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

#### Origin of report

| Party:  | Belgium  |
|---|--|
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| Submission  |  |
| Signature of officer responsible for submitting report: |  |
| Date of submission:                                     | 28/09/07   |
| Time period covered by this report:                     | Entry into force of the Protocol till now on.                    |

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 Division of Biosafety and Biotechnology (SBB) of the Scientific Institute of Public Health (IPH), acting as national Focal Point for the BCH, has been involved in the preparation of this report for scientific and BCH-related matters.

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):

Belgium has provided the central portal of the Biosafety Clearing-House with comprehensive information regarding the following items:

- Existing national legislation for implementing the Protocol, including information required by Parties for the advance informed agreement procedure;
- National laws applicable to the import of GMOs intended for direct use as food or feed, or for processing;
- Contact details for competent national authorities (including their respective responsibilities), national focal points, and emergency contacts;
- Final decisions and corresponding risk assessment reports regarding the domestic use of GMOs that may be subject to transboundary movement for direct use as food or feed, or for processing (Article 11);
- National biosafety websites;
- Detailed information regarding experts nominated to the roster of experts.

This information is also available from the Belgian Biosafety Clearing-House (BBCH - http://www.biosafetyprotocol.be), the Belgian node of the BCH. The BBCH also provides for the following additional information:

- Scientific guidelines for implementing the Protocol;
- Full list of final decisions regarding the release of GMOs;
- Searchable databases providing data (including summaries of risk assessment) about all deliberate releases of GMOs into the environment in Belgium for research and development or for any other purposes than placing on the market.
- First interim national report (2005) on implementation of the Cartagena Protocol.

Belgium is constantly working to improve the information flow in this area. Further improvements will also depends on the forthcoming development at EU level in the implementation of a community node of the BCH.

## 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<br>does not exist<br>/not<br>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  |  |   |
| b) National laws, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing  | X  |  |   |

| (Article 11.5);   |  |  |   |
|---|--|--|---|
|   |  |  |   |
| c) Bilateral, multilateral and regional agreements and arrangements (Articles 14.2, 20.3(b), and 24.1);   |  |  | X   |
| 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  |  |   |
| e) In cases of multiple competent national authorities, responsibilities for each (Articles 19.2 and 19.3);   | X  |  |   |
| f) Reports submitted by the Parties on the operation of the Protocol (Article 20.3(e));   | X  |  |   |
| g) Occurrence of unintentional transboundary<br>movements that are likely to have significant<br>adverse effects on biological diversity<br>(Article 17.1);   |  |  | X   |
| 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<br>does not exist<br>/not<br>applicable |
| h) Illegal transboundary movements of LMOs (Article 25.3);  |  |  | X   |
| 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   |
| j) Information on the application of domestic regulations to specific imports of LMOs (Article 14.4);   |  |  | X   |
| 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  |  |   |
| 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  |  |   |

| 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 |
|---|---|---|
| n) Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12.1);   |   | X |
| o) LMOs granted exemption status by each Party (Article 13.1)   |   | X |
| 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 |
| q) Summaries of risk assessments or<br>environmental reviews of LMOs generated by<br>regulatory processes and relevant information<br>regarding products thereof (Article 20.3(c)). | X |   |

#### *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 a member of the EU, Belgium has to implement the EU legislation on GMOs, which is consistent with the provisions of the Protocol (see common EU report).

- a. Belgium has transposed the directive 98/81/CE on the contained use of GMOs in regional decrees: the decree of Walloon Government of 4 July 2002; the decree of Flemish Government of 6 February 2004 (mending decree of 6 February 1991), the decree of Government of the Brussels-Capital Region of 8 November 2001
- b. Belgium has transposed the directive 2001/18/CE on the deliberate release and placing on the market of GMOs in the royal decree of 21 February 2005
- c. Belgium has designated competent authorities (see BCH) for the implementation of all international, European and Belgian legislations relative to GMOs (transposition of directives 98/81/CE and 2001/18/CE; regulation 1946/2003 relative to the export of GMOs; regulations 1829/2003 relative to food and feed GMOs; contact point in case of unintentional transboundary movement of GMOs. For regulation 1830/2003 relative to labeling and traceability, the competence distribution in Belgium is still under discussion and under study by layers; however, practically, the obligations are already assumed for most of the GMOs presently on the market, i.e. GMOs intended for food and feed
- d. Belgium has established procedures and taken practical measures to implement the provisions of those regulations:

A cooperation agreement has been established (1997) between the Federal State and the Regions to facilitate the implementation of the obligations, especially concerning risk assessment of GMOs and decisions of authorizations. A national consultative council, composed of academic and administrative representatives of the Federal State and the Regions, helped by several academic experts groups, managed by the Division of Biosafety and Biotechnology of the national Scientific Institute of Public Health, gives advice to the concerned ministers in case of decisions on authorizations or refusal of introduction and /or use of new GMOs. A Biosafety Leading Group, composed of administrative and political representatives from the federal and regional levels (ministries of environment, health, agriculture, economy, foreign affairs) conveys to take positions on European and international environmental issues on GMOs. A GMO Steering Group, composed of federal administrative and political representatives of environment and health ministries, meets regularly to exchange information, tasks, and insure coherent policies concerning GMOs ("green" – for agricultural purposes - , but also "red"- for pharmaceutical purposes - GMOs).

Practical dispositions have been developed and will be improved following experience to insure the respect of their obligations by stakeholders, especially concerned industries. Contacts are established with customs responsible persons.

A national agency ( National Agency for the Safety of Food Chain ) is in charge of GMOs controls in the food chain ( presence and labelling ) . Federal inspectors are in charge of field inspections for field trials. Till now, no commercial GMOs have been planted. Coexistence regulations between GMOs ans no-GMOs cultures are in the process of being established .

- Sanctions to violation of th Community regulations have been established ( law of March 1, 2007, concerning various dispositions art. 32 to 36 modifying law of July 21, 1991 concerning social and various dispositions )
- A national GMO day, conveying all stakeholders and the press has been organized on 30 November 2004, with presentations by national, European and international representatives on GMOs legislations and measures at the different levels.

Articles 7 to 10 and 12: The advance informed agreement procedure
See question 1 regarding provision of information to the Biosafety Clearing-House.

| 5. Were you a Party of import during this reporting period?  |                         |  |
|--|-------------------------|--|
| a) yes   | X- at least potentially |  |
| b) no  |                         |  |
| 6. Were you a Party of export during this reporting period?  |                         |  |
| a) yes   |                         |  |
| b) no  |                         |  |
| 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  |                         |  |

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

| 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  | X                 |
| d) not applicable – not a Party of export  |                   |
| 9. Did your country take decisions regarding import under domestic regulatory frame by Article 9.2(c).   | eworks as allowed |
| a) yes   | X                 |
| b) no  |                   |
| c) not applicable – no decisions taken during the reporting period   |                   |
|  |                   |

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

In the EC, the implementation of the export part of The Cartagena Protocol is insured par regulation ( EC ) 1946/2003 . Following this regulation , the exporter itself is responsible for the notification to be addressed to the Party of import . The CION and the competent authority ( CA ) of the Party of export have however to receive a copy of that notification . Besides statistical purposes, that copy can be useful in case of emergency or for control of infringements and establishment of sanctions . We ( as CA ) have established practical procedures with the exporter ( mainly industrial ) sector relatively to the timeframe to send us the copies, the format of the copies of exporting documents ( requirements of Party of import/requirements of the Carthagena Protocol ) , the language of those documents .

Till 2003, we (as CA) received tens of copies of notifications, all of them to export LMOs developped in contained use in Belgium and aimed at deliberate release for field trials abroad. Most of the importing countries were non-Parties, which in itself raises some questions (see answer to question 56).

In the context of that procedure, some difficulties arose in the semantic interpretation of some requirements of the Protocol . This is the case with some items of Annex I of the Protocol that specifies the information to be present in notifications under articles 8, 10 and 13.

In particular, what does mean in item (k) of Annex I: "a previous and existing risk assessment report ....." that the exporter should address to the CA of the potentially importing country in the notification, before any 1<sup>st</sup> transboundary movement of a given LMO to that country? To what kind of report is it here referring; and is it acceptable that *no existing previous report* would be furnished as an answer to that requirement?

Another unclear aspect is the number of and the relationship between various events allowed to be presented in one single notification, in order to make the procedure clear and workable.

Finally, the language of the notification is puzzling in itself, if it has to be understood by the Party of import ( to take the AIA ) , the Party of export ( at least to casually establish sanctions ) and the Compliance Committee .

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:

See common EC answer

#### 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 cap respect of living modified organisms intended for direct use as food or feed, or for pro   |                   |  |
| a) yes (please give details below)   |                   |  |
| b) no  |                   |  |
| c) not relevant  | X                 |  |
| 14. Did your country take decisions regarding import under domestic regulatory frame by Article 11.4?  | eworks as allowed |  |
| a) yes   | X                 |  |
| b) no  |                   |  |
| c) not applicable – no decisions taken during the reporting period   |                   |  |
| 15. If your country has been a Party of export of LMOs intended for direct use for food or feed, or for processing, during the reporting period, please describe your experiences and progress in implementing Article 11, including any obstacles or impediments encountered: |                   |  |
| Not applicable . No Party of export of LMOs-FFPs during that period.   |                   |  |
| 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: |                   |  |
| See common EC answer   |                   |  |
|  |                   |  |

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 i unable to do so for some reason, please describe your experiences in implementing Ar any obstacles or impediments encountered: |   |
| Not applicable.  |   |

# 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   |   |
| b) no  | X |
| 20. If your country has entered into bilateral, regional or multilateral agreements or ar you have been unable to do so for some reason, describe your experiences in impleme during the reporting period, including any obstacles or impediments encountered: |   |
| Not Applicable . See common EC answer .  |   |

### Articles 15 and 16 – Risk assessment and risk management

| 21. If you were a Party of import during this reporting period, were risk assessments of decisions taken under Article 10? (Article 15.2)  | carried out for all                                      |
|--|--|
| a) yes   |  |
| b) no (please clarify below)   |  |
| c) not a Party of import / no decisions taken under Article 10   | X- no decisions taken under Article 10; see answer to Q. |
| 22. If yes to question 21, 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 / no decisions taken under Article 10   | X- idem Q. 21  |
| 23. If you took a decision under Article 10 during the reporting period, did you requir bear the cost of the risk assessment? (Article 15.3)   | re the notifier to                                       |
| 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 / no decisions taken under Article 10   | X- idem Q. 21  |
| 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 transbour of living modified organisms? (Article 16.3)   | ndary movements |  |
| a) yes – fully adopted  | X               |  |
| b) not yet, but under development or partially adopted (please give further details below)  |                 |  |
| c) no   |                 |  |
| 26. Does your country endeavour to ensure that any living modified organism, whether 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)  | X               |  |
| b) no (please give further details below)   |                 |  |
| 28. Please provide further details about your responses to the above questions, as well as description o  |                 |  |

your country's experiences and progress in implementing Articles 15 and 16, including any obstacles or impediments encountered:

Belgium has implemented a comprehensive system of risk assessment dealing with all uses of GMOs. Accordingly, all regulatory-related aspects of the uses of GMOs are assessed altogether in a coordinated way, independently of the specific concerned regulation(s).

The main legal basis is the "Cooperation Agreement between the Federal State and the Regions on the administrative and scientific coordination concerning Biosafety" (1997). This cooperation agreement establishes a common scientific evaluation system for the Federal State and the Regions, consisting in the Biosafety Advisory Council and the Division of Biosafety and Biotechnology of the Scientific Institute of Public Health.

The Biosafety Council advises the competent authorities about the safety for human health and the environment (including genetic and ecological aspects related to biodiversity) of any activities using GMOs, in particular the deliberate release of LMOs in the environment and the placing on the market of GMOs. The Council is composed of academic and administrative representatives appointed by the Regional and Federal competent authorities. It is assisted by about a hundred experts organised in thematic ad hoc groups.

The Division of Biosafety and Biotechnology (SBB) is in charge of the secretariat of the Biosafety Council. It is composed of an administrative secretariat, a multidisciplinary group of biosafety scientists and a laboratory for biosafety research and gene detection. The SBB also offers direct scientific support to the competent Federal and Regional authorities in the field of risk assessment of activities involving GMOs.

Belgium is actively involved (through several laboratories) in the European Network of GMO Laboratories. ENGL is a platform of EU experts active in the development, harmonisation and standardisation of means and methods for sampling, detection, identification and quantification of GMOs or derived products in a wide variety of matrices, covering seeds, grains, food, feed and environmental samples. ENGL provides assistance to the Community Reference Laboratory (CRL) for GM Food and Feed, particularly with respect to the validation of analytical methods for the event-specific quantification of GMOs that are under marketing approval.

Moreover, BE representatives are present in various international scientific meetings tackling the question of risk assessment of new LMOs in development ( trees, fishes, pharmaplants, viruses ).

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:  |   |
| Not applicable.   |   |

#### Article 18 – Handling, transport, packaging and identification

31. Has your country taken measures to require that living modified organisms that are subject to

| conditions of safety, taking into account relevant international rules and standards? (Article 18.1)  |                        |           |
|---|------------------------|-----------|
| a) yes (please give details below)  | X-<br>common<br>answer | see<br>EC |
| 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:

See common EC answer + answer to Q. 4.

*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 Division of Biosafety and Biotechnology (SBB) of the Scientific Institute of Public Health has been appointed as Belgian Focal Point for the BCH. According to decision BS-I/3, the BCH National Focal Point liaises with the Secretariat regarding issues of relevance to the development and implementation of the Biosafety Clearing-House, including information clearance before publication to the BCH central portal, and liaison with the Secretariat regarding the technical aspects of national participation to the BCH.

Through the SBB, Belgium actively participated in the development of the pilot phase of the Biosafety Clearing-House, notably by contributing to the work of the group of technical experts on the BCH, established by the CBD Secretariat to provide advice on technical issues associated with the

implementation of the pilot phase of the BCH.

In the framework of some capacity-building activities (see below), the SBB also provided the Secretariat with regular input regarding the structure and functionalities of the central portal.

Moreover, Belgium has been active since many years in the development and management of Internet-based systems for information sharing in the field of biosafety, in particular:

- The "Belgian Biosafety Server" (BBS http://www.biosafety.be). It is runned by the SBB since March 1996 and provides information on scientific and regulatory aspects of biosafety related to activities carried out using GMOs. The BBS was one of the first website worldwide fully dedicated to biosafety and it is still today a reference at international level.
- The "Belgian Biosafety Clearing-House" (BBCH http://www.biosafetyprotocol.be), set up in 2001. This was done in response to the recommendation of the first meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP-1) which "encouraged Governments with national databases to facilitate the establishment of linkages to the Biosafety Clearing-House". Since that time, the BBCH has been regularly updated.
- The GMO portal of the FPS Health Food Chain Safety and Environment (http://www.ogm-ggo.be), set up in 2005. This site provides general information on all international, European and Belgian legislations on GMOs, a.o. the Cartagena Protocol, awareness on the present debates, news, and several links to more detailed documents.

Some work has also been performed at the technical level. The interoperability with the central portal using a pull mechanism was tested. The main obstacle encountered regarding technical developments was the high level of technical expertise needed to comply with the technical choices made by the Secretariat.

Another limiting factor was the very slow implementation of a network of interoperable BCH nodes at EU level. Very recently, the development of GMOREGEX, a workflow, information dissemination and exchange application has been completed by the EC. This application includes the EC-BCH module which will allow automated submission of the information generated during the authorisation process and relevant to the BCH data exchange to the BCH Central Portal. Belgium is currently involved in the pilot phase of the GMOREGEX/ EC-BCH application. It can be expected that these latest development at EU level will allow further technical improvement of the BBCH in the next few months.

In that context, Belgium also participated in 2 meetings among the BCH national Focal Points in the Member States of the EU aimed at reviewing and defining the modalities of collaboration within the EU's BCH focal points.

Last but not least, the development and management of the BCH at Belgian level have also been made difficult due to the lack of human and financial resources specifically assigned for that purpose.

#### *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 |  |

39. If you answered yes to the previous question, please provide information on your experience including description of any impediments or difficulties encountered:

Belgium fully applies the confidentiality provisions contained in the EU legislation on GMOs (see EC contribution). These provisions apply equally to domestic and foreign producers of GMOs.

In particular, all experts and members of the Biosafety Council involved in the assessment of GMO dossiers are requested to sign a declaration of confidentiality. The declaration stipulates that these persons will respect the confidentiality/restriction of any information brought to their attention during the performance of their work, will not divulge any information to third parties, will not use any information for their own benefit or that of any third party and will not make any information available to the public, even after completion of their assignment.

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:

#### 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:

Belgium has contributed to effective implementation of Article 20 of the Protocol in developing country Parties with the initiative: "Biosafety Clearing-House: Data Search and Input". This initiative is currently suspended.

The initiative was co-organised by the Division of Biosafety and Biotechnology (SBB) and the Belgian focal point for the Convention on biological diversity (CBD). The programme consisted in a two- or three-weeks course held in Brussels, Belgium. The primary objective was to train BCH national Focal Points from developing countries to enable them to retrieve information from the BCH and to provide information through the BCH. □ The training course allowed the participants to learn how to use the central portal of the BCH, to implement and manage a local database (including management of a network of partners), to present information required under the Protocol and other relevant biosafety-

related information. 

The training was restricted to participants from developing countries, designated as BCH national Focal Point or directly involved in information sharing under the Cartagena Protocol on Biosafety. Depending on the participants, the course was given in French and/or in English.

This training was an extension of the partnering project established since 1998 by the Belgian CBD focal point in the context of the Clearing-House Mechanisms (CHM) of the Convention. The training was made possible through a financing of the Directorate-General for Development Cooperation (DGDC) of Belgium.

The following training courses have been held:

- 13-31 October 2003, gathering representatives from Cameroon, Djibouti and Madagascar.
- 18-29 October 2004, with delegates from Niger, Burkina Faso and the Centrafrican Republic.
- 9-23 May 2005, gathering representatives from Congo Brazzaville, Mauritania and Togo.
- 21 November 2 December 2005, gathering representatives from Burundi, Mali and Senegal.
- 8-19 May 2006, gathering representatives from Comoros, Guinea and Côte d'Ivoire.

Because of the limited finances of the DGCD and the present multilateral and bilateral development cooperation programmes between Belgium and developping countries, it was not possible till now, despite repeated trials by the BE-NFP of the Protocol since 2004, to organize other types of capacity building activities in less favoured countries like to participate to risk assessment training or other technology transfer . Things are however presently moving towards a more encouraging situation in that respect .

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 be cooperation for technical and scientific training in the proper and safe management of the extent that it is required for biosafety? |   |
| a) yes – capacity-building needs fully met (please give details below)   |   |
| b) yes – capacity-building needs partially met (please give details below)   |   |
| 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   |  |  |
| b) yes – limited extent   |  |  |
| c) no   |  |  |
| 50. If yes, do you cooperate with other States and international bodies?  |  |  |
| a) yes – significant extent   |  |  |
| 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   |  |  |
| c) no   |  |  |
| 52. Does your country, in accordance with its respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and make the results of such decisions available to the public? (Article 23.2)   |  |  |
| a) yes – fully  |  |  |

| b) yes – limited extent  |                 |
|--|-----------------|
| c) no  |                 |
| 53. Has your country informed its public about the means of public access to the Biosa House? (Article 23.3) | nfety Clearing- |
| a) yes – fully   |                 |
| 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:

Belgium maintains on-line information systems that provide the public with up-to-date information on the legislative framework for LMOs, applications for LMO authorisations, decisions taken by relevant authorities, risk assessment aspects and guidelines, and measures provided as part of risk management. To date, the main information source for these purposes is the "Belgian Biosafety Server" (which can be accessed at http://www.biosafety.be). This information is rather for a warned public.

In accordance with European Community and national requirements, Belgium is also actively contributing to information exchange systems established at Community level to provide public information about LMOs.

In 2003, two "citizens fora" (one in the Walloon Region, one in the Flemish Region) were organized by the Federal Public Service for Health, Food Chain Safety and Environment and the organization Fundation for Future Generations at the communal level for statements, questions-answers sessions and discussions between scientists, officials and local citizens around the problematics of GMOs biosafety. A report of those meetings was made by the Fundation for Future Generations.

On 30 November 2004, the DG Environment (National Focal Point for the Protocol) of the Federal Public Service for Health, Food Chain Safety and Environment organized a GMO day open to all stakeholders and representatives and the press; national, European and international representatives made talks in order to explain all legislations concerning GMO's biosafety, from international to national ones; debates were organized in various workshops on actuality subjects related to the matter (coexistence, comparison of legislations in various countries, USA-EC WTO conflict, enlargement of the evaluation, ...)

Belgium has established practical procedures, on the basis of previous ones, for public consultation in the case of field trials with GMOs organised in Belgium ( for marketing, the consultation process is in charge of the Commission). Since 2004 up to now, no field trials took place in our country anymore.

Belgium has been largely involved in the GMO's negociating process under the Aarhus convention and has actively been supporting the "Almaty amendment" ( 2005 ) that establishes public participation in decisions on deliberate release into the environment and placing on the market of genetically modified organisms . It has to be noted that the amendment specifies that this requirement should be complementary and mutually supportive to the provision of the national biosafety framework of the Parties , consistent with the objectives of the Cartagena Protocol on Biosafety . Belgium has launched in

2007 its administrative work in oreder to be able to ratify the Almaty amendment .

#### 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:   |   |  |
| See common EC answer. See also answer to Q. 10   |   |  |
| Following regulation CE/1946/2003 implementing the exporter duties of the Cartagena Protocol, the EU Member States should behave similarly towards non-Parties as towards Parties, thus having also to send notifications and respect the AIA procedure. In case of export of LMOs aimed a deliberate release into the environment of some non-Parties, it could however be difficult to ascertain that the risk assessment will be made in conformity with what is required in regulation 1946/2003 and that is in conformity with the requirements of the Protocol.  This seems to us an important question to raise in relationship with the casual responsibility of the Party of export in the final decision taken under the AIA procedure, that should be clarified in the case of transboundary movements towards non-Parties; this, taking especially into account Art. 24.1 of the Protocol ( transboundary movements of LMOs between Parties and non-Parties shall be consistent with the objective of the Protocol) and decision BS-I/11, annex § c. ( Parties to the Protocol should, when exporting LMOs to non-Parties, ensure that risk assessment is carried out in accordance with the provisions of the Protocol) |   |  |
|  |   |  |
| Article 25 – Illegal transboundary movements   |   |  |
| See question 1 regarding provision of information to the Biosafety Clearing-House.   |   |  |
| 57. Has your country adopted appropriate domestic measures to prevent and penalize, 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  |   |  |
| 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:   |   |  |

See first common EC answer.

For non-food GMO's, Belgium has recently established sanctions to violation of the EC GMO-legislation and their transposition in Belgian legislation, in a law of March 1, 2007 concerning various dispositions (- art. 32 to 36 - ) and amending art. 132 of a law of July 21, 1991 - concerning social and various dispositions - .

For GMO's and derived products entering in the food/feed chain, theses sanctions are developped by the Federal Agency for he Safety of th Food Chain (competent control authority)

General remark: impossible to avoid all illegal transboundary movements as long as no technical (analytical) means are developed to allow general distinction between GM- and non-GM organisms.

Measures taken in BE (in 2006) to limit illegal transboundary movements of specific LMOs fishes.

- Ban on the import and commercialisation of coloured and fluorescent ornament fishes ( in addition to on GM fishes ).
- precise information on this ban for customs responsible workers, inspectors inside the country and animal shops

#### *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                       | X |
| d) not a Party of import    |   |

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     | X |
| c) no                       |   |

62. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 26, including any obstacles or impediments encountered:

In 2005, the Federal Ministry of Environment has financed a research project ordered by the DG Environment ( National Focal Point for the Protocol ) of the Federal Public Service for Health, Food Chain Safety and Environment to a research team of the University of Leuven, on the socio-economical impacts of GMOs, interesting developed and developing countries. On the basis of some case studies previously developed by that team, this financing aimed at establishing a methodology for the study of such impacts, respecting the wording of the Cartagena Protocol ( socio-economic impacts of GMOs related to impacts on biodiversity and on indigeneous and local populations ). In that original approach, rather than focusing on the GMO innovation, the case by case relevance of GMO cultures is compared to other types of cultures and technologies potentially able to solve the same problem, considering impacts for and from the environment, the agricultural practices, the health, the local population expectations and incomes ( producers and consumers ), the market, ..... After cases studies in developed countries, the

team has also considered cases studies in developing countries. This entire work has led to a Ph.D. thesis. For details on the research of that group, see <a href="https://www.gena.ucl.ac.be">www.gena.ucl.ac.be</a>. To find part of the study financed by the Federal Ministry of Environment, see <a href="https://www.ogm-ggo.be">www.ogm-ggo.be</a>

#### Article 28 – Financial mechanism and resources

| 63. Please indicate if, during the reporting period, your Government made financial re other Parties or received financial resources from other Parties or financial institutions of implementation of the Protocol.   |   |
|--|---|
| a) yes – made financial resources available to other Parties   | X |
| b) yes – received financial resources from other Parties or financial institutions   |   |
| c) both  |   |
| d) neither   |   |
| CA Plans and defined a decided at the second and the second and the second at the seco | 1 |

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:

See common EC answer + answer to Q. 42

#### 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:

Based on the Precaution principle and in order to reach the main objectives of the Cartagena Protocol Protocol, various research projects have already been financed in BE (besides that mentionned in answer to Q. 62), among which:

- in 2004 : establishment of a methodology of study on the potentail of hybridization of GM- cultures with indigeneous flora of Belgium, with Colza as a case study ( see report on www.ogm-ggo.be )
- in 2006-2007: establishment of an inventory of Belgian monitoring networks (environment, agriculture, human and animal health) that could be used to monitor any negative unforeseen impact of commercialized LMOs.

#### 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: