



Meridian Institute

Connecting People to Solve Problems

**Workshop on Liability and Redress
Article 27 of the Cartagena Protocol on Biosafety**

WORKSHOP PROCEEDINGS

16 July 2002

WORKSHOP PROGRAM

Workshop on Liability and Redress

Article 27 of the Cartagena Protocol on Biosafety

Sunday, 21 April 2002

The Hague
The Netherlands

Cartagena Protocol on Biosafety, Article 27, Liability and Redress

“The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analyzing and taking due account of the ongoing processes in international law on these matters, and shall endeavor to complete this process within four years.”

Please note that panelists participated in the workshop in their personal capacity.

09:00 Welcome, Agenda Review, Objectives

Todd Barker and Rex Raimond, Meridian Institute

Anne Daniel,¹ Senior Counsel, Legal Services, Environment Canada, Canada

Jimena Nieto,¹ Head, International Affairs Office, Ministry of the Environment,
Colombia

09:15 Article 27 and the ICCP Process

To enhance understanding of the history and context of the international discussions on Article 27, this panel included a review of the language in Article 27 of the Biosafety Protocol, a description of the history of the article, a review of the relevant recommendations of ICCP-2, and an overview of some of the substantive and procedural issues regarding liability and redress under the Biosafety Protocol.

Speakers:

Jimena Nieto, Head, International Affairs Office, Ministry of the Environment,
Colombia

Christoph Bail, Head, Directorat-General XI, Environment, Nuclear Safety and Civil
Protection, European Commission

Dan Leskien, Advisor on Genetic Engineering, The Greens/EFA in the European
Parliament (*Mr. Leskien had to cancel his participation at the last moment.*)

¹ Ms. Daniel and Ms. Nieto chaired the workshop in their personal capacity.

Conrad von Kameke, Director, Government Affairs, Monsanto Company;
Chair, Liability Working Group EuropaBIO

10:15 **Possible Activities and Scenarios of Concern**

The panel provided information about possible activities and scenarios of concern in relation to Article 27 of the Biosafety Protocol.

Speakers:

Juerg Bally, Senior Advisor, Swiss Agency for the Environment, Forests and Landscape, Switzerland

Kristin Dawkins, Vice President, International Programs, Institute for Agriculture and Trade Policy

Mary Fosi Mbantenkhu, Head, Biodiversity Protection Unit, Division of Programmes and Sustainable Development, Ministry of the Environment and Forestry, Cameroon

Willy De Greef, Head, Regulatory Affairs, Syngenta International AG

Piet Schenkelaars, Schenkelaars Biotechnology Consultancy

11:30 **Damage and Causation**

This panel addressed issues relating to damage in the context of Article 27, including the possible relationship with the definition of damage in the Convention on Biological Diversity.

Speakers:

Rene Lefeber, Legal Counsel, Ministry of Foreign Affairs, The Netherlands

Ruth Mackenzie, Program Director, Biodiversity and Marine Resources, Foundation for International Law and Development (FIELD)

Stanley Abramson, Attorney, Arent Fox Kintner Plotkin & Kahn, PLLC

Jimena Nieto, Head, International Affairs Office, Ministry of the Environment, Colombia

Piet Schenkelaars, Schenkelaars Biotechnology Consultancy

12:45 **LUNCH**

14:15 **Standards of Liability and Channeling**

The panel addressed issues relating to possible standards of liability for damage resulting from certain activities or incidents with LMOs, and questions relating to channeling liability for such damage to specific persons or entities.

Speakers:

Anne Daniel, Senior Counsel, Legal Services, Environment Canada, Canada

Stanley Abramson, Attorney, Arent Fox Kintner Plotkin & Kahn, PLLC

Arthur Mpeirwe, Research Associate, Advocates Coalition for Development and Environment (ACODE)

Alfonso Ascencio, Third Secretary, Legal Affairs, Permanent Mission of Mexico to the United Nations

15:30 **General Discussions**

Open Question and Discussion Session.

16:25 **Closing Remarks**

Anne Daniel, Senior Counsel, Legal Services, Environment Canada, Canada

Jimena Nieto, Head, International Affairs Office, Ministry of the Environment, Colombia

Todd Barker and Rex Raimond, Meridian Institute

16:30 **Adjourn**

Website and More Information

Additional information on the workshop can be obtained from Todd Barker at +1-802-899-2625 or tbarker@merid.org, or Rex Raimond at +1-970-513-8340 x 230 or rreimond@merid.org. Information regarding the workshop is also available from the Meridian Institute web site (www.merid.org/liability).

SUMMARY
Workshop on Liability and Redress
Article 27 of the Cartagena Protocol on Biosafety

Introduction

Meridian Institute with support from The Rockefeller Foundation organized a one-day workshop on liability and redress under the Cartagena Protocol on Biosafety (Biosafety Protocol). The workshop was held on 21 April 2002, immediately before ICCP-3 (22-26 April 2002, The Hague, The Netherlands), and was organized based on recommendations made by participants in the meeting held by Meridian Institute in September 2001 in Grottaferrata, Italy,² and after consultations with individuals following ICCP-2 (1-5 October 2001, Nairobi, Kenya). The recommendation was to develop activities that would increase understanding of Article 27 and liability and redress issues among delegates – with an emphasis on developing country delegates – to the Intergovernmental Committee on the Cartagena Protocol (ICCP).

The workshop provided an overview of some of the substantive and procedural issues related to liability and redress. Experts from NGOs, governments and industry presented information in a panel presentation format. Panels were followed by an opportunity for workshop participants to raise and discuss issues with panelists and other workshop participants. Four panels of experts presented information on the following topics:

1. Article 27 and the ICCP Process;
2. Possible Activities and Scenarios of Concern;
3. Standards of Liability and Channeling; and
4. Damage and Causation.

Many other topics, such as financial security, insurance, jurisdiction, mutual recognition and enforcement of judgments, etc., warrant discussion in the context of liability and redress under the Cartagena Protocol on Biosafety. However, due to time constraints, these topics were not addressed at the Workshop.

Meridian Institute facilitators wrote this Workshop Summary based on their detailed notes; it does not represent a summary negotiated by the panelists or participants.

Panelists agreed to participate in the workshop in their individual capacities, not as formal representatives of their institutions.

² Meeting summaries are available from the Meridian Institute web site, www.merid.org. From the home page, click on Meridian Projects on the left side of the screen; scroll down to Liability and Redress under the Cartagena Protocol on Biosafety; click on the link to the meeting summary in the project description.

Panel 1 - Article 27 and the ICCP Process

To enhance understanding of the history and context of the international discussions on Article 27, this panel included a review of the language in Article 27 of the Biosafety Protocol, a description of the history of the article, a review of the relevant recommendations of ICCP-2, and an overview of some of the substantive and procedural issues regarding liability and redress under the Biosafety Protocol.

Speakers:

Jimena Nieto, Head, International Affairs Office, Ministry of the Environment, Colombia
Christoph Bail, Head, Directorat-General XI, Environment, Nuclear Safety and Civil Protection, European Commission

Dan Leskien, Advisor on Genetic Engineering, The Greens/EFA in the European Parliament (*Mr. Leskien had to cancel his participation on the day of the workshop.*)

Conrad von Kameke, Director, Government Affairs, Monsanto Company;
Chair, Liability Working Group EuropaBIO

Summary of Panel Presentations:

Jimena Nieto described the history of negotiations on liability and redress in the context of transboundary movement of living modified organisms (LMOs). The Biosafety Protocol negotiations, based on article 19(3) of the Convention on Biological Diversity (CBD), started at the Conference of the Parties (COP) to the CBD in the Bahamas in 1994. During COP-2, parties instituted the Biosafety Working Group (BSWG) to elaborate a Biosafety Protocol. The BSWG met six times between 1996 and 1999.

Ms. Nieto explained that during the negotiations, liability and redress was considered an important topic for many countries, especially developing countries. However, it was not until the third meeting of the BSWG that liability and redress was placed on the agenda. It was immediately clear that positions were highly polarized and by the fourth meeting of the BSWG, observers identified the following three basic positions:

1. A call for substantive provisions addressing issues such as who will be liable, how will compensation be provided, etc. This position was held by many developing countries and the African Group circulated a proposal containing text for a liability and redress provision.
2. A call for an enabling clause that would allow the Conference of the Parties serving as the Meeting of the Parties to the Protocol (COP/MOP) to continue negotiations on liability and redress.
3. A proposal for a so-called “zero option,” which would leave liability and redress outside the topics covered by the Protocol.

Ms. Nieto noted that negotiations on liability and redress remained highly contentious throughout the process (as illustrated by the statement “no liability, no Protocol,” which was worn by some delegates during the final BSWG meeting in Cartagena), with delegations from many developing countries calling for a liability and redress regime, and others, especially those from developed countries, stating that the issue was too complicated to be dealt with in the context of these negotiations. Not until a separate working group was established (chaired by the UK), solely concerned with liability and redress, did the negotiations progress and move toward the development of an enabling clause with some substantive aspects or a clear timeframe. Ethiopia, the UK, Canada, the United States, India, Austria, Cameroon, and Colombia were among the countries that were active in these negotiations. Parties finally reached agreement on the text of Article 27 during the after hours of the extraordinary Conference of the Parties (ExCOP), which followed the final BSWG meeting in Cartagena in February 1999.

Christoph Bail added comments about the history of Article 27 and commented on the process of the ICCP.

He briefly characterized the European Union (EU) position on liability and redress during the Biosafety Protocol negotiations as one recognizing the importance of the issue, but being apprehensive about the delay negotiations on the topic might cause to reaching agreement on the Protocol. The EU favored a process that would allow the parties to discuss liability and redress after the Biosafety Protocol would enter into force.

Mr. Bail also highlighted a workshop that was held in 1998 and co-hosted by the government of the UK and the European Commission (EC). The workshop brought together 30 Biosafety Protocol negotiators, lawyers and academic experts to exchange ideas about liability and redress for the transboundary movement of LMOs. During this workshop it became clear that an enabling clause would be the most likely way forward in the Biosafety Protocol negotiations. The enabling provision of Article 27 was agreed on in Cartagena and adopted by the parties when the ExCOP was resumed in Montreal in January 2000.

Mr. Bail noted that Article 27 mandates the COP/MOP to adopt a process and endeavor to come to a result. He said that “endeavor” indicates that the parties need to be very serious about the issue and process, and are committing to a result. The activities of the ICCP regarding Article 27 have been limited but very useful. At ICCP-1, Solagrál hosted an interesting side event on liability and redress. In preparation of ICCP-2 in Nairobi, the CBD Secretariat had prepared useful documents containing, inter alia, an assessment of the relationship with other international liability and redress instruments, and a compilation of submissions by governments on their relevant national regimes. ICCP may continue to gather information and may start to clarify the terms of reference of an ad-hoc open-ended working group.

Mr. Bail highlighted the availability of a new book on the Biosafety Protocol,³ which contains 50 contributions from key negotiators. Two contributions, those by Kate Cook and Worku Damena, describe the negotiations regarding liability and redress.

Dan Leskien was scheduled to speak on the scope and mandate of Article 27, but had to cancel his participation at the very last moment.

Conrad von Kameke addressed the scope and mandate of Article 27. Mr. Von Kameke asked participants to take a step back and wonder if they are asking the right questions. He reminded participants of the words of Aristotle: “He who wants to find rightly, must first have doubted rightly.”

He took a closer look at the wording of Article 27,⁴ specifically the wording regarding the adoption of a *process*, the *appropriate* elaboration of international rules, *damage* resulting from transboundary movement of LMOs, and *taking due account of the ongoing processes in international law*. Mr. Von Kameke’s comments focused on the following passages from Article 27:

1. “...shall, at its first meeting, adopt a process...”

Comments—

- Mandate of Article 27 is to adopt a process.
- Mandate is not to produce a specific product.
- Parties need to agree on a process before entering into discussions on substantive issues.
- Outcome of the process is open, and includes a range of options (including referring to existing instruments governing liability and redress).

2. “...with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress...”

Comments—

- Constant process check: must not be inappropriate and must take into account legal and scientific contexts and reality.
- Scientific: how do we account for the fact that (1) we know what the major causes are for loss of biodiversity and (2) we know biotechnology is not among them (Mr. Von Kameke added that the scientific community in the United States and Europe conclude that genetically modified plants are at least as safe as

³ Christoph Bail, Robert Falkner, Helen Marquard, editors (2002) “*The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development?*” The Royal Institute of International Affairs and Earthscan Publications Ltd., London.

⁴ Article 27 - Liability and Redress

“The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analyzing and taking due account of the ongoing processes in international law on these matters, and shall endeavor to complete this process within four years.”

- comparable, non-GM plants, and that research commissioned by the European Commission indicates the safety of biotechnology).
- Legal: How do we draw the line between Biosafety Protocol process and national sovereignty rights?
3. “...for damage resulting from transboundary movements of LMOs,...”
Comments—
- Qualitative element: must reflect and remain within objectives of the Biosafety Protocol and CBD and conservation of biological diversity.
 - Quantitative element: How to draw the line between damage versus mere change? Criteria must fit qualitative criterion - be science-based.
 - Systematic watch out: Article 27 of the Biosafety Protocol and Article 14 of the CBD process outcomes cannot conflict, and must be coherent.
4. “...taking due account of the ongoing processes in international law...”
Comments—
- How do we avoid conflicting definitions within the CBD system?
 - Can we afford separate definition processes (i.e., content-wise, resource-wise, time-wise)?

Summary of Discussions:

The discussion between workshop participants and panel is summarized as follows:

- A participant asked if LMOs should be considered invasive species by definition and therefore a major cause of biodiversity loss.

One panelist responded by asking why an LMO would be more invasive than a non-GMO. Invasiveness depends on the properties of the plant, not on how the plant gets its properties (i.e., breeding, evolution, GM). The assumption that GMO is by definition invasive is questionable. Endless numbers of new, traditionally bred varieties have replaced old varieties and may be just as or even more invasive than an LMO.

Another panelist remarked that this also raises the process issue of what the link between Article 27 and Article 14(2) of the CBD will be. LMOs, just like other species, may cause loss of biodiversity. Do you choose to develop a specific regime for one of the causes, or do you prefer a horizontal regime that deals with all causes of damage to biodiversity or the environment? The EC has gone down the road of proposing a horizontal regime for environmental damage, which will clarify what the definition of biodiversity damage. The question of damage to biodiversity may be a horizontal question and it may be useful to deal with it in the context of the CBD. However, there may be specific aspects of LMOs that require different treatment in the context of the Biosafety Protocol.

- A participant asked if damage in the context of the CBD, which also deals with knowledge about biodiversity, includes loss of traditional knowledge.

One panelist responded by stating that Article 27 covers transboundary movement of LMOs and damage should be limited to the negative impact of transboundary movement of LMOs on biodiversity.

Another panelist asked why the definition of damage should be restricted to loss of biodiversity, and added that it might include loss of livelihood and damage to animal and human health.

The first panelist responded that the intent of the Biosafety Protocol has to guide interpretation of the word “damage.” The reason why the nations of the world agreed on the CBD was that people were worried about the fact that we are losing biodiversity. The fact that some people are calling for a liability regime, with a preventive and compensatory effect, needs to be related to the intent of protecting biodiversity.

Another panelist added that many countries have liability regimes that cover damage to health and property. We should not try to reform civil liability rules that exist and have existed for centuries. Attempts to establish environmental liability regimes have largely failed because of the difficulty of harmonizing these existing systems.

A panelist mentioned that most countries have legal and regulatory regimes that provide clear rules about liability for damage to property and health. These will be very difficult to harmonize. Even the task of defining damage to biodiversity will be very difficult. It will be even more complicated if we need to find a definition for damage to livelihood. This may cause extreme confusion in terms of a legal regime.

- A participant asked a question about damage versus change: To what extent does change constitute damage? For instance, does ecosystem change negatively impact ecosystem services? He added that there seem to be many unanswered questions about the cause of damage and whether GM “contamination” is damage.
- A participant stated that we should not only think about whether we can afford liability regimes; we should also consider what will happen if we afford it and what if we do not.

Panel 2 – Possible Activities and Scenarios of Concern

The panel provided information about possible activities and scenarios of concern in relation to Article 27 of the Biosafety Protocol.

Speakers:

Juerg Bally, Senior Advisor, Swiss Agency for the Environment, Forests and Landscape, Switzerland

Kristin Dawkins, Vice President, International Programs, Institute for Agriculture and Trade Policy

Mary Fosi Mbantenkhu, Head, Biodiversity Protection Unit, Division of Programmes and Sustainable Development, Ministry of the Environment and Forestry, Cameroon

Willy De Greef, Head, Regulatory Affairs, Syngenta International AG

Piet Schenkelaars, Schenkelaars Biotechnology Consultancy

Summary of Panel Presentations:

Juerg Bally prefaced his comments on possible activities and scenarios of concern with the statement that Article 27 gives parties a clear mandate to add a new element to the Biosafety Protocol. He stated that even though the Biosafety Protocol establishes international rules for the safe handling, transportation and release of biotechnology, you cannot exclude that even with the best safety measures, damage may occur. Mr. Bally addressed scenarios and activities in a transboundary context that should be considered in discussions regarding Article 27.

The following comments are taken from Mr. Bally's PowerPoint presentation with several additions based on the notes taken by Meridian Institute facilitators.

Possible activities and scenarios of concern fall in the following two categories:

- Contained use of organisms
- Release of organisms into the environment, with the following sub-categories:
 - Release for experimental purposes with LMOs (e.g., field trials)
 - Marketed LMOs (e.g., seeds and commodities)

Different scenarios may occur within each category:

- Unintended transboundary movement (e.g., an incident occurs in country A and consequent damage is suffered in country B).
- Intended transboundary movement (e.g., an LMO is manufactured in country A; imported and handled in country B; an incident occurs and damage is suffered in country B.)

In each scenario, negotiators should address the questions of who should be liable and what is an appropriate standard of liability.

Kristin Dawkins highlighted information based on her work with farmers in the United States and elsewhere. She asserted that farmers are being held liable for problems resulting from the rapid and untested commercialization of genetically modified crops. Farmers choices are limited due to circumstances including seed purchase contracts that include indemnification of companies; limited supplies of non-GM seed; seed stock contamination; crop contamination due to cross-pollination; higher seed costs for conventional seeds; diminishing benefits from chemical avoidance; loss of a \$200 million market in Europe; and loss of bacterial Bt.

Ms. Dawkins commented that litigation in the United States is proliferating; for example, there are 435 patent infringement cases and nine class action suits over StarLink; organic canola producers in Saskatchewan are suing Monsanto and Aventis; an unknown number of tort cases (farmers suing other farmers based on trespass or nuisance); and a recent petition to USDA for a criminal investigation into companies allegedly moving unapproved GM canola seeds within the United States. Although these cases are national, they show a potential for cross-border legal problems, as illustrated by alleged concentrations of GM maize found along roadways in Mexico, suggesting that the transport of imported GM maize and planting of imported GM maize intended for food and feed is a cause of the pollination of farmers varieties and wild maize varieties in this center of origin. Ms. Dawkins predicted that socio-economic effects of such cross-border movements of LMOs would follow, and that human health and environmental impacts, including impacts on biodiversity may be slower to occur and more difficult to measure.

Ms. Dawkins concluded that acts of commission and omission in trade, transport, handling and use of LMOs present threats to biosafety and the loss of biodiversity and called for careful study of environmental and food security impacts. She called attention to pending field-testing of some 400 bio-pharmaceuticals that she believes involves risks to human health, and genetic contamination with consequent impacts on environment and biodiversity. She called for an international liability regime that would be designed to avoid and prevent, mitigate and compensate for such damages and channel responsibility to patent holders, manufacturers, exporters, and parties of export, and suggested that negotiators consider the Oil Pollution Fund as a potential model.

Mary Fosi addressed the topic of possible activities and scenarios of concern from the perspective of a person from Africa and a developing country. She stressed that providing food security is in the hands of peasant farmers, who ensure food security by saving the best seeds and passing them down the generations. They depend solely on the production of foodstuffs. If LMOs impact the available agricultural diversity, this can modify the livelihoods of people and countries. Therefore, if LMOs inadvertently cause damage, a system must be in place to correct the damage caused.

In the discussions on liability and redress, it is important to consider general principles of international law, especially those laid down in the Rio Declaration including the precautionary principle, and the polluter pays principle. Environmental and health impacts of LMOs may take a long time to manifest themselves, and may be partially

unforeseen. Thus, it is important to have a system for liability and redress that provides security for those impacted by damage caused by LMOs.

Ms. Fosi advocated for the development of an international liability regime that would channel liability to a chain of potentially responsible parties, including the developer/patent holder, transporter, handler, and/or user, as defined in the UNEP International Technical Guidelines for Safety in Biotechnology. She envisioned a fund at the international level that will be set aside to ensure that there is recourse in case of damage. She raised the question of what should be done if damage occurs in advance of an agreement on the implementation of Article 27 of the Biosafety Protocol, and mentioned the StarLink case as one example of an incident with an LMO that might fall under a liability regime. She asked if liability should be retroactive to deal with possible harm resulting from current activities.

Willy De Greef focused his presentation on the biological scenarios and scientific information that should be the basis for discussions regarding activities and scenarios of concern. The following comments are taken from Mr. De Greef's PowerPoint presentation with several additions based on the notes taken by Meridian Institute facilitators.

1. Biological Scenarios

- The starting point (of discussions on possible activities and scenarios of concern) has to be the biological realities related to the behavior of plants and other organisms.
- This is also the starting point of all the safety assessment systems developed over the past 20 years. Almost all are derived from Organisation for Economic Co-operation and Development (OECD) guidelines on contained use, small-scale field trials, large-scale field trials, and commercial scale release.

Mr. De Greef added the comment that the OECD's guidelines in the 1986 report "Recombinant DNA Safety Considerations" (the so-called Blue Book) were developed based on "what if" scenarios, because at the time little data existed about the behavior of LMOs. We now have 20 years of experience with LMOs and the existing guidelines have held up well.

2. Out-crossing and Impact

- The fact that GM crops would occasionally outcross is not the issue; the issue is whether the result of that out-crossing has a negative impact on biodiversity.

3. The History of GM Crop Use

- Six years of large scale growing of GM crops under massive regulatory scrutiny has not seen the realization of any scenario of biodiversity damage.
- All of the effects seen so far fall are well within the range of expected impacts and confirm that GM crops behave like conventional varieties.
- Fifteen years of public biosafety research confirms that the behavior of GM crops can be thoroughly predicted on the basis of what we know of conventional crops.

4. Benefits?

- After 6 years of commercial growing of GM crops, the environmental and socio-economic benefits become clearer.
- Herbicide tolerant crops help achieve zero tillage agriculture, a major objective towards more sustainable farming.
- Bt cotton turns out to have as much advantage for very small farmers in developing countries (China, India, South Africa) as in the North.

Piet Schenkelaars commented on the types of impacts, activities and scenarios that are being studied by scientists and provided the following information to complement and inform the legal deliberations on liability and redress.

Mr. Schenkelaars indicated that many questions regarding the risks of biotechnology products compared to conventional products remain unanswered. He mentioned that the discussion about risks and, in particular, what changes to biodiversity, agricultural diversity, and the environment should be considered harmful has scientific aspects, but also has important political, ethical, and legal aspects. Regarding the scientific aspects, he stated that no single study has conclusively addressed the question of damage caused by GM products, and information has to be gleaned from the risk assessments that have been conducted. In this context, the EC's assessment of risk assessments conducted in the EU indicates that GM products may not be inherently more dangerous than conventional products.

Mr. Schenkelaars indicated that out-crossing between wild and domestic varieties is a natural process, and indicated that the scientific criteria to determine whether a species is invasive are the same for GM products and conventional products. Just as conventional crops can be invasive, so can GM products, especially products that may have a competitive advantage (e.g., salt or drought tolerant plants).

Mr. Schenkelaars stressed the importance of establishing baseline data on the state of biodiversity and the environment in order to be able to determine whether there is an impact resulting from the use of GM products. The decision on whether an impact should be considered damage is largely political and social.

Summary of Discussions:

- A participant mentioned that the evolution of human culture and its socio-economic impacts have resulted from technical developments, fire, cultivation crops, transportation, etc. He asked why, regarding the notion that impacts on socio-economic circumstances should be included in the definition of damage, changes resulting from use of biotechnology should be treated differently by the legal system than changes resulting from other technology.

He indicated that Article 26⁵ of the Biosafety Protocol might offer relevant guidance. It suggests that socio-economic impacts can be considered but only if these impacts result from damage to biodiversity.

A panelist responded that the issue is whether change negatively impacts society. If that is the case, then liability should be attached to these negative impacts.

Another panelist stated that the precautionary principle should guide the discussions and it suggests that we put measures in place in case damage resulting from LMOs occurs. This panelist also suggested that Article 26(2) includes all socio-economic impacts.

- A participant asked the following question regarding the statement that the impacts and behavior of GM plants are no different from conventionally bred plants: How do you explain the massive regulatory oversight, the use of the term substantial equivalence in the U. S. regulatory system, and the controversy over StarLink corn?

A panelist responded that even though the European and U.S. regulatory systems are elaborate, companies have submitted the same information to European and U.S. regulatory agencies. In several cases, different decisions were drawn in the EU and the U.S. about whether to approve a product or not.

Panelists disagreed on whether the U.S. Food and Drug Administration (FDA) actually requires industry submissions of risk assessments regarding LMOs or whether these submissions are voluntary. One argued that submissions were voluntary and that companies have not submitted in-depth risk assessments. Another argued that the FDA requires compulsory submissions and that companies have complied with FDA requests.

- A participant stated that biotechnology has been used, for instance, to insert a powerful defoliant in cauliflower and asked how that would be better than, for instance, flaming.

A panelist responded that there are many ways to get zero-tillage and farmers are looking for more options. Too often in the debate over biotechnology, one technology is considered “good” and another “bad.” This panelist stressed the need to create a toolbox from which farmers can choose the appropriate tools.

⁵ Article 26 - Socio-Economic Considerations

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

- A participant suggested that the benefit argument (i.e. there are benefits to biotechnology) does not relate to discussion about a need for a liability regime. For instance, there are other regimes, such as a regime regarding hydrocarbons or satellite technology, where people generally assume that there are benefits to the product or technology, but still have opted for the development of an international liability regime.

A panelist added that, in terms of benefits, we need to look at the distribution of benefits. Socio-economic benefits are going to companies while farmers are not benefiting socio-economically.

- A participant suggested that liability regimes have been created for high-risk activities and for low risk activities that may potentially cause significant damage, and asked how the low risk argument relates to Article 27. He indicated that this should not be a debate over whether GMOs are “good” or “bad”, but whether a liability regime can have some benefits.

A panelist responded that the arguments regarding benefits and low risk associated with LMOs are relevant to the question of whether we need a new liability regime to deal with these issues, or if the existing regimes are sufficient considering the fact that LMOs have a small environmental footprint.

- Another participant stated that impacts of LMOs should be assessed and addressed at ecosystem level and the discussions should consider ecosystem impacts, instead of regional or national impacts.

Panel 3 – Damage and Causation

The panel addressed issues relating to damage in the context of Article 27, including the possible relationship with the definition of damage in the Convention on Biological Diversity.

Speakers:

Rene Lefeber, Legal Counsel, Ministry of Foreign Affairs, The Netherlands

Ruth Mackenzie, Program Director, Biodiversity and Marine Resources, Foundation for International Law and Development (FIELD)

Stanley Abramson, Attorney, Arent Fox Kintner Plotkin & Kahn, PLLC

Jimena Nieto, Head, International Affairs Office, Ministry of the Environment, Colombia

Piet Schenkelaars, Schenkelaars Biotechnology Consultancy

Summary of Panel Presentations:

Rene Lefeber focused his presentation on the general objectives of a liability regime and the potential consequences of different objectives for the definition of damage. The following comments are taken from Mr. Lefeber's PowerPoint presentation with several additions based on the notes taken by Meridian Institute facilitators.

5. Possible Objectives of a liability regime are:
 - Protection of victims;
 - Protection of industry; and,
 - Protection of environment.
6. Typical elements of a liability regime for the protection of victims include:
 - Strict liability;
 - Compulsory insurance; and,
 - Procedural safeguards.
7. Typical elements of a liability regime for the protection of industry include:
 - Limited liability (in time and amount);
 - Channeling of liability (usually to one person, who may be responsible for compulsory insurance); and,
 - Exclusive regime (i.e., victims can only sue on the basis of this liability regime, not on other law or regimes).

Several international agreements dating from before the 1970s contained liability regimes that protected industry as well as victims. Examples are the nuclear liability regimes and the oil pollution damage regimes. Since the 1970s and 1980s, international agreements have started to move away from industry protection. For instance, the Lugano Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment and the Basel Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and their Disposal

provide for unlimited liability, provide for minimum liability limits, and/or channel liability to multiple persons.

8. Typical elements of a liability regime for the protection of the environment include:
- Implementation of preventive and reinstatement measures;
 - Recovery of costs of preventive and reinstatement measures; and,
 - Compulsory intervention by public authorities.

The EC's proposal for a Directive on Liability for Environmental Damage is a good example of a regime targeted to the protection of the environment.

9. These different objectives of a liability regime have several consequences for the concept of damage.
- If the objective is to protect victims, damage should focus on loss of or damage to persons or property, and related economic losses such as income or profit. For example, the Oil Pollution Conventions focused on the protection of victims, not the environment.
 - If the objective is to protect the environment and biodiversity, damage should focus on costs of preventive measures, costs of reinstatement measures, and interim losses.
 - If the objective is to protect industry, the concept of damage should be limited (e.g., it would only cover direct damages), and the definition of damage should be precise.

Ruth Mackenzie focused her presentation on the relevance of definitions of damage in existing international instruments and stated that the effectiveness of any regime will depend largely on the definition of damage. In this context, it is important to recognize key considerations that include the objectives in Article 1⁶ of the Biosafety Protocol and language in the CBD, which addresses food security, livelihoods, environment, socio-economic considerations, etc. She suggested that the focus of a liability and redress regime should not be solely on biodiversity damage.

The question according to Ms. Mackenzie is how to link the expressed concerns and potential risks of LMOs with the scope of the regime in the context of the definition of damage. Although the focus should be on damage to the environment, it may not be appropriate to limit it to just damage to the environment, and she posed the question: what can we learn from other regimes, such as the Convention on Persistent Organic Pollutants, and the work of the International Law Commission? Most international

⁶ Article 1 - Objective

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

liability regimes cover specific categories of damage, including personal injury and damage to property and, increasingly, environmental damage. The definition of damage to the environment is generally limited. In most cases it covers only *reasonable* costs of reinstatement or restoration of the environment, and costs of preventive measures. Generally speaking, the definition of environmental damage is limited to economic damage related to environment. It is important to realize that existing international liability regimes focus on single pollution incidents and do not treat damage to biodiversity separately from environmental damage.

Ms. Mackenzie suggested looking beyond international regimes for examples of creative ways to address damage of a long-term, diffuse and gradual nature such as those feared to be associated with LMOs. These characteristics may require long-term monitoring and assessment, the costs of which have been recognized as damage by the UN Compensation Commission. Furthermore, the definition of damage should address broader issues of food security, socio-economic impacts and the definition of biodiversity. She suggested looking at, for instance, European Union legislation, national environmental liability regimes, and definitions of damage or adverse effects in national regulatory systems for inspiration. There is considerable discussion over whether definitions in regulatory regimes are appropriate for liability regimes, but the special features of LMOs require creativity in developing a regime.

She mentioned that although some argue that damage to property and human health are adequately dealt with by national legal regimes, negotiators should consider whether all countries really have private law systems that are adequate for dealing with the unique aspects of LMOs.

Stanley Abramson also discussed considerations regarding damage and paid special attention to the issue of preventing damage. The following comments are taken from Mr. Abramson's PowerPoint presentation with several additions based on the notes taken by Meridian Institute facilitators.

1. Where should we look for guidance on the definition of damage?
 - Look to Articles 1 and 4 of the Biosafety Protocol for objectives and scope of the Protocol.
 - Objective of the Protocol – Article 1 (relates to certain activities involving LMOs “that may have adverse effects ...”).
 - Scope of the Protocol – Article 4 (relates to certain activities involving LMOs “that may have adverse effects ...”).
 - CBD Article 14, Paragraph 2⁷ - Damage to biological diversity from the transboundary movement of LMOs.

⁷ Article 14 - Impact Assessment and Minimizing Adverse Impacts

1. ...

2. The Conference of the Parties shall examine, on the basis of studies to be carried out, the issue of liability and redress, including restoration and compensation, for damage to biological diversity, except where such liability is a purely internal matter.

2. Definition of damage should include:
 - Effect must be “adverse” (Articles 1 and 4)
 - Effect must result in “impairment” (Webster’s Dictionary definition of “damage”)

3. When does liability attach?
 - Must have actual damage (as opposed to speculation or an effect that is not “adverse”). The determination of damage should be fact specific and science-based
 - Must have damage that exceeds a de minimis threshold. “Significant” damage is used in many national systems and international agreements including CBD.

4. Damage to what?
 - Biological diversity (CBD Article 14, Paragraph 2: Damage to biological diversity from the transboundary movement of LMOs).
 - Within context of CBD and Protocol.
 - Look to “the conservation and sustainable use of biological diversity, taking also into account risks to human health” only once adverse effect on biological diversity is established.
 - Human health issues triggered only if an adverse effect on biological diversity leads to an adverse effect on human health.

5. Causation (Damage from what?)
 - There should be an absolute requirement to prove causation.
 - All elements in the causation chain must be proven, including “harm” (actual, significant, etc.); identification of a specific genetic trait; and the causal relationship between the harm and the transboundary movement of LMO containing the identified genetic trait (“damage resulting from” Article 27; “from transboundary movement” CBD).

6. Prevention
 - Look to the Objective of the Biosafety Protocol – Article 1: “to contribute to ensuring an adequate level of protection [from certain activities involving LMOs] that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health”
 - By making damages a priority, we risk focusing on the wrong end of the timeline.
 - Damages may or may not ever occur, but if damages ever do occur, it will most likely follow commercialization.

Mr. Abramson focused the attention of the workshop participants on regulation and product stewardship as methods to address both prevention of damage and liability.

- Regulation takes effect at the front end of the process (e.g., field test, market entry).
- Regulation is designed to address both harm and liability.

- Regulation provides assurance to the public that a product is safe for its intended use.
- Product stewardship can be thought of as the legal, ethical and moral obligation of developers to assess their products and technologies to ensure that they are safe as well as socially and environmentally responsible.
- Effective Science-based Regulation + Proactive Product Stewardship = Prevention.

Piet Schenkelaars built on his presentation for the panel on *Possible Activities and Scenarios of Concern* and stressed again that scientific knowledge on the possible harmful effects of LMOs needs to be further developed. He suggested that environmental risk assessments in general have a relatively high level of uncertainty, and continued by stating that field-testing of LMOs has focused on agronomic performance of LMOs and, to a lesser extent, has addressed the possible ecological effects of LMOs.

He explained that some groups have suggested augmenting risk assessments with monitoring programs for released LMOs to detect any harmful effects. However, there is no agreement on issues such as the need for long-term monitoring, what monitoring protocols that should be used, or an adequate monitoring timeframe. Mr. Schenkelaars explained that, if monitoring takes place, scientists would monitor to verify whether the effects of out-crossing remain below a certain threshold established by regulatory bodies. Scientists can contribute to the establishment of such thresholds by generating information on the effects of out-crossing on the genetic integrity of a species.

Jimena Nieto responded to the previous panelists from a developing country perspective. She indicated that many developing countries approach these discussions mainly from the perspective of providing protection to the victims who suffer damage. She mentioned the difficulty involved in negotiating a definition of damage, and mentioned as an example of difficult negotiations those on the Protocol on Liability and Compensation to the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal. From the perspective of a developing country delegate, she indicated that she would like to see the definition of damage be as broad as possible, including harm to human health, environment, biodiversity, etc., and added that, despite the difficulty of developing a clear definition, socio-economic impacts should be included in the definition because this is an important concern for many developing countries.

She continued by stating that an international liability and redress regime should be developed that offers countries that do not have adequate national regimes something to fall back on in case of damage. The regime would have to be designed to accommodate for the differences between developing and developed countries, companies, and individuals that may be involved in transboundary scenarios where harm occurs.

Prevention is an important issue, and Ms. Nieto indicated that a strict liability regime could have the effect of prevention by encouraging the use of maximum safety standards to avoid damage and possible liability.

Her final comment regarded the links between the processes under Article 27 of the Biosafety Protocol and Article 14(2) of the CBD. The CBD process regarding a definition of damage to biosafety has progressed very slowly, and many developing countries are concerned that it may hamper progress of negotiations on Article 27.

Summary of Discussions:

- A participant asked what might be considered impairment and how you might measure a *de minimis* threshold (i.e., damage to biodiversity at low levels is difficult to measure).

A panelist suggested that with regard to establishing a *de minimis* threshold, we can look for analogies in how scientists judge losses caused by plants that have been used for decades.

- A participant asked if there should be a separate protocol if an international regime for liability and redress were to be developed, and if this protocol should include provisions for monitoring.

A panelist suggested that developing a separate protocol or including a liability and redress regime in an amendment to the current Protocol are both options. He suggested that there may be other options to consider.

The participant suggested that the fact that the CBD's decisionmaking procedures have not yet been agreed upon may become problematic in the further negotiations on Article 27.

- A participant asked if there should be a fund to assist developing countries in restoring damage.

One panelist stated that, during the Protocol negotiations, industry made an informal offer to develop a compensation fund under the provision that no new liability regime would be developed under the Biosafety Protocol.

- A participant explained that countries have autonomy and jurisdiction over their natural resources and make decisions as to which LMOs to allow into the country. Could a state be made liable in case no other responsible party can be found that is able to restore the damage?

A panelist suggested that the rules of state liability under customary international law apply irrespective of Article 27 if an act by a state causes pollution to other states. Under customary international law, state liability requires a breach of an international obligation. The problem is that this is a due diligence standard similar to fault-based liability.

- A participant made the observation that panelists held broadly divergent views on the definition of damage, and asked for further explanation of the narrow interpretation of damage in the context of Article 27.

A panelist responded that one should look broadly at the Biosafety Protocol and at other relevant mechanisms such as national regulatory regimes. Technology developers look at two elements: 1) agronomic performance of their products and, 2) the demands of regulatory authorities. In the United States, three government agencies regulate LMOs under five separate provisions of law. Under these provisions, companies must submit data about potential harm and they must meet specific criteria, no matter how large or small the product or proposed activity (one seed or one hundred acres of planted seeds). These extensive regulations to prevent harm should be taken into account when developing a definition of damage.

- A participant suggested that the EC's proposal is limited in the sense that it does not provide for a civil liability regime, and it only concerns damage caused by approved GMOs.

A panelist stressed that the EC proposal is a shift in thinking in how to structure a liability regime to prevent damage to the environment. The number of liability regimes is increasing and many are complementary, but it may be difficult to prevent conflict between these regimes. There are many ways to resolve such conflicts, for instance, by using priority provisions. In the case of the Biosafety Protocol, it focuses on specific activities that make conflict with other regimes less likely.

- A participant also asserted that the EC made the policy choice to limit applicability of the proposal to damage to biodiversity in the so-called "nature protection zones." Overall, this does not help us with a better definition of biodiversity.

Panel 4 - Standards of Liability and Channeling

The panel addressed issues relating to possible standards of liability for damage resulting from certain activities or incidents with LMOs, and questions relating to channeling liability for such damage to specific persons or entities.

Speakers:

Anne Daniel, Senior Counsel, Legal Services, Environment Canada, Canada

Stanley Abramson, Attorney, Arent Fox Kintner Plotkin & Kahn, PLLC

Arthur Mpeirwe, Research Associate, Advocates Coalition for Development and Environment (ACODE)

Alfonso Ascencio, Third Secretary, Legal Affairs, Permanent Mission of Mexico to the United Nations

Summary of Panel Presentations:

Anne Daniel mentioned the three basic concepts of standards of liability and channeling and raised a number of policy questions.

Ms. Daniel said there are three basic standards of liability -- fault-based liability, strict liability, and absolute liability. Under a fault-based liability regime, the victim has to prove negligence on the part of the person he holds responsible for damage. Strict liability makes a specific person liable regardless of fault, but offers limited exonerations. Absolute liability makes a specific person liable regardless of fault and does not allow exonerations.

Standard of liability issues are what we traditionally think of in the context of an international liability regime, but we need to realize the policy choices that need to be made in the context of making decisions on the appropriate elaboration of international rules and procedures under Article 27. Ms. Daniel emphasized that liability can serve a back-up purpose, but that parties need to address prevention as well.

Ms. Daniel indicated that the main policy reason for developing a liability regime is to enable recovery for the victim – victim meaning either people or the environment or both. Her understanding of the EC proposal for a directive on environmental liability is that it focuses on damage to the environment and chooses the state as the principal protector of the environment, a type of approach used in a number of Canadian statutes.

She suggested that a number of policy issues have to be addressed that will influence the eventual decisions on liability and redress under the Biosafety Protocol and in particular a possible standard of liability and the persons to be identified as liable parties (channeling). These policy issues include the following:

- A balance must be struck between protecting the environment and protecting the interests of other players, including industry.

- An equitable solution has to be found taking into account that most activities are not illegal. Negotiators should keep in mind that the primary activities that are regulated by the Biosafety Protocol are those that fall under the Advance Informed Agreement (AIA) procedure.
- If it is decided to develop a liability regime, parties have to consider who would be in the best position to prevent damage. For example, in the Basel Convention either the notifier or disposer may be liable depending on specific circumstances. A long list of actors may be involved in activities with LMOs. Some of these have been mentioned, but it also includes the party of import. As discussions continue, people need to be careful to use clear terminology (e.g., producer could mean a farmer, a GMO developer, or others).
- If decisions are made about channeling liability, parties have to consider the insurability of the actor, and issues regarding the long-term liquidity of these actors.
- Furthermore, negotiators have to consider exonerations from liability (in the context of the standard of liability) and definitions of damage.
- Negotiators should also consider how an international legal regime would be implemented in national regimes.

Stanley Abramson raised the question whether strict liability is either necessary or appropriate for LMOs. He emphasized that strict liability may have inequitable results if people are made responsible even if damage was not foreseeable or was partly caused by the fault of others.

He suggested that strict liability may be appropriate for ultra-hazardous activities, but that LMOs are not inherently dangerous as shown by a recent report from the EC. Other activities are known to cause adverse effects to biodiversity. Certain "traditional" farming practices have led to soil erosion, overuse of chemicals, and deforestation.

Mr. Abramson proposed a tiered approach that imposes strict liability for those activities known to cause adverse effects, and fault-based liability for those that have not been proven to have adverse effects. This approach would allow people to focus their resources on priority activities that are known to cause damage, with the ultimate goal of protecting biodiversity.

Arthur Mpeirwe advocated for the development of a regime based on strict liability. He felt it is an appropriate standard for the transboundary movement of LMOs for the following reasons:

- Even though there is not yet positive evidence that LMOs pose danger of harm to the environment or biodiversity, Mr. Mpeirwe suggested that there is growing evidence that they are potentially dangerous. Based on the precautionary principle, it would be appropriate to set a high standard.
- Strict liability would serve as a measure of prevention, because it would make operators, and other actors take extra caution.

- Even though the chances of harm from LMOs may be remote, that does not mean it cannot happen. Strict liability would facilitate restoration of harm in case something does happen.

Mr. Mpeirwe indicated that liability should be channeled to a person who is able to restore what has been damaged. A chain of actors may be involved in the transboundary movement of LMOs, and they should all be held jointly and severally liable, so that a victim can choose a party who is most likely in a position to restore or compensate.

At a regional level, an Organization of African Unity (OAU) model law that was discussed in an OAU workshop in May 2001 contains the standard of strict liability for harm caused by LMOs. The model law relies on the precautionary principle and channels liability to any person who imports, is responsible for contained use, releases or places on the market an LMO or product thereof. The OAU model law was developed by persons advocating for limited use of LMOs. Mr. Mpeirwe added that, in order for a liability regime to have an effect, countries need the capacity to assess impacts of LMOs on the environment. Many African countries do not have that capacity.

Alfonso Ascencio addressed some of the more general issues regarding standards of care, in particular whether Article 27 calls for a narrow or a broad approach. He explained the arguments for taking a broad approach, emphasizing that Article 27 should be read in relation to other provisions in the preamble of the Biosafety Protocol, which refers to centers of origin and the protection of biodiversity as a common cause of humankind, and Principle 15 of the Rio Declaration.⁸

With regard to a standard of liability and channeling, a broad approach requires looking at the systems of civil liability, state liability and financing.

Mr. Ascencio stated that, although state liability is the standard in the Convention on Liability for Damage Caused by Space Objects and is being studied by the International Law Commission, many other international liability regimes favor civil liability, which includes the standards of fault-based, strict and absolute liability. In a broad approach, a civil liability system with residual state liability may be preferred. A system of civil liability with residual state liability can be found in the Antarctica Treaty. Mr. Ascencio suggested that the preferred standard of care in the civil liability system should be strict liability and added that even under a system of strict liability, the causal relationship between an LMO and damage has to be proven, which may be very difficult to do.

To finance compensation for damage caused by LMOs, funds should be established (e.g., Oil Pollution Compensation Funds), because they provide security when damage may only become apparent after a very long time.

⁸ Principle 15

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

Mr. Ascencio ended his presentation by stating that a broad perspective when dealing with LMOs promotes the reference found in the preamble of the CBD that “the conservation and sustainable use of biological diversity will strengthen friendly relations among states and contribute to peace for humankind.”

Summary of Discussions:

- A participant observed that several participants suggest that strict liability should be the standard of liability, because it would act as a deterrent. If you channel strict liability to those who may have the capacity to pay compensation, it is a real possibility that this person is further removed from the actions that cause the harmful impact. In that case you have created a strict liability regime that absolves downstream users of biotechnology, which may undercut the deterrence element of the liability scheme.

A panelist suggested that by making the chain of actors jointly and severally liable you do not let downstream actors off the hook, but instead you spread the cost of compensation and ensure that you do get compensation.

Another panelist observed that this also goes to a question of equity -- a regime should look for an equitable balance between interests of victims, environment, and industry. Imagine a situation where an LMO gets released after it meets all requirements in the advance informed agreement procedure. After ten years it turns out that the release was not a good one. How should such a situation be addressed? What is fair?

A panelist offered that we do not always know the consequences of adopting the standard of strict liability. A strict liability regime may act as a deterrent, but we need to be thoughtful about the potential consequences of using liability to deter. What if it will prevent companies from marketing their products? Who is the ultimate loser if there are benefits from GMOs?

- A participant stated that a broad list of actors could be held responsible, and the state of import could be one of them. Can the state of import be held liable for a decision it makes based on information provided by the notifier who performed a risk assessment under the AIA?

A panelist suggested that negotiators need to address this question, especially in the context of socio-economic impacts. Should an importing country be made liable or is it a matter that will be resolved through political means (i.e., the ballot box)? The party of import has the sovereign right to decide what comes into its jurisdiction. States will most likely not favor state liability as a standard for damage resulting from LMOs. However, negotiators and states should consider all situations. One situation can be that the decision to import was the single most important cause for the damage to occur. Another situation can be that advice from the expert (from the roster of

experts) was the most important cause of damage. In these situations, you should consider where can you best leverage prevention.

Another panelist observed that developing countries originally argued for state liability, because strict liability would favor victims by making claims easier. Strict liability and state liability may both work to facilitate restoration and compensation.

- A participant asked if a mix of state and strict liability might work, in which strict liability is attached to intrinsically dangerous materials and/or activities.

One panelist suggested that a mixed system could maximize options for restoration and compensation.

Another panelist suggested that state liability in international law usually means that liability is channeled to the states to compensate for damage. This is a different approach than using at the domestic law level a mix of state remediation funded by those causing damage and civil liability.

- A participant stated that many countries in Africa and elsewhere do not have the capacity to regulate or assess impacts of LMOs, and need to build their capacity to do so. This circumstance should be taken into account when developing a liability regime.

A panelist responded that capacity building is critically important, but we have to ask ourselves if it is better to focus on capacity building in terms of developing a new liability regime or if we should focus on the front end regulatory regime that allows developing nations to protect their biodiversity and at the same time share in the benefits of biotechnology.

Another panelist suggested that there is a lot being done to help countries develop regulatory systems.

- A participant asked why a standard of strict liability for LMOs is unacceptable to industry when it has accepted the standard of strict liability in the context of contamination caused by chemicals.

A panelist responded that many of the impacts of hazardous waste are easy to identify and quantify. For LMOs, it is difficult to establish a connection between damage and activity. We need to wait for science to catch up.

- A participant offered that polymerase chain reaction (PCR) testing⁹ to quantify LMOs in products is relatively easy and can be used to establish damage.

A panelist responded that you may be able to detect LMOs using PCR testing, but that still leaves the question whether the occurrence of LMOs causes any harm.

⁹ Polymerase chain reaction (PCR) testing is a common form of DNA analysis.

- A participant asked how access to regulatory procedures should be given to people, especially people who may have concerns about socio-economic impacts.

A panelist stated that access to justice is a serious concern. One way to address it is to make sure that governments make good their regulatory obligations of, for instance, investigating harm, issue and enforce orders to stop planting, and impose civil and criminal penalties.

Another panelist indicated that at national level people have access to justice through public participation. Access to justice at the international level is a difficult question. In the context of damage to environment, the question of who acts on behalf of the environment has not been definitively answered.

A participant stated that the Permanent Court of Arbitration has developed Optional Rules for Arbitration of Disputes Relating to Natural Resources and/or the Environment that offer a forum for access to justice to anyone with legal personality.

Final Session – Open Discussion

During the final session of the workshop, all panelists joined with the workshop participants in an open discussion on liability and redress and Article 27 of the Biosafety Protocol.

To facilitate reading of this summary, the authors have reorganized some of the comments. In cases where the discussion came back to issues that had been partially addressed during earlier sessions, the relevant comments have been grouped with the comments from the earlier sessions.

- A participant revisited the old question of why GM crops should be regulated differently from other crops. Based on the U.S. National Academy of Sciences' recent report "Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation," the participant observed that biotechnology is being developed during a time when a growing part of the public is concerned over the impact of transgenic plants on the environment, and suggested that the higher standards applied to GMOs may well be applicable to other plants.
- A participant asked how a liability regime and definition of damage would relate to pharmaceuticals. How would you apply the principle of proportionality to countries in development that export agricultural plants and import health biotechnology?

A panelist suggested that pharmaceuticals are subject to specific liability rules in countries. For instance, in the EU, every country has rules specifically for pharmaceuticals.

Another panelist added that in the discussion over medical biotechnology and agricultural biotechnology, it became clear that the pharmaceutical sector had an elaborate system in place that governed regulation and clinical testing. There was no need to go beyond that. Furthermore, it should be kept in mind that developing countries are both receivers and producers of biotechnology. For instance, India and Cuba have very strong programs in medical biotechnology. Cuba has developed a very successful hepatitis B vaccine. Egypt has a strong agricultural biotechnology program and has been successfully testing potatoes that are resistant to Cuba moth. People in developing countries are concerned whether the release of a GMO to farmers in developing countries will affect their export market in the EU, (for example, because moving products to the EU requires massive resources to comply with regulations). A panelist stated that it might be true that Article 5¹⁰ of the Biosafety Protocol contains a limitation for pharmaceuticals. However, this is a

¹⁰ Article 5 - Pharmaceuticals

Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations.

limitation that relates to the fact that the World Health Organization (WHO) deals with these issues. There is no compelling reason why Article 27 should exclude pharmaceuticals, because the WHO is not setting standards for pharmaceuticals produced in genetically engineered plants. Field-testing of pharmaceuticals in plants needs our attention.

- A participant stated that the fundamental underlying demand for a liability regime is because of the large number of holes in existing regulatory systems. For instance, the U.S. FDA does not require industry to submit risk studies. Even a pending update of regulations only prescribes mandatory consultations between agency and companies about studies and new products. Regulatory systems are not going to prevent events.

A panelist disagreed and stated that the U.S. FDA has required risk studies and is moving toward increased regulation. More importantly, every product that is on the market went through voluntary studies and careful review by government agencies. The current move to a more mandatory regime is a response to public requests and is not based on risks associated with the existing system. A concern is to make sure that regulatory agencies have the proper resources to assess studies.

Another panelist suggested that the kind of data that is needed for a sound scientific risk assessment will depend on the environment in which a product will be released. Releasing a GM potato in the Netherlands is less likely to have an effect on biodiversity than if the same GM potato is exported to Peru or Colombia (centers of origin). In the latter case, the risk profile will be very different and different issues have to be addressed in the risk assessment. This also has a bearing on channeling; an importer needs to have capacity to review risk assessments and say if the product will be safe in its' own country.

A panelist stated that many developing countries have no national law on biosafety at all. In Colombia, transgenic soy was found in imported food for orphans. If some health effect had occurred, Colombia would have to rely on the general rules of liability, which would have made it very difficult to seek redress in this transboundary case. Therefore, it is very important for developing countries to have an international framework and a process that will catalyze an international framework.

- A participant explained that in relation to genetic engineering for pest resistance, damage to the value of Bt sprays may result from farmers not implementing buffer zones and/or insect resistance management measures. Negotiators should take this scenario into account.
- A participant asked the panelists what could be learned from the Percy Schmeiser case.

One panelist suggested that the case of Schmeiser concerns problems of out-crossing, and offers lessons for the position of poor developing country farmers who are dependent on seed saving. Are they at risk from companies like Monsanto suing

farmers based on liability regimes? National legislation should go a long way to protect small-scale farmers from these situations.

Another panelist urged participants to read the Canadian court ruling, because it makes clear that the court found sufficient evidence that the amount of genetically modified crops found on Schmeiser's land could not physically be the result of out-crossing. The court ruled that Schmeiser planted the GM crop without paying for it.

- A participant stated that many biotechnology products are patented with the purpose of making an economic profit. However, there are many developers who do not (intend to) earn money from their inventions. They should be treated differently, for instance, by developing two tiers in state and other forms of liability. You could, for instance, develop a fund to compensate for shortfall in compensations that would be financed by a percentage of proceeds of royalties.
- A participant stated that some exporters have been reluctant to release information to importers based on the protection of business secrets. In some cases, even a minimum amount of information was refused to the importer. What are legal implications of withholding information from an importer?

A panelist suggested that if a developer of any regulated product fails to provide an importer with information, the developer would most likely be liable for damage resulting from his actions.

Another panelist stated that in this case an importer cannot take an informed decision regarding the import of the product.

**Workshop on Liability and Redress
Article 27 of the Cartagena Protocol on Biosafety
Attendees (21 April 2002)**

Stanley Abramson*
Arent Fox Kintner Plotkin & Kahn,
PLLC
1050 Connecticut Avenue NW
Washington, DC 20036
United States
phone number: 202-857-8935
fax number: 202-857-6395
e-mail: abramsos@arentfox.com

Soledad Aguilar
Lawyer
Direccion de Asuntos Ambientales
Esmeralda 1212
Buenos Aires 1007
Argentina
phone number: 54-11-48197414
fax number: 54-11-48197413
e-mail: saq@mrecic.gov.ar

Andrzej Aniol
Plant Breeding & Acclimatization
Institute
Radzikov
Blonie 05-870
Poland
phone number: 48-22-725-4711
fax number: 48-22-725-4714
e-mail: a.aniol@ihar.edu.pl

Alfonso Ascencio*
Third Secretary
United Nations
Permanent Mission of Mexico
2 United Nations Plaza, 28th Floor
New York, NY 10017
United States
phone number: 212-752-0220
fax number: 212-688-8862
e-mail: ponchoascencio@hotmail.com

Marc Auer
Senior Environmental Officer
Federal Ministry for the Environment
Godesberger Alle 90
D-53175 Bonn
Germany
phone number: 49-228-305-2665
fax number: 49-228-305-2695
e-mail: auer.marc@bmu.de

Christoph Bail*
Head, Environment and Development
Unit
European Commission
Directorate General Environment
Av. Beaulieu 9
Brussels 1160
Belgium
phone number: 32-2-295-4099
fax number: 32-2-296-9557
e-mail: christoph.bail@cec.eu.int

Juerg Bally*
Senior Adviser
Swiss Agency for the Environment,
Forests, and Landscape
CH-3003 Bern
Switzerland
phone number: 41-31-322-5429
fax number: 41-31-324-1569
e-mail: juerg.bally@buwal.admin.ch

Jafar Barmaki
Ministry of Foreign Affairs
Ferdosi Avenue, Kousk Street
Building No. 8.2
Tehran
Iran
phone number: 98-21-321-2671
fax number: 98-21-6704176
e-mail: jbarmaki@yahoo.com

Workshop on Liability and Redress
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Attendees (21 April 2002)

A. Behrens
e-mail: a-behrens@gmx.net
Larry Bohlen
Friends Of The Earth
1025 Vermont Avenue NW
Suite 300
Washington, DC 20005
United States
phone number: 202-783-7400
fax number: 202-783-0444
e-mail: lbohlen@foe.org

Edward Brans
Vrije University
Faculty of Law
Room 6A-34
De Boelelaan 1105
1081 HV Amsterdam
The Netherlands
phone number: 31-20-444-6287
e-mail: bransedward@hotmail.com

Jeffrey Burnam
Deputy Assistant Secretary of State for
the Environment
U.S. Department of State
Bureau of Oceans and International
Environmental and Scientific Affairs
2201 C Street NW, Room 7831
Washington, DC 20520
United States
phone number: 202-647-3004
fax number: 202-736-7351
e-mail: burnamjm@state.gov

Beth Burrows
President/Director
The Edmonds Institute
20319-92nd Avenue West
Edmonds, WA 98020
United States
phone number: 425-775-5383
fax number: 425-670-8410
e-mail: beb@igc.org

Cedric Cabanne
Biotechnology Campaigner
Friends Of The Earth
France
At 2 b rue Jules Ferry
93100 Montreuil
France
phone number: 33-1-48-51-1895
fax number: 33-1-48-51-3323
e-mail:
cedric.cabanne@amidelaterre.org

Anne Chetaille
Chargeée d'études Environnement
SOLAGRAL
45 Bis Avenue de la Belle Gabrielle
Nogent-sur-Marne Cedex 94376
France
phone number: 33-1-4394-7345
fax number: 33-1-4394-7336
e-mail: chetaill@solagral.asso.fr

Lorenzo Consoli
EU Political Adviser
Greenpeace-European Unit
Chaussee de Haecht 159
B-1030 Brussels
Belgium
phone number: 32-2-274-1906
fax number: 32-2-274-1910
e-mail:
lorenzo.consoli@diala.greenpeace.org

Leticia Rodrigues da Silva
Gerente de Normatização e Avaliação
Agencia Nacional de Vigilância
Sanitária
Gerencia Geral de Toxicologia
SEPN 515 Bloco B, Ed. Omega
Brasilia DF 70770-502
Brazil
phone number: 61-4481082
fax number: 61-4481076
e-mail: leticia.silva@anvisa.gov.br

Workshop on Liability and Redress
Article 27 of the Cartagena Protocol on Biosafety
Attendees (21 April 2002)

Anne Daniel*
Senior Counsel
Legal Services
Environment Canada
Department of Justice
351 St. Joseph Boulevard, 6th Floor
Hull, Quebec K1A 0H3
Canada
phone number: 819-994-5733
fax number: 819-953-9110
e-mail: anne.daniel@ec.gc.ca

Kristin Dawkins*
Vice President, International Programs
Institute for Agriculture and Trade
Policy
2105 First Avenue South
Minneapolis, MN 55404
United States
phone number: 612-870-3410
fax number: 612-870-4846
e-mail: kdawkins@iatp.org

Willy De Greef*
Head of Regulatory Affairs
Syngenta International AG
WRO-1004-825
CH-4002 Basel
Switzerland
phone number: 41-61-697-5765
fax number: 41-61-697-5234
e-mail: willy.degreef@syngenta.com

Marjana Dermelj
Umanotera
The Slovenian Foundation for
Sustainable Development
P.O. Box 4440, Resljeva 20
1000 Ljubljana
Slovenia
phone number: 386-1-439-7100
fax number: 386-1-439-7105
e-mail: marjana@umanotera.org

Hannes Descamps
Legal Counsel, Expert on Environmental
Liability
Europe and Environment Division
Smidsestraat 38-900 Ghent-B
Koning Albert II-laan 20, P.O. Box 8
Brussels 1000
Belgium
phone number: 32-2-553-79-12
fax number: 32-2-553-81-65
e-mail:
hannes.descamps@lin.vlaanderen.be

Maria America Duarte
Ministerio Da Saude
Esplanada Dos Ministerios
Brasilia
Brazil
phone number: 55-61-315-3048
fax number: 55-61-315-2607
e-mail: erica.duarte@saude.gov.br

Gaëtan Dubois
Biologist
Brazilian Institute of the Environment
Directorate of Licensing and
Environmental Quality
Sain Av. L4 Norte, Ed. Sede Do Ibama
Bloco "c" - Sala 126
CEP. 70 800-2000, Brasilia D.F.
Brazil
phone number: 55-61-316-1332
fax number: 55-61-316-1355
e-mail: jdubois@sede.ibama.gov.br

Agbényo Dzogbede
ADT-Togo
B.P. 91090
Lomé
Togo
phone number: 298-222-1731
fax number: 298-222-1732
e-mail: adt_togo@cafe.tg

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Article 27 of the Cartagena Protocol on Biosafety
Attendees (21 April 2002)

Ossama El-Tayeb
Scientific Advisor
Egyptian Environmental Affairs Agency
Department of Nature Protection
Microbial Biotech Ctr, Faculty of
Pharmacy
University of Cairo, Kasr El-Aini Street
Cairo 11562
Egypt
phone number: 202-336-3222
fax number: 202-362-0122
e-mail: omtayeb@link.net

Dominique Hervé Espejo
Lawyer
University of Chile
Environmental Law Centre
Casilla 94, Correo 22
Santiago
Chile
phone number: 56-2-678-5354
fax number: 56-2-678-5355
e-mail: dherve@derecho.uchile.cl

Mary Fosi Mbantenkhu*
Head, Biodiversity Protection Unit
Ministry of the Environment and
Forestry
Division of Programmes & Sustainable
Development, Permanent Secretariat for
the Environment
B.P. 5506
Yaoundé
Cameroon
phone number: 237-222-1106
fax number: 237-222-9604
e-mail: mary_fosi@hotmail.com

Harold Foster
International Relations Office
U.S. Department of State
2201 C Street NW
OES/ETC, Room 4333
Washington, DC 20520
United States
phone number: 202-647-0199
fax number: 202-736-7351
e-mail: fosterhd@state.gov

Silvia Francescon
Ministry for the Environment
Via Cristoforo Colombo 44
Roma 00147
Italy
phone number: 39-06-57228120
fax number: 39-06-57228177
e-mail:
francescon.silvia@minambiente.it

Amanda Gálvez
Adviser
Ministry of the Environment, Natural
Resources and Fisheries
Fernandez Leal No. 43
Col. Barrio de la Concepcion
Mexico D.F. 04000
Mexico
phone number: 52-5-422-3539
fax number:
e-mail: galve@servidor.unam.mx

Helmut Gaugitsch
Federal Environment Agency
Spittelauer Laende 5
Vienna A-1090
Austria
phone number: 43-1-31304-3710
fax number: 43-1-31304-3700
e-mail: gaugitsch@ubavie.gv.at

Workshop on Liability and Redress
Article 27 of the Cartagena Protocol on Biosafety
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Alessandro Gianni
Ministry Of The Environment
Via C. Bavastro 12S
00152 Rome
Italy
phone number: 39-06-5722-8013
fax number: 39-06-5722 8000
e-mail: agianni-tt@yahoo.it

Antonietta Gutiérrez-Rosati
Universidad Nacional Agraria La Molina
Biology Department
Avenida La Molina 2135
Sol de La Molina
Lima 12
Peru
phone number: 511-349-5647 x 272/273
fax number: 511-479-2866
e-mail: antonietta@terra.com.pe

Victoria Henson-Apollonio
Senior Research Officer
International Service for National
Agricultural Research
Laan van Nieuw Oost Indie 133
2593 BM The Hague
The Netherlands
phone number: 31-70-3496153
fax number: 31-0-70-3819677
e-mail: v.henson-apolloonio@cgiar.org

Carly Howard
Intern
Washington Biotechnology Action
Council
3807 South McClellan
Seattle, WA 98144
United States
e-mail: howardcarly@hotmail.com

Maria Angelica Ikeda
Secretary
Ministry of External Affairs
Divisao Do Meio Ambiente
Anexo 1-Sala 439
Brasilia-DF CEP: 70170
Brazil
phone number: 55-61-11-6673
fax number: 55-61-322-5523
e-mail: maikeda@mre.gov.br

Birthe Ivars
Legal Advisor
Norwegian Ministry of Environment
P.O. Box 8013 DEP
0030 Oslow
Norway
phone number: 32-2-351-5298
fax number: 32-2-234-11-50
e-mail: birthe.ivars@skynet.be

Thomas Jacob
Manager, International and Industry
Affairs
Dupont
External Affairs
1007 Market Street, D-11072
Wilmington, DE 19898
United States
phone number: 302-774-6873
fax number: 302-773-2010
e-mail: tom.jacob@usa.dupont.com

Martha Kandawa-Schulz
Chair
Namibian Biotechnology Alliance
Faculty of Science, University of
Nambia, Private Bag 13301
Windhoek
Nambia
phone number: 26-461-206-3635
fax number: 26-461-206-3791
e-mail: kschulz@unam.na

Workshop on Liability and Redress
Article 27 of the Cartagena Protocol on Biosafety
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Henrik Kjellin
Ministry of Justice
Rosebadaa Y
S-1033J Stockholm
Sweden
phone number: 46-8-7026-79135
fax number: 46-8-8405-3601
e-mail: henrik.kjellin@justic.ministry.se

John Komen
Associate Research Officer
International Service for National
Agricultural Research
ISNAR Biotechnology Service
P.O. Box 93375
2509 AJ The Hague
The Netherlands
phone number: 31-70-3496161
fax number: 31-70-3819677
e-mail: J.Komen@cgiar.org

Iza Kruszezwska
ANPED, The Northern Alliance for
Sustainability
20 Church Lane
London SW17 9ZL
United Kingdom
phone number: 44 20 8672 3454
fax number: 44 20 8672 3454
e-mail: iza@cpa-iza.u-net.com

Antonio La Viña
Program Director
World Resources Institute
10 G Street NE, Suite 800
Washington, DC 20002
United States
phone number: 202-729-7640
fax number: 202-729-7620
e-mail: tonylav@wri.org

Carolina Lasén Diaz
Staff Lawyer
Foundation for International
Environmental Law and Development
52-53 Russell Square
London WC1B 4HP
United Kingdom
phone number: 44-207-637-7950
fax number: 44-20-7637-7951
e-mail: carolina.lasen@field.org.uk

Fernando Latorre
Foundation for International
Environmental Law and Development
52-53 Russell Square
London WC1B 4HP
United Kingdom
phone number: 44-207-637-7950
fax number: 44-207-637-7951
e-mail: fernando.latorre@field.org.uk

René Lefeber*
Legal Counsel
Ministry of Foreign Affairs
67 Bezuidenhoutseweg
PO Box 20061
The Hague 2500 EB
The Netherlands
phone number: 31-70-348-55-54
fax number: 31-70-348-5128
e-mail: Rene.Lefeber@minbuza.nl

Dan Leskien*
Advisor on Genetic Engineering
European Parliament
The Greens/EFA in the European
Parliament
Rue Wiertz
B-1047 Brussels
Belgium
phone number: 32-2-284-1692
fax number; 32-2-284-2560
e-mail: dleskien@europarl.eu.int

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Article 27 of the Cartagena Protocol on Biosafety
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Mwananyanda Mbikusita Lewanika
Principal Scientific Officer
National Institute for Scientific and
Industrial Research
P.O. Box 310158
Lusaka
Zambia
phone number: 260-1-282488
fax number: 260-1-283533
e-mail: sanyanda@hotmail.com

Li Ching Lim
Third World Network
228 Macalister Road
10450 Penang
Malaysia
phone number: 604-226-6728
fax number: 604-226-4505
e-mail: ching@I-sis.org.uk

Li Lin Lim
Third World Network
228 Macalister Road
10450 Penang
Malaysia
phone number: 604-226-6728
e-mail: twnet@po.jaring.my

Sarah Lukie
International Affairs Consultant
Global Industry Coalition
701 Pennsylvania Avenue NW
Suite 600
Washington, DC 20004
United States
phone number: 202-624-1214
fax number: 202-624-1298
e-mail: slukie@larlan.com

Ruth Mackenzie*
Foundation for International
Environmental Law and Development
52-53 Russell Square
London WC1B 4HP
United Kingdom
phone number: 44-20-7637-7950
fax number: 44-207-637-7951
e-mail: ruth.mackenzie@field.org.uk

Mariëlle Matthee
Research Fellow
T.M.C. Asser Institute
Schimmelpennincklaan 20-22
2517 JN The Hague
The Netherlands
phone number: 31-70-3420380
e-mail: m.matthee@asser.nl

Alistair McGlone
Legal Adviser
Department for Environment
Food and Rural Affairs
55 Whitehall
London SW1A 2EY
United Kingdom
phone number: 44-20-7270-8337
fax number: 44-20-7270-8353
e-mail:
alistair_mcglone@detr.gsi.gov.uk

Dessalegne Meston
Environmental Protection Agency
P.O. Box 12760
Addis Ababa
Ethiopia
phone number: 251-1-62-4760
fax number: 251-1-61-0077
e-mail: envpa@telecom.net.et

Workshop on Liability and Redress
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Kirk Miller
Director of International Programs
North American Export Grain
Association
1300 L Street NW, Suite 900
Washington, DC 20005
United States
phone number: 202-682-4030
fax number: 202-682-4033
e-mail: info@naega.org

Hugh Moeser
Deputy Director
Department of Foreign Affairs
Environmental Relations Division
125 Sussex Drive
Ottawa, Ontario K1V 8J8
Canada
phone number: 613-996-4300
fax number: 613-995-9525
e-mail: hugh.moeser@dfait-maeci.gc.ca

Arthur Mpeirwe*
Advocates Coalition for Development
and Environment
P.O. Box 29836
Kampala
Uganda
phone number: 256-41-530798
fax number: 256-41-344810
e-mail: ampeirwe@acode-u.org

Jimena Nieto*
Head, International Affairs Office
Ministry of the Environment
Calle 37 No. 8-40 Piso 2
Bogotá
Colombia
phone number: 57-1-288-9860
fax number: 57-1-288-6954
e-mail: jnieto@minambiente.gov.co

Ingrid Nöh
Head of Section
Federal Environmental Agency
Bismarckplatz 1
D-14193 Berlin
Germany
phone number: 49-30-8903-3250
fax number: 49-30-8903-3380
e-mail: ingrid.noeh@uba.de

Nicola Notaro
European Commission
Rue de la Loi 200
B-1049 Brussels
Belgium
phone number: 32-2-29-90-499
fax number: 32-2-29-69-557
e-mail: nicola.notaro@cec.eu.int

Elleli Huerta Ocampo
Conabio
Liga Perifénco-Insurgentes Sor 4903
Col. Parques del Pedregal
Mexico, D.F.-C.P. 01410
Mexico
phone number: 52-55-5528-9117
fax number: 52-55-5528-9131
e-mail: eheurta@xolo.conabio.gob.mx

Sol Ortiz
INE-SEMARNAT
Perifénco Sur 5000
So Piso. Col. Cuicui/Co
Mexico D.F.
Mexico
phone number: 52-55-5424-6415
fax number:
e-mail: solortiz@ine.gob.mx

Workshop on Liability and Redress
Article 27 of the Cartagena Protocol on Biosafety
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Liz Peri
Department for International
Development
1 Palace Street
London SW1E 5HE
United Kingdom
phone number: 44-207-023093
fax number: 44-207-023-0624
e-mail: l-peri@dfid.gov.uk

Rhonda Piggott
Director
Foreign Affairs and Trade
Environment Strategies Section
RF Casey Building
John McEwen Crescent
Canberra ACT 2600
Australia
phone number: 61-2-6261-1885
fax number: 61-2-6261-2594
e-mail: rhonda.piggott@dfat.gov.au

Dane Ratliff
Assistant Legal Counsel
Permanent Court of Arbitration
Peace Palace
2517 KJ The Hague
The Netherlands
phone number: 31-70-302-4196
fax number: 31 70 302-4167
e-mail: dratliff@pca-cpa.org

Laura Reifschneider
International Environmental Resources
Vincent Van Goghlaan 65
2343 RM Oegstgeest
The Netherlands
phone number: 31-71-301-4014
fax number: 31-84-832-5834
e-mail: IntEnvRes@cs.com

Ignacio Ruiz Love
Director General De Comunicación e
Información
CIBIOGEM
Picacho-Ajusco No. 154, 6o. Piso, ala
"A"
Col. Jardines en la Montaña
Deleg. Tlalpan, C.P. 14210, Mexico,
D.F.
Mexico
phone number: 52-5631-7361
fax number:
e-mail: iruiz@cibiogem.gob.mx

Kristina Ryan
Policy Officer
Ministry of Foreign Affairs and Trade
Environment Division
Stafford House 40, The Terrace
Wellington
Private Bag 18 901
Wellington
New Zealand
phone number: 64-4-473-2189
fax number: 64-4-494-8507
e-mail: ryan@mfat.govt.nz

Piet Schenkelaars*
Consultant
Schenkelaars Biotechnology
Consultancy
Bio Science Park
Niels Bohrweb 11-13, 2333
CA Leiden
The Netherlands
phone number: 31-71-523-5089
fax number: 31-71-523-5090
e-mail:
pschenkelaars.sbcbiotech@wxs.nl

**Workshop on Liability and Redress
Article 27 of the Cartagena Protocol on Biosafety
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Raymond Solomon
Director
Ministry of Health and the Environment
Department of the Environment
P.O. Box 673
Church Street
Basseterre
Saint Kitts and Nevis
phone number: 869-465-4040 x 128
fax number: 869-466-3915
e-mail: raycsolomon@hotmail.com

Dennis Stephens
Expert Counsel
Canada Grains Council
Suite 1215
220 avenue Portage
Winnipeg (MB) R3C 0A5
Canada
phone number: 204-925-2130
fax number: 204-925-2132
e-mail:
dstephens@canadagrainscouncil.ca

Richard Tapper
Consultant
WWF International
Environment Business and Development
Group
16 Glenville Road
Kingston upon Thames KT2 6DD
United Kingdom
phone number: 44-208-549-1988
fax number: 44-208-549-1988
e-mail: rtapper@dircon.co.uk

Elmo Thomas
Directorate of Research and Science
Private Bag 13391
Windhoek
Namibia
phone number: 264-61-270-6152
fax number: 264-61-270-6143
e-mail: ethomas@mheutst.gov.na

Clarine Verhoog
Intern
Washington Biotechnology Action
Council
Orteliusstraat 342 II
1056 PS
Amsterdam
The Netherlands
phone number: 31-20-6161269
fax number:
e-mail: Clarinev@hotmail.com

Juan Lopez Villar
Adviser on Genetic Engineering
Friends Of The Earth
International
Rue Blanche 29
1060 Brussels
Belgium
phone number: 32-2-542-0187
fax number: 32-2-537-5596
e-mail: juan.lopez@foeurope.org

Conrad von Kameke*
Director, Government Affairs
Monsanto Company
Under den Linden 21
10117 Berlin
Germany
phone number: 49-30-20-92-41-33
fax number: 49-30-20-92-43-11
e-mail:
conrad.von.kameke@monsanto.com

Workshop on Liability and Redress
Article 27 of the Cartagena Protocol on Biosafety
Attendees (21 April 2002)

Xueman Wang
Programme Officer, Legal and Policy
Affairs, Biosafety Protocol
Convention on Biological Diversity
Secretariat
World Trade Centre
393, Saint-Jacques Street, Suite 300
Montreal, Quebec H2Y 1N9
Canada
phone number: 514-287-7054
fax number: 514-288-6588
e-mail: xueman.wang@biodiv.org

Gert Willemse
Acting Director, Biodiversity
Management
Ministry of Environmental Affairs and
Tourism
Department of Environmental Affairs
and Tourism
Fedsure Forum Building
Private Bag X447
Pretoria 0001
South Africa
phone number: 27-12-310-3836
fax number: 27-12-320-7026
e-mail: gwillemse@ozone.pwv.gov.za

Philemon Yang
Cameroon Ambassador to Canada
Ministry of External Relations
170 Clemow Avenue
Ottawa, Ontario K1S 2B4
Canada
phone number: 613-236-1522
fax number: 613-236-3885
e-mail: philyunji@aol.com

Kathryn Youel Page
U.S. Department of State
2201 C Street NW, Room 6420
Washington, DC 20007
United States
phone number: 202-647-1370
e-mail: pageky@state.gov

Meridian Institute Staff

Todd Barker
Partner
Meridian Institute
29 Tarbox Road
Jericho, VT 05465
United States
phone number: 1-802-899-2625
fax number: 1-802-899-2956
e-mail: tbarker@merid.org

Rex Raimond
Mediator
Meridian Institute
PO Box 1829
Dillon, CO 80435
United States
phone number: 1-970-513-8340 x230
fax number: 1-970-513-8348
e-mail: rraimond@merid.org

Shawn Walker
Project Coordinator
Meridian Institute
1101 14th Street NW
Suite 420
Washington, DC 20005
phone number: 1-202-354-6450
fax number: 1-202-354-6441
e-mail: shawnwalker@merid.org