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

Origin of report

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| Date of submission: | | |
| 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 process of preparing this report is as follows:

1. Researches and surveys undertaken prior to the preparation of the report

Upon request by the Biosafety Administration Office of the State Environmental Protection Administration of China (hereafter referred to as SEPA) in Dec 2006, the Nanjing Institute of Environmental Sciences (hereafter referred to as NIES) has since started preparing the First National Report on the Implementation of the Cartagena Protocol (hereafter referred to as the first national report). Some initial studies and surveys were undertaken and a work plan drafted in preparation for work on this report.

2. Coordination meetings organized, the project launched and responsibilities identified for each

department and institution involved

A meeting of the Coordination Group for CBD implementation was held at SEPA in Feb 2007, during which the work plan for preparing the first national report was adopted and responsibilities and tasks for each department and institution involved were identified. At the same time, SEPA invited all relevant departments and institutions to recommend their specialists for the compilation of the first national report. All departments have provided positive support and recommended their specialists as requested.

3. Information collected and analyzed for drafting the report

The expert group, which is composed of specialists recommended by the following ministries and institutions, had its first meeting on Feb 27, 2007 and identified specific responsibilities and work as per the work plan adopted.

Ministry of Foreign Affairs

Ministry of Science and Technology

Science and Technology Development Centre of the Ministry of Agriculture

Plant Protection Institute of Chinese Academy of Agricultural Sciences

Institute of Animal and Plant Quarantine

Chinese Academy of Inspection and Quarantine

Institute of Zoology of Chinese Academy of Sciences

Chinese Academy of Forest Sciences

China Academy of Chinese Medical Sciences

Fudan University (representing the Ministry of Education)

State Intellectual Property Office

Nanjing Institute of Environmental Sciences

After the meeting, specialists of different departments and institutions started researches and surveys at their own departmental or sectoral level, collected information concerning the actions taken, achievements made, experience gained and lessons learned in the implementation of the articles of the Protocol and analyzed the difficulties encountered. They also identified the needs for capacity building and drafted departmental or sectoral reports, on the basis of which the draft national report was prepared.

4. Expert group meeting called to discuss and modify the first national report

On April 5, 2007 the second expert group meeting was called in Beijing to discuss and revise the drafts prepared by different departments and institutions. A draft report was compiled for reviews and comments.

5. Comments solicited from different departments and institutions

In May 2007, all member departments of the Coordination Group for CBD Implementation were requested to comment on the draft report with a view to further improving and revising the report.

6. A meeting of the Coordinating Group called to discuss and review the first national report

On July 4, 2007, a meeting of the Coordination Group for CBD Implementation was called in Beijing, at which the first national report was reviewed and adopted.

7. The first national report translated into English and submitted to the Secretariat

Based on the Coordination Group's comments and suggestions, the first national report was further revised, improved and submitted for approval. The first national report was translated into English and has been submitted to the Secretariat.

Departments participating in the preparation of the report:

State Environmental Protection Administration (SEPA)

Ministry of Science and Technology (MOST)

Ministry of Education (MOE)

Ministry of Agriculture (MOA)

State Forestry Administration (SFA)

General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)

Chinese Academy of Sciences (CAS)

In preparing this report references have been made to the following:

- [1] State Environmental Protection Administration. National Biosafety Framework of China. Beijing: China Environmental Science Press, 2000
- [2] Compiled by Biosafety Office of SEPA. The proceedings of the Workshop on "Implementation of National Biosafety Framework of China". Beijing: China Environmental Science Press, 2005
- [3] Compiled by Ministry of Agriculture. A collection of rules and regulations on biosafety management of agricultural genetically modified organisms. Beijing: China Agriculture Press, 2005
- [4] Order No. 20 of State Forestry Administration, Implementation Regulations on Examination and Approval of Forest Genetic Engineering Activities(effective from July 1, 2006)
- [5] General Administration of Quality Supervision, Inspection and Quarantine, The Measures for Inspection

and Quarantine of Import & Export of LMOs (effective from May 24, 2004)

- [6] Documents of General Administration of Quality Supervision, Inspection and Quarantine related to GMO issues (2003 2007).
- [7] Compiled by State Forestry Administration. The Technical Procedure of Risk Assessment on Genetically Modified Forest Plants and Their Products and Implementation Regulation on Packaging and Labelling of Tree Seeds"

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):

China is in the initial stage of developing and establishing the Biosafety Clearing-House Mechanism. Responsible government authorities release through their own websites information related to the living modified organisms and their products. Main problem at present is that an information exchanging mechanism between different government departments is not quite in place and information exchange among different departments is not very smooth. Besides, ways and channels by which relevant information is submitted to BCH are not completely clear.

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

| Type of information | Information | Information | Information |
|---|-------------------|-------------------|----------------|
| | exists and is | exists but is not | does not exist |
| | being provided to | yet provided to | /not |
| | the Biosafety | the Biosafety | applicable |
| | Clearing-House | Clearing-House | |
| a) Existing national legislation, regulations and | X- Regulations on | | |
| guidelines for implementing the Protocol, as well | Safety of | | |
| as information required by Parties for the | Agricultural | | |
| advance informed agreement procedure | Genetically | | |
| (Article 20.3(a)) | Modified | | |
| | Organisms, | | |
| | Regulations on | | |
| | Risk Assessment | | |
| | of Agricultural | | |
| | LMOs, | | |
| | Regulations on | | |
| | Import of | | |
| | Agricultural | | |
| | LMOs, | | |
| | Regulations on | | |
| | Labelling of | | |
| | Agricultural | | |
| | LMOs, | | |
| | Regulations on | | |
| | Approval of | | |
| | Agricultural | | |
| | LMOs for | | |
| | Processing, | | |
| | Measures for | | |
| | Inspection and | | |
| | Quarantine of | | |
| | Import and Export | | |

| | | | 1 |
|--|-------------------------|-------------------|----------------|
| | of LMOs, Regulations on | | |
| | Examination and | | |
| | Approval of | | |
| | Forest Genetic | | |
| | Engineering | | |
| | Activities | | |
| b) National laws, regulations and guidelines | X- Regulations on | | |
| applicable to the import of LMOs intended for | Safety of | | |
| direct use as food or feed, or for processing | Agricultural | | |
| (Article 11.5); | LMOs | | |
| c) Bilateral, multilateral and regional agreements | | | Tr or |
| and arrangements (Articles 14.2, 20.3(b), and | | | X- Not exist |
| 24.1); | | | |
| d) Contact details for competent national | X- SEPA is the | | |
| authorities (Articles 19.2 and 19.3), national | national focal | | |
| focal points (Articles 19.2 and 19.3), national | point, currently | | |
| emergency contacts (Article 17.2 and 17.3(e)); | the national | | |
| emergency contacts (Article 17.2 and 17.5(e)), | authority | | |
| e) In cases of multiple competent national | untity | | |
| authorities, responsibilities for each (Articles | | | X- To be |
| 19.2 and 19.3); | | | determined in |
| · · | | | the future |
| f) Reports submitted by the Parties on the | | | X- Not exist |
| operation of the Protocol (Article 20.3(e)); | | | |
| | | | |
| g) Occurrence of unintentional transboundary | | | X- Not exist |
| movements that are likely to have significant | | | A- Not exist |
| adverse effects on biological diversity | | | |
| (Article 17.1); | | | |
| Type of information | Information | Information | Information |
| | exists and is | exists but is not | does not exist |
| | being provided to | yet provided to | /not |
| | the Biosafety | the Biosafety | applicable |
| | Clearing-House | Clearing-House | ** |
| h) Illegal transboundary movements of LMOs | | | W. Nick of the |
| (Article 25.3); | | | X- Not exist |
| | | | |
| i) Final decisions regarding the importation or | X- Part of | | |
| release of LMOs (i.e. approval or prohibition, | information is | | |
| any conditions, requests for further information, | provided through | | |
| extensions granted, reasons for decision) | http://www.agri.g | | |
| (Articles 10.3 and 20.3(d)); | ov.cn/xzsp_web/ | | |
| (7)) | and | | |
| | http://www.stee.a | | |
| | gri.gov.cn/biosafet | | |
| | <u>y/spxx/</u> by | | |
| | Ministry of | | |
| | Agriculture on | | |
| | final decision on | | |
| | approved | | |

| | import/release of LMOs | |
|---|--|-------------------|
| j) Information on the application of domestic regulations to specific imports of LMOs (Article 14.4); | | X- Not applicable |
| 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- Information of approving by MOA on import of agricultural LMOs for processing is provided by the Ministry of Agriculture through http://www.stee.agri.gov.cn/biosafety/spxx/t20051107488946.htm | |
| 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- Information of approvals by MOA on import of agricultural LMOs for processing is provided by the Ministry of Agriculture through http://www.stee.agri.gov.cn/biosafety/spxx/t20051107488946.htm | |
| 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- MOA provides the approval procedure for applying for import of agricultural LMOs through http://www.agri.g ov.cn/xzsp_web/ | |
| n) Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12.1); | | X- Not exist |
| o) LMOs granted exemption status by each Party (Article 13.1) | | X- Not exist |

| 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- Not exist |
|---|--------------|
| 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- Not exist |

Article 2 – General provisions

| 3. Has your country introduced the necessary legal, administrative and other measures for implementation of the Protocol? (Article 2.1) | |
|---|---|
| a) full domestic regulatory framework in place (please give details below) | |
| b) some measures introduced (please give details below) | X |
| c) no measures yet taken | |

4. Please provide further details about your response to the above question, as well as description of your country's experiences and progress in implementing Article 2, including any obstacles or impediments encountered:

While developing modern biotechnology, China has been paying very close attention to the potential adverse impacts brought by genetically modified organisms on the environment, biodiversity and human health. In national-level research projects, topics particularly for biosafety are developed to study on risk assessment and management of LMOs. In 1999, China released "Biosafety Framework of China". The framework development was a global pilot project of UNEP in this regard and its implementation in China was coordinated by SEPA, involving the Ministry of Agriculture, the Ministry of Science and Technology, the Ministry of Education, the State Forestry Administration, Chinese Academy of Science, State Food and Drug Administration. The Framework presents the national biosafety policy systems, relevant legal and statutory systems, technical standard systems and needs for capacity building, taking into account the international trends of biosafety management and the actual situation of biotechnology development in China.

Safety of LMOs is a complicated issue, involving a number of aspects of environment, health, morality and ethics, social, economic and scientific and technological development. That is why biosafety management involves a number of government departments, whose current responsibilities are outlined below.

The State Environmental Protection Administration (SEPA) has been coordinating participation in the international negotiations related to the Biosafety Protocol. Since the Protocol came into effect, SEPA has brought together relevant departments and specialists in thematic studies and research on national legislation, administration and capacity building. The Biosafety Administration Office has been set up as the national focal point for the Protocol and BCH to coordinate external communication and domestic environmental management related to biotechnological issues .

The Ministry of Agriculture (MOA) has set up the Biosafety Office of Agricultural LMOs, which is responsible for nation-wide supervision and inspection of agricultural LMOs, such as research, experiment, production, processing and import/export etc.

The General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) has set up a biosafety unit under the division of animal/plant quarantine and supervision, which is responsible for inspection and quarantine of the import and export of LMOs.

The State Forestry Administration (SFA) has set up a Safety Committee for Forest Genetic Engineering and Forestry Biosafety Office, which is responsible for the safety supervision of forest LMOs.

The Ministry of Health (MOH) is responsible for the safety supervision of genetically modified food.

The Ministry of Science and Technology (MOST) has set up a National Centre for Biotechnology Development, which is responsible for the biotechnological R & D

The Ministry of Education (MOE) is responsible for organizing relevant universities and institutions to study on biotechnology development and safety assessment.

The Chinese Academy of Sciences (CAS) has made studies on biotechnological research/development and safety assessment.

Since it promulgated the first law on biosafety management in 1993, China has during over 10 years gradually promulgated some regulations regarding biosafety and LMOs. These regulations have laid down relevant rules in different aspects of LMOs and they play a very important role in China's biosafety management. The regulations on biosafety and LMOs that China has adopted so far are mainly the following:

- Regulations on Risk Management of Genetic Engineering (1993);
- Regulations on Approval of New Biological Products(1999);
- Regulations on Safety of Agricultural LMOs (2001);
- Regulations on Risk Assessment of Agricultural LMOs (2001);
- Regulations on Import of Agricultural LMOs (2001);
- Regulations on Labelling of Agricultural LMOs (2001);
- Management Procedures for Risk Assessment of Agricultural LMOs (2002);
- Management Procedures for Import of Agricultural LMOs (2002);
- Review and Approval Procedures for Labelling of Agricultural LMOs (2002);
- Measures for Inspection and Quarantine of Import and Export of LMOs (2004);

- Regulations on Risk Management of Pathogenic Microorganism for Laboratory Use (2004);
- Regulations on Examination and Approval of Forest Genetic Engineering Activities (2006);
- Regulations on Approval of Agricultural LMOs for Processing (2006).

Though the above regulations have provided an important legal basis for biosafety management in China, compared with the actual needs for supervision of LMOs and the biotechnological development, China's legal systems in this regard are not adequate and cannot fully meet needs for biosafety management. As biotechnology develops and improves, China will further improve its legal systems and safety management mechanisms on LMOs, so that China could better implement relevant provisions in the Biosafety Protocol.

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 | X | |
| b) no | | |
| 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 jurisdiction of your country? (Article 8.2) | 1/ under the | |
| 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 Parreview a decision it had made under Article 10 on the grounds specified in Article 12. | | |
| 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 frame by Article 9.2(c). | eworks as allowed | |
| a) yes | X | |

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

| b) no | |
|--|--|
| c) not applicable – no decisions taken during the reporting period | |

10. If your country has been a Party of export of LMOs intended for release into the environment during the reporting period, please describe your experiences and progress in implementing Articles 7 to 10 and 12, including any obstacles or impediments encountered:

China has not exported any LMOs during the reporting period and is not a Party of export of LMOs.

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:

Based on the Regulations on Risk Management of Agricultural LMOs, the Regulations on Risk Assessment of Agricultural LMOs and the Regulations on Import of Agricultural LMOs, the Ministry of Agriculture is responsible for examining and approving agricultural LMOs that will be exported to China. Results are given within time limit specified in the Protocol and made available on the website of MOA.

In the Measures for Inspection and Quarantine of Import and Export of LMOs, requirements are specified for the quarantine of genetically modified animals/plants and their products, genetically modified microorganisms and their products and genetically modified foodstuff. Only those that have successfully passed the transgenic tests can be allowed into the country. The Regulation on Examination and Approval of Forest Genetic Engineering Activities specifies the requirements for applications of importing genetically modified trees for research, experimentation, production or business operation purposes.

Main obstacles that China faces include inadequate information sharing of imported LMOs, shortage of testing technical standards, reference standards and reference materials.

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 |
| b) not yet, but under development | |
| c) no | |
| d) not applicable (please give details below) | |
| 13. Has your country indicated its needs for financial and technical assistance and capacity-building in respect of living modified organisms intended for direct use as food or feed, or for processing? (Article 11.9) | |
| a) yes (please give details below) | |
| b) no | X |

| c) not relevant | |
|--|-------------------|
| 14. Did your country take decisions regarding import under domestic regulatory fram by Article 11.4? | eworks as allowed |
| a) yes | X |
| b) no | |
| c) not applicable – no decisions taken during the reporting period | |

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

Up to now China has not exported any LMOs and has no experience in this regard, nor has it encountered corresponding obstacles.

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:

China is importing annually scores of million tons of genetically modified soybean and corn for processing and for animal feed. The relevant government department is accepting, reviewing and approving the imports of LMOs intended for direct use as food of feed, or for processing as per the Regulations on Risk Management of Agricultural LMOs, the Regulations on Import of Agricultural LMOs and the Measures for Inspection and Quarantine of Import and Export of LMOs, so as to maintain normal imports and trading. For exporters of LMOs intended for direct use as food of feed, or for processing, all the regulations and statutes require detailed and accurate information.

As of now decision making is largely concentrated in MOA and AQSIQ for imports of LMOs intended for direct use as food of feed, or for processing. Main problems are technical ones with risk assessment, defining threshold for limit, effective identification and traceability.

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 X | |
| b) no | |
| 10. If your country, has used the simulified are added during the grounding applied on if you have been | |

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:

In the Regulations on Risk Management of Agricultural LMOs and relevant Regulations, the circumstances where the simplified procedures will apply are clearly provided. And for all import applications applicable to simplified procedures there are clear-cut procedures of accepting and

approving. In Sep 2004, MOA issued the Bulletin No 410, which provides the ecological area-based approval procedure and simplified procedure for processing applications for the Biosafety Certificate (for commercialization) of genetically modified pest-resistant cotton. Scope of application covers: if a transgenic pest-resistant cotton strain is already given the Biosafety Certificate (for commercialization), and can be propagated in the same ecological area, then one-time application can be good for production and the Biosafety Certificate (for commercialization) for a number of provinces (regions, municipalities) in the same ecological area. In the case of transgenic pest-resistant cotton strain already issued with the Biosafety Certificate (for commercialization) and is meant for use in cross boundary ecological areas, one may directly apply for the Biosafety Certificate (for commercialization) of one province (region, municipality) of the ecological area for one strain. For new transgenic pest-resistant cotton strain cultivated by using transgenic pest-resistant cotton strain already awarded with Biosafety Certificate (for commercialization), one application for the Biosafety Certificate (for commercialization) may cover a whole province (region, municipality) for one strain.

In Oct 2006, MOA issued Bulletin No 736. For agricultural LMOs already awarded with biosafety certificate (for commercialization and for import), which the applicant wishes to continue to use in the original approved area after the certificate expires, the simplified procedure provided in the bulletin will apply. For transgenic pest-resistant cotton strains already with Biosafety Certificate (for commercialization), application will be subject to the procedure specified in the Bulletin No 410 issued by MOA.

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? | |
|--|--|
| | |
| X | |
| rrangements, or if enting Article 14 | |
| As of now China has not entered into any bilateral, multilateral regional agreements or arrangements for | |
| | |
| r | |

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 | X |
| b) no (please clarify below) | |

| c) not a Party of import / no decisions taken under Article 10 | |
|--|---|
| 22. If yes to question 21, did you require the exporter to carry out the risk assessment | ? |
| a) yes – in all cases | X |
| 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 | |
| 23. If you took a decision under Article 10 during the reporting period, did you require bear the cost of the risk assessment? (Article 15.3) | e the notifier to |
| a) yes – in all cases | X |
| 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 | |
| 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) | |
| | |
| details below) | ndary movements |
| details below) c) no 25. Has your country adopted appropriate measures to prevent unintentional transbour | ndary movements |
| details below) c) no 25. Has your country adopted appropriate measures to prevent unintentional transbour of living modified organisms? (Article 16.3) | - |
| details below) c) no 25. Has your country adopted appropriate measures to prevent unintentional transbour of living modified organisms? (Article 16.3) a) yes – fully adopted b) not yet, but under development or partially adopted (please give further | - |
| details below) c) no 25. Has your country adopted appropriate measures to prevent unintentional transbour of living modified organisms? (Article 16.3) a) yes – fully adopted b) not yet, but under development or partially adopted (please give further details below) | X er imported or |
| details below) c) no 25. Has your country adopted appropriate measures to prevent unintentional transbour of living modified organisms? (Article 16.3) a) yes – fully adopted 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 locally developed, undergoes an appropriate period of observation commensurate with | X er imported or |
| details below) c) no 25. Has your country adopted appropriate measures to prevent unintentional transbour of living modified organisms? (Article 16.3) a) yes – fully adopted 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 locally developed, undergoes an appropriate period of observation commensurate with generation time before it is put to its intended use? (Article 16.4) | X er imported or a its life-cycle or |
| details below) c) no 25. Has your country adopted appropriate measures to prevent unintentional transbour of living modified organisms? (Article 16.3) a) yes – fully adopted 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 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 | X er imported or a its life-cycle or |
| details below) c) no 25. Has your country adopted appropriate measures to prevent unintentional transbour of living modified organisms? (Article 16.3) a) yes – fully adopted 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 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) | X er imported or a its life-cycle or |
| details below) c) no 25. Has your country adopted appropriate measures to prevent unintentional transbour of living modified organisms? (Article 16.3) a) yes – fully adopted 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 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) | X er imported or a its life-cycle or 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:

Risk assessment and risk management of LMOs is the important ground on which government departments base their approval on scientific research, environmental release and commercialization of LMOs, and is key content of implementation of relevant articles of the Protocol. So to make effective risk assessment on LMOs, and monitoring of their impacts will serve as an impetus to biosafety management and development of genetic engineering.

Risk assessment and risk management of LMOs require the concerted efforts of all relevant government departments. The efforts for key relevant departments to strengthen their capabilities of risk assessment and risk management of LMOs are described below in detail:

(1) SEPA

As the national focal point for the Protocol and the department responsible for national environmental safety management related to biotechnology, SEPA has organized all relevant departments in rounds of international negotiations related to the Protocol. Since the Protocol entered into force, SEPA has organized relevant departments and experts in the implementation and related negotiations, drawing up the national plan of protocol implementation and undertaking studies on related legislation, risk assessment, risk management and capacity building. In line with the level of LMOs research and development, SEPA has, step by step, laid down the technical specifications for LMOs risk assessment and risk management, enhanced its effort in building capacities for risk assessment/management and managed well environmental safety of LMOs.

(2) MOA

MOA is the government department directly responsible for the agricultural LMOs. MOA issued in 2001 several regulations for agricultural LMOs and established technical supporting systems for safety supervision on agricultural LMOs. Over the past few years risk assessment on agricultural LMOs has been gradually practiced and regulated, but needs to be further improved as modern biotechnology develops in China. MOA has its unique advantage in this area. It has a better and more updated understanding of the LMOs research and development. And it also has advantage in environmental assessment on pests of agricultural LMOs.

(3) **MOH**

The Ministry of Health has the function of assessing the health risks of LMOs and their products. The

Regulation on Genetically Modified Food covers safety assessment and nutritional quality evaluation of genetically modified food. However this statute has not been actually implemented. Current work of MOH is mainly cooperating with MOA in health assessment of LMOs that are being intended for commercialization, and making tests and analysis of their hypersensitivity, toxicity and nutrients.

(4) SFA

The State Forestry Administration is the government department directly responsible for the guidance and supervision of the research, testing, production, utilization, approval of import/export that are related to genetically modified forests and trees. SFA has for this purpose, set up Safety Committee for forest genetic engineering and Forestry Biosafety Office. SFA has issued the Regulations on Examination and Approval of Forest Genetic Engineering Activities, which specifies that importing transgenic tree species from abroad for purposes of research, experiment, production and business transactions must be registered, requiring that material /proof should be provided that no harm or adverse effect has been found through scientific tests on human beings, animals and plants, micro organisms and ecological environment of the exporting country / region and that risk assessment should be made the same way as with transgenic tree species in China.

(5) AQSIQ

According to the Safety Management Regulations on Genetic Engineering and the Measures for Inspection and Quarantine of Import and Export LMOs, AQSIQ carries out inspection and quarantine of LMOs and their products which have been import/export and transit by the test on transgenic compositions in order to safeguard transboundary movement of LMOs while protecting China's ecological environment, agriculture/forestry production and the health of human beings and animals.

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 chave led, to an unintentional transboundary movement of a living modified organism that had, or chave 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 affect potentially affected States for the purposes specified in Article 17.4? | ould y, |
|---|------------|
| a) yes – all relevant States immediately | |

| 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:

China is a responsible country and has set up a series of laws and regulation in a great effort to eliminate illegal and unintentional transboundary movement of LMOs. MOA, as required by the State Council, has drawn up the Contingency Plans for Agricultural LMOs Emergencies, providing for contingency mechanisms and emergency measures for unexpected events of LMOs.

| 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 liv organisms 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 for information? (Article 18.2(a)) | 'may contain' living |
| a) yes | |
| b) not yet, but under development | |
| c) no | X |
| 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:

In the process of safety management on transboundary movement of LMOs, China has followed all relevant standards and technical specifications by ISO and CAC. The Regulations on Risk Management of Agricultural LMOs, the Regulations on Labelling of Agricultural LMOs, the Measures for Inspection and Quarantine of Import and Export LMOs have all served to regulate the transportation, packing and labelling of LMOs.

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:

In accordance with the Protocol, China has set up national biosafety clearing-house mechanism http://www.Biosafety.gov.cn/. Main focus of national BCH is releasing integrated biosafety information in China, including information of economic, social, environmental aspects of LMOs, government policy, laws and statutes, rules and regulations and safety management. At the same time other government departments responsible for LMOs management have set up their respective websites: for MOA is http://www.stee.agri.gov.cn/Biosafety/, to provide information about government policy, laws and statues related to agricultural LMOs, relevant technical standards, guidance for admin procedures etc and to regularly update the list of Biosafety Certificates (for commercialization) of agricultural LMOs in provinces(regions, municipalities) and approvals of import of agricultural LMOs for processing; for AQSIQ is http://dzwjyjgs.aqsiq.gov.cn/zjygl/ and http://www.apqchina.org/gmoindex.asp, to release rules and regulations concerning inspection and quarantine of LMOs in/ out of China and answering questions of public concern, also playing the role as a node of BCH.

However there are certain inadequacies in the current biosafety information sharing system in China:

- 1) Biosafety information is scattered in different departments, among which the information communication mechanism is yet to be improved
- 2) Inadequate participation of the public and lack of media exposure, information resources are not fully used.

$Article\ 21-Confidential\ information$

| 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 noting information submitted under the procedures of the Protocol or required by the Party of the advance informed agreement procedure that was to be treated as confidential? (Articles) | f import as part of |
| a) yes | X |
| If yes, please give number of cases | 25 |
| b) no | |
| c) not applicable – not a Party of import / no such requests received | |
| 39. If you answered yes to the previous question, please provide information on your including description of any impediments or difficulties encountered: | experience |
| The departments responsible for risk management of LMOs have strictly followed requirements in relevant laws and regulations in protecting the legitimate rights of applicants. Art 27 of the Regulations on Risk Assessment of Agricultural LMOs stipulates, "staff at approving units accepting the agricultural LMOs application and specialists participating in the assessment shall keep the applicant's technical and business secrets, those that have relations of interest with the applicant or his close relatives shall not get involved in the case". | |
| 40. If you were a Party of export during this reporting period, please describe any implementation of the requirements of Article 21: | |
| China has not yet exported any LMOs. | |
| 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 | |
| c) not applicable – not a developed country Party | X |
| 42. If yes to question 41, how has such cooperation taken place: | |
| | |

| 43. If a developing country Party, or Party with an economy in transition, during this your country contributed to the development and/or strengthening of human resources capacities in biosafety for the purposes of the effective implementation of the Protoco developing country Party or Party with an economy in transition? | and institutional |
|---|-------------------|
| a) yes (please give details below) | X |
| b) no | |
| c) not applicable – not a developing country Party | |
| 44. If yes to question 43, how has such cooperation taken place: | |
| In 2006 the Ministry of Commerce organized "international training course on application biotechnology in food industry", providing training for managerial/technical personned developing countries' government / scientific/technological institutions and those from | l of other |
| 45. If a developing country Party or a Party with an economy in transition, have you be cooperation for technical and scientific training in the proper and safe management of 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 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) | 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 be cooperation for technical and scientific training for enhancement of technological and 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:

The Chinese government has attached great importance to the capability building of biosafety management. Since the Protocol was signed and ratified, different government departments responsible for biosafety management have invested human resources, material and financial efforts and through cooperation with international organizations and other countries, into the capacity building in such fields as LMOs risk assessment and risk management, and safety control in food and environment. Main indications of such efforts are: a series of technical standards in biosafety management and testing manuals, setting up of laboratories of LMOs research, environmental monitoring and composition inspection and purchase of relevant facilities and equipment, holding of seminars and training courses on LMOs risk assessment and biosafety management.

However, limited by human and financial resources, China has its inadequacies in biosafety capability building. China hopes to take an active part in the relevant international biotechnological management, LMOs risk assessment and risk management, and their related research and training to enhance the capacity of its research/management personnel. China also hopes to undertake long-term and effective cooperation with relevant institutions in countries with well-developed biotechnology and improve its capacities and mechanisms for biosafety management.

Article 23 – Public awareness and participation

| 49. Does your country promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health? (Article 23.1(a)) | |
|---|---|
| a) yes – significant extent | |
| b) yes – limited extent | X |
| c) no | |
| 50. If yes, do you cooperate with other States and international bodies? | |
| a) yes – significant extent | |
| b) yes – limited extent | 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 | |
| b) yes – limited extent | X |
| c) no | |

52. Does your country, in accordance with its respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and make the results of such decisions available to the public? (Article 23.2)

| a) yes – fully | |
|-------------------------|---|
| b) yes – limited extent | X |
| c) no | |

53. Has your country informed its public about the means of public access to the Biosafety Clearing-House? (Article 23.3)

| a) yes – fully | |
|-------------------------|---|
| b) yes – limited extent | X |
| c) no | |

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

The National Biosafety Framework of China jointly issued by SEPA, MOA, MOST, MOE, SFA, CAS and SFDA (State Food and Drug Administration), in its "policy system framework for national biosafety management", has specially mentioned the set-up of the system by which to involve public participation in the biosafety issues, pointing out that "China will set up appropriate mechanism by which the public may participate in biosafety management, i.e. to encourage the public to take part in the biosafety management and in the process of assessing the impacts on environment and to obtain information about modern biotechnology and biosafety management. In the case of environmental release of LMOs, it will be necessary to inform the local residents and organizations concerned".

All relevant government departments responsible for LMOs management will make the latest development and information of LMOs and biosafety management available to the public through websites, news releases and press conferences, and by issuing publicity material, publishing popular science papers and holding seminars, so as to enhance public awareness and to urge the public to participate in the biosafety management. At the same time, mass media of the country also take an active part in the promotion and education of biosafety. In cooperation with the relevant government departments, the mass media provides the public with relevant information of biosafety management through news release, interviews and news reports.

Present status of pubic participation in biosafety issues in China is: the public is quite concerned with the biosafety issues, especially GM-food foodstuff. However the public needs further information and advice.

Article 24 – Non-Parties

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

55. Have there been any transboundary movements of living modified organisms between your country and a non-Party during the reporting period?

| a) yes | X |
|--------|---|

b) no

b) no

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

During the reporting period China has followed the requirements of national laws and regulations to ensure the safe transfer and use of LMOs in the transboundary movements between China and non-parties to the Protocol.

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 transboundary movements of living modified organisms carried out in contravention of 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 | |

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:

In accordance with relevant Chinese laws and regulations clear-cut rules are provided regarding punishment for violations of regulations concerning transboundary movement of LMOs. The Regulations on Risk Management of Agricultural LMOs stipulates in its Article 50: "For imports of agricultural LMOs without permission of the agricultural authorities, the agricultural authorities will order the stop of such import and confiscate what is already imported and the illegal income obtained there from". For illegal income exceeding 100,000 RMB, a fine will be imposed to the amount of over 1 time and below 5 times of the illegal income. In case there is no illegal income or illegal income is below 100,000 RMB, a fine ranging from 100,000 RMB to 200,000 RMB will be imposed". Its Article 51 says "for importing, carrying and sending by mail agricultural LMOs without declaring to Inspection and Quarantine Units at ports, or engaging in transboundary movement of agricultural LMOs without approval by AQSIQ, the Inspection and Quarantine Units at the port or AQSIQ shall give punishments as per rules for quarantine of import/export of animals/plants." The SFA issued the Regulations on Examination and Approval of Forest Genetic Engineering Activities, to forbid illegal transboundary movements of transgenic trees species and lay down specific rules for giving penalties.

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 | X |
| c) no | |
| d) not a Party of import | |

61. Has your country cooperated with other Parties on research and information exchange on any socioeconomic impacts of living modified organisms, especially on indigenous and local communities? (Article 26.2)

| a) yes – significant extent | |
|-----------------------------|---|
| b) yes – limited extent | X |
| c) no | |

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:

Main imports of LMOs to China as of now are GM-Soybeans, GM-cotton, GM-corn and GM-rape. Except for the transgenic cotton which may be used for commercial plantation, all other transgenic crops are used for processing. Foreign R & D companies are importing transgenic crop species for research purposes in small area of environmental release. Risk assessment on imported LMO is in compliance with the Regulations on Risk Assessments of Agricultural LMOs and is important part of risk assessment on ecological safety as well. In recent years China has undertaken researches on the socio-economic impacts by GM-cotton, GM- rice and GM-poplar trees.

For all that China has relatively inadequate research on the socio-economic impacts of LMOs and is facing many obstacles and impediments. On one hand China has complex ecological environment and its economy developed on an imbalanced basis. On the other hand China is short of research staff and inadequate financial support. And thirdly, the rapid development of LMOs is presenting big challenges to the monitoring and management.

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:

During the period of 2003 to 2005 the Chinese government has received from GEF and UNEP a grant of USD 997,400 and implemented the "Project of National Biosafety Framework of China". Up to now China has not provided any other Parties with financial aid.

Other information

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

Comments on reporting format

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

This national report adopts the multiple-choice format with space provided to describe the status of implementation of the Protocol and problems encountered by the Parties since the Protocol entered into force. While this format makes selection of answers easy and convenient, it is difficult to prepare detailed descriptions where all choices selected cannot reflect the actual situations of the Parties. We suggest that the Secretariat, when designing the report format and wording, solicit comments and suggestions from the Parties so as to better reflect the implementation details of that Party.