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Implementing the Biosafety Protocol: Key Challenges

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Photo by Dr Klaus Schumacher, International Grain Trade Coalition'

Summary

• The Cartagena Protocol is becoming a global source of rules and norms for GMO trade but important elements will need to be negotiated by the parties to make it a more comprehensive regulatory system.

• The most urgent task is to agree upon rules on identifying GMO content in bulk agricultural trade, which is central to importing countries' ability to carry out risk assessment and implement domestic regulations on GMO traceability and labelling.

• The parties will have to decide on how the compliance mechanism is to work. Proposals for a sanctions-based approach in this context have proved to be highly controversial.

• Parties also need to consider the financial implications arising from cases of non-compliance, as part of the wider need to promote effective capacity-building in developing countries.

• In negotiating these elements, the existing parties (mainly GMO-importing countries) face a strategic trade-off: whether to push ahead with their implementation agenda or seek a broader consensus, including with (non-party) GMO-exporting countries.

Introduction

Four years after its adoption and one year after its entry into force, the Cartagena Protocol on Biosafety is on its way to becoming a key global source of rules and norms for trade in genetically modified organisms (GMOs). However, certain important elements that would make it a comprehensive regulatory system are still being negotiated and a number of other agreed elements await full implementation. To be sure, no multilateral environmental agreement (MEA) has ever been created *in toto*, without needing revision or elaboration. International regime-building can be an arduous, lengthy and often frustrating effort. The key challenge now is for the biosafety treaty to evolve in a manner that is seen as legitimate and practical by both exporters and potential importers of genetically modified organisms.

In moving towards full implementation, the parties to the protocol have to spell out detailed requirements for identifying genetically modified (GM) varieties in the bulk agricultural commodity trade; define and elaborate on procedures for the functioning of the newly created compliance mechanism; continue to develop a coherent framework for capacity-building; and embark on a lengthy negotiation of rules on liability and redress in case of damage resulting from trade in particular GMOs. In late 2004, the number of ratifications of the protocol passed 100, and more countries have signalled their desire to join the treaty. However, most current parties to the protocol represent, on balance, the importer rather than the exporter perspective on GMO trade. Key GMO-exporting countries, such as Argentina and Canada, are still deliberating whether to ratify the agreement, while others, particularly the United States, are unlikely to accede to the agreement in the near future.

In reaching decisions on controversial issues, therefore, the existing parties face a fundamental dilemma: whether to push ahead with stringent rules on implementation, which might deter exporting countries from ratifying; or whether to go slow and seek a broad consensus, also with non-parties, on the outstanding issues. This dynamic between parties and non-parties was particularly striking in the first Meeting of the Parties to the Cartagena Protocol, held in Kuala Lumpur in February 2004. This briefing paper reviews the progress made so far in making the Cartagena Protocol operational and outlines the pressing implementation challenges that the protocol now faces.

Background to the Cartagena Protocol on Biosafety[1]

Genetic engineering is seen by many as a revolutionary technological advance in agriculture. Unlike traditional methods of plant and animal breeding, genetic engineering allows the direct manipulation of genetic material in plants and animals, through inserting, removing or altering genes. This new technology permits both genetic change across the boundaries of species and a more rapid and targeted form of modification. The nature and relative novelty of this technology have, however, given rise to a fierce international debate over the desirability and safety of genetic engineering in agriculture and food production.

Much of the opposition to genetic engineering in agriculture reflects concern over the ecological impacts of the release of GMOs into the environment or human health impacts of consuming food with GM content. Environmentalists and consumer advocates are concerned about the potential long-term effects of GMOs on ecosystems and human health, and urge policy-makers to be guided by caution. Developed and developing countries have also voiced concerns about the potential impact the new technology would have on their agricultural systems and communities. Many see genetically modified crops as unsuitable for small-scale subsistence farmers in poor countries and fear large multinational companies will dominate seed production and distribution. These concerns prompted international efforts to create a global biosafety treaty, leading to the adoption of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD) in January 2000.

The biosafety negotiations

The Cartagena Protocol is the first international treaty dealing with the transboundary movement of genetically modified organisms. After its 50th ratification last year, the treaty entered into force on 11 September 2003. The Cartagena Protocol is the result of nearly four years of at times acrimonious negotiations between GMO-exporting and -importing countries. What started as a relatively unnoticed set of multilateral negotiations in 1996 was soon catapulted into the limelight of the global trade–environment conflict, mainly owing to the growing controversies over genetic engineering in agriculture in the late 1990s.[2] Developing countries' concerns about their ability to manage biotechnology and the European Union's (EU) precautionary stance on GMOs in agriculture provided the main impetus for creating stringent international biosafety rules. The small but powerful Miami Group of GMO exporters, comprising the United States, Canada, Argentina, Australia, Chile and Uruguay, initially opposed these but eventually accepted a compromise agreement in January 2000.

The main objective of the Cartagena Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs).[3] Despite its coverage of human health- and biodiversity-related safety aspects of LMOs, the emphasis is on ensuring safety in the transboundary movement of LMOs. The protocol is thus both an environmental and a trade agreement, insofar as it explicitly regulates the international trade

in genetically modified material. The domestic use of LMOs remains largely in the hands of national regulatory authorities, although the protocol provides guidance and assistance in this area.

It is expected that the Cartagena Protocol will be of central relevance for developing countries, many of which are only now beginning the process of developing domestic biosafety regulations. The protocol provides these countries with guidelines for carrying out risk assessment, strengthens their sovereign right to subject international trade in GMOs to such risk assessment and supports the creation of regulatory institutions through capacity-building and information exchange. Capacity-building initiatives are currently under way to support the creation of national biosafety frameworks, provide training on risk assessment and management, and boost scientific and regulatory capacity in general.

Key provisions of the protocol

The central regulatory element of the biosafety treaty is the advance informed agreement (AIA) procedure, which applies to the first intentional transboundary movement of LMOs for intentional introduction into the environment of the importing country.[4] The procedure seeks to ensure that importing countries have the opportunity to assess the environmental or human health risks associated with the LMO before agreeing to its import. It obliges exporters to notify importers in advance of the first shipment and to supply a detailed description of the LMO. After acknowledging receipt of the information within 90 days, the importing party must communicate its decision, which is to be based on risk assessment, within 270 days: it may approve or prohibit the import, request further information or extend the deadline by a defined period of time, stating the reasons for the decision. Both the importing and exporting parties may, at any time, initiate a review of the decision in the light of new scientific information.

Although applying to all LMOs in principle, the Cartagena Protocol exempts certain types of LMOs either from the entire agreement or from specific provisions. Article 5 excludes the transboundary movements of LMOs which are pharmaceuticals for humans from all provisions of the agreement.[5] Among the LMOs exempted from the AIA procedure are LMOs in transit and LMOs destined for contained use in accordance with the standards of the Party of Import (Article 6); and LMOs intended for direct use as food or feed or for processing (LMO-FFPs) (Article 7.3). The latter represent the vast majority of internationally traded LMOs – so-called agricultural commodities – and were the subject of protracted negotiations in the final stage of the biosafety talks. A simplified procedure was agreed for commodities, which creates certain information requirements for exporting countries but not a requirement for country-by-country prior notification (see discussion below). The protocol does not, however, affect the right of any party to regulate any of these exempted LMOs through domestic legislation. Likewise, parties can inform the Biosafety Clearing-House that they wish to exempt certain imports of LMOs from the AIA procedure (Article 13), and the Conference of the Parties to the CBD serving as the Meeting of the Parties to the Protocol (COP/MOP, the decision-making body) may in future decide to exempt additional LMOs from application of the AIA procedure.

The protocol requires importing countries to base their decision on risk assessment, which is to be carried out 'in a scientifically sound manner' (Article 15). Specific guidelines for risk assessment are detailed in Article 15 and Annex III of the agreement. During the negotiations, developing countries demanded the right to take into account socio-economic considerations, which Article 26 permits, provided that this is consistent with other international obligations. A hotly contested question in the negotiations was the extent to which the precautionary approach should be applied in decision-making. The compromise reached allows importing countries to take a decision – for example to ban LMO imports – where there is a lack of relevant scientific information and knowledge about adverse effects (Article 11.8). The inclusion of precautionary language in the operational text of the agreement marks a significant advance in international environmental law towards a more formal recognition of the precautionary principle. It also serves to strengthen the prerogative of importing nations to decide on whether or not to allow LMO imports into their territory.

On the basis of Article 18.3 of the CBD, the protocol also establishes a Biosafety Clearing-House as the central mechanism for the exchange of scientific, technical, environmental and legal information on LMOs covered by the protocol (Article 20). It is designed to assist parties in implementing the protocol and to provide them with speedy access to relevant information in order to carry out risk assessment. The clearing-house will play a critical role in providing access to information on agricultural commodities placed on the market and on legislation by importing countries regarding their import. A detailed overview of the protocol's information-sharing obligations is provided in Table 1.

Progress since adoption of the biosafety treaty

As it stands, the biosafety treaty is still very much in a state of evolution. Many contentious issues were left unresolved in the final round of the biosafety negotiations in January 2000, including detailed rules on identification of GMOs in trade, coordinated capacity-building for developing countries, compliance and enforcement mechanisms, and rules on liability. These and other issues will now have to be addressed by successive meetings of the parties over the next few years. At the first such meeting, held in early 2004 amid growing controversy over GMO trade, the parties took important steps towards implementation of the protocol.

Between the adoption of the protocol in 2000 and its entry into force in 2003, an Intergovernmental

TABLE 1: INFORMATION-SHARING OBLIGATIONS FOR DIFFERENT CATEGORIES OF LMOS

Category of LMOs	Exporter obligations for information-sharing/soliciting importer agreement
LMOs transferred for intentional introduction into the environment	**In advance:** Notification and solicitation of agreement from importing party prior to transfer; detailed information about the LMO to be provided with this notification. **With transfer:** Documentation which ***clearly identifies them as LMOs***, and ***specifies their identity and relevant traits and/or characteristics***; requirements for safe handling, use and storage; contact point for further information; declaration that transfer is in accordance with exporter's protocol obligations.
LMOs transferred for food, feed or processing (agricultural commodities)	**In advance:** Instead of country-by-country, notification to a centralized Biosafety Clearing-House (BCH) of domestic approvals of LMOs that may enter international trade in the future. Information to be supplied to the BCH includes approved domestic uses of the LMO and a risk assessment report done in order to secure domestic approval. **With transfer:** Documentation which clearly identifies that unsegregated bulk agricultural commodity shipments '***may contain' LMOs***; that they are not meant for intentional introduction into the environment; contact point for information. This is subject to further negotiations.
LMOs transferred for contained use	**In advance:** No obligations. **With transfer:** Documentation that clearly identifies them as LMOs; requirements for safe handling, transfer and use; contact point for further information.
Transfers of processed products deriving from LMOs	**In advance:** No obligations. **With transfer:** No obligations. *Where appropriate*, an obligation on all parties to provide regulatory information or summary risk assessments about LMO products to Biosafety Clearing-House.

Source: Table 2 in Aarti Gupta, 'Information as Influence in Anticipatory Governance: The Case of Biosafety', in Ronald B. Mitchell et al., *Global Environmental Assessments: Information, Institutions and Influence* (Cambridge: MIT Press, forthcoming).

Committee for the Cartagena Protocol (ICCP) met three times to prepare for the first Meeting of the Parties. While the ICCP could not take binding decisions on the development of the protocol, it nevertheless helped to get the Biosafety Clearing-House off the ground and made recommendations on a long list of outstanding issues. When the First Meeting of the Conference of the Parties serving as the Meeting of the Parties (COP/MOP-1) met in February 2004, an ambitious work programme had thus been set. But whether the first meeting would succeed in reaching key decisions on operational and institutional aspects of the treaty was far from clear.

In the end, COP/MOP-1 proved to be a success. The fact that most GMO-exporting nations have yet to ratify the agreement gave the existing parties an opportunity to push ahead with their implementation agenda. But on the key issue relating to identification of transgenic content in agricultural commodity shipments, COP/MOP-1 could only agree on interim rules that will need to be reconsidered at future meetings. The following sections discuss this and other major issues of contention and potential options and solutions in these areas.

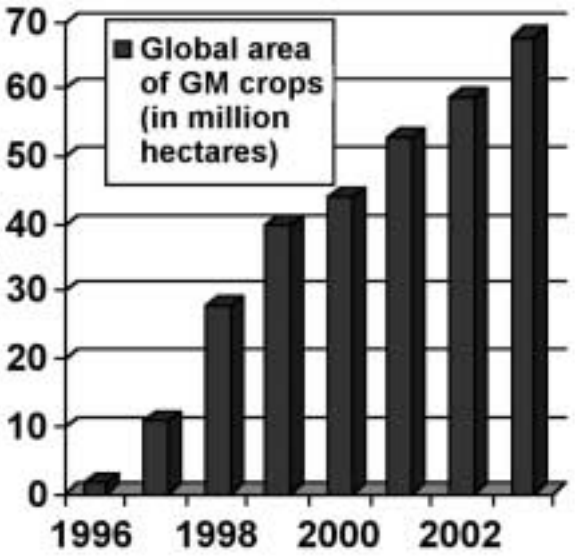
Identifying GM content in agricultural commodity trade

Background

As pointed out above, the Cartagena Protocol contains a special, simplified procedure for LMOs intended for direct use as food or feed, or for processing (LMO-FFPs). Agricultural commodities make up the vast

majority of transnational GMO shipments and are therefore of particular commercial significance to both exporting and importing nations. An estimated 300 million tonnes of grains, oilseeds, pulses and other crops are traded internationally each year, and the ongoing liberalization of agricultural markets is likely to increase farm trade in the future. Since the mid-1990s, the share of GM crops in agricultural markets has risen steadily, raising concerns among exporters that stricter biosafety rules may act as protectionist trade barriers.

FIGURE 1: GROWTH IN COMMERCIAL USE OF GENETICALLY MODIFIED CROPS (1996–2003)
Source: International Service for the Acquisition of Agri-Biotech Applications: *www.isaaa.org*.



The Cartagena Protocol's rules on LMO-FFPs oblige a party to inform other parties through the Biosafety Clearing-House of its decision to authorize domestic use of LMOs that may be subject to transboundary movement. On the basis of this information, importing parties take a decision on whether or not to accept the import of such commodities. The main difference between this and the AIA procedure is that, in the case of agricultural commodity shipments containing LMO-FFPs, exporters do not need to notify and inform importing parties directly, and the prior approval requirement does not automatically apply. However, importing parties may subject agricultural commodity imports to a domestic procedure similar to AIA, including prior notification and approval. Moreover, Article 11.8 of the protocol allows importing countries to apply the precautionary approach in reaching a decision on LMO-FFPs. It is worth mentioning that, because of the specific focus of the protocol on living modified organisms, the procedure for LMO-FFPs does not apply to all categories of what are generally referred to as GM foods. It does not cover trade in food products that are derived from GM products but do not contain an LMO (e.g. processed food made with a refined processed oil derived from GM soya).

Debates and decisions at COP/MOP-1 in Kuala Lumpur

The question of how to identify GM content in agricultural commodity shipments was the final stumbling block that nearly derailed the biosafety talks in 2000. A last-minute compromise reached in the final hours of negotiation allowed the protocol to be concluded. The compromise called for bulk agricultural commodity shipments containing transgenic varieties to state that they 'may contain' LMOs (rather than specifying which ones or providing any additional information). The compromise further stated that more detailed information requirements were to be decided by the parties to the protocol not later than two years after its coming into force (see Box 1). Not surprisingly, then, elaborating on the 'may contain' requirement for bulk commodity trade was at the centre of conflict at COP/MOP-1. Exporting countries and industry argued that there was no need, at present, to go beyond the 'may contain' obligation. Others, including the EU and developing countries, pushed to elaborate and expand on this obligation. In the end, another compromise was struck: the main obligation on exporters was still restricted to the need to state that shipments 'may contain' LMOs, but parties and others were 'urged' to provide additional detailed information. The parties also decided to establish an open-ended technical expert group to further elaborate on identification requirements for agricultural commodities and adopted terms of reference for its work. COP/MOP-1 thus put in place an interim solution but critical issues relating to identification requirements remain to be decided by the next meeting of the parties.

BOX 1: CARTAGENA PROTOCOL, ARTICLE 18.2(A): HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

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 of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

As before, negotiations over identification and documentation requirements for bulk commodity shipments pitted GMO exporters against potential importer nations. Two questions proved particularly controversial: what kind of information exporters have to supply, and in what form this information is to be provided. With regard to the former, the majority of the parties demanded detailed information, including the names of the LMOs concerned and details about genetic transformation events. The EU and most

developing countries view this as an important condition for carrying out risk assessments and facilitating traceability systems. In contrast, industry groups and the delegations representing exporter interests were keen to keep the required information to a minimum and argued for maintaining the existing requirement merely to state that shipments 'may contain' LMOs. This, they insisted, would allow importing nations to consult relevant information on authorized LMOs in exporting nations supplied through the Biosafety Clearing-House. On the question of how this information is to be provided, the GMO-exporting nations rejected demands for the introduction of separate documentation in favour of the use of existing commercial invoices to indicate the presence of LMO content in shipments.

Because most of the GMO-exporting nations have not yet ratified the agreement, they were able only to express their reservations but not to exercise a veto over these proposals. Brazil and Mexico, which are parties, emerged, however, as opponents of more stringent requirements relating to agricultural commodities at COP/MOP-1. Their perspectives signal important and on-going shifts in alliances across developed and developing countries. Brazil, in particular, is one of the large developing countries with both importer and exporter concerns, while Mexico has to contend with the fact that it is party to a protocol that its main trading partners, the United States and Canada, are not.

In the end, the Kuala Lumpur meeting could devise only interim solutions. Thus, COP/MOP-1 decided to request the use of commercial invoices until the question of a stand-alone document is finally decided. Further, it decided merely 'to urge' parties to ensure that the precise name and the transformation event code of the LMO, and possibly its unique identifier (see discussion below on identification requirements), be declared in accompanying documentation. The working group established at COP/MOP-1 will take the discussion on these issues forward, with a view to reaching a final decision on the details of documentation and identification requirements at COP/MOP-2 (2005) and COP/MOP-3 (2006).

The working group, which will meet for the first time in March 2005, will have to deal with three key issues, among others:

- the form of documentation to accompany agricultural commodity shipments, particularly whether existing commercial invoices or a stand-alone document will be required;
- the content of the accompanying information, and particularly the use of a unique identifier system; and
- the question of thresholds in identifying LMOs in shipments.

Documentation requirements

On the question of accompanying documentation on which LMO presence is to be declared, parties remain divided, with industry groups arguing against the use of separate documentation, which they see as creating an additional and unnecessary bureaucratic burden. Most developing countries are still keen to introduce a requirement for a stand-alone document, although they could not secure unstinting support from the EU for this demand in Kuala Lumpur.

A key rationale that developing countries offered for a stand-alone document was that it would make it easier for custom authorities to distinguish shipments which may contain LMOs from the many transactions (accompanied by commercial invoices) where no LMOs were being traded. In the absence of a stand-alone document, all relevant commercial invoices would have to be examined to locate information about LMO content. Norway (as a vocal supporter of the developing-country demand for a stand-alone document) distributed a template in Kuala Lumpur that countries could, in their individual capacity, post on the Biosafety Clearing-House as their preferred form of documentation to accompany LMO-FFPs in trade. This conflict again points to an on-going dynamic in the overall protocol negotiation and evolution: whether the extra financial or human resource-related burdens of distinguishing between GM and non-GM shipments should fall on exporters or importers.

It points, furthermore, to the all-important issue of trust among different entities involved with GM trade. Developing countries (supported by NGOs) distrust corporate intentions in opposing a stand-alone document, while agricultural traders fear that the use of a stand-alone document would attach a 'stigma' to GMO shipments. It remains to be seen whether COP/MOP-2 can find a solution which addresses such concerns, while ensuring that a harmonized policy emerges. It would be an undesirable outcome for all if individual countries started posting different stand-alone documents on the Biosafety Clearing-House as their preferred options.

Identification requirements

As regards content, the parties are also equally divided between those that want the accompanying documentation to provide detailed information about the identity of any LMO contained in a shipment, preferably using a unique identifying system, and those, including industry groups, that oppose detailed identification requirements. Agricultural traders argue that the reality of the mingling of GM and non-GM varieties in the grain harvesting, storage and transportation system, together with the possibility of adventitious presence of GM content, make identification of every genetic transformation event in a large commodity shipment near-impossible. They point further to the lack of an internationally harmonized sampling and testing system and the difficulty of establishing with sufficient certainty the presence of minute quantities of GMOs. It is certain that this issue will prove one of the sticking points in

the forthcoming Meeting of the Parties next year.

A first step towards finding a compromise was made when at COP/MOP-1 the EU proposed the use of the OECD's unique identification system in this context. The OECD's work on unique identifiers for transgenic plants, which is often compared to the ISBN system in the publishing world, was developed with the help of experts from GMO-exporting nations and has found the support of some industry groups, particularly in Europe. The unique identifier consists of a single alphanumeric code based on the genetic transformation event, which can be used to access more detailed information held in relevant databases such as the Biosafety Clearing-House. Although trade associations such as the International Grain Trade Coalition oppose the use of unique identifiers in accompanying documentation – but support it as part of the information supplied to the Biosafety Clearing-House – the EU's adoption of the OECD unique identifier for certain products may set a precedent that will shape markets before an international agreement is reached. It is as yet the most promising answer to the question of identification, although it will need to be extended beyond transgenic plants to cover all LMOs that fall under the protocol's scope. If developing countries can agree to a technical system that was developed by the OECD rather than a more inclusive international organization such as UNCTAD, the South's preferred institutional host, then a broad coalition in favour of the unique identifier system may emerge at the next COP/MOP.

The question of thresholds

Critical to the success of the future negotiations on agricultural commodities will be a broad agreement on the question of thresholds in identifying LMO content in shipments. This is by far the most controversial and difficult issue on the agenda for the parties. Substantial negotiations on this issue have yet to start, and in all likelihood COP/MOP-2 will leave it to be resolved at the next COP/MOP in 2006. Setting a threshold for identifying LMO presence in shipments will be of great commercial significance to agricultural producers and traders; it will also, in large measure, determine the future relevance of the Cartagena Protocol and its attempts to balance importers' right to know with exporters' interest in a commercially workable system.

Industry groups have pushed for a 5 per cent threshold to be applied across the board for all types of LMO shipments, which would mean that the identification requirement applied only to shipments containing 5 per cent or more of LMO content. This, they argue, would be a realistic level that would limit the disturbance caused to existing commodity trade flows. It would guarantee that adventitious presence of GM content, which may result from cross-pollination or accidental mixing of seed during production and conditioning, does not cause shipments to be identified as 'containing LMOs'. LMO-exporting nations such as Canada and the United States support the industry view and also recommend a 5 per cent threshold, which was included in a controversial trilateral agreement between the North American Free Trade Agreement (NAFTA) countries of Mexico, the United States and Canada. But while the 5 per cent threshold may be commercially viable, it is considered by many parties to be unacceptable.

Some parties have already established thresholds for domestic labelling regimes, and the variety of approaches chosen so far is likely to complicate the search for an international standard. The EU's labelling and traceability rules, which entered into force in April 2004, require that all food and feed containing GMOs, and food produced from or containing ingredients produced from GMOs, be labelled as containing GMOs. In the case of adventitious presence of GMOs, any product containing more than 0.9 per cent of approved GM material is to be considered a GM product. A 0.5 per cent threshold applies for adventitious presence of GMOs not yet formally authorized. Australia and New Zealand have adopted a threshold of 1 per cent, South Korea 3 per cent, and Japan and Indonesia 5 per cent. Russia is to lower its 5 per cent threshold to 0.9 per cent and China has recently introduced a zero per cent threshold for its labelling scheme. Moreover, the existing national rules differ not only with regard to the tolerance level for GMO presence but also with regard to the GMOs and GM products covered. As countries will want to see their domestic regulations supported by international rules, finding a compromise on thresholds is likely to prove one of the most controversial aspects of the next two COP/MOPs.

Compliance mechanism

Background

In principle, all parties to an international treaty should have an interest in strong compliance mechanisms, to ensure full implementation and prevent free-riding by the few at the cost of the many. In practice, however, most multilateral environmental agreements use only 'soft' mechanisms that seek to facilitate implementation through creating transparency and providing assistance. The possibility of taking stronger, even punitive, measures in cases of non-compliance remains the exception in MEAs. Environmental treaty-making has thus developed a practice of creating compliance mechanisms that are non-judicial, non-adversarial, participatory and of a facilitative nature. These procedures aim at preventing disputes arising from instances of non-compliance and at clarifying the application of MEA rules and provisions.

Debates and decisions at Kuala Lumpur

At COP/MOP-1 in Kuala Lumpur, developing countries expressed concerns about proposed language that sought to strengthen the biosafety protocol's compliance mechanism, to include the possibility of punitive sanctions against non-compliers. Developing countries, in particular, were concerned that they might be faced with punitive measures in the event of

capacity-related non-compliance. Outspoken opposition to strong compliance rules also came from GMO-exporting nations, most of which as non-parties were, however, not able to block final decisions. The controversial issues included: who would be entitled to initiate the compliance procedure; in what capacity the members of the compliance body – the Compliance Committee – would serve; what information they would be able to consider and from whom; and what kinds of measures could be used against non-compliant countries.

The EU pushed for adoption of strong provisions that included the right of all parties to trigger the compliance procedure and the possibility of taking sanctions against persistently non-compliant parties. The EU further demanded that members of the Compliance Committee serve in their personal capacity rather than as representatives of governments. Some elements of the EU's proposal provoked strong objections, especially the use of punitive measures. Developing countries called for a recognition of the principle of 'common but differentiated responsibilities' in compliance decisions, while GMO-exporting countries demanded a balance of exporter and importer perspectives in Compliance Committee membership. In the end, the parties agreed to

TABLE 2: COMPLIANCE ISSUES AT COP/MOP-1: AREAS OF CONFLICT AND OUTCOMES

Controversial issues	**South**	**EU**	**Miami**	**Outcome in KL**
Compliance based on principle of common but differentiated responsibilities (CDR)?	YES	NO	NO	No reference to CDR; but special needs of different regions recognized
Balance between exporter and importer views on committee?	Not necessary	Not necessary	Necessary	No overt balancing of different views required
Should members of committee serve: *As representatives of their governments* OR *In their personal capacity?*	Some prefer members to represent their countries	In their personal capacity	Objectively and in the best interests of the protocol	Members nominated by parties and elected by COP/MOP must serve 'objectively and in their personal capacity'
Who can trigger compliance procedure? *Self-trigger* OR *Party-to-party*	Self-trigger and party-to-party, as long as both are directly involved	Party-to-party	Self-trigger (Australia); multilateral trigger via the COP (Canada)	Both self- and party-to-party trigger (but only if triggering party is 'affected or likely to be affected')
Information sources to be considered *Only parties? OR Also from others (NGOs, academics, industry)?*	From parties and other relevant sources. No NGOs (China)	Information from all sources may be considered	Information from all sources may be considered	From parties Also from CBD, COP/MOP, BCH, and relevant international organizations
Punitive measures?	NO Only cooperative measures	YES For repeated non-compliance	NO Only cooperative measures	Could not be resolved. To be considered by COP/MOP-3

establish a Compliance Committee consisting of 15 government-nominated members reflecting a regional balance, who will serve 'objectively and in a personal capacity'. This compromise language is taken from the Basel Convention on trade in hazardous waste, highlighting a phenomenon that negotiators remained keenly aware of during protocol compliance discussions: the precedent-setting nature of any one MEA.

On the critical issue of who can initiate non-compliance proceedings, parties agreed that any party can bring a case of non-compliance where it is itself concerned (self-trigger) or where it is 'affected or likely to be affected, with respect to another Party' (party-to-party trigger). The Compliance Committee can consider relevant information submitted by concerned parties but also from other sources, such as international organizations. In cases of non-compliance, it is the COP/MOP that will decide on measures to be taken, based on recommendations from the committee. These may include provision of assistance, issuing a caution and publishing the case through the Biosafety Clearing-House.

On the highly contentious question of punitive measures in cases of persistent non-compliance, the parties failed to reach a consensus and left the issue for future COP/MOPs to decide. Only the EU pushed hard for possible punitive measures for repeated non-compliance. It remained somewhat unclear throughout the discussions *whose* non-compliance the EU was most worried about: was it exporting-country non-compliance, as might be intuitively assumed, or was it rather the spectre that exporting countries would trade in LMOs with non-compliant importing countries, most likely developing countries which are parties to the protocol? In either case, the option of punitive sanctions is seen by some as particularly key for the biosafety protocol, because the protocol does not prohibit trade with non-parties, unlike the Montreal Protocol on ozone depletion and the Basel Convention on trade in hazardous waste. Indeed, instead of prohibiting trade with non-parties, the protocol permits bilateral agreements between parties and non-parties, although it requires that such trade be consistent with the objectives of the protocol. In this context, a strong compliance mechanism (with the possibility of trade restrictions as a punitive measure) acquires much greater importance.

Challenges and opportunities ahead

Now that the Compliance Committee has been established and will probably meet for the first time in March 2005, what are the challenges it faces? Two key issues that may affect its functioning and effectiveness are: (a) how the incentives to bring a case before the Compliance Committee will develop, which will influence how busy or idle it will be; and (b) how the committee's recommendations will be financed.

Regarding the first issue, it is interesting to speculate on whether the Compliance Committee will be flooded with cases or have very few brought before it. The Basel Convention Compliance Committee has not had a single case submitted to date; in contrast, the Compliance Committee of the Aarhus Convention[6] has received numerous cases, partly because civil society groups are able to trigger the compliance procedure. Either scenario poses its own challenges, with consequences for effective compliance with the protocol. How busy the Compliance Committee might be is at least partly linked to the controversial issue of punitive sanctions, which as noted above remains to be decided. If compliance remains purely facilitative and cooperative, this may provide an incentive for greater numbers of self-trigger cases, by countries that lack the capacity to implement the protocol. Self-triggering in such cases would provide developing countries, in particular, with another means to seek to enhance their capacity to implement the protocol. Although this is, in itself, not necessarily a negative development for the protocol or the Compliance Committee, the underlying problem of inadequate capacity will need to be addressed through capacity-building (see discussion below).

This leads directly to the second key issue: the question of who will shoulder the burden for financing committee recommendations, especially in cases of self-trigger. As stated in the final decision, the Compliance Committee can recommend provision of technical assistance or measures such as 'drawing up a compliance plan'. Such recommendations are likely to be costly to implement. Who will foot the bill? Since there has been no specific talk to date of a voluntary fund, contributions will have to come from the Global Environment Facility (GEF) as the protocol's financial mechanism or from contributions made by parties to the protocol. Yet most current parties are developing countries, with the exception of the EU and some OECD countries.

This potential challenge to effective functioning of the compliance mechanism is also a more general challenge facing implementation of the protocol. Currently, there is at least a three-tier stratification of countries seeking to influence the evolution and implementation of the protocol. These include (a) parties to the protocol; (b) countries that have signed but not yet ratified the protocol; and (c) countries that have neither signed nor ratified the protocol (and the Convention on Biological Diversity in the case of the United States). This results in a situation where, although rules are developed through negotiation and compromise with all of the above groups, the burden of implementation and particularly of financing falls on parties. Brazil, in particular, as one of the largest current contributors to the protocol budget, has voiced this concern. This dynamic may affect the future evolution of the protocol.

Capacity-building and liability rules

The need for capacity-building in developing countries was widely recognized in the biosafety negotiations and remained uncontroversial during the preparations for COP/MOP-1. The Cartagena Protocol itself provides

only a loose framework for international capacity-building efforts. Article 22 merely stipulates that 'Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety' and refers to 'existing global, regional, subregional and national institutions and organizations' as well as private-sector involvement as vehicles for capacity-building.

The challenge for the parties is now to establish greater coherence among the flurry of capacity-building activities that have been started over the last few years. International organizations such as the GEF, UN agencies, bilateral donor agencies, regional networks, NGOs and industry groups have all offered their support to developing countries in building technical, scientific and regulatory capacity, causing concern about potential duplication and even competition between these initiatives.

The three ICCP meetings between 2000 and 2002 made good progress on developing interim guidelines for internationally coordinated capacity-building in biosafety. Based on the ICCP's recommendations, COP/MOP-1 adopted interim guidelines on a Roster of Experts, decided on an action plan and agreed to a coordination mechanism, the functions of which will be discharged by the protocol secretariat. The only time discussion on capacity-building became heated in Kuala Lumpur was when the group of African countries questioned the involvement of the private sector, arguing that industry ought to be seen as part of the problem, not part of the solution.

What remains unclear, however, is the effect capacity-building is going to have on the ground in developing countries. Critics have argued that capacity-building programmes have been slow in significantly improving developing countries' ability to carry out comprehensive risk assessment and management. Part of the problem is the sheer scale of the capacity gap that needs to be filled. Much of the capacity to carry out field trials and monitor releases of GMOs into the environment has to be created at the local and regional level. In large countries such as China and India, this means that a vast number of scientific and regulatory experts need to be trained and funded – a task to which international assistance can make only a small contribution. For example, Chinese environmentalists point out that while the country has a national GMO approval system in place, its ability to monitor the long-term effects of GMO releases is severely limited. While China is a leading developing country in the development, testing and commercialization of GM crops, most of its provincial governments employ only one expert in charge of biosafety monitoring. It is unlikely, therefore, that existing international capacity-building programmes can fill the gap in this area.

The need for greater financial support is likely to grow even further as more countries ratify the protocol and new capacity-building needs are identified. Building up biosafety capacity requires training in a wide range of areas and professions, including scientists, lawyers, administrators, policy-makers, customs authorities and enforcement agencies. Moreover, future COP/MOP decisions may also increase the demand for capacity-building: a future liability regime would require additional capacity-related activities, and should the Compliance Committee recommend action plans in cases where non-compliant parties have 'self-triggered' the compliance procedure, the question of funding such plans would arise, as discussed above.

At the moment, no decision has been taken on how such new capacity-building needs will be met. A voluntary fund has been mooted but no specific proposals or commitments by donor countries have been made. Should the Global Environment Facility not fill the gap, the default option may be greater reliance on bilateral or private-sector initiatives in the future, with the risk that these will focus selectively on countries which are key markets for GM products, leaving capacity needs elsewhere unmet. The situation is complicated by the fact that developing countries are in a relatively weak bargaining position over financial contributions, having been the main *demandeurs* in the biosafety negotiations. This contrasts with the Montreal Protocol, where the large donor countries had an interest in financing implementation of the phase-out schedule for ozone-depleting substances in the developing world and provided generous financial contributions through the Multilateral Ozone Fund.[7] In the protocol, the financial outlook is further complicated by the fact that developing countries not yet party to it (such as Argentina or Chile) are also demanding a share of available resources from the protocol's financial mechanism to help them prepare for possible ratification of the protocol.

Towards a liability regime?

A key demand by developing countries in the biosafety negotiations was the creation of a system for liability and redress in the event of harm caused by a LMO. Developing countries wanted to ensure that clear rules existed on who can claim compensation from whom and for what types of damage traded LMOs may cause to the environment, human health and socio-economic interests. The demand was rejected by the developed nations, and Article 27 of the Cartagena Protocol instead declared that COP/MOP-1 should 'adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress', which is to be completed within four years. The scene was therefore set for a straightforward decision by COP/MOP-1 to decide on the procedural rules to launch a process for elaborating a liability regime. The Kuala Lumpur meeting agreed terms of reference for an open-ended ad hoc working group of legal and technical experts on liability and redress that is to present its final report on proposed international rules and procedures by 2007.

However, the discussion in Kuala Lumpur revealed once again the gulf that persists between proponents and opponents of a liability regime. Countries

representing biotechnology industry or exporter interests expressed concerns about, *inter alia*, the ability to define incidents of damage caused by GMOs, and to establish who is legally responsible for paying compensation; the threat of co-mingling and adventitious presence of GMOs in commodity shipments, which might give rise to liability claims; and how responsibility is to be allocated among the wide range of actors involved in international GM trade, including export and import authorities, biotechnology firms, commodity traders, seed companies and farmers.

This wide gulf on questions of liability was evident in the views submitted by parties and major stakeholders in response to a questionnaire, which is intended to prepare the ground for the first meeting of the technical group of experts on liability and redress.[8] At this stage, no consensus is in sight on either the need to create a liability regime or the contours and concepts of such a legal instrument. With a deadline of 2007 for finishing its work, the liability working group is unlikely to enter into any serious negotiations very soon. This can, of course, change with market imperatives and biotechnology product developments. The *Starlink* controversy in the US, which resulted from the discovery of unauthorized GM corn in food products, made liability concerns relating to lost export markets a reality that has to be considered now by all parties involved in GM research and production. Observers point to another potential future hotbed of liability concerns and claims relating to GM crops: the increasing use of food crops to manufacture pharmaceutical products. The floodgates of liability claims will open if such products inadvertently enter the food chain. Given the enormous resistance of many to liability discussions within the protocol, it appears unlikely that the biosafety treaty will go further and faster than the market dictates. Nevertheless the global discussion now has a clear institutional home, which is a substantial step forward.

Conclusions

In the face of continued controversy over GMO regulation and international trade, the first Meeting of the Parties to the Cartagena Protocol was a significant step forward. The fact that most GMO-exporting nations, including the United States, Canada and Argentina, have yet to ratify the agreement gave the existing parties an opportunity to press ahead with their implementation agenda. Whether the Cartagena Protocol can provide a comprehensive system of biosafety governance remains to be seen. Future Meetings of the Parties will have to add more components to the treaty, many of which remain controversial. But in taking further decisions over the next few years, the parties will have to balance the desire to strengthen the protocol with the need to encourage ratification by some of the world's largest agricultural trading nations.

Encouraging wider participation, particularly by the GMO-exporting nations, is in the interest of all parties: it would strengthen the legitimacy of the biosafety protocol and reduce the likelihood of conflicts between parties and non-parties over the application of the protocol's rules. Moreover, it would enlarge the pool of potential donor countries to help with the costs of treaty implementation and thus limit the demands that are likely to be made on wealthier parties from the South, such as Brazil.

But wider participation comes at a price. The biosafety negotiations nearly failed in 2000 because of the wide gap between GMO-exporter and -importer positions. This gap is still clearly visible today. With parties such as Brazil and Mexico moving closer to some of the positions of the Miami Group of GMO-exporting countries – there has even been talk of the emergence of a 'Miami Plus' group – the COP/MOP process has to contend with all the old tensions as well as new and shifting alliances. Greater diversity of interests among developing countries and future ratification by members of the ex-Miami Group will make decision-making on the outstanding issues more difficult. The next two meetings of the parties in 2005 and 2006, therefore, will prove to be of critical importance to the future of the Cartagena Protocol.

Endnotes

[1] For a thorough analysis of the protocol, and the negotiations that led up to it, see Christoph Bail, Robert Falkner and Helen Marquard (eds), *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development?* (London: RIIA/Earthscan, 2002) and Aarti Gupta, 'Governing Trade in Genetically Modified Organisms: The Cartagena Protocol on Biosafety', *Environment,* vol. 42, no. 4 (May 2000) pp. 23–33. A detailed commentary on the protocol's provisions is provided in Ruth Mackenzie, Francoise Burhenne-Guilmin et al., *An Explanatory Guide to the Cartagena Protocol on Biosafety* (Gland, Switzerland: IUCN, 2003).

[2] On the international trade conflict over GMOs, see Robert Falkner, 'Trading Food: The Politics of Genetically Modified Organisms', in Brian Hocking and Steve McGuire (eds), *Trade Politics* (London: Routledge, 2nd edition, 2004), pp. 249–60, and Duncan Brack, Robert Falkner, and Judith Goll. *The Next Trade War? GM Products, the Cartagena Protocol and the WTO*, Briefing Paper No. 8 (London: RIIA, 2003).

[3] The protocol speaks of LMOs instead of the more commonly used terms 'genetically modified organisms' or 'transgenic organisms', which are often used interchangeably. This paper uses the term LMOs when discussing specific protocol provisions and the terms GMOs or GM in more general discussions.

[4] See Aarti Gupta, 'Advance Informed Agreement: A Shared Basis for Governing Trade in Genetically Modified Organisms?', *Indiana*

Journal of Global Legal Studies, vol. 9, no. 1 (2001), pp. 265–81.

[5] Unless stated otherwise, articles referred to in this paper are from the Cartagena Protocol.

[6] UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters.

[7] Robert Falkner, 'The Multilateral Ozone Fund of the Montreal Protocol', *Global Environmental Change,* vol. 8, no. 2 (1998), pp. 171–5.

[8] UNEP/CBD/BS/TEG-L&R/1/INF/1, 20 September 2004.

Further reading

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Mackenzie, Ruth, Françoise Burhenne-Guilmin et al., *An Explanatory Guide to the Cartagena Protocol on Biosafety* (Gland, Switzerland: IUCN, 2003).

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