

# **THE CARTAGENA BIOSAFETY PROTOCOL: OPPORTUNITIES AND LIMITATIONS**

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## 1. Context

The conclusion of the Cartagena Protocol on Biosafety in Montreal in January of this year was a welcome step toward providing safety in trade in genetically modified living products. Being the first international treaty explicitly addressing both environment and trade negotiated since the establishment of the World Trade Organization, it is also an important signpost on the road to good environmental and health regulation in the globalized world.

The negotiations were highly contentious from the commencement in 1996, as developing countries, under the leadership of Tewolde Egziabher of Ethiopia, proposed a comprehensive text to achieve a high level of regulation of genetically modified living organisms. Exporter nations resisted, seeking a regime which would result in speedy approvals and admission of these products globally. The EU played an equivocal role, seeking to protect its current regulatory system, while not creating barriers to the expansion of its biotechnology industry. The US government, though not entitled to sign the Protocol since it has not ratified the Convention on Biological Diversity which is the legal basis for it, had the largest government delegation at negotiation sessions and used its influence globally to push for a weak instrument. The biotechnology industry was also present throughout in large numbers, as were a smaller number of highly-informed NGO representatives, including scientists and lawyers.

In January 1999, negotiations for the Protocol collapsed in Cartagena, Colombia, largely due to the intransigence of exporter nations, for whom Canada was the leading speaker. These countries then attempted to further block the Protocol by moving these trade issues to the World Trade Organization via a Biotechnology Working Group proposed by Canada in Seattle. However, this attempt failed, and in the aftermath of Seattle, there was renewed pressure on governments to demonstrate that trade considerations would not again over-ride environmental protection. The Canadian government had been widely condemned at home and abroad for its stance in Cartagena and at Seattle, and went to Montreal with a slightly more flexible position. Public pressure on governments was intensified in Montreal through public forums and demonstrations.

Juan Mayr, Colombian Environment Minister, chaired the sessions in Colombia and throughout 1999, worked to re-start the negotiations, convening an informal session in Vienna in the fall. He also chaired the final session in Montreal and demonstrated an exceptional strategic mind. He invited environment ministers from all countries to the meeting, and originated a "Round Table" negotiating structure with spokesmen from the five major groupings of countries<sup>(1)</sup>, observed by all delegates. He also skillfully used his prerogatives as Chairman to provide text that moved negotiations forward.

As a member of the Advisory Committee on the Biosafety Protocol for the Canadian government from 1996 to the present, and as a participant in three sessions of negotiations, twice as a

member of the Canadian delegation, I observed the process of negotiations closely. The Canadian Environmental Law Association wanted to see a Protocol that provides a high level of safety regarding the risks of genetically modified living products, and also, a positive precedent for international law on both trade and the environment. Our focus has been on achieving a protocol that is practical and will actually work. We consider that the result demonstrates both a positive beginning and hard lessons about international trade negotiations. This paper reviews the negotiating mandate, the global regulatory system that results from the Protocol, its positive and negative elements, and the work that remains to be done to make it effective.

## 2. Mandate

The mandate to negotiate the Protocol is found in the 1992 Convention on Biological Diversity, which provides in Article 19(3):

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.

The *Convention* also provides, in Article 8 which concerns In-situ conservation of biodiversity:

8 (g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, **taking also into account the risks to human health:** (emphasis added).

The mandate for the Protocol on living modified organisms (LMOs) was a goal pursued by developing countries at Rio in 1992. Biological diversity is richest in Southern countries, where numerous countries are centres of origin for diverse species including important agricultural crops.<sup>(2)</sup> However, it is in Northern countries of North America and Europe that genetic modification of these and other living organisms is proceeding rapidly, with proliferation of the LMOs through trade. Developing countries wanted an international instrument that would mandate regulation of this trade to protect against the potential environmental and human health risks that may arise from the products, as identified in scientific evidence. That the products can reproduce and can transfer genetic material to species in the receiving environment entails a range of potential impacts, biological and socio-economic, on local species, Southern agriculture, local communities, and human health. Throughout the negotiations, the inclusion on human health was resisted by Northern countries, and its inclusion was accepted only late in the process.

## 3. Scheme of the Protocol

"Advance informed agreement" or "AIA" is the basic tool established by the Protocol. In accordance with Article 19(3) of the Convention, it establishes a scheme for the prior provision of information about intended transfers of LMOs to authorities of the receiving country, requiring that the transfer not occur until that country has made a decision about the importation.

The receiving country's decision may be to permit the import; permit it only with conditions; prohibit it; or request further information prior to making a decision.

#### 4. Scope

Pursuant to Article 4, the Protocol applies to

.... transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

However, "pharmaceuticals for humans that are addressed by other relevant international agreements or organisations" are excluded, although veterinary pharmaceuticals are included (Art.5) and the AIA provisions do not apply to LMOs in transit (crossing through a country to a destination outside it) or destined for contained use <sup>(3)</sup> in the receiving country (Art. 6). The Parties to the Protocol may negotiate further exclusions in the future (Art. 7(4)). Special information provisions not AIA, apply to commodities ("LMOs intended for direct use as food or feed, or for processing" (Art. 7(2)).

#### 5. Advance Informed Agreement

The Advance Informed Agreement procedure will apply prior to the first intentional movement of an LMO for intentional release in a receiving country (Art.7(1)). (However, commodities will be treated differently, as discussed below.) The AIA procedure involves three basic steps: notification, acknowledgment of receipt of notification, and decision-making.

**Notification:** The exporting country or company will send a notice to the relevant authority ("competent national authority") of the receiving country (Party of import) regarding a planned transfer of an LMO, including information specified in Annex I of the Protocol. (Art.8 (1)). The information required is extensive, including details of the trading companies, dates of the planned transfer, and detailed scientific information about the LMO, its genetic composition and origins, intended use, any existing risk assessment, suggested methods for handling, regulatory status of the LMO in the country of export, and results of any previous notice by the exporter to other states regarding the LMO (Annex I).<sup>(4)</sup>

**Acknowledgment of receipt of the notice:** Within ninety days of receipt of the notice, the importing country shall acknowledge its receipt, indicating whether the information is sufficient and whether the transfer will be governed by the importing country's domestic regulatory scheme (which must be consistent with the Protocol) or the Protocol's Article 10(Art.9 (2&3)). A Party's failure to provide acknowledgment of receipt of the notice "shall not imply its consent" to the transfer (Art.9(4)).

**Decision procedure:** Within ninety days, the importing country will inform the notifier whether the transfer will require written consent or may proceed without it. It then has 270 days to decide whether to approve it, with or without conditions, prohibit it, request additional information, or extend the time for decision (Art.10, (2&3)). Any decision other than unconditional approval shall include reasons (Art.10 (4)) but a country's failure to communicate a decision within 270

days "shall not imply its consent" to the transfer. In making its decision, the party must consider a risk assessment, carried out by itself or the exporter, according to the detailed requirements of Annex II, to

evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also in to account risks to human health (Art. 15)(1)).

The party may require that the exporter pay for the risk assessment (Art. 15(3)) and may also require risk assessments on subsequent (not only first) imports (Art.12(4)).

Countries are entitled to use a precautionary approach in decision-making:

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking into account risks to human health, shall not prevent the Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question ...in order to avoid or minimize such potential effects (Art.10(6)).

Having reviewed the necessary risk assessment, (and hopefully within 270 days) the country shall make a decision regarding the transfer, and communicate it to the exporter and to a Biosafety Clearing House, now established within the clearing-house mechanism under the Convention on Biological Diversity (Art.10(3) and 20).

The internet-based Clearing House is an key element of the Protocol for this new international scheme of regulation. On it countries will post decisions on individual transfers of LMOs as well as non-confidential information relevant to the implementation of the Protocol; existing domestic laws; information required by countries for the AIA procedure; bilateral, regional and multilateral agreements; summaries of risk assessments of LMOs generated by domestic regulatory processes (including regarding products of LMOs); and more general scientific information which may assist the parties (Art.20).

**Risk management:** Countries are also required to establish mechanisms to manage the risks associated with LMOs, considering both risks to biodiversity and to human health (Art. 16).

They are entitled to:

ensure that any living modified organism, 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 (Art.16(4)).

This provision echoes both concerns of Northern NGOs, that approved LMOs in our countries have not been subject to long-term safety testing, and concerns of Southern countries that long term testing is required, for example, to establish the impacts of LMOs on local agriculture. Though unnoticed by most commentators, this provision has the potential to shield decisions about LMO imports based on dissatisfaction with Northern short-term testing and approval regimes prevalent in Northern countries.

**Review of decisions:** Importing countries may review and change a decision at any time in the light of new scientific information about an LMO, and shall then inform any company or country affected. Similarly, exporters may request a review given changed circumstances (Art. 12).

**6. Alternative decision schemes:** As noted above, Parties have a choice between using the Protocol provisions or a domestic regulatory scheme that is consistent with the Protocol, for some or all LMOs (Art. 9 and 14(4)). In addition, a country may use a simplified procedure, allowing shipment at the same time as notification, or exempt certain LMOs from the AIA procedure (Art. 13). Further, countries may enter into bilateral, multilateral or regional agreements to govern this trade provided that these agreements are "consistent with the objective of this Protocol" and "do not result in a lower level of protection" than that of the Protocol (Art. 14). Trade with non-parties should be "consistent with the objective of this Protocol" (Art.24). Since the US which is the largest exporter of LMOs will remain a non-party, not having ratified the *Convention on Biological Diversity*, this provision is an important attempt to extend the Protocol's requirements to countries trading with the US. However, whether it will succeed in achieving that result, remains uncertain.

**7. Treatment of LMOs intended for direct use as food or feed, or for processing:** These products, commonly called commodities, comprise close to 90% of the LMOs that are traded, and include Canadian canola, soybeans, corn and potatoes. The six exporter countries of the Miami Group called during the negotiations for the Protocol, opposed the application of AIA to commodities, and succeeded in obtaining a lower level of information and regulation to apply to them.

Article 11 provides that countries which approve a LMO that is a commodity shall list that approval on the Biosafety Clearing House within 15 days together with information specified in Annex III. This includes details of the applicant for domestic approval; information about the LMO; related centres of origin and centres of genetic diversity; approved uses of the LMO; a risk assessment; and handling instructions. Countries may make decisions on importing these LMOs under domestic regulations, or in the absence of a domestic scheme, pursuant to a risk assessment and within 270 days, although absence of a decision shall not imply consent. Again, countries are entitled to rely on a precautionary approach in the absence of scientific certainty.

Applying this approach of generic approval to individual shipments of the LMOs can only occur if individual shipments are labelled, indicating that they contain a specific LMO. However, commodities traders and the Miami Group of governments argued that this is impossible, since the products are combined both domestically and in foreign ports with other products, so that the contents of a final shipment cannot be foreseen, and cannot be labelled. Despite other countries' widespread skepticism about these claims, the Miami Group would not budge. The Protocol therefore only requires limited documentation on LMO commodities shipments:

Art. 18 (2) Each Party shall take measures to require that at a minimum documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed or for processing clearly identifies them as "may contain" living modified organisms and as 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 2 years after the entry into force of this protocol.<sup>(5)</sup>

Therefore, countries wishing to regulate the actual arrival of these products will have no option but to test individual shiploads, unless and until the planned negotiations regarding documentation result in changes to the shipping systems (segregation of genetically modified foods) and accompanying identification of products.<sup>(6)</sup>

## **8. Socio-economic considerations**

In response to Southern concerns regarding the impacts of LMOs on communities, and potential agricultural dislocation, the Protocol allows countries to consider socio-economic considerations in decision-making, "especially with regard to the value of biological diversity to indigenous and local communities" but only "consistent with their international obligations" (Art.26). This wording leaves unresolved the compatibility of such criteria with the World Trade Organization agreements.

## **9. Liability and Redress**

The question of liability and redress for damage from LMO trade will be subject to further negotiations, to be completed within four years (Art.27). This is a disappointing result for Southern countries for whom a liability regime was a priority. They rightly argued that the potential for negative impacts on southern agriculture from LMOs could result in serious damage for which no satisfactory international legal regime currently provides redress.

## **10. Dispute resolution**

In accordance with Article 27 of the *Convention on Biological Diversity*, the dispute settlement process in the *Convention* applies to disputes under the Protocol as well. This entails a process of negotiation, mediation, arbitration or submission to the International Court of Justice, or conciliation. However, it is generally assumed that Northern countries are more likely to submit disputes over LMO trade to the WTO Dispute Settlement Understanding process.

## **11. Relationship to trade agreements**

This issue was a black cloud hanging over the entire period of negotiations and particularly the last year. The Miami Group supported wording in the body of the Protocol which would have prevented it from an impact on potential future trade disputes regarding LMOs, likely to be played out in the WTO, specifically:<sup>(7)</sup>

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.

After vigorous and often hostile debate, the Protocol concluded with inclusion of trade language only in the Preamble, as follows:

***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

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.

In my view, this wording creates the opportunity for the Protocol to be rightly interpreted as the agreed international standard with regard to trade in these products, a standard that "meshes" with the internationalization and harmonization requirements of the WTO agreements on Technical Barriers to Trade and Sanitary and Phytosanitary Standards. Other elements of the Protocol will also be important in any future interpretation of trade law applicable to these products. These include the Precautionary principle<sup>(8)</sup>, the inclusion of human health<sup>(9)</sup>, the shielding of domestic regulatory regimes<sup>(10)</sup>, and the inclusion of socio-economic factors in decision-making.

## 12. Ongoing issues

For the Protocol to enter into force requires ratification by 50 countries. In addition to the need to establish the Clearing House Mechanism and to continue negotiations mandated by the Protocol regarding documentation and liability and redress, the Protocol provides for cooperation in capacity-building in developing countries and Eastern Europe (Art. 22). Developing countries emphasized their need for this to achieve appropriate levels of safety; Northern countries and the private sector favour it in the belief it will result in speedier approvals for trade in their products. The financial mechanism established under the Convention will be the mechanism for the Protocol (Art.28). The Protocol also provides for an assessment and review five years after it comes into force, and at five year intervals afterwards (Art.35).

Within Canada, implementation raises the question of whether Canada will first sign and ratify it, and then enact the required domestic legal obligations. Hopefully, International Trade Minister Pettigrew's recent statement on the Protocol indicates a readiness to do so.<sup>(11)</sup>

## 13. Significance of the Protocol

First, will the Protocol lead to a reliable international regulatory approach that provides a high level of safety in LMO trade, both for biodiversity and human health protection? Although it has that potential, important uncertainties remain.

**Commodities:** The treatment of commodities is an obvious gap and affects the bulk of LMO trade. Whether that gap can be bridged depends on the ongoing documentation discussions, and the Miami Group can be relied upon to object to more meaningful standards. One of the unfortunate aspects of the Canadian position throughout the negotiations was its failure to reflect the changes in market planning that are currently occurring within Canadian industry.<sup>(12)</sup> Trends in the market are crucial to future negotiations regarding documentation; if exporters continue to experience market uncertainty or significant market collapse for LMOs, they will move more quickly to meaningful segregation and labelling. If the market accepts these products, there is no reason to expect change in the Miami Group stance and the documentation discussions will likely not result in meaningful identification of these products. Countries may then resort to testing individual shiploads, as Thailand did recently, causing consternation in some Canadian industry representatives. However, this is an expensive, difficult, and unsatisfactory result. It is crucial, to achieve high levels of safety, that segregation and labelling occur.

**Varying schemes:** Next, the variety of schemes permitted under the Protocol may result in a mish-mash with inconsistent standards. The variety includes the Protocol's approach, the possibility of relying on domestic regulations, recourse to bilateral, regional and multilateral agreements, simplified procedures, and exemptions of specific LMOs from the Protocol. Although alternative schemes should be consistent either with the Protocol or with the objective of the Protocol, there is no mechanism that will ensure that they are.

**Developing country capacity:** The ability of developing countries to regulate LMOs is a fundamentally difficult problem, given their lack of capacity and is likely to contribute to uneven results internationally.

These elements will all affect on the level of safety that ultimately results under the Protocol. It is important, however, for other political and legal issues it affects.

**Priority on the environment:** The Protocol provides an important and positive precedent in international law, both for environmental protection and for trade law. Being the first international negotiation that is explicitly both about trade and the environment, it ended in an agreement that is more positive for the environment than exporters anticipated. For Canada, dragged reluctantly along, this marks a break with the one-dimensional direction of trade policy of the past twelve years.

**Precautionary wording:** The strong and repeated precautionary wording of the treaty in the body of the Protocol rather than only in the Preamble is also an important precedent in a trade agreement, and re-opens a door in the WTO. That it appears in a treaty championed by developing countries may have a further positive influence on ongoing North/South debates about the role of environmental standards as alleged trade barriers.

**Shielding domestic law:** Further, the Protocol provides a strategy for the preservation of domestic environmental and health standards from the challenges under trade law, namely by creating a shield for them through a new multilateral agreement. This approach merits further study as a response to the increasing intrusion of international trade and investment regimes in domestic public interest regulation.

**Presence of environment ministers:** The presence of environment ministers at the negotiations was clearly crucial to the result, and Chairman Mayr, the Colombian Minister of Environment, deserves our thanks for this brilliant strategy. While others have argued in the past about the need to involve other ministries and ministers in trade negotiations, I have been skeptical (based on experience in Canada) that such a strategy would make a difference. It is also worth recalling that the strong stance of EU environment ministers, and the strength of the EU position on LMOs is founded on the political reality of determined public opposition to LMOs in food in Europe. Nevertheless, in Seattle, the EU Trade Commissioner was willing to sabotage these negotiations by moving them to the Canada-sponsored WTO Biotechnology Working Group, and he was stopped there by the EU Environment ministers. They then maintained a strong stance in the Protocol negotiations, and by supporting developing countries on many important issues, contributed to the result. Trade activists need to pursue such allies in non-trade ministries on future issues.

**NGO contributions:** The role of NGOs throughout the negotiations merit much collaborative study. In Montreal, there was clearly a useful cooperation between the NGO people in the sessions, arguing with the negotiators and those outside keeping pressure on governments through demonstrations, clever press work, and rapid responses to new developments. There is value in showing the negotiators that they are under scrutiny, are being criticized in the press, and will be identified for anti-environmental decisions and trade obsessions. As Bob White, former President of the Canadian Labour Congress has said, we need dialogue inside and protests in the streets. I would welcome an opportunity for a joint evaluation of NGO efforts throughout the years of the negotiation, when it was tracked by highly informed and politically sophisticated people from all parts of the world.

**Collaboration between southern countries and NGOs:** Throughout the negotiations, there was a welcome collaboration between Northern and Southern NGOs, and NGO support for the efforts of the majority of the Developing Countries, operating as the Like Minded Group and their steadfast spokesman Tewolde Egziabher. Hopefully this collaboration can contribute to a better basis for North/South relations on trade and environment questions.

**The need for strong domestic regulatory regimes:** The Protocol also reminds us of the necessity for domestic organizing and regulatory campaigns to continue. The public mobilization that led to EU domestic laws on genetically modified foods and that continue to exist are, after all, the reason that the EU ministers could not agree to weaker terms. There is clearly a need to continue the campaigns here against GE foods, and for affective labelling.

**The role of Canada:** Canada's role as the speaker for the Miami Group and for the US, and its refusal to budge on the commodities trade raise real questions about Canada's self-proclaimed role as a UN leader and promoter of human security. The issue here, in the view of the South and NGOs, includes basic food security. The prominence of the economic ministries (Department of Foreign Affairs and International Trade, Industry Canada, and the Canadian Food Inspection Agency) and the lesser role of Environment Canada<sup>(13)</sup> and Health Canada in the negotiations testify to the continued dominance of one-dimensional goals in Canadian trade policy. This is particularly evident given the absence of any reflection of the changes currently at play in Canadian industry marketing strategy. The stance of Canada in the continuing work of ratifying and implementing the Protocol will be an important signpost of whether the lessons of Seattle are being learned in Ottawa.

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*Michelle Swenarchuk has been a member of the Advisory Committee to the Canadian government on the Biosafety Protocol since 1996. She attended two sessions of Protocol negotiations as a non-governmental representative on the Canadian negotiating team, and three sessions as an accredited independent NGO representative.*

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## Endnotes

1. The groups were the Miami Group (Canada, US, Australia, Argentina, Uruguay and Chile); the EU; the Like-Minded Group (most of the Developing Countries); the Compromise Group (Japan, Mexico, Norway, Switzerland, Singapore, South Korea, New Zealand) and the CEE (Central and European countries).
2. Examples of centres of origin include India for rice, Peru for potatoes, and Mexico for corn.
3. "Contained use" is defined in Article 3(b) to include "any operation....within a facility, installation or other physical structure" which involves LMOs controlled to limit their contact and impact on the environment.
4. Countries are to establish domestic legal requirements that exporters provide accurate information, for purposes of both Article 8 (Notification) and Article 11 (Commodities trade notifications). (Articles 8 (2) and 11(2)).
5. Articles 36 and 37 provide that the Protocol may be signed between May 15, 2000 and June 4, 2001, and will enter into force on the ninetieth day after deposit of the fiftieth instrument of ratification, acceptance, approval or accession by states or regional economic integration organizations.
6. In contrast, shipments of LMOs for contained use or for intentional introduction into the environment will require documentation that identifies them as LMOs, and provides appropriate information regarding the LMO and requirements for safe handling, storage, transport and use. (Art.18 (2)(b&c))
7. A full analysis of the relationship of the Protocol to international trade agreements is beyond the scope of this paper, but will follow subsequently.
8. The precautionary principle appears in the Preamble (Para.4); the Objective (Art.1, the precautionary approach); Art.10(6) decision-making; and Art.11(8) decisions regarding commodities.
9. Human health considerations appear throughout the Protocol, namely, in the Preamble para 5, Objective Art. 1; 2(2) General Duty; 4 General Scope; 7(4) potential exclusions by COP; 10(6) Precaution in decision making; 15(1) consideration in risk assessment; 16(2) consideration in risk management; 16(5a) cooperation in risk management to reduce effects; 17 (1) unintentional movements and emergency measures, (3c) information about possible effects, (4) consultation to minimize effects; 18(1) handling, transport, packaging and identification; 21(6c) risk assessment information not considered confidential; 23(1) promotion of public awareness re safe use; Annex II, Risk assessment, (1)restatement of the objective (8b) inclusion of health in risks to be assessed.
10. This occurs in Art.9(2c) and (3) re the decision-making process; Art.11(4) re commodities; Art.14(4) application of domestic regulations regarding specific imports.

11. In a speech in Ottawa on February 16, 2000, Mr. Pettigrew stated, "The recent agreement on a biosafety protocol is a very positive sign that all the nations of the world can work together and make progress on trade while protecting our global environment."

12. One reflection of the current thinking appears in the words of Greg Arason, President and CEO of the Canadian Wheat Board, in his speech of October 19, 1999, entitled "Marketing in an Era of Biotechnology;" "In our view no transgenic varieties should be registered for commercial production in Canada until either they have achieved full commercial acceptance in all of their potential markets, or until we have cost effective technologies to segregate by variety through the system." Available at <http://www.cwb.ca>.

13. John Herity of the Biodiversity Convention Office of Environment Canada did play an influential and positive role as Co-chair of the Canadian delegation.