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REPORT OF THE SECOND MEETING OF THE OPEN-ENDED AD HOC GROUP ON BIOSAFETY: 12-16 MAY 1997

The second meeting of the Open-ended *Ad Hoc* Working Group on Biosafety (BSWG-2) met from 12-16 May 1997 in Montreal and continued its discussions on the elaboration of a protocol on safety in biotechnology. Working from *aide-memoires* tabled by Chair Veit Koester (Denmark), delegates discussed a range of issues, including: objectives; procedures for transfer of living modified organisms; competent authorities, information sharing and a clearinghouse mechanism; capacity-building; and risk assessment and management. BSWG-2 also convened contact groups to consider the proposals on definitions of key terms and studies to be completed by the Secretariat in preparation for BSWG-3.

Koester opened BSWG-2 by urging delegates concentrate on core issues and identify the elements of a biosafety protocol for their next session. Under his guidance, delegates displayed a cooperative spirit and agreed to a structure for discussions and the programme of work for this meeting as well as future meetings. After previous meetings characterized by some as "talk shops," many BSWG-2 delegates left Montreal satisfied they had at last begun to move from generalities to specifics and taken substantial steps toward a protocol. Despite this progress, some fundamental disparities of opinion, particularly on the scope of the protocol, remain, which threaten to derail the process when negotiations get underway.

A BRIEF HISTORY OF THE BIOSAFETY ISSUE

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 rapidly. Modern biotechnology can also introduce a greater diversity of genes into organisms, including genes from unrelated species, 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).

Biotechnology has led to advances in medicine, and promises to improve agricultural products and industrial processes as well. Agricultural biotechnology can improve the resistance of plants to pests or environmental stresses, and can increase the commercial value of agricultural products. Other uses for biotechnology include environmentally-friendly industrial processes that may reduce the use of harsh or toxic chemicals.

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

Two categories of intended use of LMOs — contained use and field release — are recognized. LMOs intended for contained use are usually research material and are subject to well-defined risk management techniques involving laboratory containment. LMOs developed for agricultural and, in some cases, industrial

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biotechnology, are intended for field release. Field testing of LMOs is a new undertaking, and the interaction of LMOs with various ecosystems continues to generate questions about safety. Some of the concerns about field release of LMOs include: unintended changes in the competitiveness, virulence or other characteristics of the target species; the possibility of adverse impacts on non-target species and ecosystems; the potential for weediness in genetically modified crops; and the stability of inserted genes.

BIOSAFETY UNDER THE BIODIVERSITY CONVENTION

The Convention on Biological Diversity (CBD), which was negotiated under the auspices of the United Nations Environment Programme (UNEP), was adopted in May 1992 and was opened for signature at the Earth Summit in Brazil on 5 June 1992. It entered into force on 29 December 1993. As of 23 April 1997, 168 countries had become Parties to the Convention.

Article 19.4 of the Convention provides for Parties to consider the need for and modalities of a protocol, including advance informed agreement (AIA) in particular, to ensure the safe transfer, handling and use of living modified organisms derived from modern biotechnology that may have an adverse effect on biological diversity and its components.

The first Conference of the Parties to the CBD, which was held from 28 November - 9 December 1994, established an Open-ended *Ad Hoc* Group of Experts on Biosafety. This Group met in Madrid from 24-28 July 1995. According to the report of the meeting (UNEP/CBD/COP.2/7), most delegations favored the development of an international framework on biosafety under the Convention. The proposed elements of such a framework, as drafted in Madrid, are divided into two categories — those favored unanimously and those favored by a subset of delegates representing primarily developing countries. In the annex to the report, paragraph 18(a) lists the former elements, which include: all activities related to LMOs that may have adverse effects on biodiversity; transboundary movement of LMOs, including unintended movement; release of LMOs in centres of origin/genetic diversity; mechanisms for risk assessment and management (RAM); procedures for advance informed agreement; facilitated information exchange; capacity-building; and implementation and definition of terms. Paragraph 18(b) lists the latter elements, including: socio-economic considerations; liability and compensation; and financial issues.

In another meeting relevant to the biosafety process, the UNEP Panel of Experts on International Technical Guidelines for Biosafety met in Cairo, Egypt, from 11-14 December 1995 to adopt a set of international technical guidelines for biosafety (UNEP Guidelines). The UNEP Guidelines (UNEP/Global Consultations/Biosafety/4) are intended to provide a technical framework for risk management commensurate with risk assessment, without prejudice to the development of a biosafety protocol by the COP of the CBD.

At COP-2, which took place in Jakarta, Indonesia, from 6-17 November 1995, delegates met to consider the need for and modalities of a protocol on biosafety. From the outset it was clear that delegates intended to set in motion a negotiation process to develop a protocol on biosafety. While developed country delegations wanted to focus on "transboundary transfer of any LMO", developing countries preferred a "protocol on biosafety in the field of the safe transfer, handling and use of LMOs." The compromise language that was adopted by the COP calls 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, setting out appropriate procedures for advance informed agreement."

The decision also established an Open-ended *Ad Hoc* Working Group on Biosafety (BSWG) to meet to "elaborate, as a priority, the modalities and elements of a protocol based on appropriate elements from paragraph 18(a)" of the report of the Madrid meeting, and to "consider the inclusion of the elements from paragraph 18(b) as appropriate." Other terms of reference for the BSWG (UNEP/CBD/BSWG/1/2) state that the Working Group shall: elaborate key terms and concepts; consider AIA procedures; identify relevant categories of LMOs; and develop a protocol whose effective functioning requires that Parties establish national measures and that takes into account the precautionary principle. The Working Group shall also: develop a protocol that provides for a review mechanism and seeks to minimize unnecessary negative impacts on biotechnology and does not hinder unduly access to and transfer of technology; take into account gaps in the existing legal framework; develop a protocol with a view to the largest possible number of ratifications; and use the best available scientific information.

BSWG-1, which was held in Aarhus, Denmark, from 22-26 July 1996, began the elaboration of a global protocol on safety in biotechnology. Although the meeting produced little in the way of written results, it represented a forum for defining issues and articulating positions characteristic of the pre-negotiation process. The meeting revealed several interesting dichotomies, including a fracture in the G-77/China bloc over elements to be included in the protocol, as well as strikingly divergent perspectives on biotechnology. Nonetheless, governments listed elements for a future protocol, agreed to hold two meetings in 1997 and outlined the information required to guide their future work.

By adopting decisions III/5 (additional guidelines to financial mechanisms) and III/20 (biosafety issues), COP-3 affirmed its support for a two-track approach through which the promotion of the application of the UNEP International Technical Guidelines for Safety in Biotechnology can contribute to the development and implementation of a protocol on biosafety, without prejudicing the development and conclusion of such a protocol, and endorsed recommendation II/5 of SBSTTA-2 with regard to capacity-building in biosafety.

An International Workshop to Follow-up on the UNEP International Technical Guidelines for Safety in Biotechnology was held in Buenos Aires on 31 October - 1 November 1996.

The nineteenth meeting of the UNEP Governing Council, held from 27 January – 7 February 1997 in Nairobi, adopted decision 19/16 on biosafety. The decision urges governments and subregional and regional organizations to promote the implementation of the Guidelines by designating focal points in countries to apply the Guidelines, and urges governments to promote safety in biotechnology by contributing relevant information to UNEP's International Register on Biosafety. The Governing Council also requested the Executive Director to: continue to promote the implementation of the UNEP International Technical Guidelines for Safety in Biotechnology, particularly in developing countries; explore with other UN and international bodies the mutual sharing of information about organisms with novel traits; and organize within two years a second international workshop on the state of the art of the implementation of the Guidelines.

REPORT OF BSWG-2

BSWG Chair Veit Koester (Denmark) opened the session on Monday, 12 May 1997, and recalled that COP-3 had entrusted the Working Group to complete its work on a biosafety protocol by the end of 1998. He noted that the Commission on Sustainable Development (CSD) at its most recent meeting had called upon the BSWG to complete its work rapidly. He stated that the meeting

must concentrate on core issues and identify elements that would enable delegates to review a draft text for a protocol at BSGW-3 in October.

Mr. Zedan (UNEP) highlighted a number of developments since BSWG-1, including actions taken by SBSTTA, COP-3, the Bureau of the African Ministerial Conference on the Environment and the nineteenth UNEP Governing Council. He also noted that many countries have begun formulating national biosafety mechanisms and submitting their project proposals for GEF support.

CBD Executive Secretary Calestous Juma summarized the activities of the secretariat since COP-3, including the first expert group meeting on marine and coastal biodiversity and implementation of the clearinghouse mechanism. He stated an expert workshop on the *modus operandi* of the CBD would be convened in November.

Delegates completed their discussions on the composition of the Bureau, which will remain in office until COP-4 in May 1998. The Bureau consists of the following members: Diego Malpede (Argentina); Veit Koester (Denmark); Behran Gebre Egziabher Tewolde (Ethiopia); Sandra Wint (Jamaica); Sateeaved Seebaluck (Mauritius); Ervin Balazs (Hungary); David Gamble (New Zealand); Alexander Golikov (Russian Federation); Antonio G.M. La Vina (Philippines); and Bum Soo Kwak (Republic of Korea).

Delegates then emphasized a number of priority issues for consideration. MALAYSIA, supported by SOUTH AFRICA, proposed focusing on the objective of the protocol, a definition of LMO, AIA, mechanisms for risk assessment, capacity-building, financial issues, and liability and compensation. With the PHILIPPINES, he also sought inclusion of socio-economic considerations. The EU stressed the importance of establishing procedures in case of international transboundary movement of LMOs. JAPAN, NORWAY and the REPUBLIC OF KOREA emphasized that the protocol should be consistent with the objectives of the CBD and should not exceed its scope. AUSTRALIA supported limiting the scope of the protocol to key issues such as information sharing and capacity-building. The US highlighted AIA and information sharing as the two central items for consideration. NORWAY emphasized risk assessment and capacity-building. Delegates raised a number of other considerations. The REPUBLIC OF KOREA and ARGENTINA said the protocol needs to be flexible to accommodate future advances in science and rapid technological change. The REPUBLIC OF KOREA, ARGENTINA, AUSTRALIA, JAPAN and SOUTH AFRICA said the protocol must be consistent with WTO rules. JAPAN and the REPUBLIC OF KOREA called for minimizing negative impacts on biotechnology or limitations on access to biotechnology. ETHIOPIA noted that African countries were "once bitten twice shy" and had accordingly submitted a detailed draft protocol.

The GREEN INDUSTRY BIOTECHNOLOGY PLATFORM stressed that the protocol should only apply to organisms that had been modified using recombinant DNA techniques and threaten to have an effect on biodiversity. Products of LMOs should not be included. The THIRD WORLD NETWORK called for the inclusion of: the precautionary principle; ethical, social and human health risks; public participation; and strict liability. She called for a moratorium on the release of LMOs until a legally-binding protocol is concluded.

ORGANIZATION OF WORK

During the meeting, delegates discussed a range of issues relevant to the formulation of a protocol, including: objectives; procedures for the transfer of LMOs, including AIA; competent authorities; information sharing and a clearinghouse mechanism; capacity-building; and risk assessment and management. Delegates had the following documents before them: a compilation of views of governments on the contents of a future protocol (UNEP/CBD/BSWG/2/2); a background document on existing international agreements related to biosafety (UNEP/CBD/BSWG/2/3); a bibliography concerning potential socio-economic effects of biotechnology (UNEP/CBD/BSWG/2/4); and a glossary of terms relevant to a biosafety protocol (UNEP/CBD/BSWG/2/5).

On the basis of his review of items that have been addressed by government submissions, the Chair tabled a number of conference room papers as *aide-memoirs*, which contained specific questions under each issue area and provided a structure for discussions. Delegates' views on these issues were compiled by the Chair in several "elements papers" and reviewed once more by delegates, who added items and proposed modifications. The Chair's final drafts of the "elements papers" were compiled and annexed to the report of the meeting. These papers, along with new and existing submissions from countries, will serve as the basis for discussion at BSWG-3.

Delegates established a contact group to consider action on the proposals regarding definitions. The group did not attempt to define terms but recommended work on a consolidated document dealing with definitions for BSWG-3. Contact groups were also established to consider proposals made during BSWG-2 on studies to be completed by the Secretariat in preparation for BSWG-3.

OBJECTIVE

The Chair distributed an informal *aide-memoire* on the aim of the protocol that stated: "The aim/objective of the protocol is to establish international action on biosafety that should offer an efficient and effective framework for the development of international cooperation aimed at ensuring safety in biotechnology through effective risk assessment and management for the transfer, handling and use of any LMO resulting from modern biotechnology that may have adverse impacts on the conservation and sustainable use of biological diversity, taking into account the risks to human health and taking also into account Articles 8(g) and 19 of the Convention." He acknowledged a lack of consensus on the protocol's objective and requested that delegates temporarily accept the text, which was drawn from the Jakarta Mandate and the Madrid meeting.

CANADA, JAPAN, AUSTRALIA and the EU proposed incorporating language from the Jakarta decisions on the protocol and mentioning that the aim should focus on transboundary movements. AUSTRALIA, supported by the EU, noted that the text only drew from the preamble of the Jakarta Mandate and proposed using language from the body of Decision II/5 (capacity-building). MALAYSIA and INDIA said the language lacked specificity and called for a clearer statement of intent. Delegates decided to revisit the issue at BSWG-3.

PROCEDURES FOR LMO TRANSFERS

The Chair introduced an informal *aide-memoire* that presented a series of questions for consideration of procedures for specific transfers of LMOs. The text asks what procedures should be included in the protocol and states that the central question is whether protection requires explicit consent, implicit consent or both. Explicit consent, as seen in the Basel Convention procedure for Prior Informed Consent (PIC), implies that the absence of a reply from the importing country within a specified time frame does not constitute consent, but is instead a violation of the Protocol, which can be addressed according to the Protocol's dispute settlement mechanism. Implicit consent implies that consent is deemed given if no reply from the importing country has been received within the specified time.

The EU noted two objectives: providing relevant information and giving importers the right to deny or accept movement of LMOs. Supported by SWITZERLAND, he stressed a choice of

AIA (explicit consent) or simple notification (implicit consent). Response options could include consent with or without conditions, a request for additional information, a rejection of the application for movement or a notification of a need for more time for consideration. NORWAY favored explicit consent for all initial transfers of substances, but with an obligation for the importing country to respond within 90 days. For subsequent exports a notification procedure could be used. CANADA defined LMOs covered by specific AIA procedures as including only those with adverse effects and noted that explicit consent should be given in a timely fashion. Acknowledgement of receipt of application for movement should also be required. NEW ZEALAND favored both forms of consent, stressing flexibility and transparency as guiding principles. AUSTRALIA highlighted several components of AIA, including: the need for a system for notification of intent; a definition of the LMOs to be covered; and principles for risk assessment. The US said the decision of whether to apply implicit or explicit consent hinges on the type of LMO and that AIA explicit consent should only apply to the first shipment.

ZAMBIA, BRAZIL, the PHILIPPINES, SRI LANKA, CAMEROON and BANGLADESH stressed the need for explicit consent, stating that implicit consent at this stage is unacceptable as it could give importing countries an unfair responsibility arising from their different bureaucratic or communication conditions. COLOMBIA said AIA should be applied in every case and, with ZAIRE, called for a procedure requiring the exporter to notify a competent authority in the importing country of all potential risks and to wait for explicit consent from the importing country. INDONESIA noted that explicit consent systems would generate information-sharing opportunities. The GERMAN WORKING GROUP ON BIODIVERSITY and the THIRD WORLD NETWORK noted that the consequences of LMO movements may not be visible until later and that explicit consent for all movements allows an opportunity for revision.

PERU suggested that the decision of whether to apply explicit or implicit consent should lay with the importing country, which should mandate the standards for notification and importation. CHINA supported inclusion of both types of consent, but noted that the terms of implicit consent should be determined on a bilateral basis. MAURITIUS supported explicit consent but reserved judgement on a total ban on implicit consent. MALAYSIA noted that the decision of applying implicit or explicit consent should be made when LMOs have been determined. BRAZIL said a simplified procedure should be considered for subsequent transboundary movements of the same LMO. The MARSHALL ISLANDS, JAPAN and INDIA called for explicit consent, but in a manner different from that of the Basel Convention.

The *aide-memoire* also asked whether the applicable procedures for consent should be fixed within the protocol or left for the importing country to decide. ZAMBIA supported minimum information requirements to protect poorer countries. CANADA and NORWAY supported fixed criteria in order to provide predictability and consistency. SWITZERLAND and JAPAN said the protocol should provide for flexibility in procedures. INDIA said that importing countries should have the right to decide about their procedures.

On the question of which LMOs the procedures should apply to, many countries, including INDIA, BELARUS, SRI LANKA, ZAMBIA, PHILIPPINES, NEW ZEALAND, MAURITIUS, LESOTHO, MALAYSIA, CUBA and UGANDA, favored applying the AIA procedure to all transfers. BRAZIL noted that a simple procedure could provide maximum flexibility to importers and exporters. BANGLADESH and the CENTRAL AFRICAN REPUBLIC called for post-release monitoring activities. The EDMONDS INSTITUTE stated that even if an LMO's characteristics are known one cannot predict its effects in all environments.

BURKINA FASO specified coverage of LMOs that are the result of biotechnology. Other countries, including JAPAN, the EU, the US, CANADA, the REPUBLIC OF KOREA, NORWAY, THAILAND, CHINA and MYANMAR, specified LMOs that pose a possible risk for biodiversity and/or human health. JAPAN also favored excluding those LMOs not reproducible in the environment, covered under another international agreement, and for which risk has not been established. NORWAY noted this view is consistent with the CBD. THAILAND noted that products created from LMOs, such as vaccines and food products, might be covered under trade regulations. CHINA warned that dealing with LMOs according to type and use may not always be consistent under the protocol.

MALI asked how developing countries could know the risks they would run in accepting LMOs. TOGO, supported by the CENTRAL AFRICAN REPUBLIC, pointed out that the stability and behavior of many LMOs are still not ascertained, thus risks will continue to exist. AUSTRALIA, NIGER, MEXICO and CUBA advocated a flexible approach allowing an importing country to decide which LMOs needed an AIA, based on risk and other factors such as intended use. CHINA favored this for exceptional cases.

On the question of intended uses to which the procedure should apply, BRAZIL, the EU, SRI LANKA, BURKINA FASO, BANGLADESH, ZAMBIA, MAURITIUS, LESOTHO, MALAYSIA, UGANDA and the EDMONDS INSTITUTE favored applying AIA to LMOs for all intended uses. The PHILIPPINES favored flexibility on procedures depending on purpose, such as a simpler procedure for LMOs in transit. JAPAN stated that LMOs for research should not be restricted if there are adequate health and environmental safety measures. INDIA also said that LMOs for research could be treated differently from LMOs for commercial uses. CANADA, NORWAY and SWITZERLAND favored excluding LMOs intended for contained use. The US, supported by MYANMAR, specified applying AIA to LMOs intended for field testing or first growth in the importing country.

On the question of distinguishing between initial and subsequent transboundary movements of LMOs, INDIA, SRI LANKA, BANGLADESH, ZAMBIA, MAURITIUS, LESOTHO and the EDMONDS INSTITUTE favored making no distinction. The PHILIPPINES preferred AIA for all movements but said the procedure might differ depending on timing. NORWAY felt that notification with implicit consent might be used for subsequent movements. NEW ZEALAND, NIGER, MALAYSIA and the EU favored subsequent streamlining where there are no changes in use. UGANDA and AUSTRALIA proposed leaving this question to the importing party.

On whether there should be special provisions for LMOs for which commercialization has been prohibited within an exporting country, NORWAY said the protocol should not contain a ban on domestically prohibited products *per se*, but should provide a special procedure. Information about such prohibitions should be made available through the clearinghouse mechanism. MALAYSIA and BURKINA FASO said that no exports should be permitted for domestically prohibited products.

The US stated that the reasons for prohibiting an LMO domestically could hinge on its effects within domestic ecosystems, which could be different within other countries' ecosystems. The EC said there is no need for specific provisions for these cases. CANADA emphasized that the decision to import lies with the importer, but the exporter should provide complete information. CHINA, supported by NEW ZEALAND, cautioned that the inclusion of specific provisions within this protocol could lead to confusion where transfer of an LMO is already prohibited under another international agreement. INDIA supported

information sharing on LMOs, but said the importing country should decide. The RUSSIAN FEDERATION said there should be no obligation on the exporter to provide information, but the importer should have the right to request and obtain information.

On whether there should be special provisions for transferring an LMO that is also produced in the country of import, a number of delegations noted that if the LMO in question was exactly the same as a domestically-produced LMO, the issue should be addressed under rules concerning non-discriminatory trade practices. INDIA, ETHIOPIA, GEORGIA and COLOMBIA warned of the difficulty involved in determining whether an LMO to be imported has the exact genetic makeup as that of a domestic LMO. THAILAND noted the difficulty of determining when a product becomes domestic and provided an example wherein rice genes were once imported and are now grown domestically. The Chair proposed noting that the issue would be addressed under provisions on non-discrimination.

Many delegations addressed the issue of whether the importing country, after receiving notification of a shipment, should have the opportunity to choose between a general or simplified procedure and whether there should be a general provision that permits unilateral or bilateral deviation from the general procedure, and the use of a simplified procedure or no procedure at all. COLOMBIA said the protocol should contain a high level of detail for AIA procedures. The US stated that the level of complexity was not as important as the act of notification itself. JAPAN called for flexibility in the protocol and highlighted the use of bilateral declarations. ETHIOPIA, ZAMBIA, NORWAY and INDIA noted that a decision regarding LMOs in one country could affect many in a region and called for agreed minimum standards and procedures. With ZAIRE, they noted that many countries need capacity-building assistance. MALAYSIA said the protocol should contain minimum standards and not allow for unilateral derogation. She supported using simplified procedures, provided that the specific terms are defined. NEW ZEALAND called for a case-by-case approach.

The US supported cooperative agreements that eliminate the need to apply AIA in all cases, provided they are concluded in a voluntary and non-discriminatory manner, and pointed to the PIC procedure for hazardous chemicals contained in the Basel Convention. ETHIOPIA noted the major differences between hazardous chemicals and biological materials and stated that careless decisions regarding LMOs could affect neighboring countries. He opposed the elimination of AIA. JAPAN said unilateral decision-making was not acceptable. ZAMBIA said the use of bilateral agreements regarding the transfer of LMOs defeats the purpose of the CBD. The COUNCIL FOR RESPONSIBLE GENETICS called for strong regulatory regimes in exporting countries.

The *aide-memoire* asked whether there should be one or more types of simplified procedures for cases in which the general procedures do not apply. It also notes that these simplified procedures could include implicit consent if the general procedure is defined as requiring explicit consent or a simple notification procedure with no possibility for the importing country to react. MALAYSIA noted that the protocol may define specific circumstances where general notification procedure requirements may not apply. AUSTRALIA said importing States should make decisions regarding the subsequent importation of the same LMO at the time of first import. The US called for a single simplified procedure, noting the administrative burden of establishing a shipment-by-shipment procedure. CAMEROON called for a simplified procedure incorporating explicit consent. CHINA sought flexibility for importing countries.

On who should trigger the procedure, the EU, the PHILIPPINES, COLOMBIA, NEW ZEALAND and JAPAN said the exporting country should trigger the procedure in the importing country. ZAMBIA and CAMEROON said the exporting country should notify the competent national authority in the importing country. CAMEROON added that the importing country should have sovereignty to designate its authorities. AUSTRALIA said the protocol should be flexible to allow notification to come from the entity that is most appropriate. THAILAND said the product-owner should trigger the procedure. BRAZIL said the importing State should trigger AIA.

On the kind of information to be provided, the PHILIPPINES and ETHIOPIA said the exporting country should notify the importing country regarding characteristics of the LMO, the venues of intended release and all potential risks. JAPAN stated it would be better to prepare the list later, once LMOs have been identified. NORWAY said risk assessment should be carried out prior to the first export of an LMO and submitted to the competent authority of the importing State. The EU called for the establishment of a technical annex and LMO-specific risk assessment guidelines. AUSTRALIA said risk assessment should begin with the initial exportation and include a description of the LMO, its biological characteristics, an assessment of the receiving environment, the method of transfer and the reproductive capacity of the LMO.

MALAYSIA urged that information be timely and complete to allow the importing country to make an informed decision. She sought inclusion of information regarding safe disposal in case of accidental release, intended uses of the LMO and its effects on human health and the environment. ZAMBIA supported the PHILIPPINES and said the exporting country should also be required to provide certification that release of the LMO is not banned in the country of origin. CHINA said the importing country should apply to its own government for importing procedures, as it is ultimately a government action.

The MARSHALL ISLANDS warned against restricting information for purposes of business confidentiality. Full risk assessment depends on capacity and risk assessment mechanisms. NEW ZEALAND listed categories of information from its own legislation and stressed an ongoing interchange of information, with allowances for confidentiality, as appropriate. COLOMBIA supported Malaysia and added that the competent national authority of the importing country should be able to ask for additional information. She said the protocol must have a clause on handling the confidential information given to the importing country. SRI LANKA called for the protocol to provide a system for scientific verification of information. CAMEROON noted that information should be provided in the official languages of the importing country, and should include a description of LMOs, safety requirements, mitigation measures in case of accidental release and risk assessment.

The REPUBLIC OF KOREA listed five information elements: specific regulations for safe handling and use; preliminary risk assessment; risk management procedures; practical information on transfer of the LMO; and assessment of socio-economic implications. The RUSSIAN FEDERATION called for information requirements to be based on OECD and other international regulations, with some flexibility. The THIRD WORLD NETWORK and the EDMONDS INSTITUTE called for information on insurance coverage for adverse effects in the host country.

On the prescribed period of time for a response from a competent authority regarding an LMO transfer, the EU called for time limits depending on various factors such as whether the competent authority has requested further information. JAPAN agreed, noting that the time limit should start from the date the applicant submits all necessary information. NEW ZEALAND, supported by AUSTRALIA, called for a reasonable but not infinite

period, noting that the protocol creates a contractual arrangement giving balanced rights and obligations to all Parties.

NORWAY proposed a 90-day limit that would allow an importing country to ask for additional time. The RUSSIAN FEDERATION stated that any time limit would depend on the amount of information received and the country's ability to digest it. INDIA, supported by MALAYSIA, SRI LANKA and MAURITIUS, opposed a time limit on response. Response is subject to factors such as capacity constraints and the adequacy of information provided. The PHILIPPINES and PAPUA NEW GUINEA stated that any time limit should be used only as a guideline, without consequences for failure to respond. CAMBODIA noted that developing countries lack the resources for studies to obtain adequate information, thus flexible and sufficiently long periods for response are needed. MAURITIUS suggested a time limit on acknowledgement of application.

On the kind of actions to be taken in response to the information within notifications, JAPAN stated that an importing State can accept or reject with reason or request more information. MALAYSIA said the types of action taken by an affected country are its prerogative and can include consent or prohibition, either absolutely, provisionally or conditionally. NORWAY noted that the importing country can consent specifically or provisionally provide an interim consent or decline. Where information is lacking, the burden of proof lies with the State of export. ETHIOPIA said that a non-response should never amount to implicit consent for import and neighboring countries should be informed of decisions. PERU recommended that each country develop domestic legislation assuring that they would respond within a reasonable amount of time.

Regarding a review mechanism on decisions taken by the importing country, NORWAY said if there is new information the importing country can alter the AIA. Duty to inform about new information should be shared with all importing States. An exporter of an LMO should be able to ask for review when new information emerges. Also, a third party or a neighboring country should be taken into account in environmental impact assessments. MALAYSIA said an affected country should trigger a review when new information arises. The exporting country could trigger it if the review is agreed jointly by both sides. The US said this is a decision for the exporting country and did not support an independent review body. The REPUBLIC OF KOREA suggested interested Parties or neighboring countries should be given the right of consultation during the review. The AUSTRALIAN GENE ETHICS NETWORK said that adjacent countries and citizens should have access to the appeal process and socio-economic consideration should be grounds for appeal.

On 14 May, the Chair presented his draft element paper on procedures for specific transfers of LMOs (UNEP/CBD/BSWG/2/CRP.4). The Chair informed delegates this was not a negotiated document but should be viewed in conjunction with the Report of the Meeting and submissions from governments. The paper contains sections on notification, information that may be required, periods of time for response and review mechanisms. The paper also addresses the cases in which the procedures should apply and contains sections that allow for no deviations or exceptions, sections allowing deviations or exceptions under certain circumstances and sections addressing specific cases, such as banned chemicals. The paper also contains a range of options regarding simplified procedures and consent.

The section on the information that may be required contains a chapeau noting the channels through which information will flow, primarily competent authorities of States. The EU, the US and JAPAN all supported language noting that information may be communicated to the importing State's competent authority directly from the private sector, rather than through the exporting State's competent authority. The US also proposed noting the private sector's potential as a source for information. The EU proposed addressing AIA and simple notification procedures in separate sections and including a paragraph noting that confidentiality must be ensured.

The elements paper also contains a list of 22 types of information that may be required, such as: origin, name and taxonomic status of recipient organisms; purpose of genetic modification; results of risk assessments and tests; and intended use of the transferred LMO. The EU and US proposed noting that the list is neither exhaustive nor agreed by all. INDONESIA proposed adding "the status of the donor organism" and "the way and method of genetic modification." CANADA requested "information on relevant previous notifications and decisions."

On the period of time allowed for response, the EU added a paragraph to prolong the time period if the organization is waiting for requested information. INDIA suggested having no time limit. On the review mechanism, NORWAY warned against implying that a mechanism should be established to overrule a State's sovereign decision. The US opposed setting up a new review mechanism beyond that mentioned in Article 27 of the CBD on dispute settlement. The section was deleted.

Regarding exceptions and deviations from the consent procedure, the EU proposed noting that the simplified consent procedure should not pertain to an LMO bound for contained use**.** NORWAY proposed that all initial exports of an LMO shall be subject to an AIA procedure requiring explicit consent and notification shall apply to subsequent exports of LMOs requiring specific consent. The PHILIPPINES proposed replacing references to "explicit consent" with "AIA procedures," but INDIA noted that the protocol applies to transfers other than shipments. The US proposed new paragraphs stating, *inter alia*, that the transfer of LMOs covered by other agreements should be governed by those agreements and detailing the procedures and coverage for AIA.

Regarding simplified procedures, the US called for provisions on cooperative agreements for imports and exports and allowing a Party to indicate that that the AIA procedures do not apply. INDIA added language noting that the protocol shall allow a single, explicit and standardized procedure "in all cases." On consent, the EU proposed that a single notification and consent could cover several similar transboundary movements to the same party of import.

During the final Plenary, delegates accepted the Chair's draft element paper (UNEP/CBD/BSWG/2/CRP.4), which will reflect these amendments. They also accepted an addendum to the draft report of the meeting, which contains, *inter alia,* a summary of discussions on transfers of LMOs, including AIA (UNEP/CBD/BSWG/2/L.1/Add.1).

COMPETENT AUTHORITIES/FOCAL POINTS

The Chair's *aide-memoire* on competent authorities (UNEP/CBD/BSWG/2/CRP.2) asked: should the protocol require Parties to designate competent authorities or focal points or both; should there be a single competent authority or focal point per Party; and should there be an option for regional focal points. The *aide-memoire* also noted possible responsibilities such as: receiving notifications; transmitting information to other Parties; evaluating risk assessment; taking decisions on notifications under AIA; transmitting decisions on AIA; and enforcement. The *aide-memoire* also asks when the competent authorities or focal points should be designated.

Delegates offered a range of views on the designation and number of authorities and focal points. The EU and the RUSSIAN FEDERATION said there could be many competent authorities and preferred one focal point per Party. SOUTH AFRICA favored more than one focal point and/or competent authority and noted

that the responsibilities would depend on whether the focal point is the same body as the competent authority. SWITZERLAND and SRI LANKA favored an obligation to appoint one of the competent authorities to be a focal point. NORWAY called for one authority, regardless of the title, with clear responsibilities. MALAYSIA favored a competent national authority with a more formal role than a focal point. CANADA distinguished the "point of contact" role of the focal point from the decision-making role of the competent authority.

Many delegations, including the EU, CAMEROON, PAPUA NEW GUINEA, SRI LANKA, SWITZERLAND, CANADA, RUSSIA and PERU, favored including an option for regional focal points. A number of delegations, including the EU, NORWAY, PERU, SWITZERLAND and AUSTRALIA, said the responsibilities for competent authorities should not be prescribed or fixed because of countries' different capacities. CANADA added risk assessment to the proposed responsibilities. MALAYSIA said the competent authority should make regulations on transfer and release, risk assessment and management decisions, and should impose national procedures beyond those in the protocol if necessary.

The EU, PAPUA NEW GUINEA and SWITZERLAND said competent authorities should be designated as soon as possible. NORWAY and CANADA proposed that they be established no later than the entry into force of the protocol. CAMEROON said each country should designate their authority prior to ratifying the protocol. The MARSHALL ISLANDS, supported by MAURITIUS, PAPUA NEW GUINEA and MALAYSIA, noted that national authorities may be "responsible," but that without technical and financial assistance many of them will not be "competent" to handle biosafety matters.

In the final Plenary, delegates accepted the Chair's draft element paper on competent authority(ies)/focal point(s) (UNEP/CBD/BSWG/2/CRP.8). The paper outlines the options presented by delegates regarding the number and type of competent authority(ies)/focal points, the time by which they should be designated and their responsibilities.

INFORMATION SHARING AND THE CLEARINGHOUSE MECHANISM

The Chair introduced an *aide-memoire* on Information Sharing/Capacity-Building/Public Awareness/Participation (UNEP/CBD/BSWG/2/CRP.3). The *aide-memoire* posed a number of questions related to information sharing between Parties, such as: should there be a provision for sharing of information on actions taken under the transfer procedures; if so, should the provision apply only to Parties; and what information on actions should be shared. On publicly available information, the aide-memoire asked: should the protocol contain a provision for information sharing through the CBD clearinghouse mechanism (CHM); what information should be provided to through the CHM; and who should provide information to the CHM.

On information sharing between Parties, NORWAY, supported by INDIA, mentioned that the CBD already obliges Parties to provide all the information they have. Numerous countries, including the US, CANADA, MALAYSIA, COLOMBIA, SOUTH AFRICA, MALAYSIA, INDONESIA and MAURITIUS, however, distinguished between general information and information-sharing through the AIA procedure.

BRAZIL called for as broad a range of data as possible on all LMOs. COLOMBIA noted that information on AIA procedures might be confidential and provided bilaterally. The protocol should have a clause to deal with information the exporting country feels is confidential, in order to give it appropriate treatment. The EU also called for a provision on confidentiality. The Chair noted that confidentiality is related to whether information should be restricted to the Parties. CANADA said a database or clearinghouse mechanism has two roles, increasing public awareness and access and providing information on regulatory notification and actions, the former requiring complete public access and the latter requiring limited access for inputting data for decision-makers.

On the type of information to be supplied, a number of ideas were suggested, including:

- information on LMO-related products (EU);
- all publicly available information on LMOs (US, INDIA) and safety assessments of them (US);
- focal points/competent authorities and national legislation and changes made in the AIA system (NORWAY, JAPAN);
- refusals of LMOs, measures taken to implement the protocol, environmental and/or health effects, and accidental movements or release of LMOs (NORWAY);
- transboundary movements of LMOs (NORWAY, INDIA, AUSTRALIA);
- risk assessments and management (CANADA, AUSTRALIA);
- summaries of regulatory requirements (CANADA) and actions (US);
- decisions made (INDIA, JAPAN);
- LMOs prohibited by individual countries and those that have passed risk assessment procedures under AIA (AUSTRALIA);
- ongoing post-release monitoring by regulatory authorities (AUSTRALIAN GENE ETHICS NETWORK); and
- an international list of experts in different countries (BANGLADESH).

JAPAN warned that information on individual transfers is technically difficult and perhaps not needed. MAURITIUS noted that information sharing and LMO movement are part of technology transfer. CAMEROON, supported by the US, stressed inclusion of information from other groups, such as NGOs, and other countries, as contained in the African Group's submission.

The RUSSIAN FEDERATION differentiated between information sharing and a clearinghouse mechanism. He sought clarification on who should supply information to whom and whether focal points should be the central nodes. JAPAN favored a clearinghouse mechanism but the Secretariat of the protocol may play a role in compiling national regulations and any changes in them. Information from exporters could also be provided to the Secretariat through national competent authorities for further distribution. BRAZIL stated that national competent authorities should be responsible for depositing information on national actions and public data on LMOs that have been reviewed in the country. SOUTH AFRICA felt national focal points should be the suppliers of information to the clearinghouse mechanism, other focal points and national competent authorities and the users of LMOs. CUBA, BRAZIL and the US favored drawing on existing structures for information-sharing.

On whether there should be a common format for information, CANADA called for a standard format or template regarding the naming of LMOs and the treatment of confidential information. The EU requested the Secretariat to submit a draft format for consideration at later meetings. The US noted that relevant information varies according to LMO and there are many complicating factors that must be taken into account. BANGLADESH called for a technical subcommittee to produce a draft format. MALAYSIA called for the provision of information regarding use and biological characteristics of an LMO in the format.

On including a mechanism to revise information and provisions for confidentiality, SOUTH AFRICA, SRI LANKA and ZAMBIA said that confidentiality should not impede information exchange or undermine decision making. CANADA agreed to confidentiality provisions but noted the need to clarify modalities. The US said

confidential business information should not be part of general information exchange but can be revealed as appropriate to national focal points. He called for a mechanism for ensuring that information remains confidential.

Regarding publicly available information, the *aide-memoire* asked: whether the protocol should provide for an article on public awareness; what mechanism should be used to promote public awareness; what action should be addressed; and who is responsible for public awareness. CANADA said that means of communication other than electronic access require further exploration and that no new institutions regarding the CHM should be established. He also said that delegates should have a better understanding of the way in which transfers of LMOs were currently taking place and the volume of those transfers, particularly those involving commodities. Supported by the US, he proposed forming a contact group to develop precise instructions for the Secretariat regarding the preparation of a report on the methods and volume of LMO transfers, particularly regarding commodity transfers.

On 14 May, NEW ZEALAND reported on the contact group on commodities. He noted the group's recommendation that the Secretariat prepare a study to define the range of LMOs in commodity transactions. Upon being asked to adopt the recommendation, the G-77/CHINA said its approval would hinge on approval for four other studies, on the socio-economic implications of biotechnology and on the impacts of LMOs on animals, fisheries and indigenous farming. Further discussion of the proposed studies was deferred. During the final Plenary, delegates accepted a document on the future work of the BSWG (UNEP/CBD/BSWG/2/L.1/Add.3), which notes *inter alia* that CANADA modified its proposal and will arrange for an informal roundtable on the subject at or before BSWG-3.

During the final Plenary, delegates also accepted the Chair's draft element paper on information sharing (UNEP/CBD/BSWG/2/CRP.9). The paper contains the options presented by delegates related to information sharing between Parties and includes examples of the type of information that could be shared, such as information on accidental LMO movements, LMOs released on the market and the amount of LMOs exported. The paper also contains options related to the CHM, protection of confidential information and a standardized format for information sharing.

CAPACITY-BUILDING/PUBLIC PARTICIPATION/ PUBLIC AWARENESS

Discussions on capacity-building, public participation and public awareness were based on the Chair's *aide-memoire* on Information Sharing/Capacity-Building/Public Awareness/Participation (UNEP/CBD/BSWG/2/CRP.3).

CAPACITY-BUILDING: The *aide-memoire* asked: what is the primary aim of capacity-building; would a capacity-building mechanism serve other functions, such as providing advice on queries from importing Parties; and should the protocol contain specific provisions related to capacity-building.

A number of aims for capacity-building were suggested. ZAMBIA and SOUTH AFRICA highlighted strengthening indigenous capacities to implement the biosafety protocol, including developing biotechnologies suitable to their situations. BRAZIL stressed strengthening implementation of the protocol, legislation and monitoring, and ensuring compliance with biosafety regulations. JAMAICA highlighted strengthening informed decision-making on LMO transport and risk assessments. AUSTRALIA noted the need for capacity-building for developing countries particularly and, supported by SOUTH AFRICA, highlighted risk assessment and management. CUBA's aims included development of policy and information systems, biotechnology capacity, and technical competence to identify and control risks in the use and dissemination of LMOs.

ZAMBIA, the EU, BRAZIL and SWITZERLAND referred to the UNEP International Technical Guidelines for Safety in Biotechnology. A number of other ongoing efforts to promote capacity-building were also mentioned, including CBD Article 18.2 on the promotion of technical and scientific cooperation (SWITZERLAND), COP decisions III/20 and III/5 on GEF financing (EU, BRAZIL), UNIDO, (EU), the SBSTTA, Agenda 21 organizations, WHO, FAO and bilateral alliances (AUSTRALIA).

The EU proposed that the protocol refer to the need for capacity-building but not include a specific provision. AUSTRALIA noted that capacity-building can be enhanced through information-sharing. However, the REPUBLIC OF KOREA stressed the priority of capacity-building needs. The RUSSIAN FEDERATION stressed identification of needs and priorities at the national level and steps to be taken. SOUTH AFRICA noted that the provision of resources, such as training and expert advice, is a component of capacity-building, both at the regional and national levels. BRAZIL said a capacity-building mechanism should include a list of expert advisors, a data base, training and provision of other resources. TOGO and NIGER also stressed that financial assistance must come in a timely way to ensure capacity-building strengthens application of the protocol. ETHIOPIA expressed dissatisfaction with the lack of commitment to new resources for capacity-building. The Chair pointed out that financial aspects would be discussed at later sessions.

In the final Plenary, delegates accepted the Chair's draft elements paper on capacity-building (UNEP/CBD/BSWG/2/CRP.10). The paper states that the aim of capacity-building includes: facilitating the elaboration of national legislation related to biosafety; permitting the competent authority to make informed decisions on risk assessment; and promoting the establishment of appropriate institutional mechanisms. The paper also contains proposals made by delegations related to a clearinghouse specifically for biosafety information and regional training centers.

PUBLIC AWARENESS/PARTICIPATION: With regard to public awareness and participation, the Chair's *aide-memoire* asked: should the protocol provide for an article on public awareness; what mechanism should be used to promote public awareness; what action should be addressed; and who is responsible for public awareness. It also asked whether the protocol should provide for public participation, what it should address and who would define the level of participation.

A number of delegations, including BANGLADESH, NORWAY, AUSTRALIA, the EU, ETHIOPIA, MALI and CAMEROON, supported the inclusion of public awareness provisions. COLOMBIA called for national and international mechanisms. BRAZIL noted the need to protect confidential information. MALI emphasized the importance of NGO involvement. NEW ZEALAND, the RUSSIAN FEDERATION and JAPAN did not support including a specific mechanism and said each Party should decide for itself. SOUTH AFRICA noted that Article 13 (public education and awareness) of the CBD already covers this issue. The THIRD WORLD NETWORK recalled that confidentiality concerns were second to the rights of citizens and that prior informed consent cannot be left at the domestic level.

The EDMONDS INSTITUTE and ECOROPA stressed the need for public participation. The PHILIPPINES supported the importance of NGO participation. BRAZIL said the protocol should not mandate public participation in regulatory affairs. The EU, NEW ZEALAND and INDIA supported public participation provisions. The US noted that without public participation the actual effect of LMOs is hard to gauge.

During the final Plenary, delegates accepted the Chair's draft element paper on public awareness and participation (UNEP/CBD/BSWG/2/CRP.11). The paper includes proposals on whether the protocol should specifically address public awareness and potential public awareness mechanisms. The paper also contains options regarding the types and levels of public participation, some of which highlight NGO roles.

RISK ASSESSMENT AND MANAGEMENT

On 14 May, the Chair introduced UNEP/CBD/BSWG/2/CRP.5, an *aide-memoire* on risk assessment and risk management. Most speakers favored putting provisions for risk assessment in the protocol. SWITZERLAND and the US, however, did not fully agree. Most speakers favored provisions as the basis for decisions for transboundary movement, rather than just for information sharing. ETHIOPIA, supported by SOUTH AFRICA and the US, added that risk assessment is the basis for decision-making in general. SRI LANKA stressed risk assessment for the safe transfer, handling, and use of organisms that may have adverse effects. SWITZERLAND offered the alternative aim of guaranteeing a minimum level of harmonization in risk assessment.

ETHIOPIA, supported by NORWAY, SRI LANKA, INDIA and the US, stated that the protocol should contain general principles, detailed provisions and minimum standards. BANGLADESH preferred detailed provisions; SWITZERLAND and NEW ZEALAND, general principles; SOUTH AFRICA, general principles as well as minimum standards. COLOMBIA agreed on minimum standards, and warned that States must be able to make detailed standards that do not conflict with national laws.

ETHIOPIA, NORWAY, SRI LANKA and BANGLADESH called for the provisions to be legally-binding. SWITZERLAND preferred provisions as reference points only. NEW ZEALAND, supported by the US, favored leaving "implementing methods" to national competent authorities. ETHIOPIA, SRI LANKA, INDIA BANGLADESH, NEW ZEALAND and SOUTH AFRICA suggested that general provisions be included as an article of the protocol, with details possibly provided in an annex.

Numerous bases for risk assessment were proposed, including information about the relevant organism and the relevant receiving environment (NORWAY), available scientific information (SRI LANKA), information provided by the exporter or exporting country (INDIA, SOUTH AFRICA, COLOMBIA), environmental impact assessments, the clearinghouse mechanism and public participation (BANGLADESH), and any information the assessor considers relevant (SOUTH AFRICA).

Countries generally concurred that the sources for the provisions could include UNEP guidelines and other sources such as country submissions. Most speakers said competent authorities in the importing country should be responsible for risk assessment. To this were added: an institution accredited by the competent authority, or an applicant to export (SRI LANKA, SOUTH AFRICA) and focal points (BANGLADESH). The US said that the importer is ultimately responsible but risk assessment could be facilitated through third parties in the short term or through regional centers of excellence.

The EU stated that all decisions should be based on prior scientific risk assessment and that competent authorities must have access to information relevant to risk assessment. General positions on risk assessment should be in the protocol and more detailed information in an annex. AUSTRALIA said the protocol should include general principles, not specific procedures, which should serve as guidelines only.

MALAYSIA supported incorporating specific requirements to provide information as the primary basis for decisions. Supported by most developing countries, she said decisions could also be based on socio-economic and ethical considerations. If they lack the technical capacity, specific provisions for assistance will be necessary. ZAMBIA, INDONESIA, CUBA, MALI and THAILAND called for general principles establishing that the Parties will perform risk assessments and adopt measures and said the protocol must have a detailed annex with the minimum standard of information that would be required for risk assessment.

Regarding who should perform the risk assessment, the EU said assessments are the responsibility of the importer and the exporter should provide information. MALAYSIA noted that the applicant should be responsible for the assessment and decisions should rest with national authorities. Financial responsibility lies with the country trying to undertake the transfer. NORWAY and INDONESIA noted that the exporting State bears responsibility for providing information and the importing State has the responsibility to analyze and decide on the risk assessment. The US stated that the risk assessment should be provided by the exporting company, but it is up to the importing country to analyze it. The REPUBLIC OF KOREA and the RUSSIAN FEDERATION said that responsibility for risk assessment lies with the importing State, but stressed that the exporter, company or State, must perform risk assessment and provide information. SAMOA and THAILAND said that risk assessment is the responsibility of authorities and governments.

The COUNCIL FOR RESPONSIBLE GENETICS said that risk assessment must consider the distribution of potential harms among different groups within a society. The AUSTRALIAN GENE ETHICS NETWORK, supported by ZAMBIA, stated that discussions should focus on assessment of risks versus benefits. Socio-economic elements should be included and given equal emphasis with other factors. The BIOTECHNOLOGY INDUSTRY ORGANIZATION, supported by SRI LANKA, stated that any risk assessment exercise needs to be focused and the first step is hazard identification.

Many delegations supported the inclusion of a provision for risk management in the protocol. CAMEROON, INDIA, BRAZIL, CHINA, NORWAY, NEW ZEALAND, BURKINA FASO and TOGO stated that Article 8(g) — which states that each Party to the CBD shall establish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs that are likely to have an adverse environmental impacts — was relevant to the issue of risk management and should be referenced in the protocol. MALAYSIA noted the relevance of Article 8(g) but said it need not be included in the protocol as it already appears in the CBD. The US did not support the inclusion of Article 8(g) in the protocol.

Regarding the purpose of the risk management provision, MALAYSIA, CAMEROON, INDIA, BRAZIL, CHINA and MAURITIUS said the purpose should be to provide a basis for decisions on transboundary movement. CAMEROON and the BIOTECHNOLOGY WORKING GROUP sought recognition of the need to provide for liability, insurance and compensation. INDIA stated that the purpose of the risk management provision should also be to assign responsibilities in case of accidents. NORWAY and BURKINA FASO said the purpose of a risk management provision should be for information sharing and to provide a basis for decision making. SRI LANKA said the purpose should be to provide a basis for safe transfer and handling. NEW ZEALAND said a risk management provision should serve as a basis to manage the likely effects of movements of LMOs.

On the format of the risk management provision, INDIA, CHINA, MAURITIUS, the US and BURKINA FASO supported the use of general principles. MAURITIUS and BURKINA FASO also supported the use of detailed provisions in an annex. BRAZIL supported the use of detailed provisions. ZAMBIA called for the inclusion of detailed minimum standards. SRI LANKA supported

the use of general principles, detailed provisions and minimum standards.

Regarding the enforcement capabilities in the risk management provisions, MALAYSIA, CAMEROON, CHINA, NORWAY, BURKINA FASO, TOGO and MAURITIUS supported legally-binding risk management provisions. AUSTRALIA and NEW ZEALAND disagreed. SRI LANKA sought liability compensation covered by national legislation.

As to the form of the provisions, MALAYSIA, NEW ZEALAND and BURKINA FASO called for the inclusion of risk management provisions in an article within the protocol. SRI LANKA, MAURITIUS and TOGO sought inclusion of risk management provisions in an annex. CHINA said the format for risk management provisions should be flexible. The majority of delegations supported the use of the UNEP Guidelines as well as other sources for the elaboration of provisions on risk management in the protocol. NEW ZEALAND, BURKINA FASO and TOGO said both the exporting and the importing country should share responsibility for risk management. ECOROPA recommended tapping the capacity in risk assessment and management of the insurance sector; this will depend on the final position taken on liability and compensation.

During the final Plenary, delegates accepted the Chair's draft elements paper on risk assessment and management (UNEP/CBD/BSWG/2/CRP.12). The paper contains proposals on whether to include risk assessment provisions and the level of specificity required. The paper also reflects delegates' proposals on: the Party responsible for risk assessment, whether the provisions for risk assessment will be legally-binding; and overall aim and basis of risk assessment.

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS

The Chair introduced an *aide-memoire* on unintentional transboundary movement of LMOs/handling, transport, packaging, and transit requirements for transboundary movement of LMOs (UNEP/CBD/BSWG/2/CRP.6). The *aide-memoire* asked: should unintentional transboundary movement be covered by the protocol and, if so, which procedure should apply, who should trigger it and should information on the movement be shared with Parties.

UNINTENTIAL TRANSBOUNDARY MOVEMENT: Most speakers felt that unintentional transboundary movement (UTM) should be covered by the protocol. CHINA asked whether the concept includes natural disasters or actions. He noted that if it covers accidents due to UTMs it is related to Article 14.1(c) of the CBD. AUSTRALIA and NORWAY specified that it should cover unintended releases or accidents, which would be covered by AIA procedures, as well as unintended movement. ZAMBIA preferred a separate provision for purely accidental or natural releases such as pollen. The EU specified LMOs that are likely to have adverse effects. INDONESIA asked how to define UTM of LMOs and the extent to which it has occurred, and whether there would be a time limit on identifying it. SWITZERLAND, supported by JAPAN, felt that UTMs are already covered adequately in Article 14.1(c) and (d) of the CBD, but reference might be made to them in the provisions on information-sharing.

Most speakers felt that full information should be given by the party from which the UTM originates to the affected party, and that information should also be shared with third parties. BRAZIL noted that all experience with LMOs is to be eventually deposited in the information-sharing mechanism. At the time of movement, information should be given to any third party that might be affected. He called for linkage to a liability and compensation clause for the protocol. AUSTRALIA emphasized information-sharing through the proposed clearinghouse mechanism. NIGER stressed the importance of giving information for risk assessment and management generally and sharing information with all Parties notwithstanding confidentiality. The EU stressed speed and effectiveness in whatever procedure is adopted, so that appropriate measures may be taken rapidly.

As to who should trigger the procedure, proposals included the originating party, the affected party, and other States, particularly potentially affected third parties, depending on where the UTM or release is first identified. NORWAY and the EU noted that this question covers legal responsibility. Ultimately the country where the release has occurred must take action, which will require developing a legal basis under CBD Article 14. MOZAMBIQUE specified that the procedure should be triggered through the competent authority of the originating State or the affected State. MAURITANIA noted that Article 8 of the CBD requires the Party responsible for the release to trigger the procedure or, if not, the affected country or any other country that might be affected. SRI LANKA specified the exporting party as the trigger, through its competent authority. BRAZIL and ZAMBIA specified the affected country's competent authority; the country of origination should alert that authority. BELARUS said for natural disasters the originating country should trigger the mechanism. For illegal activities, the damaged party or a third party could trigger the procedure.

MAURITIUS reiterated the need to strengthen developing countries' capacity to deal with these risks. INDIA added that compatibility with Article 14.2 of the CBD requires redress measures in the protocol. BELARUS called for a mechanism modeled on the CBD procedure for dispute settlement.

HANDLING, TRANSPORT, PACKAGING AND TRANSIT: On the handling, transport, packaging and transit requirements for transboundary movement of LMOs, the *aide-memoire* asked: to what extent should handling, transport, packaging and transit be covered by the protocol and to what extent are these issues already covered by other international agreements. Many delegates, including INDONESIA, BARBADOS, UGANDA, LESOTHO, NORWAY and BRAZIL, agreed that these issues should be covered by the protocol. BARBADOS and BURUNDI emphasized the importance of these issues for trans-shipment countries. LESOTHO urged the inclusion of "labelling" among the items. NORWAY said the LMO must be accompanied by movement documentation from origin to use or release. Provisions in the protocol should be general and the Parties could develop a detailed packaging provision.

The EU, supported by NEW ZEALAND, said that questions related to transfer should be referred to the ECOSOC committee of experts on the transfer of dangerous goods. BRAZIL said these issues should be explicitly covered by the protocol and details included in an annex. NEW ZEALAND said the protocol should not be prescriptive but should encourage all interested Parties to observe appropriate safety considerations. MALAYSIA said that handling and transit are separate issues and noted that transit issues are not adequately covered by international agreements. ECOROPA supported consistent labelling procedures for LMOs "from cradle to grave."

During the final Plenary, delegates accepted the Chair's draft element paper on unintentional transboundary movement of LMOs, including accidental and emergency cases (UNEP/CBD/BSWG/2/CRP.13) and on handling, transport/packaging/and transit requirements for transboundary movements of LMOs (UNEP/CBD/BSWG/2/CRP.15). These papers include all of the proposals made by delegates during discussion.

MONITORING AND COMPLIANCE

The Chair introduced his *aide-memoire* on monitoring and compliance (UNEP/CBD/BSWG/2/CRP.7). On monitoring, the *aide-memoire* asked: is there a need for individual Parties to report on the implementation of their commitments; if so, what matters

should the reports address (e.g., the operation of the AIA and notification procedures; adoption of national regulations); and how should the reports be processed (e.g., referred to the COP; scrutinized by an expert committee). On compliance, the *aide-memoire* asked if the provisions of the protocol would be sufficiently normative in character to justify establishing a procedure for reviewing the implementation of commitments by individual Parties. If so, what type of process should be developed, who should trigger it, how should it operate and what should be its objective.

Many delegations agreed that Parties should report on the implementation of their commitments and the provisions of the protocol would justify some type of review process. Delegates expressed a range of views on the level of reporting and type of review. UGANDA said that reports should be processed through the clearinghouse mechanism and, on compliance, the procedure should be cooperative, conciliatory and judicial when necessary. Its objective should be sharing of experience and information. CAMEROON and NEPAL also supported a fixed system for monitoring implementation. JAMAICA called for a prescribed format for required information that could be updated annually and said that a review process should not interfere with State sovereignty. With the US and BRAZIL, he said a Party on its own behalf or the Secretariat through a committee established by the COP could trigger the review. SOUTH AFRICA expressed concern regarding the financial implications of establishing a standing review body.

The EU stated that individual Parties should report on implementation and all reports should be made available to the COP. With the US and BRAZIL, he said the provisions should be cooperative, transparent, non-judicial and advisory. The goal should be friendly settlement of differences through practical guidance and assistance. AUSTRALIA and BRAZIL said that firm positions on compliance procedures should be deferred until the obligations are clearer. JAPAN stated that monitoring will be covered under information-sharing provisions and separate section was unnecessary. ETHIOPIA, supported by LESOTHO, said monitoring should not focus only on whether obligations are being fulfilled but whether the consequences of LMOs within a country are being checked. On compliance, there may be situations when judicial powers would be required.

Following this discussion, the Chair presented two additional questions for delegates: should the protocol contain an article on non-discrimination and should the protocol address transfer of LMOs between Parties and non-Parties. He said the concept of non-discrimination entailed that Parties are treated in the same manner and no discrimination is drawn between international and national activities. INDIA and MALAYSIA said the CBD is founded on principles of equity and objected to an article of this type within the protocol. During the final Plenary, delegates accepted the Chair's draft elements paper on monitoring and compliance (UNEP/CBD/BSWG/2/CRP.14), which reflects the range of proposals made during discussions.

CLOSING PLENARY

In the final Plenary, delegates accepted the Chair's draft report of the meeting (UNEP/CBD/BSWG/2/L.1) and reviewed and amended each of the Chair's draft elements papers. The amended versions of these texts will be compiled into a Chair's summary of elements and attached to the report of the meeting. Delegates also accepted an addendum on the future work of the BSWG (UNEP/CBD/BSWG/2/L.1/Add.3) and detailed list of the Chair's review of items that have been addressed by country submissions (UNEP/CBD/BSWG/2/CRP.1/Rev.1).

The addendum notes, *inter alia*, governments were invited to submit legal texts on the following issues: AIA; notification procedures; risk assessment and management; unintentional transboundary movements; handling, transportation, packaging and transit requirements; competent authorities/focal points; information sharing/clearinghouse mechanism; capacity-building; and public awareness/participation. Governments that have already submitted texts were encouraged to revise them. Proposals must be submitted by 1 August 1997.

The Secretariat will develop draft articles on: financial issues; institutional framework; scope of jurisdiction; relationship with other international agreements; and settlement of disputes. Delegates agreed that the Secretariat's work programme for the next meeting should include creation of an alphabetical list of terms requiring definition with country submissions of definitions for each.

Regarding future studies, the document notes that Canada withdrew its proposal for a study on criteria for confidential information and decided to convene an informal roundtable discussion on commodities at or before BSWG-3. The document also notes that CAMEROON, on behalf of the G-77/CHINA, requested a study on socio-economic considerations. During the final Plenary, CAMEROON withdrew the request for the study and proposed a roundtable meeting at BSWG-3. Following a request from the Central and Eastern European States, delegates agreed to a study on existing international, UNEP, UNIDO and OECD information-sharing systems for BSWG-3.

The Chair closed the meeting by thanking everyone for their cooperative work. The EU noted its efforts to fund developing countries and encouraged other donor States to follow suit. CANADA, speaking informally for the JUSCANZ countries, congratulated the Chair for his effective plan and accomplishments during BSWG-2. The Chair adjourned the meeting at 2:00 pm on Friday, 16 May 1997.

A BRIEF ANALYSIS OF BSWG-2

Chair Veit Koester opened the second session of the Open-ended *Ad Hoc* Working Group on Biosafety by urging delegates concentrate on core issues and identify the elements of a biosafety protocol for their next session. Under his guidance, delegates displayed a cooperative spirit and agreed to a structure for discussions and the programme of work for this meeting as well as future meetings. After previous meetings characterized by some as "talk shops," many BSWG-2 delegates left Montreal satisfied they had at last begun to move from generalities to specifics and taken substantial steps toward a protocol. Despite this progress, some fundamental disparities of opinion, particularly regarding the scope of the protocol, remain, which threaten to derail the process when negotiations get underway.

If the initial questions raised at BSWG-2 on advanced informed agreement (AIA) alone are indicative of negotiations to follow, delegates have a sizable task ahead of them. Delegates discussed whether AIA will be required for all LMO imports or only under certain conditions, whether importing or exporting countries will be responsible for assessing and managing risks from LMOs, which party will be responsible for notifying and taking action in case of unintended movements, whether there will be any legal requirement for compensation or liability placed on producers or exporters of LMOs, and whether LMO-containing commodities will be treated under this protocol at all. Equally lengthy debates are also looming over risk assessment and management, responsibilities for unintended movements of LMOs, compensation and liability, and treatment of commodities produced with LMOs.

The developing countries' insistence on addressing the impact of the movement of LMOs on socio-economic conditions could prove to be the most troublesome. Many, but not all, developing countries and developing country NGOs expressed strong concerns

about the ramifications of LMO transfers, such as loss of employment and export markets, uncontrolled growth in the power of multinational corporations and an dangerous expansion of the concept of patentability. In contrast to BSWG-1, which witnessed a rift among developing countries, BSWG-2 saw a seemingly more unified G-77/China, at least in their call for a study on socio-economic issues in response to a developed country call for a study on genetically-modified commodities. While both proposals for studies were ultimately withdrawn in favor of roundtable discussions, the G-77/CHINA exhibited a strong, if fleeting, unity on the issue. Some observers cautioned, however, that several deep-seated divergences of opinion remain unsettled and will likely emerge at future meetings.

Other position shifts were also apparent, most notably in the cooperative demeanor of some developed country delegations that were, as one observer noted, "obstructive" at BSWG-1. Some delegations that previously appeared adamantly opposed to the development of a protocol provided cautiously constructive interventions in Montreal. While it is far too early to assume an emerging consensus on a protocol or a successful outcome, the behavior of some delegations exhibited an acknowledgement of the importance of being "at the table" as the negotiations unfold and consensus on its necessity emerges.

Failure to achieve that consensus would not bode well for the Convention or the state of the world's biological resources. The Convention has devoted a considerable amount of its time and energy to this issue, drawing criticism from some that there are a myriad of more urgent threats to biodiversity, such as habitat loss, overproduction and consumption and increased population pressure. Given the fluctuations in country and regional positions, it is too early to speculate on successful outcome.

In the calculations of some, the likelihood of agreeing on a draft text is great. However, any adopted protocol must still be ratified. Because of the perceived threat of strong international oversight and difficulties with ratification, successfully completing a protocol will be tempered by the fact that its effectiveness is limited if it is too restrictive. Nonetheless, a protocol lacking sufficient restrictions would prove equally ineffective-leaving delegates between an LMO and hard place. Biotechnology is expanding at an unprecedented rate and any unforeseen consequences may not wait on the adoption or ratification of a protocol.

The Chair invited delegates, for the next meeting, to submit legal texts on some of the items discussed and said the Secretariat will propose text as well, which will hopefully take the process one step further toward a protocol. However, as the potential commitments become more focused, so too must the subjects to which they apply and, as seen at this meeting, consensus is anything but clear. There are a number of difficult questions awaiting future BSWG meetings and the whether any or all of them emerge at the next session meeting remains to be seen. Only one thing remains certain. Given the magnitude of the protocol's possible implications, the urgency of the problem and the relatively short time frame for negotiations, some tough decisions will need to be taken soon. As one observer noted, these global negotiations in particular do not have "all the time in the world."

THINGS TO LOOK FOR

AD HOC GROUP ON BIOSAFETY: The third meeting of the *Ad Hoc* Group on Biosafety (BSWG-3) is scheduled for 13-17 October 1997 in Montreal. During BSWG-2, delegates discussed the possibility of a fourth meeting to be held February/March 1998. They also considered a fifth meeting in late 1998. For more information, contact the CBD Secretariat, 393 Saint Jacques St., Office 300, Montreal, Quebec, H2Y 1N9, Canada; tel: +1-514-288-2220; fax: +1-514-288-6588; e-mail: biodiv@mtl.net.

CONVENTION ON BIOLOGICAL DIVERSITY: The third meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA-3) will be held in Montreal from 1-5 September 1997. The Fourth Meeting of the Conference of the Parties (COP-4) will be held in Bratislava, Slovakia, from 4-15 May 1998. For more information, contact the CBD Secretariat.

OTHER CBD MEETINGS: A meeting of the Liaison Group on Forest Biological Diversity will be held in Helsinki, Finland, from 25-28 May 1997. A Latin American and Caribbean regional meeting on the Clearinghouse Mechanism is tentatively scheduled for July in Colombia. A workshop on the implementation of Article 8(j) (traditional knowledge) is tentatively scheduled from 10-14 November 1997 in a venue to be determined. For more information, contact the CBD Secretariat.

FIRST INTERNATIONAL CONFERENCE ON INTELLECTUAL PROPERTY OF INDIGENOUS PEOPLES FOR THE NEW MILLENNIUM: This conference, entitled "Conferencia Internacional: La Propiedad Intelectual de los Pueblos Indigenas ante el Nuevo Milenio," is scheduled for 2-6 June 1997 and will be hosted by WATU/Accion Indigena and Secretaria de Estado para la Cooperacion International y para Iberoamerica. For information contact: Margrieth Nazareth Cortes, WATU/Accion Indigena, P. de la Chopera, Semisotano, 28045 Madrid, Spain; tel: +34 1 473 3031; fax: +34 1 473 2501; e-mail: watu@mad.servicom.es

INTELLECTUAL PROPERTY RIGHTS III: This conference, entitled "Intellectual Property Rights III — Global Genetic Resources: Access and Property Rights Workshop," will be held at the Holiday Inn Capitol, 550 C Street, SW, Washington DC, USA from 4-6 June 1997. The conference will review factors affecting global access to plant genetic resources and the effect of intellectual property rights on the exchange of these materials. For further information contact: American Society of Agronomy, 677 South Segoe Road, Madison, WI 53711, USA. To register via the Internet try http://www.agronomy.org/ipr/

INTERNATIONAL CONFERENCE ON MEDICINAL PLANTS CONSERVATION, UTILIZATION, TRADE AND BIOCULTURES: This meeting is scheduled from 16-20 February 1998 at the National Institute of Advanced Studies, Indian Institute of Science Campus, Bangalore, India. The meeting will focus on the issue of medicinal plants for survival. For further information contact the Foundation for Revitalisation of Local Health Traditions (FRLHT), No. 50, 2nd Stage, MSH Layout, Anandnagar, Bangalore 560 024, India; tel: +91 80 333 6909/0348; fax: +91 80 333 4167; e-mail: root@frlht.ernet.in.

SPECIAL SESSION OF THE UN GENERAL ASSEMBLY: The Special Session of the UN General Assembly is scheduled for 23-27 June 1997. The session will conduct an overall review and appraisal of progress in implementing the UNCED agreements since the 1992 Earth Summit. For more information, contact: Andrey Vasilyev, UN Division for Sustainable Development, tel: +1-212-963-5949, fax: +1-212-963-4260, e-mail: vasilyev@un.org. Also visit the Home Page for the Special Session at http://www.un.org/DPCSD/earthsummit/.