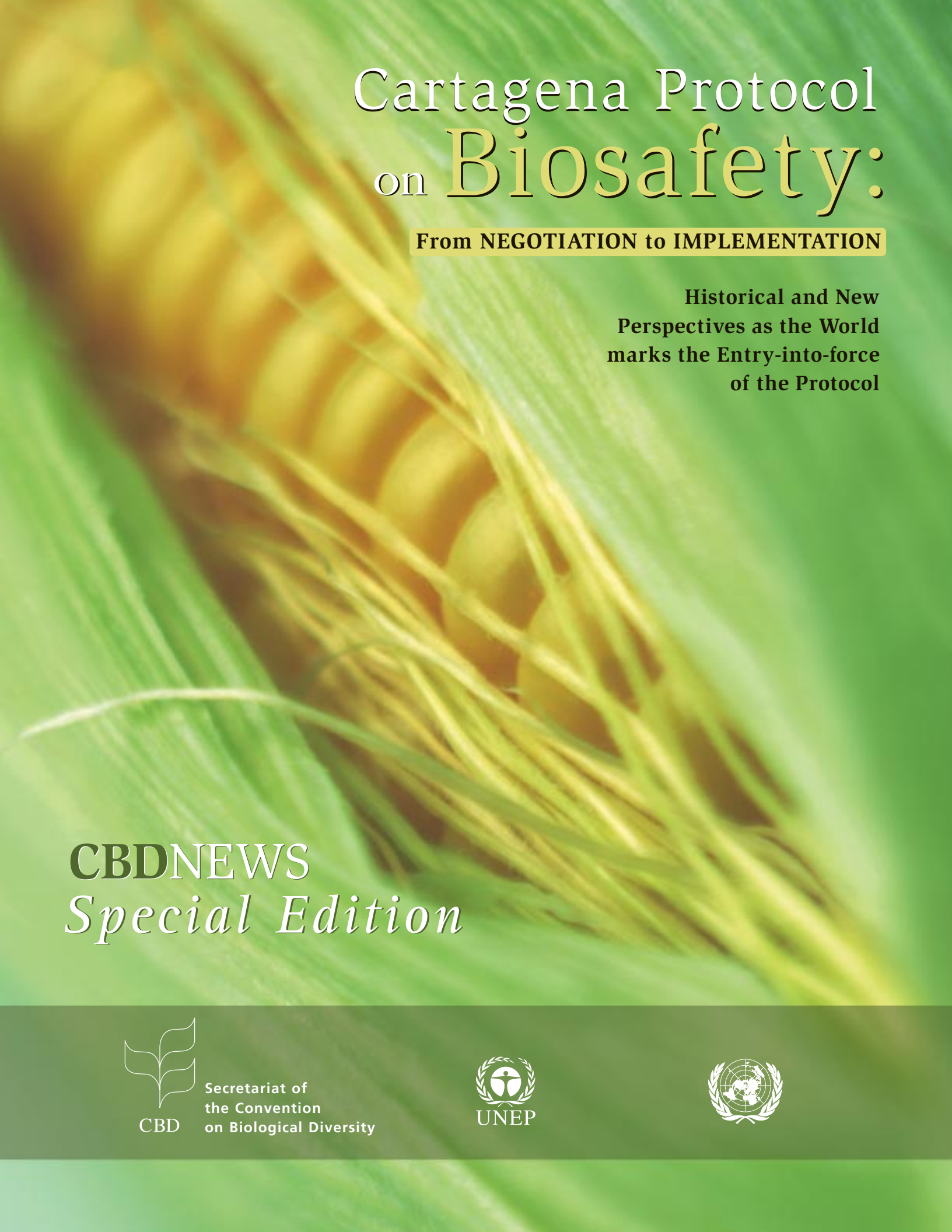

Cartagena Protocol on Biosafety:

From NEGOTIATION to IMPLEMENTATION

Historical and New Perspectives as the World marks the Entry-into-force of the Protocol

CBDNEWS
Special Edition

CBD Secretariat of the Convention on Biological Diversity

UNEP

Photo: D. Barbour, IDRC

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EDITORIAL
Entry into force of the Cartagena Protocol
Towards Effective Implementation

Hamdallah Zedan
Executive Secretary
Convention on Biological Diversity

The entry into force of the Cartagena Protocol on Biosafety on 11 September 2003 marked the beginning of a new phase in the history of the Protocol; a turning point from negotiation to implementation.

Emerging from the outcomes of the 1992 United Nations Conference on Environment and Development (UNCED), including Agenda 21 and the Convention on Biological Diversity, the Protocol has gone through an interesting history, which Veit Koester and Juan Mayr highlight in this publication.

The Biosafety Protocol has its roots in of the Convention on Biological Diversity (CBD), especially Article 19.3 which obliged Parties to the CBD to consider the need for and modalities of a protocol setting out appropriate procedures in the field of the safe handling and use of any living modified organism (LMO) that may have adverse effect on biodiversity. The three objectives of the CBD are: the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising from the use of the genetic resources.

The Protocol is one of the tools for implementing the Convention, especially with regard to the provisions to regulate, manage or control risks associated with transfer, handling and use of LMOs that may have adverse effects on the conservation and sustainable use of biodiversity, focusing on their transboundary movement. The CBD Strategic Plan, which was adopted by the sixth meeting of the Conference of the Parties (COP), contains a number of strategic objectives related to the Protocol including, among others, to ensure that by the year 2010:

- The Cartagena Protocol on Biosafety is widely implemented
- Every Party has a regulatory framework in place and functioning to implement it
- All Parties have available adequate capacity as well as increased resources and technology transfer to implement it, and that
- Every Party to the Cartagena Protocol on Biosafety is promoting and facilitating public awareness, education and participation in support of the Protocol.

As the world community celebrates the Protocol's entering into force, many people are now pondering how to ensure its effective implementation. As for other international agreements, implementation of the requirements of the Protocol will be an on-going and iterative process. The primary step, however, is the translation of those requirements into appropriate domestic laws and other practical implementation measures. Currently, more than 100 developing countries are in the process of developing national biosafety frameworks (NBFs) with support from the Global Environment Facility through its implementing agencies. A few countries, such as China, Colombia and Uganda have started implementing their NBFs. As well, many developed countries are also reviewing and aligning their existing laws with the Protocol.

Developing countries, however, face a number of challenges, including low levels of awareness about the Protocol and a lack of necessary human, institutional and technological capacities. There is an urgent need for countries and organizations, in a position to do so, to provide additional financial and technical assistance and facilitate access to and transfer of technology to enable developing countries to promote awareness and build their capacities. The article by Piet Van der Meer discusses the opportunities and challenges in building capacities for the effective implementation of the Protocol and highlights a number of issues that need to be taken into account.

Another critical challenge for the effective implementation of the Protocol is to ensure that all countries are able to access and effectively use the Biosafety Clearing-House (BCH). The BCH is not only essential to enable Parties to make available specific information in accordance with their obligations under the Protocol, but also to allow them to access relevant information to make informed and timely decisions regarding the import and export of LMOs. The BCH in its current format has two main components: a central portal and a distributed network of national components. The connectivity between the central portal, which is administered

by the Secretariat, and the national components is essential for the Protocol to function effectively. The article by François Pythoud provides a good overview of issues regarding the BCH.

While the ultimate responsibility to ensure that the Protocol's provisions are effectively implemented lies with the contracting Parties, they cannot achieve its objective on their own. Active involvement and cooperation of other relevant stakeholders, including business and industry, NGOs, scientists, researchers and the media is critical. All stakeholders must take on their respective roles and responsibilities. The articles by Chee Y. Ling and Lim Li Lin as well as by Val Giddings discuss possible ways for promoting the involvement of the public and the private sector, respectively.

The objective of the Protocol will not be effectively achieved if each and every country does not actively promote biosafety at the national level. In this regard, it would be desirable for all countries to ratify and implement the Protocol. If not, non-Parties are encouraged to adhere to the Protocol and contribute appropriate information to the Biosafety Clearing-House, as provided for in Article 24 of the Protocol.

Although the Protocol is an environmental treaty, there is no doubt that it has implications for international trade in LMOs since it seeks to regulate their movement from one country to another. The Protocol states, in its preamble, that trade and environment agreements should be mutually supportive. While the objective of the Protocol is to contribute to ensuring an adequate level of protection to biological diversity against the potential adverse effects of LMOs, taking also into account risks to human health, the negotiators of the Protocol endeavored to ensure that trade in LMOs is not unduly hindered. The Protocol attempts to reconcile the respective needs of trade and environmental protection in light of the rapidly growing biotechnology industry. The articles by Tewolde Egziabher and Richard Ballhorn discuss this from the developing and developed country perspectives, respectively.

Since the Protocol was adopted in January 2000, much has been done to prepare for its entry into force and implementation. The Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP), which met three times, prepared draft recommendations on a number of important issues expected to be addressed by the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP. 1) due to take place from 23 to 27 February 2004 in Kuala Lumpur, Malaysia. The article by Ambassador Philemon Yang, Chairman of the ICCP, gives a good summary of the accomplishments of the ICCP in its mandate to undertake the preparations necessary for the first COP-MOP, and provides an insight into the issues facing that first meeting and the likely outcomes.

During the preparatory period, the CBD Secretariat has undertaken a number of activities aimed at facilitating the operation of the Protocol following its entry into force, including among others: the development of the pilot phase of the Biosafety Clearing-House, organization of training workshops in its use, establishment of the roster of experts in biosafety, development of databases of capacity-building activities, responding to requests from different stakeholders and providing clarification on issues regarding the Protocol as well as promoting public awareness. It has also made available information materials to assist countries in their preparations to become Parties to the Protocol and to implement it effectively.

In conclusion, I wish to congratulate all the States that have already ratified or acceded to the Protocol and to urge those that have not yet done so to follow suit as soon as possible. I would also like to express my sincere gratitude to all the authors who have contributed to this Special Edition of the CBD News. The purpose of this publication is to promote general public awareness about keys issues under the Biosafety Protocol. I am sure the information, views and historical perspectives shared in this Special Edition will make a valuable contribution to the successful transition from negotiation to implementation of the Protocol.
I wish you good reading.

Biosafety, Biotechnology and the Environment

Klaus Töpfer
Executive Director
United Nations Environment Programme

Biotechnology and Biosafety are intertwined in the context of the environmental and human health issues within the Convention on Biological Diversity (CBD), and in particular in Article 19 of the CBD ("Handling of biotechnology and distribution of its benefits").

Introduction

Article 19 of the CBD, paragraphs 1 and 2, calls upon Parties to provide for the effective participation in biotechnological research activities and the sharing of its benefits, especially for developing countries. At the same time, paragraph 3 calls for Parties to consider a protocol on biosafety. That protocol, the Cartagena Protocol on Biosafety, was adopted in January 2000.

While it is generally recognised that biotechnology has potential benefits for the protection of the environment and for improving human health, by the same token questions have been raised about the potential adverse effects of its products on the environment. Over the last thirty years, since the development of recombinant DNA techniques to make specific modifications to organisms for use in medicine, food production and agriculture, biosafety issues have steadily gained recognition at national, regional and international levels. This has been an important factor in the development of the Biosafety Protocol.

The Cartagena Protocol on Biosafety is very important, particularly for developing countries. It is an international agreement that specifically focuses on the transboundary movement of genetically modified organisms (GMOs). Although GMOs are neither inherently risky nor safe, it is generally recognised that the potential to create new genetic combinations and the relatively limited experience with GMOs warrant national and international regulation. Countries always had the sovereign right to regulate GMOs and their products at the national level, and they typically do this by reviewing certain technical information to determine safety. The Protocol now establishes an international, legally-binding framework that allows countries, in particular, those that do not yet have in place a regulatory regime for biosafety, to make informed decisions on the import of GMOs into their country.

The role of biotechnology in the protection of the environment

Positive contributions of biotechnology have been recognized in different areas such as human health, agricultural production of food, feed and fibres and environmental protection. Agricultural biotechnology has received quite substantial attention compared with environmental biotechnology. Nevertheless, the development of bio-engineered crops or transgenic crops has to take into consideration environmental issues when it comes to field-testing and release into the environment. It is estimated that in 2002 Genetically Modified crops covered a total area of 58.1 million hectares, globally, and this total is predicted to increase.

As a broader perspective on the potential benefit of biotechnology in agriculture, it has been argued that better agricultural efficiency will lead to less pressure on agricultural land and consequently less pressure on forests as well as other ecosystems. Further, it is argued that the use of pest- and disease-resistant crops and pesticides from a biological origin does not affect the environment as negatively as the use of persistent, harmful synthetic pesticides. The same can be said for reduction in the use of chemicals, energy and water in industrial processes where (micro)-organisms are used instead of chemicals under high energy input.

In addition to a potential indirect benefit to forests and other ecosystems resulting from less pressure on land use, biotechnology can also have direct benefits for ecosystems such as forests. Tropical forests are falling at the rate of approximately 1% per annum or 29 ha. per minute. Tissue culture of tree species is being used to rapidly multiply propagules of tree species that are difficult to produce by conventional methods or where the demand for seeds exceeds the supply. Some of the trees include Camphor, Mvule and Eucalyptus. Recent research indicates that there have also been several field trials involving

Photo: Bill Bradshaw

genetically modified (GM) trees. Since 1988, about 184 GM field trials of trees have been reported globally. Certain modifications are designed to use trees for bio-regeneration of polluted soil. GM trees are also being developed to reduce the current use of chemicals in the production of paper products. GM microorganisms can also be usefully introduced to control pollutants, tertiary oil recovery and frost damage. GMOs are already being used to convert nitrogen in the air into a form that plants can use to produce protein without the input of chemical fertilisers.

Tissue culture conservation procedures can also provide germplasm banks with tools for conservation of genetic resources. For instance *in-vitro* cultures of accessions, including those of endangered species, can be conserved and perpetuated for the future. Embryo transfer has been used to safeguard the conservation of some animals such as the Bongo, one of the largest of the forest antelopes, while cryopreservation of semen from elite bulls has been used in artificial insemination. In the field of pharmaceutical development genetically modified vaccines are now being used for control of livestock diseases.

Biological treatment of waste by microorganisms has been applied in the bioconversion and biodegradation of agricultural and industrial wastes. Bioconversion is based on the use of microorganisms or related enzymes geared towards converting the desired substances. Biotechnology has been used in the production of alternative energy sources through the conversion of agricultural and municipal waste leading into biogas, a source of energy based on anaerobic fermentation.

The need for adequate and transparent safety measures

The need for adequate biosafety measures to protect the environment stems from the fact that the genetic modification technology is a relatively new technology, which raises – as with any new technology – questions about potential risks to the environment and human health. The limited experience with the technology also calls for efforts to apply the technology in the most judicious way so as to reduce the risk of any potential adverse effects on the environment or human health. In developing transparent systems, every country needs to create a system that takes into account the interest of all stakeholders. A transparent system will involve the technology developers and the technology users and will have the ingredients of sound technologies backed by scientific information. A transparent system will take into account social and economic concerns and is based on priorities decided upon by the countries. This essentially calls for the development of national biosafety frameworks in consultation with all stakeholders and for the implementation of such frameworks in which workable and transparent systems are set up to handle requests for permits, monitoring and inspections, public information and participation.

Proposals for promoting access to, and transfer of, environmentally sound technologies.

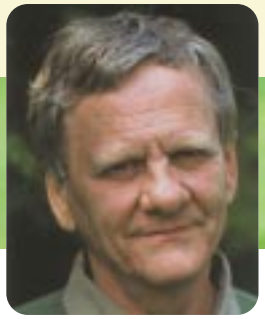
The Biosafety Protocol is a next step in a process that started with UNCED (Rio, 1992) towards the promotion of safe development and use of biotechnology. This protocol needs to be supported by national mechanisms that will have the necessary human and institutional capacity for its implementation. By setting transparent mechanisms for decision making, countries will be creating an enabling environment for the development and use of biotechnology.

The UNEP-GEF project on Development of National Biosafety Frameworks and the projects on Implementation of National Biosafety frameworks endeavour to create the necessary capacity for developing countries so as to enable those participating countries to implement the Protocol and to fulfil their obligations under the Protocol. Further information about these projects is contained in the article on capacity building in this Newsletter.

Availability of information and people with skills to develop the appropriate technology and to avoid to the extent possible any negative impacts to environment is critical. The Biosafety Clearing-House (BCH) has been established to facilitate the exchange of biosafety information. A public that is informed about biotechnology and biosafety can play its rightful role in technology development and transfer. Hence there is a need for campaigns for public awareness.

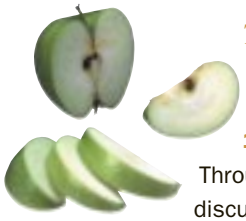
Conclusion

Biotechnology is an emerging technology that has the potential to bring about dramatic changes in our lives by addressing food and health problems as well as poverty. While conventional biotechnology has been with us for a long time, modern biotechnology (genetic modification) is relatively new and its judicious application is necessary. The protection and management of the environment to ensure environmental health is paramount for the survival of humankind and biotechnology has some of the tools that can be used for environmental protection. It is in this context that UNEP supports the Cartagena Protocol on Biosafety for it can help ensure the safe development and use of genetically modified organisms.



The History Behind the Protocol on Biosafety and the History of the Cartagena Biosafety Protocol Negotiation Process

Veit Koester
External Professor
Roskilde University Centre, Denmark



The history behind the Cartagena Protocol on Biosafety (CPB) and its actual negotiation is rather complicated with a multitude of actors and many different processes involved.

1. Introduction

Throughout this history biosafety-related issues were discussed in a number of international fora at the same time and in many instances parallel exercises made a complicated issue even more complicated. At least one of the forums, namely the third WTO Ministerial Conference held in Seattle in 1999, could be seen as having been initiated in order to disrupt the CPB negotiation process. Both because of the many processes and also the complicated subject matter, it is impossible to outline the history of behind the CPB in a satisfactory manner. What follows is only a very brief overview undoubtedly marked by my personal experience. No doubt other participants in the process would have written "the history behind and of" in a different way focusing on other issues.

The road to the CPB is, roughly speaking, characterized by five phases containing elements typical for any process leading to an international environmental agreement.*

2. The first phase – problem identification

The first phase (1970s and '80s) can be described as the period when the biotechnology issue emerged. As public concern grew over the implications of genetically modified organisms (GMOs) arising from biotechnology, questions arose in various fields. On the scientific front, there were queries regarding the possible harmful effects of GMOs while environmental discussions focused on whether GMOs would further sustainable development or not.

3. The second phase – framework development

The late 1980s and the beginning of the 1990s saw the development of an international framework to address biosafety issues as well as biosafety guidelines. An Informal Working Group on Biosafety was created in 1985 (comprising UNIDO, UNEP, WHO and later FAO) and the UNIDO Voluntary Code of Conduct for the Release of Organisms into the Environment (1992) as well as the OECD Safety Considerations for Biotechnology were issued. Likewise, in 1993 the FAO Draft Code of Conduct on Biotechnology (1993) was elaborated. During the same period, Agenda 21 was adopted (in June 1992) during the UN Conference on Environment and Development. Chapter 16, section 4, of Agenda 21 called for the development of "compatible safety procedures into a framework of internationally agreed principles as a basis for guidelines to be applied on safety in biotechnology, including considerations of the need for and possibility of an international agreement….". During this phase, the UK and the Netherlands also initiated, and to a large extent, elaborated UNEP International Technical Guidelines for Safety in Biotechnology (1995).

4. The third phase – the CBD negotiation process

The third phase (1988-1992), partly overlapping phase 2, can be characterised as the Biodiversity Convention (CBD) negotiation process. This process was rather peculiar with regard to the biosafety issue. While biotechnology was at the centre of CBD negotiations from the earliest days, biosafety as an international concern only emerged much later in the process.

At the 8th meeting of the CBD process in November 1991, Malaysia tabled a proposal on international safety measures with regard to GMOs. This proposal is the origin of Article 19 (3) of the CBD and therefore also the origin of the CPB. It contained a core element that prevailed throughout the negotiations and later became a core element of the CPB, although formulated differently. The element was prior informed consent from countries where GMOs are to be introduced. In a report to Plenary during the meeting, I stated that Malaysia should be congratulated for having taken this initiative in respect to biosafety, not knowing – of course – its implications for the future negotiations and even less that it would, at the end, result in a brand new international legally-binding agreement, the CPB.

The circle, which started with the Malaysian proposal, will be closed with the first COP-MOP to be held in Malaysia in February 2004 – a fair and extremely nice closure.

At the very last moment of the final negotiations in May 1992, Malaysia agreed to the present formulation in Article 19(3) provided that the US agreed to the proposal that the financial mechanism of the CBD should work "within a democratic and transparent system of governance" (present Article 21 (1), one of the most important "last minute trade-offs" and probably a *conditio sine qua non* for the conclusion of the CBD.

Photo: Ken Tong, IISD with assistance from Franz Dejon, IISD

Clearly, while the issue of an international regulatory mechanism on biosafety was raised barely half a year before concluding the negotiations in order for the CBD to be signed at UNCED in June 1992, it was one of the most difficult to resolve. It is a pity that the negotiation history of the CBD has never been documented. However, it is not too late. It is my sincere hope that the Parties of the CBD at COP 7 will make funds available for the elaboration of a record of the CBD negotiations under the auspices of the Executive Secretary of the CBD.

The adoption and signature of the CBD with its Article 19 (3) containing a legal obligation for the Parties to the CBD to consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe handling and use of any LMO that may have adverse effect on the conservation and sustainable use of biodiversity constituted the first turning point. Article 19 (3) together with Article 8 (g) on domestic measures and some obligations with regard to biosafety contained in Article 19 (4) provided the basis for the fourth phase, i.e. the issue-definition phase.

5. The fourth phase – issue-definition phase

The fourth phase (1992-1995), also partly overlapping the second phase, can be described as the issue-definition phase. It covers the period from the adoption and signature of the CBD until and including the "Jakarta Mandate".

As a first step, the then Executive Director of UNEP, Dr. Tolba, established a panel of experts to facilitate the consideration of the need for and modalities of a protocol on biosafety. In the course of 1992/93, this panel (the so-called "Panel IV") prepared a report containing recommendations on the elaboration of a protocol as well as on the contents of such a protocol. Only two experts, one from a country and another from an IGO, disagreed with the report. I am pretty sure that most of the panel's recommendations are reflected in the CPB in one way or the other, despite the fact that the report was never circulated as an official document at meetings of the Intergovernmental Committee on the CBD (ICCBD) nor at COP 1 in 1994. However, the issue of biosafety itself was on the agenda of COP 1, and Parties agreed to establish a process with a view that a decision on whether or not to elaborate a protocol could be taken at COP 2.

In May 1995, a panel of experts (the "Cairo Panel") met in order to prepare a report to be included as a basis for the following step, the meeting of an Open-ended *Ad Hoc* Group of Experts. However, the report of the Cairo Panel did not contain clear recommendations. The large majority of the *Ad Hoc* Group of Experts, which met in July 1995 (Madrid), favoured the development of a protocol on biosafety, but there was considerable disagreement on a number of possible elements.

Finally, at COP 2 in November 1995 in Jakarta, Indonesia, a decision was taken to establish an Open-ended *Ad Hoc* Working Group on Biosafety to elaborate a protocol on biosafety specifically focusing on the transboundary movements of LMOs (BSWG). This was the second turning point, which marked the beginning of the actual Protocol negotiations. ►

It is interesting to note that in the Jakarta Mandate, the notion of "any LMO resulting from biotechnology" was restricted to "LMOs resulting from modern biotechnology". It is also interesting to compare the definition of LMO currently in the CPB with the statement of Malaysia at the Nairobi Final Act Conference (22 May 1992). Malaysia understood the term "living modified organisms" to mean "genetically modified organisms", the notion that a few countries fought so hard – and successfully – to avoid. Probably a number of scientists would argue that the difference between the definition of LMOs in the Protocol and the definition of GMOs is hardly identifiable.

6. The fifth phase – the negotiation phase

The final phase (1996-2000) can be defined, broadly speaking, as the negotiation phase, from the first session of the BSWG in July 1996 and to the resumed ExCOP in Montreal in January 2000. This phase is the main subject of the study *The Cartagena Protocol on Biosafety – Reconciling Trade in Biotechnology with Environment and Development?*, edited by Christoph Bail and others (Earthscan 2002). Furthermore, as a Record of the Negotiations is being prepared under the auspices of the CBD Secretariat and as Juan Myar Maldonado in covering the last part of this phase (February 1999 to January 2000) in this publication, I will restrict myself to a very brief overview of this phase, which can be divided into three sub-phases resulting in four turning points.

The first sub-phase covers the two first sessions of the BSWG (July 1996 and May 1997). It constitutes the element-definitions phase resulting *inter alia* in a decision to invite governments to submit to the third meeting legal texts on most of the substantive elements and to request the Secretariat to develop draft articles on most of the remaining issues. This is the **third turning** point, agreement to begin building a formula or drafting.

The next sub-phase (October 1997 to February 1999) can be described as the draft-producing and negotiation phase. It includes the remaining four sessions of the BSWG (October 1997, February 1998, August 1998 and February 1999) and the ExCOP (February 1999) and constituted two turning points.

The **fourth turning point**, which occurred at the last meeting of the BSWG in February 1999, characterized the final bargaining phase. While delegations had been reluctant to negotiate at the previous meetings, this being the last BSWG, delegations had to take their final positions. Unfortunately, this session failed to produce an agreed protocol text, but the ExCOP, which followed immediately after the last BSWG session to formally adopt the CPB decided to adjourn and revert- to the final bargaining phase, but now on the basis of clean draft protocol, i.e. a draft without brackets. This – in my opinion – constitutes the **fifth turning point**.

The third sub-phase (February 1999 to February 2000) under the able and inspiring chairmanship of Juan Mayr resulted in the adoption of the protocol, constituting the **sixth turning point**, the conclusion of the negotiations.

The **seventh turning point** was the entry into force of the CPB on 11 September 2003. The adoption by the first COP-MOP decisions of crucial importance for the future implementation and effective functioning of the Protocol will no doubt constitute yet another turning point.

7. A few reflections on the difference between the CBD and CPB negotiation processes

It is tempting to conclude with a brief analysis of some of the differences between the CBD and CPB negotiation processes, notwithstanding the different nature of the two instruments. The comparison will be limited to what was envisaged to be the last meeting of the CBD and of the CPB processes respectively, i.e. with regard to the CPB the period finishing with the meetings in February 1999 (i.e. the two first sub-phases identified in section 6 above). I hope this will provide some elements that might explain why the CBD process was successfully concluded and why the CPB process in the first instance failed.

The CBD process comprised in reality 10 meetings, the seven last meetings in the course of only two and half years, with a total of approximately 80 meeting days. The CPB process comprised only 6 meetings with approximately 45 meeting days, also covering a period of three and a half years.

The first draft text of the CBD was ready before the 6 last meetings meaning that the negotiations from there on were based on a legal text. The draft text of the CPB was not available before the third BSWG session, and much effort was devoted at this

and the following meetings to trying to reduce the various legal texts to draft articles that could be negotiated.
The fifth revised draft text of the CBD, which was to be considered at the last meeting (11 – 22 May 1992) contained approximately 250 brackets while the draft negotiating text of the Protocol presented at the last session of BSWG (14 – 24 February 1999) included approximately 500 brackets.

The number of participating countries and organizations in the CBD process grew from 24 (at the first meeting) to 96 governments (at the last meeting) and from 10 (first meeting) to 22 (third and last meeting) organizations in the CBD process, while the comparable numbers in the CPB process were from 82 governments and 35 IGOs and NGOs (at BSWG-2) to 138 governments and 75 IGOs and NGOs (at BSWG-6).

Almost none of the most controversial 10-15 core issues, i.e. 30 out of 39 articles, were resolved before the last meeting of the BSWG. The situation was not that bad before the last meeting of the CBD process.

While at least some of the outstanding issues at the last meeting of the CBD process were not interrelated, most of the controversial problems confronting the last BSWG were related to each other. Furthermore, outstanding issues at the last BSWG were to some extent viewed in five different ways by five groups of countries. I am leaving aside in the present context that with regard to some issues there were only two sides, – the one represented by the US (and a few other governments) and all the remaining countries on the other.

Delegations at the last meeting of the CBD process faced the fact that if they did not succeed at the last meeting the convention would not be ready for UNCED, meaning that the whole future of the CBD would be at risk. Delegations at the last meeting of the BSWG did not have a similar perspective, and maybe some of them even had instructions to try to block consensus.

I certainly do not question the approach that was agreed in the CPB process, namely to build on a bottom-up process, i.e. to negotiate on the basis of a draft protocol, building on legal texts provided by delegations instead of a draft instrument elaborated by the secretariat, as was the case in the CBD process. Maybe it is even the very approach chosen for the CPB process that resulted in the successful conclusion. But if the subject of international environmental negotiations is a complex one, scientifically, technically, and legally, the bottom-up approach is surely extremely time-consuming with regard to establishing a reasonable basis for negotiations. Also it creates psychological barriers in the sense that every bit and part of the basis for negotiation is "owned" by this or that delegation, which will always be reluctant to give in on its carefully drafted proposals.

Neither do I regret that the participation in the CPB negotiation process was considerably broader than in the case of the CBD negotiation process – of course not. Any global negotiation process should be carried out in a framework as broad as possible, furthering transparency and improving ownership with regard to the final outcome. However, the time needed for international negotiations is often directly proportional to the number of actors.

Although rarely true and objective, history is always interesting. But now the time has come to leave the history of the creation and birth of the CPB and concentrate on its future.

* The phases and sub-phases described in section G also appear in: Mackenzie, Ruth, et al (2003) *An Explanatory Guide to the Cartagena Protocol on Biosafety*. IUCN, Gland, Switzerland.

Doing the Impossible: The Final Negotiations of the Cartagena Protocol

Juan Mayr
Chair of the ExCOP and
Former Colombian Minister of the Environment

To do the impossible, that was the great challenge that arose from the sixth meeting of the Open-ended Ad Hoc Working Group on Biosafety (BSWG), held in Cartagena de Indias, Colombia, in February 1999 and its efforts to finalise a text for the Biosafety Protocol to be approved at the first extraordinary meeting of the Conference of the Parties to the CBD (ExCOP).

Cartagena de Indias received the participating delegations with enthusiasm and optimism. As Colombia's Minister for the Environment, I was host for the event and also Chair for the ExCOP, held in the last two days of the BSWG meeting for the Protocol. However, as the meeting progressed it was evident that the positions of the different delegations were increasingly disparate – almost 600 brackets inserted to the text - consensus for the Protocol was far from sight.

Time was running out, but the differences remained. So, in the absence of any agreement, Veit Koester, Chair of the BSWG since its inception in 1996, took the decision to present a Chairman's text as a way to achieve a balanced Protocol in response to the divergent positions. The text was consulted with the Chair's Group of Friends and presented to the other delegations as a definitive version, with no further brackets to be included and consensus required for any further changes. This led to discontent among the many delegations whose basic concerns were not taken into account in the text.

It was at this moment, and at the request of Koester himself, that I took the negotiations into my own hands. The impossible had to be done.

It was no secret that these were one of the most difficult and complex negotiations between trade and environment, with numerous interests in play and varying positions of countries towards the development of biotechnology industries, their capacity to produce and commercialise living modified organisms (LMOs), capacity to manage safety, and developments in national legislations. Furthermore, the Protocol being the first legally-binding instrument under the Convention on Biological Diversity, its successful negotiation was vital.

There were three main groups of countries namely: (1) the Miami Group, which included the main producers and traders of LMOs namely USA, Canada, Australia, Argentina, Chile and Uruguay; (2) the Like-Minded Group, which comprised the majority of G-77 countries; and (3) the European Union. In a series of informal consultations with all three groups during the weekend prior to the start of the ExCOP, I asked each group to nominate a spokesperson, to be accompanied by no more than three advisors. Organising dialogue and identifying the controversial themes within the Chair's text bought some time. During these informal meetings the dialogue flowed; each group was frank and open in expressing their position, while the others listened with attention, generating a certain confidence. It led to a change in the atmosphere and a greater enthusiasm at the start of the plenary of the ExCOP .

As Chair of the ExCOP, I immediately established a group of 10 negotiators who could be accompanied by all the delegations that they represented. In this way no one could feel excluded. There were five negotiators from the Like-Minded Group, two from the Miami Group, one from the European Union, one from the Central and Eastern European countries, and one from the Compromise Group, which included Switzerland, Japan, Mexico, Norway and South Korea (New Zealand and Singapore joined this group later in the process).

There was tremendous effort by all the negotiators to reach agreement on the text, and all but the Miami Group had made concessions in order to reach consensus. This led, understandably, to considerable frustration, and we took the decision to suspend the ExCOP and give ourselves more time for the negotiations to mature.

Looking back, the attitude of the Miami Group was in fact a blessing in disguise. Aside from having the burden of a failed negotiation on their shoulders, public opinion began to question why it had not been possible to reach agreement on the regulation of trans-boundary movement of LMOs in order to minimize risks of any possible environmental damage. The international media and interest groups began to question the risks associated with biotechnology products, and the need to exercise precaution over their use and commerce. In many ways the Cartagena negotiations caused a domino effect: faced by increasing critics, Monsanto, one of the major companies involved in biotechnology development, announced the suspension of trade of the "terminator" seed; Japan began labelling of transgenic products; another company, Gerber, announced that it would not use transgenic ingredients in their baby food products, and a multitude of European consumers took to the streets in protest against genetically modified (GM) foods.

Prior to the finalisation of negotiations, however, two other important meetings took place, even though they were of an informal nature. In Montreal in July 1999, all delegations expressed their desire to reach a successful end to the negotiations within one year. Another preparatory meeting was planned, to agree an agenda on the controversial points, and it was decided to use the same format as in Cartagena to facilitate dialogue.

At the second meeting, held in Vienna in September 1999, aside from the governments, NGO and private sector there was also participation by the media to guarantee transparency and understanding about the negotiations. The meeting in Vienna concentrated on clarifying concepts on the controversial issues and finding shared criteria. There was some change to the format of the negotiations, such as the reduction of spokespersons for the groups to five. Also, like in a lottery, we invited the spokespersons to take from a bag one of the five coloured balls that would define the order for interventions, in order to promote participation and a certain rhythm during the negotiation process. Building on the consensus reached in Vienna, I prepared a Chairman's proposal with possible solutions for the main controversial themes, and sent it to all governments prior to the final meeting (known as the resumed session) of the ExCOP that was going to be held in Montreal in January 2000.

Prior to re-starting the ExCOP, an event of considerable international importance took place at the World Trade Organisation (WTO) Ministerial meeting in Seattle. The agenda of that meeting included a proposal to establish a group on biotechnology under the Committee for Trade and Environment (CTE) and to recommend legal developments within the WTO agreements, which in other words, meant that any discussion about biotechnology would be subordinate to WTO rules. To great surprise, that Ministerial meeting collapsed due to massive protests and the demand for transparency in multilateral negotiations. ►

Consequently, the atmosphere in Montreal in January 2000 was very different from that of Cartagena in February 1999. The general public was aware of what could happen in the negotiations, and more than 100 journalists from around the world were present, along with a large number of protestors who remained day and night outside the building to pressure for a successful Protocol. To guarantee the highest level of political decision-making, I invited Environment Ministers to accompany the negotiations, and their participation in the final hours of the negotiations was fundamental for a successful agreement. It was an open and transparent meeting, and a participatory setting. Five teddy bears of different colours – Justice, Testaverde, Brown, Rodriguez and Smith – showed the order for the interventions, helped to alleviate tension, and put a touch of humour and human warmth into the negotiations.

Despite moments of despair in the early hours of the last morning of negotiations, what we all achieved in Montreal was the product of the trust and credibility, which we all shared in our involvement with the Protocol. The final result is not perfect. But I do believe that its content is a balanced reflection of all that we were sure of and not so sure of at that time. The implementation of the Protocol will undoubtedly be the best test of whether we were right.

Successful completion of the negotiations was due to many factors and events. One of the most important was the change from the traditional United Nations (UN) scheme of negotiation to a more realistic format, which can be referred to as "The Vienna-Setting". This has already been adopted in some UN negotiations such as the Rio +10 preparatory process in Bali and the Johannesburg World Summit on Sustainable Development. However for the Vienna-Setting to work it is essential to take into account that the dynamics of discussions of the basic issues of the world today such as technology, trade, biosafety, food or climate change do not necessarily follow the North-South split or the UN traditional regional groups. Negotiations also depend much on the human element.

Faced, as we are, by one of the most difficult moments in our recent human history, in a globalising world where multilateralism is increasingly threatened, the coming into force of the Cartagena Biosafety Protocol could not be more opportune.

Many factors – such as the legal dispute brought to the WTO by the US against the European Union for its moratorium on GMOs; the new biosafety legislation in Europe; the imposition in bi-lateral trade negotiations on developing countries that have limited scientific capacity to establish possible risks, to accept GM products; and the growing public awareness about the issue – all make the Protocol one of the most important legal instruments of our times in the protection of environment and human health.

Domesticating the Biosafety Protocol:

Development of National Legal, Administrative and Other measures to Implement the Protocol at the Country Level

Wang Dehui and Zhang Shigang
State Environmental Protection Administration of China

The Cartagena Protocol on Biosafety, adopted by the contracting parties to the Convention on Biological Diversity (CBD) on 29 January 2000 after more than five years of negotiation, aims at ensuring adequate safety in the transboundary movement and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity and human health.

The Chinese government pays high attention to all safety aspects of LMOs at different stages: their development, release into the environment and their use. China participated in all the working group meetings and negotiations of the Protocol and played an active role in its adoption. China signed the Protocol on 9 August 2000 and is now in the process of ratification.

China has always attached great importance to the establishment of the legal and policy framework for biosafety management and for implementing the Protocol at the national level. Some administrative departments under the State Council have promulgated departmental regulations relevant to biosafety. Examples include the Safety Administration Regulation of Genetic Engineering, promulgated by the former State Commission on Science and Technology in 1993 and the Regulation on Biosafety of Agricultural LMOs, which was issued by the State Council as well as the accompanying administrative rules on risk assessment and labeling, which were promulgated in 2001.

Between 1997 and 1999, China implemented the Development of National Biosafety Framework (NBF) project funded by the Global Environment Facility (GEF) through the United Nations Environment Programme (UNEP). Most departments relevant to biosafety issues were involved in the development of the NBF and the public was consulted during the process. The NBF process resulted in policy and regulatory frameworks for national biosafety management, established the framework of technical guidelines for risk assessment and risk management of LMOs, and specified the priority requirements as well as actions for capacity building of national biosafety management. The overall objective for national biosafety management is to ensure that the risks to biodiversity, human health and environment likely to be caused by modern biotechnology and its products will be minimized, while promoting the research, development and commercialization of modem biotechnology. The principle of precautionary approach should be observed in the development, environmental release and use of LMOs. China supports the policy to strengthen the prevention and control of the potential adverse effects of LMOs on biological diversity and human health, and also opposes any hindrance to international trade on the pretext of biosafety:

Biosafety relates to various government departments. Relevant institutions are designated for the management of biosafety in China. As the National Focal Point and one of the national competent authorities for biosafety, the State Environment Protection Administration (SEPA) is responsible for coordinating the negotiation and implementation of the Protocol at the national level. The Office of Biosafety Management under SEPA is in charge of overall management and the international liaison on biosafety affairs. As one of the national competent authorities, the Ministry of Agriculture (MOA) is responsible for the implementation of some stipulations and rights related to the Protocol. The Office of Biosafety on Agricultural LMOs has been set up under MOA. There are also other departments that are involved in biosafety management in China, such as the State Food and Drug Administration, the Ministry of Science and Technology, the Ministry of Health and the National Quality Inspection Administration.

China has strengthened its scientific research on risk assessment and risk management of LMOs, established national laboratories on biosafety, prepared draft technical guidelines for the risk assessment and risk management of LMOs, and initiated ►

safety assessment and environmental monitoring of the contained use and environmental release of some transgenic crops and the commercial production of transgenic cotton. Public media such as radio, TV, newspapers and the Internet are used to disseminate biosafety knowledge and to enhance public awareness of biosafety. China has also established a pilot Biosafety Clearing-House (www.biosafety.gov.cn).

The Protocol stipulates legal systems, administrative systems and a set of procedures for LMOs that are to be intentionally introduced into the environment, or to be used directly as food or feed or for processing, such as risk assessment, Advance Informed Agreement (AIA), Biosafety Clearing-House, labeling, liability and redress. Although departmental regulations on biosafety have been promulgated, there exist gaps in the legal system, policy framework, administrative system and capacity building for biosafety in China. A comprehensive biosafety regulation encompassing all aspects of the Protocol is needed at the national level. A set of administrative systems needs to be set up, such as AIA for the transboundary movement of LMOs, environmental impact assessment (EIA) for environmental release of LMOs, emergency plans, compensation for environmental accidents caused by LMOs, public participation, packaging, transportation and waste handling of LMOs. The mechanism of inter-departmental coordination and integrated supervision on biosafety should be established, and risk assessment and environmental monitoring on the environmental release of LMOs should be strengthened.

From the experiences and, lessons learned, China would suggest the following major actions and steps for countries to implement the Protocol at the national level:

1. Promote the coordination among relevant ministries for the purpose of ratifying the Protocol as soon as possible;
2. Designate the National Focal Point and national competent authorities for the Protocol;
3. Prepare and promulgate national laws and regulations on biosafety;
4. Establish inter-departmental committee on biosafety;
5. Prepare and publish guidelines for the risk assessment and risk management of LMOs;
6. Set up the administrative system (e.g. AIA EIA, labeling) and risk emergency response system for the environmental release, commercial production and transboundary movement of LMOs;
7. Establish and update Biosafety Clearing-House;
8. Strengthen scientific research on biosafety and monitoring of environmental release of LMOs;
9. Promote public participation in and public awareness of biosafety,
10. Promote international cooperation on biosafety.

Towards the Future Implementation of the Biosafety Protocol:

Key Areas for Action at the International Level

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The entry into force of the Cartagena Protocol marked the beginning of a new phase of action at the national and international levels.

The Protocol is premised upon a system of functioning national biosafety frameworks and upon information exchange. Action at the international level is needed to ensure that all Parties are in a position to exercise their rights and meet their obligations under the Protocol, as well as to enhance the mutual understanding by Parties of those rights and obligations. The elaboration and clarification of the principles and rules enshrined in the Protocol by the Conference of Parties serving as the meeting of Parties to the Protocol (COP-MOP), the establishment of procedures and mechanisms to promote implementation, and cooperation between the Protocol and other relevant international agreements and organisations will all be central in achieving the Protocol's objective.

The Protocol specifies certain future work to be undertaken by the COP-MOP, and establishes timeframes for action. While some of these issues are of an administrative and budgetary nature, many others address implementation issues that were either not necessary or not possible, for reasons of a lack of consensus among governments or a lack of time, to articulate them fully in the Protocol itself. In addition to those items on which the COP-MOP is explicitly required to act, the mandate of the COP-MOP, in Article 29(4) of the Protocol, also incorporates "other issues necessary for the effective implementation of the Protocol".

The issues on which the COP-MOP is required to take action at its first meeting include a core cluster of those related to capacity-building. While a number of important capacity-building initiatives related to the Protocol are already underway, the early decisions to be taken by the COP-MOP on the basis of ICCP's deliberations will be important in laying the groundwork for the effective implementation of the Protocol. These include decisions on capacity-building, on facilitating decision-making under Article 10(7), on the role of the roster of experts, and on the recommendations to the CBD COP regarding guidance to the GEF. Closely related to this cluster of issues will be the decision on the functioning of the Biosafety Clearing-House (BCH), reliable access to which is central to all aspects of implementation of the Protocol, particularly the provisions regarding living modified organisms for direct use as food or feed or for processing (LMO-FFPs).

The first meeting of the COP/MOP will also have to establish certain processes and mechanisms that may elaborate or add to the body of substantive obligations of the Parties. In particular, processes will need to be considered to advance consideration of detailed requirements for documentation accompanying transboundary movements of LMO-FFPs under Article 18(2)(a), and to consider the appropriate elaboration of rules and procedures with regard to liability and redress. While both remain extremely contentious issues, it is important to the early credibility of the Protocol that processes are set in place that seek to complete work on these issues within the timeframes envisaged in the Protocol.

COP-MOP.1 must also consider and approve compliance procedures for the Protocol. Much work has already been undertaken on this issue by the ICCP, but some significant issues remain to be resolved, particularly as regards what entities may trigger the compliance procedures. For the foreseeable future, many compliance issues seem certain to remain inextricably linked to questions of capacity, for example to respond to and take decisions on notifications of proposed transboundary movements of LMOs. While some assistance will be available to Parties through the roster of experts and other mechanisms established under Article 10(7), such mechanisms cannot substitute for adequate legal frameworks and assessment, ►

monitoring and decision-making capacities at the national level. The design and application of the compliance mechanism will therefore need to be sensitive and responsive to the capacity constraints faced by many Parties. At the same time, they must be capable of addressing compliance issues and should therefore, in my view, incorporate a variety of trigger mechanisms and response measures.

In addition to this challenging agenda, there are numerous other issues which seem to merit additional consideration by the COP-MOP. Initial suggestions for questions that might be addressed under Article 29(4) have included: the categorisation of LMOs; risk assessment and risk management; establishment of harmonised rules for unique identification systems; and transboundary movements of LMOs involving non-Parties (ICCP recommendations 2/6 and 3/8). A number of other important implementation issues could be taken up here. One might envisage the COP-MOP considering for example: how to ensure that or evaluate whether bilateral, regional or multilateral regional arrangement or agreements are 'consistent with the objective of the Protocol' and 'do not result in a lower level of protection'; what types of LMOs fall into the category of LMOs that pharmaceuticals for humans and are addressed by other relevant international agreements or organisations' for the purposes of Article 5; or further work to clarify relevant socio-economic considerations within Article 26.

In addition to work that will take place in the COP-MOP, cooperation and coordination with other relevant international organisations will also play a key role in promoting effective implementation of the Protocol. A flurry of international activity on biotechnology and biosafety in recent years has given rise to a complex body of relevant international rules and standards, some of which are still under development. International organisations and instruments relevant to the Protocol include those addressing agriculture, food safety and health, such as the Food and Agricultural Organization of the United Nations (FAO) and the International Plant Protection Convention (IPCC), the Codex Alimentarius and the World Health Organization (WHO). Efforts at coordination with these and other relevant bodies need to address both policy coordination – ensuring that states' rights and obligations regarding the regulation of LMOs are "mutually supportive" – and operational coordination. At the policy level, the relationship that has attracted the most attention has been that between the Protocol and relevant agreements established under the World Trade Organization (WTO). Enhancing policy coordination and mutual supportiveness between these two bodies of international law requires ongoing two-way communication. In this regard it is important that the CBD is granted observer status in relevant WTO committees, and, of course, that representatives of the WTO and of other relevant intergovernmental organisations, continue to attend meetings held under the auspices of the Protocol.

At the operational level, the CBD has by now extensive experience in a variety of mechanisms designed to facilitate cooperation between international organisations, including the establishment of memoranda of cooperation, and the development of targeted joint work programmes. Such mechanisms can also be useful in promoting implementation of the Protocol and have already been taken up in the case of the IPPC in pursuance of ICCP recommendation 2/12. Operational cooperation will be of particular importance, for example, in the fields of information exchange and data management, particularly the functioning of the BCH, capacity-building, and implementation and enforcement mechanisms. In this regard, many relevant organisations have already been mentioned in the reports and recommendations of the ICCP.

In addition, as has already been the case in the drafting of the Protocol itself, there may be much that can be drawn from practice and procedures developed under other multilateral environmental agreements (MEAs), in relation, for example, to documentation requirements, reporting formats and monitoring. Of particular relevance here are other agreements which address the transboundary transfer of hazardous or potentially hazardous materials, such as the Basel and Rotterdam Conventions.

Building Capacities for the Effective Implementation of the Biosafety Protocol:

Challenges and Opportunities

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It was a sincere pleasure to receive the invitation to contribute to this CBD News Special Edition. The subject of capacity-building, which I was asked to address, has occupied me frequently over the past years.

Introduction

This article address three topics namely: (1) Challenges and opportunities in capacity-building for the effective implementation of the Protocol; (2) Experiences from previous and on-going biosafety capacity-building initiatives; and (3) Identification of new and innovative funding options and delivery strategies.

1. Challenges and opportunities in capacity-building for the effective implementation of the Protocol.

For the Protocol to function in practice, countries need to have systems in place that allow them to process notifications, to carry out risk assessments, etc.

This requires that countries establish what we call a "national biosafety framework", which includes a policy, a regulatory regime, a system to handle notifications, systems for monitoring and inspections, and systems for public information and participation.

The establishment of a national biosafety framework is not something that suddenly became necessary because of the Protocol. Since 1992, Article 8g of the Convention on Biological Diversity (CBD) has called for the establishment of such national mechanisms.

Yet, the coming into force of the Biosafety Protocol presents a new challenge.

On the one hand, countries need to establish a well thought-through biosafety framework that is workable, transparent, and consistent with the Protocol and other international agreements.

This process usually follows two phases: a development phase and an implementation phase. This two-phase approach is also reflected in the GEF Initial Strategy on Biosafety, which was aimed at assisting countries to be prepared for the coming into force of the Biosafety Protocol. It is important to recognise that although we can make use of over 20 years of experience with national biosafety frameworks, these two phases still will take several years.

On the other hand, and this is the challenge, countries need to be able to start "working with the Protocol" after they have become Parties.

This challenge is similar to the task of someone who is planning to build a house, and must at the same time cook meals in a kitchen that mainly exists on the drawing board. Obviously, capacity-building projects face a similar challenge.

The work of UNEP with regard to the GEF Initial Strategy on Biosafety consists of – among others:

- the UNEP-GEF Project on Development of National Biosafety Framework and
- the UNEP-GEF Projects on Implementation of National Frameworks.

To address the challenge described above, UNEP-GEF initiated several activities on different fronts to assist countries in building a well-founded national biosafety framework in two phases, as well as to make tools available that countries can use immediately. ►

More detailed information about these UNEP-GEF-activities can be found on the UNEP-GEF Biosafety web site (www.unep/.ch/biosafety).

2. Experiences from previous and on-going biosafety capacity-building initiatives.

Having come across many biosafety capacity building projects over the last ten years, I believe that the following aspects such as: country ownership, duration, peer review, regular evaluation, forward thinking, and last but certainly not least – coordination, are important for the success of biosafety capacity building projects.

Country ownership

Projects need to be country driven, i.e. requested and executed by the countries. Organisations assisting in capacity building need to be available for assistance and guidance, but the real "drive" needs to come from the countries requesting the support. Projects that are 'forced upon' countries, often lead to nothing, because there may be no drive to get things done, and – worse – there may be no commitment for continuation.

Duration

Given the legal and scientific complexity of this field, and given the high 'turn over' of staff in the countries, long projects of several years are often preferable to a series of short projects.

Peer review

It is no help to countries if the support they are being given consists of an exotic approach that is not widely viewed as being valid and workable. It is therefore important to regularly present the approach taken to a review by peer experts. This is particularly the case for the scientific components of the implementation phase.

Regular evaluation

Biotechnology and biosafety evolve rapidly. It is therefore important to regularly re-evaluate the progress of a project, and adjust where necessary. While it is important to start a project with a clear plan, that plan should not be a straightjacket.

Forward thinking

The success of a capacity building project depends to a large extent on the continuation afterwards. This requires that part of the work should be aimed at 'follow up' when the projects are over. It is generally recognised that (sub) regional collaboration is one of the best mechanisms to foster continuity and maximise resources.

Coordination

Over the past few years, biosafety capacity-building initiatives have emerged in great numbers from a variety of sources. In many cases, the funding sources have been unaware of similar initiatives and there has been immense duplication of work that has wasted resources and sometimes was counter-productive.

That situation is slowly improving, but is still far from satisfactory.

I believe that one of the most promising opportunities to avoid duplication is the Coordination Mechanism that has been called for by the ICCP (see Document UNEP/CBD/ICCP/3/10, Recommendation 3/5 on Capacity-building) and on which the CBD Secretariat has taken some very useful initial actions.

Key to any coordination of effort is information, and all involved in biosafety capacity-building are called upon to enter and update their information in the capacity building database of the BCH (http://bch.biodiv.org/Pilot/Home.aspx).

For the same reason, one of the first steps in the planning stage of any biosafety capacity-building project should be to consult the BCH to check whether similar initiatives are planned or being carried out already.

3. Identification of new and innovative funding options and delivery strategies.

Funding options

Presently, there are many planned and ongoing biosafety capacity-building initiatives funded by international and national organisations, Governments, NGOs and the private sector. The amount of money involved over the next five years is somewhere over US dollars 100 million.

Photo: N. Mckee, IDRC

Before looking at 'new and innovative' funding options, I believe that we should first focus on coordination. I am convinced that considerable amounts of money can be saved by improved coordination.

Delivery strategies

If we don't act soon, one of the major challenges in biosafety capacity building will be the lack of experts who can act as trainers.

At the moment, only a handful of people have substantial practical experience in developing and implementing national biosafety frameworks and are available and capable of giving training.

Already now, with the growing number of projects, it is becoming increasingly difficult to get experienced people to be trainers in a workshop, and this problem will get worse over the next couple of years.

There is an urgent need to start searching for experts and then training those experts so that future demand will not far outstrip current supply.

In addition, a clear strategy needs to be devised to address this problem in a more strategic and structured way, something that could be picked up by the liaison group that is part of the coordination mechanism mentioned above.

This ties in with what I mentioned earlier about the need for (sub)regional collaboration.

When thinking about sub-regional collaboration, we should also be thinking about the longer term 'delivery strategy' of capacity building, which in my view should go in the direction that capacity building is largely managed by experts and organisations within the (sub)regions.

The Biosafety Clearing-House: Maximizing the Use of Modern Information Communication Technologies to Share Information and to Fulfill Requirements under the Cartagena Protocol

François Pythoud
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Access to and exchange of information was among the few non-controversial issues during the negotiation of the Cartagena Protocol.

Indeed, everybody agreed that safe and transparent trans-boundary movement of living modified organisms (LMOs) would require an efficient global system to ensure the exchange of pertinent biosafety related data between countries developing and producing LMOs and countries importing and using them. Following this common view, the Biosafety Clearing-House (BCH) was established in Article 20 as one of the key tools to assist countries to implement the Cartagena Protocol. There was a common understanding that the BCH should take advantage of the most recent information communication technologies and should therefore be mainly Internet-based.

The development of the BCH then became one of the top priorities of the Intergovernmental Committee for the Cartagena Protocol (ICCP), the objective being to ensure its full operability at the date of entry into force of the Protocol. The Pilot Phase of the BCH was launched following the first meeting of the ICCP in Montpellier in December 2000, to build experience and provide feedback for the development of a functional and accessible Internet-based BCH as well as to identify and address the capacity needs of countries. Two years and two ICCP meetings later, version 2 of the Pilot Phase was released on February 1, 2003, and should serve as the basis for the transition to the fully operable BCH.

The BCH today:

The structure of the BCH as it stands today is defined by its content, namely the different elements of biosafety-related information, as well as by its functions, which include mechanisms for registering and retrieving information. This is illustrated by the "Central Portal" and the "Management Center". The "Central Portal" offers a unique entry point to access the different elements of information, whereas the "Management Center" allows Parties to register and manage relevant national data.

At the technical and technological level, the Pilot Phase of the BCH took advantage of the experience gained during the last ten years by the Secretariat as well as the Parties to the Convention on Biological diversity (CBD) in the development of the Clearing-House Mechanism (CHM) of the CBD. In fact the Protocol explicitly establishes the BCH as part of the CHM. This integrated approach should ensure full compatibility between the two systems as well as efficient use of human and technological resources of the Secretariat. However, despite this close technical integration, the nature of information provided to the BCH is intrinsically different from that found on the CHM. In particular, information from the BCH will be used in legally-binding regulatory procedures and decisions, which has significant implication in terms of data quality control as well as compliance or liability.

The types of information accessible through the BCH can be divided into two groups: those mandated by the provisions of the Protocol and those that have been recommended by the governments through the ICCP to assist countries in implementing the Protocol. This second group includes the roster of experts on biosafety, the database on capacity-building needs and opportunities, a bibliographic search mechanism, Web links to relevant biosafety resources or even discussion forums.

The information specifically mandated by the Protocol could also be classified in two categories that could be described as "importer-driven data" and "exporter-driven data". The "importer-driven data" (e.g. national focal points, competent authorities, relevant biosafety legislation, national decisions, risk assessment reports) are provided by national governments to facilitate implementation of the Protocol and decision making under the Advance Informed Agreement procedure (AIA). The exporter driven data (e.g. the final decisions regarding the domestic use of LMOs that may be subject to transboundary

movement for direct use as food, feed and processing according to article 11.1) are essential for the implementation of the procedure under Article 11 of the Cartagena Protocol.

The BCH is organised on a decentralised basis, which should be adaptable to the high degree of variation in national capacities, infrastructure and needs. Governments can register information directly to the central database through the Management Centre or by sending data to the Secretariat using more traditional means. Another alternative is the development of national or regional components of the BCH whereby information located on a remote database could be accessed through the Central Portal by users. This approach allows governments to keep full control of and responsibility for their own data, and to facilitate updating of that information. Common formats for the different sets of information have already been developed to facilitate the establishment of a network of databases that are interoperable with the Central Portal.

One of the major issues faced by the Pilot Phase of the BCH was the relatively limited amount of data provided by governments, which made it difficult to test in real conditions the tools and common formats developed for the Pilot Phase. To circumvent this situation and also to benefit from existing databases containing information on approved LMOs, close partnership was established with other international organisations such as the ICGEB and the OECD. Those partnerships resulted in access through the BCH to databases such as the bibliographic database of the ICGEB or the product database of the OECD and enabled the Secretariat team to design and successfully test interoperability between independent databases.

Challenges for the future

The main challenge for the efficient operability of the BCH will be capacity building to ensure the full participation of all Parties and governments. As a first priority, all Parties to the Protocol should be able to register information directly to the central database through the Management Centre. The next step would be to develop national or regional databases and to aim to make such databases interoperable with the Central Portal. This will require significant and more targeted capacity-building efforts tailored to the needs of each country or region. Such efforts should not only include human resources, but also infrastructure, since many developing countries do not have sufficiently stable and rapid Internet connections to run standard information technology applications efficiently. At the regional level, priority should be given to the development of regional nodes to either host information or provide technical support. Strengthening of capacity building requires additional financial resources and better use of existing resources. UNEP has ►

therefore submitted to GEF a proposal on Building Capacity for effective participation in the BCH as an add-on module to the current GEF Project on development of National Biosafety Framework. Additionally, a transparent and effective co-ordination mechanism should be established under the supervision of the Secretariat to ensure efficient synergies with existing initiatives.

The BCH should be sufficiently flexible to adapt itself to the existing capacities, needs and requests from users in order to facilitate registration and retrieval of information. For example, some countries already have domestic information requirements related to the use of LMOs which are registered in national databases. Due to the regulatory system, the structure of the domestic database is often different from those of the BCH. This should be taken into account in order to avoid duplication of information as well as to promote interoperability. Along this line, it is also essential to develop tools such as thesaurai and controlled vocabularies to improve search facilities and to facilitate the use of different languages.

The BCH should also give access to information on all LMOs approved for use in the environment or as food, feed or for processing since these data are essential to achieve the objectives of the Protocol. This is an important issue since the legal requirements under the Protocol only apply to the LMOs approved after its entry into force. Therefore the ongoing collaboration with international organisations should continue to ensure access through the Central Portal to existing databases such as the OECD Product database. Similarly, countries that are not Parties to the Protocol should be encouraged to participate. Criteria should also be developed to allow participation of non governmental organisations, including industry.

The development of the Pilot Phase of the BCH in less than 4 years illustrates how the application of modern information management technologies can be used to build a powerful tool to assist the implementation of a multilateral environmental instrument. Such an impressive result was made possible in such a short time thanks to the full commitment of the Secretariat's staff and the support of the ICCP and its Bureau, as well as the members of the expert groups. The tool is there – the challenge will now be for all Parties, governments and relevant stakeholders to support the transition from the pilot phase to the fully operational and functional BCH by actively providing data and critically testing the BCH between 11 September and the first meeting of the Parties (MOP1) in February 2004 in Kuala Lumpur.

The success of this transition will allow MOP1 to take the necessary steps to reinforce the role of the BCH, not only as a tool to support the implementation of the Protocol, but more importantly as the first stone to build a global biotechnology information network to help achieve the objective of Agenda 21 towards sustainable development of modern biotechnology.

Integrating Scientific Information in the Future Implementation of the Protocol

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The Protocol was conceived as the first binding international instrument linked with the Convention on Biological Diversity and as a result, it must adhere to a series of laws and agreements already established by the international community.

This, and the fact that the Protocol is interwoven with environmental issues, marked its evolution and the concepts that guide its very essence. However, the context in which it will be applied depends exclusively on deliberations by Parties and Governments who have final responsibility for the Protocol's development and implementation.

It is commonly accepted that the underlying objective of the Protocol is to promote what can be loosely defined as the "common good." However, extreme dogmatic perspectives threaten the broad humanistic objective guiding the Protocol. These perspectives may be understood as being less expansive and adhering to a more "reductionist" view of the Protocol.

For Parties and Governments to meet the aspirations of their citizens and communities and to comply with their obligations under the Protocol, it may be necessary for them to embrace ideas that go well beyond the more restrictive interpretation of the Protocol's provisions. A more holistic or "integrative" approach may better reflect the aspirations of the community and ensure the successful implementation of the Protocol.

Behind these different viewpoints, there are two alternative approaches attempting to guide the development of the Protocol. One is the "the precautionary principle", which is strongly endorsed by the environmental community, among others. The other, which is articulated by those supporting a more restrictive interpretation of the Protocol, espouses a "strict observance of scientific information". These two different perspectives strive to influence the process of decision-making within the regulatory framework.

Despite the significant difference between these two approaches in impacting on the decision-making process, both highlight the overriding importance of access to information and knowledge for effective implementation of the Protocol.

Within this context, the precautionary principle was developed to address uncertainties in available information and knowledge and/or in the identification of existing gaps in science and knowledge, particularly when science supports the view that its findings are not final and may be open to further investigation and interpretation. To invoke the precautionary principle is, therefore, to consider relative knowledge in support of informed decision-making, particularly when the implications of decisions require great responsibility and caution. It is for this reason that the two approaches may be considered to be complementary, and beyond their respective special interests, may both in fact support the Protocol's objective.

In other words, because access to information is one of the most critical elements in the decision making process, it becomes essential to know what information is required, where it is located, and the most efficient mechanisms to guarantee full access to it.

When determining the information required to support risk analysis and decision-making, it is difficult to refer to purely " scientific information". This would imply more restrictive access to classes of information required for decision-making and may weaken the supporting mechanisms. It is highly beneficial to encourage and indeed accept the inclusion of information from different sources, explicitly recognizing that broader participation by different sciences and disciplines reflects more adequately the different needs and is critical for effective decision-making. While this view is generally accepted, it is not simple to implement and put in practice.

The countervailing view relies on a reductionist approach, which argues that only some areas of science can produce "scientific information" and that many other scientific areas and domains cannot claim to adhere to a high level of scientific rigour. ►

Therefore, when considering the question of what type of information is required in support of the decision-making process, several issues come to the fore. First, information required may fall under the rubric of all information that offers Parties and Governments the ability to make informed decisions. Second, that for this to occur, full participation by all sciences, including human sciences (biological, statistical, social, economic, etc.) is required. And third, access to information must be broad, rather than restrictive. It should not be not limited to those aligned with special interests.

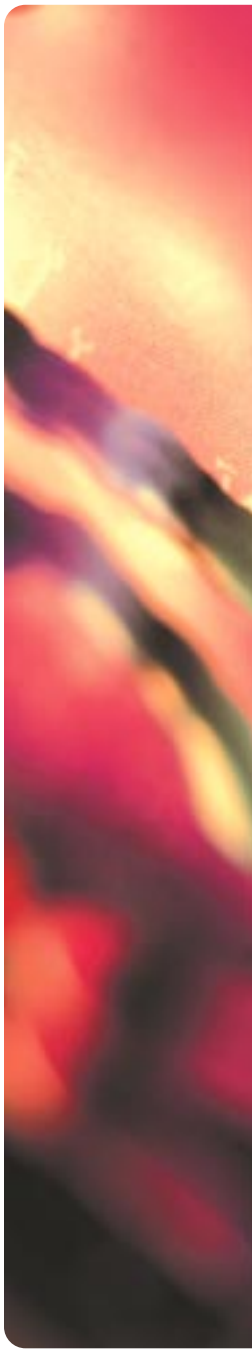
Presently, little information exists to answer the main questions faced by countries when undertaking risk analysis and developing strategies for risk management. As a result, it becomes critical to not only collect information, but also create new information that incorporates findings from the biological, environmental, economic and social disciplines.

Moreover, because much of the information is dispersed and not available in peer-reviewed international literature, it is deemed to be of lesser scientific value. Compounding this problem is the fact that the information at times is only available at the national level and applied by local scientists from government departments and the private sector, thereby limiting its dissemination and incorporation into mainstream international scientific literature. However, the importance of such information should not be underestimated, particularly since it may include reports and findings of studies grounded in local realities, reflecting the uniqueness of communities and especially their interrelations and impacts on particular ecosystems. Also this literature records the biological richness and vulnerability of the centres of origin and centres of diversification of the species. To ignore the value of this information would be harmful to the overall goals of the Protocol; indeed, the value of this information should be recognized as essential for the effective analysis and management of the risks posed by living modified organisms (LMOs).

It is necessary to identify with clarity the existing gaps in information and to strengthen research at the national level to generate new information. This implies collection and integration of dispersed data, identification of uncertainties and development of solutions based on a broad definition of scientific research. In summary, these activities ensuring adequate information retrieval and use, particularly with regard of needs found at the national, sub-regional and regional level, are absolutely essential if the objective is to build an information system which truly meets the needs of its users.

A common-sense strategy to ensure the viability of an effective information system is to promote alliances among universities, research institutes and the private sector at the national and international level. Focusing on biosafety issues, these alliances would encourage high levels of public participation and transparency, create an atmosphere of mutual support and trust, and enable researchers from developing countries to retrieve information, and equally importantly, to contribute information.

Building an effective information system that makes it possible to undertake research and study of the different aspects, including surveys of the concerns voiced by different communities and countries, requires adequate financial resources. And to ensure equitable participation, these financial resources must be made available to developing countries.



In parallel it is absolutely necessary at the national level to strengthen and/or to promote an equitable "system" for sharing information through inter-institutional, interconnected networks. These networks in turn would interconnect with the National Focal Points (NFPs). The NFP will interact with other focal points in other counties, creating sub-regional and regional network(s), which may be further strengthened by interconnecting the private nodes, thereby giving greater plurality to the "system".

It is important to note efforts made during the pilot phase of the Biosafety Clearing-House (BCH) and to discuss more optimal ways to organize and make information available to the BCH. In these efforts, the use of common formats was discussed and implemented, and appears to assist greatly in the facilitation of information exchange. In addition, use of common formats encourages "uniformization" of information.

There is a need for latitude in the treatment of these issues, to allow for the inclusion of other issues and particularities that better respond to diverse interests. The aim is to broaden the information base offered to users with the understanding that this will more

effectively promote the “common good”. It is also important to ensure that the system is interactive and encourages dialogue and two-way communication. All participants must contribute equally to the system, rather than having some participants being only passive receivers of information and not information providers as well. Teaching and learning forms a dialogue, and effective exchange of knowledge occurs when all participate as equal members.

In conclusion, the recommended strategy to strengthen the generation and dissemination of available scientific information for the analysis and management of risks must include:

1. Efforts at the local level to:

- Identify, collect and disseminate existing and relevant scientific information for decision making.
- Identify gaps in existing information.
- Strengthen the research capabilities related to biosafety issues.
- Strengthen the alliances among groups of researchers, academia and the private sector to obtain information quickly.
- Establish inter-institutional networks for a fluid interchange of information.

2. Attention to the needs at sub-regional and regional level for:

- The establishment of sub-regional and regional nodes of information exchange when and where necessary.
- The availability of experts from the sub-region or region to reinforce national deficiencies, as needed.

3. Strengthening the Biosafety Clearing-House:

- Implement necessary activities to populate available databases, develop effective communication systems with National Focal Points and other sources of information, recognizing that the BCH is the most efficient integration mechanism and guide for the implementation of the Protocol.

Promoting and facilitating informed public participation in the implementation of the Biosafety Protocol and the national and international levels

Lim Li Lin and
Chee Yoke Ling
Third World Network

The Biosafety Protocol in Article 23 requires Parties to promote and facilitate public awareness, education and participation in the decision-making process with regard to biosafety, and also requires mandatory public consultation and disclosure of results of decisions to the public.

The issue of genetic engineering (GE) and biosafety has captured unprecedented public interest and concern around the world. Apart from the scientific discussion, disagreement and uncertainty surrounding genetic engineering, many other ethical and socio-economic concerns and realities are issues that have to be addressed in biosafety regulation at the international and national levels.

At the national level, the implementation of the Biosafety Protocol is only one part of a wider and more comprehensive national system of biosafety regulation that countries put in place to meet the objectives of the Biosafety Protocol. As the Biosafety Protocol is an international agreement of minimum standards for biosafety, the provisions regarding public participation are the minimum requirements that all Parties must fulfill.

Parties can thus provide for wider and stronger participation, including the right to information, effective participation in decision-making and effective access to judicial and administrative proceedings. The last is particularly relevant in the formulation of a liability regime that will provide effective redress and remedy. There are valuable precedents in existing laws including the 'Aarhus' UN/ECE Convention on Access to Information, Public Participation in Decision-Making, and Access to Justice in Environmental Matters, and national environmental and social impact assessment procedures in many countries.

During the negotiations of the Biosafety Protocol, the active commitment and involvement by some sectors of the public, including non-governmental organisations (NGOs) and scientists helped to introduce valuable information, ideas and points of view that contributed positively towards the understanding of biosafety and the development of the Biosafety Protocol.

Often, developing countries are at a disadvantage with poor information flows, and the multidisciplinary and holistic nature of biosafety requires the engagement of all sectors of society, including the wider scientific community, that may not normally be present in negotiating fora or regulatory bodies. The process was also further complicated by the powerful trade interests of major producers of genetically modified organisms (GMOs) and associated products. It was effective public participation that greatly helped to maintain the integrity of the discussion on scientific, environmental, health and socio-economic issues.

These experiences are also important at the national level. Public participation can be a valuable tool on many levels — in the development of the national biosafety law or system, in the decision-making on specific GMOs, and in the wider debate on genetic engineering and sustainable development in a particular country. The latter is often not considered seriously at all but some countries, which introduced GMOs without consulting the public on these issues at the outset, have experienced a public backlash as a result.

With limited resources and the uncertainties around even the claimed benefits of GMOs and associated products, developing countries need to be able to consider non-genetic engineering options to meet their developments priorities. These priorities necessarily require public discussion. The role of the public in developing countries in the areas of monitoring and enforcement should also be fully recognised given the limitations on resources.

The Biosafety Protocol in Article 23 recognises that for public participation to be meaningful, there must be access to information, and public awareness and education. A number of challenges present themselves. For example, how are scientific issues to be presented to the public in a manner that is understandable

Photo: C. Dupuis, IDRC

by the layperson? Or how should scientific uncertainty and scientific disagreement be communicated to the public?

A frequent misconception is that the public is critical and skeptical of genetic engineering simply because people are ignorant. And that the public is to be 'educated' so that there can be public acceptance of genetic engineering, and the public will then confirm the policy decisions that have already been taken. Or that the scientific discussion should be left to the scientists in the policy arena, while the public is left to comment on the ethical and socio-economic concerns that plague genetic engineering.

With polarised views and vastly divergent interests, a credible public awareness, education and participation process enables all views to be heard and debated on all issues, avoiding dishonest value judgments on the kinds of information and the way it is presented to the public.

This also presents an opportunity to hear from all available expertise in the public from all fields, outside of the commonly used pool of expertise. Experience has also shown that the public can well discuss scientific issues if these have been communicated in a way that people can understand, and that the public has an insightful wisdom in dealing with scientific uncertainty and science policy that must be heard if science is truly to serve the needs of society.

Another key challenge in public participation is to reach out to the sectors of the public that are not organised, outside of the usual NGOs and civil society groups that are generally considered as representing the public views. These groups include farmers, especially the small farmers in developing countries, and consumers in general.

Integral to the implementation of effective public participation is access to information. Thus Article 21 on "confidential information" needs to be implemented in a manner that is consistent with Article 23 and the spirit and objectives of the Biosafety Protocol.

During the Biosafety Protocol negotiations, the Africa Group (supported by a number of other developing countries) argued that a provision on protection of trade secrets and confidential business information was not necessary since these are already adequately protected under other related laws. The World Trade Organisation (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) already provides for such protection with prescribed criteria.

However, the Protocol provision remained at the insistence of some developed countries. Unfortunately it also evolved from "confidential business information" to just "confidential information" arguably going even beyond the TRIPS requirements.

Thus Parties will have to be clear about defining the scope and conditions for claims for protection of confidential information in national biosafety laws. It is important to emphasize that the regulatory authorities have the right to all information necessary for decision-making and that Article 21 only refers to information that is confidential in relation to the public.

Experience reaffirms that it is only in an open and transparent system that all available information, views and assessment can be brought together to ensure sound and responsible collective decision-making. Since the possible consequences of hazards posed by genetic engineering to the environment and human health are so serious, information disclosure to the public – and especially scientists in the public domain - is crucial.

There is already increasing public mistrust with the revelation of highly questionable corporate practices in recent years, and the growing number of cases where scientific dissent and evidence of hazards of genetic engineering are subject to intense pressure from industry. Critical scientists have also been known to be personally vilified. Thus, to implement the spirit of Article 23, Parties have to design national laws and systems for sound technology assessment of genetic engineering with the involvement of the public at both the design and implementation stages.

Fostering Private Sector Involvement in the Implementation of the Cartagena Protocol: Proposals for Consideration

L. Val Giddings
Vice President for Food and Agriculture, Biotechnology Industry Organization

Representing over 2,200 firms from more than 130 countries worldwide specializing in plant and animal agriculture, food production, human and animal health care, and the environment, the Global Industry Coalition (GIC) played an active and vital part in the negotiation of the Biosafety Protocol.

The private sector: a key stakeholder

It viewed its role during the negotiations as providing concrete information on the realities of international trade in LMOs, existing international and national regulatory requirements and practices, and the potential implications of the various proposals under debate. The GIC offered this input in the context of obligations under the Convention on Biological Diversity (CBD) to promote technology transfer and cooperation and the distribution of the benefits of biotechnology, while at the same time providing an adequate level of safety, as part of the global quest for the conservation and sustainable use of biological diversity.

The role of the GIC, along with the International Grain Traders Coalition, the International Seed Federation, and other private sector organizations and associations concerned and involved with the Protocol, is even more critical at the implementation stage. Indeed, as the Protocol becomes reality for 50 countries on 11 September 2003, never has it been more important for the private sector to assist governments and the international community by providing detailed information on commercial practices, possibilities, and limitations based on its extensive experience with the regulation and trade of LMOs.

Possible benefits to the private sector of the Protocol

Workable, predictable, transparent, and effective regulatory structures are not only welcome, but also necessary for the private sector to operate. In the countries where biotechnology first was developed, the existence of flexible, science-based and effective regulatory mechanisms to ensure appropriate risk assessment and risk management of activities in this field were put in place early on. The Protocol, by offering a structure for ensuring science-based risk assessment of LMOs prior to intentional introduction into the environment, may offer the possibility for more countries to engage in appropriate and informed decision making and avail themselves of the benefits of biotechnology while providing for biosafety.

A lasting benefit of the Protocol for all concerned is the establishment of the Biosafety Clearing-House (BCH). A centralized mechanism that provides clear and accessible information about legislative requirements, the regulatory status of LMOs, risk assessment outcomes, and contact points for more information is critical for the regulated community, regulators and the public alike. Over time, it is anticipated that the BCH may lead toward greater harmonization and even more extensive information exchange. Of great interest will be the information ultimately posted by developing countries as their scientific institutes and research organizations identify and develop solutions to local challenges using modern biotechnology.

Key challenges in Protocol implementation

As much potential as the BCH offers, key challenges in the implementation of the Protocol begin with the fact that the BCH is not yet fully operational for lack of information provided by countries Party to the Protocol. In some cases, information simply has not been posted; in others, there are clear misunderstandings about the nature of the information required. For example, many countries have provided detailed information about the various governmental bodies involved in biosafety regulation without providing a clear indication of to whom a notification should be sent. The relationship between the legislation that can be found on the BCH and the Protocol is unclear in most cases because countries have not entered a declaration clarifying that the domestic legislation is intended to apply. Furthermore, given that it appears that legislation found in other databases has been imported into the BCH, it is unclear whether the legislation that appears is the correct and complete version.

The private sector also is concerned that key implementation issues will not be resolved until February 2004 at the earliest. Critical aspects of the Protocol with which the private sector ultimately will be expected to comply therefore will remain unknown for an extended period of time after entry into force of the Protocol. Effecting change in commercial practice requires the existence of clear expectations and requirements and a reasonable period of time to incorporate any new obligations. While some have suggested voluntary compliance with the recommendations of the Intergovernmental Committee on the Cartagena Protocol (ICCP), it is evident that the Conference of the Parties serving as the Meeting of the Parties may or may not adopt these recommendations. Further, it is unclear how issues that did not enjoy consensus during the ICCP process will be resolved. The resulting uncertainty creates a serious challenge for the private sector.

In addition to uncertainty, the private sector is concerned about unrealistic expectations and interpretations of the Protocol at both the international and national levels. Interpretations and implementation decisions that exceed the requirements of the Protocol can result in serious negative effects on international trade, research and development in both developing and developed countries and, fundamentally, countries' access to food, feed, seeds, and other desired products. The view that including "products thereof" in domestic implementing legislation for environmental safety somehow constitutes "stricter" legislation is one example. Such provisions clearly exceed the requirements of the Protocol; indeed, they were considered and rejected during the negotiations for good cause. Rather than offering more protection, inclusion of "products thereof" in domestic implementing legislation will inevitably overburden government regulators without environmental benefit.

Forcing the development of new, technology-specific liability provisions in the absence of corresponding technology-specific risk is another aspect that would negatively impact technological development and even the environment. Companies already are held liable for damage they cause, regardless of whether it involves the use of one technology or another. However, the establishment of biotech-specific liability regimes at the international or national levels would create disincentives against using modern, sustainable technologies. Such disincentives would include making the use of these technologies more expensive, legally risky even when they are shown to be at least as safe as conventional technologies, and difficult to insure, without enhancing the preventive effect of regulatory systems. These and other effects have not been fully considered by many engaged in the implementation debate. ►

Enhancing private sector involvement

During the ICCP process, the private sector has been identified as a key stakeholder in Protocol implementation and a critical player in building the capacities necessary for countries to implement and comply with the Protocol. Indeed, the private sector is routinely called upon to contribute and must do so if the Protocol is to be workable and effective and technology transfer and cooperation as envisaged in the CBD and in Agenda 21 is to succeed. It is surprising, therefore, that some appear committed to circumscribing the role of the private sector rather than encouraging its active engagement.

This was seen during the ICCP process, for example, when some governments proposed a limited role for the private sector in capacity building. It is routinely seen when the private sector is called upon to assist with identified capacity-building needs but its efforts to respond directly to these requests are viewed with suspicion and sometimes even rejected.

Photo: Cédric Deton

The ICCP process has been marked by increasing recognition of the important role of the private sector, alongside other stakeholders, on implementation issues. Further enhancing private-sector involvement in the implementation of the Protocol will require not only calling upon the private sector to act but an open mind and willingness to consider the contributions it offers. Providing more timely and direct opportunities for the private sector to offer its views on the potential implications of various options for implementing key Protocol proposals also would encourage greater private sector participation in the process. Countries with functioning regulatory systems in place routinely engage in discussions with the private sector and other stakeholders about the implications of regulatory options under consideration. Building into the process additional platforms for these kinds of practical exchanges of views at the international level could foster a more practical, science-based approach that would ensure better decision-making on implementation matters.

The Biosafety Protocol: Documentation and International Trade

Dennis Stephens, Canadian Grain Council

The Cartagena Protocol on Biosafety will have a profound effect on the international trade in grains, oilseeds, pulses and special crops.

Background

Effective September 11, 2003 the transboundary movement of most living modified organisms (LMO's) to or from countries that are Parties to the Protocol must be accompanied by appropriate documentation.

The Protocol impacts both Parties and non-Parties. Article 24 of the Protocol states that transboundary movements of LMOs between Parties and non-Parties shall be consistent with the objectives of the Protocol - in other words, countries that have not ratified the Protocol but that export LMOs to Parties must also comply with the Protocol's provisions implemented in the importing country. Thus, entry into force will ultimately impact both Party and non-Party countries that export LMOs to countries that are Parties to the Protocol that have national implementing legislation.

Article 18 requires the safe handling, packaging and transport of LMOs covered within the scope of the Protocol. In addition, paragraph 2(a) describes the requirements for the transboundary movement of LMOs for food, feed or for processing, 2(b) covers LMOs destined for contained use and 2(c) addresses shipments of LMOs for intentional introduction into the environment.

The text in Article 18 is of a general nature and unfortunately many documentation issues remain unresolved after three meetings of technical experts and three meetings of the Intergovernmental Committee on the Cartagena Protocol. These issues have been deferred for resolution to the COP-MOP.1 to be held in Malaysia in February 2004. As a result, some confusion on documentation requirements may exist.

Industry's objective is to implement the Protocol to protect the world's biodiversity while maintaining the benefits of the current low cost global handling and transportation system. Two major international industry groups have evolved to advise governments in these matters. The Global Industry Coalition (GIC) was formed early in the process to advise countries during the negotiations leading up to the signing of the Protocol in Montreal in 2000. The GIC now has 2,200 firms from more than 130 countries and includes companies from a variety of industrial sectors including plant and animal agriculture, food production, human and animal health care, and the environment. The GIC (see article by Val Giddings) continues to be active during the Protocol's implementation process.

The International Grain Trade Coalition (IGTC) was formed in 2001 in recognition that the Protocol could have a profound impact on maintaining a low cost bulk handling system to ensure an inexpensive food supply for world consumers. Today the IGTC has 17 members representing more than 1000 organizations in more than 80 countries. The IGTC represents importers, exporters and food, feed and industrial processors. On documentation issues, the IGTC has concentrated on Article 18.2(a) while GIC has focussed on Article 18.2(b) and (c).

Article 18.2(a)

With the Protocols' coming into force, the IGTC is urging an early resolution of the outstanding issues associated with Article 18.2(a) in order to avoid unnecessary disruptions in commodity trade. The transboundary movement of these commodities is staggering. For food, feed and processing alone, the volume of international trade each year amounts to about 200 million tonnes of cereals, 30 million tonnes of rice, more than 70 million tonnes of oilseeds and more than 7 million tonnes of pulses.

The IGTC encourages major exporters to use Article 24 of the Protocol to bring greater clarity to documentation requirements for grain destined for food, feed and processing. Article 24 enables Parties to enter into arrangements with non-Parties on the transboundary movement of LMOs provided that the arrangements are consistent with the Protocol. Major exporters have met on two occasions in Argentina to seek agreement on how best to clarify documentation requirements under Article 18.2(a) to avoid trade disruptions. ►

The IGTC recommends that Article 18.2(a) be clarified by naming the commercial invoice as the document to be used to carry the "may contain" language, when required. If all exporters use the same document, then custom officers do not have to search through all shipping documents to see whether or not the cargo is an LMO shipment. The IGTC suggests that the "may contain" language, when required, should be as agreed upon at the Montreal Expert Committee meeting:
"Cartagena Protocol Provision: This shipment may contain living modified organisms intended for direct use as food or feed, or for processing, that are not intended for intentional introduction into the environment."

The last exporter prior to transboundary movement and the first importer after transboundary movement named on the invoice should be the contact points for further information. And finally, it is also important that the unintentional presence of LMOs in a non-LMO shipment is not a trigger for the "may contain" documentation.

There also is need to clarify when the documentation should be used. The IGTC recommends that the "may contain" documentation for transboundary movements of commodities intended for food or feed or for processing be provided for an LMO of that commodity species covered under the scope of the Protocol that is authorized in or sold from a country of export, except for those shipments for which:

(I) The exporting country does not have in commerce any LMO of that species; or
(II) The exporter and importer have contractually defined a "non-LMO shipment;" provided, that such shipment achieves a minimum of 95% non-LMO content, and that such definition does not conflict with regulations of the importing country.

Exporters are currently in discussions with major importers to seek agreements to clarify Article 18.2(a) to ensure trade is not disrupted following the Protocol's coming into force. The IGTC believes that such agreements between importers and exporters should also facilitate resolution to outstanding Article 18.2(a) issues at COP-MOP.1.

Article 18.2 (b) and (c)

Similar unresolved issues also need resolution by COP-MOP.1 with respect to the documentation requirements for Article 18.2(b) and (c). The Global Industry Coalition is preparing recommendations for language to be included on shipping documentation - based on the ICCP-3 recommendations - when exporting LMOs to Parties in order to meet the documentation requirements outlined in the Protocol.

LMOs destined for contained use (Article 18.2(b))

In order to meet the documentation requirements of Article 18.2(b) of the Protocol, GIC suggests that the following information be included on existing shipping documentation (such as commercial invoices);

(I) The following statement outlining the shipment contents: "This shipment contains living modified organisms for contained use" (may specify contents of shipment here, such as "*Bacillus subtilis* containing the a-amylase gene from *B. stearothermophilus*");
(II) The name and address of the exporter, importer or consignee, as appropriate, including contact details necessary to reach them as fast as possible in case of emergency;
(III) A brief description of any requirements for the safe handling, storage, transport and use of the LMO when safe handling requirements under other international agreements (such as the International Plant Protection Convention, or in the case of movement of genetically modified microorganisms, the UN Recommendations on the Transport of Dangerous Goods) have not already been met. In the event that there is no requirement, indicate that there is no specific requirement;
(IV) The name and address of the consignee.

LMOs for intentional introduction into the environment (Article 18.2(c))

In order to meet the documentation requirements of Article 18.2(c), GIC suggests that the following information be included on existing shipping documentation (such as commercial invoices);

(I) The following statement outlining the shipment contents: "This shipment contains living modified organisms";
(II) A brief description of the LMO, including category, name, relevant traits and/or characteristics;
(III) A brief description of any requirements for the safe handling, storage, transport and use of the LMO as provided under applicable existing international requirements (such as the requirements under the OECD Seed Schemes), under domestic regulatory framework, under the advanced informed agreement procedure, or under any agreement by the importer and exporter. In the event that there is no requirement, indicate that there is no specific requirement;
(IV) The name and address of the exporter and importer, including contact details necessary to reach them as fast as possible in case of emergency (designate which is to be used as the contact point for further information);

(V) The following declaration: "The exporter declares that the transboundary movement of this LMO is in conformity with the requirements of the Cartagena Protocol on Biosafety applicable to the exporter."

Balancing Biosafety, Trade and Economic Development Interests in the Implementation of the Cartagena Protocol:

A Developing Country Perspective

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The central focus of the Cartagena Protocol on Biosafety is to ensure the safety of movement of living modified organisms (LMOs) between countries, and of their subsequent use within countries.

1. Introduction

LMOs, as they are referred to in the Protocol, are organisms modified through the artificial (or in vitro) modification of nucleic acids, e.g. recombinant DNA technology and chimeraplasty, or through cell fusion.

Such artificial modifications, by virtue of being new to nature, may create equally new useful promises or hazards to humans and the environment. Their potential usefulness makes them appealing for development. However, their potential ability to cause harm makes the regulation of their development and use, as well as international trade in them, absolutely essential.

Both the development of, and trade in, LMOs as well as their regulation, present developing countries with difficulties that they must overcome if they are to be protected from any serious hazards and if they are not to be left behind in their attempt to catch up with developed countries. Let us look at these difficulties.

2.Poverty

Developing countries, especially the least developed among them, have very limited financial resources. Therefore, the money they can allocate for biosafety is bound to be inadequate. Even more worrying is the fact that, should a risk materialize, combating it requires financial and technical capacity that the countries do not have. Paragraph 8 of the Preamble of the Protocol recognizes this fact.

3. Socio-economic Considerations

Given this situation, one would have thought that socio-economic considerations would constitute a very important component in decision taking as to whether to import an LMO or not. But the relevant provision of the Protocol, Article 26, is very weak owing to pressure by industrialized countries to protect their structural advantages in trade and development. However, neither this weakness nor any other international law prevents a poor country from adhering to the precautionary principle and making a rigorous socio-economic assessment before importing an LMO.

4. Complex Environment

A microorganism under contained use functions optimally at high temperatures. If it escapes into the open environment it is unlikely to survive the winter cold of industrialized countries. In the hotter tropical and subtropical environments of developing countries, it may survive and flourish indefinitely. Other aspects of risk assessment in developing countries also become complicated because of the complex tropical and subtropical environments.

And yet, the Protocol fails to subject LMOs destined for contained use to the Advance Informed Agreement (AIA) procedure. However, it does allow a country to determine what it accepts as contained use. Developing countries should, therefore, put in place biosafety systems that restrict the term "contained use" only to laboratory conditions from which escape of LMOs is impossible.

5. Richer Biodiversity

It is a well-recognized fact that biodiversity increases with proximity to the Equator and decreases towards the Poles.

LMOs pose the environmental risk of passing their transgenes (and possibly other genes) to wild species. Therefore, the larger the biodiversity is, the more complex and uncertain becomes the evaluation of risks posed by LMOs.

And yet, owing to the low technical capacity of developing countries, specific knowledge on their biodiversity is very poor. ►

This makes the evaluation of risks posed by LMOs to their environments time consuming, difficult and unreliable. But pressure on them to accept many LMOs without adequate risk assessment is growing. They have to resort to caution.

6. Centres of Origin and Genetic Diversity of Crops

Crops were domesticated and diversified in certain regions of the world and not equally everywhere. Most centres of origin and diversity of crops are in developing countries. It is, therefore, obvious that a mistaken release of an LMO crop variety is more likely to introduce the unwanted gene or genes permanently into a developing country crop gene pool than into a gene pool of a developed country. This would jeopardize future prospects for food production in the world.

That is why this fact is recognized by the Protocol, in Paragraph 7 of its Preamble and in the information requirements (Annex I & II) as well as the risk assessment (Annex III) where the centres of origin and centres of genetic diversity are specifically mentioned.

Photo: Martyn Cox

It should thus be in the interests of industrialized countries not to push crop LMOs into countries of crop genetic diversity, although this is not necessarily recognized as such.

7. Greater Diversity of Environment-related Health Problems

There are more agents that cause or transmit diseases in humans in the tropical and subtropical climates, which characterize many developing countries than in the temperate zones where industrialized countries are found.

This makes evaluating the risks to human health posed by LMOs (as specified in Article 1 and Article 15.1 of the Protocol) in a developing country much more complex than evaluating them in an industrialized country. Of course, as the lower financial, technical and scientific capacity in the developing country makes the task onerous, greater caution is essential.

8. Trade and Environment

Trade rules favour industrialized countries. The Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs) is especially problematic for developing countries in the context of modern biotechnology and LMOs.

Article 27.3 (b) of TRIPs makes the patenting of microorganisms and microbiological processes compulsory, and the patenting of other life forms optional. Industrialized countries are allowing the patenting of LMOs and their sub cellular components based on this article. The cellular parts essential for modern biotechnology are already patented. This means that any endogenous modern biotechnology development and use will become bureaucratic and expensive, requiring negotiated access to the patented parts from tens of patent holders as well as having to pay royalties on them. It also means that LMOs, even when developed in-country, are controlled by the foreign patent owners of the sub cellular parts. This would infringe on the sovereignty of countries to use these materials in food production, medical and other applications.

Article 34 of TRIPs puts the burden of proof of innocence on the person accused of the infringement of a process patent. This means that when an LMO cross-pollinates with the unmodified crop of a smallholder farmer, his or her crop becomes contaminated by genes from the LMO. Most absurdly, however, he or she is assumed to be a process patent infringer. The culprits – the winds and the insects – cannot be summoned to court as witnesses. In this situation, a developing country that wants food sovereignty while guaranteeing that its farmers remain innocent of crime can only refuse the planting of LMOs of crops in its territories.

9. Liability and Redress

It would seem logical that if an LMO causes damage, its owner/developer should become liable to pay compensation for that damage. The industrialized countries do not want to rectify damage their LMOs might cause. But at the insistence of developing countries, there is now a commitment to negotiate a liability and redress regime under the Protocol (Art 27).

10. Concluding Remarks

Given these disadvantages, are developing countries going to benefit from modern biotechnology in their attempts to develop? I wonder. They have no choice but to stay safe. Therefore, they have to put in place biosafety systems firmly based on the precautionary principle, which is allowed by the Protocol (as provided for in Paragraph 4 of the Preamble; Articles 1, 10.6 and 11.8 as well as Paragraph 4 of Annex III and Article 2.4 of the Protocol).

Balancing Biosafety, Trade and Economic Development Interests in the Implementation of the Cartagena Protocol:

A Developed Country Perspective

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Background: *As one of a small number of countries with a significant export trade in Living Modified Organisms (LMO) crops, Canada worked closely with other members of the "Miami Group" of agricultural exporters to ensure that the particular interests and concerns of agricultural producers and exporters were taken into account in the negotiation of the Cartagena Protocol on Biosafety.*

"The Miami Group, from its inception, set out to design a Protocol that would both protect the environment and reflect the realities of global trade in agricultural commodities. The challenge for the group was to inject practicality and real-life experience into the negotiations with the aim of fashioning an instrument that could be implemented in an effective and meaningful way. This was a challenge given the unfamiliarity of most negotiators with global commodity trade and the refusal of some negotiators to admit that transboundary movements of LMOs had any relevance to trade and trade agreements." (The Cartagena Protocol on Biosafety - Reconciling Trade in Biotechnology with Environment & Development", Bail, Falkner & Marquard, p. 107)

When it became clear that other negotiators were unwilling to respond to exporters' major concerns, Canada, on behalf of the Miami Group, blocked consensus on the "compromise" text put forward for approval in the final hours of the negotiating session in February 1999. "In hindsight, our actions provided all negotiating groups with a second chance to negotiate a text that developers, importers and exporters of LMOs could all support"- (Bail, et al., p. 109)

Canadian officials subsequently played an active role in bringing the negotiations on the Protocol to a successful conclusion in Montreal in January 2000. Canada signed the Protocol in April 2001 and has since engaged in extensive consultation with various stakeholders and interested provincial governments and has begun work on draft regulations to implement the Protocol. As well, Canadian officials have sought to play an active role in meetings of the Intergovernmental Committee on the Cartagena Protocol in order to begin clarifying outstanding issues in order to facilitate Canada's consideration of ratification.

Canada's economic concerns: Currently, over 30 genetically modified plant varieties have been approved for cultivation in Canada and over 60 percent of all canola and an increasing percentage of all corn and soybean grown in Canada are genetically modified. Due to the nature of Canada's bulk commodity handling system, these LMOs are often blended with non-modified commodities prior to export. Exports of commodities including LMOs are in the order of Canadian $2 billion per year. Depending upon how the Protocol is implemented, it could have an impact that is positive, by providing trade certainty, or negative, by becoming a trade barrier.

While the Protocol text agreed in Montreal is a major improvement over the text rejected in Cartagena, it still raises concerns for our producer and exporter communities because of the referral to the MOP of decisions on certain important trade-related issues and uncertainty about how Parties to the Protocol will, in fact, implement its provisions.

The Canadian grains and oilseed industry is particularly concerned over the practical ramifications of the "may contain" identification requirement in Article 18 of the Protocol, notably the absence of defined thresholds for permitted non-approved and foreign material in bulk commodity shipments, the lack of reliable, standardized testing and sampling methodologies and the potential negative impact on non-genetically modified Canadian agricultural commodities that may have to be documented as they are co-mingled with LMO varieties. The concern is that ►

non-LMO commodities that are not intended to be captured under the scope of the Protocol could become subject to its provisions. These concerns apply more broadly, and not simply as a consequence of the Protocol, as other governments move to establishing thresholds and tolerances for LMOs in commodities under their domestic legislation.

The Canadian industry has also identified concerns regarding the use of the precautionary principle/approach, the possibility of an eventual liability protocol, use of socio-economic considerations in decision-making and the operation of the Biosafety Clearing-House (BCH). They have sought government assurance that the Protocol would not override current trade rights and obligations under the WTO.

In response to these and other concerns, the Canadian government launched an Action Plan in early 2003 to provide the best available intelligence and information as advice to Ministers when they consider ratification of the Protocol. The Action Plan identifies activities in four broad areas:

1) Elaborating policies related to: a) linkages, via the BCH, to industry and other civil society sources of information on LMOs, biosafety and biotechnology and; b) Public Awareness and Participation as required under Article 23 of the Protocol:

2) Elaborating and advancing internationally Canadian positions regarding issues of concern to Canadian industry stakeholders;

3) Intelligence gathering, analysis and influencing of positions of Parties and prospective Parties to the Protocol relative to issues of concern to Canadian industry stakeholders; and

4) Developing targeted bilateral arrangements with other LMO agricultural commodity exporting countries and key impor markets for Canadian LMO agricultural commodities.

The Cartagena Protocol and international trade rules: One of the basic objectives of Canada and other Miami Group members was to ensure that the trade-related provisions of the Protocol were consistent with WTO Agreements relevant to trade in LMOs, and that rights and obligations under WTO and other relevant international agreements were not changed as a result of the Protocol.

The Protocol contains three paragraphs in the preamble that: 1) recognize the mutual supportiveness of trade and environmental agreements; 2) emphasize that the Protocol does not change the rights and obligations under existing international agreements, and 3) reflect the understanding that the Protocol is not subordinate to other international agreements (although it does not have a superior status). While it cannot be ruled out that a Party to the

Protocol might seek to exploit an ambiguity in the text or misapply a provision for trade protectionist reasons, we believe that the Protocol can be read as consistent with Canada's rights and obligations under the WTO.

There are two provisions relating to the precautionary approach in the Protocol. On balance, the operative provisions on the precautionary approach achieve Canada's overall goal of consistency with WTO agreements in that they can be invoked in a way so as not to conflict with WTO rights and obligations. The provisions apply when there is a lack of scientific certainty due to insufficient scientific information and knowledge about the extent of potential adverse effects of an LMO. WTO rules recognize the right of countries to restrict imports where there is demonstrable science-based justification. They also permit, in some cases, provisional measures where there is insufficient scientific evidence to fully assess the risk.

Trade with non-Parties to the Protocol, a critical aspect to negotiations, is permitted under the Protocol. Canada was a non-Party to the Protocol at the time it entered into force and we are naturally concerned that there be no disruption of our agricultural LMO trade with any country for that reason. As well, the United States, Canada's largest trading partner, cannot legally become a Party to the Cartagena Protocol until it first ratifies the Biodiversity Convention. However, whether or not Canada becomes a Party to the Protocol in the future, trade between Canada and the United States is not expected to change in any significant way since both countries already regulate their trade in a manner consistent with the objective of the Protocol.

The Protocol incorporates the compulsory conciliation dispute settlement mechanism of the Convention on Biological Diversity. "Since this mechanism does not extend beyond compulsory conciliation, more practical and effective compliance and dispute settlement mechanisms will probably have to be developed if the protocol is to be used to avoid and resolve disputes. Any decision by a party under the protocol to exclude LMO imports is likely to have a double aspect. It is likely that the party of import will characterize it as a measure taken under the protocol, while the party of export will characterize it as a trade measure. Accordingly, a party of export that is a member of the WTO would probably be more inclined to seek a resolution of a related dispute under the WTO than under the untried protocol provisions. There is nothing in the text of the protocol that would preclude recourse to the WTO." (Bail, et al, 2002 p. 113). Moreover, a non-party in a trade dispute with a party to the Protocol could not avail itself of the Protocol dispute settlement provisions and might well only have recourse to the WTO when both are WTO members.

Improving Mutual Supportiveness: There are several practical means of improving the mutual supportiveness between the Cartagena Protocol and the WTO agreements. The Biodiversity Secretariat has for several years participated in annual MEA information sessions organized by the WTO Secretariat through which WTO members participating in the WTO Committee on Trade and Environment have been able to gain an improved understanding of the functioning of the major MEAs and the operation of their trade-related provisions.

Under paragraph 31 of the Doha Ministerial Declaration, WTO members are currently negotiating (i) "the relationship between existing WTO rules and specific trade obligations set out in multilateral environmental agreements (MEAs)." and (ii) "procedures for regular information exchange between MEA Secretariats and the relevant WTO committees and the criteria for the granting of observer status". When concluded, these negotiations should result in some form of agreed understanding of the relationship between the specific trade provisions of the protocol and relevant WTO rules, improved information flow between the Protocol Secretariat and WTO committees and an opportunity to become an observer in WTO Committees relevant to its work. For its part, the protocol secretariat and the Meeting of the Parties should continue to develop good working relationships with trade officials and persons active in the development, production, trade and use of LMOs in order to facilitate responsible LMO trade under the protocol.

From Adoption to Implementation of the Cartagena Protocol:

A Review of the Progress Made by the ICCP in Preparing for the first meeting of the COP-MOP

Ambassador
Philemon Yang
Chairman of the ICCP

In the early hours of 29 January 2000 in Montreal, when the resumed session of the first extraordinary meeting of the Conference of the Parties to the CBD (ExCOP-1) adopted the agreed text of the Cartagena Protocol on Biosafety, it was the end of one chapter and the beginning of a new one in the life of the Protocol.

From the ExCOP to the ICCP

Given the complexity and sensitivity of some of the issues and the contention around them that almost made it impossible to have agreement on the text of the Protocol until the very last minute, many people wondered if the Protocol, even though adopted, would ever enter into force. Well, the skeptics have been proven wrong. The Protocol entered into force on 11 September 2003, less than four years after its adoption. Although four years may sound long, this is in fact a remarkable accomplishment, given that the Biosafety Protocol deals with issues that were completely new for many countries, especially among the developing ones.

As it adopted the Protocol, ExCOP-1 was already looking forward: immediately after adopting the Protocol, it established the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP), an *ad hoc* open-ended body which was given the mandate to undertake, with the support of the Secretariat, the necessary preparations for the first meeting of the Parties to the Protocol. The newly established body met to elect its Bureau right after the closure of the ExCOP. The first task of this Bureau was to consider a work plan for the ICCP developed by the Secretariat, and submit it for approval to the Conference of the Parties at its fifth meeting.

Issues on the work plan of the ICCP

As is the case with many other multilateral treaties, the articles of the Protocol and their provisions do not necessarily give specific details regarding implementation, and this clarification, or operationalization, is expected to evolve gradually through the decisions of the governing bodies. By establishing an interim body to undertake the preparations for the first meeting of the Parties to the Protocol (MOP-1), the Conference of the Parties was in essence mandating the ICCP to develop recommendations on the issues that would be on its work plan in order to facilitate decision-making by MOP-1 regarding the implementation of the Protocol. The work plan of the ICCP had therefore to closely relate to what would be the agenda for MOP-1.

In developing the work plan, the ICCP Bureau was guided by two considerations: first, while it is essential to consider all articles of the Protocol and their provisions to effectively implement the Protocol, the work of the ICCP clearly had to address primarily the issues which the Protocol stipulates are to be considered at the first meeting of the Parties, namely: Article 10 (Decision procedure), Article 20 (Information sharing and the Biosafety Clearing-House), Article 27 (Liability and redress), Article 31 (Secretariat) and Article 34 (Compliance). However, a careful analysis of the text of the Protocol shows that, in order to plan its effective implementation, MOP-1 will also have to address other provisions, particularly those that relate to activities that have been identified as central to the operation of the Protocol and would promote the ratification process, such as those falling under: Article 18 (Handling, transport, packaging and identification), Article 22 (Capacity-building), Article 28 (Guidance to the financial mechanism), and Article 33 (Monitoring and reporting).

The Bureau also recommended to include in the work plan of the ICCP an item entitled “consideration of other issues necessary for the effective implementation of the Protocol (e.g. Article 29, paragraph 4)”. This would ensure that there would be an opportunity to consider additional issues that may be

deemed necessary for the effective implementation of the Protocol, such as developing a medium-term programme of work for the MOP. The work plan was approved by the fifth meeting of the COP in May 2000 and the ICCP embarked on the task of addressing the stipulated issues over the course of three meetings: December 2000 (Montpellier, France), October 2001 (Nairobi, Kenya), and finally, April 2002 (The Hague, The Netherlands).

Laying the groundwork for implementation

The ICCP is forwarding to the first meeting of the Parties to the Protocol a comprehensive package of recommendations on all the issues that were in its work plan. The recommendations are elaborate and implementation-oriented. Here are a few examples:

I) Decision procedure (Article 10.7): MOP-1 will consider a draft decision on procedures and mechanisms to facilitate decision-making by Parties of import. This puts emphasis on capacity-building (such as the use of the roster of experts), the Biosafety Clearing-House (BCH) and cooperation between Parties of import and Parties of export as the main mechanisms to facilitate decision-making by Parties of import.

II) Capacity-building: MOP-1 will have before it a comprehensive package consisting of an Action Plan for promoting capacity building for the effective implementation of the Protocol, ways and means to operationalize the roster of experts in biosafety to provide advice to developing countries in matters of biosafety, and a coordination mechanism to promote synergies and complementarity between various capacity-building initiatives.

III) Information sharing and the Biosafety Clearing-House: the pilot phase of the BCH established pursuant to the recommendation of the first meeting of the ICCP has been a tremendous tool to gain experience and expertise in the sharing of information related to biosafety. MOP-1 will be expected to adopt a decision with regard to the modalities of the operation of the BCH, building on the experience gained from the pilot phase.

IV) Compliance: MOP-1 will have before it a recommendation from the ICCP proposing procedures and institutional mechanisms to promote compliance with the provisions of the Protocol and address cases of non-compliance. ►

V) Liability and redress: the ICCP is recommending to MOP-1 to establish an open-ended *ad hoc* group of legal and technical experts on liability and redress to consider the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of LMOs. MOP-1 will also be expected to consider and approve draft terms of reference for the proposed *ad hoc* group.

VI) Handling, transport, packaging and identification: in its consideration of Article 18 of the Protocol, the ICCP dealt mainly with those issues deemed important for the smooth implementation of requirements, as appropriate, upon entry into force of the Protocol. The deliberations focused especially on the issue of documentation in the context of paragraph 2 of the Article. Given the complexity of the issue, several points remained unresolved at the end of the ICCP preparatory process and it was agreed to forward these issues to MOP-1 for further consideration. MOP-1 will be expected to take a decision on the appropriate implementation of the requirements of Article 18.2.

VII) Medium-term programme of work: MOP-1 will consider a proposal for a medium-term programme of work for the COP-MOP, i.e., outlining issues to be considered from the second to the fifth meeting of the Parties to the Protocol.

On a few issues, such as those relating to compliance and Article 18 of the Protocol, the recommendations going to MOP-1 contain some passages that are in square brackets. I consider the square brackets not as a reason for disappointment or an indication that the ICCP failed in its mandate, but rather as a sign that even on very complex and sensitive issues, the ICCP was able to achieve considerable progress on which the MOP will build and move forward.

Conclusion

During the three meetings of the ICCP, all delegations were keen to advance and displayed a spirit of cooperation, making it possible to make progress and advance understanding on the provisions of the Protocol and on how they would be implemented. This achieved at least two results: first, there is little doubt in my mind that the work done by the ICCP contributed significantly to clarifying a number of issues, thereby giving many countries the confidence they needed to ratify the Protocol and get ready for its implementation. Secondly, I am also confident that we have achieved, to the best of our abilities, the ICCP's mandate, namely, to facilitate decision-making by the first meeting of the Parties to the Protocol. In a few months' time, when the first MOP gets under way, we shall know for sure how well we succeeded in this endeavour.

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