**PRRI submission - information on identification of LMOs that are not likely to have adverse effects**

*Public Research and Regulation Initiative (PRRI) submission in response to CBD Notification 2012-016 requesting Parties and stakeholders to submit information on identification of living modified organisms that are not likely to have adverse effects on conservation and sustainable use of biological diversity, taking also into account risks to human health*

**1. Introduction.**

In the context of worsening poverty, hunger, ill health and the continuing deterioration of the ecosystems, governments and international organisations concluded in 1992 in Agenda 21 that modern biotechnology can make a significant contribution to strengthening the sustainable production of food, feed and fibre, to addressing water shortage, to improving health care and to environmental protection. This international consensus has been re-affirmed on numerous occasions, including in the Preamble to the Cartagena Protocol on Biosafety, where it is stated that modern biotechnology has great potential for human well-being.

The potential of modern biotechnological techniques is to be understood in the context of the limitations of conventional breeding:

- Conventional breeding can usually only be done by crossing sexually compatible plants and animals. For example, a disease resistance available in a wheat variety cannot be crossed into a maize plant.
- Breeding a trait into a crop can take a very long time. For example, it took apple breeders over 50 years to cross resistance against scab.
- For some species, such as bananas, sexual crossing is extremely difficult if not impossible.
- Conventional breeding results in 'linkage drag', which means that not only the desired genes are crossed into the variety of choice, but also the tens of thousands other genes of the donor.

To overcome these limitations of conventional breeding, scientists developed over the last decades techniques that made it possible to:

1) identify a specific gene responsible for a trait in an organism,
2) isolate that gene, and
3) bring it into cells through a process called "transformation" (genetic engineering).

Therefore, genetic engineering (i) can be faster than conventional breeding, (ii) is more specific, and (iii) is not limited to just the exchanging genes from related plants or species. The reason that in principle any gene from any organism (micro-organism, plant or animal) can be made to function in any other organism is because DNA is a universal code. In fact many genes found in one organism can also be found in another. For example many genes of humans are also found naturally in bacteria, plants, and animals.

It is precisely because of this potential of genetic engineering and other modern biotechnology techniques that governments and international organisations have invested and are investing very substantive budgets in modern biotechnology research, and – as agreed in Agenda 21 and in article 19 of the Convention of Biological Diversity (CBD) – collaborate internationally.

Given that with genetic engineering it is possible to combine genes in a way that is not likely to occur in nature or through conventional breeding, many countries have – again in line with Agenda 21 and the CBD – also established biosafety systems to assess whether those novel gene combinations raise questions in terms of safety for human health and the environment. Most national biosafety systems use a combination of guidance and legally binding regulations.

The regulatory approach taken in many countries is similar to the CPB, i.e. a broad scope based on novelty, complemented with a mechanism for simplified procedures and exemptions for categories of LMOs of which it has been established that they are unlikely to have adverse effects. Under the CPB, such simplified procedures and exemptions can be established on the national level (art. 13.1.b), on the bilateral or multilateral level (art. 14) and on the global level (art. 7.4).

After over 25 years of research that included tens of thousands field trials with LMOs, and after over 15 years of commercial planting of GM crops on over hundreds of millions of hectares in 30 countries worldwide, a substantial body of knowledge and experience has accumulated.

That knowledge and experience shows that for various categories of LMOs and activities the conclusion can be drawn that, in comparison with their non-modified counterparts, they are unlikely to have adverse effects on conservation and sustainable use of biological diversity, taking also into account risks to human health, (hereafter referred to as “LMOs unlikely to have adverse effects”).

Consequently, enough knowledge and experience has accumulated to allow countries to formulate simplified procedures or exemptions for various categories. In fact, PRRI believes that the formulation of simplified procedures or exemptions is long overdue in many countries, which not only has seriously hampered the potential of public biotechnology research, but also reconfirms the misperception of many that there is something inherently dangerous about LMOs. PRRI therefore commends the MOP for starting an exchange of views and experiences on identification of LMOs that are not likely to have adverse effects. PRRI envisions that the information and concepts in this present paper facilitates a more in depth consideration by the Parties.

To support such a debate, PRRI presents below some considerations that are relevant in identifying LMOs that are unlikely to have adverse effects.

**2. General observations.**

- The technique of genetic engineering in itself carries no inherent risks, and the resulting LMOs are neither inherently risky nor inherently safe. Whether or not an LMO may have adverse effects depends on the receiving organism, the introduced traits, the way the LMO is used, and the receiving environment.
- The techniques of genetic engineering do not cause more unintended changes on the DNA level than conventional crossing or induced mutations. DNA changes are naturally occurring in all organisms.
- After over 25 years of research that included tens of thousands field trials with LMOs, and after over 15 years of commercial planting of GM crops on over hundreds of millions of hectares in 30 countries worldwide, there have been no substantiated cases of adverse effects on human health or biodiversity resulting from the genetic modification.

- This latter conclusion leaves of course unchanged that unwise use of GM crops can cause unintended effects, as is the case of unwise use of any tool. For example, indiscriminate use of herbicides can result in resistance development in weeds. These effects are not the result of the genetic modification, but of poor agronomic practices, which can occur in the same way with conventionally bred herbicide tolerant plants.

While the above considerations do not suggest that LMOs are inherently safe, they are relevant in identifying categories of LMOs and applications that are unlikely to have adverse effects. Such categories can be useful to better match the level of regulatory control with the nature of the LMO, the receiving environments, and ways that the LMOs will be used in those environments.

In this context it is important to note the distinction between "LMOs that are unlikely to have adverse effects" and "applications (e.g. confined field trials) of LMOs that are unlikely to have adverse effects". The first category allows for general exemptions, while the latter category would allow for simplified procedures or exemptions for the described activities, e.g. confined field trials.

Building on these general observations, the next section discusses some more specific considerations for the identification of categories of LMOs that are unlikely to have adverse effects. The text below focuses on GM plants, to serve as a start of an exchange of views, but similar considerations can be given for GM micro-organisms and GM animals.

**3. Considerations for the identification of GM plants that are unlikely to have adverse effects.**

The traits that have been introduced in GM plants to date are to a large extent traits—such as insect resistance, disease resistance and herbicide tolerance—that are already present in many crop plants, or have been introduced by traditional breeding techniques.

Consequently the risk assessment for those cases focuses on the question whether the underlying are likely to produce adverse effects.

On the basis of the accumulated knowledge and experience it can be concluded several categories of introduced traits are unlikely to have adverse effects.

Examples of such traits include:

- Hybrid production traits based on male sterility
- Virus resistance, where the mechanism does not rely on the expression of protein, e.g. RNAi
- Enhancement of nutritional components (e.g. modified oil content, amino acid composition)
- Reduction of endogenously harmful compounds through RNAi (e.g. nicotine, allergens)
- Genes that control plant processes such as extended shelf life
- Traits of aesthetic value (e.g. flower colour)
- Control of plant processes - increased yield through dwarfing
- Insect resistance based on Bt proteins with narrow host range spectrum of affected insects
- Herbicide tolerance based on enzymes that enable the plant to tolerate exposure to specific types of herbicides, such as EPSPS, PAT and BAR.

These examples of traits and mechanisms can be extracted from the (thousands) of scientific studies and risk assessments that have been conducted the last decades, and are confirmed by the results of the many greenhouse and field trials, and by the experiences with commercial planting of some of these crops.

**4. Examples of GM plants for which risk assessments have been conducted**

Numerous GM plants expressing various traits have been assessed for risk by various countries representing a wide range of receiving environments. These GM plants have been approved for commercial cultivation, using risk assessment methodologies consistent with Annex III of the Cartagena Protocol. These LMOs can be searched within the Biosafety Clearing House LMO registry, http://bch.cbd.int/database/lmo-registry/, or more specifically for GM crops, at the following url: http://cera-gmc.org/index.php?action=gm_crop_database&mode=Synopsis. A brief summary of these examples is presented in Annex I of this submission.

The fact that the transgenic traits in these GM crops have received a favourable risk assessment in at least one country supports the conclusion that they are unlikely to cause adverse effects to the conservation and sustainable use of biodiversity in other parts of the world. Furthermore, for many of these crop/trait combinations, a significant amount of experience has been obtained in different types of receiving environments, and this lends further support to extrapolating environmental safety findings from one country to others. This concept is consistent with our experience with non-GM crop plants.

The validity of assessing risk in one country, based on observations and conclusions drawn in another country is well established. For example, the Food and Agricultural Organization (FAO) uses such an approach in assessing weediness risk for imported exotic plant species (FAO, 2005). The likelihood of not having adverse effects then increases as other countries review the same LMO in accordance with their own standards. In the case of the LMOs with which we have experience to date, risk assessments done in many of the individual countries listed in Annex I span the full range of likely potential receiving environments where these LMOs will be grown, and in cases where more than one country has conducted a risk assessment, the range of these likely potential receiving environments represented is especially robust. For example, in the North America alone, ecological zones range from Arctic Cordillera, Tundra, Taiga, Hudson Plains, Northern Forests, Northwestern Forested Mountains, Marine West Coast Forests, Eastern Temperate Forests, Great Plains, North American Deserts, Mediterranean California, Southern Semi-Arid Highlands, Temperate Sierras, Tropical Dry Forests and Tropical Humid Forests (Commission for Environmental Cooperation, 1997). Risk assessments have been done for many of these receiving environments where specific LMOs are likely to be grown. In cases such as Insect Resistant Maize, where several countries have conducted risk assessments (Argentina, Brazil, Canada, Japan, European Union, Philippines, South Africa, United States), virtually all likely potential receiving environments would have already been taken into account.

Furthermore, very large numbers of GM plants have been planted in confined field trials North America, South America, Europe, Asia and Africa (see for example http://www.isb.vt.edu/release-summary-data.aspx, http://www.inspection.gc.ca/english/plaveg/bio/st/st_11e.shtml, http://64.76.123.202/site/agricultura/biotecnologia/50-EVALUACIONES/index.php.http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1, http://mbg.jrc.ec.europa.eu/deliberate/gmo.asp, http://igmoris.nic.in/multiLocReTrail.asp, http://www.nepadbiosafety.net/abne/wp-content/uploads/2010/10/table1.pdf).

In conclusion, PRRI supports the idea to focus risk assessment efforts on those LMOs that require attention, thus enhancing the efficiency and therefore effectiveness of the advanced informed agreement process, thereby allowing the sharing of benefits of modern biotechnology, serving humankind by enhancing global food security and preserving biodiversity.

Annex I: Examples of GM plants that have been assessed for risk and judged safe for the environment

| Crop | Trait | Countries where approved for planting |
|---|---|---|
| Alfalfa | Herbicide tolerance | Canada, Japan |
| Bean | Virus resistance | Brazil |
| Carnation | Altered flower colour | Australia, Colombia, European Union |
| Chicory | Herbicide tolerance + hybrid production traits | European Union, United States |
| Cotton | Herbicide tolerance | Australia, Argentina, Brazil, Colombia, Japan, South Africa, United States |
| | Insect resistance | Argentina, Australia, Brazil, Burkina Faso, Colombia, India, Japan, Mexico, United States, South Africa, China |
| | Insect resistance + herbicide tolerance | Argentina, Australia, Brazil, Japan, South Africa, United States |
| Flax | Herbicide tolerance | Canada, United States |
| Maize | Insect resistance | Argentina, Brazil, Canada, Japan, European Union, Philippines, South Africa, United States |
| | Insect resistance + herbicide tolerance | Argentina, Brazil, Canada, Japan, Korea, Philippines, South Africa, Uruguay, United States |
| | Herbicide tolerance | Argentina, Brazil, Canada, Japan, Philippines, United States, Uruguay, South Africa |
| | Herbicide tolerance + hybrid production traits | Canada, United States |
| | Amylase for ethanol production | Canada, United States |
| | Enhanced lysine | Canada, Japan, United States |
| | Enhanced lysine + insect resistance | Japan |
| Oilseed rape (*B. napus*) | Herbicide tolerance | Australia, Canada, Japan, United States |
| Oilseed rape (*B. rapa*) | Herbicide tolerance | Canada |
| | Herbicide tolerance + hybrid production traits | Australia, Canada, Japan, United States |
| Papaya | Virus resistance | United States |
| Plum | Virus resistance | United States |
| Potato | Insect resistance | Canada, United States |
| | Insect resistance + virus resistance | Canada, United States |
| | Altered starch composition | European Union |
| Rice | Herbicide tolerance | United States |
| Soybean | Herbicide tolerance | Argentina, Brazil, Canada, Japan, Mexico, Paraguay, South Africa, United States, Uruguay |
| | Modified oil content | Canada, Japan, United States |
| Squash | Virus resistant | United States |
| Sugar beet | Herbicide tolerance | Canada, Japan, United States |
| Sunflower | Herbicide tolerance | Canada |
| Tobacco | Low nicotine | United States |
| Tomato | Extended shelf life | Japan, Mexico, United States |
| | Insect resistance | United States |