Third World Resurgence
No. 114/115, Feb./Mar. 2000
Special Edition:
(slightly reformatted but otherwise unchanged)
Published by the Third World Network, Penang, Malaysia
http://www.twnside.org.sg/

10 Articles on the Biosafety Protocol

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1. **Biosafety talks end on mixed note**
http://www.twnside.org.sg/title/note.htm

by Lim Li Lin
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After five years of difficult and painful negotiations, the Parties to the UN Convention on Biological Diversity finally concluded a Biosafety Protocol in late January at Montreal. It was public pressure and concern that finally forced recalcitrant countries (led by the US) to agree to such a Protocol. While the final outcome was a compromise document which is not fully satisfactory and leaves many questions still unanswered, the fact remains that there is now an international treaty which specifically regulates the transboundary movement of genetically engineered (GE) organisms.

AFTER almost five years of painstaking negotiations, Parties to the UN Convention on Biological Diversity (CBD) finally reached agreement in the early hours of Saturday, 29 January 2000, on a Biosafety Protocol to the CBD.
The majority of countries had mixed feelings when the Chairman of the Biosafety Protocol negotiations, Juan Mayr Maldonado, Minister of Environment for Colombia, announced the conclusion of the week-long negotiations in Montreal.
The agreement will enable importing countries to regulate the import of genetically engineered (GE) foods based on the Precautionary Principle. While the agreement speaks of the Biosafety Protocol and the World Trade Organisation (WTO) agreements being mutually supportive, it does not override rights and obligations under the multilateral agreements of the WTO.
The week spent in Montreal to conclude the negotiations had seen the deadlock over the core outstanding issues finally resolved at the end of the week, after many late-night and early-morning negotiating sessions, and under immense political and public pressure to reach agreement on the draft text.
Agreement to regulate the transfer, handling and use of living modified organisms (LMOs) - also referred to in some literature as genetically modified organisms (GMOs) - should have been reached in Cartagena, Colombia last February. However, the US-led Miami Group (comprising Canada, Australia, Argentina, Chile and Uruguay as well) scuttled agreement by refusing to allow any provision in the Protocol that would impede their free export of GE commodities.

Three core issues

Three core outstanding issues had been identified by Mayr and adopted by delegates at an informal consultation in Vienna last September. There were long-drawn discussions at Vienna to reach an understanding on concepts relating to the general scope of the Protocol, the relationship of the Protocol to other international agreements (particularly the WTO agreements), and the system for obtaining consent from importing countries to the entry of GE commodities destined for food, feed and processing.
As delegates arrived at the Montreal convention centre for the final plenary session at 9 pm on 28 January, they were greeted by lively protesters dancing and chanting,

'Shame! Shame! Shame on the Miami Group!' The protesters had spent the night outside the convention centre in a tent, in temperatures below 20 degrees centigrade, keeping a candlelight vigil begun the night before. They had vowed to stay there until a strong Biosafety Protocol was concluded.
By 9 p.m. on Friday, the last day of the negotiations, it was common knowledge that the disagreement over the Precautionary Principle and the relationship clause, considered to be the most difficult hurdle, had been resolved. Delegates and observers were expecting the plenary session to be called at any time to adopt the Biosafety Protocol. As hour after hour dragged by with sporadic announcements from the Secretariat that the plenary session would yet again be postponed for a few more hours, word began to filter through that, in the closed-door negotiations with the spokespersons of the negotiating groups, the issue of segregation and identification of GE commodities had become a major sticking point.

Holding the world hostage

Finally, the chief spokesperson of the Like-Minded Group of Developing Countries (comprising almost all the Group of 77 (G77) countries and China), Dr Tewolde Egziabher, gathered the group at the front of the conference hall, and announced that the Miami Group did not want GE commodities to be identified as such in shipping documents.
The issue, he explained, was that the Miami Group only wanted shipments of commodities to be documented as 'may contain' LMOs. As murmurs of dissatisfaction rippled through the hall, Dr Tewolde went on to explain that all the other negotiating groups, including the European Union, had accepted this clause, and that the Like-Minded Group was the last to agree to it. If the Like-Minded Group agreed to this clause, there would be a Protocol, but if they could not agree to it, there would be no Protocol, he explained.
The delegate of Antigua and Barbados stated that this clause was unacceptable, but indicated that he would not stand in the way of consensus. No other delegate registered their opposition to the clause, but there were many almost tearful faces among the dejected Group.
At the eleventh hour, the Miami Group had, yet again, held the world hostage to its demands, playing their cards so carefully that there was nothing else to be done but to agree to their rules. Minutes later, at 4.45 a.m., Mayr announced to exhausted delegates that the Biosafety Protocol was now adopted. The euphoria among delegates and observers at the conclusion of almost five years of hard work was dampened by the final compromise that they had been forced into.
The issue of commodities had been the most important issue for the Miami Group, since these currently comprise the bulk of their exports of LMOs (soya, canola, maize). Pressure from the Like-Minded Group, with support from the EU and the Compromise Group (Norway, Switzerland, Japan, Mexico, South Korea) (Singapore, initially a member of the Like-Minded Group, only joined the Compromise Group in Montreal) amidst public condemnation of the hardline position of the commodities exporters, forced the negotiation of a separate procedure for commodities.
With the procedure for the transboundary movement of GE commodities resolved, the one other issue that many delegates and observers had thought was also agreed upon was the segregation and identification of GE commodities. With the requirement to only document commodity shipments as 'may contain' LMOs, the Miami Group

was, in effect, declaring that they did not intend to segregate GE commodities from non-GE commodities, as that would obstruct the free movement of their export commodities. The Protocol now provides for rules to be established for such documentation, within two years from the entry into force of the Protocol.
But many non-governmental observers commented later that exporters of LMOs will eventually have to bow to public pressure, whatever the rules, to segregate and label LMOs as such. Public opposition to LMOs and their products has already forced many countries such as Japan and Australia to pass labelling laws. The European Union already has a law requiring segregation and labelling of LMOs and their products.

Growing public pressure

Public pressure has been growing over the last year ever since the collapse of the negotiations in February 1999. Concern by consumers, organic farmers, small farmers and concerned scientists in particular, had increased public scrutiny on the whole process and intensified demands for a strong Protocol.
On the Saturday before the Protocol negotiations began, a series of workshops and a public forum organised by a number of civil society organisations saw more than a thousand people thronging the halls to get in. An afternoon march in temperatures of as low as -40 degrees centigrade saw up to 600 people taking their concerns to the streets for more than two hours. There was also intense media spotlight on the Protocol negotiations.
As the Chairman stated in his speech at the opening plenary session, 'The whole world is watching us..... and I wonder which delegation would want to go down in history as having been the reason why this process failed.'
He emphasised that the 'developments and events of the last few months have shown us that there is a big crisis out there: citizens are questioning whether they can trust industry and their governments to ensure the safety of modern biotechnology'.
When talks resumed in Montreal, positions on the core outstanding issues had changed very little, and as the days stretched on with little agreement on any of these issues, there were real fears among delegates and observers that there would be no Protocol yet again. Many delegates had expressed frustration at the continuing efforts by the US and Canada to block any genuine development in the talks. Many had also privately believed that the US in particular did not even have a mandate to conclude a Protocol at that point.
By the middle of the week-long negotiations, when talks on all of the core issues were still unresolved, fears that the Protocol would not be concluded even in Montreal had begun to spur finger-pointing. In the corridors, talk of divisions within the Miami Group was rife. A number of delegates openly told observers that they would rather not be in the grouping.
By Wednesday, as the deadlock continued, hopes began to be pinned on the arrival of around 40 Ministers to pave the way for a political push towards securing agreement on the key issues.
The Canadian Minister of Environment, David Anderson, whose appearance had been much touted after he caved in to public pressure to attend the negotiations, was noticeably in hiding.

The Minister of Environment for France was reported to have been stood up at a meeting scheduled between them.
On the general Ð scope issue, the Like-Minded Group went against all odds to re-open discussion on pharmaceuticals for human consumption, which had been excluded completely in the Cartagena draft, as well as the contained use and transit of LMOs, which had also been effectively left out. The LMG had argued, since the Vienna consultations, for a comprehensive scope, namely, that all LMOs should be covered by the Protocol.
Parties could then, at their discretion, waive the requirement of advance informed consent for pharmaceuticals.
Persistence and finally support from the Compromise Group (with some reservation from Switzerland and Japan) swung the tide. The general scope of the Protocol now covers all LMOs, with exclusions, under certain conditions, in the subsequent articles on the three disputed areas. Though far from what the Like-Minded Group had wanted, the scope of the Protocol now does not explicitly exclude any category of LMOs, an achievement that many had privately felt was impossible to arrive at.

Commodities

On commodities, a separate article deals specifically with the procedure for the export of GE commodities destined for food, feed and processing. Global public pressure and opposition to genetic engineering, amidst increasing scientific evidence of its risks and hazards, had forced the Miami Group to agree to some sort of procedure for regulating GE commodities, when they had resisted all such attempts at Cartagena to include commodities at all.
The provisions were hard fought, but still place the onus on importing countries to initiate procedures regulating the movement of GE commodities into their countries, and do not, as such, place an international obligation on exporters to first notify importers of specific shipments, followed by informed agreement.
This is in contrast to first shipments of LMOs for release into the environment (for example, planting in the fields) which would be subject to the Advance Informed Agreement procedure. Under this, the responsibility lies with the exporter to first notify the importing country of an intent to export. Provision of full information (particularly risk assessment), followed by express consent, must occur before any export can take place.
Nonetheless, at the very least, information relating to domestic approvals of GE commodities can now be monitored through the Biosafety Clearing House mechanism. It is then up to the other Parties to inform the potential exporter of their national requirements. However, express consent is still required from importing countries.
The one victory, if it can be called that, was the inclusion of the Precautionary Principle in the Protocol. This Principle, as included in the Protocol, states that, 'Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of an 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 that LMO....'

Though not as strongly worded as all the negotiating groups, with the exception of the Miami Group, would have liked, most delegates and observers were pleased with the fact of its inclusion.

Cluster

The Precautionary Principle was negotiated in a cluster with the relationship clause as it became increasingly difficult to discuss one without the other. All but the Miami Group were advocating the position that any action to restrict or ban the import of an LMO in accordance with this Principle should not be regarded as a trade-restrictive measure.
The Like-Minded Group had consistently insisted on the Precautionary Principle as an operative provision for decision-making in the Advance Informed Agreement Procedure.
In Cartagena last February, observers were shocked when the European Union was prepared to concede to the Miami Group on this crucial point even though EU law is rooted in this Principle. Since then, public rejection of GE foods and crops in Europe and increased evidence of environmental and health hazards have raised demands for the Precautionary Principle to prevail.
Attempts by the US, Canada and Japan to shift the biotechnology issue to the WTO last December at Seattle also saw vocal protests by developing countries and several European environment ministers. The same group of ministers, joined by others, turned up in full force at Montreal. At a meeting with NGOs, the message was clear: the Precautionary Principle is needed, and the Biosafety Protocol will not be subordinate to the WTO. Ministers included those from Denmark, France, Portugal, the UK and the Netherlands.
When the Precautionary Principle was discussed at plenary, the European Union made its clearest statement since the negotiations started almost five years ago. The spokesperson for the European Union, Christoph Bail, declared that in cases of scientific uncertainty, 'governments must be able to have the freedom and sovereign right to take precautionary action, as risks that may arise may be long-term and irreversible.'
Many had feared that, given the strong opposition of the Miami Group to the inclusion of the Principle and its insistence that the Biosafety Protocol should be subordinated to other international agreements, namely the WTO agreements, a trade-off on either of the provisions would have to be accepted.
But the provision on the relationship of the Protocol to other international agreements was finally deleted, and statements relating to such relationship were added into the preamble of the Protocol. Most contentious among the preambular language was, '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'. However, this statement relegated to the preamble carries far less weight than if it were included as a substantive provision. A paragraph also follows that the previous recital does not imply a hierarchy amongst the agreements.

Historical agreement

In the end, the conclusion of the biosafety negotiations turned on the issue of commodities. Once again international negotiations became a platform for the US and the European Union to play off their growing trade war on genetically engineered organisms and their products.
Fortuitously for developing countries, public concern and opposition to genetic engineering in most of the European countries swung the political resolve of their governments to resist at all costs the free and unimpeded trade in LMOs.
In their statement at the closing plenary, France offered to host the preparatory meeting for the first meeting of the Parties before the end of this year. Many issues still have to be resolved, including those specifically provided for in the Protocol. In the end, in the urgent rush to conclude the Protocol by the session in Montreal, many issues left open since Cartagena were never addressed. Parties and negotiating groups were forced to allow these issues to remain as in the Cartagena text, in order to see a conclusion to the negotiations.
In a statement on behalf of civil society groups at the closing plenary, Chee Yoke Ling from the Third World Network said that it was a historical agreement, being the first time that international law recognised GEOs as distinct and inherently different, thereby requiring a separate regulatory framework. However, she said that the last change pressed upon the rest of the world by the Miami Group in the final hours, to avoid segregation and identification of commodities as GMOs, was disappointing. 'Nevertheless, civil society - consumers, farmers and scientists - will continue to be vigilant. The demand for segregation and labelling will not stop.'
The statement also noted that the Protocol provided for an international liability regime to be negotiated, and that governments should work on that as soon as possible.
The Protocol will be opened for signature at the fifth Conference of the Parties to the Convention on Biodiversity in May in Nairobi.

Chronology

Chronology

November 1994
First meeting of the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) in the Bahamas; sets up a Biosafety Experts Group open to all governments, and a 15-member experts panel to prepare a background paper for the Group.
May 1995
15 government-appointed experts panel meets in Cairo.
July 1995
Biosafety Experts Group meets in Madrid to work out terms of reference, with active participation from NGOs and independent scientists; controversy over the scope and elements of a biosafety protocol.
November 1995
Second meeting of the COP in Jakarta sets up a Working Group on Biosafety to negotiate a biosafety protocol, after intense debates on the scope and elements.
July 1996 until February 1999
Working Group on Biosafety chaired by Denmark's Dr Veit Koester meets six times; fails to reach agreement on all key issues, based on the Chairman's draft; Group dissolves on 22 February.
22-24 February 1999
First Extraordinary Meeting of the COP convenes under chairmanship of Colombian Minister of Environment Juan Mayr Maldonado; negotiations fail and the meeting is suspended.
1 July 1999
Informal consultation with delegates at a CBD meeting in Montreal to confirm political will to proceed.
September 1999
Informal consultations in Vienna to build goodwill and explore areas of possible agreement on three core issues (general scope, Advance Informed Agreement (AIA) scope, relationship of protocol with WTO agreements).
January 2000
Extraordinary meeting of the COP resumes in Montreal; Cartagena Protocol on Biosafety concluded and adopted.

2. Delayed, but better, Biosafety Protocol,
http://www.twnside.org.sg/title/delay.htm

by Chee Yoke Ling
Chee Yoke Ling, a former university law lecturer, is an Environment Representative of the Third World Network.

Looking back, it is clear that the collapse of the biosafety negotiations in Cartagena was a blessing in disguise. The growing strength of public concern in the interim, as a result of mounting scientific evidence of the hazards of genetically engineered crops and foods, made possible the conclusion of a more satisfactory Biosafety Protocol at Montreal.

WHEN, in February 1999, the United States and its five other members of the Miami Group (Canada, Australia, Argentina, Chile and Uruguay) brought international negotiations on the Biosafety Protocol to a standstill, it was in one sense a victory for biosafety.
As one delegate said in the early hours of the morning when more than 130 countries agreed to suspend negotiations in Cartagena, 'It is better to have a stronger Protocol in the future than to settle for an unsatisfactory solution and a weak Protocol.'
The Miami Group had wanted to block the inclusion of genetically engineered (GE) agricultural commodities in the Advance Informed Agreement (AIA) procedure proposed by the draft Protocol. This would have required exporters to firstobtain the express consent of an importing country, after risk assessment is done, before shipping any genetically engineered organisms (GEOs) to that country.
Developing countries insisted that all seeds must be covered by the AIA. 'A seed is a seed. Whether it is for planting or processing, it will enter into the environment. It will also have health impacts,' said Tewolde Egziabher, spokesperson for the Like-Minded Group of more than 100 developing countries.
Delegates had arrived in Cartagena at the same time that the story of the UK's Dr Arpad Pusztai hit the international media. The fact that he was persecuted for publicising the health hazards of GE potatoes in experiments with rats was as much news as the scientific findings.
Since then, there has been mounting scientific evidence of the dangers from GE crops and foods, doubts about supposed higher yields, growing public awareness in more and more countries, and revelations of flawed approval/regulatory systems in major producer countries, particularly the US.
By the time governments reconvened in Montreal in January, there was a strong political momentum for the Biosafety Protocol.
Thus it was that almost a year later after Cartagena, on 29 January of the first year of the new millennium, the Cartagena Protocol on Biosafety was adopted by more than 130 countries.
The merging of public outrage and scientific evidence set the stage for the global agreement to be concluded.

A decade's journey

The battle for a global legal agreement on biosafety started in 1990/1 when the UN Convention on Biological Diversity (CBD) was being negotiated and Malaysia introduced the biosafety issue to ensure that conservation and sustainable use of biodiversity would not be threatened by genetic engineering and GEOs. After massive resistance and intense debate, particularly from the US, a provision was successfully included to formulate such an agreement. However, the need for a Protocol had to be established first.
(The term 'living modified organism' used in the Convention and now in the Protocol, was adopted at the insistence of the US, designed to avoid treating GE organisms as a separate category of organisms with potentially distinct impacts.)
A number of developing countries, armed with critical information on potential problems of genetic engineering, were then instrumental in getting enough support to start negotiations on an international Biosafety Protocol. This coincided with the emergence of scientific evidence on the potential hazards on biodiversity, the environment and human health caused by GE crops, foods, vaccines and materials for environmental clean-up.
After further resistance from a handful of developed countries, mainly the US (the largest commercial producer/exporter), the Conference of the Parties to the CBD finally mandated the negotiations of a legally binding international Biosafety Protocol at its 1995 meeting in Jakarta, Indonesia.
In 1998, the US led Canada, Australia, Argentina, Chile and Uruguay into forming the Miami Group with the specific objective of excluding agricultural commodities from the scope of the Protocol. These were referred to in the agreement as LMOs for 'food, feed and processing' as opposed to those for deliberate introduction into the environment (e.g. seeds for planting or genetically engineered soil bacteria).
In February 1999, when negotiations were targeted to conclude in Cartagena, Colombia, the Miami Group stymied the talks, basically on this point.
The inter-governmental Biosafety Working Group met for the sixth and last time from 14 to 22 February in Colombia.
Entrenched and deeply divided positions (with the Miami Group essentially not wanting any Protocol at all) led to a stalemate. The Working Group chairman, Veit Koester of Denmark, issued his own Chairman's Text by pulling together what he considered to be a compromise. All delegations expressed their dissatisfaction with the process and the parts of the content not to their liking.
The Working Group, which had worked since 1995, was dissolved on 22 February, and the Extraordinary Meeting of the Conference of the Parties was constituted to take over the negotiations. This was chaired by Colombian environment minister, Juan Mayr Maldonado, since Colombia was host of the meeting. From then until dawn of 24 February, talks essentially centred on the issue of agricultural commodities, which the draft text had excluded. While countries could still take national actions, there would be no international framework to deal with this category of GEOs.
The Like-Minded Group of developing countries refused to accept the exclusion of commodities. It was precisely to establish an international obligation on exporters to obtain prior informed consent that a Protocol was sought.
A compromise by the European Union to include commodities but to deal with the issue only after the entry into force of the Protocol, was also rejected by the Miami

Group. The insistence by the Miami Group that the Protocol be subordinated to trade agreements under the World Trade Organisation also contributed to the breakdown of the negotiations.
In the end, the Extraordinary COP meeting was suspended. The Like-Minded Group officially put back on the negotiating table its list of issues, many of which it had been willing to surrender in order to bring the Miami Group on board the Protocol process.
Informal talks were then held in September 1999 in Vienna, under the chairmanship of Minister Mayr of Colombia. The stalling of the biosafety negotiations because of trade imperatives had frustrated many countries, with some indicating that the Miami Group should not be allowed to hold the world to ransom. The September informal meeting of biosafety negotiators saw a stronger commitment from European countries (due largely to public pressure and developments within Europe such as the moratorium on new GE crops), with the Like-minded Group remaining a united front.
Three core issues were identified and isolated to be resolved before proceeding to other areas of contention. These were: general scope of the Protocol; scope of the application of the Advance Informed Agreement procedure; and the relationship of the Protocol with other international agreements.
Because the Miami Group had been identified, even by mainstream media, as the stumbling block to the Protocol, and because of increasing consumer pressure, it agreed in Vienna to consider including commodities in the Protocol. However, it was clear that the US and Canada wanted only general information to be posted (via the Internet) of GEOs approved for commercialisation.
It was also clear that the Miami Group wanted the WTO agreements to prevail over the Protocol.

Attempted WTO takeover defeated

With increasing consumer rejection of GE foods and the legal requirement for segregation and labelling in Europe, the biosafety issue has become embroiled with trade matters.
At the same time, the desire to conclude the Biosafety Protocol was also strong amongst both developing and some other industrialised countries.
Thus, it was not surprising that a few weeks before the November Ministerial Meeting of the WTO in Seattle, Canada proposed that a Working Party on Biotechnology be set up under the WTO. The US simultaneously proposed that procedures for decision-making and disciplines under the agriculture sector be examined 'to ensure that trade in products of agricultural biotechnology is based on transparent, predictable and timely processes'. Japan proposed a forum to address biotechnology issues.
These moves were clearly designed to shift the international debate from the United Nations, where biosafety was being fought out on its own terms, to the WTO, where trade interests and rules would dominate. If those countries had succeeded, they would have paralysed the Protocol process and put biosafety squarely at the mercy of trade interests.
NGO protests and vehement rejection by developing countries blocked the move from the start when the proposals were tabled in Geneva.
Third World Network and the Centre for International Environmental Law prepared detailed assessments of the implications of the US-Canada-Japan initiatives and

disseminated them to WTO negotiators and officials in key developing countries. The wider NGO community was also alerted through the Internet, and Northern NGOs in turn galvanised their constituencies.

Protests grew, and this controversial issue became one more strand that broke the Seattle WTO meeting. A number of European environment ministers flew out to Seattle, voicing their objections and openly disagreeing with the European Commissioner for trade who was prepared to concede to the US-Canada-Japan proposals as part of a trade-off on other issues.

The failure to set up the WTO working group on biotechnology and the unprecedented civil society scrutiny of the Seattle meeting were a boost for the resumed Biosafety Protocol negotiations in Montreal in January 2000 which finally saw the adoption of an agreement.

3. The core issues in the Biosafety Protocol: An analysis

http://www.twnside.org.sg/title/core.htm

By Lim Li Lin
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Only the core issues of the Biosafety Protocol were negotiated at Montreal. The remaining provisions were basically the same as those negotiated at the earlier talks in Cartagena.

'IF you are destined to die, and you become lame, you are lucky'. So goes a Ugandan saying that was quoted by an African Minister to describe the Cartagena Protocol on Biosafety.

That, perhaps, is the best summation of the final agreement that was reached at 4.45 a.m. of 29 January in Montreal, Canada. The Protocol that was adopted by more than 130 countries was a heavily negotiated deal struck at the eleventh hour, in a desperate attempt to avoid a repeat of the collapse of negotiations at Cartagena, Columbia in February last year.

Six countries led by two major producers, the US and Canada, were opposed to an international law to regulate genetically engineered (GE) organisms. The majority of the rest of the world wanted a strong and comprehensive system to cover all GE organisms and products made from or containing GE organisms.

With every attempt at regulating big business including even voluntary codes of conduct at the United Nations, having been defeated over the past decades, the Biosafety Protocol was indeed an achievement.

But it is not a fully robust agreement.

Many concessions were made, primarily by the Like-Minded Group of developing countries, in an attempt to reach agreement in Cartagena. However, the talks collapsed due to the refusal of the Miami Group (the US, Canada, Australia, Argentina, Chile and Uruguay) to subject GE commodities intended for food, feed and processing to some form of regulation. At that point, the Like-Minded Group at the closing session, declared they were 'putting back on the table all the critical elements for a strong Protocol'. This meant that whatever compromises that had been agreed to by the Like-Minded Group in order to secure agreement were effectively withdrawn.

The concluding Montreal talks used the draft Protocol from Cartagena. That Cartagena version itself was never negotiated.

It was produced by the Danish chairman of the Biosafety Working Group which had met six times over almost three years to work on the Protocol. The last meeting was in Cartagena, and his draft was a desperate attempt to produce a Protocol from an unwieldy text with more than 670 brackets.

This itself is a peculiar feature of the Protocol.

Governments, individually or collectively (as in the Africa Group), had submitted detailed drafts of what they wanted as a Protocol. A large number of developing countries were the most active, providing the most detailed provisions because of their desire for a strong biosafety agreement. In contrast, most industrialised countries submitted general, even meaningless proposals. Many issues covered by developing countries, such as socio-economic considerations, liability and redress, and transit, were rejected by them.

Make or break on three issues

At 'informal consultations' in Vienna in September last year, the Chairman of the negotiations, Juan Mayr Maldonado, Minister of Environment for Colombia, identified three key outstanding issues to focus the consultations on.
These were the most contentious issues at Cartagena - the general scope of the Protocol; the application of the Advance Informed Agreement (AIA) procedure to GE commodities intended for food, feed and processing; and the relationship of the Protocol to other international agreements, especially the trade agreements.
The consultations were not intended to negotiate actual draft text, but to explore the possibility of reaching a conceptual compromise on the three issues. Little headway was made at the informal consultations in Vienna, apart from the display of more political will by the other countries to conclude an agreement.
When talks resumed in Montreal in January this year, negotiations turned on these three core issues. Given the political and time pressures to reach agreement at the end of the one week scheduled for the talks, negotiating groups were left with little opportunity to address other issues and provisions which were still of concern to them.
The Chairman reiterated the common understanding that 'nothing is agreed until everything is agreed', but in the end, negotiating groups were resigned to the fact that few provisions apart from the three areas (and those specific provisions with direct bearing on these three) would be re-opened for negotiation.
Thus, a large part of the Protocol was never conclusively negotiated, and remains as of the Cartagena version. The Protocol's conclusion was really dependent on the trade-off reached on the three core issues and some related provisions.

Advance Informed Agreement for first import only

At the heart of the Biosafety Protocol is the prior informed consent system since transboundary movement is the focus of the agreement. Called the 'Advance Informed Agreement' (AIA) procedure in the Protocol, this applies only to the first intentional transboundary movement of certain GE organisms for release into the environment.
The large bulk of GE organisms are not covered, including commodity seeds for food, animal feed and processing; and organisms which are merely transiting through the territory of a Party. In addition, Article 7(4) states that the meeting of the Parties to the Protocol can identify living modified organisms (LMOs) which are not likely to

have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, in order to exclude these LMOs from the AIA procedure. This 'exclusion list', however, must be agreed upon by all parties.
The Like-Minded Group of developing countries had wanted AIA to apply to the first transboundary movement of all GE organisms. This itself was a compromise, since the nature of GE organisms as living and evolving organisms requires a case-by-case approach, thus a fresh consent for each import.
This was a principle for AIA which was dropped when the major producer countries did not support it.
The AIA procedure provides for notification (the notification must include the relevant information about the LMOs) by the exporting Party to the importing Party for the first intentional transboundary movement of LMOs. This triggers a process of decision-making based on full information and risk assessment, according to the Precautionary Principle. The primary responsibility is on the exporter to notify and provide information. The basis of the risk assessment is set out in Annex III to the Protocol.
The inclusion of the Precautionary Principle is very significant. Under the Protocol's AIA procedure, this means that lack of scientific certainty regarding the adverse effects of a LMO on the conservation and sustainable use of biodiversity, taking into account human health risks, can be a basis for prohibiting an import, imposing conditions on the import, or requesting more information.
However, time limits are imposed on importing countries that are Parties to the Protocol. Thus, within 270 days of the receipt of notification by the exporter of an intended transboundary movement, the Party of import must declare its decision. This is a step back, as countries are now not bound by any time limit and considering that the European Union took almost two years to approve GE maize.
Though there must be express consent before any export can take place, the time limits may now be used against a country.
The US and industry have always demanded 'timely' decision-making, and in this respect, they have gained an advantage.
If it is a conditional consent to, or a rejection of, the import, then reasons for that decision must be given.
Decisions may be reviewed in light of new scientific evidence, and the procedure is set out in Article 12.

General scope of the Protocol

The general scope of the Protocol applies to 'the 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.'
The term 'living modified organisms' (LMOs) is used throughout the text of the Protocol instead of the more commonly used terms, 'genetically modified organisms' (GMOs) or 'genetically engineered organisms'. The term was adopted at the insistence of the United States in the course of the negotiations of the Convention on Biological Diversity, under which the Protocol was negotiated.
The US had opposed the use of the term 'genetically modified' and wanted to downplay, semantically, the connotations of the term. The US was adamant that GE food and crops were no different from conventional varieties, and should be accorded

the same treatment, as they introduced no special hazards. It was, however, always understood that LMOs are GMOs, and the definition of the term in the Protocol is clear on this point.
A key fight during the course of the five-year negotiations was for the inclusion of 'products thereof' in the scope of the Protocol. This was strongly advocated by the Like-Minded Group. 'Products thereof' would include products derived from LMOs such as tomato paste made from GE tomatoes, and soy proteins, a product of transgenic soya beans. However, 'products thereof' are now excluded entirely from the scope of the Protocol and, as such, remain unregulated internationally.
In the Cartagena draft text of the Protocol, exclusions to the general scope were contained within Article 4. Article 4(2) excluded the transboundary movement of LMOs which are pharmaceuticals for humans, and LMOs 'that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health'. These LMOs would be listed in an annex to the Protocol.
Transit (passing through the territory of a third party) of LMOs and LMOs destined for contained use were also effectively excluded from the general scope of the Protocol. Certain exceptions, however, were made, for example, in the case of unintentional transboundary movements which may require emergency measures to be taken.
At the informal consultations in Vienna, the Like-Minded Group submitted a proposal for a comprehensive scope of the Protocol. That proposal brought all LMOs under the general scope of the Protocol, with AIA required for the first intentional transboundary movement of a specific LMO intended for a specific use. Only a written notification from the exporting Party would then be required for subsequent transboundary movements.
The proposal also allowed the importing Party the right to decide whether or not to require AIA for LMOs which are pharmaceuticals for humans and LMOs destined for research in contained use.
In addition, the exporting Party would be under an obligation to inform or notify the Party of transit if LMOs will pass through the territory of that country.
This proposal was obviously unacceptable to the other negotiating groups and no detailed discussions ensued thereon.
In Chairman Mayr's 'non-paper', which was a draft proposal on actual language for the three core issues, and which was distributed prior to the resumption of negotiations in Montreal, the recommendation for the general scope of the agreement was to retain Article 4 of the Cartagena draft, with all its exclusions.
Thus, the Like-Minded Group faced an uphill battle to re-open the scope of the Protocol. This battle was crucial to the Like-Minded Group as all LMOs carry the same risks and hazards whether they are used in agriculture, medicine, or research, and regardless of whether they are classified as commodities or pharmaceuticals. An international agreement to regulate LMOs should not arbitrarily exclude any category of LMOs on any basis.

Science backed opening of scope

Fortunately, a lot of new scientific evidence had emerged since Vienna, which bolstered the arguments of the Like-Minded Group for a comprehensive scope.
A scientific report by the Institute of Science in Society, UK, which was released at the negotiations in Montreal, revealed that a huge variety of artificial genetic material

(naked/free nucleic acids) are made in the laboratory by genetic engineering biotechnology. These are being released without controls into the environment. They are used as research tools, in industrial productions and in medical applications. (Under the Protocol's loose definition of 'contained use', most of these applications would be considered to be contained.)
According to the report, these genetic material are potentially the most dangerous xenobiotics (substances which are foreign to nature) to pollute the environment as nucleic acids can be taken up by all cells to multiply, mutate and recombine indefinitely. There is abundant evidence that extraneous nucleic acids taken up can have significant and harmful biological results, including cancer in mammals.
Another report on the environmental risks of genetically engineered vaccines, published by the Directorate for Nature Management, Norway, was also released in Montreal. The report concludes that 'from an ecological and environmental point of view, many first generation, live, genetically engineered vaccines are inherently unpredictable (and) possibly dangerous' and should not be used on a large scale until the problems identified have been addressed and clarified.
However, in practice, the risks are considered non-existent from the medical and scientific points of view simply because no investigations addressing them have ever been made.
In the final text, the general scope of the Protocol in Article 4 provides for a comprehensive scope, covering all LMOs, and does not specifically exclude any category of LMOs.
However, the two articles that follow (i.e. Article 5 and 6) limit the application of the Protocol with regard to pharmaceuticals, transit and contained use. These are new compromise provisions that only surfaced in Montreal, and an improvement on the Cartagena text.
Importantly, the provision to exclude from the entire scope of the Protocol, LMOs that are 'not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health' was dropped, closing a very large loophole. However, it must be noted that Article 7(4) could potentially exclude some LMOs, on the same basis, from the AIA procedure.

Pharmaceuticals: In and out

Article 5 states that, 'Notwithstanding Article 4 and without prejudice to the right of a Party to subject all LMOs to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of LMOs which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations'.
LMOs which are pharmaceuticals for humans include GE vaccines and insulin which, according to growing scientific literature, have environmental and health risks.
In other words, some LMOs which are pharmaceuticals for humans may be excluded entirely from the scope of the Protocol depending on whether or not they are addressed by other international agreements or organisations. But a lot depends on the interpretation of the terms used in this provision, for example, 'addressed' and 'relevant'. The former can mean anything, including legal regulation, codes of conduct or guidelines and standards.
It is envisaged that 'other international organisations' is meant to refer to the World Health Organisation (WHO).

However, the WHO does not deal with GE pharmaceuticals as such. Furthermore, it only sets standards for human health and safety and does not take into account impacts on the environment and biological diversity.
In any case, it is merely a standard-setting body which prescribes standards that members are encouraged to adopt.
Ceding jurisdiction from a legally binding international agreement to such a non-legally binding standard-setting organisation would result in a much lower obligation on Parties with respect to LMOs which are pharmaceuticals for humans. It also leaves open the question of whether or not standards which have been or might be set by such international organisations or any other international agreements are able to or will take into account the special hazards and risks of LMOs which are pharmaceuticals for humans.
In addition, leaving some LMOs which are pharmaceuticals for humans out of the entire scope of the Protocol also means excluding this category of LMOs from a liability and redress framework. (The framework for liability and redress under the Protocol is meant to be concluded within four years from the entry into force of the Protocol.)
So, we now have a situation where the regulation of some GE pharmaceuticals falls entirely under other international agreements and organisations which would set standards for domestic laws. The remainder will be covered by the Protocol.
This is a clear result of the resistance by some industrialised countries to protect the interests of the pharmaceutical sector from comprehensive international rules.
By separating the strands of biosafety oversight, there is a retreat from the rationale of the Protocol in the first place: a hard-fought recognition that there was no international legal regulation of genetically engineered organisms. While there is a role for the WHO, the Protocol should be the overarching legal standards-setting forum.
Yet, a victory to some degree was achieved by the Like-Minded Group in that there is no total exclusion. The debate also emphasises the urgency for national and regional regulation of this group of GE organisms and materials (see box).

Why GE pharmaceuticals have to be regulated Potential Environmental and Health Hazards These constructs intended for therapeutic and prohylactic use are general expression vectors and LMOs and carry exactly the same environmental and health risks as any other constructs and LMOs.	
Examples	Rationale
Edible vaccines (i.e. potatoes, bananas)	These are LMOs by definition
Viral vaccines	Viruses are 'organisms' as defined in Protocol and hence viral vaccines are LMOs
Naked viral genome vaccines	Naked viral genomes are often more infectious than the intact viruses

Naked viral vectors for gene therapy	They are intended to be incorporated into the genome of human cells and be replicated
Naked DNA vaccines & vectors	They are known to incorporate into cellular genomes to be replicated, whether intended or not
Naked nucleic acid vectors and vaccines	RNA can be reverse-transcribed into cDNA and become incorporated into cellular genomes to become replicated. RNA is the genetic material of the majority of viral families, and RNA recombination is much more common than previously thought
References: Unregulated Hazards: 'Naked' and 'Free' Nucleic Acids, Ho, M.W., Ryan, A, Cummins, J, and Traavik, T, ISIS-TWN Report, Jan 2000. An Orphan in Science: Environmental Risks of Genetically Engineered Vaccines, Traavik, T, Directorate for Nature Managemant, Norway, 1999.	

Transit countries win some protection

Article 6(1) on transit states that, 'Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of LMOs through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3 of this Protocol, regarding the transit through its territory of a specific LMO, the provisions of this Protocol with respect to the AIA procedure shall not apply to LMOs in transit'.

What this means is that the AIA procedure, a system of prior notification by the exporting Party to the Party of import which triggers a decision-making process by the importing Party based on risk assessment and the Precautionary Principle, will NOT apply to LMOs that are merely passing through the territory of a third party.

The regulation of the transboundary movement of LMOs in transit will be left to domestic laws and regulations, and the Protocol does not set internationally binding minimum standards.

All other aspects of the Protocol which are unrelated to the AIA procedure will still apply. However, in effect, few operative provisions in the Protocol will apply to LMOs in transit, since the Protocol deals almost exclusively with the transboundary movement of LMOs from one Party to another, and the AIA procedure is at the heart of the Protocol.

The substantive provisions that do apply to LMOs in transit include risk management, unintentional transboundary movements and emergency measures, and liability and redress. Since documents accompanying transboundary movements of LMOs now require LMOs to be identified, transit states can have access to this important information as part of the normal access to such documents.

Again, though transit states do not have an international right to advance notice and prior consent as they had wanted, they obtained more than in the Cartagena draft. The mood then was to effectively exclude transit.

Contained use which is uncontained

Article 6(2) on contained use states that, 'Notwithstanding Article 4 and without prejudice to any right of a Party to subject all LMOs to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the AIA procedure shall not apply to the transboundary movement of LMOs destined for contained use undertaken in accordance with the standards of the Party of import'.

The language in this provision is highly ambiguous, particularly the last proviso, 'undertaken in accordance with the standards of the Party of import'. One reading of the phrase 'standards of the Party of import' could be domestic standards for contained use, for example, certification of a laboratory or other installation or facility as having met standards of containment, which may have nothing to do with the approval procedure for imports. These standards may even be non-legally binding guidelines.

This reading would mean that LMOs that are being exported for contained use will be exempted from the AIA procedure by the mere fact of existence of domestic standards on contained use.

Exempting LMOs for contained use from the AIA procedure on the basis that there are such domestic standards would go against the whole rationale of biosafety regulation for the transboundary movement of LMOs. This would leave developing countries, especially those without the necessary laws or biosafety capacity, in a vulnerable position when the reverse is needed, i.e. that the responsibility for care starts with the exporter.

Another reading of the phrase 'standards of the Party of import' could mean domestic regulatory procedures which includes provisions for the import of LMOs for contained use. This reading is a rational interpretation of this provision.

In other words, the AIA procedure will not apply to the transboundary movement of LMOs destined for contained use, where there are procedures laid down by the importing Party for the import of LMOs for contained use, in addition to biosafety standards for the actual use, and these standards must be adhered to by the exporting Party. If an importing Party has not set such standards for contained use, the AIA procedure will have to apply to transboundary movements of LMOs destined for contained use in that country.

Unfortunately, a fundamental problem lies with the definition of 'contained use' itself. In the Protocol, 'contained use' means 'any operation, undertaken within a facility, installation or other physical structure, which involves LMOs that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment'.

This is an extremely loose definition that allows many kinds of deliberate releases into the environment to qualify as contained use. For example, open field trials with fencing or other physical barriers; caged transgenic fish or other aquatic LMOs in ponds or other marine environments; and the deliberate release of liquid and solid wastes of laboratories creating GE organisms, would qualify as contained use under the Protocol (see box).

Why 'contained-use' regulation must be tightened up

THE definition of 'contained use' in the Biosafety Protocol includes many kinds of

deliberate release (see Box 1). The current regulation of contained use, as for example in the EU Contained Use Directive, actually includes 'tolerated releases' which should be prohibited in the light of existing scientific knowledge (see Box 2). In short, 'contained use' is not contained.

Regulatory oversight on contained use was established in the 1970s largely on the basis of assumptions, every one of which has been contradicted by scientific findings since. The major inadequacy is that the regulation takes no account of the ability of transgenic DNA and RNA to persist in all environments and to transfer horizontally to unrelated species. Furthermore, biologically 'crippled' strains of transgenic microorganisms, assumed not to survive in the environment, are now known to persist or to proliferate. The ecological impacts due to potential changes in the composition of natural microbial populations are unknown and unpredictable. In all cases where the release of transgenic microorganisms into the environment has been monitored, effects on the composition of soil microbial communities have been found.

Instead of tightening the regulation to reflect the new knowledge, and in accordance with the Precautionary Principle, there has been progressive deregulation of 'tolerated releases' of potentially the most hazardous LMOs and transgenic DNA.

It is imperative that the regulation of contained use is tightened up to reflect existing knowledge and in accordance with the Precautionary Principle.

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Box 1: Examples of 'contained uses' in the Biosafety Protocol which are deliberate releases

* Caged transgenic fish or other aquatic LMOs in open ponds, lakes and marine environments
* Vacinations with transgenic viruses and naked nucleic acid vaccines
* All forms of gene therapy
* Xenotransplantation using transgenic animal organs
* Open field-trials with fencing or other physical barriers
* Transgenic organisms enclosed in cages or other containers and destined for deliberate release
* Liquid and solid wastes of transgenic livestock contained in the laboratory
* Liquid and solid wastes of laboratories creating transgenic organisms destined for deliberate releases

Box 2: Examples of hazardous 'tolerated release' from contained users

* 'Diluted' air and liquid streams of live transgenic micro-organisme greatly in excess

of the minimum infective dose of virulent bacteria such as E.coli 0157
* Undiluted liquid wastes from commercial and other users containing live transgenic microorganism not considered to be pathogenic, though we now know that non-pathogens can be converted into pathogens by acquiring unit-blocks of virulence genes or 'pathogenicity islands'
* Solid wastes of killed transgenic microorganisms and viruses, whether pathogenic or not, with large amounts of free or potentially free transgenic DNA containing antibiotic resistance genes, virulence and other genes which are likely to transfer horizontally to other microorganisms in the environment and create new bacterial and viral pathogens
* Solid wastes of killed cell cultures containing pathogenic viruses or transgenic DNA with viral oncogenes and other genes with harmful biological effects which may transfer horizontally to human cells and contribute to cancer
* Amplified nucleic acid sequences constructs, plasmids, transposons, artificial vectors which are known to be invasive to genomes of all cells

This loose definition of contained use may also create a 'double exclusion' for LMOs which are pharmaceuticals for humans. Even though some LMOs which are pharmaceuticals for humans may fall within the scope of the Protocol, they may nevertheless still be excluded from the AIA procedure on the basis that they are destined for 'contained use', i.e. that the human body qualifies as contained conditions. GE pharmaceuticals that are consumed by humans are, however, deliberate release into the environment as human waste can still contain genetic material originating from the GE pharmaceutical.
Parties may and should set higher domestic standards for contained use than that provided for under the Protocol. As a minimum, what is effectively a deliberate release into the environment should be clearly considered as such and thus should be subject to the full AIA procedure.
The right to set higher domestic regulatory standards is entrenched in Article 2(4), which states that nothing in the Protocol shall be interpreted as restricting the right of a Party 'to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol' and is in accordance with its other obligations under international law. This would also extend to formulating definitions in the Protocol which are more appropriate for biosafety.
As with transit, all other provisions in the Protocol, apart from the provisions relating to the AIA procedure, will still apply to LMOs destined for contained use. But again, the exemption of LMOs for contained use from the AIA procedure shifts the regulation of the transboundary movement of such LMOs to national laws and does not set internationally binding minimum standards. For developing countries, this means the burden of care is fully on their shoulders.

LMOs intended for direct use as food, feed or for processing

The main disagreement that sank the negotiations in Cartagena last February was the refusal of the Miami Group (almost all are major exporters of genetically engineered commodities) to accept any measures that would hinder the trade of GE commodities intended for food, feed or processing (LMO-FFPs).

LMO-FFPs are clearly within the general scope of the Protocol, but the Miami Group was opposed to the application of the AIA procedure to LMO-FFPs. These make up more than 90% of the Miami Group's exports of LMOs.

Biosafety Protocol - main provisions

THE Biosafety Protocol is a historic agreement, being the first time that international law recognises GE organisms as distinct and inherently different thereby requiring a separate regulatory framework.

Only the core issues were fully negotiated in Montreal, while the rest of the Protocol (which was drawn up in Cartagena) was accepted as part of the package without further negotiation. The Protocol provides minimum standards, and reaffirms a government's right to take national action.

The main provisions are:

* * Advance Informed Agreement:

The Advance Informed Agreement (AIA) procedure applies automatically to the first shipment of LMOs to be introduced intentionally into the environment, with decisions to be made according to the Precautionary Principle. The obligation is on the exporter/exporting Party to give notice to the importing Party, thus triggering the AIA. Decisions relating to approvals of LMOs under the AIA must be preceded by risk assessment. The Protocol specifically provides that an assessment can also be required under domestic law for subsequent shipments. Risk assessment criteria are listed in the Protocol.

Parties must then implement risk management measures to regulate and control risks identified in the risk assessment.

* An information exchange system, basically on the Internet, is provided separately for LMOs for food, feed or processing instead of the AIA.

* GE pharmaceuticals for humans are covered by the Protocol, except where they are dealt with in other international agreements or organisations.

* No AIA for LMOs for 'contained use' and LMOs in transit. This means there is no automatic international obligation to inform the importing Party of a specific movement.

** Identification and segregation:

a) Documents accompanying transboundary movements of LMOs for intentional introduction into the environment and those for contained use, must identify the organisms as LMOs. b) Documents accompanying LMO-FFPs need only to state that the shipment 'may contain LMOs'.

* * A system for liability and redress where the transboundary movement of LMOs causes damage or harm to biodiversity and human health, is to be worked out within four years after the Protocol comes into force.

** Parties can enter into 'side agreements' on issues under the Protocol, as long as these are consistent with the objectives of the Protocol and do not result in a lower protection than that provided for by the Protocol. There are fears that this may still weaken the Protocol as Parties may be tempted to avoid or dilute certain obligations through these agreements. This provision was not fully negotiated even though many developing countries did not want it at all.

** Parties can trade with non-Parties, under agreements consistent with the objectives of the Protocol. The major concern here is that a powerful non-Party, such as the US, may insist on weak agreements. This will amount to non-Parties enjoying the benefit of trade without the responsibility of biosafety.

** Parties are obliged to promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs by, inter alia, providing access to information on LMOs that may be imported, consulting the public in decision-making processes regarding LMOs and making the results of such decisions available to the public.
** In making import decisions, Parties can take into account socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biodiversity, especially with regard to the value of biological diversity to indigenous and local communities. However, this has to be consistent with their international obligations. Thus, the issue of the relationship with the WTO agreements rears its head again.
** In cases of unintentional transboundary movements of LMOs (e.g., an accident) which may cause harm, there are obligations to alert affected Parties and to take emergency measures.
** Information submitted to a Party of import, as required by the Protocol, can be claimed to be confidential by the exporter. Thus the public's right to know is restricted. However, the following information cannot be considered to be confidential: name and address of the exporter; general description of the LMO; summary of the risk assessment and any emergency response plans.
** Parties can apply the Precautionary Principle, i.e., where there is no scientific certainty after a risk assessment is carried out, a Party can take the necessary steps to stop or restrict the import of an LMO. This is because an LMO, once released, can multiply and mutate, and cannot be recalled. able.

But as the Like-Minded Group explained at the consultations in Vienna, there is no difference between a LMO earmarked for planting and a LMO-FFP, and they have identical impacts on human health and the environment. Particularly in many developing countries, given the lack of capacity for enforcement, regardless of what a seed is intended for, such a distinction may not be able to be maintained once it enters the country. Hence, only a system 'as robust' as the AIA procedure would be acceptable to the Like-Minded Group for the regulation of LMO-FFPs.
(A recent study commissioned by the UK Ministry of Agriculture, Fisheries and Food concluded that DNA is not degraded under most commercial processing conditions, and that current animal feed is likely to contain substantial amounts of undegraded DNA. Thus, the secondary horizontal transfer of intact antibiotic resistance genes to bacteria from transgenic crops processed into feed cannot be ruled out, and other components of transgenic DNA may also have significant health impacts on livestock and human beings up the food chain.)
A proposal put forward by the Compromise Group - Switzerland, Norway, Mexico, Japan and South Korea (Singapore only joined the Compromise Group in Montreal) - in Vienna formed the basis of the discussion for an 'alternative AIA' which would apply to LMO-FFPs. However, after some headway made in these discussions, the Miami Group was forced to admit that it was not prepared to accept any new obligations that might limit or prevent exports of LMO-FFPs. They made it clear they were unwilling to cause any major disruption to their agricultural trade system. As such, they were only prepared to discuss mechanisms based on information sharing and insisted that the only way to address the range of views on LMO-FFPs is through domestic regulatory frameworks. This declaration effectively stymied the discussions on this issue in Vienna.

Pressure on the Miami Group to agree to some system for LMO-FPPs continued, and in Montreal a procedure was finally agreed upon. Article 11 requires a Party to inform all other Parties of an approval for domestic use, including introduction into the market, of a LMO-FFP that may be subject to transboundary movement.
This information must be communicated to the Biosafety Clearing House (basically a website administered by the Secretariat to the Convention on Biological Diversity) within 15 days of the final decision and, at a minimum, must include the information specified in Annex II. This information is less than that required for the AIA procedure. Although additional information may be requested, it falls on the potential importing Party to know what to seek. A better approach would have been to at least require the same information as in the AIA.
If a Party does not have access to the Clearing House (e.g. due to lack of Internet facilities), it must inform the Clearing House in advance. In such a case, the relevant information has to be provided in writing to the national focal point of that Party.
From there, a Party may take a decision on the import of that LMO-FFP under its domestic law. This procedure applies only to the first import of LMO-FFPs.
In the absence of a domestic regulatory framework, developing countries and countries in transition may follow the procedure in Article 11, after it makes a declaration in the Clearing House to do so. Again, this procedure applies only to the first import of the LMO-FFP. A Party can, before deciding on the first import, undertake a risk assessment in accordance with Annex III of the Protocol, which sets out the basis for risk assessment.
But a decision must be made within 270 days from the Party's declaration to the Clearing House that it will be making its decision as provided for in the Protocol for developing countries and countries in transition. (But developing countries and countries in transition are not bound, under the Protocol, by the 270-day time limit if they are applying their domestic laws and regulations.)
For this category of countries, however, express consent for the import of LMO-FFPs is still required.
This system for the transboundary movement of LMO-FFPs is in no way as robust as the AIA procedure for LMOs for intentional introduction into the environment. Rather, it is what the Miami Group wanted - for the transboundary movement of LMO-FFPs to be regulated through domestic regulatory frameworks and for the international framework to only lay down mechanisms for general information sharing.
The special provision for developing countries and countries in transition only applies so long as these countries do not have domestic regulatory frameworks. Though still lacking, the AIA procedure at least provides for notification by the exporting Party to the importing Party for the first intentional transboundary movement of LMOs. This triggers a process of decision-making based on full information and risk assessment, according to the Precautionary Principle. There must be express consent before any export can take place. The primary responsibility is on the exporter.
Notification of domestic approvals via the Clearing House mechanism shifts the burden to importing Parties to initiate procedures for assessing whether or not a particular LMO-FFP should be admitted into its territory. There may be a considerable time lag between the domestic approval and the actual transboundary movement of that LMO-FFP, if the LMO-FFP is even finally exported. A potential importing Party cannot even be sure whether or not the LMO-FFP will actually be exported to its country. All this increases further the burdens of finance and capacity of potential importing Parties, which are largely developing countries.

This system also basically shifts the regulation for the transboundary movement of LMO-FFPs to domestic regulatory frameworks. It does not set internationally binding minimum standards. Nevertheless, like the AIA procedure, it does operationalise the Precautionary Principle in import decisions.
Article 11 assumes that developed countries have adequate domestic regulatory frameworks in place, which is not necessarily the case. On the other hand, developed countries are not bound by the 270-day time limit.

Segregation and labelling

In the final hours of negotiations in Montreal, the Miami Group held out to the last on the provision that would most severely disrupt their exports of LMO-FFPs. Article 18 on handling, transport, packaging and identification became the final bargaining chip for whether the Protocol would be concluded or not. The Miami Group was only willing to accept that LMO-FFPs would be identified in shipping documents as 'may contain' LMOs and as not intended for intentional introduction into the environment. All the other negotiating groups had no choice but to give in to this demand in order to see the Protocol finally concluded.
In addition, a further clause was added - '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 then two years after the entry into force of this Protocol'. This is expected to be on the agenda of the meeting to be hosted by France at the end of this year as part of the preparations to implement the Protocol.
What this provision now means in effect is that exporters will not have to segregate GE commodities from non-GE commodities, as potentially, all commodities may contain LMOs. But as public pressure and consumer demand grows for segregation and labelling, this final trump card merely stalls an inevitable process.

Relationship with WTO

The draft Cartagena text contained a provision that would have effectively subordinated the Protocol to other international agreements, primarily the World Trade Organisation (WTO) agreements. Article 31 stated that, 'The provisions of this Protocol shall not affect the rights and obligations of any Party to the Protocol deriving from any existing international agreement to which it is also a Party, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity.'
Under international law, the interpretation of treaties is governed by the Vienna Convention on the Law of Treaties. The rule is that a later agreement supersedes an earlier one, and an agreement on a specific subject prevails over a general one. Since the Biosafety Protocol comes after the trade agreements and deals specifically with biosafety, in a conflict of laws, the Protocol has to be given priority.
Having a savings clause in the Protocol would have meant pre-empting the application of the Vienna Convention in interpreting the relationship of the Protocol to other international agreements. Even then, the Miami Group had wanted to delete the qualifying phrase which referred to harm or threat to biodiversity. The EU favoured a clear provision on the precedence of the Biosafety Protocol, while the

Like-Minded Group said no provision was needed as the Vienna Convention on the Law of Treaties would apply.
In the September meeting in Vienna, the discussions on this issue went round in circles, and finally concluded with four statements of agreed concepts. Based on that, Minister Mayr proposed a Chairman's solution to delete Article 31 and add the following in the preamble to deal with this issue - (Recognising that there are other international agreements relevant to sustainable development with rights and obligations; (Recognising further that trade and environment agreements and policies should be mutually supportive; (Emphasising that this Protocol and other international agreements are of equal status.
In the final text, Article 31 was deleted and the following language was added to the preamble: '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'. This language relegated to the preamble carries far less weight than a substantive provision. Preambular language in international agreements, however, sets the framework for their interpretation. The effect appears to be a return to the general international law of interpretation.
However, this position is still vulnerable, as there are specific provisions in the Protocol that also refer to other international obligations. Article 2(4) on the right of Parties to take more protective domestic biosafety action qualifies this right - such action has to be 'in accordance with its other obligations under international law'. The provision on socio-economic considerations (Article 26) also makes reference to the other international obligations of Parties.
In the end, a lot will depend on the forum where any dispute is arbitrated. The WTO need not be the only forum where biosafety disputes are settled, as the CBD itself provides for a dispute resolution procedure, which is also applicable to the Protocol. Therefore concerned countries should, as a matter of priority, explore ways and means of defending the integrity of the Protocol in its implementation stages.

Dispute options under the CBD need to be further explored.

However, the US, the largest producer of GE organisms and products, cannot be a Party to the Protocol as it is not a Party to the CBD. Since it is unlikely that it will join the CBD, any dispute initiated by the US will ultimately be brought to the WTO, where dispute settlement decisions are increasingly in favour of the interests of big corporations and powerful countries. If this trend continues without urgent reform of the WTO, the embryonic Protocol will be stillborn.

Conclusion

Viewed from the perspective of biosafety and what most developing countries had wanted, many key issues had been compromised, and even lost. On the other hand, industry backed by a few governments had not wanted any Protocol at all, and fought against crucial principles and issues. They have had to accept the beginnings of international legal regulation.

The inclusion of the Precautionary Principle for decision-making on imports is a significant step forward. This was adamantly rejected by industry until the end. So, while the Protocol may be starting with a limp, it is nevertheless the first step towards a system that can be strengthened. The spreading and intensifying of public awareness, more open scientific debate and political commitment by more governments can well nurture a robust international legal framework.

4. The way forward

http://www.twnside.org.sg/title/way.htm

by Chee Yoke Ling

Now that the Biosafety Protocol has been negotiated, what are the steps that can be taken to fill in the gaps left by the Protocol? Some key dates and suggestions for consideration are set out below.

THE Protocol will be opened for governments to sign when the Conference of the Parties to the CBD meets in May in Nairobi.

Only Parties to the CBD can be Party to the Protocol. After signing, 50 countries have to ratify the Protocol for it to be enforced.

Since the Protocol provides a framework of minimum standards, national governments should formulate domestic laws, based on the Precautionary Principle, that ensure the highest standards of biosafety.

Since the Protocol is not comprehensive in scope, does not cover all the necessary aspects of biosafety regulation, and focuses only on some aspects of transboundary movements of GE organisms, domestic laws should strive to fill the gaps.

While countries always had the sovereign right to regulate GE organisms and products at the national level, the Protocol now establishes an international legal framework as well.

France will host a meeting to prepare for the first meeting of the Parties by the end of 2000. Procedures for segregation and identification of LMO-FFPs are expected to be on the agenda.

These details have to be worked out within two years after the entry into force of the Protocol.

That meeting should also initiate the development of a liability and compensation system. It is provided that an agreement should be reached within four years after the Protocol comes into force.

The Ad Hoc Task Force on GE food set up under the WHO/FAO Codex Alimentarius (a body that sets the food safety standards for voluntary adoption by national governments) will meet in mid-March in Japan, and the General Principles body will meet in June in Paris. The precautionary Principle is expected to be central to the March meeting. The June meeting will specifically focus on the Precautionary Principle.

Developing countries should also take measures to ensure that their interests are adequately considered in the ongoing discussions at the Organisation for Economic Cooperation and Development (OECD). They should also monitor the bilateral discussions between the European Community (and its member States) and the United States relating to GE organisms and products under the Transatlantic Economic Partnership dialogue. These were started to deal with the trade impasse between the two blocs.

At a meeting with European environment ministers and the EU Commissioner for Environment during the Montreal negotiations, NGOs were told that the dialogue will take the form of a forum, conducted with transparency. Interested NGOs from the countries concerned will be able to monitor future discussions. Environment and

health officials will also be involved, and any transatlantic discussion will presumably not be confined to trade officials.
It would be vital for the South - governments and NGOs - to closely follow these developments, and actively participate to ensure that biosafety and related socio-economic considerations are safeguarded in decision-making regarding GE organisms and products.

5. Biosafety negotiations – flashbacks

http://www.twnside.org.sg/title/flash.htm

Tewolde Berhan G Egziabher,
the spokesperson of the Like-Minded Group (Group of 77 & China) at the Montreal and Cartagena talks and who has been involved in the biodiversity negotiations since the Nairobi Conference in 1991, reflects on his experience as a negotiator from the Third World at the biosafety talks.

Old friends and new issues

FOR me, it all started in 1991. The Convention on Biological Diversity (CBD) was being negotiated. I was in Addis Ababa University, a biologist busy with academic activities - teaching, research, academic and research administration - all noble, all universal, all easy to idealise, or even idolise.
But a good friend of mine, Dr Melaku Worede, woke me up rudely. He did not mean to. He headed our crop genetic resources centre (gene bank) then. The government had asked the gene bank to be involved in the CBD negotiations. Dr Melaku said that my knowledge and experience made me suitable and he asked me to go to Nairobi to represent Ethiopia in the negotiations. I accepted. I did not know that I was committing myself to a decade-long, possibly longer, fight on trade in life.

Some are more equal than others

Nairobi confronted me with the reality of naked power politics behind human life in the real world and my idealised global government.
First shock: humanity consisted of 'white' faces, with a sprinkling of 'black', and hardly any 'yellow': global ethnic distribution and representation in the United Nations system were (and still are) obviously negatively correlated!
On my first day in Nairobi, I needed one page of a document photocopied. I went to an office which seemed to deal with documents. I dared get in. I was nearly physically pushed out by a white man and told that such services were not given to delegations. As I was being ushered out, two delegates, both white and using a distinctly North American accent, came in, and they were given a wad of photocopied material together with their original document, which they had obviously left for photocopying. We all belong to the United Nations, I thought, but some more so than others, and I would always be one of the 'others'!
Seven years later, as Head of the Ethiopian Delegation, I submitted to the CBD Secretariat our view on the interaction between the CBD and trade-related aspects of intellectual property rights (TRIPS) to be distributed at the Fourth Conference of the Parties (COP IV). When I arrived in Bratislava, I discovered that it had not been distributed. I asked the Secretariat. A black man told me that it was because what I had asked to be distributed was a government position and that it was not the Secretariat's business to distribute such information. I had flipped through the information documents already produced and distributed by the Secretariat.
They had extensive suggestions by specific OECD (Organisation for Economic Cooperation and Development) countries - all white: it is not the colour of the face

that confronts you that counts. But seven years had made me wiser. I am sorry to say that I resorted to blackmail: I told my 'black brother' that I accepted his explanation, but that, also, I would scrutinise the information documents and if I found any government's position written in them, he would be in trouble.
He scratched his head and said that he would distribute our document. He did, though he took an inordinately long time, and produced only a token number of copies. We had to supplement that by paying for photocopying services: even the UN system impoverishes the poor more.
You must know, and make sure that they know you know. Even at the United Nations truth emanates from the OECD, unless otherwise proven beyond any reasonable doubt. I learnt of this fact during my first day of negotiations for the CBD.
It was then still being doubted in many august quarters that indigenous and local communities are innovators in the conservation and sustainable use of biological diversity. The only explanation I could find then was that the local and indigenous communities do not belong to the OECD.
I also realised OECD members were stating that modern biotechnology (meaning genetic engineering) was important for the conservation and sustainable use of biological diversity, and their statement was being accepted. Except for keeping parts of organisms alive through tissue culture, with its attendant unwanted genetic changes through somaclonal variation, I could not see then, and I still cannot see now, how modern biotechnology can help in the conservation and sustainable use of biological diversity - but I can visualise many other possibly useful applications! I think that they were, and still are, being OECD-hoodwinked. No wonder then that the US delegation wanted intellectual property rights (IPRs), and it was accepted, but we wanted Community Rights, and we could not manage even to get the self-evident Farmers' Rights included in the CBD. Article 8(j) was as far as we could go then.
But a concerted fight works even from non-OECD quarters, and the situation has now, in 2000, changed markedly. This is because we knew, and we made them know that we knew. Even the substantial equivalence of genetically modified organisms - I am not sure if it was so called at the time of the negotiations in Nairobi, but it was so explained by the US delegation - has at last now been shown to be untenable.
Knowing and letting it be known that you know works within a non-OECD context as well, among 'allies' as well. For example, as leader of the African Group in the biosafety negotiations, my heaviest burden early on was the South African delegation.
It all started in 1996. The African Group in the first biosafety negotiation session in Aarhus, Denmark, had asked the Ethiopian delegation to prepare an African draft protocol.
We did. The Third World Network helped us in various ways to setup an African review workshop to modify, as need be, and adopt the draft protocol.
The South African delegation came to black Addis Ababa, all white, representing a multiracial government. It was headed by a man bent on embarrassing us on the ground that we were poor and dirty. His first move was to look at our humble hotel accommodation and state that he would go to the Hilton Hotel at his own expense.

Destructive

More importantly, he adopted progressive-sounding terminology while invariably twisting the issues towards unregulated free trade in genetically modified organisms

and their products. I knew he wanted to disrupt. I made him know that I knew this. He did not want to be openly labelled as disruptive. He knew that his government would find out and would not be pleased. I knew, therefore, that he would not openly and officially declare a stand different from an African position.
He kept filibustering our meetings. Many of my other African colleagues wanted his delegation to break rank with us. I managed to convince them to be patient because we needed a common African front. I knew him. He knew that I knew him.
Finally his government also saw through him and withdrew him from its delegation: relief!
Sometimes it is useful that 'they' think that you do not know. When we presented the African Draft Protocol, many, even the venerable journal Nature, I am told, believed that some NGO had written it for us. Some said it was Greenpeace. Others, more generously inclined towards the South, thought it was the Third World Network. Other culprits were also suggested. They sniggered at us. Our inclusion of resuscitated organisms as sources of risk only made us look even more loony in their eyes.
Nobody but we ourselves wrote our draft, though we benefited from many comments. As for resuscitated organisms, we still believe that they are risky. We are really not thinking of Jurassic Parks, as a delegate from Costa Rica once remarked. Check against OECD scientific literature, e.g. the journal, Science. You will find them covered there.
But their belittling us gave us a headstart in getting unobtrusively united. By the time they knew that we really knew what we were saying, we had cemented an African unity of purpose, and blackmail and intimidation directed at individual delegations in order to break up our unity always backfired.
Even as late as the ill-fated negotiations in February 1999 in Cartagena, the chief negotiators of the Miami and European Groups underestimated us. They were so pre-occupied with sealing a deal between themselves that, in the now-infamous roundtable negotiations of the last few days, I became certain that they did not think I was even following the 'intricacies' of their transactions. When it looked as if they were about to finalise their deal, I pointed out that that deal was worthless since I could not join in it, and that they had to deal with me as well, not only among themselves. They had both to admit that was right. When we left the roundtable, one of them commented to me that I did not know what was good for us.
I remember physically fighting only three times in my life, and that was before the age of 12. But I felt like knocking him down. Of course he was bigger than me and it would have been a futile gesture. It would have been a futile gesture even if he were a midget. So, I only said 'shut up' and left him. To be fair, he took no noticeable offence. And I realised afterwards that neither did I take lasting offence.
In the informal consultations in Vienna in September 1999, the Like-Minded Group pointed out that the scope of the Protocol as proposed in Cartagena, in which most types of genetically modified organisms or GMOs (those for pharmaceuticals, research, contained use, in transit) were made to fall outside the Protocol except for 2-3 specified articles, left so little in the Protocol that it made it an almost empty dummy. The OECD delegations hid behind the facade that, if we started going back on the scope as stated in Cartagena, we could never finish, and that, therefore, the Like-Minded Group was being unreasonable.
But we had never accepted the Cartagena scope as adequate. We pointed out that, for example, the article on the Meeting of the Parties was not included in the 2-3 specified articles, and that, as the scope stood, the Meeting of the Parties could never discuss pharmaceuticals, research, contained use or transit of GMOs. This first

produced silence. Then it led to the acceptance that we would have to enumerate all the articles that would not apply (negative listing) or all the articles that would apply (positive listing) to each category of GMO. It took a whole day of messy debate to show that the listing would remain too messy to maintain whichever way we approached it. This forced everyone to grudgingly accept that the exceptions to consider concerned only the Advance Informed Agreement (AIA) procedure, as we had always insisted, not the whole scope.
When delegations hide murky thinking or murky intentions behind a semblance of neatness, it is good to stir up the dregs. But how did we manage to stir them up? We were delicately treading with the Miami Group on negotiating commodities: they had to 'humour' us. The Compromise Group saw the sense we were aiming at, though they did not think that the advantages were worth the possible delay. The Central and Eastern European Group were not sure at first, but they found our Meeting of the Parties argument compelling.
The European Group knew that we knew that they wanted no exploration of hidden motives; and they knew that we meant business in leaving no room for hidden motives. Everybody knew that we knew that they knew what was wanted, and they preferred it all to remain unstated. So they could not stop us from revealing how confused the article on scope was. As a result we now have a comprehensive scope (Articles 4, 5 and 6), though still with more exceptions to the AIA procedure than we had originally wanted.

You must have friends

We had friends. Africa is financially so poor that the African Group would not have functioned, let alone played an important role in uniting the South, without friends. But we soon made friends who filled in our gaps. For example, the Third World Network gave us critically needed assistance, and facilitated critically needed interactions, both South-South and South-North. African telecommunications are so poor that had it not been for the Gaia Foundation of London acting as an information relay station among African delegations, we could not have been effective. And had our many, many other friends (too many to enumerate here) - governmental, non-governmental, academic and research - all over the world not helped, we would not have managed to stay as informed and as effective as we did.
But the African Group was not a juggernaut organisation as claimed by some. It was merely a small but clear flame protected from gusts by friendly hands from all over the world. It helped that we had this self-generating huge support network while our 'opponents', at least at first, saw us as poor, isolated and ignorant.
Perhaps the most exciting friendships were formed across barriers. I really grew to love some of my friends from the Miami Group. 'Love' has many levels and hues. Being opponents makes us explore one another more keenly than even being friends. I would love having the majority of the Miami Group delegates as friendly neighbours with whom to keep exchanging mundane ideas of daily routine over coffee!

Do you ever know your limits?

In Cartagena in February 1999, the Ad-hoc Working Group on Biosafety wound up its work in failure. It was early morning.

For several days, I had not been sleeping for more than three hours out of 24. I was finding it difficult to imagine managing to reach my hotel before falling asleep. And then somebody, I think that she/he/it was from the Secretariat, patted me and told me that I was needed, that I had to go to the round-table arrangement to negotiate yet once more with the Miami Group and the European Group.
I instantly woke up. We negotiated for several hours. Then a couple or so hours of sleep only, then negotiating, wheeling and dealing the whole day and night with only another couple of hours of sleep the next morning. Then a whole day and night of the same as previously, sometimes stumbling, sometimes short-tempered, but with my mind absolutely clear. And the love and care and support of everyone - someone with a glass of juice, someone with a sandwich, with a touch, and all with smiles and many with lovely words!
Supra-individual energy keeping me going on? An innate strength that I did not know I had urging me on? I do not know. All I know is that the Miami Group had to change their negotiator, and I was told that the European Group negotiator had, towards the end, failed to stay awake. I am asthmatic, and older than either of them. I do not know how or why I managed it. But I stayed on to the end. When it finished I do not recall how I got into my room and into bed. I woke up 11 hours later, only to eat and sleep about 10 hours more.

Success, but could it have been more?

My overall evaluation of Montreal in January 2000 is that we, the Like-Minded Group, succeeded in getting more than I had thought would have been salvageable from the Cartagena mess.
But then, our unity and our strength had already been tested and found to hold. It was good. And it will continue to be good. But at a personal level, nightmare and dream did not blend as exhilaratingly as they had in Cartagena. One surreal week is enough!

6. The 'Cartagena/Vienna setting': Towards more transparent and democratic global negotiations

http://www.twnside.org.sg/title/vienna.htm

by Chee Yoke Ling
Chee Yoke Ling, a former university law lecturer, is an Environment Representative of the Third World Network.

While it was public pressure that finally pushed the negotiations in Montreal to a successful conclusion, the process was greatly facilitated by the innovative and transparent procedures initiated by the active but impartial chairman of the meeting, Minister Juan Mayr Maldonado of Colombia. Dubbed 'the Cartagena/Vienna setting' (since these procedures were first adopted in the Vienna preparatory meeting that followed the collapse of the negotiations in Cartagena), they provide a democratic alternative to the secretive negotiating processes that have characterised the WTO, and a healthy precedent for future global meetings.

IN Cartagena last year, it was clear, by the time the Ad Hoc Working Group was dissolved after two and a half years' work, that the polarised positions of the countries could not be resolved through the conventional UN style. Countries which were frustrating the process could evade openly putting forward their positions and rationale (if there were any apart from trade protection) and hide behind statements devoid of content. Those in favour of a comprehensive biosafety agreement had to keep defending and explaining their stand.

There were many occasions where these delegates almost appeared to be on trial. The balance of representation was also skewed. The more than 100 countries in the Like-minded Group (LMG) of developing countries had only one spokesperson, having agreed to speak as one voice. On the other hand, six countries in the Miami Group had one full representation (predominantly voicing the interests of a non-Party, the US). The European Union on many issues were aligned with the Miami Group, and their combined force could easily defeat the LMG proposals.

It was at this point that the chair of the Extraordinary Meeting of the Conference of the Parties to the Biodiversity Convention which had taken over the negotiations, Minister Juan Mayr Maldonado of Colombia, stepped away from UN tradition.

The first step taken was to reconfigurate the number of spokespersons, and this was a turning point towards a more equitable representation of views and positions in the closed-door smaller 'contact group' that was set up to try to resolve the controversy over the general scope of the Protocol and the scope of the application of the Advance Informed Agreement procedure.

Significant

The LMG was given four representatives to speak. The Miami Group had two representatives and the EU, Central American/Caribbean countries, Central and Eastern Europe (including Russia) had one spokesperson each. (In subsequent meetings, Central American and Caribbean countries merged with the LMG to speak

as one voice.) The Compromise Group, initiated by Norway and Switzerland to ensure they could participate in the negotiations, had one representative.
Each spokesperson was allowed to bring two advisers, chosen by each Group from amongst themselves. This was very significant because normally, Northern delegations would have a large team overwhelming the under-represented South. Often, the US delegation itself would exceed an entire region's total number of delegates.
However, it was agreed at the end of Cartagena that an open process was crucial. All contact group meetings which followed in Vienna and Montreal were open to all governments.
Between Cartagena and Montreal, over one year, a confidence-building exercise took place which also helped to crystallise the core issues that could break the impasse on the Protocol.
On 1 July 1999, taking advantage of the presence of a large number of countries at a meeting to prepare for the 5th meeting of the Conference of the Parties to the Biodiversity Convention scheduled for May 2000, Minister Mayr held an informal consultation to confirm that there was indeed political will to conclude an agreement. Where key negotiators were not present, their views were sought, too.

Transparency

It was agreed that an informal consultation on the core and related issues, left pending from Cartagena, would take place in Vienna in September.
In his summary of the 1 July consultation, the minister stated that he 'consider(ed) transparency as being critical to the preparations of the (Vienna) meeting'. He thus promised to keep all governments informed about his consultations by forwarding to all national focal points, through the Secretariat, 'all correspondence and minutes'. He also highlighted the important role of the Bureau and Secretariat in achieving transparency of the process.
In Vienna, each negotiating group met on its own for two days.
This was especially important for the LMG, which had no opportunity to meet between negotiation sessions. In contrast, the EU and Miami Groups met frequently as groups and bilaterally outside the global meetings. The third day was spent on interactions amongst the groups 'to test the waters, gauge the mood and identify critical issues', as Minister Mayr put it.
The last two days, chaired by the minister, identified common conceptual ground and possible solutions, without venturing into precise wordings of the controversial provisions.

Easy consultation

A second innovative development was introduced in Vienna. Instead of sitting in their country seats by alphabetical order in the usual fashion, delegates sat as their respective Groups. The advisers sat behind the chief spokespersons, and in the case of the LMG, delegates from each region sat behind their regional advisers. This arrangement enabled easy consultations amongst delegations.
In addition, each negotiating group now had one chief and one alternate spokesperson. The LMG, given its size, was asked to elect a chief spokesperson,

and two others from each of the three regions (Asia, Africa and Latin America/Caribbean) as regional spokespersons to assist the chief person. The Brazilian delegate was also the alternate spokesperson for the LMG. Any of the regional advisers could join the discussions when asked by the chief spokesperson. The order of speaking in plenary then followed a pattern. Minister Mayr used coloured balls, with each chief spokesperson picking one from a bag at the start of each plenary session. Each session had a different colour sequence.
This approach eased the flow of discussion. By going round each Group to elicit views in this way, and by the Chair actively asking questions to clarify positions, the atmosphere was significantly transformed. Delegates and observers alike felt that the result was exchanges that were more frank and less couched in obtuse diplomacy.

This method of conducting a plenary became known as the 'Cartagena/Vienna setting'.

The physical setting of a roundtable in Montreal with delegates actually seeing each other as they spoke was a basic but important additional feature in group dynamics. It also made consultations among the members of each Group more convenient during negotiations.
Good humour was a component, too, when coloured teddy bears were used instead of balls, which proved to be elusive in Montreal!
The clearer grouping of countries and interests that evolved in the Biosafety Protocol process provided a much more transparent picture of country positions. The replacement of the Group of 77 and China with the LMG (the former minus Argentina, Chile and Uruguay, which joined the Miami Group) in Cartagena was another turning point. Developing countries went from near-paralysis to active unity as a negotiating group.
The time provided regularly, or when requested, for internal group consultations in the midst of negotiations was particularly valuable for developing countries to discuss ongoing developments amongst themselves, make assessments and maintain their joint stands.
It was interesting that while the Compromise Group operated on a principle of bridging polarised positions, the countries did not make consensus amongst themselves a rule. So, on issues where there was no agreement, the lowest common denominator would not be presented. This was useful, as individual countries were then free to express their views informally with other like-minded delegates. For example, Norway supported the inclusion of contained use in the general scope of the Protocol in Montreal even though they had two years earlier given up this crucial area 'in the spirit of compromise', while Mexico was strong on the need for an international liability regime, even though there were other Group members that did not share the same views. By the last meeting in Montreal, Mexico, Japan, South Korea and Singapore had joined the Group. The move by Singapore, which LMG countries had found to be more aligned to the Miami Group position, was good for the continued solidarity of the LMG (Singapore had initially been a member of the LMG).

Access for NGOs

In Montreal, plenary sessions were conducted in the Cartagena/Vienna setting where rounds of views on key issues were heard. Where contact groups were set up to further explore an issue and negotiate text, these were open to all government delegations. Regular reports to the plenary were made, again in the Cartagena/Vienna setting.
In Vienna and Montreal, the Chairman met informally with the spokespersons and representatives of each negotiating group.
In Vienna, he also met separately with non-governmental organisations (NGOs) and industry. It was in response to the NGO request for access that a decision was made to have instantaneous audio reception in a 'spill-over' room next to the government consultation room. NGOs and international organisation representatives, as well as government delegates (if there was lack of space in the other room), were thus able to follow the discussions.
In Montreal, all observers, including the media, were able to sit in the plenary sessions.
As negotiations intensified, and plenaries had to be postponed, notices were prominently displayed and ample time given for delegations to re-convene.
There were remaining frustrations caused by the lack of interpretation facilities in the contact groups, and non-English-speaking delegates had to work with English draft text. This is a serious shortcoming in all global negotiations, and really needs to be overcome since more and more legally binding agreements are being made which have a huge impact on countries and peoples.
Also, the large group of developing countries in the LMG during the Montreal session had to meet in the plenary hall without even microphone support, sometimes needing to shout at each other to be heard. While many recognised the problem of insufficient Secretariat funds, such a lack of fundamental facilities was very unfortunate. More worryingly, it reflects the power of money over democratic processes. The bulk of the meetings for this Protocol were financed from voluntary funds, with the Secretariat scrambling for support from one meeting to the next. The lack of core funding for the participation of developing countries and economies in transition, and to a large extent the inadequate Secretariat support, were due to a few rich countries not wanting a Protocol in the first place.
However, there was enough commitment to a Biosafety Protocol which made the final conclusion possible.
While the humour and personal dynamism of Minister Maldonado was a major factor, delegates found the actual approach and process very useful.
Unlike in other negotiations, especially those in the trade arena such as in the World Trade Organisation, there was far less confusion and mistrust amongst delegations, especially those from developing countries. In many respects, the process made it possible for the narrow trade interests of the major Miami Group countries to be publicly exposed and even isolated.
At the final plenary, a number of delegates suggested that the Cartagena/Vienna setting would be a good precedent for other global negotiations.
While the powerful interests of a few countries still won the day in many ways, the Cartagena Biosafety Protocol did see a fairer fight. The procedures were predictable and allowed for more open, transparent and democratic meetings.

7. The CaMV promoter story

http://www.twnside.org.sg/title/story.htm

by Mae-Wan Ho

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The Biosafety Protocol concluded in Montreal reaffirms the precautionary principle but the problem is one of ensuring that the principle is implemented, as illustrated by the case of the CaMV promoter. The CaMV promoter is a gene-switch from the cauliflower mosaic virus which is incorporated into practically all current GM crops. Recent scientific findings reveal it may be highly unsafe. But many of the scientists themselves are refusing to read the implications of the findings or to draw the right conclusions in accordance with the precautionary principle.

The CaMV promoter - a recipe for disaster?

THIS was the title of a scientific paper co-authored by myself and my colleagues, Angela Ryan from the Open University UK and Prof. Joe Cummins from the University of Western Ontario, Canada, and submitted to the journal Microbial Ecology in Health and Disease last October. The journal-s Editor, Prof. Tore Midtvedt, a distinguished medical microbial ecologist working in the Karolinska Institute of Sweden, promptly posted our paper on the journal's website before publication and put out a press release. Within two days, someone managed to solicit at least nine critiques, including one from Monsanto, which were posted on a website funded by the biotech industry and widely circulated on the Internet. The critiques varied in tone from the moderately polite to the ill-mannered.

We wrote a detailed rebuttal, which was likewise circulated and posted to the same website. In January, Nature Biotechnology published a distorted, one-sided and offensive account of our paper, concentrating on the criticisms and ignoring our rebuttal completely.

Our paper reviews and synthesises existing scientific findings on the cauliflower mosaic viral (CaMV) promoter that is in practically all GM crops already commercialised or undergoing field trials. The findings suggest to us that artificial gene-constructs containing the CaMV promoter may be especially prone to breaking and joining up with other genetic material, thereby increasing the chance that it can be transferred horizontally to unrelated species. The potential hazards are harmful mutations, cancers, reactivation of dormant viruses and generation of new viruses.

These considerations are especially relevant in the light of recent findings by Arpad Pusztai and his collaborator Stanley Ewen (The Lancet 354, p.1353, 1999), that transgenic potatoes - containing the CaMV 35S promoter - may be unsafe for young rats, part of the effects being attributed to the construct or the genetic engineering process, and hence common to all GM crops.

More significant still, secret documents belonging to the US Food and Drug Administration have come to light as the result of a civil lawsuit against the agency's approval of GM foods mounted by a coalition of scientists and religious leaders. These documents reveal that the first GM crop to be commercialised, the Flavr Savr

tomato, actually failed to pass the standard safety tests (see www.biointegrity.org). Since then, no comprehensive safety testing has been done on any GM foods. In line with the precautionary principle, we recommend the immediate withdrawal of all GM crops and products containing the CaMV promoter, until and unless they can be proven safe.

Prof. Joe Cummins was the first scientist to question the safety of the CaMV promoter back in 1994 in connection with the Flavr Savr tomato. He pointed out that the promoter could recombine with other viruses to generate new disease-causing viruses. His warning was ignored.

Like supporters of the biotech industry who insist there is no difference between genetic engineering and conventional breeding, our critics deny any difference between the CaMV promoter as a stable, integral part of the virus itself and the promoter in artificial gene constructs which are already known to be unstable. So much so that the structural stability of artificial vectors - made by joining bits of genetic material from viruses and other genetic parasites of many different organisms - is a textbook topic (see Old, R.W. and Primrose, S.B. (1994). Principles of Gene Manipulation 5th ed., Blackwell, Oxford).

What is a 'promoter'?

A 'promoter' is a stretch of genetic material that acts as a switch for turning genes on. Every gene needs its own promoter. But the promoter is not a simple switch like that for an electric light, which has only two positions, either fully on or fully off. Instead, the gene promoter has many different parts or modules that act as sensors, to enable it to respond, in ways we do not yet fully understand, to signals from other genes and from the environment. These signals tell it when and where to switch on, by how much and for how long. And under certain circumstances, the promoter may be silenced, so that it is off all the time.

The role of the promoter of a normal gene in an organism is to enable the gene to work appropriately in the complex regulatory circuits of the organism as a whole. The promoter associated with each of the organism's own genes is adapted to its gene, while the totality of all the genes of the organism have been adapted to stay and work together for millions, if not hundreds of millions of years.

When genetic engineers transfer foreign genes into an organism to make a GMO, they also have to put a promoter in front of each of the genes. The promoter plus the gene it switches on make up a 'gene-expression cassette'. Several gene-expression cassettes are usually stacked, or linked in series; one or more of them will be genes that code for antibiotic resistance, which will enable those cells that have taken up the foreign genes to be selected with antibiotics. The stacked cassettes are then spliced, in turn, into an artificial gene carrier or 'vector'.

The vector itself is generally made by joining together parts of viruses and other infectious genetic parasites (plasmids and transposons) that cause diseases or spread antibiotic and drug resistance genes.

In the case of plants, the most widely used vector is the 'T-DNA' which is part of the tumour-inducing plasmid ('Ti plasmid') of Agrobacterium, a soil bacterium that infects plants and gives rise to plant tumours or galls.

The role of the vector is to smuggle genes into cells that would otherwise exclude them. More importantly, the vector can invade the cell's genome and so enable the

gene-expression cassettes it carries to become incorporated into the genetic material of the cell.
The artificial transgenic constructs are very complicated and unstable, and are designed for invading the genome - the totality of the cell's own genetic material which is organised in specific ways.
However, the genetic engineer cannot control where and in what form the vector jumps into the genome of the cell. And this is where the first unpredictable effects arise. Each transgenic line or GMO is unique, and gives rise to different unintended effects. In the case of food, this can mean unexpected toxins and allergens.

Why use a promoter from the CaMV?

Like all viruses, CaMV is a genetic parasite that has the ability to infect cells and hijack the cell to make many copies of itself in a short period of time. Its promoter is therefore very aggressive and, in its isolated form, is active in all plants, monocots, dicots, algae, and the E. coli bacteria that live in the gut of all mammals. Hence, the CaMV promoter is very popular with genetic engineers. It can make the gene placed next to it turn on full blast in any plant genome, at perhaps a thousand times the volume of any of the organism's own genes. Having it in the genome is rather like having the loudest phrase of a heavy-metal piece, played with the most powerful amplifier, over and over again, throughout a live performance of a Mozart concerto. What the CaMV promoter does is to place the foreign gene outside the normal regulatory circuits of the host organism, subjecting the host organism to unremitting metabolic stress. This will multiply the unintended, unpredictable effects in the GMO. It may also be another reason why GMOs are notoriously unstable (Finnegan, J. and McElroy, D. (1994). Bio/Technology 12, 883).
Another characteristic of the CaMV promoter is that it is modular in structure, with parts that are common to and interchangeable with promoters of other plant and animal viruses.
A key recent finding is that the CaMV promoter contains a 'recombination hotspot' - a site where the DNA tends to break and join up with other DNA, thus changing the combination and arrangement of genes (Kohli et al (1999). The Plant Journal 17, 591, 1999). Furthermore, the CaMV promoter recombination hotspot strongly resembles the borders of the T-DNA vector carrying the foreign gene constructs, which are also known to be prone to recombination. Actual recombination has been demonstrated in the laboratory between viral genes engineered into plants and infecting viruses, resulting in new viruses.

Structurally unstable

Artificial constructs of all kinds are already known to be structurally unstable, and recombination hotspots are expected to further exacerbate the instability. This implies that parts, or all of the foreign gene-constructs may be more likely to jump out of the genome and successfully invade the genomes of unrelated species, in principle, all species interacting with the GM plant: bacteria, fungi, earthworms, nematodes, protozoa, insects, small mammals and human beings. This process is uncontrollable and cannot be recalled. The gene-constructs have been designed to be invasive and to overcome species barriers; once released, they will invade different organisms

especially bacteria which are in all environments, where they will multiply, mutate and recombine.
The major consequences of the horizontal transfer of gene-constructs are the spread of antibiotic resistance marker genes among bacteria and the generation of new bacteria and new viruses that cause diseases from the many bacterial and viral genes used.
The generation of new viruses could occur by recombination with live or dormant viruses, which we now know to be present in all genomes, plants and animals included. Recombination between viral genes in GM plants and infecting viruses has been demonstrated (Wintermantel, W.M. and Schoelz, J.E. (1996). Virology 223, 156-64.) Recombination with defective, dormant animal viral promoters may also occur. Recombination of CaMV promoter modules with defective promoters of animal viruses may result in recombinant promoters that are active in animal cells. This may reactivate the virus, generate new viruses or give functional viral promoters causing over-expression of one or another of dozens of cellular genes now believed to be associated with cancer.

What our critics say, and why they may be mistaken

Our critics believe the CaMV 35S promoter is not harmful because people have been eating the virus in infected cabbages and cauliflower for many years.
First, what we have been eating is mainly intact virus and not naked viral genomes. One of the most surprising recent discoveries is that the naked viral genome - the genetic material taken out of the viral protein coat - is found to give full-blown infections in non-host species that are not susceptible to the intact virus (see Rekvig, O.P. et al (1992). Scand. J. Immunol. 36, 487-95).
Moreover, as said earlier, the 35S promoter in the CaMV is a stable, integral part of the virus, and cannot be compared to the 35S promoter in artificial gene-constructs. We know that the 35S promoter in the virus does not transfer into genomes because pararetroviruses, such as CaMV, do not integrate into host genomes to complete their lifecycle; and replication of the virus takes place in the cytoplasm away from the genetic material of the cell (Covey, S., et al (1990). Proc. Nat. Acad. Sci. USA 87, 1633-7). But that says nothing about the 35S promoter in the gene-constructs that are integrated into host genomes.
As proviral sequences (non-active genomes of viruses) are present in all genomes, and as all viral promoters are modular, and have at least one module - the 'TATA box' - in common, if not more, it is not inconceivable that the 35S promoter in artificial constructs can reactivate dormant viruses or generate new viruses by recombination. The CaMV 35S promoter has been joined artificially to the cDNAs of a wide range of viral genomes, and infectious viruses produced in the laboratory (Meyer, M. and Dessens, J. (1997). J. Gen. Virol.78, 147-51). There is also evidence that proviral sequence in the genome can be reactivated (Nowora, T. et al (1999). Virology 255, 214-20).

Worse

Our critics point out that plants are 'loaded' with potentially mobile elements, and therefore adding another cannot be harmful. However, this can only make things

worse. Most, if not all, of the elements will have been 'tamed' in the course of evolution and hence no longer mobile. The integration of transgenic constructs containing the 35S promoter may mobilise the elements. The elements may in turn provide helper-functions to destabilise the transgenic DNA, and may also serve as substrates for recombination to generate more exotic invasive elements.
In signing on to the International Biosafety Protocol in Montreal in January, the US, British, French and more than 150 other governments agreed to implement the precautionary principle,which is also sound science. The available evidence clearly indicates that there are serious potential hazards associated with the use of the CaMV promoter. All GM crops and products containing the CaMV promoter should therefore be withdrawn both from commercial use and from field trials unless and until they can be shown to be safe.

Acknowledgment

I am very grateful to Joe Cummins and Angela Ryan for helpful discussions in preparing this account.

8. The 'Golden Rice' - a big illusion?

http://www.twnside.org.sg/title/rice.htm

by Florianne Koechlin
Florianne Koechlin is a biologist and the managing director of Blueridge Institute in Switzerland.

A new variety of rice genetically engineered to incorporate provitamin A is being held out as the panacea for the widespread problem of vitamin-A deficiency. Florianne Koechlin challenges this claim and suggests that there are more practical and viable methods to tackle this deficiency.

A TEAM from the Swiss Federal Institute of Technology in Zurich has developed a strain of transgenic rice containing provitamin A. Three gene-constructs were inserted into the rice genome which complete the biochemical pathway needed for vitamin-A production in the rice grain. The work had been funded by the Rockefeller Institute (USA) and the European Union.
Vitamin-A deficiency (VAD) is known to cause partial or full blindness (Xerophthalmia) and to exacerbate illnesses such as diarrhoea or measles in children. VAD is associated with malnutrition and afflicts in the first place the very poor in Asia, Africa and Latin America. The Food and Agriculture Organisation (FAO) and World Health Organisation (WHO) estimate that about 250 million people (mainly small children and pregnant women) are threatened by VAD (1995).
'We can help these people in the future', says Ingo Potrykus, principal investigator of the team, and he and his colleagues are determined to give the transgenic rice free of charge and without any restrictions to 'the poor farmers in developing countries'.
An article on the provitamin-A rice appeared in the journal Science on 14 January 2000 (p. 303); Science sent a pre-print of the article to 1,700 journalists around the world and Mary Lou Guerinot, who wrote the commentary in Science, remarks: 'One can only hope that this application of plant genetic engineering to ameliorate human misery without regard to short-term profit will restore this technology to political acceptability.'
One of the most comprehensive interventions to reduce VAD was the international 10-year project the UN and FAO started together in 1985. Further plans were decided on at the World Summit for Children (1990) and the World Food Summit (1996).

Three strategies are used to fight VAD:

1. Food fortification (e.g. margarine containing vitamin A in the Philippines; sugar fortified with vitamin A in some Latin American countries).
2. Supplementation: Administration of high-dose vitamin-A capsules twice a year and,
3. Food-based projects or dietary approaches, information on nutrient habits. Vitamin A is found in meat, fish, eggs and milk products. Provitamin A is found in plants, especially in green leafy vegetables and fruit.

In most countries the first two strategies have priority. They are easy to administer and show fast results. The third strategy, which is more complex, was neglected for a long time, but it is becoming increasingly important.

Following are some examples of food-based projects:

In Bangladesh there is a very high prevalence of VAD. FAO started a food-based project (concentrating on home gardens) in 1993, together with Helen Keller International (HKI) and 14 NGOs: the introduction of small home gardens with vitamin-rich vegetables and fruits, the taking-up and improvement of traditional cultivation methods, discussion-rounds, education programmes, etc. Families without any land were helped to grow vines up the sides of their houses and plant beans, pumpkins and bottle-gourds in the vines - all of which have commonly eaten leaves. Women, having noticed improvements in their children's health, started to work for the project, which spread like a snowball-system. From the very beginning the projects were integrated in the communities and supported by NGOs. Around 600,000 households (or over three million persons) are part of the project (1998). The project was monitored scientifically by the UN and HKI. Of course there were also drawbacks, but MW Bloem and his team from HKI (1996) confirmed that:

1. The level of health of the participants had improved.

2. Only small plots of land are needed to provide sufficient vitamin A.

3. A surprising finding was that the greater the variety of fruits and vegetables a person ate, the better was the uptake of provitamin A. An increase in the number of varieties seemed to bring about significant improvement, independent of the quantity of food eaten (possible reasons: better bioavailability, synergy effects). Families with scattered gardens most often plant the biggest variety of fruits and vegetables and had a better uptake of provitamin A. It is mainly the very poor families, who cannot afford their own home gardens, who cultivate scattered gardens.

In Thailand the 'door opener' for a food-based project was the vitamin-A-rich, green leafy vegetable, ivy gourd (Smitasiri et.al., 1992). Ivy gourd is cultivated with relative ease and grows wild in many communities. The three-year project (1988-1991) consisted of a collaborative, rather than 'top-down' approach, and put much weight on social marketing, developing many innovative and low-cost approaches: radion broadcasts (involving eight main channels), posters, comics and T-shirts with the ivy gourd and video and cassette tapes. Mothers, school teachers and health and agricultural workers participated, as did Buddhist monks. A prominent monk made a recording to encourage people to support the project. Theatre groups and puppet shows involved the kids. Well-known folk-singers produced tapes which sang the virtues of the ivy gourd. Regular monitoring and yearly collection and evaluation of all information helped in the implementation of new and/or corrective activities and the evaluation of the effectiveness.

In Mali, Burkina Faso, Niger and many other African countries, the seasons are usually very short. Drying of nutrient fruits and vegetables is traditional, and low-cost solar drying techniques can guarantee minimal loss of provitamin A during the drying process. Dried mango-slices do retain high levels of provitamin A for as long as six months.

In the final FAO report of the 10-year project, there was a consensus that the food-based approach, though widespread, needs much enhancement. Food-based approaches improve the nutrition in general. John R Lupien, director of the Food and Nutrition Division of FAO in Rome, concludes: 'A single nutrient approach towards a nutrition-related public health problem is usually, with the exception of perhaps iodine or selenium deficiencies, neither feasible nor desirable.' The statement of Franz Simmersbach, FAO is even clearer. 'It is as if Vitamin-A research makes researchers blind!' Simmersbach adds: 'Unless you give priority to operational field work, research and programmes related to food and nutrition education, the children we identified as being in need will not profit from all of this in time.' (FAO, 1996)
Bruno de Benoist, from WHO in Geneva, is convinced that a holistic approach, including both food fortification (for a first input) and dietary approaches, is necessary. He and others believe that the vitamin-A rice could perhaps be of additional help, among many other approaches.
Barbara Underwood, one of the leading experts in VAD, advocates for a new paradigm: 'The current usual paradigm of food, nutrition and health institutions must change from a vertical approach to a holistic, flexible system approach that includes empowering communities to be involved, as well as monitoring and adjusting the system to the dynamics of local changes.' She adds: 'Lessons learned from successful interventions in developing countries indicate that sustainable solutions are attainable only if all stakeholders are successfully engaged in partnerships that include the poor.'
Much success has already been achieved. Donald McLaren from the International Center of Eye Health, London, and an expert in VAD since the late 1960s, remarks that great progress has been made in this area: 'For example, the number of young children with xerophthalmia has fallen by about two-thirds in the past 20 years.'
Bruno de Benoist from WHO is more cautious. He confirms that in some countries (such as Indonesia, India and Bangladesh) the number of afflicted children has dropped significantly, although exact trends are hard to predict because of the absence of figures.
And according to the World Bank, investments in all three programmes to prevent vitamin-A deficiency are among the most cost-effective of interventions to improve health. (For example, the abovementioned three-year project in Thailand to promote production and consumption of vitamin-A-rich foods was estimated to have a per-capita cost of US$0.42; see FAO and ILSI (1997.)

The 'golden rice' - a big illusion?

Besides being an isolated and single-nutrient approach, the transgenic-rice project raises other doubts as well:

1. Biology
The provitamin-A rice only exists in a laboratory. There is no evidence of whether the plant shows the expected properties in different eco-systems (it is a common observation that transgenic plants, while they may perform well in laboratories, fail in nature, especially if they contain not one but three, added gene-constructs).
Furthermore the uptake of provitamin A depends on many factors. Provitamin A has to be absorbed by the guts and then built up to vitamin A in the body. This only functions in the presence of fat or oil, because provitamin A is only fat-soluble. Poor

people's diets often lack fat; they would excrete the provitamin A undigested. Worm infections or diarrhoea can lead to vitamin-A deficiency.
According to de Benoist from WHO, bad hygienic conditions and dirty water are important factors for the incidence of VAD.
The bioavailability of provitamin A is still poorly understood (e.g. carrots produce provitamin A in a hardly digestible crystal form; they should be cooked, and some oil added, to allow the uptake. On the other hand, provitamin-A absorption is much easier from oranges). Furthermore, evidence is growing that malnutrition with health consequences often also extends to iodine, iron (the main factors), and to vitamins C and D, folate, riboflavin, selenium and calcium. 'There is no 'quick fix' or 'magic bullet' solution,' remarks Lupien from FAO.

2. Patents
Ingo Potrykus plans making the transgenic rice available to poor farmers for free, without any patent claims. He even publicly denounced patenting: 'So many fields of research are blocked by corporate patents. I had to ignore them or I couldn't move at all. Scientists should start now by simply breaking the law,' he says. What company wants the negative publicity of putting me in jail for fighting poverty?' (The Progressive Populist, St. Louis, USA, August 1999).
But there is another side to Potrykus: in former times he used to work at the Novartis-owned Research Institute FMI and he still has very close connections to this company. Database research revealed that Potrykus is named as 'inventor' and thus has interest in 30 plant-related patents, most of them belonging to Novartis. In 1992 'No patents on Life!' Switzerland filed opposition to patent No. EP 0164575:'Direct transformation of genes into plant hereditary material'.
One of the inventors is Potrykus; the patent belongs to Ciba-Geigy, now Novartis. The latest Novartis patent with Potrykus as inventor was issued in February 1999 (No. US 5976880). Furthermore Potrykus admits himself that he filed a patent application for the transgenic rice ('before others do it') and that his group used some patented processes to construct the rice (possibly with himself as inventor). It could be that Novartis promises to give up all claims. Novartis plans to merge its agro-division this year with the Swedish-British company AstraZeneca to create a new agro-giant Syngenta. Will this Swedish-British-Swiss company also give up all patent claims say, in seven years, when Thai farmers want to use it in their crops?

3. Culture
The transgenic provitamin-A rice has a deep yellow colour. But for decades Southern people 'learned' that 'whiter than white' (for bread and rice) was the symbol of progress, quality and Western superiority. Now, all of a sudden, scientists expect them to prefer the yellow colour. FAO's experiences with VAD programmes show that a careful appreciation of cultural habits, traditions and beliefs is key to the success of such programmes. These habits and traditions cannot be changed overnight.
Once again we encounter the typical Northern attempt to solve the problems of the South with a technocratic 'magic bullet' approach. But we know from the experience of the last 50 years that this kind of isolated and one-dimensional approach hardly ever works.

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9. Farmers say 'no' to genetic engineering

http://www.twnside.org.sg/title/farmer.htm

TWN Joint Press Conference

Increasingly, farmers around the world are viewing genetic engineering as a threat to their livelihood. As delegates met to negotiate a Biosafety Protocol in Montreal, Greenpeace and the Third World Network held a joint press conference to allow the voices of small and independent farmers from Brazil, Mexico, the US, Canada and France to be heard in the negotiations. The following account of the press conference provides profiles of these farmers and summarises some of the main concerns raised by them.

FARMERS around the world view genetic engineering as a threat to their livelihood. Five farmers from Brazil, Mexico, the US, Canada and France shared their views and experiences in a press conference in Montreal where delegations from more than 130 countries met to negotiate an international agreement on genetically modified organisms (GMOs). Greenpeace and Third World Network held a joint press conference on 26 January to allow the voice of the small and independent farmers to be heard in the negotiations.

Extra costs

Farmers in Mexico, Brazil and France are facing extra costs to satisfy the demand for non-genetically engineered (GE) food. Demand for 'clean' certification has created new testing, labelling and transport costs for farmers to guarantee no genetic contamination of their crop. 'These costs should be borne by the biotech industry, not by us,' said Antonio Wunsch from Brazil and Jean-Yves Griot from France.
In Mexico, the home of the world's corn crop, small and indigenous farmers are worried about genetic contamination of their traditional varieties. 'There are about 5,000 traditional varieties of maize in Mexico and we could lose them,' said Porfirio Encino from Mexico.
In industrialised countries where organic produce is the fastest growing food trend, organic farmers are facing a new threat: the loss of their livelihood due to genetic contamination. 'When GE pollen from a neighbouring field contaminates an organic crop, the farmer could lose his organic status which he has worked years to achieve,' said organic farmer Steven Gilman from the US.

Futile

In Canada about 60% of canola is GE. The unintended contamination of conventional canola in the fields and during transport makes all attempts at segregation futile. 'We are told by consumers to start segregating but it does not work and we are losing our market. A moratorium on new crops is now insufficient, we have to first clean up the mess created by GE canola,' said Hart Haiden from Canada.

Steve Gilman, USA

Steve Gilman has been farming organically since 1976. On his Ruckytucks Farm near Saratoga, NY, he grows a wide variety of vegetables and herbs for local restaurants, a Community Shared Agriculture (CSA) project and other markets.
He is Chair of the Organic Advisory Group at Cornell University in Ithaca, NY. He has served on the Administrative Council of the US Department of Agriculture's (USDA) Sustainable Agriculture Research and Education (SARE) programme, Northeast region, for the past three years.
He is currently authoring an Organic Manuals Series for advanced farmers and conventional farmers seeking to make the transition to organic agriculture.
The wide-scale field release of agricultural biotechnology has a negative economic impact on organic farmers through potential pollution by genetically altered organisms which may threaten Organic Certification status. Environmentally, the spread of transgenic materials impacts beneficial insects and microorganisms which are relied upon by organic farmers for pest and disease control.
Due to millions of acres now being planted with genetically altered strains of transgenic Bt corn, cotton, potatoes, tomatoes, melons and beets, organic farmers stand to lose forever the effectiveness of this important biocontrol agent through pest resistance.
The genetic engineering agenda has commandeered the lion's share of publicly financed agricultural research dollars to the detriment of organic and other sustainable agriculture initiatives. In comparison to industrialised agribusiness and its highly reductionist genetic technologies, organic farming produces comparable yields while utilising a holistic, ecological approach to food production with beneficent environmental and health effects.

Jean-Yves Griot, France

He has been a milk farmer and cooperative member since 1977. He is the President of the Reseau Agriculture Durable which represents 25 farming groups and over 1,500 members. He also holds the Chevalier de la Legion d'Honneur.
French farmers and consumers do not want GE foods, particularly in the context of other food crises such as mad cow disease and dioxin contamination of Belgian food.
There are no economic gains for farmers particularly now that consumers are also concerned about genetic contamination of animal feed. Increased costs are incurred due to labelling, testing and cleaning of silos and transport containers. The farmers' cooperatives are trying to establish contacts with Brazilian non-GE farmers.
Clear labelling and any additional charge should be on seed producers and not on the farmers or consumers.

Hart Haiden, Canada

Born and educated in Germany, he worked in different European countries, Saudi Arabia and South Africa on agricultural projects before emigrating to Canada.
He was a grain farmer for 20 years in British Columbia and operated a seed business. Since 1997 he has operated an organic health food processing plant.

He is currently Chair of the developing Canadian Centre for Sustainable Agriculture Inc., and a Director of the Canadian Organic Growers Association.
Sixty percent of canola is currently genetically engineered in Canada. Current regulations are insufficient to deal with crop contamination and weed resistance. Canadian farmers are now faced with a drop in large international markets - the market has gone for organic and is rapidly disappearing for traditional canola, as more countries adopt labelling and more consumers reject GE, such as in Japan. Segregation is insufficient to protect non-GMO crops since insects will cross-pollinate and accidents during cleaning and handling of seed will cause mixing. Canada should be adopting the precautionary principle - not promoting new GE crops. We need to clean up the mess created by GE canola.

Antonio Wunsch, Brazil

Antonio Wunsch is a 45-year-old professional farmer from Tres de Maio in the Rio Grande de Sul region of Brazil. The region declared itself a genetic-engineering-free zone in 1999.
Wunsch has been actively working to improve the social and economic conditions of the small farmers in his community. In 1983-1989 he was President of the Rural Union of Workers of Tres de Maio (Sindicato dos Trabalhadore Rurais de Tres de Maio).
Since 1995 he has worked with a soy farmers' cooperative, Cotrimaio, first as Secretary Director and from 1998 on as President.
Soy farmers in Rio Grande do Sul are trying to create new contacts with buyers in Europe, where consumers want confirmation that it's GE-free. But due to smuggling of GE soy there are lots of extra costs for farmers e.g. cleaning transport containers after they have been used to transport GE soy.
In Brazil the public is very aware of the GE problem. The state of Rio Grande do Sul prefers to stay GE-free. However, rumours of smuggling GE soy from Argentina have done great damage to the reputation of Brazilian non-GE soy. But the smuggling appears to be much less common than thought: from 600 tested cases, only three were found to contain GE.
Brazilian soy farmers growing non-GE soy think that the Biosafety Protocol must contain clauses for labelling and any costs incurred by farmers must be borne by GE promoters, not consumers or farmers.

Porfirio Encino, Mexico

Porfirio Encino is from the indigenous group Tzeltal from Chiapas state. He works for a local farming organisation, Asociacion Rural de Interes Colectivo Independiente (ARIC). He is an indigenous leader and he has been in charge of the development commission, agricultural commission and relationships coordination from the ARIC. Encino also works for UNORCA (Union Nacional de Organizaciones Regionales Campesinas Autonomas), where he is in charge of the indigenous commission and biodiversity.
This is a farming organisation in Mexico which works to improve social participation and conditions for farmers through development of their capacities in harmony with

their environment and through the sustainable use of natural resources. At the moment, 280 organisations from over 30 states belong to UNORCA, which represents around 200,000 families.
There is no information and no scientific studies on health and cultural effects in Mexico.
Small farmers, particularly indigenous farmers, are afraid their seed diversity is under threat. Confusion surrounding regulation and the lack of enforcement makes the situation worse. He wants strong regulation on imports and use. Only medium-scale farmers think GE could potentially bring any benefits.

10. Trouble in the garden

http://www.twnside.org.sg/title/garden.htm

by Peter Montague
Peter Montague is with the National Writers Union, UAW Local 1981/AFL-CIO.
The above article appeared in Rachel's Environment & Health Weekly #685 as the first half of a 2-part article.

By the end of 1999, agricultural-biotechnology companies worldwide found themselves in deep trouble as investors lost confidence in them and drove stock prices down. A principal reason for this debacle was the forced disclosure by the US Food and Drug Administration that its own scientists had expressed grave doubts about the safety of genetically modified crops.

WALL Street investors lost confidence in agricultural biotechnology during 1999.[1,2,3] Agricultural biotechnology is by no means dead, but investors drove down stock prices of ag biotech companies during 1999 in a stunning reversal for the industry. The Wall Street Journal said 7 January 2000, 'With the controversy over genetically modified foods spreading across the globe and taking a toll on the stocks of companies with agricultural-biotechnology businesses, it's hard to see those companies as a good investment, even in the long term.'[2]
Hardest hit was Monsanto, the St. Louis chemical giant that had spent five years and billions of dollars morphing itself into a 'life sciences' company, betting its future on biotechnology in pharmaceutical drugs and agricultural crops. As the Wall Street Journal wrote 21 December 1999, 'Billions of dollars later, that concept of a unified 'life sciences' company - using technology to improve both medicines and foods - has become an affliction itself for Monsanto. The crop-biotechnology half of the programme has grown so controversial that Monsanto has agreed to a deal that is likely not only to push biotech to the back burner, but also to cost Monsanto its independence. And investors are reacting harshly.'[3]

Selling off

Monsanto agreed late in 1999 to merge with Pharmacia & Upjohn, Inc. and the combined company will be run not from St. Louis but from Pharmacia headquarters in Peapack, New Jersey. Monsanto's ag biotech business will be spun off into a separate company and as much as 19.9% of it will be sold.
Two other leaders in ag biotech, the Swiss pharmaceutical giant Novartis AG, and the Anglo-Swiss drug firm AstroZeneca PLC, announced during 1999 that they will combine their ag biotech divisions into one and sell it off, 'effectively washing their hands of crop biotechnology,' the Wall Street Journal said.[3]

Thus by the end of 1999, ag biotech companies found themselves in trouble, worldwide, for the first time. Here is a short list of reasons why:

- A lawsuit against the US Food and Drug Administration (FDA) forced the release of government documents showing that FDA scientists had expressed

grave doubts about the safety of genetically modified foods even as the agency was publicly declaring such foods 'substantially equivalent' to traditional crops.[4] It seems clear from these documents that the scientific integrity of the US regulatory system has been compromised for political purposes, to provide a 'fast track' for the rapid, large-scale introduction of genetically modified foods.

- The insurance industry has consistently refused to write policies covering liability for harm caused by genetically modified organisms. Steven Suppan, research director at the Institute for Agriculture and Trade Policy (IATP) in Minneapolis, said last June, 'It is worth asking what kind of regulatory system approves for commercialisation a technology whose risks are so undetermined that the products developed from the technology have not been insured? An intuitive response is that the US rejection of liability suggests that US agribusiness and the US government have less confidence than is proclaimed publicly in the safety of the products approved and in the integrity of the product review process,' Dr. Suppan said.[5]

- A growing body of literature has begun to show that genetically modified crops are creating new kinds of environmental problems for farmers, and that genetically modified crops are exacerbating already-severe economic problems on American farms.[6]

- Europeans and others overseas have continued to insist that the safety of genetically modified foods has not been sufficiently documented and that import of such foods must be prohibited, or they must be labelled. The doubts expressed by FDA scientists, and the growing list of economic and environmental problems, are likely to stiffen European resistance to genetically modified seeds, crops, and foods.

- It became apparent in 1999 that the public rationale for promoting genetically modified foods - that such foods would 'feed the world' - was based on wishful thinking, not economics. It is now clear that US genetically modified crops are too expensive to 'feed the world.'[6]

- The rationale for refusing to label genetically modified foods unravelled in 1999 as biotechnology companies began to announce new crops with special traits (rice with increased vitamin A, for example). For years, biotech companies, the US Department of Agriculture (USDA), US Environmental Protection Agency (EPA), and FDA have argued that labelling genetically modified foods was impossible because it would require food companies to segregate genetically modified crops from conventional crops and it simply couldn't be done. All the crops were mixed together in the grain elevator, so labelling would be impossible, they said.

This silly and disingenuous argument evaporated in 1999. As soon as biotech firms announced specialty foods created by genetic engineering, the labelling problem miraculously disappeared. Labelling is suddenly easy - indeed, required - because consumer's can't be expected to pay premium prices for specialty foods if those foods aren't clearly identifiable on the grocery shelf.

Polls have shown that more than 80% of American consumers want genetically modified foods labelled as such. Now that labelling is acknowledged as feasible, will the biotech industry, USDA, EPA, and FDA bend to the public will and start labelling ALL genetically modified foods? Not on your life. Government and industry argue with one voice that labelling is not necessary because genetically modified foods are 'substantially equivalent' to the conventional foods they have replaced. They even say labeling would be 'misleading' because it would imply that there are differences between biotech foods and conventional foods.

Federal regulations governing biotech foods are founded on the premise that there are no 'material differences' between genetically modified crops and conventional crops. This argument, it turns out, was thoroughly discredited by FDA scientists before the regulations were issued.

The FDA spent 1989-1992 developing regulations governing genetically modified foods for humans and feed for animals. This was back when President Bush and Vice-President Quayle were advocating 'regulatory relief' for industry.

The FDA's rules - which were announced by Mr. Quayle in 1992 - allow a biotech company like Monsanto or DuPont to decide for itself whether its food products are 'generally recognised as safe', (GRAS). If a company decides that its new genetically modified corn or soybean or potato or wheat is 'generally recognised as safe' then no safety testing is required before the products are introduced into the food supply. The FDA said these rules - like all their rules - are based on 'sound science.'

However, during 1999 a lawsuit filed by the Alliance for Bio-Integrity in Fairfield, Iowa, forced the FDA to release some 44,000 pages of internal documents for the first time.[4] Among them was a series of memos from FDA scientists commenting on the FDA's proposed 'substantially equivalent' policy for biotech foods.

A key issue is whether 'pleiotropic effects' will occur when new genes are inserted into plants to give the plants desirable new traits. Pleiotropy means that more than one change occurs in a plant as a result of the new gene. For example, a gene that allows a plant to grow better under drought conditions might also make the entire plant grow smaller. The smaller size would be an unexpected 'pleiotropic' effect.

No data

FDA regulations assume that pleiotropic effects will not occur when new genes are inserted into conventional foods such as corn or potatoes or wheat or soybeans. Therefore, the FDA says, genetically modified crops are 'substantially equivalent' to conventional crops.

Internal memos make it abundantly clear that the FDA's scientific staff believes pleiotropic effects will occur when new genes are inserted into food crops. [In the following quotations, words inside square brackets have been added for clarity but words inside normal parentheses were in the original memos.- P.M.]

Commenting on the FDA's proposed biotech regulations in early 1992, Louis Pribyl, an FDA microbiologist, wrote 6 March 1992, 'It reads very pro-industry, especially in the area of unintended effects.... This is industry's pet idea, namely that there are no unintended effects that will raise the FDA's level of concern. But time and time again, there is no data to back up their contention, while the scientific literature does contain many examples of naturally occurring pleiotropic effects. When the introduction of genes into [a] plant's genome randomly occurs, as is the case with the current

[genetic modification] technology (but not traditional breeding), it seems apparent that many pleiotropic effects will occur.'
'Many of these effects might not be seen by the breeder [meaning Monsanto or DuPont or other biotech firms] because of the more or less similar growing conditions in the limited trials that are performed. Until more of these experimental plants have a wider environmental distribution, it would be premature for FDA to summarily dismiss pleiotropy as is done here,' Dr. Pribyl wrote.
On the same subject, a memo from the Division of Contaminants Chemistry within the FDA's Division of Food Chemistry and Technology said 1 November 1991, 'Pleiotropic effects occur in genetically engineered plants... at frequencies up to 30%. Most of these effects can be managed by the subsequent breeding and selection procedures. Nevertheless, some undesirable effects such as increased levels of known naturally occurring toxicants, appearance of new, not previously identified toxicants, increased capability of concentrating toxic substances from the environment (e.g., pesticides or heavy metals), and undesirable alterations in the levels of nutrients may escape breeders' attention unless genetically engineered plants are evaluated specifically for these changes. Such evaluations should be performed on a case-by-case basis, i.e., every transformant should be evaluated before it enters the marketplace.'
Instead of heeding the concerns of its scientific staff, the FDA issued biotech food rules that assume no pleiotropic effects will occur, therefore no safety testing is required. All biotech foods are assumed to be safe. The stage was thus set for confidence in biotech foods to plummet as soon as word leaked out that the scientific underpinnings of the regulatory system had been compromised.

Endnotes

[1] I am indebted to Steven Suppan, research director at the Institute for Agriculture and Trade Policy (IATP) in Minneapolis, who provided me with several brief, thoughtful summaries of the state of agricultural biotechnology. Contact: ssuppan@iatp.org. Telephone (612) 870-3413.
[2] Christina Cheddar, 'Tales of the Tape: Seed Co. May Yet Reap What They Sow,' Wall Street Journal, 7 January 2000, pg. unknown.
[3] Scott Kilman and Thomas M. Burton, 'Biotech Backlash is Battering Plan Shapiro Thought Was Enlightened,' Wall Street Journal, 21 December 1999, pg.A1.
[4] The FDA documents are available at http://www.bio-integrity.org/list.html. And see Marian Burros, 'Documents Show Officials Disagreed on Altered Foods,' New York Times, 1 December 1999, pg. A15.
[5] Steven Suppan, unpublished paper, National Summit on the Hazards of Genetically Engineered Foods, 17 June 1999, Capitol Hilton Hotel, Washington, D.C.
[6] Some of this literature is summarised in Charles M. Benbrook, World Food System Challenges and Opportunities: GMOs, Bio-diversity, and Lessons From America's Heartland,' unpublished paper presented 27 January 1999, at University of Illinois. Available in PDF format at http://www.pmac.net/IWFS.pdf.

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