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

Origin of report

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Submission	
Signature of officer responsible for submitting report:	
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 Swedish Environmental Protection Agency (EPA) was assigned by the Government to prepare the first draft of the report and present it to the Ministry of the Environment.

The authorities responsible for the safe handling of GMOs in Sweden were asked to provide information on their experience with the implementation of the Cartagena Protocol.

The Swedish Work Environment Authority, the Swedish International Development Cooperation Agency, the Swedish Board of Agriculture and the Swedish Chemicals Agency along with the Swedish EPA have contributed to the report.

The Swedish Rescue Services Agency informed they had nothing to contribute.

A draft report was sent to a broad range of stakeholders, including NGOs and other private organisations. Comments were received from the Swedish Work Environment Authority, the Swedish Board of Agriculture, the Swedish Rescue Services Agency, the Swedish Board of Fisheries and the Swedish International Development Cooperation Agency, and these comments were included to a wide extent in the draft submitted to the Swedish Government by the Swedish EPA.

Obligations for provision of information to the Biosafety Clearing-House

1. Several articles of the Protocol require that information be provided to the Biosafety Clearing-House (see the list below). For your Government, if there are cases where relevant information exists but has not been provided to the Biosafety Clearing-House (BCH), describe any obstacles or impediments encountered regarding provision of that information (note: To answer this question, please check the BCH to determine the current status of your country's information submissions relative to the list of required information below. If you do not have access to the BCH, contact the Secretariat for a summary):

Sweden awaits clarification from the European Commission regarding the provisions of Article 15 of EC Regulation No 1946/2003. Article 15 concerns the information to be submitted to the BCH from the EU Member States and the European Commission. The question is if decisions on field trials are covered by Article 15. Awaiting this clarification, Sweden will submit decisions on field trials if there is a possibility that the LMO will be exported as an LMO-FFP. No such decision has been taken during the reporting period.

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

Type of information	*Information exists and is being provided to the Biosafety Clearing-House*	*Information exists but is not yet provided to the Biosafety Clearing-House*	*Information does not exist /not applicable*
a) Existing national legislation, regulations and guidelines for implementing the Protocol, as well as information required by Parties for the advance informed agreement procedure (Article 20.3(a))	X- All is provided, but most is EC regulations.		
b) National laws, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing (Article 11.5);	X- This is provided by the European Commission		
c) Bilateral, multilateral and regional agreements and arrangements (Articles 14.2, 20.3(b), and 24.1);	X- Since Sweden is a member of the EU, all agreements and arrangements involving the EU apply to Sweden and are provided to the BCH by the European Commission		
d) Contact details for competent national authorities (Articles 19.2 and 19.3), national focal points (Articles 19.1 and 19.3), and emergency contacts (Article 17.2 and 17.3(e));	X- Yes, this information is provided by the national focal point to the BCH.		

e) In cases of multiple competent national authorities, responsibilities for each (Articles 19.2 and 19.3);	X- Yes, see 2 (d)		
f) Reports submitted by the Parties on the operation of the Protocol (Article 20.3(e));		X- The only relevant report is the first interim national report. This report was sent to the Secretariat in August 2005.	
g) Occurrence of unintentional transboundary movements that are likely to have significant adverse effects on biological diversity (Article 17.1);			X- There has been no occurrence of the kind mentioned.
Type of information	*Information exists and is being provided to the Biosafety Clearing-House*	*Information exists but is not yet provided to the Biosafety Clearing-House*	*Information does not exist /not applicable*
h) Illegal transboundary movements of LMOs (Article 25.3);			X- There has been no occurrence of the kind mentioned.
i) Final decisions regarding the importation or release of LMOs (i.e. approval or prohibition, any conditions, requests for further information, extensions granted, reasons for decision) (Articles 10.3 and 20.3(d));	X- Decisions taken by the EU are to be provided by the European Commission.		
j) Information on the application of domestic regulations to specific imports of LMOs (Article 14.4);			X- NA
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- NA
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- Such decisions are made at the EU level		

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- Provided by the European Commission.		
n) Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12.1);	X- Provided by the European Commission.		
o) LMOs granted exemption status by each Party (Article 13.1)			X- Do 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- Do 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- Yes. Some summaries of risk assessments have been made for field trials which have been performed during the reporting period.		

Article 2 – General provisions

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

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

As an EU Member State, Sweden complies with European Community law. The relevant law is EC Regulation 1946/2003, which went into effect in November 2003. This Regulation states the obligations of the EU with regard to exports of GMOs to third countries. EC Regulation 1829/2003 on genetically modified food and feed, and Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending directive 2001/18/EC, both went into effect in April 2004.

Sweden has made clarifications and specifications of rules and regulations, at both the national and institutional levels, in order to ensure that the rules of the Protocol function smoothly.

The EC legislation on biosafety is reflected in Swedish legislation such as the Ordinance (1998:900) on Supervision in Accordance with the Environmental Act, amended by Ordinance (2006:1502), and the Ordinance (2002:1086) on the Deliberate Release of Genetically Modified Organisms into the Environment, amended by Ordinance (2006:1504).

Sweden has implemented EC Directive 90/219/EEC as amended by Directive 98/81/EC on the contained use of genetically modified micro-organisms in Ordinance (2000:271) and in regulations issued by the

Swedish Work Environment Authority.

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

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

5. Were you a Party of import during this reporting period?	
a) yes	
b) no	X
6. Were you a Party of export during this reporting period?	
a) yes	
b) no	X
7. Is there a legal requirement for the accuracy of information provided by exporters 1/ under the jurisdiction of your country? (Article 8.2)	
a) yes	X
b) not yet, but under development	
c) no	
d) not applicable – not a Party of export	
8. If you were a Party of export during this reporting period, did you request any Party of import to review a decision it had made under Article 10 on the grounds specified in Article 12.2?	
a) yes (please give details below)	
b) not yet, but under development	
c) no	
d) not applicable – not a Party of export	X
9. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 9.2(c).	
a) yes	
b) no	X
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:	
According to EC legislation, the export of GMOs is primarily an issue between the exporter and the Party	

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

of import. Swedish authorities are responsible for supervising the exporter's compliance with the rules.
Question 7. An "environmental sanction charge" shall be paid by physical and/or legal persons who violate Article 4 of EC Regulation 1946/2003 by failing to make a notification in writing (Section 1 and Point 5.1 in the Annex of the Swedish Ordinance (1998:950) on Environmental Sanction Charges). The penalties laid down in the Swedish Environmental Code, Chapter 29, Section 9.7–8, relate to the violation of Articles 6, 12 and 13 of EC Regulation 1946/2003.
Question 9. According to EC legislation (EC Directive 2001/18/EC and Regulation 1829/2003), all decisions concerning imports for placing on the market, including LMOs for deliberate release into the environment, are made at the EU level.

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:

According to EC legislation (EC Directive 2001/18/EC and Regulation 1829/2003), all decisions concerning imports for placing on the market, including release into the environment, are made at the EU level. No decisions regarding the release of GM crops onto the market for cultivation have been made during the period covered by this report. Decisions on releases in the form of field trials are made at the national level. Decisions on field trials are always based on an application corresponding to the provisions of Articles 7–10 and 12. Consent must be given by the competent authority before release into the environment and there is no difference if the LMO is nationally produced or imported.

Concerning GMMs in contained use: It is probable that genetically modified micro-organisms (GMM) both from risk class 1 (no risks for human health) and higher risk classes, intended for contained use, were both imported and exported during this reporting period. However, Articles 7–10 and 12 do not apply to GMMs intended for contained use. Notwithstanding this, the Swedish Work Environment Authority has answered several questions concerning import or export rules, mainly from universities. The GMMs in question were mainly intended for contained use in research laboratories. Sweden does have rules that regulate the contained use of GMMs, according to EC Directive 90/219/EEC as amended by Directive 98/81/EC. Also, the rules laid down in EC Directive 2000/54/EC on biological agents are applicable to GMMs. Biological agents or GMMs in risk classes 3 or 4 must not be used without the consent of the Swedish Work Environment Authority. Export or import is not considered to be "use" in this sense, though.

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	
c) not relevant	X

14. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 11.4?	
a) yes	
b) no	X
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:

Sweden has not been a Party of export of LMO-FFPs.

Question 12. Regarding imports, EC legislation (Directive 2001/18/EC, Regulation 1829/2003 and Regulation 1830/2003) requires the applicant to provide extensive information. If the information is deemed to be incorrect, that will be interpreted as a violation of the rules. Chapter 29, Section 5.1, of the Swedish Environmental Code lays down the penalty for inaccuracy in notification and environmental information required by law.

Regarding exports, an environmental sanction charge shall be paid by physical and/or legal persons who violate Article 4 of EC Regulation 1946/2003 by failing to make a notification in writing (Section 1 and Point 5.1 in the Annex of the Swedish Ordinance (1998:950) on Environmental Sanction Charges). The penalties laid down in the Swedish Environmental Code, Chapter 29, Section 9.7–8, relate to the violation of Articles 6, 12 and 13 of EC Regulation 1946/2003.

Question 14. According to EC legislation (EC Directive 2001/18 and Regulation 1829/2003), all decisions concerning imports for placing on the market, including LMO-FFPs, are made at the EU level.

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:

Sweden has not been a Party of import of LMO-FFPs. Maize MON810 has been used in Sweden for the production of beverages; but since the origin of the GMO was Germany, this was not a case of importing. Use has been in accordance with EC regulations.
For further information, Sweden refers to the report from the European Commission.

Article 13 – Simplified procedure

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

17. Have you applied the simplified procedure during the reporting period?	
a) yes	
b) no	X

18. If your country has used the simplified procedure during the reporting period, or if you have been unable to do so for some reason, please describe your experiences in implementing Article 13, including any obstacles or impediments encountered:

Article 14 – Bilateral, regional and multilateral agreements and arrangements

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

19. Has your country entered into any bilateral, regional or multilateral agreements or arrangements?	
a) yes	X
b) no	
20. If your country has entered into bilateral, regional or multilateral agreements or arrangements, or if you have been unable to do so for some reason, describe your experiences in implementing Article 14 during the reporting period, including any obstacles or impediments encountered:	
Concerning biosafety, Sweden has entered into agreements only as a member of the EU. As an EU Member State, Sweden complies with European Community law. The relevant law is EC Regulation 1946/2003, which went into effect in November 2003. This Regulation states the obligations of the EU with regard to exports of GMOs to third countries. EC Regulation 1829/2003 on genetically modified food and feed, and Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, both went into effect in April 2004. These two Regulations are primarily the responsibility of the Swedish Board of Agriculture and the National Food Administration. Regulations on traceability and labelling must be implemented primarily by the food and feed industry and by retailers, under the supervision of local authorities. Sweden refers to the report from the European Commission	

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 the notifier to bear the cost of the risk assessment? (Article 15.3)	
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)	
c) no	
25. Has your country adopted appropriate measures to prevent unintentional transboundary movements of living modified organisms? (Article 16.3)	
a) yes – fully adopted	
b) not yet, but under development or partially adopted (please give further details below)	X
c) no	
26. Does your country endeavour to ensure that any living modified organism, whether imported or locally developed, undergoes an appropriate period of observation commensurate with its life-cycle or generation time before it is put to its intended use? (Article 16.4)	
a) yes – in all cases	X
b) yes – in some cases (please give further details below)	
c) no (please give further details below)	
d) not applicable (please give further details below)	
27. Has your country cooperated with others for the purposes specified in Article 16.5?	
a) yes (please give further details below)	
b) no (please give further details below)	X
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:	
Questions 21, 22, 26 and 27. Sweden has not been a Party of import. But several notifications for placement on the market have been made via the EU application system. EC legislation stipulates that all notifications must contain a risk assessment as outlined in EC Directive 2001/18/EC. This implies an assessment of the LMO on a generation-time basis. Risk assessments are to be evaluated by all Member States. Risk assessments contained in notifications made under EC Regulation 1829/2003 are evaluated by the European Food Safety Authority and the competent authorities of the Member States Question 23 The notifier bears the costs of the risk assessment included in the notification. In Sweden, the notifier must pay the authorities' cost of evaluating the notification and the cost of processing in the EU legal system. Notifications originating from other Member States will be evaluated by Swedish authorities at no cost. Question 24. Monitoring is required by EC Directive 2001/18/EC and the Swedish Ordinance (2002:1086) on the Deliberate Release of Genetically Modified Organisms into the Environment. Question 25.	

The provisions are in place but the interpretation of "unintentional transboundary movement" has not been agreed upon. The question is if a dispersal of transgenes from field trials which happens in spite of different containment mechanisms should be regarded as a risk of unintentional transboundary movement.
The Swedish Board of Agriculture conducts tests of seed consignments which may possibly contain GMOs. The respective Swedish authorities are responsible for supervising all activities involving LMOs.

Question 26.
The Swedish Environmental Code states in Chapter 13, Section 8, that:
"An investigation shall be carried out prior to the contained use and deliberate release of genetically modified organisms. It shall constitute a proper basis for an acceptable assessment of the damage to health and the environment that the organisms are liable to cause. The investigation shall be made in accordance with scientific knowledge and proven experience. Such an investigation shall also be made before a product containing or consisting of genetically modified organisms is placed on the market."

The requirements placed upon the investigation are further defined in the Ordinance (2002:1086) on the Deliberate Release of Genetically Modified Organisms into the Environment.

Article 17 – Unintentional transboundary movements and emergency measures

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

29. During the reporting period, if there were any occurrences under your jurisdiction that led, or could have led, to an unintentional transboundary movement of a living modified organism that had, or could have had, significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States, did you immediately consult the affected or potentially affected States for the purposes specified in Article 17.4?	
a) yes – all relevant States immediately	
b) yes – partially consulted, or consultations were delayed (please clarify below)	
c) no – did not consult immediately (please clarify below)	
d) not applicable (no such occurrences)	X
30. Please provide further details about your response to the above question, as well as description of your country's experiences in implementing Article 17, including any obstacles or impediments encountered:	

Article 18 – Handling, transport, packaging and identification

31. Has your country taken measures to require that living modified organisms that are subject to transboundary movement within the scope of the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards? (Article 18.1)	
a) yes (please give details below)	X
b) not yet, but under development	
c) no	
d) not applicable (please clarify below)	

32. Has your country taken measures to require that documentation accompanying living modified organisms for direct use as food or feed, or for processing, clearly identifies that they 'may contain' living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for information? (Article 18.2(a))	
a) yes	X
b) not yet, but under development	
c) no	
33. Has your country taken measures to require that documentation accompanying living modified organisms that are destined for contained use clearly identifies them as living modified organisms and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned? (Article 18.2(b))	
a) yes	X
b) not yet, but under development	
c) no	
34. Has your country adopted measures to require that documentation accompanying living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter? (Article 18.2(c))	
a) yes	X
b) not yet, but under development	
c) no	
35. Please provide further details about your responses to the above questions, as well as a description of your country's experiences and progress in implementing Article 18, including any obstacles or impediments encountered:	
Article 12 of EC Regulation 1946/2003 implements Article 18 of the Protocol as regards the specification of required documentation and handling. Sweden is furthermore a Contracting Party to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). EC Council Directive 94/55/EC on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road stipulates that the ADR rules shall be extended to cover national traffic as well. Directive 96/49/EC on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail is also applicable. Accordingly, GMOs classified as dangerous goods are transported according to the ADR rules. For Class 6.2 ("Infectious agents"), this involves requirements for packaging, labelling and accompanying documentation. In other respects, Sweden refers to the report from the European Commission concerning the legal framework.	

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:
The problems Sweden has faced concern unclarity in EC Regulation No 1946/2003, Article 15, where responsibilities concerning the provision of information to the BCH are divided between the Member States and the European Union. But this lack of clarity is most likely not of great importance for the main function of the BCH.

Article 21 – Confidential information

37. Does your country have procedures to protect confidential information received under the Protocol and that protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms? (Article 21.3)	
a) yes	X
b) not yet, but under development	
c) no	
38. If you were a Party of import during this reporting period, did you permit any notifier to identify information submitted under the procedures of the Protocol or required by the Party of import as part of the advance informed agreement procedure that was to be treated as confidential? (Article 21.1)	
a) yes	
If yes, please give number of cases	
b) no	
c) not applicable – not a Party of import / no such requests received	X

39. If you answered yes to the previous question, please provide information on your experience including description of any impediments or difficulties encountered:
Article 25 of EC Directive 2001/18/EC and Article 30 of EC Regulation 1829/2003 implement Article 21 of the Protocol. This is further implemented in the Swedish Secrecy Act (1980:100) and the Secrecy Ordinance (1980:657).
40. If you were a Party of export during this reporting period, please describe any impediments or difficulties encountered by you, or by exporters under your jurisdiction if information is available, in the implementation of the requirements of Article 21:
Sweden is not a Party of export.

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)	X
b) no	
c) not applicable – not a developed country Party	

42. If yes to question 41, how has such cooperation taken place:

1. East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development

The Swedish International Development Cooperation Agency (Sida) has been supporting the East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (BIO-EARN) since 1999. The BIO-EARN Programme was developed by the Stockholm Environment Institute (SEI) in close collaboration with the East African network partners.
Between 2002 and 2005, Sida provided 56 million SEK to the programme as a whole; biosafety capacity-building is one of the core components of the programme.

The mission of the BIO-EARN Programme is to build capacity in biotechnology in Ethiopia, Kenya, Tanzania and Uganda and to promote appropriate research and related policies. The programme aims to use biotechnology in a sustainable manner in order to help improve livelihoods, ensure food security and safeguard the environment.

Overall programme objectives are to enable the countries in the region to develop biotechnologies and policies according to their own needs, abilities and opportunities; to promote collaboration in biotechnology, biosafety and biotechnology development to address key challenges and opportunities in the region; and to foster communication between scientists, policy makers, biosafety regulatory officials and the private sector, nationally and regionally.

Selected institutions in Ethiopia, Kenya, Tanzania and Uganda receive support through a regional network. Swedish institutions host PhD students, with East African students dividing their time between East African and Swedish institutions. In the area of biosafety and biotechnology capacity-building, there are 3–5 network partners in each country. The programme involves more than 70 researchers and more than 100 policy makers in the region. The BIO-EARN Programme is coordinated by the Stockholm Environment Institute (SEI) and the Ugandan National Council for Science and Technology (UNCST).

The accomplishments of the programme relating to biosafety capacity-building and biosafety and biotechnology policy development until 2006 could be summarised as follows:

Biosafety Capacity-Building

- *The BIO-EARN Programme has produced 3 East African PhD graduates with Biosafety specialization*

The focus of the PhD project has been to investigate the potential risk of gene flow in an East African context, focusing on pollen transfer and seed dispersal mechanisms.

- *The BIO-EARN Programme has improved ecological risk assessment capacity in the region*

Through the training of MSc and PhD students in combination with the training of already established researchers, a platform for sharing risk assessment data is under development. Common risk assessment/management decision support material has also been developed assisting scientifically sound decisions whether or not to approve GM crops in the future.

- *The BIO-EARN Programme has greatly improved biosafety regulatory implementation in the region*

Six regional biosafety workshops, involving more than 200 individuals, have improved the ability of East African biosafety regulatory officials in the committees and agencies involved to implement biosafety regulations and carry out biosafety assessments. These workshops have also enabled individuals from countries lacking biosafety regulatory structures (Ethiopia and Tanzania) to effectively participate in the development of national and institutional regulatory structures. The programme has also contributed to improving existing regulatory structures in Kenya and Uganda through detailed implementation studies. These studies will also benefit Tanzania and Ethiopia in their final design of biosafety frameworks. A BIO-EARN biosafety resource book, developed by the biosafety regulatory officials in the region, will also facilitate biosafety implementation in the region.

- *The BIO-EARN Programme has facilitated regional biosafety information sharing and harmonisation of biosafety regulatory frameworks*

The workshops, seminars and common projects have developed a regional platform for biosafety information sharing. For example, the BIO-EARN capacity-building activities have catalysed the drafting of biosafety guidelines in Ethiopia. The above-mentioned BIO-EARN biosafety resource book will also facilitate regional information sharing.

Biotechnology Policy Development/Awareness Raising

- *The BIO-EARN Programme has created awareness among policy makers and scientists on key biotechnology issues*

The programme has helped to expose policy makers and scientists to new policy areas not covered by traditional institutions of higher learning and on which information and guidance were lacking. Individuals and material from the BIO-EARN Programme have been heavily used in the policy making process in all four countries.

Facilitating Regional Collaboration

- *The BIO-EARN Programme has stimulated regional collaboration and sharing of knowledge and experiences*

A large number of regional workshops and seminars and collaboration in the various research and policy projects have greatly increased regional collaboration. For example, Ugandan policy makers have been assisting Tanzania in developing the proposal for a policy framework for biosafety guideline drafting. The ability to share experiences and develop future collaborative projects has therefore strengthened the basis for scientific and policy collaboration in the region.

Stimulating Dialogue between Policy Makers and Scientists

- *The BIO-EARN Programme has stimulated dialogue between policy makers and scientists in the region*

As a consequence of BIO-EARN Programme activities, East African researchers have been encouraged to communicate with high-level policy makers. A number of national awareness meetings and site visits have facilitated the dialogue between policy makers and scientists on how best to use biotechnology R&D

for country development purposes.

2. Swedish International Biodiversity Programme (SwedBio)

SwedBio is a Sida-funded programme at the Swedish Biodiversity Centre. The SwedBio Collaborative Programme focuses on all aspects of biodiversity and ecosystem services relevant to local livelihood and poverty alleviation from a rights perspective, and on the development of tools, methods and policies that support the sustainable use of biodiversity. In the cases where SwedBio programmes are relevant to biosafety capacity-building, this is integrated in other activities relating to biodiversity and genetic resources. The initiatives listed below, which receive support through SwedBio, are the most relevant in this respect.

a) Support relating to the implementation of multilateral agreements of relevance to biodiversity

The objective of the Sida "multi-vote" is to support the implementation of multilateral environmental agreements. The amount allocated to SwedBio (about 2 million SEK annually) is intended for processes of relevance to biodiversity. SwedBio focuses primarily on supporting a fuller and more meaningful participation and engagement by civil society in key international meetings, events and processes. Priority has been given to supporting involvement and participation by NGOs, indigenous groups and local communities in COP7 of the CBD and MOP1 of the Cartagena Protocol on Biosafety in Malaysia in February 2004, as well as COP8 of the CBD and MOP3 of the Cartagena Protocol on Biosafety in Curitiba, March 2006. Relevant support measures here are:

- Third World Network (TWN): "Workshops and side events on biodiversity and biosafety during COP7/MOP1 to the CBD";
- Environment Liaison Center International (ELCI): "Civil society engagement process for the Convention on Biological Diversity";
- Asia Indigenous Peoples Pact (AIPP): "Participation of indigenous representatives in preparatory meeting plus in COP7/MOP1 to the CBD";
- 'SEARICE/CBDC: "Projecting and sharing the CBDC experiences and lessons in international biodiversity platforms".

b) Supporting strategic biodiversity initiatives

The support given to SwedBio from Sida's "global environment vote" is intended both to provide long-term organisational support and to support more short-term initiatives such as awareness-raising, studies, workshops, etc. Support measures of relevance to biosafety capacity-building and awareness-raising in these respects include:

- Third World Network (TWN): "Biodiversity and Biosafety Programme";
- Sociedad Peruana de Derecho Ambiental (SPDA): "The use of biotechnology and the introduction of genetically modified crops in centres of origin and diversity – emerging scientific, policy and legal issues in Peru and the Andean region";
- GRAIN "Harnessing Diversity";
- Erosion, Technology, Concentration (ETC) Group: "The ETC Century";
- Africa Biodiversity Network (ABN): "Strengthening the African Biodiversity Network and its International Alliances: Developing and Implementing Biodiversity-Related Policy, Legislation and Practice in Africa".

3. Genetic Resources and Intellectual Property Rights

Each year between 2003 and 2006, Sida has supported the course "Genetic Resources and Intellectual Property Rights" implemented by the Swedish Biodiversity Centre, Svalöf Consulting AB and the Stockholm Environment Institute. The aim of the course is to train senior national actors from developing countries in the implementation of obligations under different international treaties and conventions relating to biological issues, such as WTO/TRIPS, UPOV-91, FAO ITPGRFA, WIPO IGC, and CBD including the Cartagena Protocol on Biosafety. The main focus of the course is on the understanding of the interconnections between the treaties relating to genetic resources and those relating to intellectual property rights as well as on the importance of a comprehensive strategy when countries implement them.

So far during the four years in which the course has been implemented, almost 100 people from the Andean Community, Southern and East Africa, South East Asia, China and Central Asia have benefited from it.

4. Master Programme in Management of Biological Diversity

The Master programme supported by Sida and implemented at the Swedish Biodiversity Centre takes an interdisciplinary approach to conservation and sustainable use of biological diversity and the relationship between biological diversity and human societies. The course syllabus includes basic elements of capacity-building related to the Cartagena Protocol on Biosafety.

Baltic Biosafety: A Nordic-Baltic capacity-building project

The overall aim of the project was to contribute to the safe and sustainable use of modern biotechnology in the Baltic States. The objective was to transfer experience and expertise from the relevant Swedish authorities in the area of biosafety to their counterparts in those states. The target group consisted of officials at the ministries of agriculture and the environment as well as at inspection bodies and institutions dealing with biosafety matters. The project was financed in cooperation with counterparts in the Baltic States, the Baltic Environmental Forum (www.bef.lv) and the Swedish EPA. The four planned workshops were held according to schedule. Each workshop combined lecturers and team activities in order for the participants to apply their knowledge of their national laws and institutions to the specific subject.

The subjects addressed were as follows:

The first workshop dealt with contained use of genetically modified micro-organisms. The participating experts were from Finland, Denmark and Sweden.

The second workshop focused on the Biosafety Protocol. The participating experts were from Denmark (Veit Koester, one of the Protocol "fathers"), Norway, Finland and Sweden.

The third workshop was concerned with deliberate releases of genetically modified plants. The participating experts were from Finland and Sweden.

The fourth workshop dealt with the new EC Regulations on traceability and labelling, and the public participation aspect of GMOs. The experts were from Denmark and Sweden.

On average, each workshop included approximately 35 participants from the Baltic States, representing the various authorities and institutions targeted by the project. This turnout was due entirely to the knowledge and experience of the Baltic Environmental Forum, with its large network of contacts in the Baltic States.

Reports from the workshop can be found at www.bef.lv

Biosafety in Vietnam: A capacity-building project

The Swedish Environmental Protection Agency currently (during 2007) gives support to the Vietnamese authorities in their work to set up new rules concerning genetically modified organisms and genetically modified products. The Vietnamese draft contains rules implementing the Cartagena Protocol.	
43. If a developing country Party, or Party with an economy in transition, during this reporting period has your country contributed to the development and/or strengthening of human resources and institutional capacities in biosafety for the purposes of the effective implementation of the Protocol in another developing country Party or Party with an economy in transition?	
a) yes (please give details below)	
b) no	
c) not applicable – not a developing country Party	X
44. If yes to question 43, how has such cooperation taken place:	
45. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training in the proper and safe management of biotechnology to the extent that it is required for biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	
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	X
46. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training in the use of risk assessment and risk management for biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	
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	X
47. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training for enhancement of technological and institutional capacities in biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	
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	X
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:	

Article 23 – Public awareness and participation

49. Does your country promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health? (Article 23.1(a))	
a) yes – significant extent	X
b) yes – limited extent	
c) no	
50. If yes, do you cooperate with other States and international bodies?	
a) yes – significant extent	X
b) yes – limited extent	
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	X
b) yes – limited extent	
c) no	
53. Has your country informed its public about the means of public access to the Biosafety Clearing-House? (Article 23.3)	
a) yes – fully	X
b) yes – limited extent	
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 Swedish GMO authorities have a joint website (www.gmo.nu) for information on GMO regulations, including a link to the BCH website. All of these authorities provide specific information on GMOs on	

their websites, in relation to their competence.

The Swedish Environmental Protection Agency has launched a small website on the Protocol (www.biosakerhet.se). The homepage of the Swedish EPA (www.naturvardsverket.se) contains general information on GMOs.

The task assigned to the Swedish Gene Technology Advisory Board is to promote, by means of consultation, uses of gene technology which are ethically defensible from the standpoint of human and animal health. That task includes the dissemination of knowledge concerning the development of gene technology. The public should be informed in such a way that its interests in ethical and safety issues are safeguarded, while public debate on such issues is stimulated.

Question 51
In Sweden, the principle of public access to official documents is applied. In principle, anyone is entitled to read the documents held by public authorities. This means that all documents received, letters, decisions and reports are, in principle, official documents and must be made available for anyone to read. Access to official documents can, however, be restricted if they may be kept secret in order to protect specified interests, namely:

- the security of the Realm or its relations with another state or international organisation;
- the central fiscal, monetary or currency policies of the Realm;
- the inspection, control or other supervisory activities of a public authority;
- the interest of preventing or prosecuting crime;
- the public economic interest;
- the protection of the personal or financial circumstances of private subjects; or
- the preservation of animal or plant species.

The website of the Swedish Board of Agriculture (www.sjv.se) contains information about which GM crops have been approved for import and/or cultivation within the EU. The EU Joint Research Centre (JRC) maintains a website with information about pending and approved applications for GMOs, http://gmoinfo.jrc.it/

Question 52

All interested parties are entitled to comment upon the approval of placement on the market and field trials. Depending on the scope of the application and the legislation under which it is notified, the public can submit comments via the Joint Research Centre website, the European Commission or the competent authorities' websites.

According to Chapter 2, Section 10, of the Swedish Ordinance (2002:1086) on the Deliberate Release of Genetically Modified Organisms into the Environment, the supervisory authority shall consult the public and other interested parties before reaching an approval decision regarding release into the environment of a genetically modified organism. This is applicable to field trials.

When Sweden is asked for its opinion regarding the placing on the market of GMOs, the relevant authority refers non-confidential parts of the application to organisations with an interest in the matter (e.g. environmental NGOs, the association of organic farmers, and the main Swedish farmers' organisation). The same procedure is used as regards notifications for field trials. During the process, the various organisations are informed of developments. All applications, opinions, etc., are recorded by the

relevant authority and, with the exception of confidential information, are accessible to the general public.

For decisions regarding activities involving genetically modified organisms and micro-organisms (GMM) for contained use, there is no legal obligation to consult the public. EC Directive 90/219/EEC and the Swedish Ordinance (2000:271) refer to the possibility of consulting the public in individual cases; but so far, the Swedish authorities have deemed that to be unnecessary. Decisions on contained use of GMM or GMO are usually not made public, but are accessible to the public upon request and within the limits imposed by issues of confidentiality.

The development cooperation programmes of SwedBio (see Article 22) support, to some extent, public awareness and participation through development cooperation. The content of those programmes is presented under Article 22.

Article 24 – Non-Parties

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

55. Have there been any transboundary movements of living modified organisms between your country and a non-Party during the reporting period?	
a) yes	
b) no	
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:	
Swedish authorities have on some occasions been asked to give information to an importing party about an LMO that was to be exported from Sweden. The exported LMO was intended for research purposes. Both GMMs and GMOs intended for contained use have been both imported and exported during this reporting period. Sweden does not regulate the import or export of GMMs or GMOs intended for contained use for research purposes. Sweden does, however, regulate the use of GMMs and GMOs.	

Article 25 – Illegal transboundary movements

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

57. Has your country adopted appropriate domestic measures to prevent and penalize, as appropriate, transboundary movements of living modified organisms carried out in contravention of its domestic measures? (Article 25.1)	
a) yes	X
b) no	
58. Have there been any illegal transboundary movements of living modified organisms into your country during the reporting period?	
a) yes	
b) no	X

59. Please provide further details about your response to the above question, as well as description of your country's experiences in implementing Article 25, including any obstacles or impediments encountered:
Any infringement of EC Regulation No 1946/2003 will be regarded in Sweden as an infringement of the Environmental Code and the penalties laid down in the Code will apply.

Article 26 – Socio-economic considerations

60. If during this reporting period your country has taken a decision on import, did it take into account socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities? (Article 26.1)	
a) yes – significant extent	
b) yes – limited extent	
c) no	
d) not a Party of import	X

61. Has your country cooperated with other Parties on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities? (Article 26.2)	
a) yes – significant extent	
b) yes – limited extent	
c) no	X

62. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 26, including any obstacles or impediments encountered:
Chapter 1, Section 1, of the Swedish Environmental Code (1998:808) stipulates that, among other factors, socio-economic considerations must be taken into account when the provisions of the Code are applied; this includes GMO assessments. The Ministry of Agriculture is preparing rules on the co-existence of GM crops and conventional crops in Sweden.

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	X
b) yes – received financial resources from other Parties or financial institutions	
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:
Sweden has provided, through the Ministry of the Environment, resources to all three funds for the implementation of the Cartagena Protocol on Biosafety. The three funds are: 1. General Trust Fund for the Core Programme Budget of the Protocol (**BG** Trust Fund);

2. Special Voluntary Trust Fund for Additional Voluntary Contributions in Support of Approved Activities of the Cartagena Protocol on Biosafety (**BH** Trust Fund);
3. Special Voluntary Trust Fund for Additional Voluntary Contributions to Facilitate the Participation of Parties in the Cartagena Protocol on Biosafety (**BI** Trust Fund).

During 2006, Sweden has provided, in all, 700,000 SEK to the three funds, and in particular Sweden has supported the participation of LDC in the expert meetings on Liability and Redress.

Sweden has also provided, through the Ministry of the Environment, UNEP with 500,000 SEK for their fund for Capacity-Building in the Cartagena Protocol on Biosafety.

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: