

Bio.be Recommendations – Version 1¹ for fulfilling the obligations of the Cartagena Protocol on Biosafety for imports of GMO's in Belgium

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the “Cartagena Protocol”) describes approval and documentation requirements for the transboundary movement of Living Modified Organisms (LMOs²). The European Council approved the Cartagena Protocol on behalf of the European Community on 25 June 2002 (Council Decision 2002/628/EC) and enacted legislation as Regulation (EC) N° 1946/2003³ of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (the “TBM Regulation”) that implements the procedures laid down in the Cartagena Protocol.

Member Companies of Bio.be are actively involved in research, development and commercialisation of GMOs. Competing on the international scene, such activities include the frequent exchange of material with academic and industrial partners globally. This recommendation is intended to provide guidance for cases where LMOs are imported into Belgium. The recommendation is limited to the obligations relating to the Cartagena Protocol and depending on the type of material other obligations may need to be observed as well.

Summary Recommendation for import of LMOs intended for contained use

- **Since neither the Cartagena Protocol, nor the TBM Regulation require a particular approval or statement of the importer, only a permit satisfying the contained use Directive needs to be in place before the movement.**
- **The exporting party needs to ensure that appropriate documentation accompanies the shipment.**
- **On request of the exporting party, the biosafety responsible/coordinator of the importing party may issue a statement referring to appropriate permits.**

Summary Recommendation for import of LMOs intended for intentional introduction into the environment

- **The Advanced Informed Agreement procedure required by the Cartagena Protocol, is covered by the Part B approval according to the European Directive 2001/18/EEC. The Part B approval needs to be obtained before the shipment of material.**
- **The exporting party needs to ensure appropriate documentation, which may include a copy of the Part B approval, accompanies the shipment.**

¹ This recommendation was prepared by members of BelgoBiotech and communicated in February 2005. Following the creation of Bio.be, the format was adapted without any changes of the contents.

² Since there are small differences between the definition of Living Modified Organisms in the Cartagena Protocol and the definition of Genetically Modified Organisms in the European regulations, both terms are maintained throughout this recommendation.

³ Official Journal, L 287, 5.11.2003 P. 0001- 0010

1. General observations

The requirements of the Cartagena Protocol for import into the EU are covered by the existing legal framework on contained use, deliberate release and other product specific regulations. The TBM regulation is not relevant for movements between EU Member States.

This is illustrated in the preamble of the TBM Regulation:

(14) As existing Community legislation, and in particular Directive 2001/18/EC and sectoral legislation providing for a specific risk assessment to be carried out in accordance with the principles set out in that Directive, already contain rules which are in line with the objective of the Protocol, there is no need to adopt supplementary provisions with regard to imports of GM's into the Community.

The requirements of the Cartagena Protocol regarding movement of materials within the boundaries of the European Community are covered by domestic legislation as illustrated by the preamble of the TBM regulation:

(13) According to the Protocol, the Community may apply its domestic legislation in respect to the movements of GMOs within its customs territory.

and by definitions of Article 3 of the TBM Regulation

11. 'import' means the placing under a customs procedure, other than transit procedure, of GMOs introduced into the customs territory of a Party or non-Party outside the Community from a Party within the Community;

14. 'transboundary movement' means the intentional or unintentional movement of a GMO between one Party or non-Party and another Party or non-Party, excluding intentional movements between Parties within the Community;

As a consequence, for any import and subsequent use within the Community, the European and national legislation prevail, without additional requirements.

2. Import of GMOs intended for contained use

2.1 Approvals for import of LMOs intended for contained use

Article 6.2 of the Cartagena Protocol specifies for movements intended for contained use:

Art 6. 2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

Within the European legislation the "right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction" has been taken up in the European Directives 90/219/EEC⁴ and 98/81/EC⁵ on

⁴ Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms Official Journal L 117 , 08/05/1990 P. 0001 – 0014

⁵ Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of

contained use. These Directives set the “standards of the Party of import” and any contained use of a GMO requires compliance with these rules. Given this provision, any other obligation pursuant the Advanced Informed Agreement procedure is waived.

It is the responsibility of the exporter to ensure that the receiving facility is authorized to receive the material and of the receiver to obtain all necessary permits if not available. If needed, written confirmation of the availability of appropriate permits may be provided by the Biosafety Responsible/Coordinator of the receiving facility.

2.2 Documentation accompanying import of LMOs intended for contained use

The exporter needs to ensure that documentation accompanying the shipment of LMOs destined for contained use follow requirements of Article 18.2.(b) of the Cartagena Protocol.

The information provided in this section is based on the conclusions of the first Meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 1)(Kuala Lumpur, 23-27 February 2004). Specifications are subject to revision by the Conference of the Parties.

These requirements are as follows:

- Use existing documentation, e.g. the pro-forma or commercial invoice
- Identify as “Living Modified Organism” including common and scientific names of the organisms and as “Destined for Contained Use”
- Indicate name and address of consignee, and exporter or importer, as appropriate, including contact details necessary to reach them as fast as possible in case of emergency
- Include any requirements for the safe handling, storage, transport and use of the living modified organisms under applicable existing international instruments, such as the United Nations Recommendations on the Transport of Dangerous Goods, the International Plant Protection Convention and the “Organisation Internationale des Epizooties”, domestic regulatory frameworks or under any agreements entered into by the importer and exporter. In the event that there is no requirement, indicate that there is no specific requirement
- Where appropriate, further information should include
 - the commercial names of the living modified organisms, if available,
 - new or modified traits and characteristics such as event(s) of transformation,
 - risk class,
 - specification of use,
 - any unique identification, where available, as a key to accessing information in the Biosafety Clearing-House

3. Import of GMOs for intentional introduction into the environment

3.1 Approvals for import of LMOs intended for intentional introduction into the environment

The Cartagena Protocol imposes a process of Advanced Informed Agreement (AIA) before the first movement of LMOs intended to be introduced into the environment. In this note the situation is described for a third party, located outside of the Community, and preparing for an introduction into the environment in Belgium.

The main features of the AIA procedure are:

- submission of a notification to the competent authority of the importing country according to the AIA specifications for import authorization prior to the first movement
- written approval of import by the Competent Authority of the country of import

European Directive 2001/18/EC⁶ on deliberate release covers all the requirements of the AIA request.

3.2 Documentation accompanying import of LMOs intended for intentional introduction into the environment

The exporter needs to ensure that proper documentation according to Article 18.2.(c) of the Cartagena Protocol accompanies the shipment of LMOs that are intended for intentional introduction into the environment.

The information provided in this section is based on the conclusions of the first Meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 1) (Kuala Lumpur, 23-27 February 2004). It should be reviewed and updated regularly. Specifications are subject to revision by the Conference of the Parties.

These requirements are as follows:

- Use existing documentation, e.g. the pro-forma or commercial invoice.
- Identify as:
 - "Living Modified Organism"
 - a brief description of the organisms, including common and scientific name,
 - relevant traits and genetic modification, including transgenic traits and characteristics such as event(s) of transformation or, where available and applicable, a reference to a system of unique identification
- Include any requirements for the safe handling, storage, transport and use of the living modified organisms as provided under applicable existing international requirements, domestic regulatory frameworks, or under any agreement entered into by the importer and exporter. In the event that there is no requirement, indicate that there is no specific requirement
- Indicate name and address of consignee, and exporter or importer, as appropriate, including contact details necessary to reach them as fast as possible in case of emergency
- Include a declaration: "The movement of the living modified organisms is in conformity with the requirements of the Cartagena Protocol on Biosafety applicable to the exporter."
- Where appropriate, include further information:
 - the commercial names of the living modified organisms, if available,
 - risk class,
 - import approval for the first transboundary movement of living modified organisms.

⁶ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC Official Journal L 106 17.4.2001 P. 0001 - 0038

Bio.be is the Belgian biotechnology industry organisation. Founded on January 23 2006 as a result of the merger of the Belgian Bioindustries Association (BBA) and BelgoBiotech, Bio.be represents the companies and professionals involved in research, development, testing, production or marketing of biotechnology applications, as well as those servicing the biotechnology community.

Bio.be ; Boulevard Reyers, 80 ; 1030 Brussels

Tel.: + 32 (0)2 238 98 47

Fax.: + 32 (0)2 231 13 01

Email: cvc@bio.be

Website: www.bio.be