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The Biosafety Protocol is adopted in Montreal

by Françoise Burhenne-Guilmin*

The Cartagena Protocol on Biosafety was adopted on 29 January, in Montreal, by representatives of some 130 nations. The adoption is a memorable event, concluding seven years of efforts. This is the first Protocol under the Convention on Biological Diversity.

The breakthrough came at dawn, when hope of a successful conclusion had almost been given up. It took the whole night to arrive at the last compromise formula of this difficult negotiation – dealing with the treatment of "commodities" in the text.

The subject of biosafety was already on the agenda of the negotiators of the Convention, an instrument which aims to provide a comprehensive and holistic approach to all issues of relevance to biological diversity. The matter raised such controversy that it was not possible to deal with its substance in time for the adoption of the Convention before the Rio Summit, where it had to be open for signature. Instead, negotiators agreed to postpone consideration of binding rules regarding biosafety, and adopted Article 19.3 which obliged Parties to the Convention to consider at a later date the need for, and requirements 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".

The mandate was not lost sight of, and a Panel was set up by the Executive Director of UNEP in 1993. The first Conference of the Parties to the Convention (COP-1) met in Nassau, the Bahamas, from 28 November to 9 December, 1994) then proceeded to establish an Open-ended *Ad Hoc* Working Group of Experts on Biosafety. The second COP (Jakarta, Indonesia, in November 1995) discussed the consequences of the results of the experts' work, in particular the fact that a large majority of the participating delegations favoured the development of a Protocol: it decided to embark on a negotiation process to develop a protocol on biosafety "focusing on transboundary movements of any living modified organism (LMO) resulting from modern biotechnology", established an Open-ended *Ad Hoc* Working Group on Biosafety (BSWG), and provided it with detailed terms of references (Decision II/5).

After four meetings of the Group, which took place between July 1996 and February 1998, it had become clear that the goal set by the COP of completing BSWG before the end of 1998 was unrealistic. The deadline was extended until early 1999, and an Extraordinary COP convened for February 1999 in Cartagena, Colombia in order to adopt the Protocol. At the end of 1998, a set of 40 articles had been prepared, but 13 of these remained "entirely square-bracketed", indicating lack of agreement on their content. The scope of the Protocol, for example, whether products of LMOs would be covered, remained controversial, as did a series of other points, including liability provisions, and those related to the precautionary approach. Altogether, the staggering number of over 600 square brackets adorned the text!

The sixth and last meeting of the BSWG met in Cartagena immediately preceding the Extraordinary session of the COP. In spite of the efforts by delegations, as well as the Chairman of the BSWG Veit Koester (Denmark), and the President of the ExCop Juan Mayr (Colombia), the negotiations failed, and the ExCOP session was suspended. A decision gave the Bureau of COP 4, together with ExCOP Chair Mayr, the mandate to convene a resumed session if and when possible.

The shock caused by this was profound, and the *nature*, more than the *number*, of the unresolved issues was so deeply divisive that discouragement prevailed at first. Progress at Cartagena, had, however, not been negligible. Many articles had been approved provisionally; negotiating groups with specific positions had emerged. Most importantly, the very reason for which negotiations were started – to define rules for the transboundary movement of LMOs intended for introduction into the environment – had found acceptable solutions. There were four unresolved "core issues": first, the scope of the Protocol (beyond LMOs intended for introduction into the environment); second, the treatment of "commodities", a term used to describe LMOs intended for use as food, feed or for processing (LMO/FFPs); third, the precautionary approach or principle, and fourth, the relationship between the protocol and existing trade-related agreements.

Armed with these sizeable accomplishments, and a communicative energy and optimism, Chairman Mayr embarked on a series of informal consultations, first with the spokespersons of the negotiating groups which had formed in Cartagena (Montreal, July 1999); based on the expression of political will to conclude the negotiations. Mayr proceeded to convene a fully-fledged informal meeting in Vienna (September 1999), organised to allow for the exchange of views within and between groups. During the final two days, spokespersons for each group sat at a round table to address the remaining four core issues in terms of concepts rather than attempting to draft precise language. The format of the meeting became the "Vienna setting", which was used again during the third and final informal consultations, which took place in Montreal immediately before the meeting of the resumed Extraordinary COP and also during the ExCOP.

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While progress on conceptual common concerns was achieved in Vienna, it was clear that the real confrontation would take place once specific language hit the table. This is what the Montreal consultations set out to produce over the four days available to the Groups. A "non-paper" from Chairman Mayr, suggesting textual elements based on the results of the Vienna consultations, facilitated the process. Each of the Groups (Miami Group,[1] Like-minded Group,[2] EU, Central and Eastern European Group, and Compromise Group[3]) responded to the Chair draft, and agreed to his proposal to proceed with the discussion of clusters of issues: scope, commodities, relationships with other agreements, and precautionary approach.

Scope and commodities were tackled first, and encouraging progress was made in group negotiations behind closed doors, with periodic reports to shorter and shorter informal plenary sessions. Only shortly before the beginning of the ExCOP were the third and fourth clusters open for discussion – a consequence of their intense political nature.

On the eve of the ExCOP opening, the fate of the Protocol was still very uncertain – significant progress had been made but no final agreement reached, on two core issues; uncertainties still surrounded the "relationship" cluster, as well the treatment of the precautionary approach.

As a result, the formal negotiations during the ExCOP continued in virtually the same format as the informal ones, the only difference being that by mid-term the political climate became unbearable: over 30 ministers responsible for biosafety were in Montreal, and while there was no time to hear any formal statement they might have wished to make, the pressure of their presence and the active role they took in the behind-the-scenes talks became an important and politically decisive factor: a compromise on the remaining issues had to be found; a second Cartagena was not an option. Nevertheless, this nearly happened: while the rumours of a positive outcome on the question of relationships with WTO-related agreements and the precautionary approach led to optimistic prognosis about the end result, the final plenary session convened for 28 January in the late afternoon to adopt the Protocol was postponed from hour to hour. Just before midnight, it was clear that a final confrontation was taking place. Not about the relationship between the protocol and trade-related agreements, or scope... but still on the precautionary approach and also the requirement to identify commodities as containing or not containing LMOs.

The question of "segregation", "identification" and "documentation" accompanying commodities containing LMOs was a heated issue right from the start. It caught up with the negotiators as the last bastion defended by the Miami Group to agree on the otherwise acceptable negotiation package. The Miami Group had consistently argued that it was virtually impossible to ensure segregation and labelling, while the EU considered it a prerequisite to consumers' right to know. In the end, a compromise was agreed between the two groups, that commodities should be labelled as "may contain LMOs", a formula which leaves open the option to provide more information on whether the commodity contains LMOs or not. The compromise was apparently agreed upon by the other groups, including the Like-Minded Group, which hastily convened on the floor of the main room at 4 am to 'take it or break it', and agreed to consent. The Plenary was reconvened at 4.40 am, and adopted the Protocol at 4.50 by consensus. It was a breathtaking moment – and a near escape!

The Protocol was immediately hailed as a success, auguring well for the environment and sustainable development in the new millennium. It has been hailed as a success since then, from all quarters, including the environmental community, industry and negotiators themselves.

Is this enthusiasm justified? The question must be answered to a large extent in the positive, while some aspects provide justifiable cause for anxiety.

The scope of the Protocol is broad, a goal consistently pursued by the Like-Minded Group; it applies to the transboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity. Two exceptions are mentioned in separate articles (pharmaceuticals for humans which are dealt with in other international agreements; and LMOs for transit and contained use). They are both limited in extent: in the case of pharmaceuticals, Parties remain free to subject import to risk assessment if they so wish, and in the case of transit and contained use, it is not the protocol in its entirety which does not apply, only the Advance Informed Agreement (AIA) procedure.

The most difficult question on scope had been whether LMOs intended for direct use as food, feed or for processing (LMO/FFPs) should be covered or not. These include commodities such as tomatoes and corn. Some, in particular the members of the Miami Group, argued that they should be excluded, as they pose no threat to biological diversity. Many others, in particular the Like-Minded Group, argued that once these products were in circulation, it would be impossible to ensure that they were not introduced into the environment, accidentally or not. At the end of Cartagena, the principle of the inclusion of LMO/FFPs within the scope of the Protocol was established. The question then became to what extent they would be submitted to the same rules as those LMOs intended for introduction into the environment. Here, of course, large industrial interests were at stake.

The question is linked to the cornerstone of the Protocol, namely the application of the Advance Informed Agreement (AIA). The AIA procedure provides for the Party of export to notify the Party of import before the first import of an LMO for which the procedure is mandatory. The importing party has 90 days to indicate whether the import may proceed with or without written consent. If written consent is required, the party of import has 270 days from the date of receipt of the notification to indicate whether the import is approved with or without conditions, or refused, or the decision delayed for a specific period of time, or whether additional information is requested, in accordance with the Party of import national

[1] Argentina, Australia, Canada, Chile, the US, Uruguay.
[2] The majority of developing countries.
[3] Japan, Mexico, Norway, South Korea, Switzerland and Singapore.

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legislation or the protocol itself (in particular risk assessment according to Annex II). The lack of a decision within the 270 day period does not imply consent. In addition, lack of scientific certainty does not prevent the Party of import from taking a decision.

The AIA clearly applies to the transboundary movement of LMOs for intentional introduction into the environment of the Party of import. However, it can be derived from various articles in the Protocol that it does not apply to pharmaceuticals for humans, LMOs in transit or intended for contained use, or LMOs which have been identified by a decision of the meeting of Parties to the Protocol as not likely to have adverse effects on biological diversity, taking into account risks to human health. It also does not apply to the transboundary movement of LMOs/FFPs for which a significantly less demanding procedure is provided.

It has been pointed out that, as a result, the AIA applies only to a limited number of LMOs, such as seeds, which are exported with a view to being grown in the country of import.

Transboundary movements of LMO/FFPs – for instance, fruit and vegetables for direct consumption, or seeds for feed – are subject to another set of provisions.

Parties making final decisions regarding the domestic use of a LMO/FFP shall inform the other Parties through the Biosafety Clearing House Mechanism within 15 days. Importing Parties may take a decision according to their national legislation, which has to be consistent with the objective of the Protocol. Developing countries or countries in transition which do not have such regulatory framework may apply the procedure provided by the Protocol itself, *i.e.* require a risk assessment, followed by a decision within a timeframe not exceeding 270 days. Again here, failure to take a decision does not imply consent to import, and lack of scientific certainty does not prevent that Party from taking the decision it deems appropriate.

While this system remains based on the decision of the country of import, it does not require notification by the exporter, and thus is less burdensome for them. In order to function, however, it requires the identification of the LMO/FFPs through accompanying documentation. The system would otherwise be unenforceable.

The question of segregation between commodities containing LMOs and those which do not, as well as the documentation which should accompany them for transboundary movements, was a critical point from the start of the negotiations, and a major concern for the Miami Group. It was the last point to be agreed upon on 29 January, with a formula which postpones "detailed requirements" until a decision is taken on this subject by the meeting of the Parties to the Protocol, within a timeframe of two years. Until then, LMO/FFPs will have to be identified, at the minimum, as "may contain" LMOs, and as not intended for introduction into the environment.

Central to the philosophy of the Protocol is the precautionary approach; yet whether and how this should be reflected in the Protocol's text remained contentious until the very last round of negotiations, when referring to it in the Preamble as a "guiding policy principle" was acceptable to all. Mentioning it in the article on "Objective" passed the acceptability test with some difficulty, but most resistance was met by the proposed inclusion of precaution language as an accepted tool of decision-making for importing Parties of LMOs for introduction into the environment and, *a fortiori*, for LMO/FFPs. The supporters of this "operationalisation" of the precautionary approach (which included, prominently, the EU) prevailed: lack of scientific certainty shall not prevent importing Parties to take decisions, as appropriate, in both cases. This is a real breakthrough for all those who believe that precaution, distinct from prevention, has an important role to play at all levels of decision-making.

Last but not least, the relationship of the new Protocol with the WTO-related agreements was a very divisive subject. At the end of Cartagena, an article of the draft clearly declared the supremacy of trade rules over the Protocol, an objective of the Miami Group. In Vienna, the concept that both regimes should be mutually supportive and are of equal rank made its way to the negotiation table. In Montreal, the article was deleted, and replaced by a cluster of three clauses in the preamble, as follows:

"Recognising that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

"Emphasising that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,

"Understanding that the above recital is not intended to subordinate this Protocol to other international agreements".

The second clause, with an unusual "shall" in a preambular clause, is inspired by a similar clause in the preamble of the Rotterdam Convention on Prior Informed Consent (PIC), and thus is based on a precedent.

A typical compromise package, these statements, at first sight contradictory, probably embody the best achievable balance between the two regimes. Much will no doubt be said and written about these clauses in future. The final test would ultimately only take place should a dispute concerning the implementation of the Protocol be brought before a WTO dispute panel, for breach of WTO rules. This is a situation which naturally cannot be excluded, but which many consider extreme and undesirable – at least politically.

It would be more constructive and promising to put the emphasis on the first clause. Indeed, it may well be argued that the Protocol does not conflict with WTO-related rules but, rather, that it establishes international standards in a specific instance, or gives added specificity to trade rules. Such a course of thought and action would also reconcile States with themselves: after all, the States which have negotiated the Biosafety Protocol are the same as those who are Parties to the trade-related agreements!

If this were to happen, the Protocol could not only be hailed as a significant achievement in international environmental law, as well as another important step in the achievement of sustainable development, but it could also be hailed as an element in the progressive development of trade law. ❐

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