

*Origin of report*

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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 was prepared in the Ministry of Environmental Protection of Ukraine using material from the Ministry of Health Protection, the Ministry of Education and Science, the Ministry of Agrarian Policy, the Ukrainian Academy of Agrarian Sciences and the National Academy of Sciences.

The report was prepared by authorized officials of the Ministry of Environmental Protection of Ukraine as well as scientific colleagues who are specialists in the realm of genetic engineering and current biotechnology.

### *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):

As at September 1, 2005, in Ukraine, the Biosafety Clearing-House is just beginning to be created.

The basic obstacles to the Biosafety Clearing House being given information, in spite of the availability of access to the Internet and to computer technology, are related to the lack of financial resources that are essential for keeping the established units that answer for the functioning of the Ukrainian Biosafety Clearing House to remain within the structure of the Ministry.

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>Even before the Cartagena Protocol came into force, there were laws in Ukraine that contained the general requirements on observing ecological safety, which also take living modified organisms into account.</p> <p>For now, the decision was made that the Ministry of Environmental Protection of Ukraine would temporarily be responsible for performing the functions of a national coordination centre responsible for cooperation within the framework of the Cartagena Protocol.</p> <p>In Ukraine, a project has been worked up on a Government program concept on the safety of living modified organisms as well as a draft of this same government program. These documents determine the basic aspects of the government's policy in the realm of LMO safety as well as the legal, organizational and financial-economic mechanisms for its implementation.</p> <p>The Parliament of Ukraine is reviewing draft legislation that has been tabled "On the government system of biosafety given the creation, testing and actual use of genetically modified organisms".</p> <p>As at September 1, 2005, Ukrainian legislation contains a series of standards that can be used for regulating different procedural matters that relate to living modified organisms. These include:</p> <ul style="list-style-type: none"> <li>- Article 7 of Ukrainian Legislation, N<sup>o</sup> 45/95 VP, dated February 9, 1995, "On ecological testing" identifies as one of the goals of ecological testing as being documentation on the introduction of technology which could lead to negative influences on the condition of the environment;</li> <li>- Article 51 of Ukrainian Legislation, N<sup>o</sup> 152-IV, dated December 13, 2001, "On the animal kingdom" which contains the proposition according to which the development of genetically modified organisms should only take place if ecological testing by the government leads to positive results, and a ban on the use of these organisms in the absence of such results;</li> <li>- Article 25 of Ukrainian Legislation, N<sup>o</sup> 4004-XII, dated February 24, 1994, "On ensuring the health and epidemiological well-being of the population" provides for the procedures of health/epidemiological examinations when biological resources are used;</li> <li>- Ukrainian Legislation N<sup>o</sup> 771/97-VR, dated December 23, 1997, "On the quality and safety of food products and raw foodstuffs" contains a proposition regarding the necessity of having warning mechanisms regarding the health of those who use food products and raw foodstuffs</li> </ul>	

(the obligatory labeling of products that contain LMOs, government registration, certification, etc.);

- Article 25 of Ukrainian Legislation, N° 1264-XII, dated June 25, 1991, “On safeguarding the environment” contains the proposition according to which information regarding genetically modified organisms falls under the category of ecological information;
- Ukrainian Act N° 2657-12, dated July 22, 2005, “On Information” defines the procedure and mechanism for accessing information, including ecological information;
- The Ukrainian President’s decree N° 672/2004, dated June 23, 2004, “On the Interdepartmental Commission on Biological and Genetic Safety under the Council of National Safety and Defense of Ukraine” created a joint consultative body whose functions include the development of proposals on establishing priorities of the government’s policies in the area of biological and genetic safety;
- A resolution by the Ukraine Cabinet of Ministers, N° 1304, dated August 17, 1998, “Confirming that the temporary order regarding the importation, government testing, registration and use of transgenic types of plants in Ukraine be maintained” affirms the order for studying the question and the decision-making regarding their importation onto Ukrainian territory and the future use of transgenic types of plants;
- A resolution by the Ukraine Cabinet of Ministers, N° 440 dated June 20, 1995, “On affirming the Order for receiving permission for the production, preservation, transportation, use, burial, destruction and utilization of poisonous materials, including products of biotechnology and other biological agents” determines the enumeration of biotechnological products that are dealt with by the procedure for receiving corresponding permits;
- A resolution by the Ukraine Cabinet of Ministers, N° 1182, dated September 19, 2002, “On affirming the Statute regarding the Government office on safeguarding rights regarding plant types” contains the proposition according to which the Government department provides an examination of the types of plants in Ukraine to verify whether they contain genetic modification, including at the time of certification of plant types that are brought onto the territory of Ukraine or being taken from the territory of Ukraine.

***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	
b) no	
c) not applicable – not a Party of export	x

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

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	
c) not applicable – not a Party of export	x
6. 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
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:	
During the reporting period, Ukraine was not a Party of export of LMOs intended for release into the environment.	
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:	
During the reporting period, Ukraine did not make any decisions regarding the importation of LMOs intended for release into the environment.	

***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	
b) no	x
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	
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 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:	
During the reporting period, Ukraine was not a Party of export of LMOs intended for direct use for food or feed or for processing.	
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:	
During the reporting period, Ukraine was not a Party of import of LMOs intended for direct use as food or feed, or for processing.	

***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:
During the reporting period, Ukraine did not use the simplified procedure as stated in Article 13 of the Cartagena Protocol on Biosafety.

***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:
During the reporting period, Ukraine did not enter into bilateral, regional or multilateral agreements or arrangements.

***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	
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 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	
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	
b) no	x
20. Has your country adopted appropriate measures to prevent unintentional transboundary movements of living modified organisms? (Article 16.3)	
a) yes	
b) no	x
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)	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:	
<p>At the present time, we are only defining the means of developing the appropriate mechanisms, measures and strategies for regulating, reducing and controlling the risks when LMOs are used. Work has started on creating a centre for tracing LMOs.</p> <p>Meeting these requirements is being held up by the absence of a special law on the biosafety of LMOs.</p>	

***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:	
<p>In Ukraine, there are no identified cases of occurrences in the area under its jurisdiction that led, or could have led, to the unintentional transboundary movement of a living modified organism.</p>	

***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	
b) no	x
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>Ukrainian Legislation “On the quality and safety of food products and raw food materials” contains a proposition regarding measures on labeling, government registration, certification, etc. of LMOs.</p> <p>It is assumed that matters regarding requirements for documentation that accompanies the LMOs, including the requirements for indicating the intended use of the LMOs, the safe processing, storage, transportation, use, etc. will be regulated by a special legislative act (draft of Ukrainian Legislation “On the government system of biosafety during the creation, testing and actual use of genetically modified organisms” – which is being reviewed by the Ukrainian Parliament), as well as its attendant standard legislative acts.</p>	

**Article 19 – Appropriate national bodies and national coordination centres**

The Ministry of Environmental Protection has been identified as the government body that will temporarily fulfil the functions of a national coordination centre within the framework of the Cartagena Protocol on Biosafety.

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

The creation of the Biosafety Clearing House in Ukraine is in its first stages.

To get information in accordance with Article 20 of the Cartagena Protocol on Biosafety, one must get in touch with the Ministry of Environmental Protection of Ukraine.

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:

The Ukraine does not have previous experience in this area.

**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:

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:

Ukraine was not a Party of export during this 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)	
c) no – capacity-building needs remain unmet (please give details below)	x
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)	
c) no – capacity-building needs remain unmet (please give details below)	x
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)	x
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.	
Ukraine did not collaborate in these fields with other countries or organizations.	

***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 the public in the decision-making process regarding living modified organisms and make the results of such decisions available to the public? (Article 23.2)	
a) yes – fully	
b) yes – limited extent	x
c) no	
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	x
c) no	
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:	
Seminars, conferences and round tables were conducted, with the participation of NGOs, in several regions of Ukraine, at which questions regarding the use of LMOs were discussed. Information was also disseminated through the Internet.	

***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:	
There were no transboundary movements of living modified organisms through the territory of Ukraine.	

***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	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:	
Ukrainian legislation provides for conducting obligatory government ecological testing, health/epidemiological testing and scientific/technical testing before using LMOs.	

**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	
c) no	
d) not a Party of import	x
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	
c) no	x
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:	
Ukraine was not a Party of import. However, Ukraine considers the necessity for assessing the socio-economic consequences related to living modified organisms as being extremely important.	

**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	x
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:	
As for international technical help, Ukraine received financing to implement the project UNEP-GEF “The development of a framework on biosafety for Ukraine”.	

*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:

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*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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