Origin of report

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Signature of officer responsible for submitting report:	
Date of submission:	11 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:

This report has been prepared in a close collaboration with Ms Sarma Sleze, Head of Legislation Development Department of the Latvian Food center and Ms Liga Zala, Senior Officer of Analyses and Development Department.

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):

The Latvian Food center has provided the BCH with all relevant information in the listed categories.

The English text of National laws, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing will be available upon translation of the above mentioned documents will be completed.

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

Regulatory regime for GMOs and biosafety issues in Latvia consists from binding international treaties and relevant EU and national legislation.

International treaties

Convention on Biological Diversity was ratified in Latvia on 8 September 1995.

Cartagena Protocol on Biosafety to the Convention on Biological Diversity was ratified in Latvia on 22 January 2004. In accordance with Article 37 Protocol entered into force in 13 May 2004 (on the ninetieth day after the date on which Latvia deposited its instrument of ratification).

EU provisions implemented into national Regulations:

Within the accession process Latvia has harmonised and implemented the requirements of the EU Directives regarding GMOs. The applicable EU directives and relevant Council and Commission decisions are implemented into national legislation.

The requirements of the following EU directives are implemented into national legislation:

- Directive 90/219/EC of 23 April 1990 on the contained use of genetically modified micro- organisms.
- Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro- organisms.
- Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, covering the field testing of GMOs (mainly Part B) and the placing on the market of GMOs as well as products containing or consisting of GMOs, e.g. for cultivation, import or processing into industrial products (mainly Part C).

EU Regulations directly applicable in Latvia:

- Regulation (EC) No 1946/2003 of 15 July 2003 on transboundary movements of genetically modified organisms covers exports of GMOs to third countries and unintentional movements of GMOs.
- Regulation (EC) 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) 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 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.

Enforcement provisions of EU Regulations 29/03, 1830/03 and 1946/03 implemented into national legislation acts.

National legislation

Regulation on the Contained Use, Deliberate Release Into the Environment and Placing On the Market of Genetically Modified Organisms, as well as on Their Monitoring Regulation of the Cabinet of Ministers No 333; adopted on 20 April 2004

Regulation on the Monitoring Council of Genetically Modified Organisms and Novel Foods Regulation of the Cabinet of Ministers No. 511; adopted on 12 July 2005 (replaced Regulation on 19 September 2000).

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	x
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 Par review a decision it had made under Article 10 on the grounds specified in Article 12.	
a) yes (please give details below)	
b) no	
c) not applicable – not a Party of export	X
6. Did your country take decisions regarding import under domestic regulatory frame by Article 9.2(c).	eworks as allowed
a) yes	
b) no	
c) not applicable – no decisions taken during the reporting period	X
7. If your country has been a Party of export of LMOs intended for release into the e the reporting period, please describe your experiences and progress in implementing A 12, including any obstacles or impediments encountered:	
Not applicable – no decisions taken during the reporting period.	
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:	
Not applicable – no decisions taken during the reporting period.	

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

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

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

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	X
b) no	
c) not applicable (please give details below)	
10. Has your country indicated its needs for financial and technical assistance and cap respect of living modified organisms intended for direct use as food or feed, or for pro	
a) yes (please give details below)	X
b) no	
c) not relevant	
11. Did your country take decisions regarding import under domestic regulatory frame by Article 11.4?	eworks as allowed
a) yes	
b) no	
c) not applicable – no decisions taken during the reporting period	X
12. If your country has been a Party of export of LMOs intended for direct use for for processing, during the reporting period, please describe your experiences and progress Article 11, including any obstacles or impediments encountered:	
Not applicable –not a Party of export during the reporting period.	
13. If your country has been a Party of import of LMOs intended for direct use for for processing, during the reporting period, please describe your experiences and progress Article 11, including any obstacles or impediments encountered:	
The procedure for LMOs intended for direct use for food or feed is in line with	EU requirements.

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:

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

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:

The Latvia has not entered into any bilateral, regional or multilateral agreements or arrangements as per Article 14(1).

Articles 15 and 16 – Risk assessment and risk management

16. If you were a Party of import during this reporting period, were risk assessments of decisions taken under Article 10? (Article 15.2)	carried out for all
a) yes	
b) no (please clarify below)	
c) not a Party of import	X
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	
d) not a Party of import	X
18. If you took a decision under Article 10 during the reporting period, did you requir bear the cost of the risk assessment? (Article 15.3)	e the notifier to
a) yes – in all cases	-
b) yes – in some cases (please specify the number and give further details below)	-
c) no	-
19. Has your country established and maintained appropriate mechanisms, measures a regulate, manage and control risks identified in the risk assessment provisions of the F 16.1)	
a) yes	X
b) no	
20. Has your country adopted appropriate measures to prevent unintentional transbour of living modified organisms? (Article 16.3)	ndary movements
a) yes	X
b) no	
21. Does your country endeavour to ensure that any living modified organism, whethe locally developed, undergoes an appropriate period of observation commensurate with generation time before it is put to its intended use? (Article 16.4)	
a) yes – in all cases	
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)	X
b) no (please give further details below)	

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:

Procedure for risk assessment is set in accordance with EU provisions. The main responsibility for risk assessment relies to the experts of Monitoring Council of GMOs and Novel Foods. Having regard that no one application with respect to deliberate release or placing on the market of GMO as well as import of LMOs has been submitted to Council, the experts activities are limited to assessment of report made by other Competent Authorities or EFSA within the provisions set by EU regulatory framework.

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 have led, to an unintentional transboundary movement of a living modified organism to have had, significant adverse effects on the conservation and sustainable use of biolog taking also into account risks to human health in such States, did you immediately compotentially affected States for the purposes specified in Article 17.4?	that had, or could gical diversity,
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 a	*

encountered:

Not applicable.

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)	х
b) no	
c) not applicable (please clarify below)	
27. Has your country taken measures to require that documentation accompanying livorganisms for direct use as food or feed, or for processing, clearly identifies that they modified organisms and are not intended for intentional introduction into the environmentation of the information? (Article 18.2(a))	'may contain' living
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	X
b) no	
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	
30. Please provide further details about your responses to the above questions, as well your country's experiences and progress in implementing Article 18, including any of impediments encountered:	•
The EC has put in place an exhaustive set of requirements concerning the handling, transport, packaging and identification of GMOs, for any use foreseen in Article 18 of the Protocol. All EU Regulations that addresses the issues of handling, transport, packaging and identification requirement are directly applicable in Latvia.	

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:

In accordance with Latvian Law "Cartagena protocol on biosafety to the Convention on biological diversity" (adopted on 11 February 2004) the Latvian Food center has been designated as a National Focal point for liaison with the Secretariat and responsible for information sharing in accordance with provisions set by Article 20 within the Biosafety Clearing House.

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
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	
c) not applicable – not a Party of import	X
34. If you answered yes to the previous question, please provide information on your experience including description of any impediments or difficulties encountered:	
In accordance with EU legislation on GMOs the provisions on confidentiality should be equally applied to domestic and foreign producers of GMOs. All confidential information should be treated in accordance with Latvian Regulation "Law on confidentiality".	
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:	
Not applicable - not a Party of export during the reporting period.	

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	
c) not applicable – not a developed country Party	X
37. If yes, how has such cooperation taken place:	
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)	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 be cooperation for technical and scientific training in the use of risk assessment and risk biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	Х
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)

 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:
- 1. Assistance within the <u>project "Implementation of biosafety frameworks in pre accession countries of Central and Eastern Europe"</u> (2001-2003), which was funded by the <u>MATRA</u> <u>programme</u> of the Dutch government. The training workshops were intended for Governmental officials and experts of institutions and organizations who were involved in the implementation of biosafety regulations in Latvia.
- 2. OECD workshop "Risk assessment of novel foods and feeds" (2001).
- 3.Project "Baltic Biosafety" (2002-2004) in collaboration with Swedish Environmental Protection Agency (Swedish EPA), with Baltic Environmental Forum (BEF) funding support. The project aimed at capacity building of Baltic biosafety frameworks particularly focusing on contained use of genetically modified microorganisms (GMMs), transboundary movements of LMOs and release of genetically modified (GM) plants.
- 4. Training workshops UNEP-GEF and CBD-BCH regional workshops for Central and Eastern European countries.
- 5. UNEP-GEF funded project "Development of National Biosafety Framework for the Republic of Latvia" (2003-2004).

Latvian Food centre (LFC) was the legal entity appointed as Project National Executing Agency. Implementing the project activities several trainings for risk assessors and risk managers have been conducted as well as the gaps and future needs have been identified for successful implementation of National Biosafety Framework in future.

6. Collaboration within <u>EC Joint Research center European Network of Genetically</u> Modified Organisms (GMO) Laboratories (ENGL).

On 2004, the Veterinary Medicine Diagnostic center (Food and Veterinary Service, Ministry of Agriculture) became a member of ENGL.

7. Assistance within the <u>project "Strengthening of State Food Control and Supervision</u>

<u>System with training assistance"</u> (2005- 2006), which is funded by Transitional Facility

Programme for Latvia. There are several workshops for risk assessors (on general principles and methodology of the environmental risk assessment) and risk managers (inspectors of Food and Veterinary Service) on practical aspects of GMOs control and monitoring will be conducted.

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	X
c) no	
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 decision-making process regarding living modified organisms and make the results of available to the public? (Article 23.2)	
a) yes – fully	
b) yes – limited extent	X
c) no	
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	х
c) no	
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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:

The general provisions for public information and consultation are set by National regulatory acts implementing EU requirements.

Having regard that no one application have been submitted to Monitoring Council of GMOs (the Council) to permit deliberate release or placing on the market of GMOs in Latvia, there is no practical experience in the field of public consultation.

However, there is established links to show where EFSA or other Competent authorities risk assessment reports are available for public comments. This information is available on the home page of LFC.

All information related to activities of Council, including decision- making procedure, should be published on LFC home page. The Council includes representatives from professional non-governmental institutions. All meetings of Council are open for general public.

There are several activities have been conducted in order to facilitate the public awareness on GMO related issues as seminars, publication of informative brochure, creation of Biosafety website as well as activities with the involvement of mass media.

Information related to GMOs and biosafety matters necessary for the participation is available to the public (information to be included in publicly accessible databases is defined by National Regulations), but there is a room to establish appropriate mechanism to insure effective participation.

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:
Not applicable.

Article 25 – Illegal transboundary movements

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

transboundary movements of living modified organisms carried out in contravention of its domestic measures? (Article 25.1)		
a) yes	X	
b) no		

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 Latvian Law "Administrative violation codex" set national rules on penalties applicable to infringements of the provisions of biosafety framework.

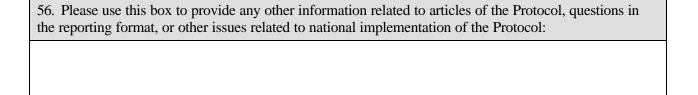
Article 26 – Socio-economic considerations

socio-economic considerations arising from the impact of living modified organisms or	ng this reporting period your country has taken a decision on import, did it take into account omic considerations arising from the impact of living modified organisms on the conservation table use of biological diversity, especially with regard to the value of biological diversity to and local communities? (Article 26.1)	
a) yes – significant extent		
b) yes – limited extent		
c) no		
d) not a Party of import	X	
52. Has your country cooperated with other Parties on research and information exchange conomic impacts of living modified organisms, especially on indigenous and local co (Article 26.2)	•	
a) yes – significant extent		
b) yes – limited extent		
c) no	X	
53. Please provide further details about your responses to the above questions, as well as description 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 other Parties or received financial resources from other Parties or financial institutions, 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	
Please provide further details about your response to the above question, as well as description of ar country's experiences, including any obstacles or impediments encountered:	
Information included in 41.point.	

Other information



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:

There were no problems to interpret the wording of the above- mentioned questions of this questionnaire.