United States Department of State

Bureau of Oceans and International Environmental and Scientific Affairs

Washington, D.C. 20520

10 May 2012

Mr. Braulio Ferreira de Souza Dias
Executive Secretary
Convention on Biological Diversity
413 Saint-Jacques Street, Suite 800
Montréal QC H2Y 1N9
CANADA

Dear Mr. Ferreira de Souza Dias:

The United States appreciates the opportunity to provide information relevant to the Secretariat's 25 January 2012 Notification SCBD/BS/MPDM/jh/67587 requesting the identification of living modified organisms 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. Such information may be relevant for the exercise of the provisions contained in Article 7.4 of the Cartagena Protocol on Biosafety, which sets out the procedure whereby the Parties may designate LMOs that are exempt from the requirement for the advance informed agreement under the Protocol.

The United States has many years of experience with LMOs in confined and unconfined environmental releases. We provide information on plants and microbes unlikely to result in harm to conservation and the sustainable use of biological diversity based on environmental reviews and practical experience to date.

Sincerely,

Genya V. Dana

Genya V. Dana, PhD
US National Focal Point for the Biosafety Clearing-House
Office of Ecology and Conservation
U.S. Department of State
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Attachment: 10 May 2012 submission entitled "Information relevant to the identification of living modified organisms 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"

INFORMATION RELEVANT TO THE IDENTIFICATION OF LIVING MODIFIED ORGANISMS 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

Submitted by the United States of America
10 May 2012

The United States is submitting this paper in response to the 25 January 2012 request from the Secretariat for scientifically sound information relevant for "the identification of living modified organisms 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."

This request from the Secretariat is part of the medium-term program of work adopted by the fifth Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety held in Nagoya, 11-15 October 2010. Specifically this request of the Secretariat is responsive to decision BS-I/12 paragraph 7 (a) (i) and decision BS-V/12.

Paragraphs IV.12 and 13 of BS-V/12 state:

> *12. Requests Parties and invites other Governments and relevant organizations to submit to the Executive Secretary (i) information on risk assessments, carried out on a case-by-case basis with regards to the receiving environment of the living modified organism, that might assist Parties in the identification of living modified organisms 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, and (ii) the criteria that were considered for the identification of such living modified organisms;*
>
> *13. Requests the Executive Secretary to compile the information received and prepare a synthesis report for consideration by the Parties at their sixth meeting.*

The United States provides the information in this paper also in order to assist the Parties to the Cartagena Protocol on Biosafety to identify living modified organisms (LMOs) that are not likely to adversely affect conservation and sustainable use of biological diversity. Such information may be relevant for the exercise of the provisions contained in Article 7.4 of the Protocol, which sets out the procedure whereby the Parties may designate LMOs that are exempt from the requirement for the advance informed agreement under the Protocol. On the basis of the global experience to date, there are quite a few potential candidates to consider for exemptions, either with or without conditions.

> *Article 7.4: "The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol 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."*

Modern biotechnology techniques as defined in the Cartagena Protocol on Biosafety in themselves do not result in the LMO having more unintended changes on the DNA level or pose a greater likelihood of harm to biological diversity than conventional genetic modification techniques. Whether or not an

LMO is likely to cause harm depends on the characteristics of the organism, the intended use and the receiving environment.

It is important to note that there have been no substantiated cases of harm to biological diversity from confined or unconfined releases of LMOs

The United States is one of many countries with substantial experience in evaluating the safe use of LMOs in the environment and in using LMOs in a wide range of activities, including research, agricultural production of plants and animals, control of animal diseases, control of insects that vector pathogens of humans and animals, and environmental remediation. Many LMOs have moved from experimental scale evaluations in the environment into large scale use, and we welcome the opportunity to provide information about some of these.

Globally to date, hundreds of species (and thousands of individual lines) of LMOs have been evaluated for releases into the environment. Some of these releases have been limited in area and duration (e.g. confined releases, such as field trials), whereas others have been evaluated for releases over larger areas over longer durations (e.g. unconfined releases such as seeds for cultivation by farmers).

The experience gained from the environmental risk assessments and from the subsequent releases indicates that many types of LMOs are unlikely to cause adverse effects to biological diversity. Those LMOs that have been safely used in confined releases in one country are unlikely to adversely affect biological diversity in another country when used in a confined release. Likewise, those LMOs that have been safely used in unconfined releases in one country are unlikely to adversely affect biological diversity in another country when used in an unconfined release.

The first environmental releases of LMOs occurred in the early 1980s. These were confined environmental releases (field trials) with genetically modified bacteria and plants. Subsequent releases have been done with LM viruses, arachnids, insects, and fish. To date, more than 200 species of LMOs have been evaluated in the United States for confined environmental releases. These include bacteria, viruses, fungi, plants, and insects (http://www.nbiap.vt.edu/search-release-data.aspx). Unconfined releases of LM plants include over 16 species, most of which are used extensively in agricultural production of food, fiber, and biofuels.

The results of environmental risk assessments in countries all over the world can be very useful in considering environmental interactions in different types of environments, because different species often have similar ecological functions. In addition, evaluating potential impacts on species is commonly done by using surrogate species in controlled experiments designed to be able to attribute effects with the LMO under consideration.

LMOs evaluated to date for confined environmental releases:

More than 200 species have been evaluated in confined releases in the United States alone. Confined releases have been conducted in numerous countries, including Australia, Canada, Netherlands, Germany, France, Spain, Italy, China, Brazil, Mexico, Nigeria, Kenya, Uganda, South Africa, Burkina Faso, Egypt, Japan, Russia, India, Pakistan, Iran, Thailand, United Kingdom, and the United States. Although many countries provide information online about confined releases with LMOs, it is sometimes challenging to find a single source for such information.

Based on the reviews and experience to date, confined environmental releases of each of these LMOs should be considered to be unlikely to result in harm to biological diversity. Many of these confined environmental releases have been done using well-established techniques used to restrict organisms in the environment until it can be confirmed that the organism is unlikely to cause harm. A number of the containment approaches used for protecting animal and plant health have been used successfully for confined environmental releases of LMOs.

The broad categories of LMOs safely released under confinement to date include those listed in Table 1 below. The herbaceous plant species include annual, biennial and perennial species.

Table 1: Partial list of the types of LMOs and their phenotypes that have been evaluated to date in confined environmental releases.

- *Bacteria, fungi, and plants engineered with marker genes, ice-minus genes, genetic constructs conferring avirulence, etc.*
- *Herbaceous crop plant species modified for resistance to various pathogens (viruses, viroids, bacteria, fungi, nematodes)*
- *Herbaceous crop plant species modified for resistance to insect feeding damage*
- *Herbaceous crop plant species modified for drought tolerance*
- *Herbaceous crop plant species modified for improved product qualities (oil profiles, slow ripening, etc.)*
- *Ornamental plants modified for altered flower color*
- *Fruit trees modified for resistance to viral pathogens*
- *Forest and ornamental tree species modified for resistance to fungal pathogens*
- *Forest and ornamental tree species modified for resistance to insect feeding damage*

LMOs evaluated to date for unconfined environmental releases:

LM plants

LM plants have perhaps been the most extensively reviewed and used LMOs used in unconfined environmental releases. These unconfined releases are typically for use in agriculture and forestry.

To date 18 LM plant species have been reviewed for environmental safety around the world. Some of these species have been grown for many years, in many countries, and over extensive production areas (e.g., maize, soybean, canola, cotton).

The species listed below have been reviewed and approved for unconfined environmental release. The types of phenotypes approved are listed for each species.

More detailed information is available online for each, and in most cases the full environmental review documents are available also. In addition to the Biosafety Clearing-House (BCH), there are two other databases that are useful for gaining access to more detailed information about the LM plants and the available environmental reviews. Each database seems to have its particular strengths, but they draw on the same primary information that individual countries make available.

- The Center for Environmental Risk Assessment (CERA) has a GM Crop Database that includes LM plants and plants regulated as “plants with novel traits” under the Canadian

regulations that do not fit the definition of LMO under the Protocol. (http://www.cera-gmc.org/?action=gm_crop_database&mode=ShowProd&data=23-18-17%2C+23-198)

- The International Service for the Acquisition of Agri-biotech Applications (ISAAA) has a GM Approval Database (http://www.isaaa.org/gmapprovaldatabase/default.asp)

In addition, information about reviews done in the United States can be accessed through the BCH or through the United States Regulatory Agencies Unified Biotechnology Web Site (http://www1.usgs.gov/usbiotechreg/).

Based on the environmental reviews and practical experience to date cultivating these plants, the confined and unconfined environmental releases of each of the plants listed in Table 2 should be considered to be unlikely to result in harm to biological diversity.

Table 2. Types of LM plants approved for unconfined environmental releases in at least one country (some have been approved in multiple countries)

- *Alfalfa – herbicide tolerance*
- *Bean – virus resistance*
- *Chicory – pollen sterility (for breeding hybrid varieties)*
- *Argentine Canola – altered oil profile, herbicide tolerance, pollen sterility*
- *Polish Canola – altered oil profile, herbicide tolerance, pollen sterility*
- *Cotton – insect resistance, herbicide tolerance*
- *Carnation – altered flower color*
- *Flax, Linseed – herbicide tolerance*
- *Maize – insect resistance, herbicide resistance, drought tolerance, pollen sterility, heat-stable alpha-amylase for ethanol production; phytase*
- *Papaya – virus resistance*
- *Plum – virus resistance*
- *Poplar – insect resistance*
- *Potato – virus resistance, insect resistance*
- *Rice – herbicide tolerance, insect resistance*
- *Soybean – altered oil profile, herbicide tolerance, insect resistance*
- *Squash – virus resistance*
- *Sugar Beet – herbicide tolerance*
- *Tobacco – reduced nicotine*
- *Tomato – altered ripening, increased solids, insect resistance*

The United States appreciates that the nature of this information submitted to the Parties via the Secretariat is not an exhaustive scientific treatise, but that it will serve to expand the dialog around the world about the LMOs whose release into the environment is unlikely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. Such dialog should make it possible for even more countries to derive the benefits from the use of LMOs to produce food, feed, and fiber; and to protect biological diversity as well as human and animal health.

LM viruses

Although recombinant vaccines for use in human medicine fall outside the scope of the Protocol, there are other uses of recombinant LM viruses as vaccines. LM viruses are being used as vaccines and are currently licensed for use in numerous countries for the control of important animal diseases.

- Rabies control - Recombinant vaccine is used in numerous countries to control rabies in populations of wild host species and thereby reduce the likelihood of rabies-infected animals passing the rabies to humans and domesticated animals. In the United States, there are currently two such recombinant live vaccines which are licensed: Rabies Vaccine, Live Vaccinia Vector and Rabies Vaccine, Live Canarypox Vector.

Several recombinant vaccines have recently entered the poultry market offering new opportunities for the sector. Examples of recombinant vaccines are:

- Newcastle Disease-Fowl Pox Vaccine, Live Fowl Pox Vector
- Marek's Disease-Newcastle Disease Vaccine, Live Marek's Disease Vector
- Fowl Pox-Laryngotracheitis Vaccine, Live Fowl Pox Vector

The United States has also licensed the use of the following recombinant vaccines to protect the health of horses and cats:

- Feline Rhinotracheitis-Calici- Panleukopenia-Rabies Vaccine, Modified Live virus, Canarypox Vector
- Equine Influenza Vaccine, Live Canarypox Vector

These are some of the currently licensed recombinant veterinary vaccines listed in the Current Veterinary Biologics Product Code book, an online resource that is updated about every six months: (http://www.aphis.usda.gov/animal_health/vet_biologics/publications/CurrentProdCodeBook.pdf).

In addition to these recombinant vaccines licensed in the United States, the European Union has approved a recombinant vaccine for its infectious bovine rhinotracheitis (IBR) eradication program. IBR is a herpesvirus responsible for respiratory disease in feedlot cattle as well as for reproductive diseases, conjunctivitis, and nervous disorders.