMOs.

This agreement seeks to ensure the transparency and flow of transboundary trade in LMOs in the region, in addition to giving Mexico access to the other two countries' scientific information on agricultural biotechnology.

At COP-MOP II of the Protocol, held last May-June in Montreal, Mexico promised to present the initial results of this agreement at COP-MOP III of the Protocol in March 2006.

***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.

31. 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:

Fast turnover of staff in charge of uploading and validating the information.

Problems with the BCH page due to a lack of standardization with regard to characters (e.g., accents), and differences in functionality between Spanish and English language versions (the English version of the BCH works much better).

**Article 21 – Confidential information**

32. 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 – Please see commentary under Question 56
b) no	
33. 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	
If yes, please give number of cases	
b) no	X – Please see commentary under Question 56
c) not applicable – not a Party of import	
34. If you answered yes to the previous question, please provide information on your experience including description of any impediments or difficulties encountered:	
In all situations, the information has been kept confidential and handled as such. This is the case for over 33 assessments made by the Ministry of Health. However, not all of the information is available.	
35. 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:	
Information unavailable.	

**Article 22 – Capacity-building**

36. 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 Nevertheless, Mexico has cooperated	X
c) not applicable – not a developed country Party	

37. If yes, how has such cooperation taken place:	
<p>Mexico has cooperated by training personnel from developing countries. The training in LMO risk assessment was provided to members of the Biosafety Committee of Nicaragua, Paraguay and Guatemala. There has been cooperation, in biosafety workshops, with technical personnel from the ministries of the Environment and Agriculture of Nicaragua, Paraguay and Peru. Furthermore, Mexican biosafety experts participated in the review of legal documents arising from changes in the country's legal framework, as in the case of Nicaragua. It was proposed that Mexican biosafety personnel, at the request of the Instituto Interamericano de Cooperación con la Agricultura (IICA – Interamerican Institute of Agricultural Cooperation), based in Costa Rica, participate in the implementation of the MODEL REGULATORY FRAMEWORK ON LIVING MODIFIED ORGANISMS FOR AGRICULTURAL USE IN CENTRAL AMERICAN COUNTRIES, in order to provide countries in the region with a document that could be used as a basis for developing their National Biosafety Frameworks, projects sponsored by GEF-UNEP. The IICA, with help from members of Mexico's GEF project, presented a PROPOSED WORK PROGRAM FOR THE IMPLEMENTATION OF RESOLUTION 381 ON BIOTECHNOLOGY AND BIOSAFETY, GENERATED BY THE JUNTA INTERAMERICANA EN AGRICULTURA (JIA – Interamerican Agricultural Meeting) HELD IN PANAMA IN NOVEMBER 2003, to establish a program to develop biotechnology in the region. At the request of Peru's GEF-UNEP project, a biosafety expert was sent to evaluate its National Biosafety Framework, to be used as the basis for compliance with the provisions of the Cartagena Protocol. The GEF-UNDP project team is developing a special training program in risk assessment and biosafety for some of the members of Colombia's GEF-World Bank project. Mexico, with over 15 years of experience in risk assessment, has shared its experience with Central American countries at various events attended by technicians, law makers and the general public, particularly during the last three years, while the demonstration project funded by GEF was underway.</p>	
38. 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?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below) As a country, we need more information and training that is adapted to our situation as a country. In order to comply fully with the Cartagena Protocol as pertains to Article 18.2a, more precise information is required with regard to experimental transformations and laboratory work to this effect.	X
c) no – capacity-building needs remain unmet (please give details below)	
b) 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	
39. 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) Yes, government departments have participated in international events where techniques and progress in risk assessment and management have been discussed, but Mexico has an internal weakness, which is the lack of government personnel trained for and dedicated exclusively to fulfilling all of the relevant international commitments that must be met.	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	

40. 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 – Please see commentary under Question 56
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	
41. 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:	
<p>The GEF-UNDP Biosafety project has given Mexico a significant push toward improving LMO risk assessment procedures. The products generated will facilitate risk analysis, particularly with regard to release into the environment. Communication among government departments has been improved, and there are now better tools with which to inform the public about assessment results and risk management. The experience gained in releasing LMOs into the environment has been shared with countries in the region in various ways, and there are plans to continue this policy. The Biosafety Law has bolstered the country's regulatory framework, and its implementation will strengthen the regulatory framework for complying with the Cartagena Protocol even more.</p>	

**Article 23 – Public awareness and participation**

42. 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	
43. If yes, do you cooperate with other States and international bodies?	
a) yes – significant extent	
b) yes – limited extent	
c) no	X
44. 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	
45. 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	
c) no	X
46. 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	
c) no	X
47. 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:	
Lack of financial resources for greater dissemination and training.	

**Article 24 – Non-Parties**

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

48. 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:
Non-parties are reluctant to provide information on cases of transformation cultivated in those countries, to identify cases that may be contained in shipments, and to describe their approximate composition.

**Article 25 – Illegal transboundary movements**

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

49. 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	
b) no	X
50. 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:	
The Law on the Biosafety of Genetically Modified Organisms went into effect on 4 May 2005 and the procedures have not been developed yet.	

*Article 26 – Socio-economic considerations*

51. 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	X
c) no	
d) not a Party of import	
52. 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	X
c) no	
53. 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:	

*Article 28 – Financial mechanism and resources*

54. 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	
c) both	
d) neither	
55. 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:	

### *Other information*

56. 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:

From Question 17(c):

They are asked to carry out a risk analysis. According to Article 60 of the Biosafety Law, the risk assessment is an act of authority.

From Question 18(c):

In national cases, our legislation indicates that the risk assessment is the process of case-by-case analysis based on the scientific and technical studies performed by the interested parties, of the potential risks or effects that the experimental release of GMOs into the environment could cause for the environment and biological diversity, as well as animal, plant and aquatic health.

According to the Biosafety Law, the potential risks for human health must be included in the risk analysis performed to obtain authorization for the GMO in question.

The Law indicates that the following guidelines must be followed when conducting the risk analysis and risk assessment:

- They must be conducted on a case-by-case basis in a transparent manner, and be based on scientific principles and the precautionary approach, according to the terms of the present Law, taking into account expert advice;
- They shall be conducted in the relevant areas of specialization;
- The lack of scientific knowledge or consensus shall not necessarily be interpreted as denoting a given degree of risk, of absence of risk, or of the existence of acceptable risk;
- The baseline should be the potential risks created by non-genetically-modified host or parent organisms if they were to be released into that environment;
- The recipient organism, the genetic modification, including genetic makeup and method of insertion, and the environment into which the GMO is intended to be released must all be taken into account, and
- The nature and degree of detail of the information contained therein may vary from one case to the other, depending on the GMO in question, its previous use and probable recipient environment. The Law also sets out the following basic steps for performing the risk analysis and risk assessment, which include: the identification of new characteristics associated with the GMO that could create potential risks to biological diversity; an assessment of whether these potential risks will actually occur, taking into account the degree and type of exposure to the GMO; an assessment of the consequences if the potential risks were to actually occur; an estimate of the potential overall risk represented by the GMO, based on an assessment of the probability that the potential risks and identified consequences will actually occur, and a recommendation as to whether or not the potential risks are acceptable or can be handled, including the definition of strategies to handle those potential risks.
- In the event of uncertainty with regard to the degree of potential risk that the GMO could create for biological diversity, the Federal Regulatory Departments (SAGARPA and SEMARNAT) shall request additional information on concrete points of the analysis, or shall adopt appropriate strategies to handle the risk and/or monitor the GMO in the recipient environment.
- In the event of danger of severe or irreversible damage, uncertainty as to the degree of the potential risks caused by the GMOs to biological diversity or human health shall not be used as a reason for the corresponding Ministry to postpone the adoption of effective measures to prevent a negative

impact on biological diversity or human health. In adopting such measures, the corresponding Ministry shall take into account: existing scientific evidence that can be used as an argument or criterion for establishing the measure; the administrative procedures established in the present Law; and trade regulations contained in the international treaties and agreements to which Mexico is a party.

Furthermore, the interested party may present, as a complement to the potential risk analysis, other analyses or considerations that examine: the GMO's contribution to solving environmental, social, production or other problems; the socioeconomic considerations linked to releasing GMOs into the environment; and an assessment of the risks of alternative technological options to deal with the specific matter for which the GMO was designed. These analyses must be supported by scientific and technical evidence, and on precedents of use, production and consumption, and may be considered by the competent authorities as additional elements for making a decision regarding experimental release into the environment, and subsequent release into the environment in the context of pilot programs and commercial release, respectively, of the GMO in question.

Finally, the Biosafety Law stipulates that the characteristics and requirements of analyses for the assessment of potential risks shall be set out in the Official Mexican Standards arising from the present Law, which are legal instruments that regulate the activities of citizens and are subject to amendment every five years, or whenever the enabling authority deems its improvement to be necessary.

From Question 19(a):

The Biosafety Law indicates, in several of its provisions, that the Ministries (SAGARPA, SEMARNAT, HEALTH), within the scope of their authority under that Law, shall order one or more of the measures contained therein, should the following occur in the course of activities involving GMOs:

- I. Originally unforeseen risks arise, which could cause damages or significant adverse effects for human health or biological diversity or animal, plant or aquatic health;
- II. There are damages or significant adverse effects for human health or biological diversity, or animal, plant or aquatic health, or
- III. GMOs for which there is no permit and/or which are unauthorized are accidentally released into the environment.

In those cases, measures may include the following:

- A. Temporary, partial or total closure of the locations and/or facilities where the GMOs are handled or stored, or where the activities generating the circumstances that give rise to the measure take place;
- B. Insuring, on a precautionary basis, the GMOs, as well as the goods, vehicles, tools and equipment directly linked to the act or omission giving rise to measure;
- C. The temporary, partial or total suspension of the activity motivating the measure;
- D. Repatriating GMOs to their country of origin;
- E. Taking the necessary actions and measures to stop the circumstances motivating the measure, and
- F. Destroying the GMOs in question, at the interested party's expense, for which the following shall apply:
  - This shall only take place if the risks or damages are severe or irreparable, and only if imposing this measure is the only possible means of preventing, lessening or mitigating the risks or damages that gave rise to the measure;
  - In order to decree the measure, the competent authority must hand down a ruling, with scientific and technical proof, that justifies the destruction of the GMO in question. It must bring the ruling to the attention of the interested party so that said party may, within five days, avail itself of its rights and, if applicable, present any proof which it may hold, and
  - While the competent authority is handing down the appropriate resolution, it may order, prior to the resolution, precautionary insurance of the GMOs, which may be carried out by the Ministry itself, or through the interested party.

Furthermore, the competent Ministry imposing the measures mentioned in the Law may apply to the other competent Ministries to enforce one or more of the measures established in other existing orders within the National Legal Framework.

When the competent Ministries order one of the above-mentioned measures, they shall indicate to the interested party the actions that must be carried out to rectify the irregularities that motivated said measures, as well as the timeframe for performing those actions, so that, upon fulfillment, an order can be issued to withdraw the imposed measures.

Should the interested party refuse to carry out the actions to rectify the irregularities that motivated the imposition of the measure or measures in question, the Ministry that has imposed the measures shall carry them out immediately, entirely at the expense of the unwilling interested party.

In the event that the interested party carries out the safety or emergency measures, or rectifies the irregularities caused, before the competent Ministry imposes one or more of the sanctions contemplated by the present Law, said Ministry must consider this to be an extenuating circumstance of the infraction committed.

From Question 20(b):

Not practically speaking, but, in the Law: with regard to this point, the biosafety legislation stipulates, in article 115, subparagraph III, that when non-permitted and/or unauthorized GMOs are accidentally released into the atmosphere, measures like the following may be applied:

- A. Temporary, partial or total closure of the locations and/or facilities where the GMOs are handled or stored, or where the activities generating the circumstances that give rise to the measure take place;
- B. Insuring, on a precautionary basis, the GMOs, as well as the goods, vehicles, tools and equipment directly linked to the act or omission giving rise to measure;
- C. The temporary, partial or total suspension of the activity motivating the measure;
- D. Repatriating GMOs to their country of origin;
- E. Taking the necessary actions and measures to stop the circumstances motivating the measure, and
- F. Destroying the GMOs in question, at the interested party's expense, for which the following shall apply:
  - This shall only take place if the risks or damages are severe or irreparable, and only if enforcing this measure is the only possible means of preventing, lessening or mitigating the risks or damages that gave rise to the measure. In order to decree the measure, the competent authority must hand down a ruling, with scientific and technical proof, that justifies the destruction of the GMO in question. It must bring the ruling to the attention of the interested party so that said party may, within five days, avail itself of its rights and, if applicable, present any proof which it may hold. While the competent authority is handing down the appropriate resolution, it may order, prior to the resolution, precautionary insurance of the GMOs, which may be carried out by the Ministry itself, or through the interested party.

From Question 32(a):

The Biosafety Law indicates that the interested parties will be able to indicate clearly, in their permit application, which information should be considered confidential according to the industrial property or copyright regime. The corresponding Ministry shall submit to established legislation in this regard and shall abstain from ordering that the information and data protected by said laws be registered and provided to third parties.

The law also indicates that the following shall not be confidential:

- I. The general description of the GMOs;

- II. The identification of the interested party or person responsible for the activity;
- III. The purpose and location or locations of the activity;
- IV. Biosafety, monitoring, control and emergency measures and systems; and
- V. Analyses of the potential risks to human health or the environment and biological diversity.

Furthermore, applicable provisions for access to public government information at the federal level throughout the country (Law on Access to Federal Public Information) shall also apply, in a complementary manner.

From Question 33(b):

We have not received any notifications since the entry into effect of the Protocol. However, our law mentions applications for release, which would be equivalent to notifications and which, to date, have taken place between a Party to the Protocol and a non-Party.

In addition, it has been mentioned in some of these applications that the origin of the seeds could be Brazil (a Party). If this is true, we should receive notification from the exporter.

From Question 40(b):

The above-mentioned goals for proper handling, risk assessment use and risk management, as well as for technical and scientific training to improve biosafety capacity, have not yet been met, because Mexico is a centre of origin and diversification of one of the most manipulated commercial crops: corn, which complicates decisions and the type of training that should be provided to Mexican government officials. Last May, the first applications for release into the environment of transgenic corn were submitted in an attempt to lift the "de facto" moratorium begun in 1998. Those applications have been assessed, but the authorizations have not been given. It is important to mention that they have been assessed using the "Policies and Guidelines for Experimenting with Transgenic Corn in Mexico" document and the expertise of the specialized Agriculture Subcommittee. The document was discussed by said Subcommittee, based on the experience of its various expert members and other scientific consultants specialized in biosafety.

The national laboratories of the ministries of Agriculture and the Environment were equipped with funds from the GEF-CIBIOGEM Mexico project. Upon a recommendation by World Bank evaluators, said project did not formally include the Health sector, which meant that this sector had to resort to national funds to equip its laboratories. Funds are currently needed to complement the equipment, and investment is clearly needed to finalize the training of specialized personnel.

There is still a series of activities to implement, once the laboratories have been equipped, regardless of the country's international position with regard to thresholds and type of monitoring, since there are no national or private laboratories that have been certified. Whatever the specifics may be with regard to monitoring the GMOs put on the market, Mexico still has a great deal to implement before it can do so.

### *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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