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

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

Re: Notification No. 2009-103

14 September 2009

Dear Dr. Djoghlaf,

On behalf of the Steering Committee of the Public Research and Regulation Initiative (PRRI) I hereby send you our response to the request for scientifically sound information regarding the identification of living modified organisms (LMOs) 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.

PRRI very much welcomes this kind of forward-looking explorations by the MOP. Having said that, PRRI also believes that some distinctions need to be made in order to help focus the next discussions in the MOP.

The overall objective of the Cartagena Protocol on Biosafety (CPB) 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".

An important phrase in this objective is ***"that may have adverse effects"***. This wording is quite different from the more specific language of article 8g of the CBD, which states that Parties shall establish and maintain national biosafety systems to control the use and release of LMOs that ***are likely to have adverse environmental impacts*** that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health. This difference in wording is understandable, because while it is quite feasible for a country to identify for its own national situation which LMOs are likely or unlikely to have adverse environmental effects, the qualifications "likely" and "unlikely" cannot always be extrapolated directly to the situation in other countries. This is why article 19.3 of the CBD and article 1 of the CPB speak of LMOs "that may have adverse effects". Relevant in this context is also article 7.4 of the CPB, which says that the procedures of the CPB shall not apply to LMOs identified by the MOP as "being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health".

One of the major benefits of the CPB is that it contains an internationally agreed methodology of risk assessment through which receiving countries can assess whether LMOs are likely or unlikely to have adverse effects. In this context, PRRI participates with enthusiasm in the work on the "Road Map" of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management (AHTEG), of which we hope that it will assist risk assessors in reaching their goal without unnecessary detours.

A key task of all biosafety regulations, including the CPB, is to identify in a scientifically sound and transparent manner which types of LMOs are likely to have adverse effects and which LMOs are unlikely to have adverse effects. For this task we can make use of the methodology of the risk assessment in the CPB as well as of data on the actual experiences with releases of LMOs.

We therefore advise that for the benefit of the discussions at MOP5 the question " which LMOs or specific traits may have adverse effects"? be split in a number of specific questions:

1. Are there LMOs or traits that *have caused adverse effects*?
2. Are there LMOs or traits of which experience shows that they *are unlikely to cause adverse effects*?
3. Are there LMOs or traits of which risks assessment has shown that they are *likely to cause adverse effects*?
4. Are there LMOs or traits of which risks assessments suggest that they *are unlikely to cause adverse effects*?

In addition, it is also important to bear in mind what is meant by '*adverse effects*'. An overarching general principle of the risk assessment as laid down in the CPB is that risk assessment is comparative, i.e. any identified risks should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment. This is why conclusions on risk assessment in the field of biosafety typically refer to whether or not the assessed LMO is "as safe as its conventional counterpart with respect to potential effects on the environment, taking also into account human health".

In this perspective, PRRI offers the following observations in answer to the above four questions:

1. Are there LMOs or traits that have caused adverse effects?

No. Since the first application of genetic modification in the 80s, many thousands of field trials have been conducted with GM organisms (to date mostly plants), and since 1996 many hundreds of millions of hectares have been planted with GM crops by many millions of farmers and consumed by hundreds of millions of consumers in developed and developing countries, without any verifiable reports of adverse effects on the environment or human or animal health.

In fact, taking a broader look, experience with those GM crops has shown environmental and socio-economic benefits in terms of increases in yield, significant reductions in use of pesticides, fossil fuels and soil erosion, less mycotoxins in grains, as well as increased farmers health and income.

2. Are there LMOs or traits of which experience shows that they are unlikely to cause adverse effects?

The above mentioned experience with the GM crops that have been commercialized thusfar and grown on a large scale, over a long period and by many farmers, suggests that these GM crop plants are unlikely to have adverse effects on the environment, human or animal health. Given that substantive experience shows that these GM crop plants (mainly soybeans, maize, cotton, and oilseed rape, with introduced pest resistance or herbicide tolerance, or a combination of both traits), are unlikely to have adverse effects, they could be eligible for exemption in accordance with article 7.4 of the CPB.

3. Are there LMOs or traits of which risks assessment suggests that they are likely to cause adverse effects?

Prior to the field trials and large scale commercial planting of GM organisms referred to above, many risk assessments have been conducted in many countries. To the best of our knowledge, in no case have authorisations for field trials or commercialisation been denied on the basis of scientifically sound indications of adverse environmental impacts.

4. *Are there LMOs or traits of which risks assessments suggest that they are unlikely to cause adverse effects?*

Bearing in mind that the method of transformation itself is neutral, i.e. that there are no risks related to process of transformation, PRRI believes that there are several types of LMOs and traits for which - on the basis of the characteristics of the host plant, the functioning of the inserted genes and experience with the resulting GMO - it can be concluded that they are as safe as its conventional counterpart with respect to potential effects on the environment, taking also into account human health.

PRRI stands ready to expand on the points made in this letter.

Yours sincerely,

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