

Biosafety Protocol: Sweet 'N' Sour

Discussions linking trade and environment are becoming increasingly controversial, involving various international institutions, arrangements and agreements. The issue took a new turn at Montreal in the beginning of this new millennium. Around 140 Member States of the United Nations met at Montreal, Canada in January 2000 to decide the fate of "Biosafety Protocol" that had failed at Cartagena, Colombia due to opposition by major agriculture exporting countries dubbed as Miami Group. Finally after intense negotiations the Protocol was adopted.

The Cartagena Protocol on Biosafety is the first binding international agreement dealing with modern biotechnology. It has been adopted under the auspices of the Convention on Biological Diversity (CBD) and specifically focus on the transboundary movements of genetically modified organisms (called 'living modified organisms i.e. LMOs under the Protocol).

The credit for the success (as far as adoption of the Protocol is concerned) goes to civil society, which by enhancing public awareness helped in putting pressure on respective governments and relevant international institutions. Secondly, the credit also goes to the Southern unity that was persistent throughout the Protocol's negotiations. Thirdly, the success is also attributed to the Colombian Environment Minister, who showed tremendous strategic skills in the negotiation process. His strategy was crucial in the adoption of the Protocol.

The Protocol is an example of the increasing effect of civil society's influence on the international trade policymaking process. From Cartagena to Montreal the drive opposing unregulated use and trade of genetically modified organisms had snowballed manifolds, consequently putting more public pressure on the Miami Group governments. Finally, the Group succumbed to the pressure and had to soften their stand that they took a year back.

That said, this Briefing Paper, endeavouring to demystify the Biosafety Protocol, is divided into three sections. In its first section the paper focuses on the negotiation aspect of the Protocol. It highlights the stands of various country-groups adopted during the negotiations. Further in this section the paper comes out with the objective and the scope of the Protocol and identifies the source that provides mandate to negotiate the Protocol.

Section II of the Paper deals with some of the important provisions of the Protocol. It describes in detail the backbone of the Protocol i.e. Advance Informed Agreement. It shows how the scope of AIA has been kept narrow by distinguishing between LMOs for intentional introduction into environment and LMO-commodities and keeping LMO-products out of its scope. The paper then briefly touches upon 'risk assessment' and 'risk management' under the Protocol. In this section the paper finally explains the precautionary principle as prescribed under the Protocol.

Last section i.e. Section III of the paper throws light on the relationship between the Biosafety Protocol and the WTO agreements. In this section it highlights the areas and nature of conflict between the two regimes. The paper puts forward legal arguments that may come up in future to prove supremacy of the one set over the other. These issues have the potentiality to raise major international law controversies. The paper argues that it is too difficult to project any solution for the ambiguities at this stage and envisage that the same will depend largely upon the changing equations in the international trade politics and the intensity, and direction of civil society movement vis-à-vis the multilateral trading system, in general, and debate on various facets of GMOs, in particular.

Section I

Introduction

After almost five years of highly contentious negotiations, parties to the United Nations Convention on Biological Diversity (CBD) finally reached an agreement on Biosafety Protocol in January 2000 at Montreal, Canada. The protocol was adopted unanimously by more than 1,000 representatives from 138 countries.

This is the first international treaty explicitly addressing both environment and trade concerns since the inception of the World Trade Organisation. Also it is for the first time that an international framework has been set up to regulate genetically modified products. Certainly, it is an important milestone regarding environmental and health concerns vis-à-vis trade in goods.

Negotiations

The seed for the Protocol was sown at the Rio Earth Summit in 1992 when 175 governments signed the CBD and agreed to develop a Biosafety Protocol for safe handling, transfer and use of Living Modified Organisms (LMOs) (*see Box 1 and 2*). Thereafter in 1995-96, the negotiations began, when under the leadership of Tewolde Egziabher of Ethiopia, the developing countries (called the Like-Minded Group, i.e. LMG) proposed a comprehensive text to achieve a high level of regulation for trade in LMOs. In January 1999, the signatories to CBD convened at Cartagena, Columbia, to agree on the Protocol (hence it is called as Cartagena Biosafety Protocol).

The text, proposed as draft Protocol by the LMG, was eventually backed by the European Union, Central and East European countries and the “compromise group” (Switzerland, Japan, Norway, Mexico, Republic of Korea and New Zealand). Despite the momentum, the negotiations collapsed at Cartagena because of strong opposition by leading agriculture exporting nations,

Box 1: Living Modified Organisms

According to Article 3(g) of the Biosafety Protocol, living modified organism means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Where, living organism according to the Protocol means any biological entity capable of transferring or replicating genetic material, including *sterile organisms, viruses and viroids*.” (emphasis added).

And the ‘modern biotechnology is defined as the application of:

- In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- Fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in the traditional breeding and selection.

Box 2: The Mandate

The mandate to negotiate the Protocol is provided by Article 19.3 of the CBD, which says:

“The Parties shall 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.”

It obliges the Parties to set up a regulatory mechanism for safe trade in and use of LMOs, of which an ‘advance informed agreement’ would be the key instrument.

Furthermore, according to Article 8(g) of the CBD Parties are required to establish means to regulate the risks associated with the use and release of LMOs which are likely to have adverse environmental impacts that could effect biodiversity, *taking also into account the risk to human health*. Throughout the negotiations, the developed countries resisted the inclusion of “human health” and its inclusion was accepted only late in the process. However, the Protocol lacks seriousness vis-à-vis the risk to human health.

called Miami Group, which includes US, Canada, Argentina, Australia, Chile and Uruguay. Canada led the group, as the US is not a party to the CBD. However, US used the Canadian shoulder to fire the salvo that derailed the Cartagena negotiations.

The Miami Group further tried their level best to mitigate the increasing public demand for the regulation of genetically modified products by moving such issues to the WTO system via a Biotechnology Working Group, proposed by Canada at the time of Seattle ministerial conference of the WTO. Unfortunately for them the Seattle meeting failed and there was unprecedented pressure on the governments to demonstrate that trade considerations do not over-ride environment protection.

In particular, Canadian government was widely condemned at home and abroad. Public pressure on governments was further intensified in Montreal through public forums and demonstrations. Furthermore, throughout the negotiation process, northern and southern NGOs showed considerable unity and cooperation.

Finally, showing great strategic skills Juan Mayr Maldonado, Colombian environment minister, who chaired the session since 1999, had called for an informal session at Vienna before the Montreal meeting. He also chaired the final session at Montreal and showing the same skill, adopted a round table negotiating structure. His approach and

strategy proved successful in the end and the Biosafety Protocol was adopted. It is open for signature from 15th to 26th May 2000 at the United Nations office at Nairobi, Kenya and from 5th June 2000 to 4th June 2001 at the UN Headquarters at New York, USA. The Protocol will come into force 90 days after the ratification by the 50th country. In the first phase 68 countries signed the Protocol.

Objective and Scope

The Protocol is aimed at regulating transboundary movement of LMOs that could adversely affect biodiversity and human health. Precisely it aims to achieve this goal by setting up an Advanced Informed Agreement. The regulation would be in accordance with the precautionary approach and would specifically focus on transboundary movements of LMOs (Article 1).

According to Article 4 of the Protocol, it covers all LMOs that have adverse effect on biodiversity and human health. However, the LMO-pharmaceuticals for humans that are addressed by other relevant international agreements or organisations are not covered by the Protocol (Article 5). This means that LMO-pharmaceuticals for animals and for human that are not addressed by any agreement are within the purview of the Protocol.

Section II

Advance Informed Agreement

The Protocol provides for an “advance informed agreement” (AIA). This is a scheme whereby the exporting country is obliged to give prior information about intended transfers of LMOs to authorities of the importing country. No transaction can occur until the importing country has made a decision on the said information. The importing country may decide to permit the import; permit it only with conditions; prohibit it; or request further information prior to making a decision. (*Also see Box 4*)

The scope of AIA is however limited. The Protocol differentiates between LMOs for intentional introduction into the environment (e.g. LMO seeds for planting) and LMO commodities (LMOs intended for direct use as food or feed or for processing) for this purpose. AIA will apply only for the former. The Protocol contains separate provisions for the latter (under Article 11). Further, AIA provisions will not apply to LMOs in ‘transit’ or destined for ‘contained use’ in the receiving country. Furthermore,

Box 3: Clearing-House

To facilitate the AIA process, the Protocol requires the establishment of an internet-based “Biosafety Clearing-House” to be run by the Secretariat to the CBD. The Clearing-House is to serve as a central point through which information relevant to the Protocol can be gathered and disseminated. The Protocol also requires Parties to identify a “national focal point” to liaise with the Secretariat and other Parties on biosafety issues and a “competent national authority” to administer the provisions of the Protocol.

it is open for the Parties to negotiate further exclusions from AIA procedure in future.

Of the total trade of LMOs, about 90% comprise of the commodities. The Miami Group, being the major exporter of these commodities, was strongly against the inclusion of such commodities under AIA. The negotiation was so contentious that it was only when the LMG agreed to the exclusion of these commodities under the AIA procedure (as provided under Articles 8, 9, 10 and 12) that the Protocol could be adopted. The Miami Group of countries, reeling under public pressure and protests vis-à-vis trade and consumption of genetically modified products, finally agreed to a compromise in the form of Article 11. (In strict sense, Art. 11 is also an AIA procedure i.e. for LMO-commodities, but it is so lax than the earlier case that using the same terminology i.e. AIA for both the cases, somewhat do not suit)

The provision of Article 11(4) suggests that it is open for the states to frame their domestic regulations to address this issue. Hence the onus is on the states to keep itself adequately equipped by evaluating the information in the Biosafety Clearing House regarding such LMOs, and seek additional information where required.

Furthermore, products of LMOs are not mentioned in Article 4 (scope) and, are not covered by the Protocol. In other words, exports of LMOs, such as milk made with genetically modified Soya, are therefore treated differently to exports of LMO commodities (e.g. GM Soya intended for processing into products) and exports of LMOs intended for ‘intentional introduction’ into environment (e.g. Soya seed for plantation).

Another controversy that may arise in future is with respect to the application of AIA procedure to the LMO-pharmaceuticals covered under the Protocol. On one hand if these pharmaceuticals are deemed as ‘products’ of LMOs then they are not covered by the Protocol at all, defying the scope under Article 4. On the other hand, one may construe that injecting an animal with an LMO drug can be considered as ‘intentional introduction’ into environment, in which case AIA shall apply. Hence, much would depend on how the same is interpreted by the competent authority in case of a dispute.

Socio-economic Considerations

In response to developing countries’ concern regarding the impacts of LMOs on communities and potential agricultural dislocation, the Protocol allows parties to take account of their socio-economic considerations in decision-making. In such consideration main emphasis should be on the “value of biodiversity to indigenous and local communities”. However, this must be consistent with their international obligations (Article 26).

As the issue of compatibility of such socio-economic conditions with the WTO agreements remains unresolved it is likely to create further confusion and conflict. Furthermore, in light of ambiguity vis-à-vis relationship between the Protocol and WTO agreements, the matter may become more complex (discussed later).

Risk Assessment & Risk Management

As the term suggests, risk assessment is to *identify* and *evaluate* the potential adverse effects (risks) of LMOs on biodiversity and human health. The Protocol obliges Parties to carry out risk assessment before making a decision to allow or disallow the import of a LMO. However, a Party of import may ask the exporter to carry out risk assessment and may also require the exporter to pay for the same. This is an important provision, particularly from the developing country's perspective, as it places the onus of proof (i.e. that an LMO poses no or low risk of adverse impact on biodiversity) on the exporters. Article 15 and Annex III of the Biosafety Protocol deals with risk assessment.

The Protocol further obliges the Parties to establish mechanisms to manage the risks associated with LMOs. According to Article 16.1, the Parties has to establish and maintain appropriate *mechanisms, measures and strategies* to regulate, manage and control risks due to a LMO identified during the risk assessment. The Parties are required to ensure that any LMO, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

Precautionary Principle

The incorporation of 'precautionary principle' in the Protocol is being projected as the most important achievement for the LMG. The issue is politically important, given the various interpretations of the "precautionary principle" that have been floating around. In making its decision, a Party must consider a risk assessment (as provided by Article 15 of the Protocol), carried out by itself or the exporter. The risk assessment must be based on scientific evidence. But if the available scientific information is insufficient, the Parties are allowed to use a precautionary approach in their decision-making.

Article 10.6 of the Protocol states the Precautionary Principle:

"Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the *extent* of the potential adverse effects of a LMO on the conservation and sustainable use of biological diversity in the Party of import, taking into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the LMO in question...in order to avoid or minimise such potential effects". (emphasis added)

It means that an importing country can impose a precautionary ban or conditions on the import of LMO for intentional introduction if the evidence on potential adverse impacts presented in the risk assessment is felt to be incomplete. Most importantly, for the purpose of

LMO-commodities also an importing party has the same recourse (under Article 11.8) to the precautionary principle as in the case of LMOs for intentional introduction into environment.

However, *prima facie* it seems that the above provision would apply only regarding the *extent* (i.e. how bad they are) of impacts and does not specifically allow precautionary action where uncertainty exist on the *nature* (i.e. what the impact actually are) of the potential impacts. However it is difficult at this stage to know what impact such semantics will have on real world decision-making.

The politics of semantics becomes more intriguing in view of the language used in Annex III to the Protocol, which details out basic criteria to be fulfilled in risk assessment report by exporters. Annex III states that "lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk". The language used herein seems to conflict with the very definition of the 'precautionary principle' which has been said to be the basic objective of the Protocol.

Box 4: AIA Procedure

The AIA procedure involves three basic steps: notification, acknowledgement of receipt of notification, and decision making.

First of all the exporting country or company is obliged to send a notice to the relevant authority (competent national authority) of the receiving or importing country regarding a planned transfer of an LMO, including certain information specified in Annex I of the Protocol, which are extensive in nature. After this the importing country shall acknowledge its receipt within 90 days of receipt of the notice. The acknowledgement should indicate whether the information is sufficient and whether the importing country's domestic regulatory scheme (which must be consistent with the Protocol) or the Protocol will govern the transfer. Importantly, the failure to provide acknowledgement of receipt on the part of the importing party shall not imply its consent to transfer.

Within the above-said 90 days the importing country must also inform the exporter that either it can proceed with the export *without* further consent, or it can only proceed once written consent has been given. If second option is chosen, the importing party has a further 180 days (within 270 days of the date of receipt of notification) to communicate in writing to the exporter and to the Clearing-House, either approving the import (with or without condition) or prohibiting the import or requesting additional information and/or seeking extension of time. Again failure to communicate a decision within the stipulated period shall not imply its consent to transfer.

Section III

The Protocol and the WTO

The Protocol's relationship with WTO agreements was negotiated along with the 'precautionary principle'. This is the most debatable issue and its outcome will decide the fate of the Protocol. Except the Miami Group, all were of the view that any action in accordance with the Biosafety Protocol should not be taken as a trade-restrictive measure. The Miami Group tried hard to push a "saving clause" in the body of the Protocol, which says, "the provisions of this Protocol shall not affect the rights and obligations of any Party to this Protocol deriving from any existing international agreements to which it is also a Party".

The relationship is important, particularly in light of the WTO Agreement on Sanitary and Phytosanitary Measures (SPS), as the two agreements may be deemed to overlap in their coverage. Their approaches are, however, contradictory in nature. While SPS Agreement is essentially deregulatory in its objective (it imposes disciplines on national regulations in order to promote trade), the Biosafety Protocol's objective is primarily regulatory in nature (it encourages countries to develop national regulations to protect the environment).

After vigorous and often hostile discussions, the relationship clause was finally deleted from the main body and the compromise reached comprises the following lines in the Preamble of the Protocol:

"The Parties to this Protocol...

...Recognizing that trade and environment agreements should be *mutually supportive* with a view to achieving sustainable development,

Emphasizing that this Protocol shall not be interpreted as implying a change in their 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..." (italics added)

Clearly, these preambular wordings are not enough to ensure a Party's measure in compliance with the Protocol that could not be successfully challenged under WTO rules. The second paragraph mentioned above originates from the "saving clause" proposed by the Miami Group, while the third paragraph cancels it out. This means we are left with the first paragraph, which says that trade and environment agreements should be *mutually supportive*.

The question is how will this be interpreted if there is a dispute? In the event of a dispute concerning LMOs, will the WTO Dispute Settlement Panel take provisions of the Biosafety Protocol into account in its ruling? Will these be interpreted as being *mutually supportive* with the WTO rules? If there is a conflict between the

provisions, which agreement will take precedence in the international law? These are some of the questions which may look easy but it is very difficult to project their answers.

The preambular texts, interpreted in international law as a statement of intent, are not normally binding. The Protocol itself therefore cannot legally establish its primacy over WTO rules in the event of a clash between the two. But according to Vienna Convention, where there are treaties covering the same subject matter, the latter treaty will prevail in the event of a conflict. Also according to general customary rule of international law, the more specific treaty should take precedence over a more general treaty. In both the cases the Biosafety Protocol should take precedence.

However, a further complication will arise when the dispute in the WTO is between a Party and a non-Party to the Biosafety Protocol. According to Vienna Convention, if there is a dispute concerning two treaties on the same subject matter between a state that is Party to both and a state that is Party to one, then "the treaty to which both states are parties governs their mutual rights and obligations". This means that the WTO rules will take precedence in a dispute where both states are members of the WTO but only one is a Party the Protocol. For instance, a case involving the USA and a Party to the Protocol.

There could be many more arguments that will maintain a sea-saw between the Protocol and the WTO rules, as far as precedence over one another is concerned. Interestingly, recently the legal division of the WTO secretariat has suggested recourse to Article IX of the Marrakesh Agreement Establishing the WTO to get the WTO General Council to provide an authoritative, harmonious interpretation of the WTO agreements with the Biosafety Protocol in order to avoid conflicts.

Clearly, the issue has potentiality to trigger a process of review of the international legal system as whole. The outcome, however, would not only be dependent on the scope of existing and relevant international laws but would also depend (rather more) on the status of international trade diplomacy, and intensity and direction of public pressure at that moment of time.

Conclusions

To conclude, it can be said that the Protocol tastes both sweet as well as sour. Many things have been achieved, while many things would have to be done to give these 'achievements' much needed practicality. The role of the civil society, both northern as well as southern, has been commendable in the whole exercise and the same tempo is required to make these efforts meaningful.

The civil society solidarity at the time of the negotiations of the Protocol provides a silver lining for an equitable and sustainable globalised world. The Protocol is also a harbinger to the increasing reliance on the UN System by the South, which is perceived as much more transparent and democratic than the WTO system.

Recommendations

For Governments:

- The governments should sign the Biosafety Protocol as soon as possible and then ratify the same at the earliest.
- Transpose the Protocol's provisions into strong and effective domestic laws and put effective institutional mechanisms in place as soon as possible.
- Provide technical and financial assistance to help poorer countries implement the Protocol.
- Seek a formal clarification with respect to the 'relationship' between the Protocol and the WTO Agreements.
- Work on developing a liability regime and dispute settlement process under the Protocol as soon as possible.
- Develop more detailed documentation requirements for LMO-commodities as soon as possible.
- Ensure that domestic development of LMOs take full account of the potential impacts on biodiversity and human health.

For the Civil Society:

- Maintain the pressure both at the national and international level in favour of a meaningful Protocol, as the same is still evolving.
- To pressurize their respective governments to enact an effective domestic law and establish institutional setup in order to regulate trade in LMOs, on the lines of the Protocol.
- To maintain pressure on the WTO system so that it does not undermine the Protocol through its dispute settlement mechanism.
- Keep an eye on the changing equation of the international trade politics and act accordingly.
- To disseminate right information vis-à-vis the Biosafety Protocol.
- Maintain the cooperation and unity among themselves.

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