



Public Research & Regulation Initiative
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To: The Members of Public Research and Regulation Initiative

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Dear colleagues,

We hereby send you an update on PRRI.

Since the last update, PRRI has again grown in the number of members, and in the number of topics for which members requested PRRI to get involved. PRRI continues to receive invitations by international organizations to provide feedback and to participate in meetings.

With PRRI growing bigger and with more diverse topics to address, PRRI will need to lean more on its working groups to keep track of relevant developments and to initiate activities. PRRI has therefore started 'beefing up' the existing working groups and established new working groups on Field Trials, Codex Alimentarius, and the Ask Force. Part of beefing up working groups is securing budgets for the working groups. For one working group PRRI has already secured funding for 2009, and for other working groups funding requests have been submitted to donors. A detailed update on the PRRI working groups is given below.

The Steering Committee invites you to join one or more of the PRRI working groups by sending an email to zuzana.kulichova@pubresreg.org.

The Steering Committee is very grateful that Dr Lucia de Souza has volunteered to help the PRRI Secretariat for a couple of hours per week in the course of 2009 and has invited her to take the role of Deputy Executive Secretary of PRRI.

As regards the activities of PRRI, in 2009, the main focus will be on 1) EU regulations and policies, and 2) Preparation of MOP5/COP10, which will be held in 2010 in Japan

This issue of the PRRI newsletter contains a detailed update on:

1. The PRRI working groups
2. Meetings attended or organised by PRRI
3. Upcoming meetings in which PRRI will participate

Finally, the PRRI website has been restructured and updated. We kindly ask you to revisit the site (www.pubresreg.org) and to check whether your references are still correct on the list PRRI members.

The update below is also placed on the PRRI web site.

Please send your feedback and questions about this update to: zuzana.kulichova@pubresreg.org.

Best regards

The PRRI Secretariat



Update on the status of the PRRI working groups

PRRI Working Group Public Sector Research in Modern Biotechnology

The aim of this Working Group is to provide information about the background, objectives and progress of public research in biotechnology.

One of the main activities of this working group is developing, in collaboration with IFPRI, the web based ABC database, which aims to provide information about public research in agricultural biotechnology. The structure of the pilot database is ready at <http://ifpri.catalog.cgiar.org/abc/index.htm>.

The Working Group and the PRRI secretariat are currently working on proposals to facilitate entering data in the database, such as annual meetings with public researchers in the context of field trials (see under WG Field Trials)

PRRI Working Group “Ask Force”

The “Ask Force” initiative is a blog on the PRRI web site that discusses articles and ‘myths’ about biosafety and biotechnology that have gained much public attention but which are not supported by peer reviewed scientific research. It is a collaborative initiative between PRRI and EFB.

To be able to ‘catch up’ with the ‘old myths’ and to quickly response to new ones, PRRI has established an Ask Force Working Group which will hopefully consist of about ten scientists. Each posting will be prepared by a PRRI member with expertise in the field and will be reviewed by members of the Ask Force Working Group. PRRI has obtained funding to give the PRRI members involved in this work some compensation for working in their spare time.

PRRI Working Group Cartagena Protocol on Biosafety & Convention on Biodiversity

This Working Group keeps track of and coordinates the PRRI involvement in the ongoing activities under the MOPs and COPS. The Co-chairs are Dr. Karen Hokanson and Dr. Lucia de Souza

This group will become active again in the course of 2009, in preparation of MOP5 and COP10 in 2010. As a part of this preparation, Dr. Lucia de Souza attended the Fourth meeting of the informal advisory committee on the Biosafety Clearing House on 17 – 18 November 2008. (More details on the meeting can be found in a section ‘meetings’ below).

PRRI Working Group EU regulations

As PRRI will focus in 2009 on EU regulations, the ‘dormant’ PRRI Working Group on EU regulations has been revitalised. Dr. Rene Custers, regulatory affairs manager of the Flemish Institute for Biotechnology, has been agreed to be one of the two co – chairs of this Working Group. Your suggestions for topics to be addressed by this WG as well as your suggestions for a second co-chair will be welcome.

As part of the work of this WG, PRRI has:

- Participated in several meetings (COST, SANCO, Ethics conference - More details on these meetings can be found in a section ‘meetings’ below)
- Produced a summary and update of EU regulations, which will be placed on the PRRI web site, and



- Will participate in the BioVision and ECB 14 meetings. (see below under ‘meetings’)

One key element of the work of PRRI in 2009 is to organize a meeting with EU policy makers, preferably EC commissioners.

PRRI Working Group on Liability & Redress

The co-chairs of this WG are Prof. Julian Kinderlerer and Dr. Hector Quemada.

Over the last few months, the main activity of this WG was preparing PRRI’s participation in the “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, which took place on 23 - 27 February 2009, Mexico City, Mexico.

(for reports see: <http://www.iisd.ca/biodiv/bs-gflr/>). The PRRI participants to this meeting were Dr. Arnold Ventura, Dr. Lucia de Souza, and Prof. Behzad Ghareyazie.

Overall, PRRI can be content with the way these negotiations have developed over the last two years. In the early days, the negotiations focused primarily on a binding strict civil liability regime addressing various forms of damage beyond damage to biodiversity. PRRI has proposed from the beginning that the most appropriate system would be an administrative system for liability for damage to biodiversity. PRRI notes with satisfaction that the key focus of the current negotiations is on an administrative system.

For its participation in the meeting in Mexico City, PRRI prepared a position paper that can be found on the PRRI website (www.pubresreg.org).

PRRI Working Group on Risk Assessment

The Co-chairs of this group are Dr. Hector Quemada and Dr. Lucia de Souza.

The recent and planned activities of PRRI at the moment are:

- Participating in the on line conferences on risk assessment on the CBD web site (December – January – see: http://bch.cbd.int/onlineconferences/discussiongroups_ra.shtml, and http://bch.cbd.int/onlineconferences/realtime_ra.shtml)
- Hosting a brainstorm meeting on risk assessment in Delft, the Netherlands on 19-20 February, (see below under ‘meetings’).
- Participation in the Ad Hoc Technical Expert Group on Risk assessment under the CPB (April 2009)
- After that; updating and expanding the PRRI guide on Risk Assessment.

PRRI Working Group on IPR-ABS-PGR (Intellectual Property Rights - Access and Benefit Sharing - Plant Genetic Resources)

Co-chairs of this group are Dr. Mike May and Dr. Niels Louwaars, with support of Prof. Julian Kinderlerer.

Since its establishment, the focus of PRRI has been mainly on international biosafety regulations. Encouraged by the effectiveness of PRRI engagement in international negotiations, PRRI members increasingly request that PRRI also gets involved in other international treaties that can have an impact on public research in biotechnology. Repeated questions raised by scientists relate to: 1) the impact of rules on access to genetic resources on public research in biotechnology, 2) the role of intellectual property rights



and alternative forms of intellectual property protection as they relate to public research in biotechnology, and 3) the interrelations and interactions between these.

The international treaties referred to are:

- The Convention on Biological Diversity (CBD)
- The World Intellectual Property Organisation (WIPO)
- The International Union for the Protection of New Varieties of Plants (UPOV)
- The Trade Related Aspects of Intellectual Property (TRIPs Agreements)
- The International Treaty on Plant Genetic Resources (ITPGR)

In response, the PRRI Secretariat prepared a proposal for a pilot project to prepare and facilitate the participation of public researchers in the ongoing negotiations of abovementioned treaties. A request for funding for this WG has been submitted to donors.

PRRI Working Group on Field Trials

From feedback from many public researchers from all over the world, it appears that challenges related to field trials are among the main hurdles in the process of making crops with improved traits available to farmers. Field trials are an essential step in the development of crops with altered traits, because only in the outdoor environment can the performance and safety parameters be verified in a meaningful way.

In preparing and conducting field trials researchers are confronted with various challenges:

- The anticipated costs and duration of complying with regulations are often inhibitive
- Designing field trials in such a way that data on performance and safety parameters can be obtained optimally, while still complying with the conditions set in permits
- How to inform the public and how to respond to concerns by the local community

These challenges seem strongest for public researchers in developing countries and in the EU.

Public research teams do not have much opportunity to learn from each other's successes and mistakes in dealing with biosafety regulations. This stands in sharp contrast to the institutional learning that happens in the large private sector biotech developers, where scientists working with different crops in all parts of the world share a functional expertise built up and codified in the companies' regulatory affairs departments. This fundamental difference in how expertise and experience is built up and used is an important reason why so many public sector biotech projects run into insurmountable problems when they move outside contained facilities.

In this context, the PRRI Secretariat has prepared a proposal for a support network for public researchers that will assist in preparing and conducting field trials with GMOs. This will be a network of biotech practitioners who have direct experience with field research on GM crops and various tools to share that experience. Requests for funding for the work of this WG have been submitted to various donors.

PRRI Working Group on Food safety / CODEX

At its meeting in May 2008, in Bonn, the Steering Committee agreed with a request from several members to establish a WG on food safety / Codex Alimentarius.

Prof. Behzad Ghareyazie has volunteered to be one of the co-chairs of that group, and seeks colleagues to join him.



Prof. Ghareyzie and the PRRI Secretariat are working on obtaining observer status for PRRI in the Codex meetings.

PRRI Working Group on Aarhus Convention

Co Chairs of this working group are Dr. Sylvia Burssens and Prof. Bruno Mezzetti..

PRRI will participate in the 11th Meeting of the Parties to be held from 6 to 8 July 2009 in Geneva.

2. Meetings attended or organised by PRRI

COGEM Symposium - The New GMO Debate: a Clash between Legislations, 2 October 2008, the Netherlands

The COGEM , the Dutch Commission for Genetic Modification, organized on 2 October 2008, a one day symposium to discuss the merits of the process based and product based legislation. Piet van der Meer presented the “Definitions in the EU and the Biosafety Protocol”, and the Canadian biosafety legislation was outlined by Dr. Stephen Yarrow from the Plant Biosafety Office in Canada, and other presentations addressed the “Possibilities and Impossibilities of the Supply Chain and the “Policy Challenges in the GMO legislation.

A programme, the list of participants and the final report can be found at <http://www.cogem.net/ContentFiles/Proceedings%20cogem%20symposium%20the%20new%20gmo%20debate%202008%20web1.pdf>

COST workshop - What role for GM technology in future competitiveness of European agri-food sector?

On 5 November 2008, the organisation “European Cooperation in the Field of Technical and Scientific Research (COST)” organized a workshop with the title “What role for GM technology in the future competitiveness of European agri-food sector?” The workshop provided an overview of international and EU developments in the use of GM technology in the agri-food sector with the objectives to assess the EU status and strategy in relation to GM in agri-food sector and to identify networking activities that will strengthen the EU agri-food sector and prevent it from losing its competitiveness in the global market.

Presentations addressed the development and applications of technology, the EU GM policy and its impacts on GMOs and agri-food sector competitiveness in Europe. During the afternoon session, Piet van der Meer gave a presentation on the overview of the EU GMOs regulations in the last 20 years and introduced PRRI.

For details of this meeting see: <http://www.cost.esf.org/index.php?id=1901>



Second PRRI Brainstorm meeting on risk assessment, 7 November 200

The PRRI brainstorm meetings on risk assessment started as a preparation of the PRRI-Biosafenet side events on risk assessment at MOP4. The first brainstorm was held in April 2008 in Braunschweig.

Given the success of that brainstorm, a second brainstorm was held on 7 November 2008 in Brussels, where the following topics were discussed:

- The steps in the risk assessment as outlined in the CPB;
- The information to be taken into account in each step;
- The comparators used in each step and the rationales for choosing a particular comparator;
- A 'flow chart' as requested by the MOP that would combine all these.

Workshop on Biological Containment System for Transgenic Crops

On 26 - 27 November 2008 a two day workshop was organized by the Consortium of a European Commission funded project "Transcontainer" at the Wageningen University and Research Centre, the Netherlands. The workshop addressed the economic and environmental assessment of the biological containment strategies that are being developed under the project and for the following plants: transgenic tomatoes and eggplants; transgenic forage grasses; transgenic poplar, transgenic oilseed rape. Different economic approaches to the assessment of the potential benefits of these technologies were presented against the potential costs that might be induced by *ex ante* regulations and *ex post* liability claims. The importance of the international regulations such as Cartagena Protocol on Biosafety was also highlighted due to its implications on the socio-economic considerations as a part of the biosafety assessment. For meaningful incorporation of socio-economic considerations during the biosafety assessment procedure appropriate models and tools need to be clearly identified.

For more details see: <http://www.transcontainer.wur.nl/uk/>.

Fourth meeting of the informal advisory committee on the Biosafety Clearing House

On 17 – 18 November 2008 the Fourth meeting of the informal advisory committee on the Biosafety Clearing House (BCH) was organized in Montreal, Canada. The discussion focused on the main activities following MOP4, such as improving usability, accuracy, completeness and availability of information that are accessible through the BCH

The following changes have been discussed:

- To improve the user friendliness of the help sections: 'The BCH', 'The Protocol' and 'Finding Information' (<http://bch.cbd.int/help/topics/en/webframe.html?Home.html>).
- To improve the BCH common formats for entering the information
- To improve the data validation and accuracy
- To identify the reasons why some parties are not committed to add information to BCH.

Following a MOP4 decision, the BCH has started to host online discussions on Risk Assessment, Capacity-Building and Article 18. For the PRRI involvements in various the online discussions see the paragraph below.



From GMP to GBP – Fostering Good Bioethics Practices Among the European Biotechnology Industry. 9 February 2009, Brussels

On 9 February 2009 a final conference of the EC FP6 funded project “From GMP to GBP was held in Brussels, Belgium. The project objective has been to improve the understanding of bioethical issues by using the daily practices of biotechnology companies and to develop a methodology of approaching the ethical issues in order to tackle the gaps between science and society, between risk and perceived risk and expected benefits and potential fears. The project has been focusing on five domains; clinical trials, cell and gene therapies, nanotechnologies, biobanks and diagnostics. The data for the project purposes was based on two interconnected approaches; a survey on ethical practices among biotech industry and an overview of existing regulations that are addressing the ethical issues.

Third PRRI Brainstorm meeting on Risk Assessment

At the brainstorm on 19-20 February 2009, in Delft, the following topics were addressed:

- Feedback from the online discussions – recommendations for PRRI participation in the next rounds.
- The issue of “problem formulation”
- A “flow chart” or “road map” for risk assessment
- Specific points of consideration on RA for GM trees, GM viruses, Plant Made Pharmaceuticals, GM Fish

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

For a report of that meeting see <http://www.iisd.ca/biodiv/bs-gflr/>.

3. Upcoming meetings

PRRI will participate in the following upcoming meetings:

- BioVision, the World Life Sciences Forum, 8-10 Marc 2008, Lyon, France. (<http://www.biovision.org/>)
- Meeting of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management under the Cartagena Protocol on Biosafety. 20 - 24 April 2009, Montreal, Canada
<http://www.cbd.int/doc/?meeting=BSRARM-01>
- Ecological Impact of Genetically Modified Organisms (EIGMO) 14-16 May 2009, Rostock, Germany,
<http://www.iobc-wprs.org/pub/index.html>
- The Co-Extra International Conference, 3 - 5 June 2009, Paris, France
<http://www.coextra.eu/pdf/report1303.pdf>
- 14th European Congress on Biotechnology, 13 - 16 September 2009, Barcelona, Spain.