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Identification requirements for shipments of genetically engineered commodities

Analysis of the decision adopted under the Cartagena Protocol on Biosafety

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The 3rd Meeting of the Parties (MOP 3) to the Cartagena Protocol on Biosafety (under the Convention on Biological Diversity), which was held from 13 to 17 March 2006 in Curitiba, Brazil, adopted several decisions which have significant implications for the production and trade of genetically modified organisms, or in the language of the Protocol, living modified organisms (LMOs).

The process by which the most important decision (relating to Article 18.2(a) of the Protocol, on identification requirements for shipments of LMOs intended for direct use as food or feed, or for processing (LMO-FFPs)) was taken was protracted, and at times it seemed as if there would not be any outcome.

At stake was whether the world continues to allow contamination of bulk commodity shipments of LMOs, or whether a system would be put in place that removes ambiguity, allowing countries of import to know exactly what LMOs are in a shipment, and which would protect countries which do not have the laws or regulations (most developing countries) that many exporting countries themselves have to protect against this contamination. At stake was also the ability to track and trace particular LMOs, allowing correlation with the risk assessments for that LMO and which is necessary for many important biosafety functions, such as monitoring, emergency measures, liability and redress and meaningful labelling.

The issue of Article 18.2(a) is the international legally binding provision that can help address the contamination of bulk commodity shipments. This is because clear identification would mean that a system of testing, segregation and identity preservation would need to be set up in the exporting countries, that could go a long way towards avoiding and identifying contamination before a shipment leaves a country of export.

It would help to ensure that the burden of making sure that contaminated shipments of LMO-FFPs are not entering the country does not rest on the importing countries. Most developing countries are importing countries, and lack the capacity and resources to test shipments at the port. There are also many

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difficulties with sampling and testing (e.g. the randomness of sampling, and obtaining false negatives in the testing results) and trying to always ensure that all contaminated shipments are accurately detected is difficult.

Exporting countries should rightfully bear the burden of ensuring that contaminated shipments do not leave their country and of ensuring that the exact LMO components and all necessary information linked to those events are communicated to the country of import. A strict segregation and an identity preservation system must be put in place by the exporting country to ensure that such contamination does not occur. In addition, testing before the shipments leave the port in the country of export will help to ensure that the system is working, and identify problems, if it is not.

Even if the main exporting countries are not Parties to the Biosafety Protocol, a good decision on Article 18.2(a) means that Parties will have to implement it at the national level as a minimum standard. Exporting countries, whether or not they are Parties, will have to comply with the laws of importing countries.

The following is a summary and analysis of aspects of the Article 18.2(a) decision taken at MOP 3:

'Contain' vs. 'may contain'

MOP 3 adopted a decision that requires clear and detailed identification for shipments of GM commodities (known as LMO-FFPs – living modified organisms intended for direct use as food or feed, or for processing – in the Biosafety Protocol). A two-stage approach is set out for cases where the identity of the LMO shipment is not known.

In situations where the identity of the LMO is known through 'means such as identity preservation systems', the shipment must be identified as one that 'contains' LMOs that are for direct use as food or feed, or for processing.

In cases where the identity of the LMO is not known through 'means such as identity preservation systems', the shipment can be identified as one that 'may contain' one or more LMOs that are intended for direct use as food or feed, or for processing. This requirement is subject to review and assessment at the 5th Meeting of the Parties (2010), 'with a view to considering a decision' at the 6th Meeting of the Parties (2012) to ensure that the shipment is identified as one that 'contains' LMO-FFPs.

This two-stage approach was essentially a compromise position put forward by Brazil, although it was weakened by an extension of the initially proposed four-year interim period to six years, when the 'contain' requirement should come into effect. The language referring to this was also weakened from 'with a view to adopting' to 'with a view to considering' a decision.

Nevertheless, and importantly, it is clearly stated that the final decision after the interim period is to 'ensure' that the documentation 'clearly states that the shipment *contains* LMOs that are intended for direct use as food or feed, or for processing'. This means that the 'may contain' language should no longer be an option after the interim period.

'May contain' poses legal uncertainty, as a shipment may or may not contain a particular LMO. Even if the term 'may contain' is used together with the provision of a list of LMOs that could be in the shipment, this potentially means that an exporter could simply list a whole range of LMOs that may be in the shipment. Both scenarios will not allow for traceability, or for product recall or ascertaining liability in case it becomes necessary.

While 'identity preservation systems' is not defined in the text or in the Protocol, it can be understood to mean segregation and testing, and is non-exhaustive. The language 'known through means such as identity preservation systems' is broad enough to cover different ways of ensuring that the identity of the shipment is preserved.

It would be important for the importing Party to define in its national law, what its requirements are in order to meet this criterion,

rather than leaving this to the country of export to define. If left to the country of export to define, it would open the door for the exporting country to constantly argue that it cannot meet the 'contain' requirement because it does not have an identity preservation system or other such means in place.

In both cases, where the shipment is identified as one that 'contains' LMOs as well as where the shipment is one that 'may contain' LMOs, the documentation accompanying them must include the following details:

— that the LMOs are not intended for intentional introduction into the environment
— the common, scientific and, where available, commercial names of the LMOs
— the transformation event code of the LMOs or, where available, as a key to accessing information in the Biosafety Clearing House (BCH), its unique identifier code
— the Internet address of the BCH for further information

(In relation to the third point, all LMOs are also known by their 'transformation event code', which distinguishes between the different transgenic lines. Some LMOs have a 'unique identifier code' which acts as a key to accessing full information about the LMO in a database. The BCH is a publicly accessible Internet-based database which is administered by the Secretariat of the Convention on Biological Diversity which provides some information about LMOs, and is part of the implementation of the Protocol.)

This means that whether or not a shipment is identified as one that 'contains' or 'may contain' LMOs, a list of transformation events or unique identifier codes that are or may be in the shipment, must be provided. These specifications are required for all shipments.

Adventitious presence and thresholds

The 'may contain' provision is further qualified by the statement – 'acknowledges that the expression "may contain" does not require a listing of LMOs of species other than those that constitute the shipment'.

The scheduled expiry of the 'may contain' language in 2012 will mean that this qualification also expires then.

Arguably, 'adventitious' (or technically unavoidable, unintentional and low-level) presence of LMOs (e.g. traces of LMOs that are found in shipments) of the same species (e.g. GM soya in a shipment of non-GM soya or a particular GM soya found in a shipment of another GM soya) is covered by the decision, where the identity of the LMOs is not known, and the shipment is identified as one that 'may contain' LMOs.

This means that such unintentional adventitious presence must also be specified in the documentation, e.g. through the provision of the transformation event code of the LMO that is unintentionally present, if it is of the same species of the LMOs in the shipment.

However, this does not mean that if a shipment is identified as one that 'contains' LMOs, there can be 'adventitious' presence of LMOs, whether of the same or different species. This is left to the national level to define, as the documentation requirements must be in 'compliance with the requirements of the country of import'.

What is only clearly excluded is 'adventitious' presence or traces of an LMO of one species in a shipment of another species (e.g. GM maize in a shipment of non-GM wheat, or GM maize in a shipment of GM soya) when the identity of the LMOs is not known, and the shipment is identified as one that 'may contain' LMOs.

Thus, the issue of thresholds, which is a percentage of GM contamination above which identification requirements are triggered, was avoided in this decision, but remains an issue to be determined at the national level, 'in compliance with the requirements of the country of import'.

Approved LMOs only

All of the above scenarios require that the LMOs in question must be approved in the Party of import. There is full flexibility for a country to require zero tolerance of unapproved and illegal contamination of LMOs, as measures must be taken to ensure that LMO-FFPs are 'authorized in accordance with domestic regulatory frameworks' and the documentation is 'in compliance with the requirements of the country of import'.

Even though the documentation accompanying LMO-FFPs is qualified to be applicable for LMO-FFPs that are in 'commercial production' (i.e. not research and field trials), this must be 'authorized in accordance with domestic regulatory frameworks'. It is not specified whether this refers to domestic regulatory frameworks in the country of export or import, and thus can be interpreted as referring to both exporting and importing countries.

In any case, the documentation must be 'in compliance with the requirements of the country of import'. This means that the importing country needs to put in place strict requirements, to ensure that even contamination by LMOs in field trials and research (which are unapproved commercially) is prohibited.

The fact that the documentation must be for LMO-FFPs 'authorized in accordance with domestic regulatory frameworks' and 'in compliance with the requirements of the country of import' implicitly extends to the approval or authorisation procedure in the country of import. Documentation requirements are only triggered once a particular LMO has been approved by the country of import.

Biosafety Clearing House

In addition, Parties and other governments are invited to make available to the BCH:

- the transformation events that are commercially produced for each planting cycle in the exporting country
- the geographical area within the exporting country where each transformation event was cultivated
- the common, scientific and, where available, commercial names of the LMOs
- the transformation event code of the LMO or, where available, as a key to accessing information in the Biosafety Clearing House, its unique identifier code

These are new requests for additional information about commercialised LMOs that countries are invited to submit to the BCH.

'Stand-alone' document

The decision postpones the issue of whether a 'stand-alone' document should be the document accompanying LMO-FFPs. A separate, 'stand-alone' document is essential, so that the competent authority responsible for biosafety can more easily gain access to, and have oversight over, the document, which would not necessarily be the case if the information was simply added onto an existing commercial invoice.

The decision asks Parties and other governments to submit information on the experience gained with the use of documentation, with a view to further harmonisation of a documentation format, including consideration of the need for a stand-alone document, which will be compiled and synthesised for consideration at MOP 5.

It is important to note that Parties can already require the use of stand-alone documents in their national laws, or within their administrative frameworks, as the decision also allows for the use of documentation as required by domestic regulatory and/or administrative frameworks. The document must include all the information specified for both shipments that are identified as containing LMOs and those that 'may contain' LMOs, and should be easily recognised and transmitted. The information requirements should also be effectively integrated, considering standard formats.

Contact point for further information

The details of a contact point for further information must be provided in the documentation. These are identified as the exporter, the importer, and/or any appropriate

authority, when designated by a government as the contact point.

This is important, as it extends the contact points for further information beyond the last exporter and first importer in the supply chain, which are usually the same grain trading companies. For example, grain exported from Brazil to South Africa may likely be exported from Cargill in Brazil to Cargill in South Africa. The grain trading companies may not hold important biosafety information, which may reside with the companies and producers of the GMOs.

Parties can also designate appropriate authorities, such as the biosafety focal point, as a contact point for further information. This would extend biosafety regulatory oversight, for example, at the entry port of a country, customs officials can contact their relevant biosafety or competent authorities for more information about an LMO-FFP shipment. This would also ensure that the competent authority responsible for biosafety knows about a shipment of LMO-FFPs entering the country, which would be particularly important if a stand-alone document is not utilised.

Capacity-building

The decision mandates that the review at MOP 5 (regarding the retirement of the 'may contain' language) shall also include an examination of capacity building efforts in developing countries. Funding is also requested to support the implementation of Article 18.2(a).

One of the issues that arose during MOP 3 was that developing country exporters need capacity-building if they are to implement the decision, particularly with respect to 'means such as identity preservation systems'. A key consideration that should be taken into account would be differentiating between the roles and needs of exporting developing country governments and responsible agencies, which may require capacity-building, and between the roles played by the international grain trading companies that may operate silos, ports and transportation systems. The latter should not be subsidised by the international community to implement 'means such as identity preservation systems'.

Furthermore, on the issue of capacity-building, developing country importers could be assisted on issues such as sampling and detection, testing and monitoring of LMO-FFPs. If there is a lack of capacity in developing country importers, quickly implementing the 'contain' requirements along with the detailed identity requirements would help address the lack of capacity to test and monitor LMO-FFP imports, as this shifts the burden and cost of assessing the LMO content of a shipment from the importer to the exporter.

Sampling and detection techniques

The decision encourages cooperation in exchanging experiences and building capacities on sampling and detection techniques. It also asks for the submission of information on experience gained with the use of sampling and detection techniques and on the need for and modalities of developing criteria for acceptability of, and harmonising, sampling and detection techniques, for consideration by MOP 4.

Importing Parties will still have to carry out random sampling and detection for LMO content in shipments, even if all the information is provided by exporters, to ensure accuracy of the information and to verify that no unapproved varieties are entering the country. Exporting countries could assist by providing the detection methods and reference materials for all approved LMOs (which should also be stipulated in domestic regulatory frameworks as one of the conditions for any approval, as it will not be possible to test for specific LMOs if the detection methods and reference materials are not made available to importing countries). This should also apply to experimental LMOs, which can contaminate seeds and crops.

Trade with non-Parties

The decision notes that transboundary movement between Parties and non-Parties shall be consistent with the objective of the Protocol. It further notes that the specific requirements for the documentation ('contain'; 'may contain'; not intended for intentional introduction into the

environment; common, scientific and, where available, commercial names of the LMOs; transformation event code or, where available, unique identifier code of the LMO; and Internet address of the BCH) do not apply to such transboundary movement. In addition, Parties should encourage non-Parties to adhere to the Protocol.

This could be understood to be simply a restatement of Article 24 of the Protocol and a general principle of international law, as clearly non-Parties cannot be bound by a decision of the Biosafety Protocol. Thus non-Party exporters do not have to put these requirements in place, although they are 'urged' to do so.

However, the specific requirements are subject to the general obligation that the documentation must comply with the requirements of the country of import, hence, Parties who are trading with non-Parties can still set up their domestic legislation to ensure that strict requirements are put in place, based on the decision as a minimum standard, which will bind all countries that they import from, whether Parties or non-Parties. It can also be argued that since only the specific requirements for documentation are noted not to apply to transboundary movements between Parties and non-Parties, the converse is applicable – that the general obligation that Parties should take measures in accordance with domestic regulatory frameworks should apply to transboundary movements between Parties and non-Parties.

In addition, Article 2(4) of the Protocol preserves the right of Parties to 'take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law', and this is recalled in a preambular paragraph in the decision.

It is therefore crucial that this decision on Article 18.2(a) be implemented, especially in Parties of import, so that exporting countries, whether Parties or non-Parties, must adhere to their domestic laws, which should be based on this decision as a minimum standard.

Nonetheless, the implications of these particular provisions need to be further examined, particularly in the light of the current push for bilateral free trade agreements by the US and other exporting non-Parties, and in the context of the World Trade Organisation (WTO) agreements.

Conclusion

In summary, the MOP 3 decision on Article 18.2(a), as the international minimum standard, will help encourage a global system of identity preservation, segregation, and traceability for LMOs, and help to prevent the contamination that is happening. It will help restore the burden to its rightful place, help to ensure that countries or regions can choose to remain GM-free and ensure that they do not receive LMOs that are not approved in their countries. The decision will eventually help importing countries to know exactly what is coming into their countries, and will help ensure important biosafety functions e.g. monitoring, meaningful labelling, product recall in the case of harm and assigning liability if damage occurs.

For all this to happen, importing Parties should now urgently ensure that the decision is implemented by incorporating these requirements, as a minimum standard, into their national laws.

Exporting Parties should also quickly implement their obligations under this decision, and put in place a proper system of segregation, testing and identity preservation sooner rather than later. An identity-preserved grain trading system is of benefit to all.

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