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Report of the participation of the Public Research and Regulation Initiative (PRRI)

in

the Fourth meeting of the Parties to the Cartagena Protocol on Biosafety (MOP-4)
12-16 May 2008

the Ninth meeting of the Conference of the Parties to the Convention on Biological Diversity (COP-9)
19 - 30 May 2008

Bonn, Germany

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1. Introduction

The Public Research and Regulation Initiative (PRRI) offers a forum for the public research sector to be informed about and involved in international agreements that are relevant to modern biotechnology, such as the Cartagena Protocol on Biosafety (CPB) and the Convention on Biological Diversity (CBD). Since it's foundation in 2004, PRRI has participated actively in the second Meeting of the Parties to the Cartagena Protocol on Biosafety (MOP2), MOP3, the eight Conference of the Parties to the Convention on Biological Diversity (COP8) and numerous other international meetings. Detailed information about PRRI and it's participation in international negotiations is published on the PRRI website (www.pubresreg.org).

This document gives a report of the participation of PRRI in MOP4 and COP9, including an assessment of the outcome of the negotiations. It concludes with steps to be taken to prepare for MOP5 and COP10 in Japan in 2010.

2. PRRI participation in MOP4 and COP9.

Over 40 scientists participated under the umbrella of PRRI in MOP4, and 10 participants in COP8. The list of participants, the preparatory documents and the statements made by PRRI, can be found on it's website.

The main objectives of the participation of the PRRI in these international negotiations are to make delegates aware that a substantial part of the research on modern biotechnology is conducted for the public good in public research institutes worldwide and assist them by making scientific knowledge available. In addition, PRRI looks after interests and concerns of the public research sector when discussing different options and their implications.

Public researchers associated with PRRI met these objectives in MOP4 and COP9 by:

- Making interventions
- Meeting with other delegations
- Organising side events
- Attending side events of others (NGO's, governments and industry)
- Engaging in informal discussions with delegates

To make all of this possible PRRI has requested and received financial support to cover the costs of the scientists participation in these meetings. Therefore, PRRI expresses its sincere appreciation to the governments of Canada, Spain and the United States, as well as to the European Commission and private sector organizations for their financial contributions.

Preparing for MOP4 and COP9

PRRI regional preparatory meetings

In order to introduce public researchers to the Cartagena Protocol on Biosafety (CPB), the Meetings of the Parties (MOPs) and to seek their input on the topics on the agenda of MOP4,

PRRI has organised a number regional preparatory meetings. At these meetings the general outline and objectives of the CPB were presented including it's relation of the CBD.

The audience was informed about the main mechanisms of the CPB, including:

- The Advance Informed Agreement (AIA) procedure for transboundary movement of Living Modified Organisms (LMOs) for release into the environment in countries that do not yet have biosafety regulations in place,
- The procedure for LMOs intended for food, feed, and processing (FFP),
- Biosafety Clearing House Mechanism,
- Agreed principles and methodology for Risk Assessment.

The PRRI regional preparatory meetings were to the extent possible co-organised with regional organisations and in conjunction with existing meetings. The following PRRI regional preparatory meetings were organised:

- Africa, Johannesburg in collaboration with FARA and AfricaBio during FARA's Science Week, 11 June 2007.
- Europe, Barcelona in collaboration with the EFB during their European Congress on Biotechnology, 17 September 2007.
- North America, Davis in collaboration with Seed Biotechnology Center during their international seed meeting, 17 September 2007.
- Latin America, Ouro Preto in collaboration with ANBio during their 5th Biosafety Congress, 21 September 2007.

Intersessional CPB and CBD meetings

Between the COPs and MOPs the CBD Secretariat organises meetings on specific subjects to prepare for the next COP or MOP. In preparation of participation of public researchers in MOP4, PRRI has submitted written input for and/or participated in the following intersessional meetings:

- Second Ad Hoc Open-ended Working Group of Legal and Technical Experts on Liability and Redress in the context of the Protocol, 19-22 Feb 2007 Montreal, Canada
- Fourth meeting of the Liaison Group on Capacity-building for Biosafety, 26 February - 2 March 2007, Lusaka, Zambia.
- The Second International Meeting of Academic Institutions and Organizations Involved in Biosafety Education and Training, 16 - 18 April 2007, Kuala Lumpur, Malaysia
- Canada Norway Expert Workshop on Risk Assessment for Future Applications of Modern Biotechnology, 4-6 June 2007, Montreal, Canada
- Twelfth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice, 2- 6 July 2007 - UNESCO, Paris, France.
- Third Ad Hoc Open-ended Working Group of Legal and Technical Experts on Liability and Redress in the context of the Protocol, 22-26 October 2007, Montreal, Canada
- Fifth meeting of the Liaison Group on Capacity-building for Biosafety, 14 - 15 February 2008, New Delhi, India
- Thirteenth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA 13), 18 - 22 Feb 2008, Rome, Italy
- Fifth meeting of the Ad Hoc Open-ended Working Group of Legal and Technical Experts on Liability and Redress in the context of the Protocol, 12 - 19 March 2008, Cartagena, Colombia
- Asia Sub-Regional Workshop on Capacity-Building and Exchange of Experiences on Risk Assessment and Risk Management of Living Modified Organisms, 7 - 9 April 2008, Kuala Lumpur, Malaysia

Preparatory meeting day before the MOP

One day before the start of MOP4, on Sunday 11 May 2008, PRRI organised a full day preparatory meeting for the PRRI participants to plan for the activities of the upcoming week. At this meeting the participating scientists were first informed about the procedures of the negotiations, discussed the items on the agenda, prepared statements on issues relevant for their field of work and prepared their presentations for the different side events.

PRRI's activities at MOP4

Daily coordination meetings
Every morning a coordination meeting was held to assess with the PRRI participants the negotiations of the previous day and discuss the progress and PRRI's interactions and interventions. Items on the agenda of the present day were discussed and if necessary statements were adjusted or new ones prepared. Finally the participation of PRRI members in side events of others was coordinated to make sure all events organized by other organisations were attended by scientists.

Plaza of Diversity
Together with the EC project BIOSAFENET, PRRI provided scientific information to party delegates at their exhibition booth on the 'Plaza of Diversity'. At the stand public researchers were present and answered questions in an informal setting. Peer-reviewed articles, posters and scientific books were made available as background information.

PRRI Side Events
During MOP4 and COP9, PRRI organised side events with the aim of providing the negotiating delegates with scientific background information on public research in agricultural biotechnology. The presentations can be downloaded on the PRRI website (www.pubresreg.org)

The following side events were held:

1. The need for public research in modern biotechnology
MOP4 - Monday, 12 May 2008,

> This PRRI side event illustrated the need for modern biotechnology, including genetic engineering, for the public good. This side event focused on "Minor" crops, with no immediate economic benefit. Public researchers presented examples of research carried out in both developed and developing countries, emphasising the important role of the public sector in these developments where the private sector often does not have an interest.
>
> The following presentations were given:
> - Environmental and Socio-Economic Benefits of Public Sector Biotechnology
> by Prof. Jonathan Gressel - Plant Sciences, Weizmann Institute of Science, Israel
> - Genetically Modified Corn & Mycotoxin Reduction
> by Dr. Felicia Wu - Dept of Environmental and Occupational Health, University of Pittsburgh, USA

2. PRRI/BIOSAFENET side event: Risk assessment research
MOP4 - Tuesday, 13 May 2008,

Since the 80s, many thousands of field trials with LMOs have been permitted world wide, and over a hundred genetically modified crop varieties have been approved for commercial growing. In short, many thousands of risk assessments have been conducted to date using the Risk Assessment methodology reflected in the CPB.
This side event started with an introduction by PRRI on practical guidance for risk assessment for releases of LMOs consistent with the methodology reflected in Annex III of the Cartagena Protocol on Biosafety.
This was followed by an overview of different initiatives in the field of biosafety research.

The following presentations were given:

- Introduction, role of Risk Assessment under the Protocol, PRRI guidance on Risk Assessment
  by Piet van der Meer - Executive Secretary Public Research and Regulation Initiative
- Overview of past and current Risk Assessment research, approaches and results (BIOSAFENET)
  by Prof. Joachim Schiemann, Dr. Mark Tepfer, Prof. Ervin Balazs, Dr. Ruud de Maagd, Dr. Julian Ma, Dr. Jeremy Sweet

This side event was a collaborative effort between two EU-funded projects: Science 4 BioReg (a project executed by the Public Research and Regulation Initiative) and BIOSAFENET (an EU-funded network of European scientists working in the field of GMO biosafety research).

3. PRRI/Golden Rice side event: Applying the Protocol methodology for Risk Assessment
MOP4 - Wednesday, 14 May 2008

During this side event a practical approach for conducting a Risk Assessment for releases of LMOs was presented. First the general methodology, consistent with the methodology reflected in Annex III of the CPB was explained to the audience and than this approach applied to the specific case of Golden Rice. In this interactive session the different steps for Golden Rice in the risk assessment were demonstrated, namely: hazard identification, likelihood estimation, evaluation of the consequences, estimation of the overall risk and the possibilities for risk management.

The following presentations were given:

- Environmental Risk Assessment Methodology
  by Piet van der Meer - Executive Secretary Public Research and Regulation Initiative
- Golden Rice and Biofortification: The Long March
  by Dr. Jorge E. Mayer - Golden Rice Project Manager Campus Technologies Freiburg, Germany

This side event was a collaborative effort between the Golden Rice Project (Campus Technologies Freiburg) and the Public Research and Regulation Initiative.

Next to PRRI's own side events, PRRI members participated actively in side events of other organizations. Because of the close collaboration with IFPRI and PBS, a number of PRRI members gave presentations during IFPRI side events. Reports of the following side events hosted by IFPRI and PBS can be found on their website (http://pbsblog.wordpress.com).

- When biotech crops grow, does knowledge flow? Institutions and the impacts of biotech crops on poor farmers
- Implementing the Protocol in Developing Countries: The Impacts of Legal, Trade, and Economic Issues on Biosafety Policy and Regulation
- Risk assessment for nontarget arthropods: principles and practice

3. PRRI positions on the agenda items of MOP4.

This section gives a brief report of the participation of PRRI in MOP4, including an introduction to the different agenda items and the main issues discussed, and the statements prepared by PRRI, as well as an assessment of the outcome of the debate at the end of the MOP4. Not all topics on the agenda of MOP4 are discussed below, since the attention of PRRI focuses on those topics that may have an impact on public research in modern biotechnology.

Items on the agenda of MOP4 relevant for public research:

- Operation and activities of the Biosafety Clearing-House
- Capacity building and the roster of experts
- Handling, transport, packaging and identification of LMOs (Article 18)
- Risk assessment and risk management (Articles 15 and 16)
- Liability and redress (Article 27)
- Subsidiary bodies (Article 30)
- Assessment and review (Article 35)
- Socio-economic considerations (paragraph 2, Article 26)
- Public awareness and participation (paragraph 1, Article 23)
- Options for implementation of the notification requirement under Article 8

Before addressing the above topics in detail, some general observations.

General Observations

A first general observation is that many members of PRRI are working day to day on finding solutions for some of the challenges that the world community faces, such as poverty, environmental degradation and poor human health in developing countries. The Cartagena Protocol on Biosafety is intended to provide Governments with tools to make informed decisions on imports of LMOs. In this context, PRRI participants to MOP4 made the observation that the contribution of some participants at MOPs (which costs many millions) seems to be aimed at slowing down or even stopping research in modern biotechnology rather than on facilitating international collaboration in public research.

A second general observation is directed to the nature of some of the documents that are distributed by some observers to MOP4. We very much welcome the right of observer participants to distribute information in the margins of MOPs. We believe that this is intended to give all participants an opportunity to make information and views pertaining to the implementation of the Cartagena Protocol on Biosafety available to the delegates.
While we understand that there are many different ways of presenting such information, and that in some cases the presentation itself may to a certain extent be provocative to gain attention, it is disheartening to see that during MOP4 some of the documentation has gone beyond the bounds of what is appropriate. PRRI has submitted a detailed letter to express it's concerns to the CBD Secretariat. The letter is published on the PRRI website, www.pubresreg.org

Opening Statement

PRRI is an organisation of public sector scientists who are involved in research and development of modern biotechnology for the public good. It believes that the Biosafety Protocol is an important instrument, because it allows for international sharing of the benefits of modern biotechnology, to which Parties have agreed in article 19 of the Convention of Biodiversity. This same article 19 is the basis of the Protocol.

The world community faces immense challenges caused by population growth, changes in consumption patterns, environmental degradation, and climate change. These developments confront us, as well as future generations, with extreme challenges for the sustainable production of food, feed, fiber and fuel. We need to empower local farmers to produce more crop per hectare, more crop per litre of water, with less input of fertilisers and-pesticides, and with less soil erosion. These challenges cannot be solved by current practices alone if we do not want to further encroach into the last natural habitats. Believing otherwise would be irresponsible to future generations.

While no single technology can solve these complex problems by itself, modern biotechnology can contribute significantly to finding solutions. The experiences with the genetically modified crop varieties that have been grown commercially since 1995 by millions of farmers, confirm this in terms of increased yield, reduced pesticide use, reduced fossil fuel use, and reduced soil erosion. PRRI wishes for all Parties to understand that there is an urgent need for intensified public research and development in modern biotechnology to address local constraints, in particular in crops of importance to developing countries.

Underlining that modern biotechnology carries no inherent risks, and that any questions about potential unintended adverse effects can be addressed adequately through the risk assessment methodology of the Protocol.

PRRI urged the negotiating Parties to constantly assess how the implementation of the Protocol might affect crucially important public research and development in modern biotechnology, to ensure that the Protocol fulfils its promise.

Operation and activities of the Biosafety Clearing-House (BCH)

At its second meeting the MOP adopted a multi-year programme of work on the BCH. At this meeting the parties reviewed the progress made on the implementation of the work programme, including the modifications made to the BCH Central Portal to improve its user-friendliness and accessibility. Other measures have also been taken to improve overall quality of the information registered in the BCH in general with particular reference to the Biosafety Information Resource Centre (BIRC).

PRRI's position on the BCH

The BCH is the entry point for public researchers who need information on the rules and the relevant competent authorities of countries, and the risk assessments upon which those countries have based their decisions regarding LMO applications. Therefore it is crucial for public research on biotechnology that this information be available, clear, and accurate.

PRRI feels that the recent changes to the BCH have helped to improve its clarity and usefulness. However, it is unfortunate that many Parties still have not complied with their obligation to place relevant, up to date information on the BCH. This lack of information is a serious hindrance to public research. PRRI urged parties and non-parties to comply with up to date, clear, and accurate information about rules, competent authorities, and risk assessment.

Final discussion of MOP4 on the issue of the BCH

The Relevant paragraphs of UNEP/CBD/BS/COP-MOP/4/18 on Biosafety Clearing-House state:

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

1. *Reminds* all parties of their obligations, and *invites* all other Governments, to submit to the Biosafety Clearing-House complete information pertaining to decisions regarding the first intentional transboundary movements of living modified organisms for intentional introduction into the environment and the risk assessments associated with such decisions;
2. *Urges* all Parties and invites all other Governments to provide relevant information to the Biosafety Clearing-House, including information pertaining to decisions regarding the release or import of living modified organisms and risk assessments taken prior to entry into force of the Protocol;
3. Invites Parties, other Governments and users of the Biosafety Clearing-House to continue to make relevant biosafety information and resources available through the Biosafety Information Resource Centre (BIRC);
4. *Requests* the Executive Secretary, with the view to facilitating the ease of access to the Biosafety Clearing-House to:
   (a) Improve the electronic tools available for the analysis of search results (e.g. different sorting options);
   (b) Include electronic links to national reports in the country profile pages; and
   (c) Undertake additional activities, such as the introduction of online tools for statistical analysis and graphic representations of data;
5. *Requests* the Executive Secretary to improve the structure of the common formats and simplify the registration procedure, for instance by increasing the use of metadata in addition to free-text entry.
6. *Also requests* the Executive Secretary to implement a procedure for the validation of information in the Central Portal of the Biosafety Clearing-House which establishes a timeframe for the confirmation or updating of information by Parties;
7. *Further requests* the Executive Secretary to continue assisting national nodes for the Biosafety Clearing-House that are interlinked and interoperable with the Central Portal through the maintenance and improvement of the two applications, 'Hermes' and the 'BCH Ajax Plug-in';
8. *Requests* the Executive Secretary to commission a study of users and potential users of the Biosafety Clearing-House in order to:
   (a) Assess what information users and potential users of the Biosafety Clearing-House would find useful; and
   (b) Prioritize the work programme of the Biosafety Clearing-House in order to focus the efforts of the Secretariat on making the Biosafety Clearing-House a useful tool;
11. *Urges* the Global Environment Facility to extend the UNEP-GEF Biosafety Clearing-House project, in its current form as a global project with a view to ensuring sustainability of national BCH nodes and providing more capacity-building support, with special attention to targeted

stakeholders (e.g., customs departments and phytosanitary inspectors), and to provide additional funding for these activities from sources other than the Resource Allocation Framework (RAF) taking into consideration the global nature of the project.

PRRI welcomes the MOP's decision to remind parties of their obligations and urge them to place relevant, up to date information on the BCH. PRRI stands ready to provide input for the study commissioned by the Executive Secretary on the userfriendliness and usefulness of this web based tool.

Capacity building and the roster of experts

The status of implementing the 'Action Plan for Building Capacities for the Effective Implementation of the Protocol and its Coordination Mechanism' (UNEP/CBD/BS/COP-MOP/4/4) was presented by the Executive Secretary. The parties discussed the main Capacity building activities and considered a report on the operational experience in using the preliminary indicators for monitoring this implementation that were adopted at MOP1 (UNEP/CBD/BS/COP-MOP/4/4/Add.1). Many countries indicated that still a lot needs to be done to build capacities and that capacity building is essential for the successful implementation of the protocol.

Furthermore, MOP4 considered criteria and minimum requirements (including minimum qualifications and experience) for experts to be listed on the Roster of Experts, a recommended quality control mechanism as well as other measures for improving the effectiveness and use of the roster.

PRRI's position on Capacity building:
PRRI believes that there have been considerable degrees of success in the implementation of the different components of the Action Plan. However unfortunately the needs and priorities of some countries still remain unmet due to a number of limiting factors and operational deficiencies that have constrained the implementation and effectiveness of the Action Plan, including: a lack of adequate funding and other resources, limited sharing of information, poor coordination among the different initiatives. A concerted effort is therefore needed to address those constraints and to improve the delivery and coordination of capacity building activities. It is also important for countries to cooperate and pool resources, including through international and regional organizations.

PRRI believes that the Action Plan as it currently stands is still relevant for the effective implementation of the Protocol. The main problem has to do with is the slow progress in its implementation due to the various constraints outlined above. Therefore, as proposed in document UNEP/CBD/BS/COP-MOP/3/4/Add.1, the MOP may wish to simply update the current Action Plan to incorporate key experiences and lessons learned during its initial implementation and adopt measures to improve its implementation and effectiveness at different levels.

PRRI's position on the Roster of Experts:
The facility of Roster of Experts on biosafety remains largely underutilized and there is a need to reexamine and update the list. For experts to be included on the roster there should be minimum requirements for fresh nominations and nominations already made should be reassessed. Sufficient details about the experts regarding the academic, practical and professional experience with publications should be the criteria for their nominations. The present form if used judiciously provides adequate details but we still need to have a proper assessment for expert's nomination.

Final decision of MOP4 on the issue of Capacity building:

The Relevant paragraphs of UNEP/CBD/BS/COP-MOP/4/18 on Capacity-building state:

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

2. *Urges* Parties, other Governments, donors and relevant organizations to provide new and additional financial and technical support to developing countries, in particular the least developed and small island developing States among them, and countries with economies in transition to address their capacity-building needs;

3. *Urges* the Global Environment Facility to provide additional financial support from sources other than the Resource Allocation Framework (RAF) for capacity-building activities in developing countries, in particular the least developed and small island developing States among them, and countries with economies in transition;

4. *Invites* Parties, other Governments and relevant organizations to provide information on their capacity-building activities to the Secretariat and the Biosafety Clearing-House at least six months before the regular meetings of the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol, in order to facilitate more comprehensive reporting on the implementation of the capacity-building Action Plan and the sharing of experiences in capacity-building activities;

6. *Welcomes* the offer of UNEP to undertake an expert review of capacity-building activities under GEF funding, in collaboration with GEF, its agencies and the Executive Secretary, with a view to assessing the effectiveness of various approaches to capacity-building and developing lessons learned and *invites* Parties, other Governments, donors and relevant organization to provide additional support to extend the review to non-GEF activities and submit the review to the BCH.

Biosafety education and training
Recognizing the need for long-tem biosafety education and training programmes to develop core expertise for the effective implementation of the Protocol,

Noting the limited number of existing biosafety academic programmes,

7. *Invites* Parties and other Governments to complete and return to the Secretariat the biosafety training needs assessment matrix developed by the second international meeting of academic institutions and organizations involved in biosafety education and training and disseminated by the Executive Secretary;

8. *Invites* relevant national authorities, in particular national focal points to the Protocol to collaborate with academic institutions and other relevant organizations in the development and/or expansion of biosafety academic programmes;

9. *Invites* developed country Parties, other Governments, GEF, bilateral and multi-lateral agencies to provide financial and other support to enable universities and relevant institutions to develop and/or expand existing biosafety academic programmes and provide scholarships to students from developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition;

10. *Invites* Parties other Governments and relevant organizations to share through BCH the existing academic and training materials;

12. *Requests* the Executive Secretary to prepare a synthesis of the information provided by Parties and other Governments in the training needs assessment matrix referred to in paragraph 7 above and make the synthesis report available through the Biosafety Clearing-House;

13. *Also requests* the Executive Secretary to initiate collaboration with relevant academic institutions involved in biosafety education and training;

Coordination mechanism

14. *Requests* the Executive Secretary to continue encouraging relevant organizations and bilateral and multilateral donor agencies to support and participate actively in the Coordination Mechanism;

15. *Also requests* the Executive Secretary to continue undertaking measures to improve the implementation of the Coordination Mechanism and provide a report to the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol;

Indicators

16. *Approves* the revised set of indicators for monitoring the updated Action Plan for Building Capacities for the Effective Implementation of the Protocol annexed to this decision;

17. *Invites* Parties, other Governments and relevant organizations to submit to the Executive Secretary, at least six months before the sixth meeting of the Parties, information on their experiences with, and lessons learned from, the use of the revised set of indicators;

18. *Invites also* Parties, other Governments and relevant organizations to take into account, when selecting or using indicators for monitoring their capacity-building initiatives, the experiences and lessons learned from relevant processes, including those described in the note by the Executive Secretary (UNEP/CBD/BS/COP-MOP/4/4/Add.1);

19. *Invites* Parties and other Governments to undertake stocktaking assessments or compile information collected under relevant assessment processes to establish their capacity-building baselines and benchmarks and communicate this information to the Executive Secretary;

20. *Requests* the Executive Secretary to prepare a synthesis report on the experiences with and lessons learned from the use of the revised set of indicators on the basis of the submissions by Parties, other Governments and relevant organizations for consideration at the sixth meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Protocol.

PRRI is pleased with the recognition of parties for the need to develop core expertise in biosafety trough the implementation of long term biosafety education programmes and recognizing the essential collaboration with academic institutions for the development of such programmes.

Final decision of MOP4 on the issue of the Roster of Experts

The Relevant paragraphs of UNEP/CBD/BS/COP-MOP/4/18 on Roster of biosafety experts:

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

1. *Adopts* the criteria and minimum requirements for experts to be nominated to the roster of experts, contained in annex I to the present decision;
2. *Adopts also* the guidelines for the roster of experts, as well as the nomination form for the roster contained in annexes II and III to the present decision, respectively;
3. *Requests* Parties and other Governments to make fresh nominations in accordance with the new criteria and minimum requirements, using the revised nomination form;
4. *Requests* the Executive Secretary to remove all existing records in the roster within three months and refill the roster with those experts who are nominated or re-nominated by Parties and Governments;
5. *Urges* Parties and other Governments to ensure that their nominees meet the criteria and minimum requirements and possess the highest professional qualities and expertise in the fields for which they are nominated and to verify that the information submitted on the nomination forms is complete and accurate before submitting it to the Secretariat;
6. *Authorizes* the Secretariat to check all nomination forms for completeness and return to the nominating Governments any nomination forms that are incomplete and/or do not meet the criteria and minimum requirements;
7. *Decides* that experts shall be maintained on the roster for a period of four years from the last update of their information, after which they will be deleted from the roster unless re-nominated;
8. *Requests* Parties and other Governments to keep the information on their nominated experts in the roster up-to-date and to undertake, or require the experts to undertake, a general review and update of their information every two years;
9. *Requests* the Executive Secretary to produce and disseminate to all Parties, other Governments and relevant organizations a simple “Guide to the Roster of Biosafety Experts”, to further sensitize them as to the nature, role and operational procedures for the roster, including the new minimum requirements for the experts to nominated to the roster and the measures to enhance its quality;
10. *Requests* the Executive Secretary to prepare a document for consideration at its sixth meeting in order to evaluate the performance of the roster;
11. *Requests* the Executive Secretary to extend the roster of experts to include a “BCH experts” category in the Biosafety Clearing-House, and *invites* Parties to nominate to the roster of experts those experts who have met or exceeded their country’s expectations;

PRRI very much welcomes the outcome of the debate on the Roster of Experts. We feel that the implementation of minimal criteria and requirements for experts to be included on the roster is crucial for the roster’s functionality. We welcome the MOP’s decision to not only apply these requirements on new applications but also evaluate those experts who have already been nominated by parties in the past. Additionally, PRRI advises that the results of the work of these experts should be placed on the BCH and hopes such a decision will be taken by the future MOP.

Handling, transport, packaging and identification of LMOs (HTPI) (Article 18)

Article 18 of the Protocol addresses the issue of handling, transport, packaging and identification of living modified organisms (LMOs).

- Paragraph 1 of the Article is about safe handling, transport and packaging of LMOs. Each Party to the Protocol has the obligation to take necessary measures that will keep LMOs handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.
- Paragraph 2 sets out obligations on each Party to take measures that require the identification of LMOs in accompanying documentation. These identification measures vary depending on the intended use of the LMOs. Accordingly there are different requirements for LMOs intended for direct use as food or feed or for processing (LMO-FFPs) (subparagraph (a)), LMOs destined for contained use (subparagraph (b)), and LMOs for intentional introduction into the environment (subparagraph (c)).
- Paragraph 3 of Article 18 provides for a possible development of standards by Parties to the Protocol, as may be needed, with regard to practices in the identification, handling, packaging and transporting of LMOs.

This agenda item was already addressed at the previous three MOPs. At this meeting, views and information submitted by Parties, other Governments and relevant international organizations were reviewed. The MOP considered the submissions made regarding the need for and modalities of developing standards with regard to identification, handling, packaging and transporting LMOs (paragraph 3 of Article 18). Furthermore, the meeting reviewed the experience gained with the use of sampling and detection techniques and on the need for and modalities of developing criteria for acceptability of, and harmonizing, sampling and detection techniques. Not many submissions were sent to the Secretariat for MOP4. Practically all parties agreed that internationally harmonised sampling and detection methods and standards are needed to facilitate trade and also bring costs of procedures involved down. A very detailed document, providing an overview of EU activities around detection and handling of GMOs has been posted at BIRC-BCH.

PRRI's position on HTPI

PRRI stated in its submission from 2007 on Art 18 that the existing documentation systems in combination with the additional guidance provided by the MOP at its first meeting are sufficient and that there is at this stage no need to develop further documentation. Our statement in MOP3 stressed the fact that the accompanying information should not degenerate into a stand-alone risk assessment, as this should have already been conducted prior to the parties agreeing to the transport.

PRRI commends the MOP for the pragmatic approach taken to review the adequacy of existing rules and standards regarding the identification, handling, packaging or transport of LMOs by requesting the Parties to submit their experiences based on existing mechanisms.

Research in modern biotechnology typically involves sending research material between research labs in countries and between countries for further development and testing in contained facilities and field trials. Researchers thereby routinely, with great care and using their scientific knowledge and experience take care of handling, transport, packaging and identification of all kinds of organisms, including LMOs.

The appropriate way for packaging, handling and labeling often has to take into account requirements resulting different regulations and guidelines, such as internal biosafety procedures, regulations for pathogens, transport regulations, phytosanitary regulations etc. In addition, transport, packaging, handling and labeling of organisms have to be done in a manner that the involved organisms are carefully protected from outside influences and contaminations.

Final decision of MOP4 on the issue of HTPI

The Relevant paragraphs of UNEP/CBD/BS/COP-MOP/4/18 on HTPI para 2(b) and (c)

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

1. *Requests* Parties and *encourages* other Governments and relevant international organizations to continue to implement the requirements under paragraphs 2(b) and 2(c) of Article 18 and associated decisions by the Conference of the Parties serving as the meeting of the Parties to the Protocol;
2. *Decides* to review this matter at its sixth meeting in light of the review of experience based on the analysis of the second national reports.

The Relevant paragraphs of UNEP/CBD/BS/COP-MOP/4/18 on HTPI para 3

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

1. *Decides* to continue to gain experience in the implementation of the Protocol's provisions regarding handling, transport, packaging and identification, and *requests* the Executive Secretary to continue to collaborate with relevant international organizations in this regard;
2. *Requests* Parties and *encourages* other Governments and international organizations to ensure that information related to standards on the identification, handling, packaging and transport of living modified organisms is available through the Biosafety Clearing-House;
3. *Encourages* Parties to participate in ongoing work on standards on handling, transport, packaging and identification of living modified organisms taking place in other relevant international organizations and, *decides* that if a gap in such standards has been identified, to consider the need for and modalities of developing the necessary standards, in particular by referring such gaps to other relevant international organizations;
4. *Requests* the Executive Secretary to organize an online conference to: (i) identify the relevant standards with regard to handling, transport, packaging and identification of living modified organisms; (ii) identify where gaps exist; and (iii) suggest possible modalities to fill the gaps; and to prepare a summary of the outcome of the conference, reflecting the full range of views expressed, for the consideration of the Conference of the Parties serving as the meeting of the Parties to Protocol at its fifth meeting;
5. *Invites* Parties, other Governments and relevant international organizations to provide the Executive Secretary with guiding questions for this online conference and *requests* the Executive Secretary to finalise the list of questions in consultation with the Bureau of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

PRRI welcomes the decision to evaluate if there are any gaps in the standards on handling, transport, packaging and identification of living modified organisms and offers it support to assist this evaluation and if such gaps exist provide advise on possible modalities to fill these gaps.

Risk assessment and risk management (Articles 15 and 16)

Risk assessment and Risk Management (Articles 15 and 16) are key articles in the protocol. A risk assessment underpins the transboundary movement of LMO's; therefore the proper functioning of the Protocol requires proper application of Articles 15 and 16. The MOP considered the need for further guidance on specific aspects of risk assessment and risk management, and if needed, the appropriate way to provide that guidance. Prior to MOP4 regional workshops on capacity-building and exchange of experiences on risk assessment and management were held, and a background document summarizing those workshops was prepared by the secretariat. Another major item that was discussed was the means by which LMO's and traits that may have adverse environmental effect could be identified.

Issues discussed by the MOP:
1. Further guidance on risk assessment and risk management,
2. Collaboration in identifying living modified organisms that may have an adverse effect,
3. Capacity-building relevant to risk assessment and risk management.

PRRI's position on Risk Assessment and Risk Management:
1. On further guidance on risk assessment and risk management, PRRI holds the position that the risk assessment methodology as described in Annex III of the Protocol is adequate to conduct any risk assessment. However, more specific guidance on how to apply this methodology in specific cases might be warranted. PRRI recommended that a consultation process be started to determine whether there were any cases where the methodology in Annex III were inadequate.
2. On collaboration in identifying LMO's that may have an adverse effect, PRRI recommended that in addition to identifying LMO's that may have an adverse effect, LMO's that were not likely to have an adverse effect should be identified as well.

Final decision of MOP4 on the issue of Risk Assessment and Risk Management:

The Relevant paragraphs of UNEP/CBD/BS/COP-MOP/4/18 on Risk Assessment and Risk Management

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

I. Further guidance on specific aspects of risk assessment and risk management:
3. Decides to establish through the Biosafety Clearing-House an open-ended online forum on specific aspects on risk assessment as referenced to in the annex;
4. Decides to establish an Ad Hoc Technical Expert Group on Risk Assessment and Risk Management according to the modality of work and the terms of reference annexed hereto;
5. Invites Parties, other Governments and relevant organizations to submit to the Executive Secretary, prior to the first meeting of the Ad Hoc Technical Expert Group, information relevant to the work of the Group, particularly on existing guidance documents on risk assessment;
6. Requests the Executive Secretary to:
(a) Convene ad hoc discussion groups and at least one real-time online conference per region prior to each of the meetings of the Ad Hoc Technical Expert Group, with the view to

identifying major issues related to specific aspects of risk assessment and risk management as referenced to in the annex;

(b) Convene, prior to the fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, and subject to the necessary financial resources being made available, two meetings of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management;

II. Collaboration in identifying living modified organisms that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

8. Requests Parties and invites other Governments and relevant organizations to submit to the Executive Secretary, not later than three months prior to the first meeting of the Ad Hoc Technical Expert Group, scientifically sound information available at that time, on the identification of living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health;

9. Requests the Executive Secretary to compile the information received and to prepare a synthesis report for consideration by the Ad Hoc Technical Expert Group and the Parties;

III. Capacity-building relevant to risk assessment and risk management

Recalling that risk assessment and other scientific and technical expertise are indicated as key elements requiring concrete action in the updated Action Plan for Building Capacities for the Effective Implementation of the Biosafety Protocol,

12. Requests the Executive Secretary to convene, in cooperation with relevant regional organizations, at the earliest convenient date and subject to the availability of financial resources, a sub-regional workshop on capacity-building and exchange of experiences on risk assessment and risk management of living modified organisms in the Pacific subregion;

13. Requests the Executive Secretary, subject to availability of funds, to coordinate and facilitate, along with other relevant United Nations bodies and other international organizations, the development of training on risk assessment and risk management in relation to living modified organisms, and to convene prior to the fifth meeting of the Conference of the Parties serving as the meeting of the Parties, regional or subregional training courses to enable countries to gain hands-on experience in preparing and evaluating risk assessment reports in accordance to the articles and Annex III of the Protocol.

14. These courses could, inter alia, cover:
    (a) How to establish interdisciplinary teamwork in the context of risk assessment;
    (b) Developing skills in using and interpreting existing information, as well as identifying and addressing information gaps; and
    (c) How to establish baseline information to be used in risk assessment;

The parties decided to establish an online forum, through the Biosafety Clearing House to provide further guidance on RA and RM, on various topics such as the following:

a. A roadmap for conducting risk assessment consistent with Annex III
b. Further guidance on risk assessment of different types of LMO's, specific traits, and different receiving environments, including monitoring of long-term effects.
c. Establishment of an ad hoc Technical Expert Group (AHTEG) to consider the same areas a. and b. listed above.

The MOP requested parties and other relevant organizations to submit to the AHTEG information to identify LMO's that may have an adverse environmental effect. Further the MOP requested the Executive Secretary of the Protocol to coordinate and facilitate training on risk assessment and risk management, subject to funds available.

PRRI will provide input for the AHTEG meetings and share the experience our members have with conducting risk assessment. PRRI has produced a guidance document on notifications and risk assessment on genetically modified crop plants to assist public research scientists preparing notifications for the deliberate release into the environment. The focus of this guide is bases on the requirements under Annex III of the Protocol and provides additional guidance on the technical and scientific information required for notification and risk assessment. PRRI plans to expand and update the guidance document

Liability and redress (Article 27)

When the Protocol was agreed, the topic of liability and redress was addressed through Article 27, which provided for the MOP to agree on a process for negotiation of rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms. The Article specifies that Parties should "endeavour to complete this process within four years."

At its first meeting the MOP agreed to setting up an Open-ended Ad Hoc Working to report back to the MOP within the four-year deadline. Decision BS-I-8 required this Group to "present its final report, together with the proposed international rules and procedures in the field of liability and redress pursuant to Article 27 of the Protocol, to the MOP."

The group met on 5 occasions, and a negotiating group termed 'friends of the co-chairs' met just before MOP4..

The MOP was presented with the final report of the Open-ended Ad Hoc Working Group including the outcomes of the meeting of the Friends of the Co-Chairs, which had finalized its work in Bonn over the previous weekend. In reality, however, little progress had been made on scope, damage and primary compensation scheme. The negotiations therefore continued throughout MOP4. On most occasions, the meetings were open, allowing representatives of PRRI to follow the ongoing debate but not to actively take part in the discussions.

PRRI presented its position on the various issues to delegates from a number of countries throughout these negotiations. [insert position here
The first and most contentious deliberations centred on the choice of instrument and whether it should be guidance or legally binding. The Group debated the following options:
1) non-legally binding guidelines,
2) legally binding regime administrative regime,
3) legally binding civil liability system,
4) a two step-approach consisting of developing one or more non-binding instruments, evaluating the effects of the instrument(s), and then considering developing one or more legally binding instruments.

There was a great divergence of view, with some delegates insisting on a legally binding civil liability regime, whilst others indicated that they would not be prepared to accept anything other

than guidance. The countries opposed to a civil liability regime proposed an administrative approach. Propopents of a civil liability regime rejected this approach, even if made legally binding, since it did not include certain elements they considered critical.

PRRI's position on Liability and Redress

Scope – damage to conservation and sustainable use of biodiversity
The Vienna Convention on the Law of Treaties states that "a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose". Given the object and purpose of the Protocol as laid down in article 1, the scope of any rules and procedures on liability and redress under the Protocol should focus on damage to the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Nature of the instrument –administrative system
Central in the debate on damage to biodiversity should be speedy and adequate remediation of damage. This goal is best achieved by a so-called 'administrative system' that empowers national competent authorities to require remediation or undertake remediation of damage and claim the costs from the responsible operator. On 22 February 2007, PRRI submitted a written document to the Ad Hoc Open-ended Working Group of Legal and Technical Expert on Liability and Redress in the context of the Protocol, analysing the different systems and further elaborated on the advantages of the administrative system. This submission can be found on PRRI's website (www.pubresreg.org)

Strict Liability, Funds and Mandatory Insurance
Strict liability, funds and mandatory insurance are typically applied in cases of activities that carry inherent risks, such as transport of hazardous chemicals. Modern biotechnology and LMOs do not carry inherent risks. On the contrary, modern biotechnology has great potential for human well-being and the environment. Whether or not the resulting LMOs can also have adverse effects on biodiversity will depend on the characteristics of the LMO and the way in which they are used. The Protocol contains an internationally agreed methodology of risk assessment to assess this. After over ten years of growing LMOs commercially on over hundreds of millions of hectares, and after many thousands of field trials, there are no verifiable reports of damage to biodiversity or human health. Strict liability will have a negative effect on technology transfer, because research institutes will become very hesitant to make research material available. Mandatory insurance will also have an immediate negative effect on public research, because insurance is either non-existent or only available at premiums that are so high that only rich multinational companies could afford it. Strict liability and mandatory insurance should only be considered for cases where the risk assessment has indicated that the involved LMOs are of very high risk.

Final discussion of MOP4 on the issue of Liability and Redress
Ultimately, the group considered a compromise proposal that included the following elements;

- a negotiated administrative system;
- guidelines on civil liability setting out minimum core elements;
- a reference to the guidelines in the legally binding regime;
- a legally binding provision on enforcement of judgments on damage from transboundary movement of LMOs in domestic courts and provisions on enforcement of foreign judgments under domestic law; and

- a review process, with the possibility of making other elements on civil liability legally binding on the basis of experience gained.
-

It was agreed, after contentious debate, that there was a 'compromise in the making' with a legally binding instrument based on the administrative approach with guidelines as suggested above. The chairs explained that finalizing a legally binding instrument at MOP 4 would be impossible, due to the requirement to circulate a draft instrument six months prior to its presentation for adoption and the convening of a legal drafting committee. He suggested that MOP 4 focus on reaching political agreement on all the issues and to convene a drafting committee before the end of 2008 followed by an Extraordinary Meeting of the MOP to adopt the legally binding instrument. Some parties noted that drafting would have to be completed before they could decide whether they support the instrument. Delegates agreed to continue negotiating on the basis of this understanding.

MOP4 therefore agreed to request the CBD Executive Secretary to establish a Group of the Friends of the Co-Chairs, Jimena Nieto and René Lefeber, concerning liability and redress in the context of the Cartagena Protocol on biosafety, with the following terms of reference:

- To hold one meeting in early 2009 and, if deemed necessary by the Co-Chairs, another meeting in early 2010 prior to MOP 5;
- To further negotiate international rules and procedures in the field of liability and redress on the basis of the annex;
- The composition of the group will be: six representatives of the Asia-Pacific region; two representatives of the EU; two representatives of Central and Eastern Europe; six representatives of the African Group; six representatives of the Latin American and Caribbean Group; and New Zealand, Norway, Switzerland and Japan;
- Advisors are selected by the Friends of the Co-Chairs and their participation may be facilitated subject to the availability of funds;
- Observers may be invited to be participants in the meetings at the discretion of the Co-Chairs; and
- The outcome will be presented to MOP 5 for its consideration.

<u>Subsidiary bodies (Article 30)</u>

This issue was considered at the first and third meetings of the MOP. MOP4 considered potential mechanisms for the provision of scientific and technical advice to the MOP including the cost estimations for the various potential mechanisms. The possible options include the establishment of a permanent subsidiary body, or use of subsidiary bodies/mechanisms that may be created on an ad hoc basis.

PRRI's opinion:
PRRI believes that science based, balanced background information on the potential risks and benefits related to LMO's is crucial for the implementation of the protocol therefore scientific advisory bodies can be very helfpul. Such scientific advisory body(ies) should consist of experts on the discussed subject, and it should be prevented that these scientific bodies become another political body in the negotiation process.

Final decision of MOP4 on the issue of Subsidiary bodies:

The Relevant paragraphs of UNEP/CBD/BS/COP-MOP/4/18 on Subsidiary bodies
The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, 1. Decides to establish, as necessary, ad hoc technical expert groups, with specific mandates to address one or more scientific and technical issues as the need arises, and to make recommendations to the Conference of the Parties serving as the meeting of the Parties to the Protocol; 2. Agrees to consider, at its sixth meeting, the need to establish an open-ended subsidiary body for scientific and technical advice under the Protocol.

PRRI welcomes the decision to establish, where appropriate, an ad hoc technical expert group. PRRI is ready to take part in these scientific consultations to provide the MOP with science based, balanced background information on the potential risks and benefits involved with using LMO's.

Assessment and review (Article 35)

The Protocol requires the MOP to undertake, five years after the entry into force of the Protocol, and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes. MOP4 considered submissions made by Parties, other Governments and relevant organizations regarding, *inter alia*, evaluation of the effectiveness of the Protocol, including a review of the decision-making procedures and mechanisms and the compliance procedures and mechanisms adopted at the first meeting, in order to identify the difficulties arising from implementation and to propose appropriate indicators and/or criteria for evaluating effectiveness. The parties discussed on the possible development of a strategic plan for the Protocol to be adopted at their meeting in 2010.

PRRI's position on assessment and review

PRRI believes that in the process of assessment and review, it should in any case be assessed to what extent the Protocol has fulfilled it's functions, namely:

- Provide countries that do not yet have biosafety regulations with a basis to make informed decisions on import of LMOs.
- Contribute to international harmonization of national regulations on areas such as definitions and risk assessment.

These functions are of key importance to public researchers, because it facilitates technology transfer and international collaboration in research and development.

Before the start of MOP4, there were no AIA decisions on imports of LMOs published on the BCH by countries that do not have biosafety regulations. This suggests that in the 5 years of the CPB being in force, the key function of the protocol has not been used. With this in mind, PRRI suggests that the process of assessment and review takes into account the following points:

1. Why are there so few, if any, decisions on import of LMOs by countries that do not have biosafety regulations in place?
2. To what extent are key elements of national regulations, such as definitions and risk assessment, harmonized with the definitions and risk assessment of the CPB?
3. What has been the impact of the CPB on technology transfer and international collaboration in public research and development?

In addition, PRRI also recommends exploring possible mechanisms for flexibility in the procedures, such as special provisions for confined field trials for research and development, which require less information and shorter procedures than placing on the market of LMOs.

Lastly, bearing in mind the wealth of experience with LMOs that has been gained over the years, PRRI believes that the time has come to identify, in accordance with article 7 paragraph 4, which LMOs or groups of LMOs are unlikely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and can therefore be exempted from the AIA procedures.

Final decision of MOP4 on Assessment and Review

The Relevant paragraphs of UNEP/CBD/BS/COP-MOP/4/18 on Assessment and Review

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

1. Requests the Executive Secretary to: (i) develop a sound methodological approach to contribute to an effective second assessment and review of the Protocol, its annexes, procedures and mechanisms, on the basis of the information contained in the first national reports, answers to the "effectiveness questionnaire", the report of the Compliance Committee, information on the Biosafety Clearing-House and any other relevant documents; and (ii) draft criteria or indicators that could apply in the evaluation of the effectiveness of the Protocol and provide an indication of the utility;
2. Invites Parties to make submissions on a strategic plan for the Protocol and requests the Executive Secretary to present a draft strategic plan for consideration at its fifth meeting on this basis.

PRRI plans to keep reminding parties of the possibility to exempt those LMOs or groups of LMOs that are unlikely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Socio-economic considerations (paragraph 2, Article 26)

The CPB encourages parties to cooperate on research and information exchange on any socio-economic impacts of LMOs, especially on indigenous and local communities. At this meeting, parties considered a synthesis of views and available case-studies concerning socio-economic impacts of LMOs (UNEP/CBD/BS/COP-MOP/4/15), and the need for possible action.

PRRI's position on Socio-economics:
In Article 26 of the CPB clearly specifies which socio-economic considerations parties can take into account when making a decision on the import of an LMO. The article is limited to taking into account socio economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, which can include potential beneficial as well as potential negative impacts.

Some examples on the potential and proven environmental and socio-economic benefits of the use of LMOs:

- Increase of yield resulting from insect and disease resistant crop plants has great socio-economic importance in the context of a growing global population.
- The reduction of insecticide use resulting from insect resistant plants with the resulting benefits for non-target organisms; the replacement of certain herbicides by safer, less persistent herbicides due to herbicide tolerant crop plants; reduction of soil erosion and pesticide run-off resulting from herbicide tolerant crop plants, and the reduction in the use of fossil-fuels due to herbicide tolerant crop plants are all beneficial to the environment and biodiversity.
- Reduction of pesticide use is not only good for the environment, but can also have direct health benefits for farmers in developing countries who are currently exposed to the pesticides which they often spray manually.
- The use of BT maize can lead to the reduction of pesticide residues and of cancer causing mycotoxins, which has direct health effects for consumers and lifestock.

PRRI believes that studying the socio-economic impacts of living modified organisms requires a comparator, in a similar way as risk assessment under the Protocol requires a comparison with the risks of using non modified organism. Therefore, comparing with the use of an appropriate non modified comparator used in current agriculture is an essential element in the research in the area of socio-economic impacts of LMOs

Final decision of MOP4 on the issue of socio-economics

The Relevant paragraphs of UNEP/CBD/BS/COP-MOP/4/18 on Socio-economic considerations (Article 26, paragraph 2)

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

1. Notes the importance of cooperation and the need for further study and research in the area of socio-economic impacts of living modified organisms, especially on indigenous and local communities;
3. Further notes the recommendations on capacity-building and socio-economic considerations from the fourth coordination meeting of Governments and organizations implementing and/or funding capacity-building activities (UNEP/CBD/BS/COP-MOP/INF/23, paras. 35-37) and invites the next coordination meeting to further consider possibilities for cooperation in identifying needs for capacity-building among Parties for research and information exchange on socio-economic impacts of living modified organisms and to submit any recommendation for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its fifth meeting;
4. Invites Parties, other Governments and relevant organizations to continue to share their research, research method and experience in taking into account socio-economic impacts of living modified organisms, through the Biosafety Clearing-House, where it could be retrievable using the search term “socio-economic”;
5. Agrees to review this item at its sixth meeting based on information that may be provided through the second national reports.

PRRI has offered its assistance to explore both the positive and negative impacts of LMOs, PRRI is very much prepared to actively contribute to the next coordination meeting.

Public awareness and participation (paragraph 1, Article 23)

Under this item, the MOP considered an interim report on the initiatives and progress made by governments. This report includes experiences gained and lessons learned, in promoting public awareness and participation concerning the safe transfer, handling and use of LMOs, taking into account information contained in the first national reports and the national biosafety frameworks. During the meeting several delegations highlighted the importance of providing sound scientific information on positive aspects of LMOs.

PRRI's opinion on Public awareness and participation

PRRI expressed in its statement that there should be no tolerance for misinformation. We see that the current flood of non-science based information and its use by the media undermines the goals of the Protocol.

PRRI also stated its concern about much effort being made to intend to provide information of potential or unsubstantiated hazards and perceived adverse effects of LMOs in general, which had been highlighted in reports, leading to fear, misconception and needless concern among the public. PRRI added that there was clear evidence of the lack of use of information of the positive economical, social and environmental benefits, and pointed out the fact that the public is completely unaware of the positive social and economic consequences of adopting modern biotechnology.

PRRI suggests that in order to add value to public participation in decision making and enhance public understanding in this subject, efforts should be taken to engage scientists with recognized credentials to assist in outreach and educational programs.

Final decision of MOP4 on the issue of Public awareness and participation

In its decision (UNEP/CBD/BS/COPMOP/4/L.11), the MOP decided to develop a programme of work on public awareness, education and participation concerning the safe transfer, handling and use of LMOs and invited parties, other governments and relevant organizations to submit to the Executive Secretary before MOP 5 their views on the possible elements of a programme of work on public awareness, education and participation and prepare a synthesis of these submissions and views.

The Relevant paragraphs of UNEP/CBD/BS/COP-MOP/4/18 on Public awareness, education and participation

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

1. *Decides* to develop a programme of work on public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms, with specific operational objectives, scope of activities and outputs and modalities of implementation;
2. *Invites* Parties, other Governments and relevant organizations to submit to the Executive Secretary, at least twelve months before the fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, their views on the possible elements of a programme of work on public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms;

3. *Requests* the Executive Secretary to prepare a synthesis of the views in the submissions made by Parties, other Governments and relevant organizations;
4 *Invites* Parties, Governments and relevant organizations to make available through the Biosafety Clearing-House, materials and information on opportunities for supporting projects related to public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms;
5. *Requests* the Executive Secretary to prepare, taking into account submissions made in accordance with paragraph 2 above a programme of work on public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms for consideration at the fifth meeting of the Parties;
6. *Welcomes* the new outreach strategy for the Cartagena Protocol on Biosafety (2008-2012) developed by the Executive Secretary (UNEP/CBD/BS/COP-MOP/4/INF/18) and *requests* the Executive Secretary to advance its implementation;
7. *Invites* Parties, other Governments and relevant organizations to cooperate with, and support, the Executive Secretary in the implementation of the Outreach Strategy;
8. *Requests* the Executive Secretary to report on the implementation of the outreach strategy at the sixth meeting of the Parties to the Protocol.

The outcome of the MOP on this item it too much focussed only on the handling, transfer and use of LMOs. No comments were made about the need for understanding of the technology and its potential benefits, by the public and decision-makers, in order to be able to have a valuable participation, and formulate proper and well-balanced decisions in the regulation regime. Since PRRI feels that the latter is very important, its members who are who are often multilingual scientists from various fields could offer independent professional expertise in proper science communication on both risks and benefits.

<u>Options for implementation of the notification requirement under Article 8</u>

The CPB requires parties of export or the exporters to notify the competent national authority of the party of import prior to the first intentional transboundary movement of LMOs for intentional introduction into the environment of the party of import. At this MOP, parties were expected to elaborate and develop, modalities for the implementation of the notification requirements under the protocol, taking into account the information on national implementation and experiences gathered through the first national reports and the Biosafety Clearing-House.

PRRI's opinion on notification requirements

The main interest of public scientists on this issue, concerns the information requirements for small-scale confined field-testing for research and risk assessment purposes. Research in modern biotechnology typically involves sending research material between research labs in countries and between countries for further development and testing in contained facilities and small-scale field trials. It is recognized that the risk associated with these small-scale activities is generally low because of the way confined field trials are conducted.

PRRI's concern is that the AIA procedure does not differentiate between small-scale field trials for research and developments and large scale commercial releases, which generally require more detailed information and longer time for assessment. This non-differentiation implies unnecessary information requirements which unduly burdens public research.

Final decision of MOP4 on the issue of notification requirements

The Relevant paragraphs of UNEP/CBD/BS/COP-MOP/4/18 on Notification requirements The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, 1. Reiterates its recommendation made to Parties to the Protocol to consider the elements referred to in paragraph 2 of decision BS-II/8 in implementing Article 8 of the Protocol; 2. Decides to review the item at its sixth meeting based on national implementation experiences that may be communicated through the second national reports.

PRRI has produced a guidance document on notifications and risk assessment on genetically modified crop plants to assist public research scientists preparing notifications for the deliberate release into the environment in with the basis requirements are addressed. Members of PRRI stand available to share their experiences with notifications and PRRI will resubmit their concerns about the non-differentiation in the requirements for small-scale field trails versus commercial release for the planned review of the item at MOP6.

4. PRRI positions on the negotiation topics of COP9.

Topics on the agenda of COP9 relevant for public research:

- Forest biodiversity / GM Trees
- Technology Transfer
- Access Benefit Sharing (ABS) and Intellectual Property Rights (IPR)
- Agricultural Biodiversity

<u>Forest biodiversity / GM Trees</u>

The multi-year programme of work of the Conference of the Parties (COP) up to 2010, provides for an in-depth review on forest biological diversity at its ninth meeting, which includes the issue of genetically modified trees and their potential environmental, cultural, and socio-economic impacts on the conservation and sustainable use of forest biological diversity.

To prepare for this COP9 item, a meeting of the Subsidiary Body on Scientific, Technical and Technological Advice was held in FAO, Rome from 18 to 22 February 2008 (SBSTTA13). SBSTTA is a subsidiary body of the Conference of the Parties (COP) to:

- provide assessments of the status of biological diversity,
- assess the types of measures taken in accordance with the provisions of the Convention,
- respond to questions that the COP may put to the body.

PRRI participated in this meeting with members of the PRRI GM Tree working Group and other scientists from the public sector working on GM Trees (Prof. Steve Strauss, Prof. Giancarlo Pasquali, Prof. Bruno Mezzetti, Dr. Emilia Caboni and Ms. Elisa Costantini) and two members of the PRRI Secretariat (Mr. Piet van der Meer and Ms. Kim Meulenbroeks).

On the opening day of the SBSTTA, PRRI organised a side event on GM trees to inform the delegates about the objectives and progress of public research on GM Trees. Scientists working

on GM Trees explained why public research in this field is important; what the possible environmental and socio-economic benefits are and why research in this field should continue. During the SBSTTA meeting itself, PRRI members closely followed the discussions and made an intervention. The presentations of the side event and the statement made, are published on the PRRI website www.pubresreg.org -> Working Groups -> GM Trees.

The outcome of the 13th SBSTTA meeting (UNEP/CBD/COP/9/3) was submitted in the form of an official report to COP9 which formed the basis for its discussions and the starting point of the negotiations in Bonn.

The relevant paragraph of the SBSTTA13 report (1 r), reaffirms the need to apply the precautionary approach to the use of GM Trees. It provides three different alternatives for implementation:

1. Develop protocols for risk assessment for GM Trees and guidance addressing socio-economic and cultural aspects of risks and benefits associated with the use of GM Trees.
2. Suspend any release of genetically modified trees pending sufficient and appreciable assessment of their potential impacts on forest biodiversity and on indigenous and local communities, including potential environment, cultural and socio-economic impacts.
3. Minimize the use of such organisms and undertake research to reduce the uncertainties associated with the use of this technology.

PRRI's participation in COP9

The following members participated under the umbrella of PRRI in COP9 and were involved in the discussions on GM Trees: Prof. Steve Strauss, Prof. Bruno Mezzetti, Dr. Mike May, Prof. Wout Boerjan, Dr. Matthias Fladung, Dr. Uwe Nehls and Dr. Allen van Deynze together with Mr. Piet van der Meer and Ms. Kim Meulenbroeks from the PRRI secretariat.

On the fist day of COP9, PRRI held a side event on GM Trees to demonstrate the rationale for public research on GM trees, providing examples of progress and considering the obstacles faced in conducting research on GM Trees. Presentations were given by Prof. Strauss and Prof. Boerjan, both presentations are published on the PRRI website.

PRRI side event: Research on GM Trees: objectives and progress
COP9 - Monday, 19 May 2008

> Public research groups all over the world are engaged in research in modern biotechnology to strengthen sustainable production of food, feed and fibre; to improve health care; and to preserve the environment and biodiversity. A significant portion of this research focuses on forest trees and fruit trees. As many of the above challenges cannot be solved using conventional techniques alone, public research in this field includes the use of genetically modified (GM) trees.
>
> A unique advantage of biotechnology is that it may help overcome the long generation time and other difficult breeding constraints that hamper the use of sexual crosses for introduction and testing of economically and environmentally important traits. It also enables the introduction of new kinds of traits not otherwise possible. This side event gave an overview of examples and progress in public research on GM trees and the rationale behind these applications including the obstacles currently faced with.

Presentations:

- Why is public research on genetically modified trees important?
  by Prof. Steven Strauss Oregon State University- USA
- Engineering lignin for pulp and bio-ethanol
  by Prof. Wout Boerjan Department of Plant Systems Biology, VIB-UGhent Belgium

The item 'Forest Biodiversity' dealing with GM Trees led to intense debates, from the beginning of the COP until the very last day including a number of late night sessions. Throughout these debates PRRI made several interventions, which can be found on the PRRI Website.

PRRI's position on GM Trees:

Classical breeding has made major contributions to improving the productivity of plantation forests. However, the current challenges caused by population growth, climate change and fossil energy shortage **cannot** be met by conventional breeding **alone**.

To meet our trans-generation responsibility, we have to find solutions today. We strongly believe that modern biotechnology, including genetic modification, can contribute significantly to finding solutions in these areas. Much of the required innovation is coming from public research institutes. On the PRRI website, and during two side event (SBSTTA13 and COP9), PRRI has cited many examples of the considerable progress made in tree biotechnology by public researchers from all over the world.

PRRI believes that questions about safety of GM trees can be addressed adequately through the case-by-case risk assessment of the Biosafety Protocol.

Given the large potential environmental and socio-economic benefits of GM trees and the extensive safety record of the hundreds of field trials with GM trees conducted worldwide, there is no scientific justification for a blanket suspension of releases of GM Trees. Field research is, in fact, the **only** way to get realistic answers to the many questions that were so well developed in the background document on GM trees. Field trials also serve as an important educational resource for all stakeholders. A suspension of field trials would be detrimental to important public research, and thus to the realization of public benefits.

Final decision of COP9 on the issue of GM Trees

The Relevant paragraphs of UNEP/CBD/COP/9/L.33 state:

1. *Urges* Parties to:

(r) Reaffirm the need to take a precautionary approach[1] when addressing the issue of genetically modified trees;

(s) Authorize the release of genetically modified trees only after completion of studies in containment, including in greenhouse and confined field trials, in accordance with the national legislation where existent, addressing long–term effects as well as

[1] Principle 15 of the Rio Declaration on Environment and Development. 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.

thorough, comprehensive, science-based and transparent risk assessments to avoid possible negative environmental impacts on forest biological diversity; [2]

(t) Also consider the potential socio-economic impacts of genetically modified trees as well as their potential impact on the livelihoods of indigenous and local communities;

(u) Acknowledge the entitlement of Parties, in accordance with their domestic legislation, to suspend the release of genetically modified trees, in particular where risk assessment so advises or where adequate capacities to undertake such assessment is not available;

(v) Further engage to develop risk assessment criteria specifically for genetically modified trees;

(w) Note the results of the Norway – Canada Workshops on Risk Assessment for emerging applications for Living Modified Organisms (UNEP/CBD/BS/COP-MOP/4/INF/13);

(x) Welcome the decision of the Fourth Meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol to establish an Ad – Hoc Technical Expert Group on Risk Assessment and Risk Management that is also mandated to address the issue of genetically modified trees; and request the Executive Secretary to make available the outcome of its work for consideration by the next meeting of the Conference of the Parties;

(y) Collaborate with relevant organizations on guidance for risk assessment of genetically modified trees and guidance addressing potential negative and positive environmental and socio - economic impacts on the conservation and sustainable use of forest biodiversity associated with the use of genetically modified trees;

(z) Provide the available information and the scientific evidence regarding the overall effects of genetically modified trees on the conservation and sustainable use of biological diversity to the Executive Secretary for dissemination through the clearing-house mechanism;

The outcome of this debate confirms again that research and development of GM trees is important and can be conducted safely and adequately within the context of existing regulatory frameworks and on the basis of science based risk assessment. PRRI welcomes the call for further exchange of information on the potential positive and negative impacts of GM Trees.

[2] Where applicable, risks such as cross-pollination and spreading of seeds should be specifically addressed.

Follow up COP9 and MOP4 - preparing for COP10 and MOP5

The fifth meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (MOP5) and the tenth meeting of the Conference of the Parties to the Convention on Biological Diversity (COP10) will be held in Nagoya, Japan from 11 to 29 October 2010.

In the period between now and COP10MOP5, PRRI will organise several COP9MOP4 follow up meetings to discuss with public researchers world wide the outcomes of the previous meetings and their views on the agenda items of next meetings. These follow up regional meetings will be to the extent possible co-organised with regional organisations and in conjunction with existing meetings.

In addition, the CBD Secretariat also organises meetings to prepare for the next COP or MOP on specific subjects. When subjects relevant for public research will be discussed it is foreseen that one or two members of PRRI actively participate in that meeting and or a written submission on the matter will be send to the CBD secretariat in advance.

Specific activities arising from COP9MOP4

During COP9MOP4 several request were made by the parties for input provided by scientist or international organisations. PRRI has in many cases offered it's assistance, expertise and scientific background information. The following specific activities are foreseen in the period running up to the next COP and MOP:

- Members of PRRI will contribution to the study to be commissioned of users and potential users of the Biosafety Clearing-House.
- Since many of the scientists who are members of PRRI are already involved in biosafety training courses as organisers and/or teachers. PRRI plans to contribute that expertise by providing input for the assessment matrix before MOP6 for the identification of biosafety training needs for long-tem biosafety education and training programmes to develop core expertise for the effective implementation of the Protocol.
- PRRI will provide input for the AHTEG meetings and share the experience our members have with conducting risk assessment.
- PRRI will provide further scientific background information on public research done on GM Trees to address the call of COP9 for further exchange of information on the potential positive and negative impacts of GM Trees.

Upcoming Intersesional Meetings

Between the COPs and MOPs the CBD Secretariat organises meetings on specific subjects to prepare for the next COP or MOP. Currently the following intersessional meetings relevant for public research are foreseen between COP9MOP4 and COP10/MOP5:

Confirmed:

- First meeting of the Group of the Friends of the Co-Chairs Concerning Liability and Redress in the Context of the Cartagena Protocol on Biosafety, 23 - 27 February 2009 Mexico City, Mexico.

Tentative:

- Second meeting of the Group of the Friends of the Co-Chairs Concerning Liability and Redress in the Context of the Cartagena Protocol on Biosafety.
- Coordination meetings for governments and organizations involved in the biosafety capacity building.
- Sub-regional workshop on capacity-building and exchange of experiences on risk assessment and risk management of living modified organisms in the Pacific subregion.
- Online conference to identify the relevant standards with regard to handling, transport, packaging and identification of living modified organisms, to identify where gaps exist and suggest possible modalities to fill the gaps.
- Ad Hoc Technical Expert Group on Risk Assessment and Risk Management (2009)
- Ad hoc discussion groups and at least one real-time online conference per region prior to each of the meetings of the Ad Hoc Technical Expert Group, with the view to identifying major issues related to specific aspects of risk assessment and risk management.
- Subregional workshops for enhancing capacity in the use of the Biosafety Clearing House (2009 and 2010)

Annex 1: List of PRRI Participants

Public researchers participating on behalf of the Public Research and Regulation Initiative (PRRI) in the Fourth meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 4) 12 - 16 May 2008, Bonn, Germany.

- Prof. Jonathan Gressel, Plant Sciences Weizmann Institute of Science, Israel, jonathan.gressel@weizmann.ac.il
- Dr. Premendra Dwivedi, Food Toxicology Div Industrial Toxocology Research Centre, India, pddwivedi@yahoo.com, pddwivedi@gmail.com
- Prof. Ismail El Hadrami, Laboratoire de Biotechnologies, Protection et Valorisation des Ressources Végétales (Biotec-VRV), Morocco, hadramii@hotmail.com; hadrami@ucam.ac.ma
- Prof. Behzad Ghareyazie, Strategic Research Center of Iran, Iran, ghareyazie@yahoo.com
- Prof. Julian Kinderlerer, University of Cape Town, South Africa, jkinderlerer@gmail.com
- Dr. Susana, Sirvas-Cornejo, Universidad Nacional Federico Villarreal, Peru, sirvascornejo@yahoo.com
- Prof. Klaus Ammann, Delft University of Technology, The Netherlands, klaus.ammann@ips.unibe.ch
- Prof. Marc van Montagu, Laboratorium voor Genetica- University of Ghent, Belgium, marc.vanmontagu@UGent.be
- Dr. Charles Mugoya, ASARECA - Biotechnology and Biosafety Programme, Uganda, c.mugoya@asareca.org
- Prof. Jaroslav Blume, Institute of Cell Biology and Genetic Engineering-Natl. Academy of Sciences of Ukraine, Ukraine, cellbio@cellbio.freenet.viaduk.net
- Dr. Nevena Alexandrova, Agrobioinstitute, Bulgeria, alexandrova@abi.bg; nevialex@yahoo.com
- Prof. Desiree Hautea, University of the Philippines Los Banos(UPLB), Philippines, deshautea@yahoo.com
- Prof. Lionel Gil, Faculty of Medicine-University of Chile, Chile, lgil@med.uchile.cl; lionelgilhormazabal@yahoo.com.ar
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- Walter S. Alhassan, Forum for Agricultural Research in Africa (FARA), Ghana, walhassan@fara-africa.org
- Dr. Felicia Wu, University of Pittsburgh, United States, few8@pitt.edu
- Dr. Mahaletchumy Arujanan, University Malaya, Malaysia, maha@bic.org.my
- Dr. Yusuf Zafar, Plant Biotechnology Division National Institute for Biotechnology & Genetic Engineering (NIBGE), Pakistan, y_zafar@yahoo.com
- Prof. Selim Cetiner, Sabanci University, Turkey, cetiner@sabanciuniv.edu
- Dr. Idah Sithole Niang, Department of Biochemistry- University of Zimbabwe, , isn@mweb.co.zw
- Dr. Gerard Barry, International Rice Research Institute, Philippines, g.barry@cgiar.org
- Dr. Georgios Sakellaris, National Hellenic Research Foundation, Greece, gsak@eie.gr
- Dr. Victor Nuñez, Corpoica, Colombia, vinuza@yahoo.com
- Dr. Luis Destefano Beltrán, Universidad Peruana Cayetano Heredia, Perú
- Dr. Mike May, Institute of Plant Biotechnology for Developing Countries, Belgium, mike.may@ugent.be

- Dr. Diran Makinde, West Africa Biosciences Network (WABNet), NEPAD Biosciences Dakar, Senegal, makinde@mweb.co.za
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- Dr. Mesmin Ndong, Institut de Recherches Agronomiques et Forestieres, GABON, ndong_ndong@yahoo.fr
- Ms. Zuzana Kulichova, Wageningen University and Research Centre, Netherlands, zuzkica@yahoo.com
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- Dr. Ruud de Maagd, Wageningen University and Research Centre, Netherlands, ruud.demaagd@wur.nl
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- Ms. Kristina Sinemus, Genuis GmbH, Germany,kristina.sinemus@genius.de
- Prof. Tomasz Twardowski, Polish Academy of Sciences, Poland, twardows@ibch.poznan.pl
- Dr. Ralf Wilhelm, Julius Kuehn-Institute, Germany, ralf.wilhelm@jki.bund.de
- Ms. Maria A. Wright, Webster University, United States, marawright1@yahoo.com
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Public researchers participating on behalf of the Public Research and Regulation Initiative (PRRI) in the Ninth meeting of the Conference of the Parties to the Convention on Biological Diversity (COP 9), 19 - 30 May 2008, Bonn, Germany.

- Prof. Steven Strauss, Oregon State University - Department of Forest Science, United States, Steve.Strauss@oregonstate.edu
- Dr. Allen van Deynze, Plant Reproductive Biology - University of California, United States, avandeynze@ucdavis.edu
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