



**REPORT OF THE RESUMED SESSION OF THE  
EXTRAORDINARY MEETING OF THE  
CONFERENCE OF THE PARTIES FOR THE  
ADOPTION OF THE PROTOCOL ON BIOSAFETY  
TO THE CONVENTION ON BIOLOGICAL  
DIVERSITY:  
24-28 JANUARY 2000**

The resumed session of the Extraordinary Meeting of the Conference of the Parties (ExCOP) for the Adoption of the Protocol on Biosafety to the Convention on Biological Diversity was held from 24-28 January 2000, in Montreal, Canada. Over 750 participants, representing 133 governments, NGOs, industry organizations and the scientific community, attended the meeting. Following nine days of negotiations, including late evening and early morning sessions, delegates adopted the Cartagena Protocol on Biosafety in the early morning hours of 29 January 2000.

The Cartagena Protocol addresses the safe transfer, handling and use of living modified organisms (LMOs) that may have an adverse effect on biodiversity with a specific focus on transboundary movements. The Protocol establishes an advance informed agreement (AIA) procedure for imports of LMOs, incorporates the precautionary principle and details information and documentation requirements. The Protocol also contains provisions regarding documentation, confidential information and information-sharing, capacity-building, and financial resources, with special attention to the situation of developing countries and those without domestic regulatory systems.

**A BRIEF HISTORY OF THE BIOSAFETY PROTOCOL**

The Convention on Biological Diversity (CBD), negotiated under the auspices of the United Nations Environment Programme (UNEP), was adopted on 22 May 1992 and entered into force on 29 December 1993. There are currently 176 Parties to the Convention. Article 19.3 of the CBD provides for Parties to consider the need for and modalities of a protocol setting out procedures in the field of the safe transfer, handling and use of living modified organisms (LMOs) that may have an adverse effect on biodiversity and its components.

**COP-1:** The first Conference of the Parties (COP-1) to the CBD, held in Nassau, the Bahamas, from 28 November - 9 December 1994, established an Open-ended *Ad Hoc* Group of Experts on Biosafety, which met in Madrid from 24-28 July 1995. According to this meeting's report (UNEP/CBD/COP.2/7), most delegations favored

the development of an international framework on biosafety under the CBD. Elements favored unanimously for such a framework included: all activities related to LMOs that may have adverse effects on biodiversity; transboundary movement of LMOs; release of LMOs in centers of origin/genetic diversity; mechanisms for risk assessment and management; procedures for advance informed agreement (AIA); information exchange; capacity-building and implementation; and definition of terms. Elements with partial support included: socio-economic considerations; liability and compensation; and financial issues.

**COP-2:** At COP-2 in Jakarta, Indonesia, in November 1995, delegates considered the need for and modalities of a protocol on biosafety. Amidst debate over the Protocol's scope, the COP adopted compromise language (Decision II/5) calling for a "negotiation process to develop in the field of the safe transfer, handling and use of living modified organisms, a protocol on biosafety, specifically focusing on transboundary movement of any LMO that may have an adverse effect on biological diversity." COP-2 also established an Open-ended *Ad Hoc* Working Group on Biosafety (BSWG) to elaborate a protocol based on elements from the Madrid report. Other terms of reference for the BSWG state that it shall: elaborate key terms and concepts; consider AIA procedures; identify relevant categories of LMOs; and develop a protocol that takes into account the precautionary principle and requires Parties to establish national measures.

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**BSWG-1:** At its first meeting, held in Aarhus, Denmark, from 22-26 July 1996, the BSWG elected Veit Koester (Denmark) as its Chair and began the elaboration of a protocol on biosafety. Although the meeting produced few written results, it functioned as a forum for defining issues and articulating positions characteristic of a pre-negotiation process. Governments listed elements for a future protocol and outlined the information required to guide their future work.

**BSWG-2:** Delegates to BSWG-2, held from 12-16 May 1997, in Montreal, discussed a range of issues, including: objectives; AIA; notification procedures for transfers of LMOs; national competent authorities/focal points; information-sharing and a clearing-house mechanism; capacity-building; public participation and awareness; risk assessment and management; unintentional transboundary movement; handling, transportation, packaging and transit requirements; and monitoring and compliance. BSWG-2 also convened a contact group to start defining key terms.

**BSWG-3:** BSWG-3 met in Montreal from 13-17 October 1997. Delegates produced a consolidated draft text to serve as the basis for negotiation. The meeting established two Sub-Working Groups to address the core articles of the Protocol, as well as a contact group on institutional matters and final clauses. Delegates addressed outstanding issues in plenary, including: socio-economic considerations; liability and compensation; illegal traffic; non-discrimination; trade with non-Parties; as well as objectives, general obligations, title and preamble for a protocol.

**BSWG-4:** At the opening of BSWG-4, which met in Montreal from 5-13 February 1998, delegates entered the "negotiation phase" in order to reduce, through consensus, the number of options under each article. Using the structure adopted at BSWG-3, delegates began consideration of several articles that had only received preliminary discussion at BSWG-3, including: principles/objectives, general obligations, non-discrimination, socio-economic considerations, and liability and compensation. Delegates also continued work on other issues previously addressed, including: matters relating to AIA, risk assessment and management, minimum national standards, emergency measures and capacity-building.

**COP-4:** The Fourth Meeting of the Conference of the Parties (COP-4) to the CBD took place from 4-15 May 1998, in Bratislava, Slovakia. In Decision IV/3, "Issues related to biosafety," the COP extended the deadline for the negotiation of a protocol from the end of 1998 to early 1999. It established an extra meeting to be followed by an ExCOP to adopt the Protocol in 1999.

**BSWG-5:** BSWG-5 met from 17-28 August 1998, in Montreal. Delegates consolidated options for 45 articles in the revised consolidated draft to 40 articles, although thirteen articles remained entirely bracketed. Polarized positions continued to emerge during discussions over whether the Protocol's scope included "products thereof," whether the Protocol would address questions of liability and redress, and if the Protocol would incorporate the precautionary principle.

**BSWG-6 & EXCOP:** BSWG-6 met from 14-22 February 1999, and was immediately followed by the First Extraordinary Meeting of the Conference of the Parties, held from 22-23 February 1999, in Cartagena de Indias, Colombia. Despite intense negotiations, delegates were not able to agree on a protocol, although identifiable negotiating groups started to emerge. The main areas of contention centered on trade issues, treatment of commodities and domestic vs. international regulatory regimes. The ExCOP adopted a decision to suspend the meeting and requested the ExCOP President and the COP-4 Bureau to decide when and where the session would resume, no later than the fifth meeting of the Conference of the Parties. Delegates decided that the Protocol will be called the Cartagena Protocol on Biosafety to the CBD. The text of the draft Protocol, set out in both the Report of BSWG-6 and the ExCOP Draft Report (UNEP/CBD/ExCOP/1/L.2/Rev.1), was transmitted to the resumed ExCOP session for further debate.

**INFORMAL CONSULTATIONS:** Three sets of informal consultations aimed at facilitating discussion on key outstanding issues were held during the period between the ExCOP's suspension and its resumption. (Note: Since the third set of consultations immediately preceding the resumed ExCOP, its report has been merged with the report of the ExCOP below.)

**Montreal (July 1999):** Based on a decision by the COP-4 Bureau, on 1 July 1999, ExCOP President Mayr met with spokespersons from the major negotiating groups that emerged in Cartagena: the Central and Eastern European countries, the Compromise Group (Japan, Mexico, Norway, South Korea and Switzerland), the European Union (EU), the Like-Minded Group (the majority of developing countries) and the Miami Group (Argentina, Australia, Canada, Chile, the United States and Uruguay). At the meeting, the groups expressed their political will to finalize negotiations and it was agreed to hold another set of informal consultations prior to resuming the ExCOP.

**Vienna (September 1999):** The second set of informal consultations met in Vienna, Austria, from 15-19 September 1999. The first two days of the meeting were devoted to consultations within negotiating groups; the third day was for informal exchanges between groups; and the final two days were devoted to resolving differences between groups on pending core issues. During the final two days of discussions, chaired by ExCOP President Mayr, negotiating groups met in the "Vienna setting," a roundtable format with two spokespersons from each group. The groups addressed the issues of commodities, the protocol's relationship with other international agreements, the protocol's scope and application of the AIA procedure. Negotiating groups agreed on a basic set of concepts for commodities and relations with other international agreements, while acknowledging that the central differences on those and other issues remain. The results were forwarded as a Chairman's Summary (UNEP/CBD/ExCOP/1/INF/3) to the resumed session of the ExCOP.

## REPORT OF THE INFORMAL CONSULTATIONS AND THE RESUMED EXCOP

### INFORMAL CONSULTATIONS

The third set of informal consultations were held in Montreal from 20-23 January 2000. The first two days of the informal consultations were devoted to discussions within negotiating groups and were chaired by ExCOP President Juan Mayr. On Saturday, 22 January, Chair Mayr opened informal discussions among the major negotiating groups in the "Vienna setting." Chair Mayr highlighted his non-paper, which provided suggested text incorporating the results of the Vienna discussions on scope, application of the AIA as it relates to commodities, and Article 31 (Relationship with Other International Agreements) of the draft Protocol contained in the ExCOP Draft Report. The negotiating groups provided opening remarks in which they reiterated their political will to conclude the Protocol.

After providing initial comments on the non-paper, Chair Mayr proposed that consultations proceed by clustering related issues into three groups. The first being commodities, including a new article in Chair Mayr's non-paper on an alternative AIA for living modified organisms intended for direct use for food or feed, or for processing (LMO-FFPs), as well as articles in the ExCOP Draft Report on: the application of the AIA procedure; handling, transport, packaging and identification; information-sharing and the biosafety clearing-house; and a new annex in the non-paper on information requirements for notifications. The second cluster was on scope, covering Article 4 of the ExCOP Draft Report. The final cluster included the Protocol's relationship with other international agreements, as well as articles from the ExCOP Draft Report on: Parties' rights to take more protective measures than those in the Protocol; the precautionary principle; non-discrimination; and socio-economic considerations. On the third cluster, the EU supported the formulation, but indicated that discus-



sion of other issues should not be reopened. The Like-Minded Group requested removal of discussion on Parties' rights to take more protective measures than those in the protocol, the precautionary principle, and socio-economic considerations, while the Miami Group argued to retain them.

The negotiating groups provided initial comments on the commodities and scope clusters, which were then discussed by contact groups on Sunday, 23 January. The "Vienna setting" convened to hear the contact groups' progress reports. After closing comments by the groups in the evening "Vienna setting," Chair Mayr indicated that he would forward the results to Monday's resumed ExCOP and closed the informal session.

### RESUMED EXCOP

*Editors' Note: Respecting the confidential nature of informal consultations and contact group meetings, the Bulletin does not use the names of countries and/or groups in its reports of these meetings.*

On Monday, 24 January 2000, COP-4 President Laszlo Miklós (Slovakia) welcomed delegates on behalf of the COP-4 Bureau. ExCOP President Juan Mayr officially opened the ExCOP for the Adoption of the Protocol on Biosafety, inviting delegates to build on the work accomplished during the recent informal consultations. He stressed the urgency to build on this momentum to solve outstanding issues and to adopt the protocol as the first international environmental treaty of the new millennium. He encouraged Ministers to attend and drew attention to a ministerial dinner roundtable he would host on Wednesday.

CBD Executive Secretary Hamdallah Zedan emphasized the significance of the negotiations for the CBD and sustainable development. He referred to the benefits of biotechnology and said the protocol would ensure that humanity enjoys the benefits of science and trade, while protecting the environment. He noted the atmosphere of cautious optimism apparent during the informal consultations and expressed appreciation to Parties that provided financial support for the participation of developing countries and those with economies in transition.

Delegates then adopted the provisional revised agenda (UNEP/CBD/ExCOP/1/1/Rev.2) and its annotations (UNEP/CBD/ExCOP/1/1/Rev.2/Add.1). Regarding the organization of work, Mayr said that the Plenary and the "Vienna setting" involving groups' spokespersons would be used and both would have translation and follow official rules of procedure. He also stated that there would not be more than two contact groups meeting in parallel. Mayr proposed keeping the contact groups on scope and commodities, which were established during the recent informal consultations. Ethiopia, on behalf of the Like-Minded Group, suggested that the contact groups be merged. Mayr invited regional groups to submit names of three representatives for the Legal Drafting Group to be chaired by Lynn Holowesko (the Bahamas). Participants heard reports from the CBD Secretariat on the credentials of representatives and on available documents, including the Draft Report of the First ExCOP (UNEP/CBD/ExCOP/1/L.2/Rev.1) and the Report of the Sixth Open-ended Working Group on Biosafety (UNEP/CBD/ExCOP/1/2).

Expanding on its statement in the opening Plenary, the Like-Minded Group reiterated the need to address related elements of Article 5 (Application of the AIA Procedure) of the ExCOP Draft Report in discussions on scope. (Unless otherwise specified, references to articles are as they appeared in the ExCOP Draft Report.) The EU inquired about initiating discussions on the protocol's relationship with other agreements. Mayr announced that the contact group on scope would address relevant elements of Article 5, but would not discuss issues related to commodities. He further noted that Article 31 (Relationship with Other International Agreements) would be addressed later.

The contact group on commodities commenced discussion on Article 17 (Information Sharing and the Biosafety Clearing-House) by drawing attention to the proposed amendments in Chair Mayr's non-paper. On Article 15 (Handling, Transport, Packaging and Identification), the group engaged in a conceptual discussion on the package proposal in the text of the Draft Protocol contained in Annex II of the ExCOP Draft Report. The group then discussed the package proposal paragraph by paragraph. Delegates focused their discussion on Article 9 *bis* (decision procedure for LMO-FFPs) in Chair Mayr's non-paper, particularly on language dealing with information provision subject to domestic regulations. The group continued its discussion into the night.

The contact group on scope met in the afternoon to discuss outstanding issues related to Article 4 (Scope), where the negotiating groups presented their general perspectives. Upon one group's proposal to start addressing the substance of the exemptions, delegates discussed the status of pharmaceuticals for humans. During an evening session, delegates continued discussions on the scope of the protocol in relation to pharmaceuticals, contained use and transit.

**TUESDAY, 25 JANUARY 2000:** On Tuesday delegates met during the morning in the "Vienna setting" to hear contact groups' reports on commodities and scope, as well as to begin a general discussion on trade-related issues and the protocol's relationship with other international agreements. Chair François Pythoud (Switzerland) of the contact group on commodities reported on Articles 15 and 17 of the ExCOP Draft Report stating that he would collaborate with groups to present a Chair's text. Regarding Article 9 *bis* (on the decision procedure for the review of LMO-FFPs) in Mayr's non-paper, he noted progress on options for decision-making procedures and capacity-building, bilateral agreements and cooperation between Parties. Chair John Herity (Canada) of the contact group on scope reported that negotiating groups provided complete explanations of their positions on pharmaceuticals for humans, transit and contained use. He also noted a proposal from the Like-Minded Group listing articles that should not apply in these cases.

After a round of comments on the progress reports, Chair Mayr stressed that discussions should focus only on the list of outstanding items in the ExCOP Draft Report. Upon a request to raise outstanding issues mentioned in official closing statements at the ExCOP in Cartagena, Mayr suggested that the Legal Drafting Group could address some of these issues. After a round of preliminary statements on the cluster of trade-related issues, Chair Mayr closed the session so that informal discussions on scope could proceed and the contact group on commodities could meet.

The "Vienna setting" reconvened again in the evening to hear reports of the contact groups. Chair Pythoud reported that the contact group on commodities made progress and was close to a final text in terms of concepts, but more time was required to find balanced wording. Chair Herity reported that after informal discussions with negotiating groups' representatives on scope, the contact group focused on transit. He noted general agreement on Article 4 (Scope) and its coverage of all LMOs that may have adverse effects on biodiversity. He said that new articles covering pharmaceuticals, transit and notification were being developed. Chair Mayr convened a new contact group under the chairmanship of Amb. Philémon Yang (Cameroon) to address the cluster of trade-related issues and the protocol's relationship with other international agreements. He stated that the contact group on commodities would continue to meet and that discussions on scope would proceed informally under the guidance of Chair Herity. The contact group on commodities reconvened in the evening to continue discussing Articles 9 *bis* in Chair Mayr's non-paper and Article 15 of the ExCOP Draft Report. The contact group on trade-related issues convened in the evening to address Articles 31 and 22 of the ExCOP Draft Report and their reformulation in Chair Mayr's non-paper.





**WEDNESDAY, 26 JANUARY 2000:** On Wednesday morning, delegates reconvened in the "Vienna setting" to hear progress reports from the contact groups. Chair Pythoud of the contact group on commodities presented text on the decision procedure for LMO-FFPs, claiming that groups were close to agreement. He noted that the group also briefly discussed Annex 1B (Information Required in Notification) contained in Chair Mayr's non-paper. Chair Yang of the contact group on trade-related issues reported on discussions on the use of preambular language contained in Chair Mayr's non-paper regarding the Protocol's relation to other international agreements. Chair Herity of the contact group on scope reported that informal consultations had not yet been resumed and proposed that they continue. Mayr suggested that the contact groups on scope and commodities be merged. He requested final text for presentation at a late evening "Vienna setting." After discussion regarding when to address the precautionary principle, Mayr stated that such issues can be examined after the core issues are resolved.

The contact group on commodities met in a morning session to discuss text proposed by the Chair on Article 18, particularly regarding provisions on safety conditions, accompanying documentation and declarations that movement of LMO-FFPs conform with the protocol's requirements. The contact groups on commodities and scope were then merged and met in afternoon and evening sessions, where delegates discussed a Chair's summary text on scope, addressing pharmaceuticals for humans, transit contained use. Co-Chairs Pythoud and Herity later presented a revised text based on informal consultations.

The contact group on trade-related issues and the Protocol's relationship with other international agreements met throughout the day, where negotiating groups presented their initial views on the issues. After a break in the evening session, Chair Yang distributed a draft Chair's text, deleting Articles 31 and 22 of the ExCOP Draft Report and adding three preambular provisions with language from the Rotterdam Convention on the Prior Informed Consent Procedure.

At 8:00 pm, Chair Mayr hosted a dinner for ministers arriving for the final days of negotiations. At the dinner, Ministers heard remarks from Chair Mayr as well as the Environment Minister of Canada, David Anderson. The dinner set the stage for more informal discussions among Ministers during the final two days of negotiations.

The "Vienna setting" convened at 11:20 pm to hear reports of the contact groups and a round of views on the precautionary principle. Mayr then requested that the contact groups on trade-related issues, and commodities and scope meet to deliver text to the "Vienna setting" on Thursday morning. Delegates continued informal discussions on scope and commodities through Wednesday night and into Thursday morning.

**THURSDAY, 27 JANUARY 2000:** On Thursday the contact group on trade-related issues met at 9:00 am to continue discussions. The "Vienna setting" convened at 1:00 pm, where Chair Mayr requested all in attendance to stand, clasp hands, and ponder how to move the process forward. The contact group Chairs then reported on their progress. Chair Yang of the contact group on trade-related issues reported that consultations continued on the basis of preambular language proposed in the Chair's draft text. Co-Chair Herity of the contact group on scope and commodities reported that some legal drafting issues had arisen in Article 4 (Scope) and that acknowledgment of a state's right to allow or prohibit the transit of LMOs still required resolution. Co-Chair Pythoud reported that discussions on Article 18 (Handling, Transport, Packaging and Transportation) had almost achieved conceptual agreement, although specific elements for identification still needed discussion. On the decision procedure for LMO-FFPs, Pythoud reported that unresolved issues included the decision procedure for countries without domestic regulatory frameworks, implicit consent, and reference to the precautionary approach.

At Chair Mayr's request, negotiating groups commented on existing proposals addressing the precautionary principle and other trade-related provisions. Chair Mayr then expanded the mandate of the contact group on relations with other international agreements and non-discrimination to consider Article 8.7 on the precautionary principle. He suggested that Pythoud serve as Co-Chair with Amb. Yang. He requested text to review for the evening's "Vienna setting." Negotiating groups then listed items outside of the core clusters that needed further consideration. Chair Mayr suggested that negotiations continue to focus on the core issues, while informal consultations conducted by Amb. Beat Nobs (Switzerland) take place on other outstanding issues, including Articles 21, 23 and 24.

The contact group on trade-related issues met again in the afternoon to continue discussions on the precautionary principle, based on text contained in the ExCOP Draft Report. After initial discussion, Chair Yang presented draft text on the precautionary principle for further discussion.

At 10:00 pm the "Vienna setting" reconvened to hear reports on trade-related issues and other outstanding items. Chair Yang reported that the contact group deliberating the precautionary principle was considering a draft text. Amb. Nobs reported on his informal consultations, noting general agreement on Articles 15 (Risk Assessment), 16 (Risk Management) and 25 (Illegal Transboundary Movement), while outstanding issues remained on Articles 24 (Non-parties), 14 (Multilateral, Bilateral and Regional Agreements) and 26 (Socio-economic Considerations). Chair Mayr requested Co-Chairs Yang and Pythoud and Amb. Nobs to provide clean text by 2:00 am. He then conducted informal consultations on the protocol's text for presentation at Friday morning's "Vienna setting." The contact group on trade-related issues continued discussions on preambular language.

**FRIDAY, 28 JANUARY 2000:** On Friday, Chair Mayr opened the "Vienna setting" at 10:30 am, noting that a draft text of the Protocol with brackets on remaining issues had been distributed at 2:00 am, and that bilateral consultations had concluded at 5:45 am. He expressed optimism that a final conclusion would be reached and was considering how to bridge the remaining gaps. He stated his preference to develop consensus text by the afternoon, however if this was not possible, he would present the Plenary with a Chair's text at 4:00 pm.

At 4:00 pm, it was announced that the final plenary would be reconvened at 6:00 pm, which was then postponed to 9:00 and finally to 11:00 pm. Over this period, Chair Mayr facilitated informal discussions with negotiating groups, primarily with regard to the precautionary principle and preambular language on relations with other international agreements.

#### **CLOSING PLENARY**

At 11:40 pm, President Mayr opened the closing plenary session. He called Ilona Jepsen (Latvia), President of the Credentials Committee, to submit the report on the credentials of representatives to the resumed session of the ExCOP. Jepsen stated that 109 delegations were in full compliance, seven delegations only partly complied, therefore were not in good order, and 17 delegations had not submitted their credentials. The report was provisionally adopted with the understanding that delegations not in order should provide their credentials within 30 days. At President Mayr's request, rapporteur Mariangela Rebuá (Brazil) submitted the report of the ExCOP in two parts, from Cartagena and Montreal, included in documents UNEP/CBD/ExCOP/1/L.2, UNEP/CBD/ExCOP/1/L.2/Add.1 and UNEP/CBD/ExCOP/1/L.2/Add.2. The reports were adopted by the ExCOP.

Chair Mayr then suspended the Plenary just before midnight to allow for translation of the draft text and to resume consultations with negotiating groups focusing on Article 18 and its provision for identification and documentation for LMO-FFPs. Mayr reconvened the Plenary at 4:40 am. He said delegates had resolved crucial problems due to hard work and flexibility. He recommended adoption of the



Draft Cartagena Protocol on Biosafety (UNEP/CBD/ExCOP/1/L.5) with one amendment to Article 18(a). The Protocol was adopted at 4:50 am. He went on to say adoption of the protocol marked a victory for the environment and for citizens of the entire world. UNEP Executive Director Klaus Töpfer highlighted the historical significance of the moment. He noted his deep admiration for Mayr and his dedicated staff. He thanked all the “mothers and fathers” of the Protocol, especially the ministers, BSWG Chair Veit Koester and the international cadre of experts.

The Plenary then considered the draft decision (UNEP/CBD/ExCOP/1/L.6) on the adoption of the Cartagena Protocol on Biosafety and interim arrangements submitted by the COP-4 Bureau. The decision consists of four parts: adoption of the Protocol; establishment of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP); establishment of a Roster of Experts for risk assessment and management; and administrative and budgetary matters. FRANCE offered to host the first meeting of the ICCP, before the end of the year 2000, which was adopted by the Plenary.

President Mayr then invited delegations to make closing statements. Statements were made by Canada, Argentina, Uganda, Ethiopia, the EU, Switzerland, Hungary, Burkina Faso, Japan, the US and Portugal. In their statements, delegates thanked President Juan Mayr and his staff for their hard work, as well as Montreal, Canada, and its citizens for hosting the meeting. Many delegations expressed their appreciation to the negotiating groups. Statements also referred, *inter alia*; to: the Protocol's role in the effective development of biotechnology; support for capacity-building; the Protocol's breakthrough on trade and environment; and maintaining a balance among public concerns, predictability for industry, and environmental protections. On behalf of the majority of NGOs, the Third World Network noted that the Protocol is the first instrument of international law to recognize the distinct nature of LMOs and congratulated delegates for breaking through the North-South/East-West divides to put the environment before trade concerns. She expressed eagerness to work again with delegates, especially on the issue of liability. The Global Industry Coalition stated that the protocol would protect biodiversity, while setting the direction to share the economic and social benefits with the world.

President Mayr extended his warm gratitude to all in attendance and adjourned the meeting at 6:00 am. After the Plenary, a brief organizational meeting of the ICCP convened under the chairmanship of Amb. Philémon Yang (Cameroon).

## THE CARTAGENA PROTOCOL ON BIOSAFETY

**PREAMBLE:** The Preamble contains references to, *inter alia*: CBD Articles 19, (Handling of Biotechnology and Distribution of its Benefits), 8(g) (Managing risks of LMOs) and 17 (Exchange of Information); CBD COP Decision II/5 (Consideration of the Need for and Modalities of a Protocol for the Safe Transfer, Handling and Use of LMOs); the precautionary approach; the expansion of biotechnology and growing public concern over potential effects on biodiversity and human health; the potential of biotechnology for human well-being; the importance of centres of origin and genetic diversity; and the limited capabilities of many countries to cope with risks associated with LMOs; as well as references to the Protocol's relationship with other international agreements and non-discrimination.

The contact group on former Articles 31 (Relationship with Other International Agreements) and 22 (Non-discrimination) contained in the ExCOP Draft Report, chaired by Amb. Philémon Yang (Cameroon), addressed the cluster of trade-related issues and the relationship of the Protocol with other international agreements. On Wednesday, 26 January, Chair Yang invited the negotiating groups to present their views on these articles and the proposals in Chair Mayr's non-paper.

The non-paper proposed deleting the articles and reflecting their content in the Preamble and a new paragraph in former Article 8 (Decision Procedure).

Regarding non-discrimination, some delegates considered a reference to non-discrimination redundant, outside the CBD's scope and not applicable to LMOs. Others stressed the importance of the principle of non-discrimination for preventing conflicts between the Protocol and other international agreements. During discussion on this issue one group suggested removing the clause exempting Parties' obligations to existing international agreements where there might be serious threat to biodiversity and asked for consideration of relevant issues in Articles 24 (Non-Parties), 26 (Socio-economic Considerations) and the precautionary principle, as contained in Article 10 (Decision Procedure). Most delegates argued that the former Article 31 was unacceptable, since it would subordinate the Protocol to international trade agreements. A Chair's text deleted Articles 31 and 22 and introduced three new preambular clauses borrowing language from the Rotterdam Convention on the Prior Informed Consent Procedure.

The results of the group's discussions were presented in the plenary on Wednesday and Thursday. The CEE and Compromise Group approved of the proposed deletion and support for preambular language. The Miami Group suggested deleting former Article 22 and indicated they would consider the Chair's proposed text, while the EU suggested deleting former Article 31 and retaining former Article 22 and stated that Chair Mayr's non-paper presents the most balanced formulation of preambular language. The Like-Minded Group noted its support for deleting both articles, and preference for preambular language contained in the non-paper.

On Thursday, Chair Mayr expanded the mandate of the contact group on Articles 31 and 22 to consider former Article 8.7 on the precautionary principle. After lengthy discussion on the precautionary principle during Thursday and Friday, delegates arrived at two bracketed options for each of the following: mutual supportiveness with other international agreements; and compatibility with other international agreements. The final clause, noting the intention not to create a hierarchy with other international agreements, was also bracketed.

The final text, the result of informal consultations, includes three new preambular clauses: the mutual supportiveness of trade and environment agreements with a view to achieving sustainable development; the statement that the Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under existing international agreements; and the explanatory statement that the above clause is not intended to subordinate the Protocol to other international agreements.

**ARTICLE 1 (Objective):** The objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biodiversity. It references the precautionary approach and risks to human health, and focuses on transboundary movements.

**ARTICLE 2 (General Provisions):** This article outlines the general obligations of Parties to the Protocol with regard to AIA and the development, handling, transport, use, transfer and release of LMOs. It reaffirms the sovereignty of States over their territorial sea and accepts the rights of the Parties to take action that is more protective of the conservation and sustainable use of biodiversity, provided that such action is in accordance with other obligations under international law, and is consistent with the objectives and provisions of the Protocol.

In discussions on Article 18 (Handling, Transport, Packaging and Identification), one group raised concern over the requirement for Parties to ensure that the development, handling, transport, use, transfer and release of any LMOs are undertaken in a manner that



prevents or reduces risk to biodiversity. After the informal consultations on other issues conducted by Amb. Nobs this specific requirement remained unchanged.

**ARTICLE 3 (Use of Terms):** This article contains definitions of, *inter alia*: COP, contained use, export, exporter, import, importer, LMO, regional economic integration organization, and transboundary movement.

**ARTICLE 4 (Scope):** This article states that, in principle, the Protocol applies to transboundary movement, transit, and handling and use of all LMOs that may have adverse impacts on the conservation and sustainable use of biodiversity, also taking into account risks to human health. During the informal consultations, substantive disagreements on scope were dealt with in a contact group chaired by John Herity. At the end of the informal consultations, Herity noted agreement to simplify Article 4 to include all LMOs. Discussions on scope continued on the basis of a summary incorporating language from the ExCOP Draft Report, Chair Mayr's non-paper and a proposal by one of the negotiating groups regarding exemptions. It was generally decided to move provisions on pharmaceuticals, contained use and transit to new articles.

**ARTICLE 5 (Pharmaceuticals) [new article]:** This article states that the Protocol does not apply to the transboundary movement of LMOs that are pharmaceuticals for humans and are addressed by other international agreements or organizations. Parties are free to subject all LMOs to risk assessment prior to decision-making on import.

During the informal consultations, the Miami Group noted that pharmaceuticals generally may not have adverse impacts on biodiversity, while the EU noted that international bodies governing pharmaceutical issues could adequately address future developments. On the first day of the resumed ExCOP, the contact group on scope deliberated whether explicit reference to exemptions would compromise the competence of the COP serving as the meeting of the Parties to respond to future developments. (Note: Subsequent references to the COP connote the COP serving as the meeting of the Parties, as specified in Article 29.) Concern was expressed regarding developments in pharmaceutical applications, such as gene-therapy, for which no other standards or institutional provisions exist. The Like-Minded Group supported including LMOs for pharmaceutical use and only compromised to the extent that the decision could be left to the COP. To address exemptions, a summary was produced containing a positive and negative list of which articles should and should not apply to LMOs intended as pharmaceuticals for humans as well as for LMOs in transit. Ultimately, it was decided that LMOs intended as pharmaceuticals for humans would be addressed by other relevant international agreements or organizations.

**ARTICLE 6 (Transit and Contained Use) [new article]:** This article states that LMOs for transit or contained use are excluded from the AIA procedure without prejudicing the right of a Party of transit to regulate the transport of LMOs through its territory or to subject LMOs intended for contained use to risk assessments or national standards.

During the informal consultations two main issues were considered: the inclusion of advance notification and necessary documentation for transit, and the need to specify and adjust the definition of contained use. On Monday, informal consultations between representatives of the negotiating groups focused on transit and the practical and logistical burdens of adhering to notification for countries of transit. After continued discussions on Tuesday and Wednesday, it was decided that the AIA procedure should not apply to LMOs in transit and LMOs for contained use.

**ARTICLE 7 (Application of the Advance Informed Agreement Procedure) [formerly Article 5]:** This article states that, subject to Articles 5 (Pharmaceuticals) and 6 (Transit and Contained Use), the AIA procedure, contained in Articles 8, 9, 10 and 12, shall apply prior to the first transboundary movements of LMOs for intentional intro-

duction into the environment of the Party of import. It further states that intentional introduction into the environment does not refer to LMO-FFPs, which are governed by Article 11 (Procedure for LMO-FFPs). It also states that the AIA procedure shall not apply to the intentional transboundary movement of LMOs identified in a COP decision as being unlikely to have adverse effects on the conservation and sustainable use of biodiversity, taking also into account risks to human health.

**ARTICLE 8 (Notification) [formerly Article 6]:** This article states that the Party of export shall notify or require the exporter to ensure notification in writing to the importer's competent national authority prior to the intentional transboundary movement of an LMO covered by the AIA procedure in Article 7. The notification shall contain, at a minimum, the information specified in Annex I (Information Required in Notification).

**ARTICLE 9 (Acknowledgement of Receipt of Notification) [formerly Article 7]:** This article states that the Party of import shall acknowledge receipt of a notification, in writing, within 90 days of its receipt. The content of the acknowledgement must include: date of receipt; whether the notification, *prima facie*, contains the information referred to in Article 8 (Notification); and whether to proceed according to the domestic regulatory framework of the Party of import, provided that it is consistent with the Protocol or according to Article 10 (Decision Procedure). The article specifies that failure to acknowledge receipt shall not imply consent for transboundary movement.

**ARTICLE 10 (Decision Procedure) [formerly Article 8]:** This article requires Parties of import to inform the notifier, within a 90-day period that the transboundary movement may proceed, either only after written consent, or without subsequent written consent. Parties are required to communicate their decision within 270 days of receipt of notification to the notifier and the Biosafety Clearing-House. The article then sets out four possible decisions that Parties may take:

- approval, including how the decision applies to subsequent imports;
- prohibition;
- request for additional information; or
- information that the 270-day timeframe has been extended by a defined period of time.

The article specifies that a failure by a Party to communicate its decision within 270 days shall not imply consent. Parties must give reasons for their decision, except for unconditional approval. Appropriate procedures and mechanisms to facilitate decision-making will be determined by the first COP to the Protocol.

The issue of the precautionary principle contained in former Article 8.7, was raised during the "Vienna setting" on Wednesday and Thursday, when Mayr asked negotiating groups to comment on existing proposals addressing it in relation to Articles 31, 22 and alternative preambular language. The Miami Group indicated that references in the Preamble, Article 1 (Objective) and Annex II (Risk Assessment) were sufficient and that operationalization in former Article 8 was not necessary. The EU, Compromise Group, CEE and Like-Minded Group supported the existing provision in former Article 8.7. The EU stressed that, while decisions should be based on science-based risk assessment and non-arbitrariness, governments should have the sovereign right to take decisions to avert irreversible damage. The Like-Minded Group stated that referring to the precautionary principle solely in the Preamble would be unacceptable.

Discussions on the precautionary principle continued in a contact group on the basis of the text contained in the ExCOP Draft Report. One group stated that the AIA procedure forms the core of the Protocol and that the precautionary principle, as part of the decision procedure, should be adequately reflected in its operational provisions. Another group stated that reference to "adverse effect" was unclear, as well as the basis on which an importing country could prohibit an import. A proposal by one of the negotiating groups suggesting new language for





the article was submitted and used as the basis for discussion. The text included two sections, one on the precautionary approach regarding import of LMOs, and another on review of actions taken by the Party of import in case of availability of additional scientific information. Negotiating groups agreed to delete language on the review of action by the Party of import.

During a line-by-line analysis of the provision, discussion addressed two issues: the basis on which a Party of import would be allowed to prohibit import of LMOs; and the criteria for a solid scientific basis to trigger an importing Party to take actions against the import of LMOs. No consensus was reached and the Chair presented a draft text for the provision based on the discussions.

The draft text suggested two options: the first stated that Parties of import may have to take decisions on the import of LMOs in order to minimize possible adverse effects, even in the absence of scientific certainty. The second option generally stated that lack of scientific certainty shall not prevent the Party of import from taking a decision. The meeting was adjourned and the two options remained bracketed.

Following Friday's informal negotiations, the first option prevailed: Article 10.6 (former Article 8.7) permits importing Parties to invoke the precautionary approach, which states that lack of scientific certainty due to insufficient information of the potential adverse effects on biodiversity shall not prevent a Party from taking a decision on the import of an LMO. The provision also allows Parties to take into risks to human health. The same issue was addressed with regard to LMO-FFPs in Article 11.8. A provision on the circumstances to be defined by concerned Parties, under which transboundary movements can take place without written consent, was deleted as a result of Friday's informal negotiations.

**ARTICLE 11 (Procedure for LMO-FFPs) [formerly Article 9 bis in Chair Mayr's non-paper]:** Article 11 outlines the notification and decision process for LMOs intended for direct use for food or feed, or for processing (LMO-FFPs), including provisions, *inter alia*, on: notification of the Biosafety Clearing-House for LMO-FFPs placed on the market; exemption of field trials for LMO-FFPs; decisions on import of LMO-FFPs under domestic regulatory frameworks consistent with the Protocol; countries lacking domestic regulatory frameworks for LMO-FFPs; the precautionary principle; and developing countries' need for capacity-building with respect to LMO-FFPs.

During the informal consultations, negotiating groups started discussions based on Article 9 *bis* proposed in Mayr's non-paper. The Like-Minded Group expressed concern over the possibility of enabling implicit consent in Article 9 *bis*. The Miami Group noted general satisfaction with the non-paper's proposal, recognized the importance of information-sharing and documentation regarding transboundary movement of LMO-FFPs, but emphasized that the AIA procedure must be workable and that decision-making procedures should consider domestic legislation more fully. The CEE stressed the need to apply the AIA to all LMOs, and preferred a separate paragraph dealing with LMO-FFPs. The EU stated that the non-paper's proposal for an alternative system was useful, and, supported by other groups, suggested moving the alternative AIA procedure to follow former Article 8. The Compromise Group noted that failure to respond should not imply consent. He also highlighted that application of AIA be based on risk assessment and capacity-building. A contact group on commodities was established to consider this and other issues.

On Sunday, contact group Chair François Pythoud reported that new text for Article 9 *bis* covered information requirements regarding transboundary movements of LMO-FFPs, the timeframe and the means of providing such information in advance. Two separate paragraphs were developed to address additional information requirements, financial and technical assistance and capacity-building in this area. In summarizing the decision procedures for LMO-FFPs, Pythoud noted the group's understanding that the main basis for decisions would be domestic regulation, although groups differed on the proce-

cedure to be followed in the absence of domestic regulations. The Like-Minded Group affirmed that language on domestic regulations and decisions on imports of LMO-FFPs still remained to be discussed.

On Tuesday, Chair Pythoud requested that negotiating groups continue discussions on the text he presented on Article 8 *bis*, which had formerly been referred to as 9 *bis*. One group suggested deleting a reference to consistency with this protocol because there was no need for standardized domestic regulatory frameworks. Other groups disagreed. In the effort to solve this problem, the following suggestions were made: referring to consistency with the objective of the Protocol; referring specifically to Articles 12 (Risk Assessment) and 13 (Risk Management); or using domestic frameworks "compatible" with the protocol.

New text merging the Chair's provisions, referring to Parties with regulatory frameworks and Parties lacking regulatory frameworks, was presented to the contact group. One group described the rationale behind the merger as capturing all the concepts in the original paragraphs, while not creating a duality between Parties that do and Parties that do not have regulatory frameworks. Some participants expressed disappointment with the merged text, saying that it complicated the decision-making process, created redundancy with other paragraphs, introduced too many new ideas, and moved the discussion backwards. On language in the Chair's text stating that an importing Party's failure to communicate its decision does not imply consent, some expressed concern that it was too prescriptive since it did not recognize that some countries' domestic regulations could allow for implicit consent. The contact group drafted new text to accommodate this concern.

On Thursday, Pythoud reported to the "Vienna setting," that a number of issues remained unresolved, including: the decision procedure for countries without domestic regulatory frameworks; implicit consent; and reference to the precautionary approach. He said he would continue bilateral and multilateral consultations with negotiating groups to resolve the remaining problems. The outstanding issues were addressed during the final informal consultations on Thursday and Friday and were finally reflected in Article 11 of the final Protocol text.

**ARTICLE 12 (Review of Decision) [formerly Article 9]:** This article permits a Party of import to review and change its decision regarding the transboundary movement of an LMO at any time. The Party of import must base its decision on new scientific information, taking into account risks to human health. The Party must then inform the notifier and the Biosafety Clearing-House within 30 days, giving reasons for the decision. The article also sets out under what conditions a Party of export or notifier may request a review, where it considers that a change of circumstances has occurred or that additional scientific or technical information is available. Parties of import are required to respond to requests for review within 90 days. Finally, the article provides for a Party of import to require risk assessments for subsequent LMO imports, at its own discretion.

**ARTICLE 13 (Simplified Procedure) [formerly Article 10]:** This article allows a Party of import to specify in advance, to the Biosafety Clearing-House, LMOs to be exempted from AIA, as well as when transboundary movements may proceed simultaneously with notification, in which case such notifications would apply to subsequent movements to the same Party.

**ARTICLE 14 (Bilateral, Regional and Multilateral Agreements and Arrangements) [formerly Article 11]:** This article sets out provisions applying to Parties who enter into multilateral, bilateral and regional agreements and arrangements with Parties or non-Parties regarding procedures for transboundary movements of LMOs, which must be consistent with the objectives of the Protocol, and not result in a lower level of protection than provided by the Protocol. The article also requires notification of the Biosafety Clearing-House of such



agreements and allows for an importing Party to determine that its domestic regulations shall apply to imports, provided that it notify the Biosafety Clearing-House.

**ARTICLE 15 (Risk Assessment) [formerly Article 12]:** This article sets out the provisions under which risk assessment will be carried out. It says that risk assessment shall be undertaken in accordance with the provisions in Annex II and be based, at a minimum, on information provided in accordance with the notification procedure and other available scientific evidence in order to identify and evaluate the possible adverse effects of LMOs on the conservation and sustainable use of biodiversity, taking also into account the risks to human health. The text also states that the importer shall ensure that risk assessment is carried out in accordance with the AIA procedure, but that the importer may require the exporter to carry out risk assessment. Finally, it requires the notifier to bear the financial responsibility for risk assessment.

This article in the ExCOP Draft Report was revisited by Amb. Nobs' informal consultation, and minor linguistic amendments were made.

**ARTICLE 16 (Risk Management) [formerly Article 13]:** This article states that Parties shall establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified under the risk assessment provisions, and elaborates on the measures and controls. The measures shall be imposed to prevent adverse effects on biodiversity, and Parties can require risk assessments prior to the first release of an LMO. The article also states that each Party shall, in order to ensure genomic and trait stability, endeavor to ensure that any LMO undergoes a period of observation commensurate with its life-cycle or before being put to its intended use. Finally, the article states that Parties shall cooperate in identifying LMOs or specific LMO traits that may have adverse effects on biodiversity, taking into account risks to human health, with a view to taking appropriate measures on the treatment of such LMOs.

**ARTICLE 17 (Unintentional Transboundary Movements and Emergency Measures (formerly Article 14):** This article details the measures that Parties are to take in the event of unintentional transboundary movements of LMOs, including notification, provision of information and consultation.

**ARTICLE 18 (Handling, Transport, Packaging and Identification) [formerly Article 15]:** This article sets out procedures for the packaging and identification of LMOs to be transported across national borders, and addresses, *inter alia*: measures to ensure that LMOs are handled, packaged and transported under safe conditions and relevant international standards, and three differentiated minimum documentation requirements for LMO categories.

On Monday, contact group Chair Pythoud initiated conceptual discussions on the "package proposal" contained in Annex II of the ExCOP's Draft Report. The significance of documentation requirements to the implementation of the Protocol was highlighted. Discussions focused on how proper documentation helps Parties reduce damage in case of accidents and that without documentation, Parties are unable to identify whether the Protocol's provisions have been respected. One participant proposed that LMOs be divided into three categories in this regard: LMOs to be released into the environment requiring stringent documentation requirements; LMOs for contained use that should be clearly identified; and LMO-FFPs that should be indicated as such. Others emphasized that all LMOs should be identified, and documentation should not only apply to the first transboundary movement, but also to subsequent movements. One group expressed its concern over the differentiated treatment of LMO-FFPs in terms of documentation, and highlighted that documentation requirements must be workable for commercial actors. One group said that this article is closely linked with other issues such as commodities

and the scope of the Protocol, and that since his group viewed the ExCOP Draft Report as more balanced, discussion on this article should not be reopened.

Conceptual difficulties were expressed regarding time frames and whether LMOs currently traded in the marketplace would be subject to the same identification requirements. Participants expressed views on the degree of certainty a Party can expect regarding the percentage of LMO content in a given shipment. Some suggested that a threshold regarding what percentage of LMO content requires identification does not exist and raises difficult legal questions. Others indicated that it is impossible to know the final destination of a shipment of LMOs or the exact quantity of LMOs in a given shipment, hence identification requirements are not obvious. In closing the discussion on the package proposal, some expressed their desire to retain ExCOP draft text while others wished to further explore a revised text based on the package proposal.

Based on discussions in the contact group, Pythoud presented a Chair's draft text on Wednesday reflecting all the principles in the ExCOP Draft Report, while allowing for flexibility when dealing with different categories of LMOs. Delegates addressed a provision on the safety conditions of LMOs when handled, packaged and transported. Certain groups expressed concern that the application of safety measures required qualification on a case-by-case basis and that they should only be applied "as appropriate."

On accompanying documentation requirements during the transport of LMOs, some groups stressed that documentation was a minimum requirement. There was discussion on ensuring that the provision covered not only the first, but also subsequent movements of LMOs. Negotiating groups confirmed the need for documentation identifying LMO-FFPs, but disagreed on exactly how LMO-FFPs should be identified. One group proposed that "any unique identification" in addition to "identity" of LMO-FFPs be specified. Another supported identification of LMO-FFPs "as not intended for intentional introduction into the environment." One group noted difficulties with the documentation requirements for LMO-FFPs, and requested the proposals be bracketed. Another questioned the appropriateness and clarity of a provision requiring a declaration that the movement of LMO-FFPs conform with the Protocol's requirements. To clarify who should make the declaration, one group suggested the provision should apply only to exporters. The provision was bracketed.

One group stated that a provision requiring the meeting of the Parties to consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport was unnecessary. One group stated that a reference to collaboration with other international bodies undermines the CBD and the Protocol and suggested language referring to consultations with other international bodies used in the ExCOP Draft Report. As suggested by the Chair, the group agreed to bracket the entire provision with this amendment. As the contact group's discussion drew to a close, conceptual agreement had almost been achieved and the negotiating groups had agreed to a differentiated approach to accompanying documentation for LMOs and, in principle, to identifying LMO-FFPs. However, the specific identification requirements remained outstanding. Consultations with negotiating groups to resolve the remaining issues continued.

During the closing Plenary, Mayr presented the final draft Protocol and requested its adoption after changes to the this article regarding documentation requirements. The changes stipulated that documentation for shipment of LMO-FFPs should state that they "may contain" LMOs and are not intended for introduction into the environment. The COP is directed to take a decision on the detailed requirements, including identity and any unique identifications, within two years.





**ARTICLE 19 (Competent National Authority and National Focal Point) [formerly Article 16]:** This article requires governments to designate national focal points and competent national authorities to liaise with the Secretariat and perform administrative functions under the Protocol.

**ARTICLE 20 (Information Sharing and the Biosafety Clearing-House) [formerly Article 17]:** This article establishes a Biosafety Clearing-House and outlines its objectives and the types of information that should be provided to it. Modalities of the operation of the Clearing-House shall be considered and decided upon by the COP serving as the meeting of the Parties at its first meeting, and kept under review thereafter.

The contact group on commodities focused on whether Parties shall be required to provide information regarding the transboundary movement of LMO-FFPs and exemptions from AIA procedures according to Articles 4, 5 and 6 to the Clearing-House. Chair Pythoud commenced discussion on this article by drawing attention to the proposed amendments in Chair Mayr's non-paper. One group claimed that a broader range of information requirements regarding national legislation is reflected in the ExCOP Draft Report than in the non-paper proposal. He noted that it is not necessary to limit information on national legislation to implementation of the protocol. Another group noted that the amendment regarding information requirements for LMO-FFPs in domestic regulations repeats a proposed new article on decision procedure of LMO-FFPs in Chair's Mayr's non-paper. Negotiating groups agreed to ignore the proposed amendments in the non-paper and retain the text contained in the ExCOP Draft Report.

**ARTICLE 21 (Confidential Information) [formerly Article 18]:** This article provides for the Party of import to permit the notifier to identify information that should be treated as confidential. It identifies information that "may not" be considered confidential, such as the general description of the LMOs, the name and address of the notifier, a summary of the risk assessment undertaken and plans for emergency response.

**ARTICLE 22 (Capacity-building) [formerly Article 19]:** This article states that Parties shall cooperate in the development and strengthening of human resources and institutional capacities in, *inter alia*: safe biotechnology management training, risk assessment and management; technological and institutional capacities; and biotechnology to the extent that it is required for biosafety. The article references the needs of developing country Parties, in particular the least developed and small island developing States, as well as countries with economies in transition.

**ARTICLE 23 (Public Awareness and Participation) [formerly Article 20]:** This article requires Parties to promote and facilitate public awareness, education and participation in the Protocol's implementation. It requires consultation with the public in the decision-making process and provision of results to the public, while respecting confidential information. It calls on each Party to inform its public about how to access the Biosafety Clearing-House.

**ARTICLE 24 (Non-Parties) [formerly Article 21]:** This article states that transboundary movements of LMOs between Parties and non-Parties shall be consistent with the Protocol's objective, and Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements. It also requires Parties to encourage non-Parties to adhere to the Protocol and contribute appropriate information to the Biosafety Clearing-House. During the informal consultations conducted by Amb. Nobs on other outstanding issues, delegates debated the wording with regard to transboundary movements between Parties and non-Parties. Amb. Nobs' informal consultations made minor linguistic changes.

**ARTICLE 25 (Illegal Transboundary Movements) [formerly Article 23]:** This article obliges Parties to adopt appropriate domestic measures to prevent and penalize transboundary movements of LMOs carried out in contravention of domestic measures to implement this Protocol. It empowers the Party affected by illegal transboundary movement to request the Party of origin to dispose of the LMOs at its own cost. It also requires Parties to make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movement. During informal consultations conducted by Amb. Nobs, general edits in legal drafting were made.

**ARTICLE 26 (Socio-economic Considerations) [formerly Article 24]:** This article allows Parties to take socio-economic considerations arising from the impact of LMOs on the conservation and use of biodiversity into account in reaching decisions on whether to allow imports of LMOs. Such decisions are to be consistent with the Parties' international obligations. It encourages Parties to cooperate in research and information exchange on socio-economic impacts. The amendment made by the informal consultations conducted by Amb. Nobs included a reference to Parties' domestic measures to implement the Protocol with regard to socio-economic considerations.

**ARTICLE 27 (Liability and Redress) [formerly Article 25]:** This article states that the first COP serving as the meeting of the Parties shall adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of LMOs. The COP will take into account any ongoing processes in international law on these matters and shall endeavor to complete this process within four years.

**ARTICLE 28 (Financial Mechanism and Resources) [formerly Article 26]:** This article establishes the financial mechanism of the CBD as that of the Protocol and, with regards to guidance to the mechanism, references the need for capacity-building and financial resources for developing countries. The COP serving as the meeting of the Parties to the Protocol shall provide such guidance to the COP of the CBD to consider and forward to the financial mechanism.

**ARTICLE 29 (Conference of the Parties serving as the Meeting of the Parties) [formerly Article 27]:** This article states that the COP to the CBD shall serve as the meeting of the Parties to the Protocol and shall keep under review implementation of the Protocol.

**ARTICLE 30 (Subsidiary Bodies) [formerly Article 28]:** This article states that any subsidiary body under the CBD may serve the Protocol upon a decision of the COP serving as the meeting of the Parties.

**ARTICLE 31 (Secretariat) [formerly Article 29]:** This article states that the CBD Secretariat shall serve as the secretariat to the Protocol.

**ARTICLE 32 (Relationship with the Convention) [formerly Article 30]:** This article states that the provisions of the CBD shall apply to the Protocol, except as otherwise provided in the Protocol.

**ARTICLE 33 (Monitoring and Reporting) [formerly Article 32]:** This article states that each Party shall monitor the implementation of the Protocol and report to the COP on measures taken.

**ARTICLE 34 (Compliance) [formerly Article 33]:** This article states that the first COP serving as the meeting of the Parties to the Protocol shall consider and approve cooperative procedures and institutional mechanisms to promote compliance and address non-compliance.

**ARTICLE 35 (Assessment and Review) [formerly Article 34]:** This article provides that the COP serving as the meeting of the Parties shall evaluate the Protocol's effectiveness, including its procedures and annexes, five years after its entry into force and every five years thereafter.



**ARTICLE 36 (Signature) [formerly Article 35]:** This article states that this Protocol shall be open for signature in Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at UN Headquarters in New York from 5 June 2000 to 4 June 2001.

**ARTICLE 37 (Entry into Force) [formerly Article 36]:** This article states that this Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

**ARTICLE 38 (Reservations) [formerly Article 37]:** This article states that no reservations may be made to the Protocol.

**ARTICLE 39 (Withdrawal) [formerly Article 38]:** This article states that a Party may withdraw from the Protocol after two years from the date on which this Protocol has entered into force for a Party.

**ARTICLE 40 (Authentic Texts) [formerly Article 39]:** This article states that the original of this Protocol shall be deposited with the UN Secretary-General.

**ANNEX I (Information Required in Notifications under Articles 8, 10 and 13):** This annex provides a list of biosafety-related information required in notifications, including, *inter alia*:

- contact information on the importer and exporter;
- name and identity of the LMOs;
- intended date of the transboundary movement;
- taxonomic information requirements;
- information on centers of origin and genetic diversity of the recipient organism and/or the parental organisms;
- description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the LMOs;
- intended use of the LMO or products thereof;
- quantity or volume of the LMOs;
- a previous and existing risk assessment report;
- suggested methods for safe handling, storage, transport and use;
- regulatory status of the LMO within the exporting State;
- result and purpose of any notification by the exporter to other States regarding the LMOs to be transferred; and
- declaration that the above-mentioned information is factually correct.

The contact group on commodities based their discussion on a new proposed text (Annex IB) in Chair Mayr's non-paper. Delegates agreed that several new elements should be added to the list, including, *inter alia*, description of the nucleic acid of LMOs, unique identification of LMOs, and suggested methods for safe handling, storage and transport and use, including labeling and documentation. Many elements from Annex I of the ExCOP Draft Report were also retained.

**ANNEX II (Risk Assessment):** This annex includes more specific detail on risk assessment, including: objective, use, general principles, methodology, and points to consider (e.g., recipient or parental organism, donor organism, vector, insert and/or characteristics of modification, LMO, detection and identification, information on intended use, and receiving environment).

**ANNEX III (Information Required for LMO-FFPs under Article 11):** This annex was added and includes a list for information required for LMO-FFPs under Article 11. Such information includes, *inter alia*:

- contact information on the applicant for a decision;
- contact information of the authority responsible for the decision;
- name and identity of the LMO;
- description of the gene modification, technique used and resulting characteristics of the LMO;
- any unique identification;
- taxonomic information on the recipient and donor organisms;
- information on centers of origin and genetic diversity of the recipient organism and/or the parental organisms;

- approved uses of the LMO;
- a risk assessment report consistent with Annex II; and
- suggested methods for safe handling, storage, transport and use.

## A BRIEF ANALYSIS OF THE EXCOP

While shivering in the cold winds and snow of Montreal during this last week in January, delegates were haunted by their failure to adopt the biosafety protocol in Cartagena nearly one year ago. The successful adoption of the Cartagena Protocol, in the early morning hours of 29 January 2000, has exorcised those ghosts and now allows governments, NGOs and others to look to the challenges ahead. Characteristic of negotiation processes, the major coalitions did not win or lose everything. "The perfect is the enemy of the good" was heard often throughout the week, reflecting that "perfect" is in the eye of the negotiator, which many equal a commonly defined good. This analysis will address the substance and dynamics of the negotiations, focusing specifically on the role of science, the larger political context and the negotiation process that enabled delegates to reach agreement.

**THE POLITICS OF SCIENCE:** The Protocol is generally designed to address the uncertainty and incomplete nature of scientific knowledge of how LMOs interact with biodiversity and the surrounding environment. A central theme underlying these negotiations was whether decision-making on risk under conditions of imperfect knowledge is a political or technical decision. Some proponents of a strong provision on the precautionary principle affirmed that policy-makers are ultimately responsible for decisions on environmental and public safety based on scientific input since they are ultimately accountable to their citizens. Determining the acceptable level of risk boils down to a political decision, and is therefore open to public dialogue. Defining a decision as "technical," exempts it from the public sphere and transparent decision-making. The fear, expressed by others, is that by its nature political decision-making tends to incorporate other non-scientific social, economic and national interests. In this view, acceptable levels of risk can and should be based on science and a regulatory system capable of assessing what those existing risks are.

While discussions focused on the risk and trade aspects of LMOs, in their final statements many delegates stressed the need to turn to capacity-building and promotion of the biotechnology industry in the developing world. Given their experiences with the Convention on Biological Diversity, some developing country delegates noted that rhetoric on sustainable development will not contribute to technology transfer, and wondered whether related provisions and commitments in the Protocol will continue to be downplayed. One participant emphasized that developing countries ultimately need to control the development of their own biotechnology industries in coordination with domestic regulatory systems, and to avoid becoming solely the franchises or markets for industrialized economies.

**THE SCIENCE OF POLITICS:** There is no doubt that the primary conflict encountered in negotiating an agreeable Protocol centered on trade and environment issues. Given the recent WTO Ministerial conference, discussion focused on whether the unsuccessful attempt to form a biotechnology working group in Seattle would strengthen the political will to conclude a Protocol in Montreal. Some feared that the existence of such a biotechnology group could pre-empt discussions on trade-related issues under the Protocol. Others thought that such a group could facilitate the technical and regulatory dimension of trade in LMOs, assuaging the concerns of LMO producers and exporters. Some delegates were surprised that the final point of contention was identification and documentation, as opposed to one of the "sexier" issues such as the precautionary principle or the relationship with other international agreements. Other participants noted that the practical issue of handling and identification presents the most tangible, and costly, initial step towards implementing the Protocol. While compromise language balancing the



precautionary principle and relations with other agreements could and presumably would be subjected to different interpretations, the cost of handling and documentation was immediate and incontrovertible. Ultimately, it will be interesting to see how the provision pushes, or more likely, is pushed by market preferences.

While the focus in Montreal was obviously to complete an agreement, placing the Protocol within the larger context of national legislation and regulatory systems gives one a richer understanding of the dialogue. A key element of the debate was balancing a Protocol in terms of level of detail and prescription for countries with and without such systems. Some participants stressed that the role of the Protocol is not to serve as a substitute in the absence of domestic systems, whereas others indicated the need for a strong framework to facilitate their development. Many delegates also raised issues related to domestic approval processes and how such regulations will co-exist with the Protocol, especially EC Directive 90/220 on the deliberate release of GMOs into the environment.

**POLITICS AND PROSE:** The series of informal discussions after Cartagena, in Montreal and Vienna, achieved two important goals: establishing a sense of ownership for the negotiating groups, and gradually clarifying the core conflicts that bedeviled Cartagena. The "Vienna setting" also accentuated the nature of the differences between the negotiating groups. Debates on scope, commodities and trade-related issues, reflected a different set of dynamics within and between the major negotiating groups, revealing splits and unique alliances among both developed and developing countries. In the final hour, many credited the mien and bearing of ExCOP President Juan Mayr for instilling delegates with a sense of levity and hope, along with a distinct imperative to conclude the Protocol. His grab-bag of colored stuffed animals used to randomly select the speaking order within the *feng shui*-structured "Vienna setting" provided both comic relief, as well as a sense of equity and transparency. Many participants discussed the nature of proper timing within the negotiation process: when to let the contact groups run their course; when to defer to informal consultations; and, ultimately, when to settle the final deadlocks behind closed doors. The absence of an official high-level ministerial segment was notable, and many appreciated avoiding the rhetorical, sleep-inducing declarations in favor of Mayr's efforts to cultivate and apply the ministers' political influence at the ministerial dinner and in informal consultations during the last crucial stages of the negotiations.

In a historical perspective, the Protocol is a definite victory for the CBD. During earlier negotiations on CBD Article 19.3 and at COP-2 in Jakarta, developing countries faced significant opposition from the North with regards to the need for a Protocol. During the course of the biosafety working groups and the ExCOP many participants lamented that the CBD had chosen to take on its arguably toughest task, as opposed to addressing a less contentious issue, such as marine or agricultural biodiversity. It remains to be seen how the Protocol's implementation will relate in concrete terms to international trade, domestic legislation, technological developments and market preferences. However, attention should also shift away from such political and social impacts to look at how the Protocol serves its original purpose to protect biodiversity. But in the face of rapid commercialization and heated public debate, countries shifted to address an increasingly pressing environmental, economic and health concern. Many delegates expressed their hope that the Protocol would take on a life of its own, truly reflecting the CBD's structure as an umbrella agreement. With the bang of gavel, after eight years, international environmental law has taken a significant step forward in addressing trade-environment concerns and operationalizing the precautionary principle.

## THINGS TO LOOK FOR

**CONVENTION ON BIOLOGICAL DIVERSITY:** The fifth meeting of the CBD's Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA-5) will take place from 31 January - 4 February 2000 in Montreal. The informal Advisory Committee of the Clearing House Mechanism will meet on 29 January 2000 at the CBD Secretariat in Montreal. A meeting of the CHM focal points is scheduled for 31 January 2000 in the ICAO building in Montreal. The *Ad Hoc* Working Group on Article 8(j) will meet from 27-31 March 2000 in Sevilla, Spain. The fifth meeting of the Conference of the Parties will take place from 15-26 May 2000 in Nairobi. For information contact: CBD Secretariat, World Trade Center, 393 St. Jacques Street, Suite 300, Montreal, Quebec, Canada H2Y 1N9; tel: +1-514-288-2220; fax: +1-514-288-6588; e-mail: [chm@biodiv.org](mailto:chm@biodiv.org); Internet: <http://www.biodiv.org/>

**GENETICALLY MODIFIED ORGANISMS AND WORLD TRADE:** This meeting, organized by the Conference Committee of Stagiaires of the European Commission, will be held on 4 February 2000 at "Charlemagne," Rue de la Loi 170, Brussels, Belgium. For information contact: Ida Belling; tel: +32-2-2953134; fax: +32-2-2957332; e-mail: [ida.belling@cec.eu.int](mailto:ida.belling@cec.eu.int); or Anna Albovias; tel: +32-2-2952355; fax: +32-2-2957332; e-mail: [st2b1@dg24.cec.be](mailto:st2b1@dg24.cec.be).

**ROYAL INSTITUTE OF INTERNATIONAL AFFAIRS:** The UK Royal Institute of International Affairs (RIIA) and Fauna Flora International have jointly organized a conference on "Biodiversity and Business" to take place from 3-4 April 2000, at Chatham House, London. The RIIA has also scheduled a conference on "Sustainability in the WTO Millennium Round and Beyond" for 27-28 March 2000 in London. For information, registration and fees contact: Georgina Wright; RIIA, Chatham House, 10 St. James Square, London SW1Y 4LE, UK; tel: +44-20-79575754, +44-20-79575700; fax: +44-20-73212045, +44-20-79575710; e-mail: [gwright@riia.org](mailto:gwright@riia.org).

**OECD:** The OECD Working Group for the Harmonization of Regulatory Oversight in Biotechnology will meet from 2-3 February 2000 in Paris. The OECD Edinburgh Conference on the "Scientific Aspects of Genetically Modified Food: Assessing the Safety of GM Food" takes place from 28 February to 1 March 2000 in Edinburgh, Scotland. For information contact: Peter Kearns, Secretary ICGB, OECD; tel: +33-1-45241677; fax: +33-1-45241675; e-mail: [icgb@oecd.org](mailto:icgb@oecd.org); Internet: [http://www.oecd.org/news\\_and\\_events](http://www.oecd.org/news_and_events).

**TRAINING COURSE ON BIODIVERSITY, BIOTECHNOLOGY AND LAW:** The International Institute for Tropical Agriculture and the Global Biodiversity Institute will host the training course from 1-24 March 2000 in Ibadan, Nigeria. For information contact: Dr. John Kilama, International Institute for Tropical Agriculture/Global Biodiversity Institute; Wilmington, DE; USA; tel: +1-302-7642074; fax: +1-302-7642809; e-mail: [Jkilama@GBDI.org](mailto:Jkilama@GBDI.org); Internet: <http://www.gbdi.org>

**JOINT FAO/WHO EXPERT CONSULTATION ON RISK ASSESSMENT OF MICROBIOLOGICAL HAZARDS:** The meeting will be held from 6-10 March 2000 in Rome. For information contact: FAO; tel: +39-6-57052287; fax: +39-6-57053369; Internet: <http://www.fao.org/mfcal>.

**THE INTERNATIONAL CENTRE FOR GENETIC ENGINEERING AND BIOTECHNOLOGY:** The International Centre for Genetic Engineering and Biotechnology (ICGEB) in Trieste, Italy, has organized two biosafety workshops: "Science and Policy in Risk Assessment of Transgenic Organisms: A Case Study Approach," from 27-31 March in Trieste, and "Advanced Research and Procedures: Case Studies for Designated Experts" from 3-8 April 2000 in Florence. For information contact: Dr. Giovanni Ferraiolo; ICGEB; Trieste, Italy; tel: +39-40-3757364; fax: +39-40-226555; e-mail: [ferraiol@icgeb.trieste.it](mailto:ferraiol@icgeb.trieste.it); Internet: <http://www.icgeb.trieste.it/biosafety/>.