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Documentation Requirements Under the Cartagena Protocol on Biosafety: The Decision by the 3rd Meeting of Parties on Article 18.2(a)

by

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The Cartagena Protocol on Biosafety sets out the rules for trade in genetically modified organisms, or in the language of the Protocol, living modified organisms (LMOs). Its objective is to ensure the safe transboundary movement of LMOs through adequate information sharing between the exporting and importing nations. The focus of the biosafety negotiations was initially on LMOs intended for direct introduction into the environment and the threats to biodiversity which could arise from the planting of genetically modified seeds. The advance informed agreement (AIA) procedures of the Protocol now regulate trade in these LMOs.

However, the vast majority of LMOs traded each year are comprised of LMOs intended for food, feed or processing (LMO-FFP) (agricultural commodities), such as soya beans, corn, rapeseed (canola) and cotton. During the negotiations of the Protocol, some agricultural export countries (especially Argentina, Australia, Canada, Chile, the United States and Uruguay, which formed the "Miami Group") opposed the inclusion of the LMO-FFPs under the AIA procedures, claiming it would be commercially unviable and impracticable to impose onerous obligations on agricultural commodities. LMO importing (mainly developing) countries disagreed and sought clearer documentation mechanisms to assist them manage the risks associated with genetically modified foods. For example, in many developing countries, grains which are imported as food can end up being used as seed during times of crisis, i.e. LMOs would thereby become embedded in their agricultural processes.

The significant commercial value of LMO-FFPs in international trade goes some way to explain the controversy that has marked the long history of negotiations on LMO-FFPs and the issue again dominated the discussions at the 3rd Meeting of the Parties (MOP-3) to the Cartagena Protocol on Biosafety in March this year. This paper will briefly review the history of the negotiations in relation to Article 18.2(a) of the Protocol, outline the recent decision made at MOP-3 in relation to LMO-FFPs, and then list the possible implications of that decision for further consideration at a proposed future meeting at Chatham House.

A Brief History of Article 18.2(a) of the Protocol

The documentation and information requirements for shipments containing LMO-FFPs was one of the final agenda items at the 1st Extraordinary Conference of the Parties in Cartagena in February 1999 and it proved to be so controversial that it nearly caused the collapse of the biosafety talks before the Protocol had even been adopted. The importing countries insisted that shipments containing LMO-FFPs should be accompanied by documentation clearly stating that it contains LMOs and specifying the type of LMO. This was opposed by the exporting countries on the basis that the increased cost of complying with stringent documentation requirements would harm global commodity trade. Despite intense negotiations at the 1st ExCOP, the parties to the Protocol were unable to agree on the type of information and documentation which should be provided with shipments containing LMO-FFPs.

The subsequent informal consultation meetings held in Montreal in July 1999 and Vienna in September 1999 did little to resolve the political gridlock between the exporting and importing nations. However, Chairman Juan Mayr used the meetings to introduce a negotiation framework based on a format which had been introduced at the 1st ExCOP in Cartagena[1]. The outcome of

[1] The Chairman created a round table for consultations comprised of two representatives from each of the five negotiation groups which had emerged during the Biosafety Working Group Meetings: the Miami Group, the Like Minded Group, the Compromise Group, the Central and Eastern European Group and the European Union.

those meetings and the growing consumer awareness and pressures from environmental NGOs exerted significant pressure upon negotiators to finally reach agreement at the resumed ExCOP in Montreal in January 2000. The majority of the outstanding issues were successfully resolved but once again, it was the documentation and identification requirements of LMO-FFPs which nearly derailed the process. Eventually, the following text was agreed:

> Article 18.2(a)
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> 2. Each Party shall take measures to require that documentation accompanying:
>
> (a) Living modified organisms that are intended 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 further information. The Conference of the Parties serving as the meeting for the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including the specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol.

The phrase 'may contain' instead of 'contains' was inserted to placate the exporters' fears that it would be commercially unviable and impracticable to identify every LMO-FFP contained in a shipment. The phrase 'may contain' limits the possibility of non-compliance procedures being brought against them. The second limb of the paragraph sets a deadline for the parties to agree on the operational framework of the provision (including the review of the words 'may contain') within two years after its entry into force; namely, by 11 September 2005.

At MOP-1 in February 2004 (in Kuala Lumpur, Malaysia), the parties to the Protocol considered the various options for implementing the documentation requirements in Article 18.2(a). The importing countries again pressed for detailed information to be provided by the country of origin to ensure that they could carry out adequate risk assessments. This is an important issue to the developing countries because they have less capacity to review and identify the risks associated with genetically modified foods and therefore require as much information as is available to enable them to test, detect and monitor incoming LMO-shipments. The importing countries proposed that the names of the particular LMOs and their unique identifiers be provided, preferably on separate documentation to the shipping invoice. As they had previously, the exporting parties argued that it was not feasible to identify every LMO-FFP which might be contained in a shipment and argued that the 'may contain' wording in Article 18.2(a) was sufficient to alert the importing country to the presence of LMOs.

The parties failed to reach a consensus and as an interim measure (until MOP-2) a compromise was agreed whereby the exporting party would identify on the commercial invoice that the shipment 'may contain LMOs' and that any such LMOs were 'not intended for intentional introduction into the environment'. To accommodate the EU and developing countries, a technical expert group was established to develop a framework for the application of the unique identifier system and the parties were 'urged' to provide the common, scientific and, where available,

commercial names and the transformation event codes[2] of the LMOs and their unique identifier codes as keys to accessing information about the LMOs in the Biosafety Clearing House.

Most LMO exporting nations had not ratified the Protocol and were only able to express their objections rather than directly take part in the decision-making. However, the role played by Brazil and Mexico (as parties to the Protocol and countries with emerging LMO export trade interests) was instrumental in retaining the 'may contain' wording in the decisions on implementing Article 18.2(a).

The primary objective of MOP-2 (from May to June 2005 in Montreal, Canada) was to agree the detailed documentation requirements of LMO-FFP shipments, including the resolution of the 'may contain' versus 'contain' debate, in order to meet the deadline of 11 September 2005. Despite intense negotiations this was not achieved. Brazil and New Zealand repeatedly blocked consensus on any proposal other than that which aligned with the existing 'may contain' terminology agreed at the resumed Ex-COP. Brazil was originally a member of the Like-Minded Group (comprised of the developing countries who were predominately importers) but had aligned itself more closely with the former Miami Group of agricultural export countries in accordance with its increasing LMO exporting interests. The two representatives from New Zealand were from the Ministry of Foreign Affairs and Trade, rather than the environmental department, which was perhaps illustrative of the emphasis New Zealand placed on the trade aspects of the Protocol and their objective of ensuring as unencumbered a trade flow as possible.

New Zealand was also resolute that the text should not set any thresholds for the adventitious presence of LMOs in shipments. The phrase 'adventitious presence' refers to the unintended and unavoidable presence of genetically modified material in non-genetically modified foods. This is a probability accepted on the basis that most plants are grown in an open field and cross-pollination is a natural phenomenon. The point which the parties could not (and still cannot) agree on is the percentage threshold of adventitious presence which would trigger the documentation requirements under Article 18.2(a).

Brazil caused further divisions by opposing the use of a 'stand alone' document to identify the presence of LMO-FFPs, notwithstanding that this had previously been agreed to in the Contact Group discussions. The majority of the parties accepted that a separate 'stand alone' document was preferable as it would enable the biosafety authority in each country to more easily access the required information and activate the necessary risk assessment procedures upon the arrival of an LMO-FFP shipment. However, Brazil was successful in limiting the documentation to the commercial invoice accompanying the shipment and 'any other documents required or utilized by existing documentation systems'.

The Decision of the 3rd Meeting of the Parties

After the failure to reach agreement on LMO-FFPs at Montreal, the parties to the Protocol were united in their goal to resolve the detailed documentation requirements at MOP-3. Brazil shifted its position and, as host country, demonstrated a high-level commitment to resolve the gridlock between the exporting and importing nations. A number of theories have been advanced to explain Brazil's new cooperative approach, including; the positive political mileage associated

[2] Every LMO has a "transformation event code" which distinguishes between the different transgenic lines.

with achieving a successful outcome as the host of MOP-3; the stronger role played by Brazil's environment ministry at the meeting; and the lengthy internal consultation process which Brazil engaged in prior to MOP-3. From a trade perspective, there were speculations that "Brazil might be counting on gaining a competitive advantage, in particular vis-à-vis other Latin American countries, by being able to put in place systems that will allow Brazilian exporters to segregate biotech from conventional products"[3]. Brazil increased its biotech crop production from 5 million hectares in 2004 to 9.4 million hectares in 2005, the largest increase in any of the exporting countries[4].

Consideration of the documentation and identification requirements for LMO-FFPs at MOP-3 was assigned to Working Group 1, chaired by Ms Birthe Ivars of Norway. Chair Ivars in turn established a contact group, co-chaired by Mr Francois Pythoud of Switzerland and Mr Luiz Alberto Figueiredo Machado of Brazil. The issue was also debated by a small group of Friends of the Chair from Monday to Friday. The decision was adopted by plenary on Friday (UNEP/CBD/BS/COP-MOP/3/15-III/10).

The negotiations revolved around the same issues which had dominated the debates at MOP-1 and MOP-2:

1. the "contain" versus "may contain" debate (including the timeline for reaching a decision to refer only to the fact the shipment "contains" LMO-FFPs);

2. thresholds for adventitious or technically unavoidable presence of LMOs and whether or not they trigger documentation requirements; and

3. the specific information which should be included in the documentation and whether there should be a 'stand alone' document.

The 'Contain' versus 'May Contain' Debate

The changing dynamics of the biosafety talks was further evidenced by the more collaborative role played by New Zealand. The representative of New Zealand stated that there "might have been some misunderstanding" about his country's view to Article 18.2(a) at MOP-2 and that New Zealand supported "documentation regulations containing the phrases 'may contain' and 'does contain'" but wished to avoid "elaborating documentation requirements that would affect shipments of non-living modified organisms, and especially organic materials"[5].

To the surprise of many of the delegates and observers, Paraguay, Mexico and Peru assumed the more resolutely exporter-orientated position which had been played by New Zealand and Brazil at MOP-2 and insisted on the retention of the "may contain" wording. Peru does not currently produce commercial genetically modified crops but it is in the process of drafting new regulations to promote biotechnology. The United States Department of Agriculture (USDA) reported in 2005 that Peru has "enormous potential for production" of genetically modified crops

[3] Young, T, 'Commentary: Cartagena Protocol on Biosafety MOP-3' in *Bridges Trade BioRes* (Vol 6, No. 6, 3 April 2006) at page 7
[4] James, C. 2005. Executive Summary of Global Status of Commercialized Biotech/GM Crops: 2005, *ISAAAA Briefs* No. 34. ISAAA: Ithaca, NY
[5] Paragraphs 161 and 162: UNEP/CBD/BS/COP-MOP/3/15

and that Peru had recently "changed its position on labeling from a restrictive perspective which established the use of GMO in a product to a more flexible view using wording such as 'may contain GMO'". The USDA also stated that its "trade interests lie mainly in Peruvian poultry and livestock industries, which demand corn and soybean meal"[6]. Mexico and Paraguay are relatively new entrants to the LMO-FFP export market and have also presumably considered the trade implications of strong documentation requirements and responded accordingly[7]. In fact, last minute amendments proposed by Mexico on the final day of the talks nearly derailed the entire process. Some observers attributed Mexico's opposition to the documentation requirements to concerns over its international trade obligations, as the only party of the North American Free Trade Agreement to have ratified the Protocol[8]. In order to placate Mexico (and to a lesser extent, Paraguay and Peru), the parties agreed to insert a further provision stating that in accordance with Article 24 of the Protocol,[9] transboundary movements of LMOs between parties and non-parties should be consistent with the objectives of the Protocol and that the specific documentation requirements do not apply to such movements. The representatives of Brazil and the European Union were particularly vocal in their opposition to the proposed amendment but 'in pursuit of consensus' Brazil eventually agreed to it.[10] Ultimately this paragraph simply reiterates the existing provisions of the Protocol, namely that the provisions are not applicable to transboundary movements between parties and non-parties.

The African parties were again vocal in their pursuit for detailed documentation and on the second day of the meeting, President Lula da Silva of Brazil submitted a proposal which was designed to address, to some extent, both the importers and exporters' concerns; namely that:

1. in cases where the identity of the LMOs are known through identity preservation systems[11], the accompanying documentation should state that the shipment "contains" LMO-FFPs; and

2. in cases where the identity of the LMOs are not known through identity preservation systems, the accompanying documentation should state that the shipment "may contain" one or more LMO-FFPs.

After lengthy negotiations the parties adopted a decision based on Brazil's proposal for the introduction of two separate classifications and agreed that in both cases the documentation accompanying the shipment should include the following details:

1. that the LMOs are not intended for intentional introduction into the environment;

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[6] 'Peru Biotechnology Annual 2005', USDA Foreign Agricultural Service, GAIN Report Number: PE5012 (7/7/2005)

[7] In 2005, Paraguay was growing 1.8 million hectares of soybean biotech crops and Mexico was growing 0.1 million hectares of cotton and soybean biotech crops: James, C. 2005. Executive Summary of Global Status of Commercialized Biotech/GM Crops: 2005, *ISAAAA Briefs* No. 34. ISAAA: Ithaca, NY

[8] *Op Cit.*, (n3) *Bridges Trade BioRes* at page 6

[9] (1) Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of [the] Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.
(2) The Parties shall encourage non-Parties to adhere to [the] Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

[10] Paragraph 170 of UNEP/CBD/BS/COP-MOP/3/15

[11] "Identity-preservation systems" are programs which are designed to keep quantities of grains, oilseeds or pulses with special qualities separate from the bulk commodity. This takes place throughout the supply chain and refers to practices in the production, handling, and marketing of grains, oilseeds or pulses that maintain the integrity and purity of the product.

3. the common, scientific and, where available, commercial names of the LMOs;

4. the transformation event code of the LMOs or, where available, as a key to accessing information in the Biosafety Clearing House, its unique identifier code; and

5. the internet address of the Biosafety Clearing House for further information.

Therefore, for both classifications (shipments which 'may contain' and those that 'contain' LMOs) the exporting party must now provide more detailed information in relation to the contents; either a list of transformation events or the unique identifier code(s).

Brazil also proposed that the parties should review and assess the experience gained with the implementation of the further documentation requirements with a view to adopting the 'contain' wording for all LMO-FFPs by MOP-5 (in 2010), allowing a 4 year interim period for the review. This proposal was watered down after further negotiations and it was decided that the parties would report the outcome of their review at MOP-5 'with a view to considering' (as opposed to 'with a view to adopting') the removal of the 'may contains' language at MOP-6 in 2012.

Adventitious Presence and Thresholds

Once again the African countries pressed for the inclusion of the adventitious presence of LMOs in the scope of Article 18.2(a) in order to shift the burden of testing to the exporting countries.[12] The European Union has already enacted domestic legislation in relation to adventitious presence in its imports and consequently sought a reference to thresholds in the decision, primarily to support its own framework. However, Brazil and New Zealand remained resolute on this issue and opposed any reference to thresholds in Article 18.2(a). The outcome of the negotiations was that the parties 'acknowledged' that the expression 'may contain' does not require a listing of LMOs other than those that constitute the shipment. Depending on the outcome of negotiations at future MOPs, this qualification should expire in 2012 when the 'may contain' language is proposed to become obsolete. Although the wording of the decision is vague, the dominant view is that the decision covers the adventitious presence of LMOs of the same species (such as different types of genetically modified soya) but does not cover the situation where there are traces of an LMO of one species in a shipment of another species (e.g. GM maize in a shipment of GM soya). [13]

The decision highlights the fact that the setting of an international threshold will continue to be one of the most difficult and controversial aspects of the protocol. Many countries have already established thresholds in their domestic regulatory frameworks with percentages ranging from 0.9% in the European Union to 5% in Mexico, Canada and the United States. The considerable variation among the countries has clearly made it difficult to reach a compromise.

'Stand-alone' document

The use of a 'stand alone' document, as opposed to the use of commercial invoices, was considered in relation to LMOs intended for contained use (Article 18.2(b)) and LMOs intended for intentional introduction into the environment (Article 18.2(c)). The discussions on the subject

[12] *Op Cit.*, (n3) *Bridges Trade BioRes* at page 5
[13] Ibid at page 5 and '*Analysis of key decisions at Biosafety Protocol meeting'* in South-North Development Monitor, 22 March 2006, page 3

are relevant because it has been discussed previously in the context of Article 18.2(a) so any progress on the matter will likely also be applied to LMO-FFPs. A number of parties supported the use of a stand alone document (Norway, Malaysia, Africa, Ecuador, India, Thailand, Belize and Antigua and Barbuda). However, the EU and Mexico asserted that further experience was needed with the existing documentation and Switzerland, Japan, New Zealand and Brazil called for more information on both systems.[14] Accordingly, the issue has also been postponed for further consideration and the parties have been requested to submit information on the experience gained with the use of this documentation to MOP-5 to assist its deliberations on the subject. In the meantime, parties can require exporters to comply with more stringent documentation requirements for LMO-FFPs in accordance with their domestic regulatory and/or administrative frameworks.

Biosafety Clearing House

Both parties and non-parties are invited to make available to the Biosafety Clearing House the following further information:

1. the transformation events that are commercially produced for each planting cycle in the exporting country;

2. the geographical area within the exporting country where each transformation event was cultivated;

3. the common, scientific and, where available, commercial names of the LMOs; and

4. 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.

This reflects the underlying objective of the Protocol to facilitate the sharing of information between parties and non-parties in relation to LMOs.

Capacity Building

The parties agreed that the review of the 'may contain' language at MOP-5 would include an examination of the capacity-building efforts in developing countries. These issues are linked because in order to implement the decision the developing country exporters (such as Peru and Paraguay) need to establish identity preservation systems. From a trade perspective, minimizing the cost of the developing country exporters complying with the Protocol will reduce their competitive disadvantage vis-à-vis the non-parties exporters (such as the US, Canada and Argentina). From an importing country perspective, capacity building is needed to assist on issues such as sampling, detection, testing and monitoring of LMO-FFPs.

What are the Implications of the Decision?

The most immediate impact will be on those parties whose domestic regulatory and administrative systems will have to be redrafted to align with the decision. Importing parties will

[14] '*Summary of the Third Meeting of the Parties to the Cartagena Protocol on Biosafety*: 13-17 March 2006', Earth Negotiations Bulletin, IISD Reporting Services, (Vol. 9, No. 351: March 2006) at page 8.

also need to consider whether to implement more onerous documentation requirements than that required by the Protocol as the Protocol specifically states that exporters must comply with domestic regulatory frameworks. However, mandatory identification requirements could affect the competitiveness of affected products in the marketplace. This suggests the possibility of ongoing tensions between the Protocol and the WTO, with parties needing to ensure that any identification requirements they introduce can be shown to conform to the requirements of the WTO.[15]

Industry in exporting countries will need to implement identity preservation systems and testing procedures so that they are in a position to notify the importing party when a shipment 'contains' LMO-FFPs. For developing country exporters this will need to occur in tandem with capacity building. The decision will require an upfront investment of resources by exporters and developers to establish the necessary company procedures and documentation to comply with the Protocol. However, some commentators argue this will not be substantial as "experience with other labeling requirements for products, wastes and other items has shown that in the longer term…the cost will be relatively limited, applying only when new products are created, or existing situations change".[16]

Importantly, the documentation requirements for Article 18.2(a) are applicable only to LMO-FFPs that are in "commercial production" (as opposed to research and field trials) and "authorized in accordance with domestic regulatory frameworks". The decision does not elaborate on whether the applicable framework is that of the exporting country or the importing country, or how it would apply to those countries that do not yet have an existing regulatory framework. As a result, the exporter may be able to decide which framework to apply, hindering further the African countries efforts to impose more stringent local labeling regulations.

Finally, as the issue of thresholds for adventitious presence of LMOs was not resolved at MOP-3 those parties who have not already set a percentage will need to do so. However, to the extent that wide differences between such thresholds continue to exist, it may become increasingly hard for parties to agree on a international standard

In addition to the practical implications, both participants and observers were encouraged by the decision and are optimistic that it signifies a move towards a more constructive approach by the parties to the biosafety negotiations. To some extent, this may be due to the fact the 'hardball tactics' employed by some countries at MOP-2 failed to secure the intended results and instead caused the talks to collapse. However, the more uncompromising exporter-orientated position adopted by Mexico, Paraguay and Peru at MOP-3 illustrate that the fast-evolving nature of the biotech industry will continue to create unpredictable results at future Meetings of the Parties as new LMO-exporters emerge and take steps to protect their trade interests.

[15] Duncan Brack, Robert Falkner and Judith Goll, *The Next Trade War? GM Products, the Cartagena Protocol and the WTO*, Briefing Paper 8 (London: Chatham House, September 2003) at page 7

[16] *Op Cit.*, (n3) *Bridges Trade BioRes* at page 2

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