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- http://www.iisd.ca/biodiv/bs-copmop3/
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- See also the official Web site of the Cartagena Protocol on Biosafety: http://www.biodiv.org/meetings/cop8mop3/default.shtml

Written and edited by: Soledad Aguilar Karen Alvarenga, Ph.D. Pia M. Kohler, Ph.D. Kati Kulovesi Elsa Tsioumani

Editor:

Pamela S. Chasek, Ph.D. <pam@iisd.org>
Director of IISD Reporting Services:
Langston James "Kimo" Goree VI <kimo@iisd.org>

A BRIEF HISTORY OF THE CARTAGENA PROTOCOL ON BIOSAFETY

The Cartagena Protocol on Biosafety addresses the safe transfer, handling and use of LMOs that may have an adverse effect on biodiversity, taking into account human health, with a specific focus on transboundary movements. It includes an advance informed agreement procedure for imports of LMOs for intentional introduction into the environment, and also incorporates the precautionary approach and mechanisms for risk assessment and risk management.

The Protocol establishes a Biosafety Clearing-House (BCH) to facilitate information exchange, and contains provisions on capacity building and financial resources, with special attention to developing countries and those without domestic regulatory systems. The Protocol entered into force on 11 September 2003 and currently has 132 parties.

NEGOTIATION PROCESS: In 1995, CBD COP-2 held in Jakarta, Indonesia, established a Biosafety Working Group (BSWG) to comply with Article 19.3 of the CBD, which requested parties to consider the need for, and modalities of, a protocol setting out procedures in the field of the safe transfer, handling and use of LMOs resulting from biotechnology that may have an adverse effect on biodiversity and its components.

The BSWG held six meetings between 1996 and 1999. The first two meetings identified elements for the future protocol and helped to articulate positions. BSWG-3 (October 1997, Montreal, Canada) developed a consolidated draft text to serve as the basis for negotiation. The fourth and fifth meetings focused on reducing and refining options for each article of the draft protocol. At the final meeting of the BSWG (February 1999, Cartagena, Colombia), delegates intended to complete negotiations and submit the draft protocol to the first Extraordinary Meeting of the COP (ExCOP), convened immediately following BSWG-6. Despite intense negotiations, delegates could not agree on a compromise package that would finalize the protocol, and the meeting was suspended. Outstanding issues included: the scope of the protocol; its relationship with other agreements, especially those related to trade; its reference to precaution; the treatment of LMO-FFPs; and documentation requirements.

Following suspension of the ExCOP, three sets of informal consultations were held, involving the five negotiating groups that had emerged during the negotiations: the Central and Eastern European Group; the Compromise Group (Japan, Mexico, Norway, the Republic of Korea and Switzerland, joined later by New Zealand and Singapore); the European Union; the Like-minded Group (the majority of developing countries); and the Miami Group (Argentina, Australia, Canada, Chile, the US and Uruguay). Compromise was reached on the outstanding issues, and the resumed ExCOP adopted the Cartagena Protocol on Biosafety on 29 January 2000 in Montreal, Canada. The meeting also established the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) to undertake preparations for COP/MOP-1, and requested the CBD Executive Secretary to prepare work for development of a BCH. During a special ceremony held at CBD COP-5 (May 2000, Nairobi, Kenya), 67 countries and the European Community signed the Protocol.

ICCP PROCESS: The ICCP held three meetings between December 2000 and April 2002, focusing on: information sharing and the BCH; capacity building and the roster of experts; decision-making procedures; compliance; handling, transport, packaging and identification; monitoring and reporting; and liability and redress.

COP/MOP-1 (February 2004, Kuala Lumpur, Malaysia) adopted decisions on: decision-making procedures; information sharing and the BCH; capacity building; handling, transport, packaging and identification; compliance; liability and redress; monitoring and reporting; the Secretariat; guidance to the financial mechanism; and the medium-term work programme. The meeting agreed that documentation of LMO-FFPs (Article 18.2(a)), pending a decision on detailed requirements, would: use a commercial invoice or other document to accompany the LMO-FFPs; provide details of a contact point; and include the common, scientific and commercial names, the transformation event code of the LMO or, where available, its unique identifier. An expert group was established to further elaborate specific identification requirements.

Agreement was also reached on more detailed documentation requirements for LMOs destined for direct introduction into the environment and contained use (Article 18.2(b) and (c)). The meeting also established a 15-member Compliance Committee, requested COP/MOP-3 to consider measures for cases of repeated non-compliance, and launched the Working Group on Liability and Redress under Article 27 of the Protocol.

LIABILITY AND REDRESS WG-1: At its first meeting (May 2005, Montreal, Canada) the Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress heard presentations on scientific analysis and risk assessment, and State responsibility and international liability. They also discussed options, approaches and issues for further consideration in elaborating international rules and procedures on liability and redress.

COP/MOP-2 (May-June 2005, Montreal, Canada) achieved a number of steps towards the Protocol's implementation, adopting decisions on capacity building, and public awareness and participation. Delegates engaged in discussions on risk assessment and risk management, and agreed to establish an intersessional Ad Hoc Technical Expert Group. They adopted the rules of procedure of the Compliance Committee, but a provision for two-third majority voting remained bracketed.

Delegates did not reach agreement on the detailed documentation requirements for shipments of LMO-FFPs, even though the Protocol had established a deadline for their approval at COP/MOP-2. Main areas of disagreement included requirements to identify which LMOs a shipment may contain, and thresholds for adventitious or technically unavoidable presence of LMOs, including whether or not they trigger the documentation requirements.

INTERSESSIONAL HIGHLIGHTS

RISK ASSESSMENT AHTEG: The Ad Hoc Technical Expert Group on Risk Assessment (15-18 November 2005, Rome, Italy) considered existing approaches to risk assessment and identified follow up measures and activities to improve risk assessment capacities. The AHTEG noted that the capacity to conduct a risk assessment is linked to the level of development of the country in question, and concluded that international guidelines and academic research is lacking regarding specific LMOs and types of risk.

LIAISON GROUP ON CAPACITY BUILDING: The third meeting of the Liaison Group on Capacity Building for Biosafety (20-21 January 2006, Tromsø, Norway) proposed to update the current Action Plan on capacity building to incorporate experiences and lessons learned during its implementation. The Liaison Group recommended financial support for country-appointed experts, even if they are not listed on the biosafety Roster of Experts.

COMPLIANCE COMMITTEE: The second meeting of the Protocol's Compliance Committee (6-8 February 2006, Montreal, Canada) considered the implementation of its rules of procedure approved by the COP/MOP-2 and reviewed general issues of compliance, including interim national reports and information in the BCH.

LIABILITY AND REDRESS WG-2: At its second meeting (20-24 February 2006, Montreal, Canada), the Liability and Redress Working Group considered issues and options for elements of rules and procedures on liability and redress, including: effectiveness criteria; scope, definition and valuation of damage; causation; channeling of liability; standard of liability; limitation of liability; and mechanisms of financial security. Following informal consultations held throughout the week, a non-negotiated and non-exhaustive indicative list of criteria for the assessment of the effectiveness of any rules and procedures referred to under Article 27 of the Protocol was annexed to the meeting's report. The report also contains proposals for operational texts on causation, and the scope, definition and valuation of damage.

A BRIEF ANALYSIS OF COP/MOP-3

Reaching agreement on detailed documentation requirements for living modified organisms for food, feed, or processing (LMO-FFPs), as specified in Article 18.2(a), was undoubtedly the core focus of the third Meeting of the Parties to the Cartagena Protocol on Biosafety (COP/MOP-3). Prior to convening in Curitiba some had even implied that failing to do so would sound the death knell of the Protocol. Indeed, just ten months earlier, COP/MOP-2 was unable to reach consensus on this same issue, thus missing the deadline for resolution laid out in the text of the Protocol. After a week of protracted negotiations, parties agreed on a compromise package that, as many delegates noted, balanced the interests of importing and exporting, and developed and developing parties.

With everyone's attention focused on reaching an agreement on Article 18.2(a), substantive discussions on other agenda items, including the rights and obligations of transit parties, risk assessment and management, and voting procedures in the Compliance Committee and consequences of repeated non-compliance, were postponed pending further review. Even the uncertainty surrounding the extent of the GEF's third replenishment, and the impact of its new resource allocation framework on biosafety projects, did not take center stage, as guidance to the GEF is only given by the CBD COP. Therefore, this brief analysis will discuss the issues at the heart of Article 18.2(a) and the substance of the compromise achieved.

Article 18.2(a) of the Protocol, which was agreed in the final minutes of negotiations on the Protocol in January 2000, provides for documentation accompanying LMO-FFPs to state that the shipment "may contain" LMOs and that these are not intended for intentional introduction into the environment. It also calls on parties to agree on more detailed documentation requirements within two years of the Protocol's entry into force (in other words, by September 2005). At its first meeting, the COP/MOP further agreed, in Decision BS-I/6, that documentation should include the LMOs' common, scientific and, where available, commercial names, and its transformation event code, or where available, its unique identifier code. COP/MOP-1 also established a technical expert group to develop more detailed documentation requirements.

The authorization to document an LMO shipment stating that it "may contain" a range of possible LMOs was the central locus of disagreement from the get-go. In the decade since the opening of the negotiations for a biosafety protocol, the phrase "contains" has taken on a life of its own, becoming the rallying cry for a wide range of stakeholders pressing for more detailed documentation requirements. Importing countries see "contain" as a means of ensuring that they are provided accurate and actionable information regarding the content of LMO-FFP shipments, while exporting countries are concerned about the feasibility of identifying every LMO-FFP that is contained in a shipment, apprehensive that the presence of unintended LMOs in a shipment might trigger non-compliance procedures against them.

These competing concerns are inextricably tied to the trade dimensions of the documentation requirements. Countries that are significant exporters of agricultural commodities warned that onerous and detailed documentation requirements were certain to impact the global commodities trade, even that of non-LMOs. They were especially wary of needing to implement traceability systems, for example involving segregation throughout the production and transport processes, in order to be able to certify whether a shipment does or does not contain LMOs. Some also feared that in the absence of such infrastructure, all commodity shipments would have to be identified as potentially containing LMO-FFPs.

Meanwhile, importing countries were eager to set up documentation requirements whereby documentation would state which LMOs were included in a shipment, rather than a longer list of LMOs that might be included in a shipment. Developing country importers, particularly African parties, stressed that shipments listing all LMO-FFPs grown in the exporting countries, without guidance as to which LMOs were most likely to be contained, pose decision-making challenges, such as the need for additional risk assessments, and capacity challenges to adequately detect and monitor the content of incoming shipments.

The Protocol does provide for parties to enact their own national biosafety legislation, which can include more stringent documentation requirements and thresholds above which documentation would have to state that the shipments contain the LMO in question. This question is closely linked to the push by some importing countries to set international guidelines or standards for establishing thresholds. Opponents raised the technical and financial feasibility of testing all shipments for trace amounts of LMOs. The international setting of thresholds was in fact at the core of failing to reach agreement on Article 18.2(a) at COP/MOP-2, where New Zealand and Brazil had serious objections to establishing any rule that would affect commodity trade in general and broke consensus at the end of a week of negotiations.

As COP/MOP-3 convened, many had focused their attention on means of bringing those two parties into the fold, and most were therefore surprised that in Curitiba it was other parties who took on firm positions on the retention of "may contain" documentation requirements, notably Paraguay, Peru and Mexico. This was seen by some as evidence of the rapid evolution of biosafety regimes, with an increasing number of countries approving LMOs for production and acknowledging the trade implications of any constraints on LMO-FFP exports.

This shift was further evidenced by the increased participation in many delegations of representatives of trade and finance ministries, sometimes replacing more familiar faces from environment and agriculture ministries. This emphasis on the trade implications of the Protocol, and more specifically the relationship between the Protocol and the World Trade Organization (WTO), was echoed across other agenda items considered by COP/MOP-3, including the definition of transit in determining the rights and obligations of transit parties and the ongoing efforts by the CBD Executive Secretary to gain observer status on relevant WTO committees. Similarly, exporting parties' pre-existing bilateral trade agreements with large non-parties, such as the US, were widely acknowledged as one of the reasons why some Latin American parties emerged as the ones most likely to resist consensus.

In the end, agreement was reached late Friday evening, after over two days of intense Friends of the Chair consultations. Throughout this process, negotiations were based on a proposal by Brazil announced by President Lula da Silva on Tuesday, and many attributed the successful outcome to the host country's high-level of commitment (further evidenced by the presence at the closing plenary of Marina da Silva, Brazil's Minister of the Environment) to reach an agreement at COP/MOP-3.

This compromise package, known as the "Curitiba Rules," requests parties to take measures to ensure that documentation accompanying LMO-FFPs in commercial production clearly states that the shipment contains LMO-FFPs in cases where the identity of the LMO is known through means such as identity preservation systems. The Curitiba Rules still allow that, in cases where the identity of the LMO is not known through such measures, documentation states the shipment may contain one or more LMO-FFPs, and acknowledges that the expression "may contain" does not require a listing of LMOs of species other than those that constitute the shipment. The Rules also provide for reviewing experience gained with these documentation requirements at COP/MOP-5, with a view to considering a decision at COP/MOP-6 to phase out "may contain" documentation. Since parties decided that future COP/MOPs will now be held every two years, this implies that "may contain" language will be allowed until 2012.

Finally, the Rules also include special provisions for capacity building, especially relating to using and developing simple, rapid, reliable and cost-effective sampling and detection techniques for LMOs. This emphasis on capacity was ever present across the COP/MOP-3 agenda, as the challenges faced even by developed countries in elaborating and implementing national biosafety frameworks came to light.

In the end, as COP/MOP-3 participants left the conference center to rest in preparation for CBD COP-8, many expressed satisfaction at having arrived at a successful outcome to what some had termed an "impossible task." Many had come focused on making sure that any decision taken at COP/MOP-3 would not lose any ground from the agreement outlined in Decision BS-I/6, with some noting that any step forward would help solidify the future of the Protocol. Others had to ensure that any requirements could be met without jeopardizing pre-existing trade agreements or triggering the Protocol's non-compliance procedures.

The significance of the compromise reached at COP/MOP-3 is undeniable – parties took a deliberate step towards reaching a consensus ten-years in the making. In the two-year intersessional period prior to COP/MOP-4, and in order to validate the success achieved at Curitiba, parties now face the imposing task of laying the necessary groundwork for taking decisions on the many issues postponed pending further review, and put in place the necessary components of an international biosafety framework.

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