



Public Research & Regulation Initiative
Secretariat
Julianalaan 67
2628 BC Delft
The Netherlands
Phone: +31-15-278-9289
Email: kim.meulenbroeks@pubresreg.org
Website: www.pubresreg.org

To:
Dr. Ahmed Djoghlaif
Executive Secretary
Convention on Biological Diversity
Montreal, Canada
Fax: +1.514.288-6588

Re: SCBD/BCH/CG/WDY/jh/60095 27 September 2007

30 November 2007

Dear Dr. Djoghlaif,

In response to the invitation to submit views and information in preparation for MOP4 concerning the Assessment and Review of the Cartagena Protocol (Article 35), the Public Research and Regulation Initiative (PRRI) submits the following thoughts for consideration by the MOP.

As with a review of any international instrument, the effectiveness of the Cartagena Protocol on Biosafety (CPB) needs to be conducted in the context of its objectives.

The overall objective of the CPB as stated in article 1 is: *“to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.”*

To understand what this objective entails, it is important to see it in the context of its legal basis, which is article 19 of the Convention on Biological Diversity (CBD).

Article 19, which is titled: *“ Handling of Biotechnology and Distribution of its Benefits”*, requires that each Contracting Party:

- takes appropriate measures to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties (para 1) ,
- to take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties (para 2).

In summary, the first two paragraphs of article 19 of the CBD call for, among other things, intensifying international collaboration in research (para 1), and in providing access to the products of biotechnology (para 2) .

Given on the one hand the anticipated international collaboration in biotechnology, which typically includes the transboundary movement of GMOs, and on the other hand the recognition that (at the time in 1992) only a relatively small number of the Parties to the CBD had established a national biosafety system in accordance with article 8g of the CBD, paragraph 3 was included in article 19.



Para 3 of Article 19 instructs the Parties to “consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.” This protocol has become the CPB, which, among other things, provides Parties that do not yet have a domestic regulatory framework for biosafety in place, with an instrument that allows them to make informed decisions. Another very important aspect of the CPB is that it can contribute to global biosafety by contributing to international harmonisation of technical aspects such as risk assessment.

PRRI submits that the above means that assessing the effectiveness of the CPB means evaluating the extent to which the CPB:

1. has provided Parties that do not yet have a domestic regulatory framework for biosafety with an instrument that allows them to make informed decisions in the field of biosafety, such as the Advanced Informed Agreement procedure (AIA);
2. contributes to international harmonisation of biosafety;
3. allows for the distribution of the benefits of biotechnology through international collaboration in research and use of the products of biotechnology.

While it is too early to come to any firm conclusions on these - interrelated - points, PRRI wishes to share the following observations for the benefit of the discussions of MOP4.

A first step in evaluating the extent to which the CPB provides Parties that do not yet have a domestic regulatory framework for biosafety with an instrument that allows them to make informed decisions in the field of biosafety, is to check the Biosafety Clearing House (BCH).

When checked on 30 November 2007, we find in the BCH under “All AIA decisions” a total of 6 entries, all of which are from countries that actually do have a national biosafety system in place.

This suggests that after 4 years of the CPB being in force, there are no AIA decisions reported to the BCH by Parties that do not yet have a domestic regulatory framework for biosafety in place.

This is highly disconcerting, because this would suggest that the international collaboration on biotechnology research and development has not been intensified, as was agreed in Agenda 21, in Article 19 of the CBD and reaffirmed in the 2005 World Summit on Sustainable Development and in the Millennium Development Goals, but has practically come to a halt.

It would be immensely regrettable if difficulties in implementing the CPB procedures would be one of the reasons for this. We therefore strongly recommend that in reviewing the effectiveness of the CPB, the MOP investigates why after 4 years of the CPB being in force, there are no AIA decisions made by Parties that do not yet have a domestic regulatory framework for biosafety in place, bearing in mind that one of the key goals of the CPB is to provide Parties that do not yet have a domestic regulatory framework for biosafety with an instrument that allows them to make informed decisions in the field of biosafety.

To assist the MOP in such an endeavour, PRRI offers the following observations.

Through informal contacts with PRRI members from all over the world, we understand that in addition to lack of capacity, there may be several other important reasons for the fact that over the last 4 years there have been very few AIA procedures applied in countries that do not yet have a domestic regulatory framework for biosafety in place.



The first reason is that there seems to be a misperception that the provisions of the CPB can only be applied after the CPB is implemented in detailed national laws or regulations. This is not the case. As of the moment a country ratifies the CPB it thereby declares that for the import of LMOs in their country the CPB applies. This means for example that for the intended transboundary movement of an LMO for a field trial in that country, that country needs to be notified in advance. Article 9 of the CPB says that in response to such a notification the Party shall inform the notifier “Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10”. This clearly shows that in the absence of a domestic regulatory framework, Parties can make decisions on the basis of the CPB. PRRI recommends that the MOP devises a strategy how to inform all stakeholders that that in the absence of a domestic regulatory framework, Parties can make decisions on the basis of the CPB.

From our PRRI members we understand that a second reason for the limited number of AIA decisions may be that the CPB in its 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. PRRI therefore proposes that the MOP considers providing guidance that helps countries make such a differentiation between small-scale R&D field releases and commercial releases.

A third reason for the absence of AIA decisions may be that Parties may not be aware that the CPB allows for risk/benefit decisions. Article 15, in conjunction with Annex III, shows that the process of risk assessment starts with an identification of potential adverse effects on the conservation and sustainable use of biological diversity, and ends with an assessment of whether any identified risks are acceptable or manageable. The use of the term ‘acceptable’ means that identified risks are ‘weighed’ against any potential beneficial impacts on the conservation and sustainable use of biological diversity. For example, the potential effects on non-target insects of an insect resistant crop plant may be outweighed by the benefits for those same non-target organisms due to a reduction of synthetic pesticides. Furthermore, article 26 of the CPB makes clear that informed decision making on LMOs not only means taking into account potential impacts on the conservation and sustainable use of biological diversity, but also socio-economic impacts, including socio-economic benefits. For further details I refer to the PRRI submission on socio-economic impacts, which is published on the PRRI web site: www.pubresreg.org.

PRRI proposes that the MOP considers providing guidance that helps countries to make risk/benefit assessments.

PRRI stands ready to assist the Parties and the Secretariat in

- devising a strategy how to inform all stakeholders that that in the absence of a domestic regulatory framework, Parties can make decisions on the basis of the CPB.
- developing guidance that helps countries make a differentiation between small scale R&D field releases and commercial releases, and in
- developing guidance that helps countries to make risk/benefit assessments.

For more information about PRRI and how it can help, please contact the Executive Secretary of PRRI, Piet van der Meer, at pietvandermeer@cs.com.

Yours truly,

A handwritten signature in black ink, appearing to read 'Marc van Montagu', is written over a light blue horizontal line.

Em. Professor Marc van Montagu
Chairman of the Steering Committee of the Public Research and Regulation Initiative