

Third World Network submission related to decision BS-VI/16: Unintentional transboundary movements of living modified organisms (Article 17)

Introduction

The Cartagena Protocol on Biosafety seeks to protect biological diversity from the risks posed by living modified organisms (LMOs), taking also into account risks to human health. It establishes an advanced informed agreement procedure for ensuring that Parties are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. Decisions are made in accordance with the precautionary approach and following the conduct of a risk assessment.

However, unintentional transboundary movements of LMOs circumvent these central tenets of the Cartagena Protocol that preserve the right of Parties to have their prior informed consent sought, and to be able to make decisions on LMO approvals based on risk assessment and in accordance with the precautionary approach.

Article 17 of the Cartagena Protocol requires Parties to take appropriate measures to notify affected and potentially affected States, the Biosafety Clearing-House (BCH) and relevant international organizations when it knows of an occurrence under its jurisdiction that leads, or may lead, to an unintentional transboundary movement of a LMO. Notifications must be provided as soon as the Party knows of such situations, and relevant information must be communicated to the affected or potentially affected States. Consultations with affected or potentially affected States are also necessary to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

Situation with regard to unintentional transboundary movements

There are several plausible scenarios of unintentional transboundary movements:

- Unintentional transboundary movements involve unauthorized LMOs that would not have undergone a risk assessment in the affected or potentially affected State.
- A risk assessment may or may not have been conducted in the Party or State of export (e.g. MIR162 maize, herbicide-tolerant alfalfa).
- In some situations, unintentional transboundary movement could involve a LMO that is unapproved anywhere in the world (e.g. LL601 rice, Monsanto herbicide-tolerant wheat, Bt10 maize).

Unintentional transboundary movement could also mean that untested and possibly higher-risk LM crops, e.g. those intended for production of industrial biochemical or pharmaceuticals would enter into the food and feed system, which is untenable from a safety point of view. When such contamination occurs in the form of seeds or grain, which are still able to reproduce and/or transmit their genetic information to other organisms, this risk would extend to a potential spread and further contamination of food, feed, seed and wild species.

Incidents of unintentional transboundary movements of LMOs worldwide have occurred with alarming frequency. According to the GM Contamination Register (www.gmcontaminationregister.org), a total of 396 known contamination incidences and illegal releases have occurred to date since 2005, when the database was first set up. The GM Contamination Register is compiled from public reports and is managed by Greenpeace and GeneWatch UK. In 2013 alone, 26 individual incidences were recorded in countries in Asia, Africa, Europe and the USA, many involving unapproved LMOs.

There is a difference in the number of the records of unintentional transboundary movements that have occurred in developing and developed countries. It

should be noted that the higher number of records of incidents in developed countries does not mean that there has been less occurrence of unintentional transboundary movements in developing countries, but could be attributed to a lack of monitoring, notification and information systems in these countries, pointing to the need to provide support to improve such systems.

In contrast to the high number of incidences compiled in the GM Contamination Register, from analysis carried out by the CBD Secretariat in 2012 (UNEP/CBD/BS/COP-MOP/6/12), only four Parties reported unintentional introduction of LMOs into their jurisdiction in the form of imports of food or seeds, while two other Parties reported potential or unverified transboundary transfer of LMOs into their territories.

In addition, very few Parties (only nine) had reported receiving information concerning occurrences that led, or may have led, to unintentional transboundary movements under their jurisdiction. The majority (133 Parties) reported that they have never received any such information, during the reporting period of the second national report.

Of the nine Parties, eight responded further, with two reporting that they have notified, for every occurrence, affected or potentially affected States and, where appropriate, relevant international organizations, of the release. Six of the other Parties reported that they have not provided any notification. Furthermore, one Party reported that it had immediately consulted the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, another reported that it has done so in some cases, and the remaining six reported that consultation was never conducted.

It is clear that there is disconnect between the known cases of unintentional transboundary movement and what is notified to potentially affected States. This could be because the source of some contamination incidents may be from non-Parties to the Protocol. When contamination originates from Parties to the Protocol, regrettably not all have appeared to fulfill their notification and consultation obligations.

Steps therefore need to be urgently taken to facilitate the implementation of Article 17. Efforts need to be made to encourage, facilitate and enable Parties to take appropriate measures to notify affected or potentially affected States of an unintentional transboundary movement. Furthermore, steps are needed in order to be able to assist Parties to detect and take measures to respond to unintentional transboundary movement of LMOs. These steps must happen even if notification is not given directly to the affected States, but information is available from other sources, e.g. media reports, non-government organizations, etc.

The following are important considerations that should be the basis of determining the scope and elements of possible guidance or tools that may facilitate appropriate responses by Parties to unintentional transboundary movements of LMOs. Some of this discussion is also relevant to paragraph 2(a) of Article 18, and thus also relevant to the request for submissions related to BS-V/8 (Handling, transport, packaging and identification of living modified organisms, paragraph 2(a) of Article 18).

Considerations for Parties from where unintentional transboundary movements may originate¹

1. Compliance with domestic regulations

Regardless of whether the source of unintentional transboundary movement is a Party to the Protocol or not, compliance with the domestic regulations of importing Parties' and those of affected or potentially affected States, including zero tolerance policies for unapproved LMOs, is necessary.

Zero tolerance policies are completely consistent with Decision BS-III/10 adopted at COP-MOP3 in 2006, as well as with Paragraph 6 of Annex 3 of the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived From Recombinant-DNA Plants (CAC/GL 45-2008) (Codex Plant Guideline). The Codex Plant Guideline states that the Annex, which provides guidance on food safety assessment in situations of low-level presence² of recombinant-DNA plant material in food, "does not eliminate ... responsibility of industries, exporters and, when applicable, national competent authorities to continue to meet importing countries' requirements, including in relation to unauthorized recombinant-DNA plant material".

2. Prevention of unintentional transboundary movements at the potential source

Proactive steps need to be taken on the part of Parties that are developing or growing LMOs, to establish and maintain measures to prevent unintentional transboundary movements. These include stringent controls of contained use, field trials and commercial plantings, including monitoring to ensure that there has been no unintentional escape of any LMO.

¹ These could include exporting Parties, and/or Parties that develop and produce or grow LMOs.

² Low-level situations are not defined in the Codex Plant Guideline, but refer to situations where low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Plant Guideline in one or more countries may on occasion be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined.

Parties of export should also ensure the conduct of a risk assessment, for all LMOs in research and field trials. In relation to risk management, Article 16(3) of the Cartagena Protocol requires that the risk assessment needed before the first release of a LMO takes into account the possibility of unintentional transboundary movements³.

3. Segregation, identity preservation and testing

Related to Article 18.2(a) of the Cartagena Protocol, exporting Parties should implement Para 4(a) of Decision BS-III/10. This requires ensuring that the documentation accompanying LMOs intended for direct use as food or feed, or for processing, clearly states, in cases where the identity of the LMO is known through means such as identity preservation systems, that the shipment contains LMOs that are intended for direct use as food or feed, or for processing.

Clear identification can be achieved by implementing a system of segregation, identify preservation and testing such that no unauthorized GMO enters the food/feed chain. Such a system would reduce the chances of unintentional transboundary movements occurring.

4. Timely notification

Paragraphs 1 and 3 of Article 17 establish clear notification obligations for Parties when it knows of any occurrence under its jurisdiction that leads or may lead to unintentional transboundary movement. Steps need to be taken to facilitate and enable the notification process to happen in a timely manner and to reach all affected or potentially affected States. This could include, for example, the setting up of a rapid alert system that immediately notifies all affected and potentially affected States.

5. Provision of information, detection methods and reference materials

Two key elements to ensure that situations of unintentional transboundary movements are adequately and responsibly dealt with in affected or potentially affected States are:

- (i) having adequate information to address the risks; and
- (ii) having the technical capacity to detect the LMOs in question.

Paragraph 3 of Article 17 specifies the minimum information that any notification to affected or potentially affected States should contain. This includes information related to the quantities and

particular characteristics of the LMO concerned, and the circumstances surrounding the occurrence leading to the unintentional transboundary movement. In addition, information should be provided on the possible adverse effects and possible related risk management measures. Paragraph 3(d) provides a ‘catch all’, requiring the provision of “any other relevant information”.

There are thus clear obligations for the Party from which an unintentional transboundary movement originates to notify and provide adequate information to affected or potentially affected States. The source of contamination should be quickly identified, along with the modes of contamination and pathways by which the contamination is spread.

Importantly, the sequence information necessary to enable detection must be provided. Regrettably, competent authorities are often not provided such sequence information and this is particularly so for LMOs in field trials.

At the international level, there are two important repositories for information related to LMOs:

- The BCH plays an important role in making the requisite information available, with paragraph 5 of Decision BS-III/10 inviting Parties and other Governments to make available to the BCH information about transformation events (what has been commercially produced, the cultivated geographical areas, the common, scientific and, where available, commercial names, the transformation event code or where available, the unique identifier code) that may presumably be inadvertently subject to transboundary movement.
- Annex 3 of the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived From Recombinant-DNA Plants (CAC/GL 45-2008) asks Codex Members to make available, to a publicly accessible central database to be maintained by FAO, information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline, including “where detection method protocols and appropriate reference material ... suitable for low-level situations may be obtained” (Para 28(i)). Furthermore, “the product applicant should provide further information and clarification ... as well as a validated protocol for an event-specific or trait-specific detection method suitable for low level situations and appropriate reference materials (non-viable, or in certain circumstances, viable)” (Para 31).

Paragraph 5 of Decision BS-IV/9 further encourages those in possession of reference materials to provide access for those agencies that may need such materials for the purpose of detection of LMOs.

³ See p. 112 of *An Explanatory Guide to the Cartagena Protocol on Biosafety*, IUCN and FIELD (2003).

Considerations for affected or potentially affected States⁴

1. Right to have zero tolerance policy

It is the sovereign right of importing Parties' and of affected or potentially affected States to decide on policy, including zero tolerance, and to require that all LMOs be risk assessed prior to approval. There is full flexibility for zero tolerance of unapproved LMOs:

- Article 25 of the Cartagena Protocol on Biosafety recognizes situations of illegal transboundary movement. Such situations, where transboundary movements of LMOs are carried out in contravention of domestic measures, are to be prevented, and if appropriate, penalized.
- Decision BS-III/10 states that measures must be taken to ensure that LMOs destined for food or feed, or for processing are "authorized in accordance with domestic regulatory frameworks" and documentation is "in compliance with the requirements of the country of import".
- The Codex Plant Guideline (Paragraph 6, CAC/GL 45-2008) states that the conduct of a safety assessment in accordance with Annex 3 of the Guideline "does not eliminate the responsibility of industries, exporters and, when applicable, national competent authorities to continue to meet countries' relevant import requirements, including in relation to unauthorized recombinant-DNA plant material".

2. Capacity for sampling, testing and detection

Affected or potentially affected States need the technical capacity to sample, test and detect incidents of unintentional transboundary movement. This is an issue recognized in the Strategic Plan of the Cartagena Protocol, which among others, envisages the following outcomes:

- (i) Guidance developed to assist Parties to detect and take measures to respond to unintentional releases of LMOs (Operational Objective 1.8);
- (ii) Easy to use and reliable technical tools for the detection of unauthorized LMOs are developed and made available (Operational Objective 1.6); and
- (iii) Personnel are trained and equipped for sampling, detection and identification of LMOs (Operational Objective 2.3).

The COP-MOP has taken a series of decisions in relation to sampling, testing and detection, including encouraging Parties and other Governments to cooperate in exchanging experiences and building capacities in the use and development of easy to use,

rapid, reliable and cost-effective sampling and detection techniques for LMOs (Paragraph 10 of Decision BS-III/10); as well as underlining the importance of accreditation of laboratories involved in sampling and detection of LMOs and encouraging those in possession of reference materials to provide access for those agencies that may need such materials for the purpose of detection (Paragraph 5 of Decision BS-IV/9).

Paragraph 5 of Decision BS-V/9 invites Parties to nominate national and international reference laboratories with the view to establishing, through the BCH, an electronic network of laboratories to facilitate the identification of living modified organisms as well as the sharing of information and experiences. Parties that do not have the infrastructure (laboratories) for detection could also benefit from the experiences and exchanges of this network of laboratories. At a November 2013 workshop of the network (UNEP/CBD/BS/WS-LMO/1/2), the development of an implementation strategy for the detection and identification of LMOs, including the specific needs for technical tools and guidance for the detection of unauthorized LMOs and unintentional releases, was discussed. Furthermore, the workshop elaborated a series of useful recommendations for the consideration of COP-MOP 7.

3. Mechanisms for implementing responses, actions and emergency measures

Guidance and capacity building is needed in relation to determination of appropriate responses and initiation of necessary actions, including emergency measures, in order to minimize any significant adverse effects of unintentional transboundary movements (Paragraph 4 of Article 17). No specificity is provided in Article 17 on the types of responses and actions that may be taken, therefore guidance on the issue would be useful.

Nonetheless, according to Article 25 on illegal transboundary movements, the affected Party may request the Party of origin to dispose, at its own expense, of the LMO in question by repatriation or destruction. This could be one option of response, action or emergency measure.

In addition, response measures are to be taken under the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress when there is damage or sufficient likelihood of damage, including that which arises from unintentional transboundary movements. These response measures, which are to be determined by the competent authority, and taken by the operator or in the event the operator fails to do so, by the competent authority, could be the same or complementary to the action envisaged under Article 17.

⁴ These could include importing Parties.