

Public Research & Regulation

Foundation with the objective to involve the public research sector in regulations and international agreements relevant to modern biotechnology

Participation of PRRI in MOP3 and COP8

Report, analysis and next steps.

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). A foundation has been established in the Netherlands for its execution and financing. Detailed information about PRRI is available at the PRRI web site (www.pubresreg.org).

The PRRI is set up in three phases:

- Phase 1 (2004-2005): Raising awareness in the public research community.
- Phase 2 (2005-2006): Preparatory 'tryout' involvement of public researchers in the Second and Third Meetings of the Parties (MOP2 and MOP3) to the CPB and to the 8th Conference of the Parties (COP8) to the CBD.
- Phase3: (2006 onwards): Multi-year, structured involvement of the public research sector in relevant international agreements and meetings.

The reports of Phase 1 and of the participation of PRRI in MOP2 are on the PRRI web site.

This document gives a report of the final part of the preparatory 'tryout' Phase 2, i.e. participation of PRRI in MOP3 and COP8, as well as an analysis of the results of the negotiations and the steps PRRI will take to prepare itself for MOP4 and COP9.

Evaluating the 'tryout' phase, the Steering Committee of the PRRI is extremely pleased to conclude that the results are beyond the best expectations. In a period of one year, starting with an introductory seminar in March 2005, followed by PRRI's first participation in the international arena in MOP2, and ending with the PRRI participation in MOP3 and COP8 (March 2006), PRRI has matured into a well-organised and well-established body in the international arena.

Based on the results of the tryout phase, the Steering Committee has concluded that:

- public researchers have become aware of the need to participate in international negotiations and are prepared to invest time and resources;
- participating as observer in international negotiations can be effective;
- subject to the availability of funds, the PRRI will participate in MOP4 and COP9, which will be held in 2008, and the preparatory meetings leading up to MOP4 and COP9. The process of preparing PRRI statements on MOP topics has been transparent and effective. The last section of this document details the process leading up to MOP4 and COP9.

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2. PRRI participation in MOP3 and COP8.

PRRI participated with over 40 participants in MOP3, and with 3 participants in COP8. The list of participants, the preparatory documents and PRRI statements are available on the PRRI web site.

The PRRI participants express their sincere appreciation to the governments of Canada Spain and the United States, as well as to the Rockefeller Foundation, the Syngenta Foundation and private sector organizations for their financial contributions, without which the participation of these public researchers would not have been possible.

PRRI extends its gratitude to the Brazilian Biosafety Association ANBio, for its invaluable help with logistics and with getting media coverage. PRRI also thanks the Forum for Agricultural Research in Africa (FARA), the Organisation of American States (OAS), the Inter-American Institute for Cooperation on Agriculture (IICA), the International Rice Research Institute (IRRI) and the program for Biosafety Systems (PBS) for their support.

The main objectives of the participation of the PRRI in MOPs are:

- making delegates aware that a substantial part of the research on modern biotechnology is conducted for the public good in public research institutes worldwide;
- making delegates aware of the concerns of the public research sector about the implications of the different options they are discussing;
- bringing more science to the negotiations and making scientific knowledge available to the delegates upon their request;
- initiating dialogues with stakeholders from the entire spectrum of viewpoints in the biotechnology debate, aimed at better understanding each other and at working together.

To achieve these goals, the PRRI organised side events, attended other groups' side events, held meetings with delegations, groups and individuals and prepared statements on the topics of the agenda of MOP4 and COP8.

The sections below discuss a) the side events held by PRRI, and b) PRRI's positions on the topics of the agenda of MOP3 and COP9.

2a. PRRI - side events

During MOP2, PRRI organised side events with the aim of providing the negotiating delegates with a general overview of public research in agricultural biotechnology.

During MOP3, PRRI organised two types of side events on more specific topics.

The first type of side event discussed an example of a non agricultural application of modern biotechnology, i.e. the production of vaccines in plants.

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The presentation by Dr. Andres Wigdorovitz from INTA, Argentina, addressed the advantages, in particular for developing countries, of using plants for the production of vaccines and pharmaceuticals. Several examples of diseases were presented that are considered to be the most important causative agents of economic loss of cattle production activity in Argentina and thus, constitute optimal candidates for developing alternative sources of immunization tools. In the side event, he presented the development of different experimental immunogens of these viruses through the expression of immunogenic proteins from these viruses in alfalfa transgenic plants. In discussions following the presentation, participants discussed the potential advantages and risks of such plants, as well as general questions such as the importance of gene switching technologies of GURT in ensuring that plant made vaccines do not end up in the food chain.

The second type of side events was organised for audiences from Africa and Latin America.

In collaboration with the Forum for Agricultural Research in Africa (FARA), PRRI organised a side event focusing on developments in public research in Africa. The side event was opened by Dr. Arnold Ventura who placed modern biotechnology in the context of poverty alleviation in the environmentally and economically challenged countries. Dr. Harold Roy Macauley introduced the background, the objectives and activities of FARA. He discussed in detail the FARA-led African Biosafety and Biotechnology Initiative (FARA-ABBI) Web-based Forum, which aims at accelerating and improving the development and implementation of biosafety systems for the effective application of agricultural biotechnology in Africa. Dr. Charles Mugoya from ASARECA presented different types of ongoing public research in modern biotechnology in Africa. The discussions following the presentations focused on the need to set priorities for public research in modern biotechnology.

In collaboration with the Organisation of American States (OAS), PRRI organised a side event focusing on biotechnology and biosafety in Latin America. This side event was held in Spanish. The side event was opened by Dr. Javier Verastegui, who briefed the participants about Latin American biotechnology development, with emphasis on the CamBioTec biosafety projects in Argentina and Chile (1998-99), and on the developments of the OAS Biosafety Project (2002-2006). Dr. Lionel Gil presented the Developments of the OAS Biosafety Project, including a detailed account of the 2-phase project, national biosafety reports in 9 countries, 3 national studies on the demand for capacity building in biosafety; workshops in different cities, on biosafety regulatory aspects, risk assessment, DNA analysis and GMO identification, biotechnology innovation management, books printed, website and other activities.

2b. PRRI positions on the negotiation topics of MOP3.

This section summarises the main points of the statements made by PRRI on topics of the agenda of MOP4 and COP8, and an analysis of the results of MOP3 and COP8. Not all topics on the agenda of MOP3 and COP8 are discussed below since PRRI focuses on those topics that may have an impact on public research in modern biotechnology.

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Before addressing those topics there are some general observations that should be made.

Firstly, most members of PRRI are working day-to-day on solutions for some of the major challenges that the world community faces such as poverty, malnutrition, poor human health and environmental degradation in developing countries. The Cartagena Protocol on Biosafety is intended to help developing solutions to those challenges by, on the one hand, facilitating international collaboration in research in modern biotechnology and, on the other hand, by providing Governments with tools to make informed decisions on imports of Living Modified Organisms (LMOs). In this context, PRRI participants to MOP2 and MOP3 felt that the process of MOPs, which costs many millions of dollars, seems to be aimed at slowing down research in modern biotechnology rather than on facilitating international collaboration. If this continues, the contribution of the CPB to fighting poverty and environmental degradation will be nil. The PRRI urges the negotiating Governments to remain vigilant of the potentially negative impacts of this process and to help redirect the debate to ensure that the CPB can do what it originally was intended to do.

A second general observation is directed at repeated attempts by some to propose bans for certain developments, such as gene-switching technologies, genetic use restriction technologies (GURTs) and genetically modified trees. These are all areas of importance to public research as they may help finding solutions to the challenges outlined above. As with any new technological development, it makes perfect sense to make a safety - benefit analysis related to this research so that well-informed decisions can be made. However, we do not serve future generations by simply putting bans on possible avenues of research and development if there are no clear indications that those developments will pose risks that outweigh the benefits. PRRI strongly supports a responsible use of the Precautionary Approach, but opposes its abuse in order to stop important research and development.

Biosafety Clearing House – BCH (MOP3)

The main elements of the PRRI position on this topic are:

- The BCH is of crucial importance because it is an entry point for public researchers if they need to know which procedures apply and whom to approach in a certain country.
- It is unfortunate that many Parties have not yet complied with their obligation to place relevant information on the BCH, including declarations whether their national domestic frameworks apply instead of the procedures of the protocol. This lack of information is a serious hindrance to public research.
- Placing such information on the BCH is not onerous but rather requires a Government official to spend a couple of hours at a computer.
- PRRI urges all Governments to help public researchers in their work by placing the relevant information on the BCH.

PRRI will keep monitoring this and remains available to provide the scientific expertise of its members in this area.

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Capacity building (MOP3)

The main elements of the PRRI position on this topic are:

- Capacity building projects need to be based on independent expert identification of the prioritised needs of countries; countries are ill-served by a 'one size fits all' approach.
- The needs and priorities of countries need to be translated into clear and realistic implementation targets.
- Coordination between donors and recipients should be much more effective and their decision-making processes should be more rigorous to avoid duplications of ongoing or planned projects.
- Quality criteria for project proposals and for executing agencies are needed. capacity building projects should be carried out by executing agencies with substantial 'hands-on' experience in implementing biosafety systems.
- There is a need for an upfront assessment of the self-sustainability of the projects and of the institutions involved.
- National projects are encouraged to also foster regional or sub-regional alignment to reduce redundancy.

PRRI is pleased that the outcome of MOP3 on this topic is in most cases similar to these viewpoints. PRRI remains available to provide the scientific expertise of its members in this area.

Roster of experts on BCH (MOP3)

The main elements of the PRRI position on this topic are:

- While supporting the original idea, the PRRI believes that the current roster of experts does not serve its intended purpose.
- Guidance needs to be provided on what constitutes an 'expert'; i.e. being an expert in this complex field requires many years of actual hands-on experience in an area that is relevant to the many interdisciplinary fields of biosafety.
- An independent peer review mechanism should be installed to screen applications before inclusion in the roster of experts.
- The Biosafety Clearing House (BCH) should clearly identify the area of expertise of the experts involved with curriculum vitae.
- The work of these experts should be made available through the BCH.

PRRI welcomes the outcome of MOP3 on this topic, which is similar to these viewpoints, and remains available to provide the expertise of its members in this area.

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Risk assessment and risk management (MOP3):

The main elements of the PRRI position on this topic are:

- Risk assessment has to be based on sound science – i.e. based on scientific reasoning, verifiable and replicable.
- Risk assessment is comparative – i.e. any risks identified in the risk assessment have to be compared with the risks of using the non-modified recipient organism.
- Information should only be requested from notifiers/applicants if it is clear how it is relevant to the risk assessment and how it will be used.
- The precautionary approach does not mean ‘zero risk’.
- The methodology in Annex III of the CPB is an adequate reflection of over 20 years of practice and at this point there is no need for further generic guidance, but rather specific guidance needs to be developed on how to apply the general methodology and principles of Annex III to specific cases. The PRRI has developed such guidance in a Guide on notifications and risk assessment for releases into the environment of LMOs, which is available on the PRRI web site.

PRRI is pleased that the outcome of MOP3 on this topic is very similar to these viewpoints. PRRI remains available to provide the expertise of its members in this area.

Subsidiary body (MOP3)

The PRRI believes that at this point in time it is preferable to rely on the system of technical ad hoc groups, which allows for flexibility on a need-basis. The Ad Hoc Technical Expert Group on Risk Assessment is a good example of such an approach.

Handling – Packaging and labelling (article 182.b and 18.2c).

The main elements of the PRRI position on this topic are:

- There is no need for a stand-alone document to fulfil the identification requirements of articles 18.2 b and c of the Protocol. The information specified in these paragraphs is intended to identify the contents of the package containing LMO's, and should not function as a risk assessment document. As required by the Protocol, such risk assessment is done prior to transboundary movement, if intended for intentional introduction into the environment. Therefore, the documentation relevant for risk assessment will already have been reviewed by the competent authority, and would already have been approved for import by that authority, a decision that should be on the Biosafety Clearing House. Thus, the documentation accompanying the item needs only to identify it, and to demonstrate that the appropriate risk assessment, if required, has been completed. Such information is easily incorporated into a simple document or label accompanying the specific item or items, examples of which have been submitted to the Executive Secretary;

PRRI continues to monitor this issue and remains available to provide the expertise of its members in this area.

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Liability and redress (MOP3)

The main elements of the PRRI position on this topic are:

- Liability and redress are important mechanisms in society, and damage to property can be - and is in most cases - adequately covered in national systems.
- Damage to biodiversity or the environment is not yet covered in many national systems and needs further debate on how to best address this.
- If this debate results in developing international rules, then the appropriate place would be under the CBD and not the CPB, there is no reason to single out biotechnology for the purpose of liability.
- A first step in this process is defining damage to biodiversity.
- The best way forward at this stage would be to develop guidelines for countries that wish to establish national liability systems for damage to biodiversity.
- Such guidelines should reflect that:
 - o proportionality, apportionment and causation are important concepts;
 - o most human activities – such as agriculture – causes changes in the environment. However, change in biodiversity is in itself not damage; the challenge is defining when a “change” amounts to “damage”;
 - o outcrossing of crops, regardless whether they are genetically modified or not, in itself is not damage to biodiversity;
 - o certain applications of agricultural biotechnology seek to correct some of the negative impacts on biodiversity from current agricultural practices.
 - o loss of benefits of not using this technology should be taken into account;
 - o proper science needs to remain present in every step of this debate.

PRRI takes note of the ongoing debate by the liability and redress group of experts and urges the group to identify means to ensure that it keeps abreast with research and developments in the areas of application being discussed. PRRI continues to offer its help in identifying public researchers who can address the group during their deliberations and provide the necessary scientific background that will lead to informed decision making.

Assessment and Review (MOP3)

The main elements of the PRRI position on this topic are:

- There is currently not enough experience with the actual functioning of the Protocol to start a detailed discussion on revising the Protocol.
- However, it is important to start shaping the parameters of the assessment process, one of which should be that an assessment be made of the impacts of the different ways of implementing the Protocol on public research.
- Once the process of review has started, we submit that the Protocol needs special provisions for confined field trials, because currently under the Protocol, the transboundary movement of an LMO for the purpose of a small scale confined research trial has to undergo the same, lengthy procedure for placing LMOs on the market.

PRRI will keep monitoring this debate closely and remains available to provide the expertise of its members in this area.

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Other scientific and technical issues relevant to the implementation of the Protocol.

The main elements of the PRRI position on this topic are:

- The need to develop guidance for decision makers on how potential benefits can be taken into account in decision-making.
- The need to start defining categories of exemptions of the AIA procedure for LMOs that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, in accordance with article 7 paragraph four of the Protocol.

The PRRI notes that neither of these points featured prominently in the negotiations. This is regrettable, because both elements are view crucial to the functioning of the CPB.

With regard to the first point, based on PRRI members experience, it is clear that decision makers are often struggling with the question about how to balance potential benefits and potential risks in decision making, and often decisions are postponed for that reason, which is highly regrettable.

As regards the second point, we believe that it is crucial for the functioning of the CPB that when sufficient familiarity has been gained to conclude that certain LMOs are not likely to have adverse, that those LMOs be exempted from the AIA procedure to avoid that scarce government resources are used for duplication of efforts. Those scarce resources are better used to focus on new cases that may have complex safety questions. In this context it is worthwhile to note that since the adoption of the CBD in 1992, over 1 billion acres have been planted with LMO crops by millions of farmers in developing and developed countries, consumed in billions of meals, and there have been no verifiable reports of adverse effects to human health or biodiversity. This does not mean that LMOs by themselves are inherently safe, but it does indicate that the current risk assessment methodology and practice are effective and that the familiarity gained can be used to start identifying LMOs that would not require AIAs in case of transboundary movements.

GURTS (COP8)

The main elements of the PRRI position on this topic are:

- Public researchers in developed and developing countries throughout the world are exploring naturally occurring gene-switching mechanisms to control one or more specific traits in plants. These applications are called "gene switching technologies". A specific use of gene switching technologies is aimed at controlling genes responsible for sexual reproduction in plants, for example by producing non-viable floral parts (e.g., anthers, pistils) or seed. These applications are called "genetic use-restriction technologies" or GURTs.
- There are many reasons why public-sector researchers are exploring these technologies, some of which are briefly discussed in a note that is available on the PRRI web site. For example, these technologies provide us with the possibility to prevent the transfer of specific, newly introduced genetic traits in plants (e.g., the production of pharmaceuticals or vaccines) to other crops or wild relatives.

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- As with any new technological development, it makes perfect sense to conduct a risk/benefit assessment related to this research, so that well informed risk-benefit assessments can be made. In the case of carefully selected GURTS applications, the potential for risk is generally very low because the resulting genetically modified plants are genetically programmed to not produce viable offspring or viable pollen. As regards the hotly debated issue of saving seed: if farmers want to use part of the seed they buy to produce seed for next year, they would not buy GURT varieties for that purpose, in the same way as they do not buy for that purpose hybrid seeds and seeds of crops that do not produce viable seeds. I.e. GURTS is a characteristic of a product that will make some farmers want to buy it and others not. However, the reasons for one farmer not to buy a product should not limit the choice for other farmers who may wish to buy those products, because the ability to maintain different agricultural production systems is a prerequisite for providing a high degree of food security and consumer choice. GURTS is another strategy that enables the co-existence of different agriculture technologies giving farmers choices in what they produce.
- PRRI therefore supports the overall thrust of the COP recommendations, including those contained in decisions V/5 and VIII/23. These decisions recognize that these technologies are still in early stages of development and therefore call for further research to be undertaken on the potential benefits and risks, which can only be done on a case by case basis. Consistent with the work on subsidiary bodies, including the SBSTTA recommendation X/11 and the last report of the Working Group on article 8 (j) on this topic, we therefore urge that this issue be addressed on a case by case basis, and that research on this technology, including any potential socio-economic impacts, continue to be undertaken with the results shared via the Clearing House Mechanism.

PRRI is pleased with the outcome of the debate of COP8 on this topic, which is consistent with the earlier conclusion of the COP, namely that these technologies are still in the early stages of development, and that we continue to undertake further research on the impacts of genetic use restriction technologies, including their ecological, social, economic and cultural impacts, particularly on indigenous and local communities using risk assessment procedures.

PRRI is concerned, however, by public statements of some groups that the COP reconfirmed a “de facto” moratorium on GURTS. As the discussions of the COP clearly shows, there was no and is no decision to ban research and development in this area. The PRRI is disconcerted by these statements, because they mislead the public about the outcome of the COP. In addition, PRRI is concerned that there is clearly a large body of misinformation on the impacts of GURTS, which is being propagated by some.

GM Trees (COP8)

The main elements of the PRRI position on this topic are:

- Public researchers in developed and developing countries all over the world are working on finding solutions for specific challenges related to forestry, such as developing methods to speed up reforestation, reducing the use of pesticides, and

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reducing the energy and chemical input in processing trees and their products. This research also includes the application of genetic modification.

- As with any new technological development, it makes perfect sense to conduct risk/benefit assessments related to this research, so that well-informed, science-based, decisions can be made.
- PRRI supports an approach that recognizes that these technologies are still in early stages of development, and that any assessment of the potential benefits and risks can, and should, be made on a case-by-case basis only. This is precisely what the Cartagena Protocol on Biosafety sets out to do.

PRRI is pleased with the outcome of the debate of COP8 on this topic, which is in line with the conclusion that these technologies are still in early stages of development, and that any assessment of the potential benefits and risks can be made on a case-by-case basis only.

4. The process leading up to MOP4 and COP9

1. The process will start with an early announcement on the PRRI web site that PRRI intends to provide a forum for public researchers to participate in MOP4 and COP9, and invites public researchers to express their interest in participation and their views regarding the topics on the agenda of MOP4 and COP9.
2. The feedback received from public researchers will be summarized in a bulleted list and distributed to the over 150 Forum members of the PRRI with a request to provide feedback.
3. In the period leading up to MOP4 and COP9, the PRRI will endeavour to organize MOP4/COP9 preparation meetings in the different regions of the world, to the extent possible in collaboration with other relevant regional organisations and in the languages of the region. Agreements have already been reached with three regional organisations: the Forum for Agricultural Research in Africa (FARA) the Organisation of American States (OAS) and The Inter-American Institute for Cooperation on Agriculture (IICA). In these meetings, public researchers will be informed and updated about the CPB and MOPs, and they will discuss the topics on the agenda of MOP4 and COP9.
4. The feedback received from these regional meetings will be summarized in a bulleted list and distributed to the over 150 Forum members of the PRRI with a request to provide feedback.
5. Based on the results of the regional meetings and the feedback from the Forum members, drafts for PRRI statements will be prepared for consideration by the Steering Committee and PRRI participants to MOP4 and COP9.