Origin of report

Party	Norway
Contact officer for report	
Name and title of contact officer:	Birthe Ivars/Beate B. Ekeberg
Mailing address:	Ministry of the Environment P.O. Bos 8013 Dep 0030 Oslo Norway
Telephone:	22 24 60 07/22 24 58 75
Fax:	22 24 27 56
E-mail:	Birthe.ivars@md.dep.no / beate.berglund.ekeberg@md.dep.no
Submission	
Signature of officer responsible for submitting report:	
Date of submission:	

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:

Prepared by the Ministry of the Environment in cooperation with the Directorate for Nature Management, the Ministry of Fisheries and Coastal Affairs, the Ministry for Foreign Affairs, the Ministry of Health and Care Services and the Ministry of Agriculture and Food.

Obligations for provision of information to the Biosafety Clearing-House

1. Several articles of the Protocol require that information be provided to the Biosafety Clearing-House (see the list below). For your Government, if there are cases where relevant information exists but has not been provided to the BCH, describe any obstacles or impediments encountered regarding provision of that information (note: To answer this question, please check the BCH to determine the current status of your country's information submissions relative to the list of required information below. If you do not have access to the BCH, contact the Secretariat for a summary):
Norway has submitted most of the information required by the Protocol to the Biosafety Clearing House. The following information has, however, still not been provided: (a) and (b) -Existing national legislation etc: The Norwegian Gene Technology Act has been translated into English and is made available through the BCH. The two most central regulations under this Act have been provided in Norwegian, but they have not been translated to English. Some other regulations (conf. reply to question 3) are also relevant for the BCH, and will be provided soon. (c) Bilateral, multilateral and regional agreements and arrangements (Articles 14.2, 20.3(b), and 24.1);A number of EC Acts on Biosafety are in the process of being incorporated into the EEA Agreement (conf. reply to question 3). Information on this agreement will be provided to the BCH when this process is finalized.

Information required to be provided to the Biosafety Clearing-House:

(a) Existing national legislation, regulations and guidelines for implementing the Protocol, as well as information required by Parties for the advance informed agreement procedure (Article 20.3(a))
(b) National laws, regulations and guidelines applicable to the import of LMO intended for direct use as food or feed, or for processing (Article 11.5);
(c) Bilateral, multilateral and regional agreements and arrangements (Articles 14.2, 20.3(b), and 24.1);
(d) Contact details for competent national authorities (Articles 19.2 and 19.3), national focal points (Articles 19.1 and 19.3), and emergency contacts (Article 17.2 and 17.3(e));
(e) In cases of multiple competent national authorities, responsibilities for each (Articles 19.2 and 19.3);
(f) Reports submitted by the Parties on the operation of the Protocol (Article 20.3(e));
(g) Occurrence of unintentional transboundary movements that are likely to have significant adverse effects on biological diversity (Article 17.1);
(h) Illegal transboundary movements of LMO (Article 25.3);
(i) Final decisions regarding the importation or release of LMO (i.e. approval or prohibition, any conditions, requests for further information, extensions granted, reasons for decision) (Articles 10.3 and 20.3(d));
(j) Information on the application of domestic regulations to specific imports of LMO (Article 14.4);
(k) Final decisions regarding the domestic use of LMO that may be subject to transboundary movement for direct use as food or feed, or for processing (Article 11.1);
(l) Final decisions regarding the import of LMO intended for direct use as food or feed, or for processing that are taken under domestic regulatory frameworks (Article 11.4) or in accordance with Annex III (Article 11.6) (requirement of Article 20.3(d))
(m) Declarations regarding the framework to be used for LMO intended for direct use as food or feed, or for processing (Article 11.6)
(n) Review and change of decisions regarding intentional transboundary movements of LMO (Article 12.1);
(o) LMO granted exemption status by each Party (Article 13.1)

(p) Cases where intentional transboundary movement may take place at the same time as the movement is notified to the Party of import (Article 13.1); and

(q) Summaries of risk assessments or environmental reviews of LMO generated by regulatory processes and relevant information regarding products thereof (Article 20.3©).

Article 2 – General provisions

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

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

Norwegian legislation on genetically modified organisms (GMO) has been in place since 1993. Norway introduced specific legislation to ensure that the production and use of GMO takes place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and the environment. Pursuant to the Agreement between the European Community, its Member States and Iceland, Liechtenstein and Norway on the European Economic Area (EEA Agreement), the legal framework of the European Communities (EC) on GMO is, or will in the near future be, implemented in Norway.

- The main legal measures include:

  - The Act relating to the production and use of genetically modified organisms (Gene Technology Act) No. 38 of 2 April 1993.
    The Act covers contained use and deliberate release into the environment, including the import and placing on the market of GMO as well as products containing or consisting of GMO, e.g. for cultivation or processing into industrial products. Directive 90/219/EC on contained use of GMO as amended by Directive 98/81/EC and Directive 2001/18/EC are implemented by the Act.
  - Regulations of 20 August 1993 No. 816 on impact assessment pursuant to the Gene Technology Act.
  - Regulations of 11 February 1994 No. 126 on reporting or authorization of contained use of GMO.
  - Regulations of 2 September 2005 on labelling, transport, import and export of GMO. The Regulations replace Regulations of 13 November 1998 No. 1066 on transport and import of GMO.
  - Regulations of 7 November 2002 No. 1290 on feedstuffs (labeling requirements)
  - Regulations of 21 December 1993 No. 1385 on labeling of foodstuffs.

The following EC Acts are in the process of being incorporated into the EEA Agreement and consequently implemented in the Gene Technology Act and Regulations adopted pursuant to it:

- Regulation (EC) 1829/2003 of 22 September 2003 on genetically modified food and feed, covering the placing on the market of GMO intended for food or feed and of food or feed products containing, consisting of or produced from GMO.
- Regulation (EC) 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.
- Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 as regards the application for the authorisation of new

genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

- Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms.
- Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) 1830/2003

We refer to the report from the EC for a detailed description of these Acts.

A list of all Norwegian legal measures pertaining to genetically modified organisms is reproduced in Annex I to this report.

The Cartagena Protocol on Biosafety is implemented in Norway through several legislative measures applying to the production and use of GMO in Norway, including transport, import and marketing. The Gene Technology Act and the Regulations mentioned above that have been adopted pursuant thereto, are the main parts of these legislative measures.

The main elements of the legislative measures are:

- Requirement for approval prior to production and use of GMO. Some cases of contained use only require reporting;
- requirement for an assessment of the impact of the production and use of GMO on health and the environment prior to approval;
- the obligation to carry out public consultation before approving deliberate release of GMO;
- the obligation to implement measures to avoid adverse effects on health and the environment, including monitoring of areas of deliberate release;
- the person responsible for the production and use of GMO has liability for damages regardless of any fault on his part when the activity causes damage, inconvenience or loss by deliberate release or emission of GMO into the environment;
- labeling requirements;
- the obligation to notify exports of GMO intended for deliberate release into the environment and secure express consent prior to a first transboundary movement;
- a set of rules for the export of GMO intended to be used as food, feed or for processing;
- provisions for identifying GMO for export.

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

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

4. Is there a legal requirement for the accuracy of information provided by exporters 1/ under the jurisdiction of your country? (Article 8.2)	
a) yes	X2
b) no	
c) not applicable – not a Party of export	
5. If you were a Party of export during this reporting period, did you request any Party of import to review a decision it had made under Article 10 on the grounds specified in Article 12.2?	
a) yes (please give details below)	
b) no	
c) not applicable – not a Party of export	X
6. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 9.2©.	
a) yes	
b) no	
c) not applicable – no decisions taken during the reporting period	X
7. If your country has been a Party of export of LMO intended for release into the environment during the reporting period, please describe your experiences and progress in implementing Articles 7 to 10 and 12, including any obstacles or impediments encountered:	
Not applicable – not a Party of export.	
8. If your country has taken decisions on import of LMO intended for release into the environment during the reporting period, please describe your experiences and progress in implementing Articles 7 to 10 and 12, including any obstacles or impediments encountered:	
Not applicable – no decisions taken during the reporting period. Norway has declared with reference to Article 14.4 that import of GMO, also those intended for direct use for food or feed, or for processing, has to be in accordance with the Gene Technology Act. The Act is compatible with the provisions of the Protocol. The Norwegian legislation is described under Question 3 above and listed in the annex. Its central element in relation to the AIA procedure of the Protocol is the Gene Technology Act. The main elements of the Act are described under Question 3 above. According to the Act, a company intending to release a GMO into the environment in Norway must first obtain a written approval, unless the GMO in question has been approved for placing on the market in the	

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

2 In the new Regulations of 2 September 2005 on labelling, transport, import and export of GMO.

EC. As a consequence of the EEA Agreement, Norway takes part in the approval procedure of GMO in the EC on the same basis as the EC Member States, with the exception of voting procedures. A GMO which has been approved for placing on the market in the EC is also approved for that purpose in Norway, unless the competent authority in Norway considers it to constitute a risk to human health or the environment or otherwise contravene the Gene Technology Act and therefore has decided to restrict or prohibit its placing on the market in Norway. Through Regulation No. 1268 of 15 December 2000 Norway has decided to prohibit 8 GMO that have been approved in the EC.

The application must be submitted to the competent authority of Norway (Directorate for Nature Management). It must include an impact assessment setting out the risk of detrimental effects on health and the environment and other consequences of the release.

The application is subject to public consultation and consideration by the Scientific Committee on Food Safety, the Food Safety Authority, the Norwegian Biotechnology Advisory Board, the Directorate for Nature Management and the Ministry of the Environment. Approval may be conditional and granted for a limited time. The conditions of the approval may be altered and the approval may be revoked if certain conditions are met.

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

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

9. Is there a legal requirement for the accuracy of information provided by the applicant with respect to the domestic use of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing? (Article 11.2)	
a) yes	X3
b) no	
c) not applicable (please give details below)	
10. Has your country indicated its needs for financial and technical assistance and capacity building in respect of living modified organisms intended for direct use as food or feed, or for processing? (Article 11.9)	
a) yes (please give details below)	
b) no	
c) not relevant	X
11. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 11.4?	
a) yes	
b) no	
c) not applicable – no decisions taken during the reporting period	X
12. If your country has been a Party of export of LMO 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:	
Not applicable – Norway not a Party of export during the reporting period.	
13. If your country has been a Party of import of LMO 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:	
Not applicable – no decisions taken during the reporting period. Norway has declared with reference to Article 14.4 that import of GMO, also those intended for direct use for food or feed, or for processing, has to be in accordance with the Gene Technology Act. The Act is compatible with the provisions of the Protocol. The Act is described under Question 3 and 8 above and listed in the annex. According to the Act, a company intending to import a GMO into Norway for the purpose of marketing for direct use for food or feed, or for processing, must first obtain a written approval, unless the GMO in question has been approved for placing on the market for direct use for food, feed or for processing in the	

3 Pursuant to Section 35 of the Act of 10 February 1967 relating to procedure in cases concerning the public administration, an authorisation to release a GMO into the environment, including marketing of the GMO to be used as food, feed or for processing, could be revoked if it is found to be based upon incorrect information from the applicant.

EC. As a consequence of the EEA Agreement, Norway takes part in the approval procedure in the EC on the same basis as the EC Member States, with the exception of voting procedures. A GMO which has been approved for placing on the market for direct use for food, feed or for processing in the EC is also approved for those purposes in Norway, unless the competent authority in Norway considers it to constitute a risk to human health or the environment or otherwise contravene the Gene Technology Act and therefore has decided to restrict or prohibit its placing on the market in Norway. Through Regulation No. 1268 of 15 December 2000 Norway has decided to prohibit 8 GMO that have been approved in the EC. Three of these (No. 3, 6 and 7 in the Regulation) are GMO for food or feed, or for processing.

In cases where an approval is required pursuant to the above, an application for approval must be submitted to the competent authority of Norway (Directorate for Nature Management). It must include an impact assessment setting out the risk of detrimental effects on health and the environment and other consequences of the release.

The application is subject to public consultation and consideration by the Scientific Committee on Food Safety, the Food Safety Authority, the Norwegian Biotechnology Advisory Board, the Directorate for Nature Management and the Ministry of the Environment. Approval may be conditional and granted for a limited time. The conditions of the approval may be altered and the approval may be revoked if certain conditions are met.

Pursuant to Regulations of 7 November 2002 No. 1290 on feedstuffs and Regulations of 21 December 1993 No. 1385 on labeling of foodstuffs, food and feed containing, consisting of or produced from GMO have to be labeled as "genetically modified (name of the product or ingredient)" or "produced from genetically modified (name of the product or ingredient)". Labeling requirements do not apply to conventional products with traces of GMO or genetically modified material up to 0,9 %, provided the presence of this material is adventitious or technically unavoidable.

Article 13 – Simplified procedure

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

14. If your country has used the simplified procedure during the reporting period, please describe your experiences in implementing Article 13, including any obstacles or impediments encountered:
The simplified procedure has not been used by Norway in the reporting period.

Article 14 – Bilateral, regional and multilateral agreements and arrangements

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

15. If your country has entered into bilateral, regional or multilateral agreements or arrangements, describe your experiences in implementing Article 14 during the reporting period, including any obstacles or impediments encountered:
Norway has not entered into any bilateral, regional or multilateral agreements or arrangements covered by Article 14(1). Norway relies on its existing legislative framework for intentional movements of GMO within the EEA and for imports of GMO into Norway in consistence with Articles 14(4), 9 (2) (c) and 11(4). This has been communicated to other Parties through the Biosafety Clearing-House.

Articles 15 and 16 – Risk assessment and risk management

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

22. Has your country cooperated with others for the purposes specified in Article 16.5?	
a) yes (please give further details below)	X
b) no (please give further details below)	

23. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Articles 15 and 16, including any obstacles or impediments encountered:

Further details q.18: Norway did not take a decision regarding article 10 during the reporting period.

Further details q. 20: The Norwegian Food Safety Authority collects samples from imported food, feed and seed which are analysed for content of GMO. The analyses of the samples are carried out by The Norwegian Veterinary Institute which has an extensive cooperation with other European GMO-detection laboratories to develop and validate GMO-detection protocols.

Further details q. 21: The Norwegian Gene technology Act requires that releases of GMO to the environment should take place stepwise in order to be able to detect unforeseen adverse effects on the environment or human health before a full scale release is granted.

Further details q. 22: Norway cooperates with the European Union in a working group under Directive 2001/18/ EC, with the aim of phasing out GMO with antibiotic resistance marker genes that may have adverse effects on human health or the environment.

Directive 2001/18/EC on the deliberate release of GMO calls for a phasing out of antibiotic resistance marker genes which may have adverse effects on human health and the environment. The Scientific Panel on Genetically Modified Organisms under the European Food Safety authority adopted an opinion in April 2004 that one category (category II) of ARMG that are being used in GMO should be restricted to field trial purposes, and that one other category of ARMG should be restricted to contained use only (category III). The opinion is available on

http://www.efsa.eu.int/science/gmo/gmo_opinions/384_en.html

The Norwegian Scientific Committee for Food Safety will deliver "An assessment of potential long-term health effects caused by antibiotic resistance marker genes in GMO based on antibiotic usage and resistance patterns in Norway" ultimo September 2005. According to the preliminary summary the Committee is of the same opinion as EFSA regarding the risk of ARMG in Groups II and III, but expresses somewhat more concern regarding the *npt*II-gene in Group I. The preliminary summary of the report is enclosed in Annex II. The final report will be made available through the Biosafety Information Resource Center on the Biosafety Clearing House, where further information on horizontal gene transfer can be found.

Further details q. 23: A risk assessment must be carried out by the notifier both for notifications of GMO intended for intentional introduction into the environment and for notifications of GMO intended for direct use as food or feed, or processing, The requirements for the risk assessment are in line with the requirements specified in annex III to the Cartagena Protocol. It should be carried out on a case by case basis, and must be based on the precautionary principle. The Norwegian authorities assesses whether the information in the risk assessment is in line with the national requirements, and ask for further documentation if the information is not sufficient as basis for a decision.

A consent under the Norwegian Gene Technology Act may be granted on condition that the notifier carries out risk management measures such as post market monitoring, isolation distances and provisions ensuring traceability of the GMO.

Norway is of the opinion that further guidelines supplementing Articles 15, 16 and Annex III on Risk Assessment to the Protocol is necessary for a common approach, which again is important to fulfil the objectives of the Protocol. The work to be carried out by the Ad Hoc Technical Expert Group established by MOP BS-II/9 on identifying the relevance of, and gaps in existing approaches to and guidance material on risk assessment and the need for capacity building activities, will be an important contribution towards the development of necessary further guidelines.

Norway is furthermore of the opinion that the reports on antibiotic resistance marker genes (ARMG) mentioned above clearly indicate that such genes are examples of specific traits covered by Article 16(5). The Parties to the Protocol are obliged to identify such traits and take appropriate measures regarding their treatment.

Norway is therefore in favour of a scientific committee being appointed with the task of providing scientific and technical guidance on risk assessment guidelines, ARMG in GMO and other tasks that might be considered important for the fulfilment of the objectives of the Protocol, such as tasks pursuant to Article 18(3) identified by Norway in the answer to Question 30 of this Report.

Article 17 – Unintentional transboundary movements and emergency measures

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

24. During the reporting period, if there were any occurrences under your jurisdiction that led, or could have led, to an unintentional transboundary movement of a living modified organism that had, or could have had, significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States, did you immediately consult the affected or potentially affected States for the purposes specified in Article 17.4?	
a) yes – all relevant States immediately	
b) partially (please clarify below)	
c) no (please clarify below)	
25. Please provide further details about your response to the above question, as well as description of your country's experiences in implementing Article 17, including any obstacles or impediments encountered:	
Further details q. 24: There were no occurrences under Norwegian jurisdiction that led, or could have led to unintentional transboundary movements of GMO.	

Article 18 – Handling, transport, packaging and identification

26. Has your country taken measures to require that living modified organisms that are subject to transboundary movement within the scope of the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards? (Article 18.1)	
a) yes (please give details below)	X
b) no	
c) not applicable (please clarify below)	
27. Has your country taken measures to require that documentation accompanying living modified organisms for direct use as food or feed, or for processing, clearly identifies that they 'may contain' living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for information? (Article 18.2(a))	
a) yes	X
b) no	
28. Has your country taken measures to require that documentation accompanying living modified organisms that are destined for contained use clearly identifies them as living modified organisms and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned? (Article 18.2(b))	
a) yes	X
b) no	
29. Has your country adopted measures to require that documentation accompanying living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter? (Article 18.2©)	
a) yes	X
b) no	
30. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 18, including any obstacles or impediments encountered:	
The Norwegian legal framework on GMO also addresses handling, transport, packaging and identification requirements pursuant to Article 18. The following are relevant to the implementation of Article 18: ▪ Regulations of 2 September 2005 on labeling, transport, import and export of GMO. ▪ Regulations of 7 November 2002 No. 1290 on feedstuffs (labeling requirements) ▪ Regulations of 21 December 1993 No. 1385 on labeling of foodstuffs. As concerns Article 18(1), the existing Norwegian legislation contains appropriate rules on the safe transport, handling and packaging of GMO. These rules are contained in: ▪ Regulations of 11 November 2002 on transport of dangerous goods by road and rail ▪ Regulations of 13 November 1998 No. 1066 on transport and import of GMO, which were	

replaced by Regulations of 2 September 2005 on labeling, transport, import and export of GMO without major changes relating to obligations pursuant to Article 18(1).

As concerns Article 18(2)(a), it follows from Sections 18 and 19 of the Regulations of 2. September 2005 on labeling, transport, import and export of GMO that exporters are required to provide the following information on a label or in a document accompanying GMO intended for direct use as food or feed, or for processing, and transmit it to the importer receiving the GMO:

- that it contains GMO;
- the unique identification code assigned to the GMO if such codes exist;
- the common, scientific and – if it exists - commercial name of the product;
- a contact point for further information;
- a declaration stating that the GMO are intended for direct use as food or feed, or for processing and not intended for deliberate release into the environment; and

For products consisting of or containing mixtures of GMO to be used only and directly as food or feed, or for processing, the unique identification code may be replaced by a list of unique identification codes for all the GMO used to constitute the mixture.

Regulations of 7 November 2002 No. 1290 on feedstuffs and Regulations of 21 December 1993 No. 1385 on labeling of foodstuffs contain rules on labeling of all GM food and feed. Any intentional use of GM ingredients in food at any level must be labeled. Labeling requirements do not apply to conventional products with traces of GMO or genetically modified material up to 0,9 %, provided the presence of this material is adventitious or technically unavoidable.

If necessary, the Regulations mentioned above will be revised when detailed requirements are adopted in accordance with the second sentence of Article 18(2)(a).

As concerns Article 18(2)(b), it follows from Sections 18 and 19 of the Regulations of 2. September 2005 on labeling, transport, import and export of GMO that exporters are required to provide the following information on a label or in a document accompanying GMO destined for contained use, and transmit it to the importer receiving the GMO:

- that it contains GMO;
- the unique identification code assigned to the GMO if such code exist;
- that it is destined for contained use;
- the common and scientific name of the product;
- any requirements for the safe handling, storage, transport and use of the GMO; and
- a contact point for further information, including the name and address of the individual or institution to whom or which the GMO is consigned.

As concerns Article 18(2)(c), it follows from Sections 18 and 19 of the Regulations of 2. September 2005 on labeling, transport, import and export of GMO that exporters are required to provide the following information on a label or in a document accompanying GMO intended for deliberate release into the environment, and transmit it to the importer receiving the GMO:

- that it contains GMO;
- the unique identification code assigned to the GMO if such code exist;
- a declaration by the exporter that the transport is in conformity with the requirements of the Cartagena Protocol applicable to the exporter;
- the common and scientific name of the GMO and its characteristics;
- any requirements for the safe handling, storage, transport and use of the GMO; and
- contact point for further information, including name and address of the importer and exporter.

Furthermore, the following EC Acts are in the process of being incorporated into the EEA Agreement and consequently implemented in the Gene Technology Act and Regulations adopted pursuant to it:

- Regulation (EC) 1829/2003 of 22 September 2003 on genetically modified food and feed;
- Regulation (EC) 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.
- Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003; and
- Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms.

We refer to the report from the EC for a detailed description of these Acts.

Norway is of the opinion that a standardized format for documentation and identification requirements for inclusion in a stand-alone document, should be developed in order to secure clearest possible identification and avoid the difficulties for traders that would result from different countries requiring different formats.

Norway is furthermore of the opinion that the question of thresholds and sampling and detection methods are important, albeit difficult matters that merit further consideration by the Parties.

Given the technical nature of these issues, Norway is therefore in favour of a scientific committee being appointed with the task of providing scientific and technical guidance on these matters. The nature and composition of such a committee is commented upon under Question 56 of this Report.

Article 19 – Competent national authorities and national focal points

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

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

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

31. In addition to the response to question 1, please describe any further details regarding your country's experiences and progress in implementing Article 20, including any obstacles or impediments encountered:
Norway has prepared a national Biosafety Clearing House portal which is available at http://bch.dirnat.no/hoved.aspx?kontroll=velkommen&spraak=engelsk . The Norwegian BCH portal contains Biosafety information in Norwegian and English, and is linked to the database of the BCH Central Portal.

Article 21 – Confidential information

32. Does your country have procedures to protect confidential information received under the Protocol and that protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms? (Article 21.3)	
a) yes	X
b) no	
33. If you were a Party of import during this reporting period, did you permit any notifier to identify information submitted under the procedures of the Protocol or required by the Party of import as part of the advance informed agreement procedure that was to be treated as confidential? (Article 21.1)	
a) yes	
If yes, please give number of cases	
b) no	
c) not applicable – not a Party of import	X
34. If you answered yes to the previous question, please provide information on your experience including description of any impediments or difficulties encountered:	

The Norwegian Gene Technology Act and the Act of 19 June 1970 No. 69 on the Freedom of Information contain confidentiality provisions that apply equally to domestic and foreign producers of GMO.

According to Section 12 of the Gene Technology Act, the Freedom of Information Act applies to cases that are dealt with under the Gene Technology Act. It follows from Sections 2 and 5a of the Freedom of Information Act and Section 13 of the Public Administration Act of 10 February 1967 that the case documents in an application for authorization of a GMO are public with the exception of information concerning technical devices and procedures, as well as operational or business matters which for competition reasons it is important to keep secret in the interests of the person whom the information concerns. However, according to Section 12 of the Gene Technology Act, the following information shall always be public:

- The description of the GMO, the user's name and address, the purpose of the use and the location of use;
- methods and plans for monitoring and emergency response; and
- assessments of the foreseeable consequences.

The applicant will have the possibility to indicate the information in the notification that should be treated as confidential, provided that verifiable justification is given in such cases. Decisions on which information will be kept confidential are taken by the Norwegian competent authority.

35. If you were a Party of export during this reporting period, please describe any impediments or difficulties encountered by you, or by exporters under your jurisdiction if information is available, in the implementation of the requirements of Article 21:

Article 22 – Capacity-building

36. If a developed country Party, during this reporting period has your country cooperated in the development and/or strengthening of human resources and institutional capacities in biosafety for the purposes of the effective implementation of the Protocol in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition?	
a) yes (please give details below)	X
b) no	
c) not applicable – not a developed country Party	

37. If yes, how has such cooperation taken place:

During the reporting period, Norway has cooperated in one capacity building project and one annual biosafety capacity building course:

<u>Assistance to build capacity for the implementation of the National Biotechnology and Biosafety Policy and the Cartagena Protocol</u>

The project is a bilateral project between Zambia and Norway. The objectives of the project are:

- To plan and organise national biosafety workshops, technical workshops, awareness campaigns and training courses in biosafety, including risk assessments and risk management;
- To establish a laboratory for qualitative and quantitative analysis of GMO and training of personnel;
- Support the Zambian initiative to participate actively in the new UNEP/GEF demonstration projects, which would greatly assist the country to fulfil its obligations under the Cartagena Protocol. The first workshop arranged by UNEP/GEF was in March 2003.
- To assist Zambia participating in international training courses, seminars and workshops relevant to the implementation of the Cartagena Protocol on Biosafety and with special focus on regional African issues.
- Implement and use the Biosafety Clearing House Mechanism, the information system of the Cartagena Protocol on Biosafety.

<u>GenØk/UNEP biosafety capacity building course: Holistic Foundations for Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms</u>

The course is designed to provide high-level policy makers, regulators, scientists and NGOs/civil society leaders, specifically from developing countries (ODA-countries), with knowledge and training in crucial GE/GMO issues. Through lectures, laboratory demonstrations, group work on case studies, and discussions, the course offers biosafety capacity building within a holistic framework.

38. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training in the proper and safe management of biotechnology to the extent that it is required for biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	
c) no – capacity-building needs remain unmet (please give details below)	
b) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	X

39. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training in the use of risk assessment and risk management for biosafety?

a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	
c) no – capacity-building needs remain unmet (please give details below)	
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
40. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training for enhancement of technological and institutional capacities in biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	
c) no – capacity-building needs remain unmet (please give details below)	
d) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	X
41. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 22, including any obstacles or impediments encountered:	

Article 23 – Public awareness and participation

42. Does your country promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health? (Article 23.1(a))	
a) yes – significant extent	X
b) yes – limited extent	
c) no	
43. If yes, do you cooperate with other States and international bodies?	
a) yes – significant extent	X
b) yes – limited extent	
c) no	
44. Does your country endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with the Protocol that may be imported? (Article 23.1(b))	
a) yes – fully	X
b) yes – limited extent	
c) no	
45. Does your country, in accordance with its respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and make the results of such decisions available to the public? (Article 23.2)	
a) yes – fully	X
b) yes – limited extent	
c) no	
46. Has your country informed its public about the means of public access to the Biosafety Clearing-House? (Article 23.3)	
a) yes – fully	
b) yes – limited extent	X
c) no	
47. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 23, including any obstacles or impediments encountered:	
In cases where an approval for handling, transfer and use of a living modified organisms is required under the Norwegian Gene Technology Act, a public consultation is to be carried out pursuant to Section 13 of the Gene Technology Act. Such consultations shall take place well in advance before the decision is made. The public consultation shall be publicly announced. The requirement to carry out a public hearing is mandatory both for commercial releases of GMO and for releases for other purposes, such as field trials. Immediately after receipt of a notification concerning release of an GMO, a public hearing is announced in a public advertiser (Norsk lysningsblad). A summary of the application in Norwegian is prepared and forwarded to stakeholders who whises to be informed of notifications concerning GMO. All the information in the application will be made available upon request, unless it contains confidential information. Normally, between 10 and 20 written responses to the public hearing are submitted. A summary or the responses is prepared, and is part of the basis for the final decision concerning the GMO.	

Norway is a Party to the United Nations Economic Commission for Europe Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention). In 2002, the Parties to the convention adopted Guidelines on Access to Information, Public Participation and Access to Justice with respect to Genetically Modified Organisms was, and in May 2005 the second meeting under the Convention adopted an amendment setting out more precise provisions on public participation in decision-making on deliberate release of genetically modified organisms. The amendment requires the Parties to inform and consult the public in decision-making on the deliberate release and placing on the market of GMO. The public have the right to submit comments and the public authorities are expected to take these into account in the decision-making process.

Norway maintains an online information system that provide the public with up-to-date information on the legislative framework for GMO, applications for GMO authorizations and decisions taken by relevant authorities. Norway's main information portals for these purposes are:

- The website of the Directorate for Nature Management; http://www.dirnat.no/wbch3.exe?p=1714
- Norway's BCH site; http://bch.dirnat.no/hoved.aspx?kontroll=velkommen
- The website of the Ministry of the Environment; http://odin.dep.no/md/norsk/tema/naturmangfold/aktuelt/bn.html
- The website of the Food Safety Authority; http://matportalen.no/Emner/gmo
- The website of the Scientific Committee for Food Safety; http://www.vkm.no/eway/default.aspx?pid=261&trg=Main_4924&Main_4924=4950:0:10,1590:1:0:0:::0:0
- The website of the Norwegian Biotechnology Advisory Board; http://www.bion.no/tema/gmo.shtml

Article 24 – Non-Parties

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

48. If there have been transboundary movements of living modified organisms between your country and a non-Party, please provide information on your experience, including description of any impediments or difficulties encountered:
Not applicable – no such transboundary movements.

Article 25 – Illegal transboundary movements

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

49. Has your country adopted appropriate domestic measures to prevent and penalize, as appropriate, transboundary movements of living modified organisms carried out in contravention of its domestic measures? (Article 25.1)	
a) yes	X
b) no	

50. Please provide further details about your response to the above question, as well as description of your country's experiences in implementing Article 25, including any obstacles or impediments encountered:
Pursuant to Sections 17, 18, 20, 21, 23, 24 and 25 of the Gene Technology Act, several measures can be used to prevent and penalize transboundary movements of GMO carried out in contravention of the Norwegian legal framework on GMO, including supervision (Section 17), right of inspection (Section 18), order to cease activity (Section 20), duty to prevent and limit damage (Section 21), compensation (Section 23), coercive fine (Section 24) and penalties (Section 25). The Norwegian Food Safety Authority exercises supervision over the implementation of the Gene Technology Act. The Authority each year takes several samples from shipments, production sites and shops containing soy beans and maize and food and feed products consisting of, containing or produced from soy beans and maize. The samples are tested by the Norwegian Veterinary Institute to check whether they contain GMO not authorized for import into and marketing in Norway. So far the sampling and testing have revealed low levels (between 0,1 and 1 %, mostly below 0,1 %) of unintentional or technically unavoidable GMO presence in conventional soy beans and maize. Due to the documentation provided by the responsible persons/companies on the measures taken to avoid such GMO presence and assessments of environmental and health risks related to such presence, Norway has concluded that the conditions for imposing penalties, which are intentional or negligent contravention of the provisions prescribed in or pursuant to the Act have not been met in these cases.

Article 26 – Socio-economic considerations

51. If during this reporting period your country has taken a decision on import, did it take into account socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities? (Article 26.1)	
a) yes – significant extent	
b) yes – limited extent	
c) no	
d) not a Party of import	X[4]
52. Has your country cooperated with other Parties on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities? (Article 26.2)	
a) yes – significant extent	
b) yes – limited extent	
c) no	X
53. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 26, including any obstacles or impediments encountered:	
Norway has not taken any decision on import during the reporting period. As stated in our interventions at MOP2, socio-economic aspects may be relevant to decisions concerning GMO. Norway introduced the Gene Technology Act to ensure that the production and use of GMO takes place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and the environment. The Norwegian Biotechnology Advisory Board has developed a discussion paper on sustainability, benefit to the society and ethics in the assessment of genetically modified organisms. It is available at the following website: http://www.bion.no/publikasjoner/sustainability.pdf It has also been published on the Biosafety Information Resource Centre of the BCH.	

[4] No decisions on import taken within the reporting period.

Article 28 – Financial mechanism and resources

54. Please indicate if, during the reporting period, your government made financial resources available to other Parties or received financial resources from other Parties or financial institutions, for the purposes of implementation of the Protocol.	
a) yes – made financial resources available to other Parties	X
b) yes – received financial resources from other Parties or financial institutions	
c) both	
d) neither	

55. Please provide further details about your response to the above question, as well as description of your country's experiences, including any obstacles or impediments encountered:

In 2003 Norway provided NOK 3 million to the Norwegian Institute of Gene Ecology, GenØk, in support of a course called "Biosafety Capacity Building Programme" as well as to establish a GMO "forecast service" for developing countries. In 2005 Norway provided NOK 1.5 million to support GenØk in developing a pilot-project called "Gateways Institutes" which aims at assisting developing countries in fulfilling their obligations under the Cartagena-protocol.

The Norwegian Government has financed the course ""Holistic Foundation for Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms" conducted by The Norwegian Institute of Gene Ecology (GenØk) for the years 2003, 2004 and 2005. About 50 participants, mainly regulators from developing countries, have taken part each year. An external evaluation of the course was done in 2004 and concluded that the course held a high technical standard, and that it provided relevant, hands-on training that the participants found extremely useful.

The annual budget of the course has been NOK 3-4 mill (+/- USD 500.000 annually)

Support has also been given to other projects implemented by GenØk/Gateways institutes; but these are in a preliminary phase of implementation
- GE Biosafety Forecast service
- Book/CD-rom project
- Masters of Science Studies with majors in Gene Ecology and Holistic GE/GMO Risk Assessment (internett based; in cooperation with GVU, UNU)

Norway also contributes through GEF.

Other information

56. Please use this box to provide any other information related to articles of the Protocol, questions in the reporting format, or other issues related to national implementation of the Protocol:
As stated in the answers to questions 23 and 30 above, Norway is in favour of a scientific committee being appointed with the task of providing scientific and technical guidance on risk assessment guidelines, ARMG in GMO and other tasks that might be considered important for the fulfilment of the objectives of the Protocol, such as tasks pursuant to Article 18(3). The scientific committee should be appointed to fulfil specific tasks, not on a permanent basis. It should receive funding from the core budget and each Party should be entitled to appoint one expert to participate in its meetings. We call upon the Secretariat to make a budget proposal for the establishement of such a committe that could meet annually or biannually as the need may be.

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:

ANNEX I

Norwegian legal measures pertaining to genetically modified organisms

- The Act relating to the production and use of genetically modified organisms (Gene Technology Act) No. 38 of 2 April 1993.

- Regulations of 11 February 1994 No. 127 regarding safety measures, classification and reporting in laboratories and installations for contained use.
- Regulations of 16 September 1994 No. 877 regarding specified forms of teaching activities involving contained use of genetically modified organisms.
- Regulations of 20 August 1993 No. 816 on impact assessment pursuant to the Gene Technology Act.
- Regulations of 11 February 1994 No. 126 on reporting or authorization of contained use of GMO.
- Regulations of 2 September 2005 on labelling, transport, import and export of GMO. The Regulations replace Regulations of 13 November 1998 No. 1066 on transport and import of GMO.
- Regulations of 15 December 2000 No. 1268 prohibiting the marketing of certain genetically modified products in Norway.
- Regulations of 6 December 1996 No. 1127 concerning systematic work on health, safety and environment in activities.

- The Act of 19 December 2003 No. 124 on Food production and Food Safety

- Regulations of 7 November 2002 No. 1290 on feedstuffs (labeling requirements)
- Regulations of 8 July 1983 No 1252 regarding production and marketing of food.
- Regulations of 21 December 1993 No. 1385 on labeling of foodstuffs.

- The Act of 14 June No. 20 concerning protection against fire, explosion and accidents involving dangerous substances and the rescue duties of the fire squad.

- Regulations of 11 November 2002 No. 1264 on transport of dangerous goods by road and railway.

ANNEX II

Summary of Norwegian risk assessment on antibiotic resistance marker genes

In September 2005, the Norwegian Scientific Committee for Food Safety (VKM) prepared a document entitled "An assessment of potential long-term health effects caused by antibiotic resistance marker genes in genetically modified organisms based on antibiotic usage and resistance patterns in Norway". A summary of this document and its main conclusions are presented below.

Background

According to Directive 2001/18/EF in the legislation of the European Union (EU), antibiotic resistance marker genes (ARMG) in genetically modified organisms (GMO) **that may have adverse effects on human health and the environment** should be identified and phased out. Present Norwegian legislation prohibits the presence of **all** ARMG in foods and feeds. The EEA agreement implies harmonisation of Norwegian legislation with that of the EU. Hence, the Norwegian authorities have asked the VKM to conduct a risk assessment of the potential effects on health and the environment caused by ARMG in GMO, based on antibiotic usage and occurrence of antibiotic resistance in Norway. The request referred to the opinion on this subject published by the European Food Safety authority (EFSA) in 2004.

Summary of the EFSA opinion

In 2004 the Scientific Panel on Genetically Modified Organisms (GMO Panel) of EFSA published an opinion on environmental and health aspects of ARMG, particularly those already in use in genetically modified plants (GMPs). The opinion considered seven different ARMG which were assessed for their potential to increase the resistance of human and animal pathogens to antibiotics after horizontal gene transfer (HGT). Two main criteria were used to assess the potential impact of putative transfer and positive selection of ARMG in pathogenic microorganisms:

1) Prevalence of the ARMG homologues in natural microbial communities
2) The extent of usage, in human and veterinary medicine, of the antibiotics(s) to which the specific ARMG confers resistance

Data on the amount of the relevant antibiotics used in EU and on the levels of resistance to the relevant antibiotics in the EU, provided the main baseline for the assessment. Based on these criteria, the EFSA GMO panel classified the ARMG into 3 groups:

Group I: Genes *npt*II and *hpt*, which confer resistance to the antibiotics kanamycin/neomycin/paromycin/butirosin/gentamicin B/geneticin or hygromycin, respectively.

Group II: Genes Cm^r, amp^r and *aadA*, which confer resistance to the antibiotics chloramphenicol, or ampicillin or streptomycin/spectinomycin, respectively.

Group III: Genes *npt*III and *tetA*, which confer resistance to the antibiotics amikacin or tetracyclines, respectively.

The conclusions and recommendations of the EFSA GMO Panel were as follows:

- There is no rationale for restricting or prohibiting the use of ARMG in Group 1.
- The use of ARMG ARM genes in Group 2 should be restricted to field trial purposes only.
- ARM genes in Group 3 should not be present in GMPs to be placed on the market or used for experimental field trials.

Summary of the assessment by the Norwegian Scientific Committee for Food Safety (VKM)

In the assessment conducted by VKM, the following potential effects were considered:

- Toxic, allergenic or environmental effects caused by *proteins* encoded by ARMG
- Health effects caused by the uptake of intact ARM *genes* into mammalian cells
- Indirect effects arising from the reduced ability to treat microbial infections after HGT and amplification of ARMG in bacteria

The VKM observed that there are clear differences between European countries, both in bacterial resistance levels and also in usage levels of antibiotics. These are the two main criteria used by the EFSA panel for classification of the ARMG. The VKM therefore focused upon occurrence of antibiotic resistance in Norway and levels of Norwegian antibiotic usage.
With the exception of the *hpt*-gene that encodes resistance to hygromycin, all the ARMG included in the EFSA opinion encode resistance to compounds that are used therapeutically in Norway. Therefore, an increase in the resistance level to these antibiotics will necessarily have an effect on antibiotic usage patterns and infection treatment efficiency in Norway. Furthermore, given the documented usage of antibiotics in Norway, the positive selection of bacteria carrying ARMG (and naturally-occurring gene homologues) may occur under certain conditions.

Conclusions from the VKM assessment

- The VKM did not identify any conditions that indicate that the release of proteins encoded by ARMG constitutes a health or environmental risk in Norway.
- The VKM did not find any experimental evidence suggesting that ARMG, or any other feed-derived DNA molecules, will produce negative effects if unintentionally taken up by, or produced in, mammalian cell cytoplasms. Furthermore, the VKM did not identify any conditions specific to Norway, as compared to the EU, when considering exposure to feed-derived DNA containing ARMG.
- The VKM opinion regarding the ARMG, *hpt*, in Group 1 is that an increase in its prevalence will constitute a minimal risk. This opinion is in accordance with that of EFSA. Little information is available on the distribution and ecology of the *hpt* gene, however, due to the limited clinical importance of the relevant antibiotics, the VKM has not identified any specific concerns on the usage of this gene as an ARMG.
- The VKM opinion regarding the ARMG, *npt*II, in Group 1, is that an increase in the prevalence of this gene might constitute a somewhat larger risk than that for the *hpt*-gene, but the risk is nevertheless regarded as low. The rationale for this opinion is that the available data suggest that the prevalence of this gene in pathogenic bacteria in Norway is low. However, veterinary usage of aminoglycosidal antibiotics such as neomycin in Europe, including Norway, may create selective conditions for bacterial transformants harbouring ARMG.
- The ARMG in Groups 2 and 3, as defined by EFSA, encode resistance to antimicrobial agents that are widely used in human and veterinary medicine in Norway. The broad usage and utility of these antimicrobial agents suggest caution should be applied in the dissemination of resistance genes in environments that are selective for bacterial transformants carrying ARMG. Therefore, the VKM is of the same opinion as EFSA regarding the risk of ARMG in Groups 2 and 3 (See above).

The VKM acknowledges that the knowledge and data gaps in the preparation of this risk assessment are considerable. This is particularly the case where events cannot be excluded, even though they are assumed to occur rarely. Further understanding of the molecular and population scale aspects of HGT processes in bacteria are necessary to strengthen the risk assessment of potential effects caused by in GMO. Parts of the knowledge which is lacking can in the opinion of the Committee only be acquired by full scale use of these genes.