

Bio.be Recommendations – Version 2¹ for fulfilling the obligations of the Cartagena Protocol on Biosafety and the European Transboundary Movement Regulation for Transboundary Movement from Belgium of Genetically Modified Organisms intended for deliberate release into the environment

The Cartagena Protocol on Biosafety (the “Protocol”) is in force since 11 September 2003. Belgium ratified the Protocol on 15 April, 2004. Furthermore, Regulation (EC) No 1946/2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms (“TBM Regulation”) came into force on 25 November 2003.

Since mid 2003 Belgian biotech companies have interacted with Belgian government officials to clarify the requirements provided by the Protocol and the TBM Regulation. In addition, through BelgoBiotech and EuropaBio, clarification was obtained from the European Commission² on the interpretation of certain elements of the TBM regulation. Based on these discussions and clarifications on proposed options, this paper summarizes the understanding and recommendation of the industry. It is acknowledged that these recommendations can be adapted as experience is acquired with the proposed way of acting or if common EU positions are adopted, different from those proposed here.

While the scope of the Protocol and the TBM cover movement for different purposes, this paper deals specifically with the export of genetically modified organisms (GMOs) to Parties and non-Parties intended for deliberate release into the environment as described in Section 1 of the TBM Regulation.

To establish these recommendations, the following assumptions were made:

- The Protocol and the TBM Regulation aim to ensure an adequate level of protection in the field of safe transfer, handling and use of GMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health and specifically focusing on transboundary movements.
- There are important differences between countries in relation to regulation and experience in handling GMOs. In order to contribute to the above goal, more attention may be required when the country of import has only limited or no experience. Such occasions can be used as opportunities for capacity building. This is particularly relevant for scientific collaborations with developing countries.
- Following the Protocol as well as the TBM Regulation 1946/2003/EC, it is the responsibility of the importing country to evaluate the validity of the methods and the results of the risk assessment. The importing country may choose to carry out itself or to ask the exporting country competent authorities to carry out the risk assessment. The Protocol asks Parties to refer to recognized methods and apply risk assessment in conformity with Annex III; non-Parties are not bound by these requirements.
- Among the importing countries where Belgian biotech companies send materials, some may have effective and well-developed legislation in place that allows them to make an informed choice thus meeting the intention of the Protocol and the TBM Regulation. Anyone intending to perform a field

¹ This recommendation was prepared by members of the working group Plant Biotechnology of BelgoBiotech. Version 2, which was established after review by the Belgian Competent Authority, replaced version 1 of February 2005. Following the creation of Bio.be, the format was adapted without any changes of the contents.

² In particular the letter dated 1/3/2004 from the European Commission DG Environment to EuropaBio and the letter dated 27/1/2005 from the European Commission DG Environment. to BelgoBiotech

release in such country has to observe the specifics of the local requirements. In any event the exporter should ensure that the information to fulfil the AIA requirements is provided.

- The Competent Authority³ in the country of export needs to have access to the relevant information on transboundary shipments in case of emergencies and to ensure that the movements are in compliance with the TBM Regulation and in particular the Advanced Informed Agreement (the “AIA”). The decision on an import and/or subsequent intended field release remains the sovereign right of the competent authority of the country of import.
- Although these recommendations are based on internationally applicable rules like the Protocol and the TBM Regulation, they are specific for Belgium as the country of export. Therefore the exporting country is the Belgian Competent Authority for the Protocol and TBM Regulation.
- Bilateral agreements between countries (non-Parties as well as Parties), bringing the objectives of the Protocol and the TBM Regulation into practice, could facilitate some recurrent exchanges, but this will not provide a short-term alternative. Those agreements should in any case be consistent with the objectives of the Protocol and should not result in a lower level of protection than that provided by the Protocol.

1. Authorization pre-dating the entry into force of the TBM Regulation

Since in this situation the importing country’s regulations have been followed to obtain either a deregulation of the product (commercial material) or an import authorization for deliberate release into the field (for pre-commercial and research material) predating the entry into force of the TBM Regulation, it is understood that such movements may continue between Belgium and the importing country based on approvals that predate the entry into force of the Protocol and the TBM Regulation.

In all cases where the movement of the material was first permitted prior the entry into force of the Protocol and the TBM Regulation, the exporter has to keep on file the official authorization document stating the date of authorization and validity period and, if available, the reference of the authorization on the BioSafety Clearing House.

2. Requirements for new movements

The transboundary movement of new events that had not received an authorization from the importing country before 25 November 2003, i.e. the entry into force of the TBM Regulation, follow the AIA process (see also “3. First TBMs during interim period”).

2.1 Application in the Country of Import.

According to the AIA process, an application in the country of import and its written approval is required before the first movement. In some cases subsequent import and/release permits may be needed according to regulation of the country of import but these do not concern the Protocol.

- Local format requirements and the AIA process

The exporter has to follow the procedures in force in the country of import in order to apply for import and/or deliberate release of the material to be tested. Whereas most local requirements cover the items required by the Annex I of the TBM Regulation in compliance with the AIA

³ Competent authority is defined by the TBM Regulation as “a competent authority designated by a Party to the Protocol, or the relevant equivalent body of a non-Party, which is responsible for performing the administrative functions required by the Protocol, or equivalent functions in the case of a non-Party, and is authorised to act on its behalf with respect to those functions”

process, there may be deviations or omissions. It is therefore accepted that in addition to the application constituted according to the guidance by the importing country requirements, an additional checklist is compiled based on the Annex I of the TBM Regulation. In this checklist exporters can refer to the information in the application for those topics that are adequately covered and additional information should be provided for topics that have not yet been addressed. A template for such checklist is provided as annex 1 to this recommendation.

Both the application and the AIA checklist are sent to the competent authority in the country of import. While the application document is prepared in the official language of the importing country, the AIA checklist is presented in English.

- **Importing Country Procedures**

Some countries, such as the USA, offer a simplified importation procedure for deliberate release into the environment of certain GMOs. Such simplified procedure is based on a preliminary assessment of the material; only materials that meet certain criteria may be imported using this “notification” procedure. So although all elements for a risk assessment are not included in the import request, a risk assessment is done by the US competent authorities when evaluating whether the material meets the “eligibility” criteria. Furthermore, the simplified notification procedure implies observance of crop specific management measures - so-called “performance standards”- which aim at optimal protection of the environment. Taking into account these simplifications, the AIA checklist will be further documented.

- **Import versus Field Trial Permits**

Some countries may provide only a field trial permit without explicit mention of importation. Other countries grant two separate authorizations, one for import and another for field release. When both permits are in use by the country of import, the one that provides all the relevant information required by Annex I of the TBM Regulation is presented to fulfil the requirements of the AIA process,

2.2 First TBM: information to the Exporting Country Competent Authority and Commission.

The first movement is determined according to material and country. The described procedure is only required for first movements.

- **Information requirements**

In line with Article 6 of the TBM Regulation, the exporter needs to provide to the competent authority of the Exporting Country and to the Commission, a copy of the following documents:

- a record of the notification
- the acknowledgement of receipt, and
- the decision of the country of import

Importing countries that are non-Parties to the Protocol often do not provide an acknowledgement of receipt of the notification as required by the Protocol. In this situation, the decision (import or field trial permit) implicitly confirms the receipt.

According to the TBM Regulation, the exporter is required to keep these records for a period of a minimum of five years.

In order to limit the administrative work and to allow inspection at the discretion of the Belgian competent authority, the exporter has the option of providing the entire notification or a summary of the information as specified in Article 16 §3 of the TBM Regulation (see template in Annex 2). The summary includes the following information:

- Name and contact details of the exporter and importer,
- General description of the GMO(s), including scientific and common name of the host organism, general description of the introduced trait(s)
- Code numbers (event numbers), references or the Unique Identifier, as appropriate, allowing retrieval of information on the material.
- Any methods and plans for emergency response, as appropriate.
- A summary of a previous and existing risk assessment, consistent with Annex II of Directive 2001/18/CE, if available to the exporter.
- A statement certifying that the information provided to the importing country complies with the AIA process and the Annex I of the TBM Regulation and that the information provided to the importing country is factually correct,
- A confirmation that the copy of the complete notification is available for inspection and where it can be obtained, should verification be required.

A copy of the complete notification can be requested by the Belgian competent authority at the contact indicated in the summary and should be delivered within 15 days of the request.

- **Timing for informing the exporting country and the Commission**

When submitting the notification to the Competent Authority of the importing country, the exporter should consider providing, if possible, to the Belgian Competent Authority a copy of the letter accompanying the notification.

In any case, after the decision is received from the Competent Authority of the country of import and in a reasonable time-frame before the first movement, a copy of all the documents forming part of the AIA process (notification and AIA checklist or summary, acknowledgement (if available) and decision) will be sent to the Belgian Competent Authority and the Commission.

- **Public Information/Confidentiality**

The Commission is in charge of making public the part of the notification that is not confidential in accordance with the confidentiality rules described in Article 16 of the TBM Regulation. For the remainder information presented in the notification and in the AIA checklist, according to the Protocol and the TBM Regulation, the exporter should indicate which of them should be kept confidential, with justification on demand.

2.3 Subsequent movements of material to the same country

If the same material is sent at later occasions, e.g. for trials in a subsequent season, to the same country, then no requirements are imposed in relation to the AIA process for informing the country of export or the Commission. Note that subsequent import and/or release permits may be required but these are not subject to the requirements of the Protocol or TBM Regulation.

3. First TBMs during interim period

3.1 Authorization between the entry into force of the TBM Regulation and the entry into effect of this recommendation.

During the period of clarification of the process to be followed in Belgium, different exporters, based on their own interpretation, have taken steps to fulfil the requirements of the Protocol and the TBM Regulation. The exporters that have shipped materials, while waiting for clarification on procedures, should provide the documentation indicated in this recommendation to the exporting country Competent Authority and the Commission for those first TBMs carried out since the entry into force of the TBM Regulation and the date these recommendations enter into effect.

AIA Notifications in process and future ones will follow the procedure described in 2 above.

3.2 Implementation of these recommendations

Version 2 of the BelgoBiotech recommendations was effective as of 1 January 2006 and replaced version 1 of February 2005. This version was transformed to a Bio.be recommendation –without changing the content- in December 2006.

4. Update of recommendations

As experience is gained with the practices described in this recommendation, adaptations may be envisaged. Furthermore, international and European harmonization may lead to new insights and approaches requiring updates of these recommendations.

Industry is committed to improving compliance processes in order to achieve the objectives of the Protocol and the TBM regulation while keeping the administrative burden to a minimum.

5. Contacts

For further clarification and information contact:

Patrick Rudelsheim
Bio.be
Working Group Green Biotech, chair

Esmeralda Prat
EuropaBio Cartagena Protocol Working Group,
member

General Partner
Perseus bvba
Patrick.Rudelsheim@perseus.be

Biosafety Manager
Bayer CropScience
Esmeralda.Prat@bayercropscience.com

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

ANNEX 1 Template of AIA Checklist to be included in all applications to importing country competent authority

This Checklist provides references to information required under the Advanced Informed Agreement process as required by the Cartagena Protocol on Biosafety and Regulation (EC) No 1946/2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms

	AIA notification requirement	Reference to notification or additional information
a	Name, address and contact details of the exporter.	
b	Name, address and contact details of the importer.	
c	Name and identity of the GMO, as well as the domestic classification, if any, of the biosafety level of the GMO in the State of export.	
d	Intended date or dates of the transboundary movement, if known.	
e	Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.	
f	Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.	
g	Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.	
h	Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the GMO.	
i	Intended use of the GMO or products thereof, namely, processed materials that are of GMO origin, containing detectable novel combinations of replicable genetic material obtained through techniques listed in Annex I A, Part 1 of Directive 2001/18/EC.	
j	Quantity or volume of the GMO to be transferred.	
k	A previous and existing risk assessment report consistent with Annex II of Directive 2001/18/EC.	
l	Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.	
m	Regulatory status of the GMO within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the GMO is banned in the State of export, the reason or reasons for the ban.	
n	Result and purpose of any notification by the exporter to other States regarding the GMO to be transferred.	
o	A declaration that the abovementioned information is factually correct.	

ANNEX 2 Template for Summary

- Name and contact details of the exporter and importer,
- General description of the GMO(s), including scientific and common name of the host organism, general description of the introduced trait(s)
- Code numbers (event numbers), references or the Unique Identifier, as appropriate, allowing retrieval of information on the material.
- A summary of a previous and existing risk assessment consistent with Annex II of Directive 2001/18/CE, if available to the exporter
- Any methods and plans for emergency response, as appropriate.
- Statement: "The information provided to the importing country complies with the AIA process and the Annex I of the TBM Regulation"
- Statement: "The information provided to the importing country is factually correct"
- A copy of the complete notification is available for inspection and can be obtained from the exporter (or other - indicate)
- Attachment: Acknowledgement of receipt (if available)
- Attachment: Decision of the country of import