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

Origin of report

Party:	Lithuania
Contact officer for report	
Name and title of contact officer:	Gintarė Blažauskienė Chief Desk Officer of GMOs division Nature Protection Department Ministry of Environment
Mailing address:	A. Jakšto st. 4/9 Vilnius LT–01105
Telephone:	+370 5 261 5339
Fax:	+370 5 266 3663
E-mail:	g.blazauskiene@am.lt
Submission	
Signature of officer responsible for submitting report:	
Date of submission:	2007 September 11
Time period covered by this report:	

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:

The Ministry of Environment is the competent authority responsible for implementation of Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

The Ministry of Environment is responsible for preparation of the National Report on the Implementation of the Cartagena Protocol to the Executive Secretary. The Ministry of Environment involved all relevant stakeholders in the preparation of the report, in order to ensure a participatory and transparent approach to its development and the accuracy of the information requested.

State Food and Veterinary Service submitted relevant information about import, export and illegal transboundary movements of GMOs. State Food and Veterinary Service performs control of food and feed products imported, exported and placed on the market of the country in accordance with the provisions of Article 4 (6) to Chapter II of the Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

The Ministry of Environment prepared draft report and dispatched via E-mail for submission of comments to national institutions occupied with biosafety issues – Ministry of Agriculture, Ministry of

Health, State Food and Veterinary Service. The Ministry of Environment specifies the National Report under the received comments from responsible institutions and their subordinated organizations. The report will be entered into the national GMOs database, providing on a server of the Ministry of Environment (http://gmo.am.lt).

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):

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*
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		
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
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)	X
b) some measures introduced (please give details below)	
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:

National policy for the safe use and handling of GMOs and GMPs has been formed by the Parliament (Seimas) and the Government of the Republic of Lithuania, which empowered the designated responsible governmental institutions: Ministry of Environment, Ministry of Agriculture, Ministry of Health, State Food and Veterinary Service. Lithuanian legislation related to biosafety sector transposes the main requirements of Cartagena Protocol on Biosafety and European Union legislation.

The main act regulating issues on genetically modified organisms is the ***Law on Genetically Modified Organisms.*** The Law adopted on June 12, 2001, (No. IX-375, amended on March 20, 2003 by the Law No. IX-1384; on June 22, 2006 by the Law No. X-720) legally came into force since 31 of December 2002. The overall objective of the Law is to determine and delineate the spheres of activities involving GMOs and GMPs, their state management and regulation, also the rights, duties and responsibilities of the users of GMOs and GMPs. Lithuania has developed and approved variety of orders under the Law.

The main legal measures include:

– ***Regulation on GMOs Deliberate Release into the Environment, Placing on the Market*** was adopted by the order No. D1-225 of the Minister of Environment on April 29, 2004 (amended on November 7, 2006 by the order No. D1-520; on March 6, 2007 by the order No. IX-1384). The overall objective of this order is to regulate use and control requirements on GMOs and GMPs deliberate release into the environment, placing on the market in the Republic of Lithuania.

– ***Order on Regulation on Contained Use of Genetically Modified Micro-organisms*** was adopted by the order No. 413 of the Minister of Environment on August 4, 2003 (amended on April 29, 2004 by the order No. D1-233; on March 4, 2005 by the order No. D1-130). The overall objective of this legal act is to enable current and potential users to participate in the world GMOs research and development market, to ensure safe contained use of GMMs, thus protecting human health and environment from possible negative harmful effects posed by GMOs.

– ***Order on Criteria for Genetically Modified Micro-organisms Classification*** was adopted by the trilateral agreement No. D1-693/V-954/B1-1107 of the Minister of Environment, the Minister of Health and the Director of State Food and Veterinary Service on December 28, 2004. The aim of this order is to set up the regulation on the requirements for the classification's level determination by the risk assessment of genetically modified micro-organisms. The risk assessment requirements lead to more

effective and explicit evaluation of potential harmful effects of the genetically modified micro-organisms to the environment and human health.

– ***Order on Regulation of Risk Assessment on GMOs*** adopted by the order No. 681/689/525/753 of the Minister of Environment, the Minister of Agriculture, the Minister of Health and the Director of State Food and Veterinary Service on December 31, 2002 (amended on October 11, 2004 by the order No. D1-530/V-698/3D-557/B1-886). The order establishes main principles, methods and performance procedures for the activities related to risk assessment of GMOs and GMPs, consisted of GMOs, posed to the human and animal health, environment and agriculture.

– ***Order on Regulation on Public Information and Participation in Issuing of Consents for Use of GMOs*** adopted by the order No. 299 of the Minister of Environment on June 11, 2003 (amended on December 30, 2005 by the order No. D1-660). The order applies for the parties (natural and legal persons, public institutions) involved in the process of information and participation during the notification and permitting to use the GMOs and GMPs in the Republic of Lithuania. It declares the rights and duties of notifier to inform public announcing the intention to use GMOs or GMPs, inviting to express and deliver comments on the application and preliminary decision taken on each specific case.

– ***Establishing of GMOs Steering Committee*** adopted by the order No. 602 of the Minister of Environment on December 18, 2001 (amended on March 20, 2003 by the order No. 127; on February 28, 2005 by the order No. D1-110). The GMOs Steering Committee is a political advisory body for the development and enforcement of national regulatory system with respect to biosafety issues. This Committee consists of members appointed by relevant state authorities, the subordinated organizations, national biotech industry, non-governmental organizations, universities, scientific institutes.

– ***Establishing of GMOs Experts Committee*** adopted by the order No. 198 of the Minister of Environment on April 25, 2003. The GMOs Experts Committee is a consultative advisory body with clear task to act as an advisor to the competent authority. The national GMOs Experts Committee is formed taking into account the risk assessment requirements from scientific staff of the following specializations: genetic, ecology, botany, health care, agriculture, veterinary, biochemistry, geochemistry, microbiology and some others.

– Order on Regulation on Arrangement of Monitoring Plan of GMOs or their Products after the Placing on the Market adopted by the order No. 601 of the Minister of Environment on December 1, 2003. The general aim of the Order is to set up and regulate the process for preparation of general monitoring (surveillance) strategy program, data analysis and subsequent reporting.

– ***Order on Regulation on GMOs database*** adopted by the order No. D1-542 of the Minister of Environment on October 18, 2004. The general aim of this Order is to set up and regulate the process for the biosafety data and information on GMOs gathering, flow, storage and management system in order to set up the national GMOs database.

– Order on Approval of the Regulations for Inspection of Genetically Modified Plants and Plant Products not Intended for Human Consumption and Animal Feed and their Propagating Material Imported to Lithuania and European Community and Carried as Transit was adopted by the order No. 3D-265 of the Minister of Agriculture on May 11, 2005 (amended on January 31, 2007 by the order No. 3D-37). These Regulations establish the control procedures for the import to the Republic of Lithuania and European Community from non European Community countries and transit of genetically modified plants, plant products and propagating material not intended for human consumption and animal feed.

– Code on Administrative Right's Violation was adopted by the Parliament (Seimas) of the Republic of Lithuania on January 29, 2004 (amended on June 15, 2006 by the Law No. X-691). The Code on Administrative Right's Violation is aplied to all natural and legal persons who evade the requirements set out in EU and national law, and who are connected with import, transit and export of GMOs in the territory of the Republic of Lithuania, deliberate release into the environment, placing on the market. The value of penalty depends on the proportion and times of infringement.

– ***Order on Control of Genetically Modified Plants and their Products, not Intended to Use as Food and Feed, which are Phytosanitary Controlled, and Genetically Modified Seeds*** adopted by the order No. 3D-515 of the Minister of Agriculture on September 14, 2004.

– ***Order on the Approval of the Procedure for Official Control of Imported non-animal Foodstuffs*** adopted by the order No. B1-354 of the State Food and Veterinary Service director on March 29, 2007.

– ***Order on the Approval of the Regulation of Official Control of Feedingstuffs*** adopted by the order No. B1-351 of the State Food and Veterinary Service director on May 22, 2007.

The Cartagena Protocol on Biosafety was ratified on September 18, 2003, at the Parliament (Seimas) of the Republic of Lithuania by adopting the ***Law on Ratification of Cartagena Protocol on Biosafety to the Convention on Biological Diversity*.**

A list of all legal measures pertaining to GMOs has been submitted to the Biosafety Clearing-House. More information about the content of these legislative acts could be found through the national GMOs database (via Internet address: http://gmo.am.lt, still in Lithuanian, but soon will become bi-lingual Lithuanian-English).

Field Code Changed

As Lithuania has joined European Union on 1 May 2004, thus the general sector policy for GMOs safe usage and handling system is similar to that of European Union. Lithuania has constructed the national legislation along the lines of the Directive 98/81/EC of 26 October amending the Directive 90/219/EEC on the contained use of genetically modified micro organisms; the Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms; of the requirements of the Cartagena Protocol on Biosafety.

Intentional and unintentional movements of GMOs between Lithuania and other Member States of European Union and the third countries are regulated by Regulation (EC) No. 1946/2003 of 15 July 2003 on transboundary movements of GMOs, with the exception of intentional within the Community.

GMOs and food products derived from GMOs, which are placed on the market, must satisfy traceability and labelling conditions, which are laid down in European Union Regulation (EC) No. 1829/2003 of 22 September 2003 on genetically modified food and feed, covering the placing on the market of GMOs intended for food or feed and of food or feed products containing, consisting of or produced from GMOs; Regulation (EC) No. 1830/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs and amending the Directive 2001/18/EC; Regulation (EC) No. 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No. 1829/2003 as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

Lithuania has prepared the draft rules on co-existence of genetically modified crops with conventional and organic farming and their propagating material with due consideration to European Commission Recommendation No. 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming, which was notified to the European Commission on 21 of March 2006.

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

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

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	X
b) not yet, but under development	
c) no	
d) not applicable – not a Party of export	
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	
b) no	
c) not applicable – no decisions taken during the reporting period	X
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:	
Lithuania has not been a Party of export of LMOs intended for release into the environment during the reporting period.	
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:	
Lithuania has not taken any decisions on import of LMOs intended for release into the environment during the reporting period. (See Report of the Commission on Implementation of the Cartagena Protocol on Biosafety by the European Community).	

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.

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

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

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	
c) not relevant	X
14. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 11.4?	
a) yes	
b) no	
c) not applicable – no decisions taken during the reporting period	X
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:	
Lithuania has not been a Party of export of LMOs intended for direct use for food or feed, or for processing, during the reporting period.	
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:	
Lithuania has not been a Party of import of LMOs intended for direct use for food or feed, or for processing, during the reporting period. (See Report of the Commission on Implementation of the Cartagena Protocol on Biosafety by the European Community).	

Article 13 – Simplified procedure

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

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:	
Lithuania has not used the simplified procedure during the reporting period.	

Article 14 – Bilateral, regional and multilateral agreements and arrangements

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

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:	
Lithuania has not entered into any bilateral, regional or multilateral agreements or arrangements as per Article 14. As Lithuania has joined European Union on 1 May 2004, the general sector policy on GMOs management system is common to that of European Union and national legislation complies with European Community law.	

Articles 15 and 16 – Risk assessment and risk management

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	
b) no (please clarify below)	
c) not a Party of import / no decisions taken under Article 10	X
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	
d) not a Party of import / no decisions taken under Article 10	X
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 below)	
c) no	
d) not a Party of import / no decisions taken under Article 10	X
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)	X
b) no (please give further details below)	

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:

Lithuania has developed a comprehensive system of risk assessment and risk management dealing with the deliberate release into the environment or placing on the market GMOs, as well as products containing or consisting of GMOs.

A specific risk assessment is carried out under the ***Order on Regulation of Risk Assessment on GMOs*** (adopted by agreement of the Minister of Environment, the Minister of Health, the Minister of Agriculture and the Director of State Food and Veterinary Service; came into force on 31/12/2002) which has been laid down on the basis of the requirements of European Union Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, and supporting documents (Commission Decision 2002/623/EC; Council Decision 2002/811/EC; Council Decision 2002/812/EC) and approximated according to the requirements of the Cartagena Protocol on Biosafety. The order establishes the main principles, methods and performance procedures for the activities related to the risk assessment of GMOs and GMPs, consisted of GMOs, posed to the human and animal health, environment and agriculture. The order applies to all natural and legal persons, releasing into the environment or placing on the market GMOs or GMPs in the territory of the Republic of Lithuania. Environmental risk assessment in Lithuania is carried out in accordance with the precautionary principle.

The Ministry of Environment, upon receipt of the application and request for the deliberate release into the environment or placing on the market GMOs, without delay, but no later than 10 days forwards it to the GMOs Steering Committee and the GMOs Experts Committee requesting them to submit possible risk assessment posed by GMOs to human health, environment and agriculture, and preliminary findings. The GMOs Experts Committee is a consultative advisory body with a clear task to act as an advisor to the competent authority in carrying out risk assessment, thus advising the GMOs Steering Committee in relation to risk assessment and risk management posed to the environment, agriculture and human health by GMOs.

Order on Regulation on Arrangement of Monitoring Plan of GMOs or their Products after the Placing on the Market adopted by the order No. 601 of the Minister of Environment on December 1, 2003. The order was drafted according the requirements of European Union Directive 2001/18/EC on the deliberate release into the environment, and the provisions of European Union Decision 2002/811/EC. The general aim of the order is to lay down and regulate the process for preparation of general monitoring strategy program, data analysis and subsequent reporting. Notifier before preparation of the monitoring plan has to develop general surveillance strategy. During the preparatory process, notifier has to evaluate several factors, among others: probability of direct, indirect, immediate or delayed impact by GMOs, possible unintended effects, GMPs characteristics according to the intended usage and receiving environment. The main goal of the monitoring is to protect biological diversity, soil functionality, surface and ground waters, sustainable/organic farming, the quality of agriculture products, plant and animals, human health from possible negative influence. The specific aim is focused on defining whether assumptions and findings during the conduction of risk assessment for human health and environment have proven; to determine unintended negative impacts for environment and human health, not evaluated during the environmental risk assessment.

Lithuania as European Union Member State considers common European Union criteria concerning GMOs risk assessment and risk management.

(See Report of the Commission on Implementation of the Cartagena Protocol on Biosafety by the European Community).

There were no obstacles and impediments encountered.

Article 17 – Unintentional transboundary movements and emergency measures

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

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 known occurrences of an unintentional transboundary movement of GMOs that had, or could have had, significant adverse effects on the conservation and sustainable use of biological diversity, taking into account risk to human health, during the reporting period.	

Article 18 – Handling, transport, packaging and identification

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	X
b) not yet, but under development	
c) no	
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	X
b) not yet, but under development	

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	X
b) not yet, but under development	
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:
Lithuanian legislation on GMOs related issues fulfills requirements covered by Article 18 of the Protocol. Lithuania as European Union Member State considers common European Union criteria concerning handling, transportation, packaging and identification of GMOs under conditions of safety. Lithuanian legal system implement regulations: - Regulation (EC) No. 1946/2003 of 15 July 2003 on transboundary movements of genetically modified organisms; - Regulation (EC) No. 1829/2003 of 22 September 2003 on genetically modified food and feed; - Regulation (EC) No. 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms; - Regulation (EC) No. 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed; - Regulation (EC) No. 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms. (See Report of the Commission on Implementation of the Cartagena Protocol on Biosafety by the European Community). There were no obstacles and impediments encountered.

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.

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:
Lithuanian Ministry of Environment is responsible for the implementation of the Cartagena Protocol on Biosafety and for submitting information to the Biosafety Clearing-House. The Ministry of Environment appointed the focal point responsible for keeping the BCH up-to-date and responsible for managing

communication between the Secretariat, respective governments and the public, validating and registering information to the BCH central portal.

During the implementation of the UNEP-GEF project on the Development of National Biosafety Framework for Lithuania (project No. GFL/2716-02-4546), there was established the national GMOs database, acting as national BCH (it could be found via Internet address: http://gmo.am.lt). Currently Lithuania registers and update data through the Management Center in the central portal of the BCH. In 2007 Lithuania started UNEP-GEF Project for Building Capacity for Effective Participation in the Biosafety Clearing-House. National GMOs database will be amended during the implementation of above mention project. All information relevant to GMOs will be transmitted and updated in the BCH through the central portal using BCH interoperability protocols (Option 4).

There no obstacles and impediments have been encountered in implementing the Cartagena Protocol on Biosafety.

Article 21 – Confidential information

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	
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	
If yes, please give number of cases	
b) no	
c) not applicable – not a Party of import / no such requests received	X

39. If you answered yes to the previous question, please provide information on your experience including description of any impediments or difficulties encountered:

Lithuania has procedures to protect confidential information received under the Protocol in accordance with the ***Law State and Public Service Confidence*** (Official Gazette, 1999, No. 105-3019, amended on April 5, 2007 by the Law No. X-1080). Lithuania as European Union Member State, applies the provisions on confidentiality in accordance with EU legislation on GMOs.

The Ministry of Environment is responsible for confidential information related to GMOs protection and for administrative, technical and other measures, which enable to protect the information from illegal destroy, alteration and usage. The confidential information cannot be disclosed and used for a commercial purpose.

Lithuanian legislation on GMOs contains confidentiality provisions that apply equally to domestic and foreign producers of GMOs. Decisions on which information will be kept confidential are taken by the Ministry of Environment as the competent authority after consultation with the notifier.

According to ***Order on Regulation on Public Information and Participation in Issuing of Consents for the Use of GMOs*** the public has full right to receive freely announced information about the usage of

GMOs and GMPs enquiring what information would like to be given. The information cannot be given in case the disclosure of it would offend its confidentiality and intellectual property rights. The Ministry of Environment nominated responsible person, who has the permission to receive and work with confidential information. There were no impediments and 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:
Lithuania was not a Party of export during the reporting period.

Article 22 – Capacity-building

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	X
c) not applicable – not a developed country Party	
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:	
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?	
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:	
Lithuania had 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, training in the use of risk assessment and risk management for biosafety, and training for enhancement of technological and institutional capacities in biosafety. Lithuania received benefit from the following projects: • The GMOs laboratory has been established at the beginning of 2004 within the premises of the National Veterinary Laboratory to the National Food and Veterinary Service, introducing relevant modern methods of laboratory practices. The National Veterinary Laboratory is accredited under DIN EN ISO/IEC 17025:2005 for the qualitative and quantitative analysis of GMOs. The laboratory is a member of European Network of GMOs laboratory, and cooperates with several European Institutions (the Community Reference Laboratory, the Institute for Reference Materials and Measurements) in validation studies new GMOs products. The samples for laboratory analysis (genetically modified food products, genetically modified plants, grains, seeds, etc.) are being carried out employing the best laboratory practices of European Union and Lithuania, using the approved methodology and standard work procedures. The main supplies of the equipment and standardization of the required procedures was completed efficiently using European Union PHARE funds of the project (No. LI 01.06.01) "Strengthening of Institutional capacity to implement European Union Requirements on Chemicals and Genetically Modified Organisms' management, IPPC and Climate Change". • BEF (Baltic Environmental Forum) Team had been involved in the implementation of the following cooperation projects: "Baltic Biosafety", lead by the Swedish Environmental	

Protection Agency (2003-2004); and "Implementation of biosafety frameworks in pres-accession countries of Central and Eastern Europe", funded by the Ministry of Environment of the Netherlands (2000-2002). The organized workshops/seminars are following: Workshop on "Traceability and labelling of genetically modified organisms" (in cooperation with Swedish EPA); 3rd Baltic biosafety workshop on "Genetically modified plants and their products"; 2nd Baltic biosafety workshop on "Biosafety Protocol"; 1st Baltic biosafety workshop on "Contained use of genetically modified micro organisms"; Training workshop "Implementation of biosafety regulations"; Workshop on "Implementation and Enforcement of EC GMOs Legislation – Handling Request and Enforcement Mechanisms"; Meeting on "Laws on Genetically Modified Organisms and the necessary regulations under the laws"; Seminar on GMOs and Biosafety; Environmental and Health Concern regarding Genetically Modified Organisms; EU approximation: Genetically Modified Organisms.

- During the implementation of the UNEP-GEF project on the Development of National Biosafety Framework for Lithuania (project No. GFL/2716-02-4546), there was formulated National biosafety policy, envisaged and implemented nationally several means for promotion and facilitation of public awareness, education and participation: organization of GMOs related seminars/workshops; National public awareness Conference (with press-conference, press-release, interviews (radio and TV, local and national mass media); development of testing phase of national GMOs database (at local website, it could be found via Internet address: http://gmo.am.lt), publications of relevant material (booklet for CPB, guide-book for GMOs safe application, etc.).
- Support for the project on the Implementation of National Biosafety Framework for Lithuania (GFL/2328-2716-4935) started from 2006 to 2010. The UNEP-GEF project aims to support the National Competent Authority to meet the Parties' s obligations foreseen under the Cartagena Protocol on Biosafety by providing the needs capacity building activities. The project, when implemented, shall contribute to the enforcement of the National Biosafety Framework, i.e. strengthening the existing institutional capacities required and human resources needed to have fully operational and enforced National Biosafety Framework in Lithuania.
- During UNEP-GEF Project for Building Capacity for Effective Participation in the Biosafety Clearing-House will be organised national workshops to raise public awareness on public access to the Biosafety Clearing-House, will be procured equipment necessary for national GMOs database amendment, all information relevant to GMOs will be transmitted and updated in the BCH through the central portal using BCH interoperability protocols.

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	X
b) yes – limited extent	
c) no	
50. If yes, do you cooperate with other States and international bodies?	
a) yes – significant extent	
b) yes – limited extent	X
c) no	

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	X
b) yes – limited extent	
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	X
b) yes – limited extent	
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:

Lithuanian legislation on GMOs promotes public awareness and participation as an integral part of its regulatory framework. ***The Order on Regulation on Public Information and Participation in Issuing of Consents for Use of GMOs*** was drafted by taking into consideration Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, European Union Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, European Union Directive 90/219/EEC on the contained use of GMOs in conjunction with the Directive 98/81/EC amending the Directive 90/219/EEC. According to this order the notifier has an obligation to inform public during the period of 10 days via different mass media about the fact of submission notification to the Ministry of Environment, the main scrutinized findings and about the fact of granted consent for the experimental release into the environment or placing on the market of GMOs in Lithuania.

According to Article 4 of the ***Order on Regulation on Public Information and Participation in Issuing of Consents for Use of GMOs,*** the Ministry of Environment has to organize the use, storage and availability of information about the GMOs and GMPs to the public through the internet database, not violating the rights of confidential and intellectual information. The public has right to make reasoned suggestions and comments, and submit to the Ministry of Environment within 40 days from the information submission about intention to use the GMOs or GMPs.

Lithuanian Ministry of Environment, supported by UNEP-GEF project on the Development of National Biosafety Framework for Lithuania, established the national GMOs database in 2004. The main tasks of the national GMOs database are to transfer data into the system, store these data, process and present them, guarantee access to the data, but also restrict access to confidential information. The GMOs database (it could be found via Internet address: http://gmo.am.lt) contains the public available information on the following categories: National Laws and Regulations; European Union Legislation; Regional and International Agreements; National Competent Authorities and Contact Points; Decisions taken on Import, Export and Transit of GMOs and GMPs in Lithuania; Notifications and Information on

contained use of GMMs; Notifications and Information on consents issued for the deliberate release of GMOs into the environment or for the placing on the market of GMOs; Roster of Experts; other related information. In the GMOs database there is the section for the direct public opinion presentation.
According to the ***Law on GMOs*** the Ministry of Environment is the main data holder and public information provider in the GMOs sector. Under the Resolution of the Government of the Republic of Lithuania, adopted in April 2004, the State Food and Veterinary Service, the Ministry of Agriculture, the Ministry of Health and their subordinated organizations provide relevant information to the Ministry of Environment.
Above-mentioned GMOs database facilitates the implementation of better conditions for public awareness raising, consultation and participation, facilitates the exchange of scientific, technical, environmental and legal information among national institutions and the public.
During the implementation of UNEP-GEF Project for Building Capacity for Effective Participation in the Biosafety Clearing-House, the Ministry of Environment will organize workshops to raise public awareness on public access to the BCH.
Information on GMOs regulation provided through the publication of leaflets, posters, articles in local and national press, and other informative materials ensure effective public awareness raising and consultation during the process of decision-making.

Lithuania as European Union Member State considers common European Union criteria concerning public awareness and participation.
(See Report of the Commission on Implementation of the Cartagena Protocol on Biosafety by the European Community).

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	
b) no	X
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:	
There have not been transboundary movements of LMOs between Lithuania and a non-Party.	

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:	
Lithuania has adopted appropriate domestic measures to prevent and penalize illegal transboundary movements of GMOs. The applicable penalties for infringements of the requirements of national legislation are effective, proportionate and dissuasive. ***Code on Administrative Right's Violation*** was adopted by the Parliament (Seimas) of the Republic of Lithuania on January 29, 2004 (amended on June 15, 2006 by the Law No. X-691). The Code on Administrative Right's Violation is applied to all natural and legal persons who evade the requirements set out in EU and national law, and who are connected with import, transit and export of GMOs in the territory of the Republic of Lithuania, deliberate release into the environment and placing on the market GMOs. The value of penalty depends on the proportion and times of infringement. There were no obstacles and impediments encountered.	

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	
d) not a Party of import	X
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:	

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:

Lithuania received financial resources from the following projects:
– UNEP-GEF project "Development of the national Biosafety Framework for Lithuania" (project No. GFL/2716-02-4546) commenced in November 2002 and completed in August 2004;
– PHARE 2001 Project (No. LI 01.06.01) "Strengthening of Institutional capacity to implement European Union Requirements on Chemicals and Genetically Modified Organisms' management, IPPC and Climate Change";
– UNEP-GEF project "Implementation of National Biosafety Framework for Lithuania" (project No. GFL/2328-2716-4935) commenced in 2006 to 2010;
– UNEP-GEF project "Building Capacity for Effective Participation in the Biosafety Clearing-House" (project No. GFL/CEE/2006/05/022) commenced in January 2007.

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:

Lithuanian Ministry of Environment is national competent authority responsible for implementation of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The Ministry of Environment appointed:

- Dr. Danius Lygis, Head of GMOs division, Nature Protection Department, Ministry of Environment, as Cartagena Protocol on Biosafety National Focal Point;
- Mrs. Gintarė Blažauskienė, Chief Desk Officer of GMOs division, Nature Protection Department, Ministry of Environment, as Biosafety Clearing-House Focal Point;
- Ms. Lina Kučinskaitė, Chief Desk Officer of GMOs division, Nature Protection Department, Ministry of Environment, as Emergency Measures Contact Point.

All information about competent national authority and national focal points has been provided to the Biosafety Clearing-House.

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:

No difficulties encountered