



Institutions for Global Environmental Change

International environmental regimes are always suffused with politics. In the case of the *Biosafety Protocol to the 1992 Biodiversity Convention*, admirably reviewed by Peter Newell and Ruth Mackenzie in the text that follows, the politics of biotechnology rose quickly to the surface. The issues facing the negotiators were immensely complex. They traversed matters of trade, environmental protection, the science, autonomy of development, and how to manage convoluted alliances of national states and their NGO allies and antagonists. This resulted in a vast array of drafts and counter-drafts that must have involved veritable armies of lawyers, plus countless negotiators and activists.

This is the inner arena of modern environmental regimes. Such are the many diplomatic trip wires and

concessionary deals, the outsider marvels that anything is achieved at all from modern environmental diplomacy. Yet a protocol did emerge, more sensitive to the environmental impacts of the trade in genetically modified organisms, precautionary science, and importing country autonomy than could reasonably have been expected at the outset. Of course, the big powers and the corporate lobbies will try to get their way, but the politics of biosafety have undoubtedly taken on a new dimension with the signing of the protocol.

Tim O'Riordan and Andrew Jordan
*CSERGE, University of East Anglia,
Norwich Norfolk NR4 7TJ, UK
Email address: t.oriordan@uea.ac.uk*

0959-3780/\$-see front matter © 2000 Elsevier Science Ltd.

PII: S 0 9 5 9 - 3 7 8 0 (0 0) 0 0 0 4 8 - 0

The 2000 Cartagena protocol on biosafety: legal and political dimensions

Peter Newell^{a,*}, Ruth Mackenzie^b

^a*The Institute of Development Studies, University of Sussex, Brighton BN1 9RE, UK*

^b*FIELD, 46-47 Russell Square, London WC1B 4JP, UK*

1. Introduction

The Cartagena Protocol on Biosafety was agreed on January 29th 2000 in Montreal. It has the potential to break new ground in a number of areas, most especially in the way it addresses the relationship between trade rules and multilateral environmental agreements and in

its incorporation of the precautionary principle. The key element of the Protocol is a prior notification and consent procedure for the export and import of genetically modified organisms (called 'living modified organisms' (LMOs) in the Protocol), known as advance informed agreement (or AIA). However, over the course of the negotiations solutions had to be found to profound disagreements between countries as to the details of this procedure, its proper scope, and many other related issues.

The deadline for finalizing the Protocol was originally set for the end of 1998. However, when negotiations broke down in Cartagena in February 1999, the future of the Protocol seemed in doubt. A series of informal

* Corresponding author.

E-mail addresses: p.newell@ids.ac.uk (P. Newell), rm9@soas.ac.uk (R. Mackenzie).

consultations led to the resumption of formal negotiations in Montreal in January, but even in the weeks leading up to this meeting many delegations seemed pessimistic about the prospects of achieving consensus on the Protocol. However, pressure on delegates to produce an accord in Montreal was heightened by the rising tide of public concern about LMOs in Europe, Japan and increasingly also Canada and the USA. If extra impetus were needed it came in the form of the 'Seattle-debacle' fuelled by civil society concerns that trade objectives may be allowed to override social and environmental objectives. Negotiations in Montreal focused on the three core issues that had proved most contentious in Cartagena: the scope of the Protocol; the relationship between the Protocol and international trade rules, including the role of the precautionary principle in decision-making; and the treatment of genetically modified (GM) commodities. Space constraints allow us only to highlight here some of the key issues at the heart of the negotiations, the divisions between the negotiators of the agreement and the outcome of their deliberations in the form of the Cartagena Protocol.

2. Background: the road to Montreal

Biosafety rose up the international agenda in the early 1990s within the context of the Convention on Biological Diversity (CBD) and the Rio UN Conference on Environment and Development. The inclusion of biosafety provisions in the CBD was controversial. Article 19(3) of the CBD called on Parties to 'consider the need for and modalities of a Protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity'. As this language suggests, there were differences among countries even at this stage as to whether or not a Protocol was needed and, if so, what its scope should be. Nonetheless, in 1995 the Conference of the Parties to the CBD decided to initiate negotiations on a Protocol on the safe transfer, handling and use of LMOs, focusing on the transboundary movement of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biodiversity.

The coalitions of interest in the Protocol negotiations represented a diverse range of opinion on a number of key issues, but coalesced in Cartagena into five negotiating groups. At the one end of the spectrum, the Miami Group, a coalition of agricultural commodity-exporting countries (including USA, Canada, Australia, Chile, Argentina and Uruguay) argued that the Protocol should protect free trade in products of modern biotechnology. Core concerns of this Group were that the Protocol

should be consistent with WTO rules and based on 'sound science', and that the scope of regulation should be limited to certain categories of LMOs which could properly be judged to pose potential risks to biological diversity. The Miami Group resisted the adoption of lengthy approval procedures, and argued against the incorporation of the precautionary principle and socio-economic considerations into decision-making on LMO imports on the grounds that this would be open to protectionist abuse.

By contrast, the 'Like-Minded Group' of developing countries put forward proposals to give importing countries extensive rights to refuse GM imports, including all products derived from LMOs. Their overriding concern was to protect those countries without the adequate regulatory or institutional capacity to handle LMO imports. In the light of ongoing scientific uncertainty over potential long-term effects, and the lack of risk assessment and risk management capacity in developing countries, they demanded the inclusion of the precautionary principle to guide decision-making on imports of LMOs, the right to take into account potential socio-economic impacts of LMOs, and effective liability and redress mechanisms (to provide compensation for any damage caused by LMOs). In addition, they sought commitments from developed countries on financial assistance and capacity building.

The EU position emerged broadly between these polarised positions, under increasing pressure from environmental and consumer groups. Central components of the EU's position were the inclusion of the precautionary principle, support for clear identification and labeling requirements for shipments of LMOs, and the need to reflect potential risks to human health in the Protocol. With an eye on the potential for a dispute in the WTO over regulatory processes for LMOs, the EU strenuously opposed the inclusion of a 'savings clause', promoted by the Miami Group, which would have expressly subordinated the Protocol to WTO rules. The EU and Miami Group were also both keen to see their own distinct regulatory approaches to biosafety reflected in any international obligations attaching to transboundary movements of LMOs.

A Compromise Group also emerged at Cartagena (consisting of Japan, Mexico, Norway, Singapore, South Korea, Switzerland, and in the final stages, New Zealand). Its objective was to be to bridge gaps between the other negotiating blocs by elaborating compromise stances. In this respect, the role of the Compromise Group was to prove critical in the final discussions in Montreal. The fifth negotiating bloc was formed of the countries of Central and Eastern Europe. These five groups were flanked by the Biotechnology Industry Organisation on the one hand, representing agricultural, food and pharmaceutical companies promoting the goals of the Miami group on trade, and an international coalition of

consumer and green groups on the other, supporting the Like-Minded Group and maintaining pressure on the EU.

Disagreement between the various groups ran to such fundamental issues as which organisms and products should be regulated under the Protocol, and what sorts of impacts should be taken into account. There was disagreement over what constituted living modified organisms, the risks associated with them in different socio-economic, ecological and cultural contexts, as well as the appropriate methods by which to evaluate the risks. As noted above, a core element of the debate was whether to include all LMOs, as well as products derived from LMOs, under the Protocol, or to limit the scope to certain categories of LMOs. In particular, the Miami Group was concerned that including all GM commodity exports (called 'living modified organisms intended for direct use for food, feed or for processing' or 'LMO-FFPs') within the purview of the Protocol would negatively impact on the huge volumes of internationally traded genetically modified commodities. Agricultural producers argued that the result would be to render international trade in these agricultural commodities unworkable: segregation costs would be too high, and foodstuffs could perish while awaiting import approval. The Miami Group and the biotechnology industry argued, in addition, that since GM commodities were not intended to be released into the environment, they would not have impacts on the conservation and sustainable use of biological diversity and thus were not properly within the scope of the Protocol. Against this position, the Like-Minded Group reminded negotiators that, in practice, grains or other LMOs intended for processing could feasibly be released into the environment either unintentionally, for example through spillage, or intentionally where quantities of grain were deliberately sown for growing. Thus, they argued, given the objective of protecting biological diversity there was no rational basis for distinguishing between GM seeds or microorganisms and GM agricultural commodities. Following extensive debate in Cartagena, it was agreed during inter-sessional informal consultations that LMO-FFPs would fall under the Protocol's scope, but disagreement continued over whether or how they should be subjected to the AIA procedure.

Risk assessment is the central component of the AIA procedure. While various views were expressed on a number of aspects of the risk assessment provisions of the Protocol, the critical disagreement focused on the proper place of the precautionary principle in relation to risk assessment. In this debate, the Miami Group insisted that risk assessments and decision-making on imports of LMOs should be based on 'sound science' and should conform to WTO requirements. These include those under the Agreement on Sanitary and Phytosanitary Measures which require that measures which restrict

trade on sanitary or phytosanitary grounds must be based on risk assessment and sufficient scientific evidence. In addition, the Miami Group insisted that the precautionary principle need not be expressly written into the operative provisions of the Protocol, since, as no *actual* threats to biodiversity or human health from LMOs had been proved, the Protocol was *in itself* a precautionary instrument. In this context, it was willing to accept references to the precautionary approach, based on Principle 15 of the 1992 Rio Declaration, in the Preamble and Objective of the Protocol. By contrast, while agreeing to the need for risk assessment, the Like-Minded Group and the EU argued that it was precisely the lack of scientific certainty and consensus around possible impacts of LMOs which necessitated the inclusion of the precautionary principle in the operative provisions of the Protocol on AIA. In addition, the fact that a particular LMO may have different effects in different ecosystems had to be taken into account.

The question of liability and redress for any damage caused by LMOs was also, and remains, a contentious issue. For the Like-Minded Group, clear and effective liability rules were crucial. Various proposals were made during the course of the negotiations, but as the deadline for conclusion of the Protocol neared it became clear that there would not be time to develop provisions on liability, even if all Parties to the negotiations had agreed that this should be done. Eventually in Cartagena an enabling clause was agreed which charges the governing body of the Protocol at its first meeting after entry into force to set in motion a process to consider liability and redress rules, with a view to completing this work within four years.

3. The Protocol

The final agreement reached in Montreal reflects a remarkable compromise, and in many respects an improvement on what was on the table at the end of the Cartagena session. On the relationship between the Protocol and international trade rules, the savings clause option was omitted. Instead, the Protocol addresses its relationship with other international agreements, including the WTO, in three separate paragraphs of the preamble. Taken separately, each paragraph could be taken to support each of the various positions promoted during the negotiation. Taken together, the language leaves the relationship unclear, but seems to suggest that trade agreements and the Protocol should be interpreted in a consistent way. The precise implications of this formulation will only become clear if disputes actually arise as to the application of the Protocol by Parties in relation to particular proposed imports of LMOs. In most respects, the Protocol does appear to be broadly consistent on its terms with the requirements of relevant WTO

law, in that for example, it requires decisions to be based on prior risk assessment carried out in a scientifically sound manner.

In terms of scope, the Protocol, meets one of the demands of the Like-Minded Group that it should be comprehensive: *prima facie* all LMOs which may have adverse effects on biodiversity, taking into account risks to human health, are covered by the Protocol. However, in subsequent Articles, certain categories of LMOs are either excluded from its provisions entirely (e.g. LMOs that are pharmaceutical for humans), or are exempted from the application of the Advance Informed Agreement procedure. The latter group include LMOs in transit, LMOs destined for contained use in the country of import, LMO-FFPs, and LMOs which may in the future be identified in a decision of the meeting of the Parties as not having adverse effects. As this list of exclusions indicates, the actual coverage of the AIA procedures is rather less far-reaching than developing countries and environmental groups would have wished. However, it is important to note that while these categories of LMOs are excluded from the Protocol's *specific* AIA procedure, this does not imply that countries may not regulate their import. Indeed this right of countries of import is recognised in various provisions of the agreement.

For LMO-FFPs a specific procedure is set out in Article 11 of the Protocol, establishing essentially a multilateral information exchange mechanism. Rather than setting out detailed notification and consent procedures here, the Protocol requires Parties to notify domestic authorisations of LMO-FFPs through the Biosafety Clearing House, and also requires Parties to make copies of relevant national laws and regulations available through the Clearing House. It provides that a Party may make decisions on imports of LMO-FFPs through their domestic regulatory frameworks (which must be consistent with the Protocol's objectives), or, if it is a developing country or economy in transition without a domestic regulatory framework, in accordance with a risk assessment and within a specified time period. The operation of the Biosafety Clearing House will be crucial to the effectiveness of the Protocol's provisions on LMO-FFPs. Parties will consider the modalities of operation of the Clearing House at their first meeting after entry into force.

Significantly, the Protocol reserves the right of Parties to take decisions on imports on the basis of the precautionary principle in relation to both LMOs to be introduced into the environment and LMO-FFPs. It states that lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects of an LMO shall not prevent a Party of import from taking a decision with regard to the import of that LMO in order to avoid or minimise such potential adverse effects. Socio-economic considerations arising from the impact of LMOs on

biodiversity may also be taken into account in import decisions.

Another important compromise in the final text was reached in relation to appropriate documentation and identification of shipments of LMOs. This provision, which had been relatively overlooked, ultimately proved to be the final sticking point in the negotiations, causing a delay of several hours in the final approval of the text in Montreal. The key issue here was whether shipments of GM commodities should be specifically identified as LMOs. Clear and specific identification of shipments is a key element for traceability and for the feasibility of domestic labeling regimes. However, the Miami Group exacted a compromise which, for the time being at least, will allow such shipments to simply be accompanied by documentation identifying that they 'may contain' LMOs, allowing the current practice of (*co-mingling?*) of GM and non-GM grains to continue. Detailed requirements on documentation will be revisited by the meeting of the Parties within two years of entry into force of the Protocol.

Another potentially critical element of the Protocol is an enabling provision which requires the first meeting of the Parties to consider and approve compliance procedures and mechanisms for the Protocol. While in other international environmental regimes to date, compliance mechanisms have tended to be rather "soft", and the Protocol itself refers to "co-operative procedures and institutional mechanisms", one might expect arguments in favour of a rather harder approach in the context of the Biosafety Protocol, in the light of concerns that have been voiced over the potential for exclusive WTO jurisdiction over biosafety disputes, and the lack of any other mandatory binding dispute settlement provisions in the Protocol itself.

4. Beyond Montreal

Success is a relative term. The Protocol goes further than the Miami Group would have liked and does not go far enough in meeting the concerns of many developing countries and environmentalists about adequate safeguards and mechanisms for compensation. Given the disagreements over the issues the Protocol should address and the divergence of views over the risks associated with modern biotechnology, it is perhaps remarkable that the Montreal meeting produced a Protocol at all. The negotiators were clearly under pressure to conclude an agreement. Nevertheless, as indicated above, a number of key decisions and controversies have been postponed.

The emergence of the Protocol undoubtedly owes a great deal to the huge increase in public awareness and concern over LMOs which occurred between the first formal negotiating session in Aarhus in 1996, and the

Cartagena and Montreal meetings. In addition, in the final stages of the negotiations, a combination of effective leadership by the Chair and innovative approaches to consultation and negotiation were instrumental in bringing about an agreement. It is also noteworthy that in the early stages of the negotiations, much of the impetus for the elaboration of the Protocol was provided by the African group, led by Ethiopia. Indeed, in 1996, the African group submitted a full text of a draft Biosafety Protocol giving a kick start to negotiations which had begun slowly, and prompting other textual proposals in response.

There will inevitably follow a period of alignment between existing biosafety regulations at the regional and national level and the Protocol during which countries will have to determine which measures are compatible with, or need to be revised in the light of, the Protocol. Although many countries have legislation on biosafety in place, few at present specifically address exports of LMOs. It is also unclear at this stage which forms and levels of technical and financial assistance will be made available to developing countries to adequately manage the risks associated with the trade in biotechnology, as well as, where they so wish, to safely develop their own biotechnology capacity.

Since the Protocol's adoption, much attention has focused on the degree to which it sets a new precedent with regard to the relationship between environmental protection and the international trade regime. This will undoubtedly continue to be the key area of interest as the Protocol is implemented and applied. However, while the preambular language of the Protocol refers to its "mutually supportive" relationship with other agreements, the other, apparently contradictory, preambular paragraphs addressing this issue only highlight the continuing disagreement between the negotiating groups. The

Protocol remains inconclusive on this vexed issue. In addition, while the Protocol clearly recognises that countries are entitled to take the precautionary principle into account in their decision-making procedures, it does not, as such, reconcile the circumstances in which the goal of environmental protection takes legitimate precedence over a country's obligations under international trade law. Thus, there clearly remains scope for conflict in the implementation of the Protocol, especially over the application of the precautionary principle to specific proposed imports. Where bilateral disputes arise, it is perhaps difficult not to assume that the interests of the more powerful exporters will prevail.

Early indications are that things may move quickly from here. Expectations appear high that, despite the onerous ratification threshold of 50, the Protocol may well enter into force in 2001 or 2002, potentially allowing in 2002 for the first meeting of the Parties, and the first key decisions in the Protocol's evolution. In the meantime, the Protocol opens for signature in Nairobi in May 2000, and an Intergovernmental Committee on the Cartagena Protocol, will meet for the first time at the end of 2000, to begin preparations for the first meeting of the Parties. As it evolves, the Protocol will necessarily interact, both at the international level and in the context of national implementation, with a range of other international and regional instruments and arrangements. These include not only the WTO regime, but also ongoing work within the Codex Alimentarius on foods derived from biotechnology, relevant FAO agreements such as the International Plant Protection Convention, and relevant work within regional and economic organisations, as well as proposals for considering biotechnology and biosafety within other fora such as the intergovernmental panel proposed at the recent OECD meeting in Edinburgh.