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### REPORT OF THE FOURTH SESSION OF THE AD HOC WORKING GROUP ON BIOSAFETY: 5-13 FEBRUARY 1998

The fourth session of the Open-ended *Ad Hoc* Working Group on Biosafety (BSWG-4) met from 5-13 February 1998 in Montreal, Canada. Delegates began negotiations on consolidated text, which will serve as the basis for further negotiations for a biosafety protocol to the Convention on Biological Diversity at the next session of the Working Group to take place in August. Chair Veit Koester (Denmark) stressed that delegates had entered into the phase of negotiations, while reiterating his injunction at BSWG-3, that "nothing is agreed until everything is agreed."

BSWG-4 built upon the work of BSWG-3 by further consolidating options contained in the draft text, while beginning the process of negotiation to clearly define divergent positions and to identify common ground for moving forward. The meeting continued to follow the structure from BSWG-3, using two Sub-Working Groups to address the core articles of the protocol and two Contact Groups on definitions and annexes and on institutional matters and final clauses. Delegates began consideration of several articles that had only received preliminary discussion at BSWG-3, including, inter alia: principles/objectives, general obligations, non-discrimination, socioeconomic considerations, and liability and compensation. Delegates also continued work on other issues previously addressed, including, inter alia: matters relating to advance informed agreement, risk assessment and management, minimum national standards, emergency measures and capacity building. In Plenary, delegates adopted recommendations to COP-4 regarding the dates of the next two meetings of the BSWG and a meeting of the COP to adopt the protocol; the deadline for government submissions for provisions to the protocol; and a request to ensure adequate financial support for the negotiating

Editors' Note: As a matter of policy, the Earth Negotiations Bulletin does not directly attribute statements made by governments in informal negotiations when requested to do so by the Chair. Given the sensitivity to the presence of non-State participants as observers to these negotiations, this report does not include the use of country attributions in the work of the Sub-Working Groups and the Contact Groups.

#### A BRIEF HISTORY OF THE BIOSAFETY PROTOCOL

Since the early 1970s, recombinant DNA technology – the ability to transfer genetic material through biochemical means – has enabled scientists to genetically modify plants, animals and micro-organisms. Modern biotechnology can also introduce a greater diversity of genes into organisms than traditional methods of breeding and selection.

Organisms genetically modified in this way are referred to as living modified organisms derived from modern biotechnology (LMOs). Although biotechnology has demonstrated its utility, there are concerns about potential risks to biodiversity and human health posed by LMOs. Many countries with biotechnology industries already have domestic legislation to ensure the safe transfer, handling, use and disposal of LMOs and their products; these precautionary practices are collectively known as "biosafety." There are no binding international agreements addressing situations where LMOs cross national borders.

#### **UNEP GUIDELINES**

The United Nations Environment Programme (UNEP) Panel of Experts on International Technical Guidelines for Biosafety met in Cairo, Egypt, in December 1995, to adopt a set of international technical guidelines for biosafety. The UNEP Guidelines are intended to provide a technical framework for risk management commensurate with risk assessment, without prejudice to the development of a biosafety protocol to the Convention on Biological Diversity (CBD).

An International Workshop to Follow-up the UNEP Guidelines was held in Buenos Aires in late 1996. The nineteenth meeting of the UNEP Governing Council, held in early 1997 in Nairobi, adopted Decision 19/16 on biosafety. The decision urges governments and subregional and regional organizations to designate focal points to promote the implementation of the Guidelines, and urges governments to contribute relevant information to UNEP's International Register on Biosafety.

#### BIOSAFETY UNDER THE BIODIVERSITY CONVENTION

The Convention on Biological Diversity, negotiated under UNEP's auspices, was adopted on 22 May 1992, and entered into force on 29 December 1993. There are currently 171 Parties to the Convention.

| IN THIS ISSUE                              |
|--|
| A Brief History of the Biosafety Protocol  |
| Report of the BSWG-4                       |
| Sub-Working Group I                        |
| Contact Group on Definitions and Annexes5  |
| Sub-Working Group II6                      |
| Contact Group on Institutional Matters and |
| Final Clauses                              |
| UNEP/GEF Briefing                          |
| Future Work and Meetings9                  |
| Closing Plenary                            |
| A Brief Analysis of BSWG-49                |
| Things to Look For                         |
|  |

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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 LMOs that may have an adverse effect on biodiversity and its components.

AD HOC GROUP OF EXPERTS ON BIOSAFETY: 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 development of an international framework on biosafety under the CBD. Elements favored unanimously for such a framework included, inter alia: 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); facilitated information exchange; capacity building and implementation; and definition of terms. Elements with partial support included, inter alia: socio-economic considerations; liability and compensation; and financial issues.

**COP-2:** At the second meeting of the Conference of Parties (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 the modalities of 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 that Parties establish national measures.

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

**COP-3:** At its third meeting, the Conference of Parties (COP-3) adopted Decisions III/5 (additional guidelines to financial mechanisms) and III/20 (biosafety issues). In so doing, the COP affirmed its support for a two-track approach through which the promotion of the application of the UNEP Guidelines can contribute to the development and implementation of a protocol on biosafety, without prejudicing the development of such a protocol.

**BSWG-2:** At the second meeting of the BSWG, held from 12-16 May 1997, in Montreal, delegates discussed a range of issues, including: objectives; advance informed agreement; notification procedures for transfers of LMOs; 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 convened a contact group to consider definitions of key terms and directed the Secretariat to compile an alphabetical list of terms requiring definition, as submitted by countries, for consideration at BSWG-3.

**BSWG-3:** At the third session of the BSWG, held from 13-17 October 1997, in Montreal, delegates produced a consolidated draft text to serve as the basis for negotiation of a biosafety protocol. 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. It also extended the mandate of the existing contact group on definitions to address annexes. Delegates also 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 the protocol. Delegates agreed, subject to approval at the fourth meeting of the Conference of Parties (COP-4) to the CBD, to convene two additional BSWG meetings and an extraordinary meeting of the COP to adopt the protocol in 1998.

#### **REPORT OF BSWG-4**

Chair Veit Koester (Denmark) opened the Fourth Session of the BSWG on Thursday, 5 February 1998. He stated that BSWG-4's objective was to develop draft text that would form the basis for continuing negotiations at BSWG-5 and be submitted to all Parties in time to meet the requirements of the six-month rule, which states that text must be submitted to the Parties six months prior to convening a COP session to adopt a protocol. Koester underscored that the BSWG was entering the negotiation phase and that participants must attempt to reduce, through negotiated consensus, the number of options under each article. He stressed the need for flexibility and productivity in all deliberations and wished the delegates good luck.

Hamdallah Zedan, speaking on behalf of the new Executive Director of UNEP, Klaus Töpfer, recalled the enormity of the task facing the BSWG at the outset and acknowledged the challenge of completing this work in 1998. He stressed the need for a precautionary approach and an accommodating spirit in these deliberations. He highlighted the complementary relationship between the UNEP Guidelines and the protocol on biosafety, and detailed a GEF Pilot Project designed to provide assistance on biosafety to developing countries and countries with economies in transition, at both national and regional levels.

Calestous Juma, Executive Secretary of the Convention on Biological Diversity, emphasized the importance of the BSWG's work in balancing benefit-sharing from modern technology with human and environmental safety. He outlined three key issues facing BSWG-4: prepare consolidated text for presentation to COP-4 so that the protocol can be adopted in December of 1998 (in order to fulfill the requirements of Article 28 of the CBD, which calls for the text of any proposed protocol to be communicated to the COP by the Secretariat at least six months before such a meeting); addressing linkages with other activities under the CBD, including benefit-sharing, technology transfers, *in-situ* conservation and technical and scientific cooperation; and financial resources for this and future meetings.

ADOPTION OF THE AGENDA: The Chair introduced the Provisional Agenda (UNEP/CBD/BSWG/4/1), which was adopted without discussion. Koester presented Chairman's Notes, (UNEP/CBD/BSWG/4/Inf.1, UNEP/CBD/BSWG/4/Inf.1/Add.1, UNEP/CBD/BSWG/4/Inf.2), which were prepared with a view to reduce redundancy in the BSWG-3 consolidated text and additional government submissions. Koester stressed that his intent was to preserve, in principle, all options, and that each group should decide whether and/or how to use the Chairman's Notes. He recalled BSWG-3's decision to allow for government submissions on seven items, previously covered as outstanding issues: Principles/Objectives, General Obligations, Non-Parties, Non-Discrimination, Illegal Traffic, Socio-Economic Considerations, and Liability and Compensation.

The Chair also introduced his *aide-memoire* dealing with recommendations by BSWG-4 to COP-4, and highlighted the importance of the decisions that COP-4 must make, including the timing and venue of the special session of the COP to adopt the protocol. Additionally, he noted that COP-4 would need to decide how to proceed after adoption of the protocol.



ORGANIZATION OF WORK: BSWG-4 organized its work following the structure established at BSWG-3, using two open-ended Sub-Working Groups (SWGs) and two open-ended contact groups. SWG-I, which addressed Articles 3-14, was co-chaired by Sandra Wint (Jamaica) and Eric Schoonejans (France). Co-Chairs for SWG-II, which addressed Articles 1, 1 bis and 15-27, were John Herity (Canada), who replaced David Gamble, and Amerjeet Ahuja (India), who replaced Hira Jhamtani (Indonesia). Co-Chairs of Contact Group I (Definitions and Annexes) were Piet van der Meer (Netherlands) and Gert Willemse (South Africa). Co-Chairs of Contact Group II (Institutional Matters and Final Clauses) were John Ashe (Antigua and Barbuda) and Katharina Kummer (Switzerland). The Chair informed the Plenary of changes in the BSWG Bureau, noting that Darryl Dunn had replaced David Gamble (both of New Zealand) and Jung Ho Choi had replaced Bum Soo Kwak (Republic of Korea).

The Chair also proposed that Contact Group I become a sub-group of SWG-I allowing to meet in parallel with and report to SWG-I. Koester also noted the intention stated at BSWG-3 that Contact Group II should eventually become a legal drafting group.

Plenary sessions were held on Saturday morning, 7 February, to consider recommendations to COP-4, on Wednesday, 11 February, to review progress under each SWG, and on Friday, 13 February, to review and adopt the final report for BSWG-4 (UNEP/CBD/BSWG/4/L.1-L.6 and Addenda).

#### SUB-WORKING GROUP I

Sub-Working Group I met in sessions each day from Thursday afternoon, 5 October, to Thursday afternoon, 12 October. The Sub-Working Group's objective was to prepare negotiating text for draft Articles 3-14, which are: Application of AIA (Article 3); Notification Procedure for AIA (Article 4); Decision Procedure for AIA (Article 5); Response to AIA Notification (Article 6); Review of Decision under AIA (Article 7); Notification of Transit Under AIA (Article 8); Simplified Procedure (Article 9); Subsequent Imports (Article 10); Bilateral and Regional Agreements (Article 11); Risk Assessment (Article 12); Risk Management (Article 13); and Minimum National Standards (Article 14). As a basis for preliminary discussion, SWG-I used: the compilation of government submissions of draft text (UNEP/CBD/ BSWG/4/3); the Chairman's Note on Articles 3-10 and 12-14 (UNEP/ CBD/BSWG/4/Inf.1); the Chairman's Note on Article 11 (UNEP/ CBD/BSWG/4/Inf.1/Add.1); and the consolidated text from BSWG-3 (UNEP/CBD/BSWG/4/Inf.5). In addition to these documents, SWG-I drew upon various aide memoires, country proposals, room documents and Conference Room Papers, which were introduced throughout the week to facilitate further discussion and consolidate text based upon SWG-I's discussions of these articles. Additionally, small informal drafting groups were convened throughout the week to streamline text, consolidate options and reduce redundancy.

Throughout BSWG-4, CG-I worked in parallel with SWG-I, on definitions and annexes. To facilitate SWG-I's work, CG-I prepared draft text on several definitions, as well as Annex I on Information for Advance Informed Agreement (AIA) Notification and Annex II on Risk Assessment.

At the first meeting of SWG-I delegates discussed procedural matters and adopted the order of work. Co-Chair Wint announced a decision by the BSWG Bureau that NGOs would be able to participate as observers, but without the right to intervene, negotiate or participate, and that they could be removed from meeting rooms at the request of any government. Substantive negotiations began the following morning.

#### APPLICATION OF THE AIA PROCEDURE (Article 3): Noting the challenges to addressing both the scope of the protocol and AIA procedure in one article, delegates created two new articles,

AIA procedure in one article, delegates created two new articles, Article 3A (Scope of the Protocol) and Article 3B (Application of the AIA Procedure).

**Scope of the Protocol (Article 3A):** Delegates' discussions revolved around how and if the scope of the protocol would differ from AIA. The options provided in the final consolidated text include: no provision; scope equivalent to AIA; and language detailing the types of transboundary movements of LMOs covered and not covered by the protocol.

Application of the AIA Procedure (Article 3B): Delegates focused on: application of AIA for contained versus uncontained use of LMOs; exemption of low-risk LMOs from AIA; scope of AIA versus the protocol; and unilateral declaration or bilateral, regional or multilateral arrangements for exempting LMOs from AIA. Several delegates preferred that circumstances for exempting LMOs from AIA be addressed in other articles, such as Article 9 (Simplified Procedure) and Article 11 (Bilateral and Regional Agreements). Options retained in the negotiating text for AIA application to LMOs include: all LMOs defined in the protocol; the first movement unless determined exempt; application of AIA procedure based upon criteria to be developed in an annex; or specifications listed within the article.

NOTIFICATION PROCEDURE FOR AIA (Article 4): One delegate noted that the main difference in the options listed in the text was whether the notification process is driven by the exporter or the importer. Other points of difference included the mechanism by which information would be made available, by whom and to whom. A developed country delegate summarized his country's position on the role and responsibilities of the importer in the AIA notification procedure. He noted three considerations — purpose, practicality and experience — for why responsibility for AIA notification should rest with the importer, and highlighted the need for capacity building in this context. Delegates debated a provision on accuracy of information provided in the notification. Some delegates felt that there was no need for such a provision, while others differed on whether the importer or the exporter should be responsible for providing the information on accuracy. Other issues included: whether "products thereof" should be mentioned along with a reference to LMOs; whether to prohibit exports from commencing before AIA had been received; and whether the requirements for AIA should be specified in Annex I or in a list to be established by the Meeting of the Parties (MOP) to the Protocol. Modifications made to the text addressed responsibility for notification and/or accuracy of information.

The consolidated text contains language with bracketed options reflecting several possibilities for the notifier, the content of the notification, and provisions requiring or obviating responsibility for accuracy of information.

RESPONSE TO [AIA] NOTIFICATION (Article 5): In discussing this article, delegates considered, inter alia: acknowledgement of receipt; the basis for approval by the Party of import; time frame for response; assessment of the content of notification; how notification should be delivered; implications of no response; and whether or not written consent is necessary. Some delegates expressed a preference to avoid too much detail, and several delegations opposed inclusion of a precise time period for response to notification. Some delegations proposed text requiring an importer to inform the notifier whether notification was received in the correct form, thereby indicating that the importer had the information necessary for the basis of a decision. Some developing countries supported text eliminating acknowledgement of receipt, while others proposed adding language stating that failure to acknowledge receipt would not result in any consequences, nor would it imply consent for transboundary movement of LMOs. Options retained for this article reflect the varying views expressed in the discussions.

**DECISION BY THE PARTY OF IMPORT (Article 6):** The key issues covered by this article include: responsibility for providing the basis of the AIA decision; criteria for determining if a transboundary movement should be permitted; and the time period for decision. Some developing countries expressed concern regarding responsibility for supplying the required information, noting that the Party of export

should provide funds to cover the cost of collecting such information, as well as capacity building for information collecting. Several delegations supported language on scientific evidence, risk assessment, risk assessment in accordance with Annex II, and socio-economic imperatives as the basis for a decision. One delegation noted that time needed for additional information should not be deducted from the allotted response period. Some delegations and one regional group stressed that text allowing for implicit approval for a transboundary movement was not acceptable. Several delegations favored listing acceptable responses after review of notification, including approval, prohibition, request for additional information, and whether and how the decision applies to subsequent imports. The consolidated text consists of options for, *inter alia*: the basis of the decision; the Party of import's obligation to confirm receipt of complete information from the notifier, transmit its decision and clarify if written consent is necessary; and whether, and in what cases, explicit approval is not required.

**REVIEW OF DECISIONS UNDER AIA** (Article 7): Delegates noted that this article covered two main issues: conditions under which the Party of import could review its decision; and conditions under which a Party of export could request review of a decision. Some delegates supported, and others opposed, the provision of finances for risk assessment undertaken by the importing State in reconsidering its decision. The consolidated text includes provisions for: a Party to prohibit a transboundary movement in light of new information; an exporter to request a Party of import to re-evaluate a decision based on a change of circumstance or additional available information; and obligation on exporters to supply new information if relevant to the decision to the Party of import; and the importing Party's right to unilaterally review a decision it has taken on any transboundary movement of LMOs.

NOTIFICATION OF TRANSIT (Article 8): While some delegations viewed this article as unnecessary, several others preferred text requiring the Party of export to obtain consent from Party and non-Party States through which LMOs will be transported, as well as text that would establish responsibility for accidents occurring in transit. The two options provided in the consolidated text include a "no provision" option, and one that would require: notification between Parties of the intent to transit LMOs; acknowledgement of notification by the State of transit acknowledgement of notification; notification by transit States regarding treatment of subsequent imports; and documentation specifying the necessary care for the LMOs while in transit.

**SIMPLIFIED PROCEDURE** (Article 9): Some delegations proposed deleting this article, since the matter could be addressed in Article 10 (Subsequent Imports) or 11 (Bilateral and Regional Agreements) or in an annex. One regional group opposed this article, stating that all LMOs should be subject to AIA. Two options are included in the consolidated text: no provision and cases where a Party may approve a simplified procedure.

**SUBSEQUENT IMPORTS (Article 10):** This article allows subsequent imports of LMOs to be exempted from AIA. Several delegations preferring mandatory risk assessment for all LMOs supported deleting this article. One delegation stressed the importance of continued AIA for subsequent imports because the application of and environment for LMOs may change. Other delegates preferred addressing the issue in other articles such as Article 6 (Decision by the Party of Import) or 9 (Simplified Procedure). The consolidated text contains five options: no provision; simple notification or exemption from AIA for subsequent imports, if AIA for the first import is given without conditions; no notification necessary unless the intended use of the LMO, receiving environment, or other factors likely to affect the risk assessment, change; necessary notification, in writing, by the Party of export and acknowledgement of receipt by the Party of import; and specified exemption of an LMO from AIA provided by the Party of import, with notification to the Secretariat.

BILATERAL AND REGIONAL AGREEMENTS (Article 11):
One delegate identified three objectives of bilateral and regional agreements: to cooperate in implementing the protocol; to identify

LMOs that may be exempt from AIA; and to integrate non-Parties into the application of the AIA procedure. Delegates stressed the importance of such agreements for facilitating information exchange and capacity building, developing appropriate codes of practice, and monitoring effects of LMOs on human and animal health and biodiversity. Several delegates supported exemption of AIA under such agreements, so long as protocol standards would be maintained. Two options were included in the consolidated negotiating text: no provision for such agreements; and an option that would allow States to enter bilateral, multilateral or regional agreements, provided they are consistent with the provisions of the protocol.

RISK ASSESSMENT (Article 12): Delegates consolidated text on the aim, scope of application, parameters and financial responsibility for risk assessment. Most delegates supported detailing the parameters of risk assessment in an Annex on Risk Assessment. Some delegations supported financing of minimum risk assessment by the exporter, while others deemed it the importing country's responsibility. Several delegations supported allowing Parties to determine risk assessment procedure based upon national legislation, with minimum requirements for national legislation to be established in the protocol. One regional group requested that risk assessment be based not only on scientific grounds, but also on the precautionary principle and on socio-economic grounds. One delegation requested that text stating that risk assessment be undertaken on a case-by-case basis. Some of the text was replaced with a referral to Annex II, which would outline either the minimum or maximum risk assessment requirements. At the end of the week, delegates considered minimum and maximum options for such an annex, as prepared by Contact Group I, and most preferred keeping requirements to a minimum. Some delegations from developing countries preferred specific rather than general guidelines on risk assessment. The consolidated text includes options relating to risk assessment to identify and evaluate possible adverse effects of LMOs on conservation and sustainable use of biological diversity; when, how, on what grounds and by whom risk assessment would be carried out; responsibility for the accuracy of information; allowing Parties to conduct risk assessment in accordance with their national legislation; and financial responsibility for risk assessment, including a provision to assist developing countries and countries with economies in transition to conduct their risk assessment.

RISK MANAGEMENT (Article 13): Several delegations noted that risk management is a domestic concern and should not be included in the protocol. Others stressed the article's importance because of variation in risk management measures from country to country. Other delegates highlighted the need for global and regional risk management. One delegate called for addition of language noting that lack of scientific certainty regarding harm should not preclude preventative measures. The consolidated text contains an option for no provision and an option for Parties to include measures for risk management in accordance with either CBD Article 8 (*In Situ* Conservation), or criteria stipulated in the protocol.

MINIMUM NATIONAL STANDARDS (Article 14): Some delegations opposed this article, because of sovereignty issues, while other delegates supported fulfillment of the requirements of the protocol as a minimum. One delegate suggested that minimum national standards could be dealt with under Article 1 *bis* (General Obligations). Delegates retained two options: one for no provision and one that would require each Party to ensure that appropriate legal, institutional and administrative measures concerning the safe research and development, manufacture, transfer, handling and use of LMOs are in place and, at a minimum, fulfill the requirements of the protocol.

**DEFINITIONS AND ANNEXES:** SWG-I considered the outcome of Contact Group I's discussions on definitions and annexes on a periodic basis throughout the week. Delegates requested clarifications and requested textual modification with regard to definitions on dealing with, *inter alia*: LMOs, organism, transboundary movement, export, import, competent authority, and focal point; as well as



Annexes on Information for AIA Notification, and Risk Assessment. SWG-I concerns were incorporated by Contact Group I into final bracketed text.

FINAL COMMENTS: At the close of SWG-I on Thursday afternoon, 12 February, the Co-Chair invited final comments on substantive or procedural matters. Delegates thanked the Co-Chairs for their efforts during the past week, and noted that general discussion on each article, with text consolidation by small groups, had worked well. One delegate suggested that including definitions in the body of the text would help to clarify the content of the articles. A representative of environmental groups thanked SWG-I for the opportunity to follow its discussions. A representative of an international organization noted the need to harmonize the risk assessment procedures being developed or utilized in various international fora. With these final comments, SWG-I concluded its work.

#### **CONTACT GROUP ON DEFINITIONS AND ANNEXES**

Contact Group I (CG-I), co-chaired by Piet van der Meer (the Netherlands) and Gert Willemse (South Africa), began its work on definitions and annexes, using the consolidated text from BSWG-3 (UNEP/CBD/BSWG/4/Inf.5) as the basis for its deliberations. The Co-Chairs reiterated that the contact group was a technical group, which would not negotiate text. Its mandate was to produce simple, unambiguous, scientifically sound and internally consistent text on definitions and annexes, to facilitate discussions in SWG-I.

**DEFINITIONS OF ORGANISM AND LMO:** Prior to beginning discussion on this issue, the Co-Chair stated that CG-I would not discuss LMOs "and products thereof" since this was a scope issue to be addressed by SWG-I. In first defining "organism," delegates used the definition in the UNEP Guidelines, which states that an organism is "any entity that is able to replicate its own genetic material, including viruses." CG-I discussed whether to specify "its own genetic material" or "genetic material" or merely to say "able to replicate." All options were retained. CG-I also considered whether to include explicit reference to viruses or to add the broader phrase able to "transfer genetic material," which would include viruses, but may also inadvertently include other elements. In response to questions from SWG-I regarding the distinction between replication and reproduction, the Co-Chair of CG-I clarified that an entity "able to replicate" would include sterile organisms, since replication was a different concept from reproduction. The final bracketed definition of an organism reflects these discussions.

Regarding the definition of an LMO, CG-I considered existing options in the consolidated text (UNEP/CBD/BSWG/4/Inf.5) as its starting point. The main difference between the options was their focus on process versus result of modification of a living organism. Some delegates preferred a focus on process, citing this as crucial to the assessment of the "biosafety level" of an LMO. Others preferred a focus on result, citing the novelty of the resulting organism as the key factor in a definition of LMOs. This viewpoint also held that defining an LMO by the process of its production would risk omitting processes that might be developed in the future. CG-I decided to include both process and result of modification in a draft definition of LMO.

In elaborating the process of LMO modification, some delegates proposed "modified by *in vitro* gene technologies" while others objected to use of the term "gene," noting that other technologies might also be used to produce LMOs. In discussing the result of LMO modification, delegates proposed language on the presence of "foreign" or "transgenic" genetic material in the modified organism. Those supporting "transgenic" noted that "foreign" would not cover, for example, mutagenesis within an organism, thereby restricting the scope of the definition. Delegates also differed on whether an LMO was "unlikely to occur in nature" or had "one or more novel traits" or both. One delegation preferred defining LMOs as organisms with "traits novel to the species in the receiving environment." The Co-Chair noted that this would make the definition of an LMO contingent

upon where it was being sent, which was a complicated way to proceed. The final bracketed definition of an LMO reflects all the diverse views noted above.

**OTHER DEFINITIONS:** CG-I discussed definitions for transboundary movement, import, export, importer, exporter, Party of import and Party of export, before referring these terms to Contact Group II for legal advice. It also discussed competent authority/focal point.

**Transboundary Movement:** Four main points of debate were whether: movement was unintentional, intentional or both; movement was from "the territory" or "the area under the jurisdiction" of a country; transboundary movement applied to extrajurisdictional areas; and the concept of transit was included within it. Following consideration by Contact Group II and SWG-I, the final bracketed text reflects various options in these areas of contention, pending further policy decisions on such issues.

**Export/Import, Exporter/Importer, Party of Export/Party of Import:** The main points of debate were whether to include transit within the term export or import; whether the country or a private entity within a country was the exporter or importer; and whether the term "Party" or "State" should be used in these definitions. Delegates had varying views on use of the term "Party" or "State", with some noting that it was not yet clear whether trade with non-Parties would be allowed under the protocol. Final bracketed definitions reflect these areas of disagreement.

Competent Authority/Focal Point: CG-I noted that these terms were used throughout the draft text, yet the distinction between them remained unclear. The group noted its understanding that "focal point" facilitated information sharing between a Party and the protocol, while "competent authority" was a regulatory authority responsible for implementing the protocol. Delegates noted, however, that the institutions performing these functions varied widely from country to country, and called for guidance from SWG-I on the distinctive tasks of a competent authority and a focal point within the protocol, before developing definitions for these terms.

**ANNEXES:** CG-I discussed Annex I (Information Required in Notification for Advance Informed Agreement) and Annex II (Risk Assessment Parameters).

Annex I: Delegates began discussion on the draft Annex I contained in UNEP/CBD/BSWG/4/Inf.5. The text listed categories of information to be provided in an AIA notification, including, *inter alia*, taxonomic status of the recipient organism, methods to ensure safe handling, a risk assessment report, intended dates of transfer and intended use of the LMO. Discussion touched upon the Annex's uncertain legal status, i.e., whether it represented obligations or guidelines, as well as its level of detail. While the need for guidance from SWG-I on these issues was noted, CG-I attempted to produce a list of essential requirements for AIA notification.

Delegates considered at some length whether an AIA notification should include a risk assessment report in every case, and whether such a risk assessment would be undertaken according to the parameters listed in (a yet undecided) Annex II. Following feedback from SWG-I, where a number of delegations noted that their submissions for Annex I were more detailed, especially with regard to risk assessment, CG-I requested policy guidance regarding the level of detail desired. CG-I also responded to concerns raised in SWG-I about "intended use of LMO" and "intended dates of transfer," where delegates noted that specific dates may not always be known, and an exporter requesting AIA may not have complete information about intended use of an LMO in an importing country. The bracketed outcome on Annex I reflects these concerns.

Annex II: Prior to commencing discussion, the Co-Chair invited statements from NGOs on this issue. An environmental group urged delegates to ensure that the scope of the protocol and Annex II minimized the release/escape of transgenic recombinant/novel DNA. An industry representative emphasized the need for Annex II to be practi-



cable, based on science, and adaptable to advances in science. In discussing the chapeau to the annex, delegates expressed divergent preferences on whether references to "human and animal health" and "the socio-economic welfare of societies" should be retained. Some delegates noted that these were policy decisions that were more appropriately placed within Article 12 (Risk Assessment) rather than in the chapeau to Annex II.

Following lengthy debates on whether to have a "minimum" or a "maximum" list of requirements for risk assessment, CG-I produced short and long versions of Annex II to illustrate the two options. In producing these lists, CG-I agreed that no list, however long, could include all the factors that might come into play in risk assessment for a particular LMO. In presenting these lists to SWG-I, the Co-Chair highlighted that the main difference between the two options was that the longer version included human health, socio-economic impacts and contained uses of LMOs, as necessary elements for inclusion in a risk assessment. In presenting its work to SWG-I, CG-I noted the need for policy guidance regarding whether to work with a shorter or longer Annex II. In preparation for future work, CG-I also compiled a list of other annexes referenced in the consolidated text. The CG-I Co-Chair noted that, in addition to the two annexes discussed at this meeting, the consolidated text called for 18 additional annexes, with significant overlap in subject matter. He noted that policy decisions regarding the need for some or all of these annexes would be necessary.

#### SUB-WORKING GROUP II

Sub-Working Group II (SWG-II), co-chaired by John Herity (Canada) and Amerjeet Ahuja (India), met daily to review and consolidate draft text on proposed Articles 1, 1 bis, and 15-27. Of these, Articles 1, 1 bis and 23-27 had only received preliminary discussion in Plenary at BSWG-3. The articles addressed the following issues: Principles and Objectives (Article 1); General Obligations (Article 1 bis); Unintentional Transboundary Movements (Article 15); Emergency Measures (Article 16); Handling, Transport, Packaging and Labeling (Article 17); Competent Authority/Focal Point (Article 18); Information Sharing/Biosafety Clearing-House (Article 19); Confidential Information (Article 20); Capacity Building (Article 21); Public Awareness/Public Participation (Article 22); Non-Parties (Article 23); Non-Discrimination (Article 24); Illegal Traffic (Article 25); Socio-Economic Considerations (Article 26); and Liability and Compensation (Article 27). As the basis for their discussions, delegates used background documents, including government submissions of draft text (UNEP/CBD/BSWG/4/3), a Chairman's Note synthesizing the report of BSWG-3 and government submissions (UNEP/CBD/ BSWG/4/Inf.2), and the consolidated text from BSWG-3 (UNEP/ CBD/BSWG/4/Inf.5). Additionally, SWG-II's deliberations were assisted by the formation of informal groups designed to streamline text and consolidate options on specific articles.

**OBJECTIVES** (Article 1): Delegates agreed to remove the word "Principles" from the original title, since the article does not currently include any principles. Delegates made little progress on consolidating the other text in this article, which may have reflected the view expressed by one delegate, that this article should be discussed after the content of other articles is finalized.

Several delegates stressed the importance of shared responsibility and cooperation, and one highlighted the importance of this provision as a benchmark against which to measure progress.

Interventions reflected some of the key differences remaining to be negotiated for the protocol including, *inter alia*: whether its scope will include "all" LMOs, LMOs resulting from "modern" biotechnology, and/or the adverse socio-economic and human health impacts of LMOs; whether the protocol will be exhortatory versus prescriptive (e.g., promote versus ensure safe transboundary movement of LMOs); and consideration of impacts on human and/or animal health.

**GENERAL OBLIGATIONS** (Article 1 *bis*): This article sets out the general obligations of Parties to the protocol, although, in this prelimi-

nary discussion, delegates differed as to length and level of detail. Several delegates noted a preference for brevity and suggested deleting options addressed in other articles. Some delegates stated that it was premature to start deliberations on general obligations until later in the negotiation process.

## UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES (merged Articles 15 and 16):

The original Article 15 addressed the responsibilities and/or rights of the Parties regarding unintentional transboundary movements. Options differed regarding, *inter alia*: need for the provision; activities covered; knowledge required to trigger responsibility; action required; scope of information required; whether information would be provided to the clearing-house; and confidentiality of information provided.

One developed country supported elimination of the article, noting relevant provisions in the CBD. One regional economic integration organization, supported by other delegates, favored providing notification to any affected Party or non-Party, including all relevant information listed in Annex I (Information Requirements for AIA). Another delegate supported text addressing releases of aquatic LMOs.

The original Article 16 included two options: "no provisions necessary" and text that called for either establishment of national measures and procedures, or incorporation of appropriate measures in risk management strategies established under Article 13 (Risk Management). Several delegations spoke against retaining a separate article, noting relevant CBD coverage, and/or stated that such measures should be left to national legislation. Others supported the provision to ensure notification, citing its importance to countries without national measures. Some delegates proposed merging Articles 15 and 16, or alternatively incorporating Article 16 into Article 13. During discussion on a Co-Chair's draft text, delegates agreed to delete the "no provision necessary" option, and to merge Articles 15 and 16. Delegates consolidated text on the elements that should be included in notification. Several delegates suggested that specifics of notification be included in an annex, while others opposed such an approach. Delegates disagreed on whether "accident" or "unintentional transboundary movement of LMOs" best captured the type of event covered by this provision. Delegates also disagreed on whether the article should cover known domestic releases of LMOs. Regarding the biosafety clearing-house, one delegation preferred no reference, while several developing countries stressed its importance.

There was no consensus on the remaining text covering, *inter alia*: actions required by the Party of origin; an affected Party's right to request emergency assistance from the Party of origin; an affected Party's right to request consultation among concerned Parties; and whether Parties must avoid actions with potential impacts on freshwater and marine ecosystems.

HANDLING, TRANSPORT, PACKAGING AND LABEL-LING (Article 17): While making considerable progress in consolidating text, delegates disagreed on the following issues: need for the article; scope of the article; reliance on existing international rules and standards versus domestic national measures; development of new international standards; and information to accompany transport, including labelling.

A developed country stated that existing and developing international law adequately cover these issues, and, therefore, preferred no article. Several developing countries preferred coverage of LMOs "within the scope of the protocol," while two developed countries preferred LMOs "subject to AIA." One delegate requested that references to LMOs always include the words "and products thereof." Several delegates supported reliance on domestic legislation, while others cited the need for clear standards to preclude development of non-tariff barriers to trade and warned that reliance on domestic legislation could lead to proliferation of different systems.



Given fears of trade discrimination, a few countries opposed the requirement that exporting countries use classification, packaging and labeling requirements as stringent as those used domestically for comparable products.

#### **COMPETENT AUTHORITY/FOCAL POINT (Article 18):**

This article would require designation or establishment of a national competent authority or focal point to receive notifications and communicate decisions on LMOs. Many delegations noted the potential for further consolidation of draft text regarding the scope and role of competent authorities and focal points. Some delegates supported simpler language detailing key obligations for national focal points, to allow flexibility for countries to establish measures in accordance with similar national procedures already in existence or under development. Others stressed the need for detailed provisions, as many developing countries lack strong institutional structures. One delegation suggested that roles and responsibilities be specified in an annex. Two countries supported a single competent authority. One delegate suggested language requiring those with multiple authorities to detail their areas of coverage.

INFORMATION SHARING/BIOSAFETY CLEARING-HOUSE (Article 19): Delegates began with four lengthy options regarding an information exchange mechanism. The draft text covered: the purpose of such a mechanism; its establishment; content; reporting responsibilities of the Parties; and access to the information. One regional group preferred establishing a database as opposed to a full clearing-house. Similarly, some developing countries expressed concern regarding a proliferation of mechanisms and their ability to access them. One delegation bracketed the words "publicly available," with regard to information, to be included in the mechanism. Another delegate added text which stated that the first Meeting of the Parties (MOP) would determine the function and scope of the mechanism, stating the article's technical aspects preclude its completion before the protocol's adoption.

**CONFIDENTIAL INFORMATION (Article 20):** This article addresses confidentiality of information submitted under the requirements of the protocol. Several developing countries preferred no article on confidential information, citing protection under existing national and international regulatory regimes, but other countries stressed the need for the article. Contentious issues included, *inter* alia: the balance between protecting confidential information and the need to provide adequate information for handling emergencies; the balance between rights and obligations of both receiving and providing Parties; and wording that might obstruct technological development. Some delegates questioned whether the text adequately addressed how confidential information would be treated under specific situations, and what information should not be considered confidential. One delegation suggested specifying an expiration date for confidential treatment. A representative of an IGO, speaking at the invitation of Co-Chair Ahuja, said that limits on confidentiality might compromise protection afforded under general principles of international intellectual property law.

CAPACITY BUILDING (Article 21): This article addresses the need to develop and strengthen human and institutional capacity in biotechnology and biosafety. The need for capacity building in biosafety and/or biotechnology was recognized by all speakers, but delegates initially disagreed on whether the issue should be in a separate article, in the preamble, or not be included at all. Much, but not all, of the support for a separate provision came from developing countries, who emphasized that capacity building in risk assessment and risk management is crucial for an effective protocol. Some developed countries preferred reliance on existing multilateral, regional and bilateral mechanisms, such as the UNEP Guidelines, the GEF and CBD Decisions III/5 and III/20 regarding capacity building in biosafety. One delegation cautioned against such reliance and stated that the COP intentionally avoided addressing this issue in detail, given the development of this protocol.

One delegate suggested categories on: general commitments; financial mechanisms; major elements of capacity building; and developed country commitments. Several developing countries stressed language on "new and additional financial resources." Some delegations supported the addition of text specifying that capacity building would be achieved through financial, as well as technical assistance, from the private sector. Delegates agreed to retain the article on capacity building.

#### PUBLIC AWARENESS/PUBLIC PARTICIPATION (Article

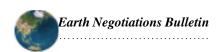
22): This article provides for education of and information to the public on biosafety and biotechnology, as well as for participation in risk assessment and decision processes for LMO releases in accordance with national legislation. Regarding the need for and scope of provisions on this issue, views ranged from no article to encouraging public participation in risk assessment decisions. Several delegates acknowledged the value of provisions on public participation within the protocol, but preferred references to public participation "as appropriate" or inclusion in the preamble.

One delegate highlighted developing countries' needs for communication tools to achieve this article's goals. Several developing countries favored: facilitation of public participation in risk assessment decisions; promotion of national, subregional and regional public awareness programmes; and public involvement in approval processes for LMO releases. Some delegates stressed the need for cooperation with other Parties and IGOs. Delegates settled on inclusion of an article on public awareness and participation with bracketed options reflecting the diverse views.

NON-PARTIES (Article 23): This article addresses the relationship between Parties and non-Parties regarding trade in and transboundary movements of LMOs. One delegation preferred deletion of this article, stating it would cause discrimination in trade relations between Parties and non-Parties. Several delegations stressed the need for its inclusion, with reference to principles of non-discrimination. Some governments supported no import or export of LMOs to or from non-Parties, although one such delegation indicated flexibility on this point. Particular concern was voiced over non-Parties gaining favorable trade advantages and the need for incentives to ratify the protocol.

One developed country highlighted the implications for movement of LMOs from Parties to non-Parties versus non-Parties to Parties. He noted that movement from non-Parties to Parties could adhere to the protocol's obligations, whereas movement from Parties to non-Parties could result in reliance on national legislative frameworks less stringent than the protocol. Options retained in the article include, *inter alia*: removing the article; provisions on no trade of LMOs with non-Parties; non-discriminatory trade conducted under a regulatory framework as stringent as the protocol's; and consideration of trade restrictions with non-Parties after five years.

NON-DISCRIMINATION (Article 24): This article addresses whether Parties may discriminate between LMOs produced locally and/or foreign LMOs, and the relationship of Party status to nondiscrimination. A number of delegates strongly opposed this article, citing, inter alia: sufficiency of existing international frameworks, such as the World Trade Organization (WTO), which covers trade in products and has a dispute resolution mechanism; a preferred focus on science and the environment, not trade; appropriateness of discrimination where a State concludes its biodiversity may be imperiled; and impracticability of enforcement. Delegates supporting this article highlighted the need for non-discriminatory application of risk assessment decisions and AIA measures; and consistency with trade-related international agreements. Several governments expressed unwillingness to take a firm position on the issue, pending the outcome of deliberations on other articles, such as AIA (Articles 4-6) and non-Parties (Article 23). Others favored addressing under General Obligations (Article 1 bis). Delegates retained three options on non-discrimination, including a "no provision" option.



ILLEGAL TRAFFIC (Article 25): This article would require Parties to adopt appropriate domestic legislation that prevents and penalizes illegal traffic in LMOs, and provides for transmission of information on such activities among Parties and/or to the Secretariat. Some delegates opposed inclusion of this article, stating that the protocol should limit its focus to the legal transfer, handling and use of LMOs, and that the article raises definitional problems. Others noted that consideration of this article was premature since it depends on decisions with regard to procedures for AIA. Of those preferring the article's deletion, some indicated flexibility on a provision calling for domestic legislation on illegal traffic. Regarding information dissemination, some delegates questioned the reference to the biosafety clearing-house, still under discussion in Article 19, as well as the involvement of the Secretariat. Final draft text included options on: no provision, development of national legislation, and national legislation combined with various provisions for information sharing.

**SOCIO-ECONOMIC CONSIDERATIONS** (Article 26): This article would require Parties to consider the socio-economic impacts of introduction, transfer, handling and/or use of LMOs. Numerous developing countries stressed the importance of this provision and requested language addressing, *inter alia*, research on socio-economic considerations related to LMOs. A number of developed countries stated that the complexity and breadth of socio-economic issues make implementation of such a provision impractical. Several developing countries countered that complexity is not an acceptable reason to avoid the issue, and that failure to address socio-economic issues here would only raise more problems later.

Others favored treatment of this issue in the preamble. During one session, Co-Chair Herity invited NGOs to present their views on this issue. One environmental NGO stated that people could not be removed from consideration of biotechnology's application and that "a protocol without this article is a protocol for genocide." Key differences among bracketed options include: no provision; allocation of responsibility (responsibility of importing country versus no specific allocation of responsibility); requirement of a seven-year advanced notification requirement regarding LMO production of previously imported commodities; and provision of financial and technical assistance to affected developing countries.

**LIABILITY AND COMPENSATION (Article 27):** This article sets out provisions for the redress of damage to biodiversity from LMOs. Several developed countries and one regional group stated their opposition to the article, noting, *inter alia*: that general international law, and specifically CBD Article 14(2) on liability and redress, adequately covers the issue; and that domestic legislation should address such issues.

In contrast, many developing countries supported retaining the article. One such delegate argued for a strict liability regime for transboundary harm from LMOs, noting their ultra-hazardous nature and citing relevant provisions of and precedents in other international agreements. Another suggested a framework with components on: general principles for liability; civil liability; compensation; measures of reinstatement; duration of liability; an emergency fund; and exceptions. One delegate stressed the injustice in profiting from biotechnology while shifting responsibility for harm to others.

Some countries questioned how the article would apply to non-Parties, while others stressed the difference between liability of the Party and the exporter. An NGO stated that without liability, insufficient incentive exists to achieve the objectives of the protocol. Noting complexities associated with harmonization of civil liability laws and the lack of time to fully develop the article before the protocol's adoption, a few countries supported revisiting the issue at the first Meeting of the Parties (MOP).

Three alternatives — no article; an article on liability and compensation; and consideration at the first MOP — reflect the range of options for consideration at BSWG-5.

## CONTACT GROUP ON INSTITUTIONAL MATTERS AND FINAL CLAUSES

The Contact Group on Institutional Matters and Final Clauses (CG-II) was co-chaired by John Ashe (Antigua and Barbuda) and Katharina Kummer (Switzerland). The mandate of CG-II was to develop language and consider issues of a legal and technical nature, rather than to discuss items in a substantive manner. CG-II considered draft Articles 28-43, and the preamble, using background documents UNEP/CBD/BSWG/4/Inf.3 and Inf.5, and also drawing on language and precedents in existing international environmental agreements, including the Kyoto Protocol under the Framework Convention on Climate Change and the Montreal Protocol on Substances that Deplete the Ozone Layer. It also reviewed definitions submitted by Contact Group I (see report on Contact Group I on page 5).

**PREAMBLE:** In discussions on the preamble, delegates disagreed on the level of detail and content to be included, maintaining text in two options, one brief and the other long. The brief option included text recognizing the value of modern biotechnology and the limited capacity of some countries to deal with its risks, whereas the long version also referenced, *inter alia:* the UNEP Guidelines and Agenda 21; the precautionary principle; capacity building; and adequate compensation for damages arising from the handling and transfer of LMOs.

#### FINANCIAL MECHANISM AND RESOURCES (Article 28):

Two options, both establishing the opportunity for developed countries to provide financial and technological resources to developing countries, were retained in the consolidated text. One of these options further specified that the financial mechanism and institutional structure defined under CBD Article 21 (Financial Mechanism) shall also serve the purposes of the protocol.

**CONFERENCE OF THE PARTIES (Article 29):** This article would establish the COP of the CBD as the Meeting of the Parties to the protocol.

SUBSIDIARY BODIES AND MECHANISMS (Article 30): This article would establish the relationship between subsidiary bodies under the Convention and the protocol.

**SECRETARIAT** (Article 31): This article would designate the Secretariat of the CBD as the Secretariat of the protocol. Options relating to the financial arrangements for its operation remain bracketed. Calestous Juma, Executive Secretary of the CBD, spoke about some of the practicalities and responsibilities that might be expected of the protocol's Secretariat, especially in regard to an information exchange mechanism.

**JURISDICTIONAL SCOPE** (Article 32): This article was deleted as the issue is fully covered by provisions in the CBD.

**RELATIONSHIP WITH THE CONVENTION (Article 33):** This article states that the provisions of the CBD relating to its protocols will apply to the biosafety protocol.

**RELATIONS WITH OTHER INTERNATIONAL AGREE- MENTS (Article 34):** Draft text on this article sets out options, including: removal of the article; provisions that the protocol will not affect rights and obligations under other existing international agreements to which a country is also Party at the time the protocol enters into force; and provisions waiving the right of Parties for complaint in specific areas of inconsistency with agreements under the WTO.

MONITORING AND COMPLIANCE (Article 35): The article was split into two separate provisions: Monitoring and Reporting (Article 35) and Compliance (Article 35 bis). Article 35 requires Parties to monitor their implementation of the protocol and report to the MOP on these measures. Some delegates noted that this covered domestic concerns, precluding the need for inclusion in the protocol. Others pointed out that most international conventions contain a provision for monitoring and reporting. Delegates debated whether reporting should occur annually, regularly, or as determined by a MOP to the protocol, with agreement coalescing for the last option.



Article 35 *bis* states that Parties shall determine procedures and mechanisms to handle Parties failing to comply with the protocol.

#### ASSESSMENT AND REVIEW OF PROCEDURES/

**ANNEXES** (Article 36): This article provides three options for the review of procedures and annexes, including: removal of the provision; and two variations for regular review and follow-up on procedures and annexes.

**SIGNATURE** (**Article 37**): This article will set the dates for opening the protocol for signature.

**RATIFICATION, ACCEPTANCE OR APPROVAL (Article 38) and ACCESSION (Article 39):** These articles were removed as they are fully covered by provisions in the CBD.

**ENTRY INTO FORCE (Article 40):** This article will set the date that the protocol enters into force.

**RESERVATIONS** (Article 41): This article has two options, including removal of the provision and a provision for no reservations to the protocol.

**WITHDRAWAL** (Article 42): This article sets the terms for withdrawal of a Party from the protocol.

**AUTHENTIC TEXT (Article 43):** This article details the languages and location of deposition for the authentic text of the protocol.

#### BRIEFING WORKSHOP ON THE UNEP/GEF PILOT BIOSAFETY ENABLING ACTIVITY PROJECT

On Wednesday afternoon, 11 February, Hamdallah Zedan and Paul Chabeda of UNEP presented a workshop on the UNEP/GEF Pilot Project, designed, in part, to determine what assistance developing countries and countries in transition will need to implement the protocol. The project has two components: assistance with creation of national biosafety frameworks and support for regional workshops on biosafety, specifically on risk assessment, risk management and transboundary transfer of LMOs with novel traits. Eighteen countries are participating in the framework component. Regional workshops will be held in Africa, Asia/Pacific, Central/Eastern Europe, and Latin America and the Caribbean.

#### **FUTURE WORK AND MEETINGS**

**BSWG-4 RECOMMENDATIONS TO COP-4:** CG-II reviewed recommendations to COP-4 and forwarded them for consideration by the Plenary on Wednesday, 11 February. The recommendations include, *inter alia*, sections on:

- the dates of the next two BSWG meetings, the second of which is to be followed by a meeting of the COP to adopt the protocol (17-28 August 1998, and December 1998 or no later than February 1999, respectively);
- the deadline of 1 June 1998 for government submissions for provisions to be included in the protocol; and
- a request to ensure adequate financial support for the process.

  No recommendation was included as to whether the COP to adopt the protocol should be an ordinary or extraordinary session.

PREPARATIONS FOR BSWG-5: Preparations for BSWG-5 were outlined in the Plenary chaired by Chair Veit Koester on Friday morning. Delegates agreed that BSWG-5 will continue with the same organizational structure, co-chaired by the same individuals, with the same mandates. Chair Koester stated that three documents will be prepared for BSWG-5. The first will be a new consolidated text, which should be considered in square brackets, based on the principle that "nothing is agreed until everything is agreed." All items not addressed at this meeting will be included, as is, from the previous consolidated text. The second document will be the Secretariat's compilation of new government submissions on provisions in the protocol. Chair Koester noted that while new submissions were allowed, the many options already in the consolidated text reflected "a menu with many exciting dishes" and called on delegates "not to send in hamburgers." Finally, to provide for an informed discussion on LMOs and "products thereof,"

an information document will be prepared by the Secretariat, based on government submissions. The deadline for submissions on this issue is 1 May 1998, to allow the Secretariat time to analyze the material, as well as obtain necessary scientific information.

#### **CLOSING PLENARY**

BSWG Chair Veit Koester opened the final Plenary on Friday, 13 February 1998. On behalf of SWG-I, Co-Chair Eric Schoonejans, introduced the group's work on Articles 3-14 (UNEP/CBD/BSWG/4/L.5) and summarized their review of definitions and annexes as prepared by CG-I. Minor amendments were made regarding footnotes to the text on the Articles and BSWG-4 adopted the document.

On behalf of SWG-II, Co-Chair John Herity introduced the group's work on Articles 1, 1 *bis*, and 15-27 (UNEP/CBD/BSWG/4/L.4 and L.4/Add.1-5). He noted that SWG-II had been able to reduce more than 75 options in 15 articles to 45 options in 14 articles. He noted that the consolidated text was not exactly "Shakespearean Prose," but that it would provide a solid basis for continuing negotiations at BSWG-5. Some minor textual amendments were made and the documents were adopted.

Contact Group I Co-Chairs Piet van der Meer and Gert Willemse summarized the outcome of their deliberations on definitions and annexes. Contact Group II Co-Chairs John Ashe and Katherina Kummer presented the group's work on Articles 28-43, and the preamble (UNEP/CBD/BSWG/4/L.2 and L.2/Add.1-5).

In reviewing the final section of the draft report of BSWG-4 (UNEP/CBD/BSWG/4/L.1 and L.1/Add.1-2), Koester noted that the dates for BSWG-5 would be changed to 17-28 August 1998, given scheduling problems for the previously announced July dates. At the close of Plenary, Chair Koester thanked the delegates, Co-Chairs, Secretariat, United Nations Offices in Nairobi, BSWG Bureau members, and interpreters for their hard work and constructive attitude, and expressed appreciation for the involvement of IGOs and NGOs. BSWG-4 came to a close at approximately 1:30 pm.

#### A BRIEF ANALYSIS OF BSWG-4

At the start of BSWG-4, Chair Veit Koester emphasized that participants must work to reduce, through negotiated consensus, the number of options in each article, and he called for flexibility and productivity in these deliberations. By the end of eight working days, including Saturday sessions, delegates had consolidated text on most of the articles for a protocol on biosafety, including provisions on highly contentious issues, such as scope, advance informed agreement, risk assessment, and consideration of liability and socio-economic impacts. Many delegates expressed satisfaction with the work accomplished and appreciation for a relatively smooth process, and appeared ready to carry the work forward to BSWG-5. As one delegate phrased it, the BSWG appeared to have found its "rhythm of working." Nonetheless, given that major differences remain on key provisions of the protocol, continued progress is essential if the BSWG is to fulfill its mandate to complete a draft protocol for presentation to the COP by the end of its next two sessions.

GETTING TO YES: Several aspects of BSWG-4 appear to have contributed to its success. Some delegates noted a more congenial and cooperative atmosphere, which facilitated clarification and refinement of divergent positions. This atmosphere may have stemmed, in part, from the group's commitment to participation. Delegates had the opportunity to participate in all Sub-Working Groups, Contact Groups and informal drafting groups, which permitted a wide exchange of views on all topics and contributed to trust and confidence in the process itself. This structure contrasted with restrictions imposed during part of BSWG-3, where reliance on regional representatives within a drafting group denied some delegates speaking rights, undermined confidence and hampered progress.



Some postulated that the many informal inter-regional meetings, which increased during BSWG-4's final days, also contributed significantly to confidence building. Several delegates stated that the interregional meetings helped them assess potential areas of compromise on issues that seemed unbridgeable in formal negotiating sessions. While these meetings probably represent the start of a long haul toward a common meeting point, it is significant that they are beginning now and not in the eleventh hour of negotiations. Also, while many had pointed to visible splits in the G-77/China at earlier meetings, this no longer seemed to be the crucial fulcrum in the negotiations. Differences surely persist, but intra-regional differences among developing countries did not seem to be any more significant than those among developed countries.

Although most participants found the process more congenial than previous sessions, not everyone left Montreal satisfied. Some stated that BSWG-4 had certainly clarified the different positions on key issues and resulted in "cleaner" text, but that openness and congeniality did not necessarily equal flexibility or a spirit of compromise. Environmental NGOs were admonished for being overly passionate, but their posture may have reflected frustration with the Bureau's decision to restrict participation to brief comments at the beginning of formal sessions. Even industry representatives noted dissatisfaction at not having more informal opportunities to talk with governments in a less-politicized environment. Nonetheless, both sides of the NGO community expressed guarded optimism that BSWG would craft a worthwhile protocol and that they would continue to have access to a system that increasingly calls for public participation and private sector involvement.

**THE MEANING OF YES:** Although delegates may have achieved a workable process, the many options regarding the substance of the protocol reflect the varying goals and agendas of the governments. It appears that many developing countries are seeking to ensure that the protocol will provide adequate safety measures, and a system of accountability and redress for harm resulting from transboundary movement of LMOs, as well as increased capacity to deal with biosafety issues. Some commented that they want to avoid a new form of dependency on the developed world. Countries with nascent biotechnology industries seemed to support technology transfer and capacity building, while keen to avoid restrictions on transfers and red tape for national industries. Some developed countries seem especially concerned with establishing guidelines to standardize reporting procedures and coordinate divergent national systems, while avoiding provisions that would be too complicated or financially burdensome to implement.

These divergent agendas are reflected in the text of the meeting, but with the notable caveat that all options remain in brackets. Outside the meeting hall, delegates often pondered how they would be able to bridge polarized positions within the limited time frame. The options for some of the most contentious issues spanned a wide range of possibilities, including removing the provision, deferring discussion until the first MOP, establishing guidelines or detailing specific provisions.

Given coalescing support for the protocol, it is clear that the political will exists to see it through. The challenge now is to ensure that a critical mass of countries is able to find the answer to the question, "What is the incentive?" This raises the central debate over the protocol's scope and how it can be crafted to represent true compromise and attract widespread support. The potential of biotechnology for human welfare is enormous and should be realized, but in a manner that is complementary to and protective of biodiversity in its broadest sense. In the bigger picture, the protocol's success or failure will certainly impact the position of the CBD in the intergovernmental arena. As the first major agreement under the CBD, the protocol will be a key test to show the commitment of the world's governments to the Convention and its objectives.

#### THINGS TO LOOK FOR

WORKING GROUP ON BIOSAFETY: The Fifth Session of the Open-ended *Ad Hoc* Working Group on Biosafety is scheduled to take place in Montreal from 17-28 August 1998. BSWG-6 is tentatively scheduled for 21 November - 5 December 1998 in Montreal and will be followed by a Conference of the Parties to adopt the protocol, pending final decision by COP-4. For more information, contact the CBD Secretariat, World Trade Center, 393 St. Jacques Street, Montreal, Quebec, Canada H2Y 1N9; tel: +1-514-288-2220; fax: +1-514-288-6588; e-mail: chm@biodiv.org; internet: http://www.biodiv.org.

**REGIONAL PREPARATORY MEETINGS FOR COP-4:** The Latin American Preparatory Meeting is scheduled for 4-6 March 1998 in Lima, Peru. The African Preparatory Meeting is scheduled for 9-11 March 1998 in Nairobi, Kenya. The Central and Eastern European Preparatory Meeting is scheduled for 23-26 March 1998 in Almaty, Kazakstan. The Asian Preparatory Meeting is scheduled for 26-29 March 1998 in Hainan, China. For more information, contact the CBD Secretariat.

FOURTH MEETING OF THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY: COP-4 is scheduled to take place from 4-15 May 1998 in Bratislava, Slovakia. The Ministerial Roundtable on Biological Diversity will be held at the meeting's start on 4-5 May 1998. For more information, contact the CBD Secretariat.

**AFRICAN REGIONAL WORKSHOP ON THE CLEARING-HOUSE MECHANISM:** The African workshop is scheduled for 5-7 March 1998 in Nairobi, Kenya. For more information, contact the CBD Secretariat.

WORKSHOP ON BIODIVERSITY AND IMPACT ASSESS-MENT: This workshop, coordinated by the IUCN, will be held 22-23 March 1998 at the eighteenth annual meeting of the International Association for Impact Assessment in Christchurch, New Zealand. For more information, contact: Andrea Bagri, IUCN, Economic Services Unit, Rue Mauverney 28, Gland 1196 Switzerland; tel: +41-22-999-0001; fax: +41-22-999-0002; e-mail: internet: http://iucn.org/themes/economics.

INTERNATIONAL ASIA-PACIFIC MYCOLOGICAL CONFERENCE ON BIODIVERSITY AND BIOTECH-

**NOLOGY:** This conference will be held from 6-9 July 1998 in Hua Hin, Thailand. For more information, contact: BIOTEC Committee; Gypsum Metropolitan Tower, 5th Floor, 539/2 Sri-Ayudhya RD, Radhevee, Bangkok, 10400, Thailand; tel: +662-642-5322; fax: +662-248-8305; e-mail: mycology@biotec.or.th; internet: http://www.biotec.or.th/diary/mycology/mycology.htm.

CONFERENCE ON GENETICALLY MODIFIED ORGAN-ISMS IN NORDIC HABITATS—SUSTAINABLE USE OR LOSS OF DIVERSITY?: This conference will be held 1-2 October 1998 in Helsinki, Finland. For more information, contact: Marja Ruohonen-Lehto; tel: +358-9-4030-0541; e-mail: marja.ruohonen-lehto@vyh.fi; or Hans Erik Svart; tel: +45-39-47-20-00; e-mail: hes@sns.dk.

**SECOND ANNUAL EUROPEAN BIOTECHNOLOGY BUSINESS CONFERENCE:** This conference will be held 27-30
October 1998 in Brussels, Belgium. For more information, contact:
EuropaBio, Avenue de l'Armee 6, B-1040 Brussels, Belgium; tel: +32-2-735-0313; fax: +32-2-735-4960; e-mail: mail@europa-bio.be; internet: http://www.europa-bio.be.

**BIODIVERSITY, BIOTECHNOLOGY & BIOBUSINESS:** 

This conference, organized by WA Branch, Australian Biotechnology Association with the Australian Department of Conservation and Land Management and Murdoch University, will be held from 23-27 November 1998 in Perth, Australia. For more information, contact: Michael Borowitzca, Murdoch University, Biodiversity, Biotechnology & Biobusiness, Congress Werst Pty Ltd, PO Box 1248, West Perth WA 6872, Australia; fax: +61-8-9322-1734; e-mail: biodiversity@science.murdoch.edu.au.