UNEP

CBD

Convention on Biological Diversity

Distr.
GENERAL

UNEP/CBD/BS/COP-MOP/6/18/Rev.1
17 September 2012

ENGLISH ONLY

CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY
Sixth meeting
Hyderabad, India, 1-5 October 2012

SUBMISSIONS ON 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

INTRODUCTION

1. Article 7, paragraph 4, of the Cartagena Protocol on Biosafety states that the advance informed agreement 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 the Protocol (COP-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.

2. At its first meeting, the COP-MOP decided to consider, at its fifth meeting, *inter alia*, a modality that might enable the identification of such LMOs. [1]

3. At its fifth meeting, the COP-MOP requested Parties and invited 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 LMO, that might assist Parties in the identification of LMOs 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 LMOs. The COP-MOP further requested the Executive Secretary to compile the information received and to prepare a synthesis report for consideration by the Parties at their sixth meeting.[2]

[1] Decision BS-I/12
[2] Decision BS-V/12.

/…

4. In light of the above decision, the Secretariat sent out a notification to Parties, other Governments and relevant organizations on 25 January 2012.[3]

5. Thirty-two Parties (Bolivia, Brazil, European Union and its Member States, Mexico and Norway), three non-Party countries (Australia, Canada and the United States of America) and five organizations (African Centre for Biosafety - ACB, Global Industry Coalition - GIC, Centre for Integrated Research in Biosafety - INBI, Public Research and Regulation Initiative - PRRI; and the Third World Network - TWN) have submitted their views on this issue as of 11 July 2012.

6. Some submissions included recommendations to the Parties while others had a list of LMOs and scientific publications. Below is a synthesis of the views submitted. A compilation of the full submissions is annexed hereto.

SYNTHESIS OF VIEWS

A. LMOs 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

7. Parties, other Governments and organisations expressed diverging views in their submissions on this topic.

8. On the one hand, the majority of the Parties who submitted views on this issue, namely Bolivia, European Union and its Member States, Mexico and Norway, as well as the ACB, INBI and TWN indicated that it is not scientifically possible to identify any LMOs that can be classified as not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks on human health and thus no LMO can be excluded from the advanced informed agreement procedure under Article 7, Paragraph 4.

9. These Parties acknowledged that the methodology that is currently used to determine the safety of an LMO is done using the general principles of conducting risk assessments, as indicated in Annex III of the Protocol, which specifies that they be carried out on a case-by-case basis taking into account non transferable criteria such as the likely potential receiving environment.

10. These Parties agreed that there is no scientific evidence or examples in the literature to indicate that an LMO would be safe for use in a likely potential receiving environment for which a risk assessment was not specifically carried out. In spite of the measurable amount of experience they have in conducting risk assessments, it is not scientifically sound to assume that the conclusions reached regarding an LMO in one likely potential receiving environment can be transferable and/or applicable to another environment without conducting another risk assessment. Accordingly, these Parties are of the view that to make *a priori* assumptions regarding the safety of an LMO in a novel potential receiving environment undermines, and is contrary to, the concept of the case-by-case approach as defined in Annex III of the Protocol.

11. Norway, INBI and TWN expressed concerns with respect to the legal implications of claiming that an LMO is not likely to have adverse effects in the context of the liability held by a producer in the event that an LMO that may have been approved for unrestricted transboundary movement, under Article 7, paragraph 4, subsequently shows signs of unanticipated adverse effects.

[3] Notification SCBD/BS/MPDM/jh/67587 (2012-016).

12. Bolivia recommended continued in-depth biosafety research and development of guidance on conducting scientifically-sound and transparent risk assessments, whereas Norway, the European Union and its Member States called for the reconsideration, by Parties, of the relevance of Article 7, paragraph 4 in light of the objectives of the Protocol.

13. On the other hand, one Party, Brazil, as well as Australia, Canada, the United States of America, GIC and PRRI supported the compilation of a list of LMOs that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks on human health with a view to arriving at a decision in accordance with paragraph 4 of Article 7.

14. Brazil, as well as Australia, Canada, the United States of America, GIC and PRRI stated that they have a long history and extensive experience in conducting stringent risk assessments on a variety of LMOs such as canola, maize, potatoes, soybeans and ornamental flowers that have been approved in a number of countries with a variety of different potential receiving environments for confined and unconfined releases as well as for commercial usage. They further noted that, under their criteria and approval processes for conducting risk assessments, only those LMOs that are deemed safe and not likely to have adverse effects, as compared to their conventional counterparts, are approved for use. They also noted that in their long experience, to date, no indication that an LMO that has been approved for use exhibited an adverse effect on biodiversity thus an extrapolation can be made that an LMO which has been approved and deemed as safe for use in one country would be unlikely to have adverse effects in another.

15. The GIC cited references of scientific literature indicating that there are no confirmed adverse effects measured as a result of LMO usage.

16. Canada, GIC and PRRI were of the view that pursuing a direction that allows the application of Article 7 paragraph 4 allows for a simplified and streamlined approval process of LMOs that have been deemed unlikely to cause adverse effects as they are introduced into new countries therefore allowing Parties more accessibility to LMOs and reduce regulatory costs.

Annex

COMPILATION OF SUBMISSIONS OF INFORMATION ON 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

CONTENTS

I. SUBMISSIONS FROM PARTIES

A. BOLIVIA

Estado Plurinacional de Bolivia

MMAyA Ministerio de Medio Ambiente y Agua

Bolivian Position on Identification of Living Modified Organisms that are not Likely to Have Adverse Effects In the Context of the Cartagena Protocol on Biosafety

May, 2012

I BACKGROUND

The Cartagena Protocol on Biosafety (CPB) in its Article 7.4, under Article 7 on Application of the Advance Informed Agreement Procedure, states that: "*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*."

In relation to Article 7.4, the Executive Secretary of CPB through Notification SCBD/BS/MPDM/jh/6758 requested to submit: (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.

The following is the position of the Plurinational State of Bolivia on the information requested above in light of the available knowledge, as well as the Bolivian experience on biosafety of living modified organisms (LMOs).

II BOLIVIAN POSITION ON ARTICLE 7.4

2.1 Restricted and conditioned application of Art. 7.4

In the context of the CPB, the consideration of LMOs 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 applies solely to the Advance Informed Agreement (AIA) procedure, and it is subjected to:

- Implementation of the precautionary approach (according to Article 1).

- Analysis of the likelihood of adverse effects based on the risk assessment findings (according to Article 7.1 that relates to decision procedures and risk assessment).

- Decision of the Conference of the Parties (according to Article 7.4).

In other words, LMOs 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, cannot be identified *a priori*; but they must be subject of a precautionary-driven risk assessment. Moreover, the determination of such LMOs is not up to a single Party, non-Party or organization, but is to be determined by a decision of the Conference of the Parties.

Moreover, in the case that such a LMO would be identified by the Conference of the Parties, it would be only exempt from the AIA procedure if consistent with the domestic law of the Parties where its transboundary movement would take place. Meaning, that such LMOs will still be subject to other CPB provisions such as, *inter alia,* review and change decisions in light of new scientific information on potential adverse effects (Article 12), risk assessment (Article 15), risk management (Article 16), handling, transport, packing and identification (Article 18), illegal transboundary movements (Article 15), socioeconomic considerations (Article 26), and liability and redress (Article 27).

2.2 Inappropriateness of defining *a priori* LMOs that are not like have adverse effects

This points addresses: (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.

Any potential identification by the Conference of the Parties of LMOs 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, will imply an *a priori* determination of absence of potential adverse effects related to the LMO in question. This is not only erroneous; but also not precautionary.

Current knowledge on biosafety of LMOs clearly points out unforeseen adverse effects on different component of biological diversity (for instance, adverse effects in the equilibrium among insect populations[1,2], the natural pollination dynamics[3], and soil biology[4,5] - just to mention some - related to insect resistant (*Bt*) crops), as well as potential adverse effects in human health (e.g. Dona and Arvonitoyannis, 2009[6]; Domingo, 2007[7]; Malatesta et al.,

1 Hilbeck A. 2002. Transgenic host plant resistance and non-target effects. In Genetically Engineered Organisms. Assessing Environmental and Human Health Effects. D.K. Letourneau, B.E. Burrows, eds. (Boca Raton, CRC Press), pp. 167-185.

2 Schmidt J.E.; Braun C.U.; Whitehouse L.P.; Hilbeck A. (2009). Effects of Activated Bt Transgene Products (Cry1Ab, Cry3Bb) on Immature Stages of the Ladybird Adalia bipunctata in Laboratory Ecotoxicity Testing. *Arch Environ Contam Toxicol* 56:221–228.

3 Ramirez-Romero R.; Desneux N.; Decourtye A.; Chaffiol A.; Pham-Delègue M.H. (2008). Does Cry1Ab protein affect learning performances of the honey bee Apis mellifera L. (Hymenoptera, Apidae)? *Ecotoxicol Environ Saf*. 70:327-33.

4 Stotzky G. (2004). Persistence and biological activity in soil of the insecticidal proteins from *Bacillus thuringiensis*, especially from transgenic plants. *Plant Soil* 266: 77–89.

5 Castaldini, M., Turrini, A., Sbrana, C., Benedetti, A., Marchionni, M., Mocali, S., Fabiani, A., Landi, S., Santomassimo, F., Pietrangeli, B., Nuti, M. P., Miclaus, N., & Giovannetti, M. (2005). Impact of Bt corn on rhizospheric and soil eubacterial communities and on beneficial symbiosis in experimental microcosms. *Appl. Environ. Microbiol*. 71: 6719–29.

6 Dona, A,; Arvanitoyannis, I. 2009. Health Risks of Genetically Modified Foods. *Critical Reviews in Food Science and Nutrition,* 49:164–175

7 Domingo, J. 2007.Toxicity Studies of Genetically Modified Plants: A Review of the Published Literature. *Critical Reviews in Food Science and Nutrition,* 47:721–733.

2008[8]). These and other potential adverse effects vary in relation to the receiving environment, the socioeconomic context of introduction, and the complex interrelation of multiple socioeconomic and ecological processes. Hence, the potential impacts of LMOs cannot be assumed to be uniform nor predictable. Accordingly, absence of adverse effects of LMOs cannot be determined *a priori*, and all LMOs need to be subject of a case-by-case risk assessment in relation to the environment and socioeconomic context of introduction.

2.3 Adequate risk assessment questions needed instead of criteria for identifying LMOs that are not like have adverse effects

This points addresses: (ii) the criteria that were considered for the identification of such living modified organisms.

Based on the previous point related to the inadequacy of pre-determining that certain LMOs are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, the notion of setting criteria for their identification is erroneous.

The pre-assumption that certain LMOs are not likely to have adverse effects, and setting criteria to identify them will easily lead to Type II errors (false positives) in biosafety research; hence, inadequate regulation. In other words, it will result in the underestimation and lack of detection of potential adverse effects[9]. The final result of this will be delaying or neglecting measures to prevent or remedy those adverse impacts[10].

The Plurinational State of Bolivia is of the view that setting criteria for identifying LMOs 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, is a mistaken approach for the effective implementation of the CPB. Instead, rigorous risk assessment based on robust and transparent biosafety research is needed. Robust biosafety research and risk assessment (namely adequate research questions, sample size and statistical analysis) will avoid dangerous and misleading conclusions on "LMOs are not likely to have adverse effects" (See article in foot note 11). Robust and transparent biosafety research and risk assessment is not only more feasible but also correct from a scientific, regulatory and ethical point of view. It is also essential in achieving the objectives of the Cartagena Protocol on Biosafety.

--- /---

8 Malatesta, M.; Boraldi, F.; Annovi, G.; Baldelli, B.; Battistelli, S.; Biggiogera, M.; Quaglino D.(2008). A long-term study on female mice fed on a genetically modified soybean: effects on liver ageing. *Histochem Cell Biol.* 130:967–977.

9 McGarvey, D. (2007). Merging Precaution with Sound Science under the Endangered Species Act. *BioScience* 57(1):65-70

10 Underwood, A.J.; Chapman, M.G. (2003). Power, precaution, Type II error and sampling design in assessment of environmental impacts. *Journal of Experimental Marine Biology and Ecology* 296: 49– 70.

11 Séralini, E-G.; de Vendômois, J.; Cellier, D.; Sultan, C.; Buiatti, M.; Gallagher, L.; Antoniou, M.; Dronamraju, K. (2009). How Subchronic and Chronic Health Effects can be Neglected for GMOs, Pesticides or Chemicals. *International Journal of Biological Sciences* 5(5):438-443

B. BRAZIL

PERMANENT DELEGATION OF BRAZIL TO THE INTERNATIONAL ORGANIZATIONS LOCATED IN MONTREAL

N. 12

The Permanent Delegation of Brazil to the International Organizations located in Montreal presents its compliments to the Secretariat of the Convention on Biological Diversity and, in regard to the Notification 2012-16, takes this opportunity to send the information provided by the National Biosafety Technical Commission (CTNBio) on living modified organisms deemed unlikely to cause harmful effects on the conservation and sustainable use of biological diversity.

The Permanent Delegation of Brazil avails itself of this opportunity to renew to the Secretariat of the Convention on Biological Diversity the assurances of its highest consideration.

Montreal, April 19, 2012.

BRAZILIAN PERMANENT DELEGATION
ORDEM E PROGRESSO
TO ICAO

Ministério da Ciência, Tecnologia e Inovação
BRASIL PAÍS RICO É PAÍS SEM POBREZA

Ministry of Science, Technology, and Innovation - MCTI
National Biosafety Technical Commission – CTNBio
Executive Secretariat

comissão técnica nacional CTNBio de biossegurança

Memo CTNBio **Brasília, February 15, 2012.**

Ms.
Carmen Ribeiro Moura
Head of the International Affairs Office

Dear Ms. Ribeiro Moura,

In regard to the Electronic Communication 0084/2012 issued by the Environmental Division (Divisão de Meio Ambiente) of the Ministry of External Relation requesting the submission of information on case-by-case risk assessments concerning the receiving environments of living modified organisms (LMO), for the purpose of assisting the Parties with the identification of LMOs deemed unlikely to cause harmful effects on the conservation and sustainable use of biological diversity, taking into account human health factors and the criteria applied to identify the respective LMOs (Decision BS-V/12, §12 COP-MOP), we offer the following observations:

1. Pursuant to Law No. 11105/05, CTNBio performs case-by-case analyses of modified organisms;
2. CTNBio's analyses address aspects, including contained use and commercial use. Since Decision BS-V/12 does not indicate the specific use, pursuant to the scope of the Cartagena Protocol, it is understood that it refers to commercial uses;
3. In regard to commercial uses, all genetically modified organisms approved by CTNBio through the present date have been deemed not to represent potential causes of significant harm to the environment or human and animal health.
4. In respect of commercial licenses for genetically modified cotton, exclusion zones have been established based on protection targets determined for certain rare wild cotton species and on the fact that the respective zones do not constitute traditional cotton producing areas.
5. With respect to the criteria applied to commercial uses risk assessments, these are set forth in CTNBio Resolution No. 05. The English version of the Resolution is attached to this communication.
6. In accordance with the information provided, we include a table of the genetic events approved in Brazil, as well as the results of the corresponding risk assessments (Reports entered).

Respectfully,

Rubens José do Nascimento
General Coordinator of CTNBio

SPO – Área 05 – Quadra 03 Bloco B – Térreo – Salas 08 a 10
Brasília , DF – CEP: 70610-200
Fones: (55)(61) 3411 5151 – FAX: (55)(61) 3317 7475
N/C: _____

Ministério da Ciência, Tecnologia e Inovação
BRASIL PAÍS RICO É PAÍS SEM POBREZA

Ministry of Science, Technology, and Innovation - MCTI
National Biosafety Technical Commission – CTNBio
Executive Secretariat

comissão técnica nacional CTNBio de biossegurança

COMMERCIALLY APPROVED GENETIC EVENT IN SOY

Case	Event	Gene	Characteristic	Company
01200.001864/2009-00	MON 87701 x MON 89788	*Cry1Ac e cp4 epsps*	Resistance to insects and glyphosate tolerance	Monsanto do Brasil Ltda
01200.006065/2007-50	A 2704-12	pat	Ammonium glyphosate tolerance	Bayer S.A
01200.006881/2008-92	A 5547-127	pat	Ammonium glyphosate tolerance	Bayer S.A
01200.000010/2009-06	BPS-CV 127-9	crs1-2	Imidazolinone tolerance	Basf S.A and Embrapa
01200.002402/98-60	GTS 40-3-2	*cp4-epsps*	Glyphosate tolerance	Monsanto do Brasil Ltda

COMMERCIALLY APPROVED GENETIC EVENT IN COTTON

Case	Event	Gene	Characteristic	Company
01200.001471/2003-01	Bollgard 531	*Cry1Ac*	Resistance to insects	Monsanto
01200.001894/2004-01	LL	*Bar*	Herbicide tolerance	Bayer
01200.004487/2004-45	MON 1445	*Cp4-epsps*	Herbicide tolerance	Monsanto
01200.005322/2006-55	Widestrike	*cry1F,cry1Ac, pat,*	Resistance to insects and herbicide tolerance	Dow
01200.003267/2007-40	MON15985	*Cry1A, cry2ab2*	Resistance to insects	Monsanto
01200.000927/2008-01	MON 531 x MON 1445	*Cry1Ac,cp4-epsps*	Resistance to insects and herbicide tolerance	Monsanto
01200.000800/2010-17	GHB614	*2mepsps*	Herbicide tolerance	Bayer
01200.002699/2010-39	Twinlik	*Cry1Ab, cry2Ae, bar*	Resistance to insects and herbicide tolerance	Bayer
01200.003606/2010-93	MON 88913	*cp4-epsps*	Herbicide tolerance	Monsanto

COMMERCIALLY APPROVED GENETIC EVENT IN CORN

Case	Event	Gene	Characteristic	Company
01200.005154/1998-36	LL	*Bar*	Herbicide tolerance	Bayer
01200.002995/1999-54	MON 810	*Cry 1Ab*	Resistance to insects	Monsanto
01200.002706/2000-04	Bt 11	*Cry 1A/pat*	Resistance to insects and herbicide tolerance	Syngenta
01200.002293/2004-16	NK 603	*epsps*	Herbicide tolerance	Monsanto
01200.000082/2006-21	GA 21	*mepsps*	Herbicide tolerance	Syngenta
01200.007232/2006-07	TC 1507	*Cry 1F/pat*	Resistance to insects and herbicide tolerance	DuPont/Dow
01200.007339/2007-08	MIR 162	*VIP3Aa20*	Resistance to insects	Syngenta
01200.003326/2008-61	MON 89034	*Cry 1A.105/Cry2Ab2*	Resistance to insects	Monsanto
01200.001016/2009-92	TC 1507 x NK 603	*Cry 1F/epsps*	Resistance to insects and herbicide tolerance	DuPont/Dow
01200.000926/2009-58	MON 810 x NK 603	*Cry 1Ab/epsps*	Resistance to insects and herbicide tolerance	Monsanto
01200.000925/2009-11	Bt11 x GA 21	*Cry1Ab/epsps*	Resistance to insects and herbicide tolerance	Syngenta
01200.005038/2009-21	BT 11x MIR 162 x GA 21	*Cry1AbxVip3xmepsps*	Resistance to insects and herbicide tolerance	Syngenta
01200.003952/2009-38	MON 89034 x NK 603	*Cry1A.105/Cry2Ab2/epsps*	Resistance to insects and herbicide tolerance	Monsanto
01200.000987/2010-59	MON 88017	*Cry2Bb1epsps*	Resistance to insects and herbicide tolerance	Monsanto
01200.001455/2010-39	MON89034xTC1507xNK603	*Cry1A.105/Cry2Ab2 Cry1F/pat epsps*	Resistance to insects and herbicide tolerance	Monsanto D ow
01200.003895/2010-21	TC1507xMON810xNK603	*Cry 1F/pat/ Cry 1Ab*	Resistance to insects and herbicide tolerance	Du Pont
01200.001788/2010-01	TC1507xMON810	*Cry 1F/pat/ Cry 1Ab*	Resistance to insects and herbicide tolerance	Du Pont
01200.000614/2011-69	MON 89034 x MON 88017	*Cry1A.105, Cry2Ab2, Cry3Bb1, cp4-epsps*	Resistance to insects and herbicide tolerance	Monsanto

SPO – Área 05 – Quadra 03 Bloco B – Térreo – Salas 08 a 10
Brasília , DF – CEP: 70610-200
Fones: (55)(61) 3411 5151 – FAX: (55)(61) 3317 7475
N/C: _____

Ministério da Ciência, Tecnologia e Inovação

BRASIL PAÍS RICO É PAÍS SEM POBREZA

Ministry of Science, Technology, and Innovation - MCTI

National Biosafety Technical Commission – CTNBio

Executive Secretariat

comissão técnica nacional de biossegurança CTNBio

COMMERCIALLY APPROVED EVENT IN BEANS

Case	*Event*	*Gene*	*Characteristic*	*Company*
01200.005161/2010-86	Embrapa 5.1	*Chimerical gene*	Resistance to gold mosaic virus	Embrapa

COMMERCIALLY APPROVED GENETIC EVENT IN MICROORGANISMS (*Sacharomyces cerevisiae*)

Case	*Event*	*Gene*	*Characteristic*	*Company*
01200.003590/2009-85	Cepa Y1978	*Farnesene synthesis*	Fuel production	Amyris

LIVING MODIFIED VACCINES FOR VETERINARY USE

Case	*Event*	*Characteristic*	*Company*
01200.002292/08-92	Recombitek	Canines/Viruses	Merial
01200.005090/2003-92	Vaxxitek MD/IBD	Birds/Marek-Gumboro	Merial
	PRV Marker	Pigs/Aujeszky	Schering
01200.001967/2007-08	Suvaxyn PCV2	Pigs /Circovirus	Fort Dodge
01200.002191/2007-33	Ingelvac	Pigs /Circovirus	Boehringer
01200.000528/2008-51	P. Circumvent	Pigs /Circovirus	Intervet
01200.000396/2008-48	Fostivac	Pigs /E. coli	Fort Dodge
01200.000394/2009-59	Vectormune FP-MG	Birds /Roup-Micoplasma	Ceva
01200.000393/2009-12	Vectormune H-MG/AE	Birds /Roup- Encephalomyelitis	Ceva
01200.000395/2009-01	Vectormune HVT-IBD	Birds /Marek-Gumboro	Ceva
01200.000392/2009-68	Vectormune HVT-NDV	Birds /Marek-Newcastle	Ceva
01200.003421/2010-89	PouvacSt	Birds / Salmonellosis	Fort Dodge
	INNOVAX	Birds /Marek and Laryngotracheitis	Intervet

SPO – Área 05 – Quadra 03 Bloco B – Térreo – Salas 08 a 10
Brasília , DF – CEP: 70610-200
Fones: (55)(61) 3411 5151 – FAX: (55)(61) 3317 7475
N/C: _____

C. EUROPEAN UNION AND ITS MEMBER STATES

Dr. Braulio Ferreira de Souza Dias
Executive Secretary
Secretariat of the Convention on Biological Diversity
United Nations Environment Programme
413 Saint-Jacques Street, Suite 800
Montreal, Quebec, Canada
H2Y 1N9

Copenhagen, Brussels, 14 May 2012

Subject: EU response to Notification 2012-016

Dear Dr. Ferreira de Souza Dias,

On behalf of the European Union and its Member States, please find enclosed the response to Notification 2012-016 in which Parties, other Governments and relevant organizations were invited (according to the COP-MOP/5 decision BS-V/12, paragraph 12) 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.

Yours sincerely,

Sonja Canger
Head of Division
Pesticides & Gene Technology
Environmental Protection Agency
Ministry of the Environment
Strandgade 29 • DK-1401
Copenhagen
Denmark

Hugo Maria Schally
Head of Unit
Multilateral Environmental Agreements;
processes and trade issues
European Commission
Dir. General Environment
Avenue de Beaulieu, 9 Brussels 1160
Belgium

EU submission in response to CBD Notification 2012-016 - Submission of 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

The EU regulatory framework foresees a case-by-case risk assessment of LMOs (recital 18, art 4.3 and Annex II of Directive 2001/18/EC) conforming to the principles of Annex III of the Cartagena protocol. These risk assessments are based on what is required in the EU legislative framework (Annex II of Directive 2001/18/EC) and on detailed guidance developed by the European Food Safety Authority[1] (EFSA).

Information on the risk assessments carried out to date within the framework of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms are publicly available on both the website of EFSA[2] and the Joint Research Center[3] (JRC) of the European Commission.

While the risk assessments referred to above include consideration of the receiving environment for a specific LMO (art 4.3 and Annex II of Directive 2001/18/EC) there is no specific assessment in respect of identifying LMOs that are *not likely* to have adverse effects on the environment or public health. From the existing evidence, the EU cannot come to the unambiguous conclusion that in any environment and under any condition a certain LMO will have no adverse effects (direct or indirect), leading to full exclusion from the scope of the Advanced Informed Agreement procedure.

[1] http://www.efsa.europa.eu/en/gmo/gmoguidance.htm
[2] http://www.efsa.europa.eu/en/gmo/gmoscdocs.htm
[3] http://gmoinfo.jrc.ec.europa.eu/gmc_browse.aspx

D. MEXICO

En respuesta a la Notificación SCBD/BS/MPDM/jh/67587 en seguimiento a la decisión BSV/ 12 de la Quinta Conferencia de las Partes que actúa como Reunión de las Partes del Protocolo de Cartagena sobre Seguridad de la Biotecnología (COP-MOP 5) que dice a la letra:

> *Pide a las Partes e invita a otros gobiernos y organizaciones pertinentes a que presenten al Secretario Ejecutivo: i) información sobre evaluaciones del riesgo, llevadas a cabo individualmente para cada caso en lo que se refiere al entorno receptor del organismo vivo modificado, que pueda ayudar a las Partes en la identificación de organismos vivos modificados que no sea probable que tengan efectos adversos para la conservación y utilización sostenible de la diversidad biológica, teniendo también en cuenta los riesgos para la salud humana, y ii) los criterios en los que se basó la identificación de dichos organismos vivos modificados;*

El Gobierno de México envía la siguiente información.

México cuenta con experiencia amplia como resultado de varios años de liberaciones a nivel experimental de Organismos Vivos Modificados. Sin embargo se considera que no se cuenta con elementos para identificar organismos vivos modificados que no sea probable que tengan efectos adversos para la conservación y utilización sostenible de la diversidad biológica, teniendo también en cuenta los riesgos para la salud humana. Para el caso de los cultivos vivos modificados, esto se debe a que la mayoría de los datos generados documentan aspectos agronómicos que no necesariamente informan de manera directa sobre efectos al medio ambiente.

La forma de reportar los resultados de las liberaciones al ambiente, en sus diferentes etapas en México, ha evolucionado conforme se ha generado experiencia. México reconoce la importancia de continuar el diálogo técnico y científico entre los reguladores y los regulados. Actualmente se está trabajando en detallar la información que deben contener los reportes de las liberaciones al ambiente de OVMs, para que estos también proporcionen información relacionada con aspectos de conservación sustentable de la diversidad biológica conforme a las metas de protección nacionales.

E. NORWAY

ROYAL NORWEGIAN MINISTRY
OF THE ENVIRONMENT

Dr. Braulio Ferreira de Souza Dias
Executive Secretary
Secretariat of the Convention on Biological Diversity
United Nations Environment Programme
413 Saint-Jacques Street, Suite 800
Montreal, QC, H2Y 1N9, Canada

Your ref	Our ref	Date
	200501695-/CLI	5 JUN 2012

Comments from Norway on Notification 2012-016

Dear Dr. Ferreira de Souza Dias,

Notification 2012-016 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.*

In our response to this notification, the Norwegian authorities would like to share some views on

- The case-by case principle of risk assessment under the Protocol
- Inductive generalization from non-existent or negative evidence (including the lack of positive evidence)
- The legal implications of the assertion "not likely to have adverse effects" under the Protocol

1. The case-by case principle of risk assessment under the CPB

The Cartagena Protocol on Biosafety, Annex III paragraph 6 states that *"Risk assessment should be carried out on a case-by-case basis."*, and in paragraph 9 it states that *"Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:"*. This includes paragraph 9(h) *"Receiving environment. Information on the location, geographical, climatic and*

Postal address
PO Box 8013 Dep
0030 Oslo

Office address
Myntgt. 2
postmottak@md.dep.no
www.miljo.no

Telephone
+47 22 24 90 90
Vat no.
972 417 882

Department for Nature Management
Telefax
+47 22 24 95 60

Our officer
Casper Linnestad
+47 45895

ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment."

The different receiving environments of an LMO, including the same geographical area in different seasons or years, may vary in important ways. For example, land use patterns, physiological or reproductive responses under different environmental conditions are well documented. Social, cultural and land management issues related to the receiving environment make a priori predictions of "not likely to have adverse effects" difficult.

A priori determination of an LMO not likely to have adverse effects may undermine the case-by-case principle of risk assessment outlined in Annex III of the Protocol. An assertion of "not likely to have an adverse effect" may be assumption-based, rather than evidence-based and therefore lack sufficient analytical rigor to be of value in upholding the objectives of the Protocol.

2. Inductive generalization from non-existent or negative evidence (including the lack of positive evidence)

The inductive inference of using past generic knowledge or experience on any LMO and applying it to novel cases has its limitations for science-based analyses of non-likelihood of adverse effects. Any assertion of non-likelihood of adverse effects that is science-based should provide statistical support with appropriately adjusted error rates for capturing small but important effects and is necessary to uphold any assertion of no effect. That is, the absence of evidence of harm is not the same as evidence of lack of harm. Hence, scientifically sound conclusions of likelihood may not be drawn and logically derived from the current state of knowledge.

We are unaware of any experience with LMOs to date that would provide credible scientific evidence, or verifiable criteria, to establish the non-likelihood of adverse effects. Such information would further be required to show relevance to risk appraisal in the given context. Empirical scientific evidence to date, and particularly the lack of verifiable absence of adverse effects, does not at present support a conclusion of low likelihood of adverse effects.

Probabilistic inference of likelihood is probably not a valid line of argumentation with the terms and central objective of the Protocol *"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."* (Article 1 of the Protocol).

3. The legal implications of the assertion "not likely to have adverse effects" under the Protocol

In our view, an assumption-based conclusion of "not likely to have adverse effect" does not provide any exclusion for instance for a product developer who would still bear liability in the event that this assumption was erroneous or that the product lost efficacy and caused damage.

Conclusion

Information leading to a conclusion of a LMO "not likely to have adverse effects" may undermine the case-by-case approach of risk assessment under the Protocol. In the case of loss of efficacy or damage resulting from a LMO, a developer will still be presented with legal liability. Further considerations on this topic by Parties would require a stringent process to determine the relevance of such a request (*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*) to meeting the objectives of the Cartagena Protocol on Biosafety.

Yours sincerely,

Birthe Ivars
Deputy Director General

Casper Linnestad
Senior Adviser, National Focal Point
for the Cartagena protocol

II. SUBMISSIONS FROM OTHER GOVERNMENTS

F. AUSTRALIA

AUSTRALIAN GOVERNMENT SUBMISSION – May 2012

Ref SCBD/BS/MPDM/jh/67587, Notification 2012-016

Information on living modified organisms that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health

Australian experience of environmental releases of living modified organisms (LMOs)

Since June 2001 regulatory oversight of environmental releases of LMOs has come under the Australian *Gene Technology Act 2000*[1]. As of 1 May 2012, Australia's Gene Technology Regulator[2] (the Regulator) has issued 93 licences for the intentional release of LMOs into the environment (Appendix A, http://www.ogtr.gov.au). This includes 13 general releases and 80 licences for limited and controlled releases (confined trials).

Each of these authorisations for release to the Australian environment was based on case by case risk assessment – the Regulator must prepare a risk assessment and risk management plan (RARMP) for each application to release an LMO into the Australian environment (see below for further details).

Details of all licences issued for environmental release of LMOs, including the full risk assessment and risk management plan, and licence conditions, are available from the Record of GMO and GM Product Dealings on the website of the Office of the Gene Technology Regulator - http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1

Prior to June 2001, the environmental release of LMOs was subject to voluntary oversight by the Genetic Manipulation Advisory Committee (GMAC). Advice to proceed was given for 107 proposed field trials of genetically modified plants and four general releases (two carnation and two cotton).

Current status of LMOs approved for unconfined general release (ie with no management/confinement conditions)

A number of LMOs have been authorised for environmental release by the Gene Technology Regulator with no specific management or confinement conditions, based on an environmental risk assessment. Table 1 lists the eight approvals authorising LMOs for unrestricted release in Australia as of 1 May 2012. These authorisations include one entry on the GMO Register for genetically modified carnations, six licences for commercial cultivation of genetically modified cotton, canola and rose, and one licence for a genetically modified vaccine for people.

The Regulator has concluded that these LMOs are able to be used in the same manner as their conventional counterparts, including cultivation throughout Australia's landscape of diverse ecosystems and land use types. They were assessed on a case by case basis as not likely to have an adverse affect on the health and safety of people or the environment.

[1] http://www.comlaw.gov.au/Details/C2011C00539, Australia's national biosafety law
[2] Australia's competent authority

GM carnation

Four LMO carnation lines, genetically modified for altered flower colour, have been placed on the Australian GMO Register[3] (see Table 1). These LMO carnations were first approved for general release by GMAC in 1995, commercially released in 1996, re-assessed and licensed by the Regulator in 2003, and included on the GMO Register in 2007 based on a further risk assessment by the Regulator which concluded that they are not likely to have any adverse affects on the health and safety of people or the environment and that no conditions on their release were necessary.

GM cotton and canola

Following environmental risk assessment, insect resistant and herbicide tolerant LMO cotton, and herbicide tolerant LMO canola have been authorised for unrestricted release in Australia (Table 1). LMO cotton has been grown commercially in Australia since 1996 and is now estimated to comprise more than 90% of the cotton crop. LMO canola has been grown commercially in Australia since 2008.

Table 1: LMOs approved for unrestricted release in Australia

LMO	Modified trait	OECD unique identifier(s)	Australian approval and risk assessment
Carnation *Dianthus caryophyllus* L.	Modified colour Selectable marker (herbicide)	FLO-4Ø644-4; FLO-4Ø619-7; FLO-11363-1; FLO-4Ø685-1	Register 001/2004
Rose *Rosa X hybrida*	Modified flower colour Selectable marker (antibiotic)	IFD-52401-4	Licence DIR[4] 090
Cotton *Gossypium hirsutum* L. Bollgard II® cotton, Roundup Ready® cotton, Roundup Ready Flex® cotton, Bollgard II® x Roundup Ready® cotton, Bollgard II®xRoundup Ready Flex® cotton	Herbicide tolerance (glyphosate) Insect resistance (cry1Ac + cry 2Ab) Selectable marker (antibiotic) Reporter gene expression	MON-88913-8; MON-15985-7; MON-88913-8 x MON-15985-7; MON-Ø1445-2; MON-Ø1445-2 x MON-15985-7	Licence DIR 066/2006
Cotton *Gossypium hirsutum* L. Liberty Link® Cotton Liberty Link® x Bollgard II®	Herbicide tolerance (glufosinate ammonium) Insect resistance (cry1Ac + cry 2Ab)	ACS-GH001-3; ACS-GH001-3 x MON-15985-7	Licence DIR 062/2005
Canola *Brassica napus* L. InVigor® x Roundup Ready® canola	Herbicide tolerance (glufosinate ammonium + glyphosate) Hybrid breeding system	ACS-BNØØ7-1; ACS-BNØØ8-2; ACS-BNØØ1-4; ACS-BNØØ2-5; ACS-BNØØ3-6; ACS-BNØØ4-7; ACS-BNØØ5-8; (and hybrids of these) x MON-ØØØ73-7	Licence DIR 108
Canola *Brassica napus* L.	Herbicide tolerance (glufosinate ammonium)	ACS-BNØØ7-1; ACS-BNØØ8-2;	Licence DIR 021/2002

[3] LMOs are only entered on the GMO Register after a period of licensing and after the Regulator is satisfied that any risks are minimal and that it is no longer necessary for the LMO to be licensed directly

[4] DIR = dealings involving intentional release to the environment

InVigor® canola	Hybrid breeding system	ACS-BNØØ1-4; ACS-BNØØ2-5; ACS-BNØØ3-6; ACS-BNØØ4-7; ACS-BNØØ5-8; ACS-BNØØ5-8 x ACS-BNØØ3-6	
Canola *Brassica napus* L. Roundup Ready® canola	Herbicide tolerance (glyphosate)	MON-ØØØ73-7	Licence DIR 020/2002
IMOJEV™ vaccine Yellow fever virus 17D	Japanese Encephalitis vaccine		Licence DIR 098

Criteria for identifying LMOs not likely to have adverse effects

The Regulator must not issue a licence for environmental release of an LMO unless satisfied that any risks to the health and safety of people and the environment can be managed. The Regulator must prepare a risk assessment and risk management plan in respect of each licence application and must consult with a range of experts and agencies.

The Regulator's approach to undertaking risk assessments for LMOs is detailed in the Risk Analysis Framework 2009[5]. This includes consideration of the LMO and introduced trait, the biology of the parent organism, and the receiving environment[6]. Criteria used to identify and assess the likelihood of adverse effects are provided by the Australian *Gene Technology Regulations 2001*[7] and include consideration of:

- the properties of the organism to which dealings proposed to be authorised by a licence relate before it became, or will become, a GMO
- the effect, or the expected effect, of the genetic modification that has occurred, or will occur, on the properties of the organism
- provisions for limiting the dissemination or persistence of the GMO or its genetic material in the environment
- the potential for spread or persistence of the GMO or its genetic material in the environment
- the extent or scale of the proposed dealings
- any likely impacts of the proposed dealings on the health and safety of people
- any previous assessment by a regulatory authority, in Australia or overseas allowing or approving dealings with the GMO
- the potential of the GMO concerned to:
    - be harmful to other organisms
    - adversely affect any ecosystems
    - transfer genetic material to another organism
    - spread, or persist, in the environment
    - have, in comparison to related organisms, an advantage in the environment
    - be toxic, allergenic or pathogenic to other organisms
- the short term and the long term

Based on these criteria the LMOs listed in Table 1 were assessed as not likely to have an adverse affect on the health and safety of people or the environment.

[5] http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1
[6] OECD, Safety Considerations for Biotechnology: Scale-up for Crop Plants (1996) www.oecd.org/dataoecd/26/26/1958527.pdf
[7] regulations 9A and 10, http://www.comlaw.gov.au/Details/F2011C00732

Post release experience of adverse effects

Licence holders are required to inform the Regulator if they become aware of any additional information indicating a risk to the health and safety of people or the environment, or of any unintended effects associated with the dealings authorised by the licence. After a licence has been issued, the Gene Technology Regulator continues to monitor the scientific and other literature for any new information in relation to LMOs, and assess this information for its potential to impact on any existing regulatory approvals.

Beginning with the field trial release of LMO virus resistant potatoes in 1992, no credible reports of adverse effects on the health and safety of people or the environment have been linked to the intentional environmental release of any LMO in Australia. A number of the LMOs authorised for unrestricted commercial release in Australia have also been released in other jurisdictions. Australia's 2009 submission to the CBD (Notification SCBD/BS/MPDM/JH/67587, regarding LMOs that might have adverse effects on the conservation and sustainable use of biodiversity) stated that "no credible information has arisen, either domestically or internationally, to support a link between GM crops approved by the Regulator for commercial release in Australia and adverse impacts on human health or the environment" and no new information has arisen to change this conclusion.

Appendix A: Total DIR Licences issued to 1 May 2012

LMO	Number of Releases		
	Total	**General**	**Limited & controlled**
Cotton	**39**	7 (insect resistance, herbicide tolerance)	32 (insect resistance, herbicide tolerance, modified fatty acid in oil, fungal resistance, water use efficiency, waterlogging)
Canola	**8**	3 (herbicide tolerance, hybrid breeding system)	5 (herbicide tolerance, hybrid breeding system, male sterility, fertility restorer, enhanced yield, delayed leaf senescence)
Sugarcane	**6**	0	6 (altered sugar, reporter gene, water use efficiency, nitrogen efficiency, shoot architecture, expression of sucrose isomerase, herbicide resistance)
Wheat	**6**	0	6 (herbicide tolerance, salt tolerance, altered grain starch, drought tolerance, altered grain composition, enhanced carbon assimilation, grain weight, heat tolerance)
Wheat/barley	**7**	0	7 (drought tolerance, altered grain starch, nutrient use, abiotic stress tolerance)
Banana	**4**	0	4 (enhanced disease resistance, enhanced nutrition)
Canola/Indian Mustard	**2**	0	2 (hybrid breeding system, herbicide tolerance)
Oilseed Poppy	**2**	0	2 (altered alkaloid production)
Pineapple	**2**	0	2 (blackheart reduction, delayed flowering)
Rose	**2**	1 (modified flower colour)	1 (modified flower colour)
Torenia (flower)	**2**	0	2 (modified flower colour, phosphate phenotype)
White Clover	**2**	0	2 (virus resistance)
Carnation	**1**	1 (modified flower colour)	0
Grapevine	**1**	0	1 (modified fruit colour and sugar composition, fruit development)
Indian Mustard	**1**	0	1 (herbicide tolerance, hybrid breeding system)
Maize	**1**	0	1 ((functional characterisation of maize genome)
Papaya	**1**	0	1 (delayed ripening)
Rice	**1**	0	1 (herbicide tolerance)
Ryegrass & Tall Fescue	**1**	0	1 (altered sugar levels, altered structural components of plant cell walls)
Cholera (vaccine)	**1**	1 (attenuation)	0
Japanese Encephalitis Vaccine	**1**	1 (altered antigenic profile)	0
Fowl Adenovirus (vaccine)	**1**	0	1 (attenuation and enhanced immuno-modulation)
Bovine Herpesvirus (vaccine)	**1**	0	1 (attenuation and enhanced immunogenicity)
Bovine parainfluenza virus	**1**	0	1 (attenuation, foreign antigen expression)

G. CANADA

12 May 2012

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

Subject: Canada submission regarding Notification SCBD/BS/MPDM/jh/67587

Dear Mr. Ferreira de Souza Dias:

Canada would like to take this opportunity to provide information relevant to the Notification SCBD / BS / MPDM / jh / 67587 from the CBD Secretariat 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.

Canada has many years of experience with environmental releases of Living Modified Organisms (LMOs). In the attached submission Canada provides information, informed by Canada's environmental reviews and practical experience to date, regarding plants and microbes unlikely to result in harm to conservation and the sustainable use of biological diversity.

Canada is of the view that future CBD activities should seek to contribute to the development of common scientific methodologies and decision-making at all levels 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.

.../2

Canada would propose that additional analysis in support of this work program should focus on LMOs which have already been approved in more than one country based on the principles in Annex III to the Protocol in order to: (1) identify common characteristics / traits of LMOs unlikely to cause a risk to biodiversity; and (2) review the commonality of information requirements and the portability of the science of risk assessment between Parties and Governments as way to consider the merits of the portability of data and the possibility of applying risk assessments either in whole or in part to a number of regulatory jurisdictions.

Sincerely,

Matt Jones
Canada's National Focal Point for the Convention on Biological Diversity
A/Executive Director
Ecosystem and Biodiversity Priorities Division,
Environmental Stewardship Branch,
Environment Canada
Place Vincent Massey (PVM) - Floor: 19
Telephone: 819-994-5076
E-mail: matt.jones@ec.gc.ca
351 St Joseph Blvd
Gatineau, Quebec K1A 0H3
Canada

Attachment:

- *Submission by Canada 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", May 12, 2012.*

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 Canada

May 14, 2012

Under the provisions of the medium-term programme of work, decision BS-I/12 paragraph 7 (a) (i), further elaborated in decision BS-V/12 as 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 (Nagoya, 11-15 October 2010), the Secretariat of the Convention on Biological Diversity has requested Parties and invited other Governments and relevant organizations to submit scientifically sound information on the identification of living modified organisms (LMO) 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.

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.

Canada has over 20 years of experience in conducting scientifically sound assessments on the safe handling and environmental release of LMOs. These risk assessments, many of which predate the coming into force of the Cartagena Protocol, are completely consistent with the principles enunciated in Annex III to the Protocol.

To date, most environmental releases of LMOs have been crops for food and livestock feed production. Canada has also conducted environmental assessments and authorized the environmental release of a recombinant live vaccinia virus as a vaccine to control raccoon rabies. This LMO virus has also been subject to comprehensive field testing and

environmental safety assessments in the EU and the US with positive outcomes. A newer version of this recombinant vaccine has recently been assessed and authorized for environmental release in Canada.

It has been nearly three decades since LMO crop plants first entered regulatory processes in the world. The application of molecular biological tools has allowed plant breeders to rapidly introduce traits that would have been difficult or impossible to introduce via more traditional breeding techniques. This has broadened the scope of genetic changes that can be introduced into plants to achieve specific breeding objectives, although it does not inherently result in plants that are less safe than those produced by more conventional techniques.

In Canada, regulatory oversight for biotechnology products is based on a regulatory approach that considers the novelty of a product, not its method of production, as the trigger for regulatory review. For example, a new agricultural product may be considered novel if it has one or more new traits or one or more changed traits, or if it has a new use. To date, the general scientific consensus is that the method used to produce a new plant variety (either conventional breeding techniques or genetic engineering) is not necessarily an effective predictor of the plant's environmental impact, although new proteins may raise unique food concerns, such as the occurrence of allergens. To date there have been no documented cases of an LMO that has been authorized for commercial release in Canada where any harm to biodiversity has been observed.

Canada has assessed and authorized more than 70 LMO crops for unconfined environmental release including varieties of canola, maize, potatoes, soybeans, squash and sugar beets[1]. Canada's experience mirrors that of other countries where many of the same products have been subject to rigorous reviews and the environmental safety of those products affirmed[2].

Highly domesticated crop species, such as those listed above carrying agronomic traits that protect against herbicide damage, insect feeding damage, virus infection, as well as those with alterations to oil composition or producing enzymes for more efficient feed processing, have been shown to be environmentally safe by one or more competent authorities, representing a wide range of environments[3].

---

[1] For a complete list with information on the status of regulated plants, with novel traits in Canada see: http://active.inspection.gc.ca/eng/plaveg/bio/pntvcne.asp

[2] Decision Documents on authorized products in Canada describing the risk assessment criteria and regulatory decisions for all products can be found at: http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/eng/1303704378026/1303704484236.

[3] For global approvals see: http://cera-gmc.org/index.php?action=gm_crop_database

LMOs intended for environmental release in Canada are regulated and undergo a rigorous environmental risk assessment and, where necessary, risk management that takes into consideration any negative effects on the functions of an ecosystem[4]. In accordance with Canada's responsibilities as a Party to the Convention on Biological Diversity, environmental risk assessments specifically address potential impacts on biodiversity. The risk assessments conducted by Canada are consistent with Annex 3 of the Cartagena Protocol and therefore, are relevant to the request by the Secretariat to identify LMOs that do not pose an unacceptable risk to biodiversity. Commonality in information requirements used by many national biosafety authorities is a strong argument for the portability of data between jurisdictions and may support the possibility of applying risk assessments either in whole or in part to a number of regulatory jurisdictions.

Canada is of the view that LMOs such as those currently approved in Canada for unconfined release, particularly where those approvals have been confirmed in more than one country with similar functioning regulatory systems, provide a starting point in identifying LMOs unlikely to cause a risk to biodiversity, also recognizing that further analysis may be required. The supporting data can easily be generated from the Biosafety Clearing House and will not be cited here.

Canada would propose that additional analysis in support of this work program should focus on LMOs which have already been approved in more than one country based on the principles enunciated in Annex III to the Protocol in order to:

I. Identify common characteristics/traits of LMOs unlikely to cause a risk to biodiversity; and

II. Review the commonality in information requirements and the portability of the science of risk assessment between Parties and Governments for LMOs unlikely to cause a risk to biodiversity in order to consider the merits of the portability of data and the possibility of applying risk assessments either in whole or in part to a number of regulatory jurisdictions.

[4] Assessment criteria for determining environmental safety of plants with novel traits, as contained in Canada's Regulatory Directive Dir94-08, can be found here: http://www.inspection.gc.ca/plants/plants-with-novel-traits/applicants/directive-94-08/eng/1304475469806/1304475550733

H. UNITED STATES OF AMERICA

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
2201 C Street, NW
Washington, DC 20520

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.

III. SUBMISSIONS FROM RELEVANT ORGANIZATIONS

I. AFRICAN CENTER FOR BIOSAFETY

Att: Mr Braulio Ferreira de Souza Dias

Executive Secretary
Convention on Biological Diversity

15/05/2012

Ref. SCBD/BS/MPDM/jh/67587 - Submission of 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.

Dear Mr Braulio Ferreira de Souza Dias

The African Centre for Biosafety (ACB) is a non-profit organisation, based in Johannesburg. We provide authoritative, credible, relevant and current information, research and policy analysis on issues pertaining to genetic engineering, biosafety, and biopiracy in Africa. The ACB has a long track record in engaging in biosafety debates at the national, regional, and international level. Please find below, our response to the following:

"The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP), in paragraph 12 of its decision BS-V/12, requested Parties and invited 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."

We understand our colleagues at the Third World Network and the Centre for Integrated Research in Biosafety, University of Canterbury, plan to make detailed submissions regarding the position of the Biosafety Protocol on risk assessment and potential adverse environmental and human health effects. That being the case, we shall restrict ourselves to information that is particular to the South African context, that we believe deserves consideration.

1. Designating certain varieties as not likely to "have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health" will likely conflict with existing national legislation and undermine biosafety best practice.

The South African GMO Regulations prohibit the undertaking of an activity involving GMO unless a 'suitable and sufficient assessment of the potential adverse effects to the environment,

PO Box 29170, Melville 2109, Gauteng, South Africa No 13 The Braids, Emmarentia, 2195
Tel: +27 (0) 11-486-2701. Fax: +27 (0)11-486-1156
www.biosafetyafrica.org.za

human and animal health and safety has been made'. The Regulations further stipulate that any risk assessment shall including: Identification of any potential adverse effect resulting from the novel genotypic and/or phenotypic characteristics of the GMO; and, an evaluation of the likelihood of these adverse effects being realized, **taking into account the level and kind of exposure of the potential receiving environment to the GMO'.**

To a large extent this accords with Annexure III to the Cartagena Protocol on Biosafety.[i] Further, Section 78 of the South African Biodiversity Act was amended in 2009, and now provides that:

"If the Minister has reason to believe that the release of a genetically modified organism into the environment under a permit applied for in terms of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997), **may pose a threat to any indigenous species or the environment**, no permit for such release may be issued in terms of that Act unless an environmental impact assessment has been conducted in accordance with Chapter 5 of the National Environmental Management Act (NEMA) as if such release were a listed activity contemplated in that Chapter."

This is supported by the GMO Amendment Act (No. 23, 2006), which created a mandatory duty for the EC to consider whether an EIA is required before approving a GMO application. In this regard, the EC is guided by the EIA regulations made in terms of the National Environmental Management Act (No. 107 of 1998).[ii]

Exemptions to these provisions are not provided for in the South African regulatory regime pertaining to GMOs, which is itself crafted to give effect to the Precautionary Principle.

2. The South Africa – Norway joint study project into insect resistant maize, MON810

The ACB feels it pertinent to draw the Secretariat's attention to the results of the Environmental Biosafety and Co-operation Project (EBCP), between South Africa and Norway.[iii] The ECBP was carried out in order to develop a framework for monitoring of insect resistant maize (MON810), and was coordinated by the South African National Biodiversity Institute (SANBI) and the Directorate of Nature Management (DN) in Norway. The study was done as part of SANBI's mandatory duty in terms of section 11(1)(b) of South Africa's National Environmental Management Act, to monitor the impacts of GMOs on the environment.

A series of scientific studies were undertaken by South African and Norwegian researchers over two maize planting seasons (2008/09 and 2009/10), on a range of areas, including: impact on target and non-target organisms, impact on soil organism diversity, and gene flow and its subsequent contribution to the development of insect resistance.

The results, published in early 2011, are noteworthy, and include:

- GM plants grown in the same environment as near isogenic-parent (non-GM counterpart), responded differently to the same environmental conditions, as shown by differences in protein expression. From these results it was concluded that: Protein expression, and thus many protein-related unintended effects, is **largely dependent on the environment and the genetic background of the crop plant**. Due to the unpredictable nature of these unintended, unwanted effects, **it is essential to monitor and identify such effects in field-based baseline studies in several growing conditions, and with several genetically modified varieties.**

- The Cry1Ab protein expressed in bacterial and maize hosts differed in protein size, and hence are likely to differ in other structural 'protein folding' characteristics. This suggests 'that the practice of using the bacterial version as a replacement for maize versions of the same transgenic protein in safety testing should be re-evaluated.'

- MicroRNA expression between MON810 and its non-GM, near-isogenic parential line, was found to differ 'significantly'. Most studies on MiRNA in plants have been conducted under laboratory conditions, which may select for a certain type of MiRNAs expressed under 'no-stress' conditions. The study concluded that 'to gain a better understanding of environmentally induced MiRNA expression and its effect on GM plants, **it is absolutely essential that MiRNA expression is studied in plants that undergo major environmental stresses.**

- A survey to monitor target pest damage to Bt maize revealed **significant differences in maize damage between geographical areas.**

- Assessing the impact of Bt maize on non-target organisms required knowledge of arthropod biodiversity in maize. In order to gather sufficient information on this, surveys were undertaken, over a period of two years, in **five South African provinces.**

Two significant conclusions can be drawn from these results. Firstly, biosafety risk assessment and risk management is highly location specific, and secondly, in the case of MON810 at least, it cannot be assumed that a GMO will have no adverse impact upon the environment.

3. Since its inception in 2003, the ACB has commented on close to thirty applications for trial and full environmental release of various GM maize varieties. Below is a summary of some of the key concerns we have raised over this period, with specific relevance to subject of this letter.

(a) Pioneer Hi-Bred's GM maize TC1507 x MON810 x NK603 (trial release): In its biosafety dossier, submitted to the Registrar: GMO Act, Pioneer states the need to test their traits using germplasm of different backgrounds, **and in different pedo-climatic conditions**. In the case of event 59122, an additional reason stated for the trial is that Pioneer proposes to add two more locations, thus the regulations require a new application to be filed.[iv] Thus, the biotechnology producers' need for vigorous testing, over a wide variety of environmental conditions, is of

tremendous importance for assessing potential problems. The fact that the South African biosafety regulations require each new trial to be applied for separately is a tacit acknowledgment of the heterogeneous nature of biosafety risk assessment and risk management.

(b) Syngenta's GM maize GA21 x Bt11 (general release): Syngenta's application acknowledged the inevitability of some seed dispersal, but states that this is 'highly unlikely' to result in the transfer of glyphosate tolerance to other plants, due to a lack of wild relatives.[v] In some cases maize pollen has been observed to disperse, and still remain viable, at a range of 400m. The risk of gene-flow to wild relatives is by definition an area specific risk, depending as it does upon local wild population characteristics. Lack of risk due to low populations of wild populations in one area cannot simply be taken as a universal given. Further, in parts of South Africa (and the African continent at large) millions of small scale farmers eke out a living on plots of land of less than 10ha in size. **Again, isolation distances deemed sufficient to prevent gene-flow between two large commercial farms may incorporate dozens of small individual farming plots in South Africa.** The viability period of pollen can vary from 3 hours to 9 days, **depending on environmental variables.**[vi]

(c) In 2009 Monsanto applied to the GMO regulatory authorities in South Africa for a field trial release permit for a GM herbicide tolerant Canola variety (Brascia Napus RT73). SANBI itself indicated that RT73 could cross with over 400 species related to Brassica, **which are found within 58km of the proposed RT73 field trials.**[vii]

(d) In 2008 the South African Agricultural Research Council (ARC) submitted an application for the commercial release of a GM potato engineered for resistance to the tuber moth. The ACB found the ARC's application to contain 'numerous flaws in the design and interpretation of experiments as well as gross omissions in the biosafety tests carried out to date.' For example, no molecular analysis into genetic stability in the field, over several generations was provided. Further, experiments to test the bioactivity of the bacterially expressed Cry1Ia1 gene were not carried out on the intended target pest, the *Phtorimea operculata* (potato tuber moth), but the *Manduca sexta* (hookworm). We found the field trial design to have considerable methodological shortcomings, and that future trials need to be carried out **from several plants at the various locations** to determine the efficacy and reliability of the transgenic line. The ARC's assessment of changes in soil microbiology presented data and evidence cited from literature that deliberately compounded **'the variables of location, soil type and seasonality that have been shown to have a greater overall effect on the microbial community compared to the difference observed between transgenic and non-transgenic crops.**[viii]

4. We could cite many more examples from our work, but believe those which we have shown serve to highlight the fundamental importance of case-by-case risk assessment for products of modern biotechnology. We feel this is of particular relevance to South Africa, being as it is the only significant producer of GM crops on the African continent. We see an alarming parallel between a process which seeks to facilitate the possible blanket approval of GM crops, and

efforts we have observed to harmonise regional biosafety laws in Africa through its regional economic communities, which have a focus and expertise on trade rather than biosafety.[ix]

We would like to thank you for the opportunity afforded us to make these submissions, and for the additional time extension we have been given.

Regards,

Mariam Mayet, Director, African Centre for Biosafety

---

[i] ACB (2011). **Overview of the GMO regulatory regime in South Africa.** http://acbio.org.za/images/stories/dmdocuments/GMO%20Regulatory%20Regime.pdf

[ii] ACB (2010). **Letter to Minister Buyelwa Sonjica: request for EIA for GM maize GA21** http://acbio.org.za/images/stories/dmdocuments/ACB_GA21_EIA_request_to_minister.pdf

[iii] SANBI (2011). **Monitoring the environmental impacts of GM maize in South Africa: The outcomes of the South Africa-Norway Biosafety Co-operation Project (2008-2010).** http://www.sanbi.org/sites/default/files/documents/documents/sanbimaizereportlr.pdf

[iv] Stafford, W (2012). **Objection to Pioneer Hi-Bred's application for trial release of multiple GM maize events.** African Centre for Biosafety. http://acbio.org.za/images/stories/dmdocuments/Pioneer_objections_16_04_2012.pdf

[v] ACB (2010). **Objections to Syngenta's application for general release of GM maize event Bt11 x GA21** http://acbio.org.za/images/stories/dmdocuments/ACB_objection_gen_release_GA21_x_Bt11_May_2010.pdf

[vi] ACB (2010). **Submission regarding Monsanto's application for a time extension of an existing permit for activities with GMOs in South Africa – Trial release.** http://acbio.org.za/images/stories/dmdocuments/ACB_objection_MON87460_Lutzville.pdf

[vii] Stafford, W. (2009). **ABC's objections to Monsanto's application for field trial release of herbicide-resistant canola (*Brasica Napus* RT73).** African Centre for Biosafety http://acbio.org.za/images/stories/dmdocuments/Monsanto_Canola_objection.pdf

[viii] ACB (2008). **OBJECTIONS BY AFRICAN CENTRE FOR BIOSAFETY IRO APPLICATION FOR GENERAL RELEASE OF GENETICALLY MODIFIED POTATO MADE BY THE AGRICULTURE RESEARCH COUNCIL (ARC)** http://acbio.org.za/images/stories/dmdocuments/ACB_GM_potato_objection.pdf

[ix] ACB (2010). **Comments on COMESA's draft policy on GMOs.** ACB briefing paper, No.17. http://acbio.org.za/images/stories/dmdocuments/COMESA%20Comments-2010.pdf

PO Box 29170, Melville 2109, Gauteng, South Africa No 13 The Braids, Emmarentia, 2195
Tel: +27 (0) 11-486-2701. Fax: +27 (0)11-486-1156
www.biosafetyafrica.org.za

J. GLOBAL INDUSTRY COALITION

30 April 2012

VIEWS ON 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

GLOBAL INDUSTRY COALITION

The Global Industry Coalition (GIC)[1] is submitting the following information in relation to the request for scientifically sound information on "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 one of the provisions of the medium-term programme of work, decision BS-I/12 paragraph 7 (a) (i) and is further elaborated in decision BS-V/12 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 (Nagoya, 11-15 October 2010).

Paragraphs IV.12 and 13 of BS-V/12 explicitly 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 GIC supports the efforts of the Secretariat towards identification of LMO's 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. With 27 years of global experience conducting risk assessments and a 17 year history of safe commercial use, the GIC strongly believes that Parties should take advantage of the full flexibility allowed by the Protocol in using existing data, data sharing, and regional cooperation in the review and assessment of available data to reduce unnecessary regulatory costs.

[1] The Global Industry Coalition (GIC) for the Cartagena Protocol on Biosafety receives input and direction from trade associations representing thousands of companies from all over the world. Participants include associations representing and companies engaged in a variety of industrial sectors such as plant science, seeds, agricultural biotechnology, food production, animal agriculture, human and animal health care, and the environment.

Introduction

The GIC welcomes the opportunity to share information on risks assessments that have been conducted over the past 27 years, beginning in 1985 with the risk assessments that were conducted prior to the first field trials of GM crops and bacteria. By 2011, 29 countries globally have commercialized GM crops and conducted the associated risk assessments (ISAAA). It is notable that in over 27 years of field trials in countries around the world, no reports of adverse impacts to biodiversity have been confirmed based on routine monitoring by regulatory authorities or in the scientific literature.

We believe that at this point, there are opportunities to realize efficiencies in regulatory processes with respect to products that have been commercialized across varied receiving environments, taking advantage of risk assessments that have been conducted by regulatory authorities in other jurisdictions and the body of scientific information that has been gathered on the history of safe use. Particularly for those products that have been approved for commercialization by numerous regulatory authorities globally, we believe that it is not necessary to repeat risk assessment de novo, which is needlessly costly and provide no increased environmental protection.

Parties should be encouraged to find ways to utilize all available information to assist with regulatory decision making in order to more efficiently utilize the limited resources of regulatory authorities. Much information on existing environmental risk assessments for currently commercialized products is already easily available through the Biosafety Clearinghouse (e.g. http://bch.cbd.int/database/lmo/decisions.shtml?documentid=14750). Additional improvements to the operability of the Biosafety Clearinghouse will assist in making relevant information available to regulators. Further, the Cartagena Protocol on Biosafety and the Convention on Biological Diversity both stress the importance of transnational cooperation. To this end, Parties may seek efficiencies in the review process through cooperation on regional data reviews, while maintaining local decision making authority.

The information provided in this submission updates previous submissions by the GIC on Risk Assessment and Risk Management. In January 2009, the GIC submitted a compilation of environmental risk assessment guidance, which also included references and background information on risk assessment for crops, trees, plant made pharmaceuticals and transgenic animals. In September 2009, the GIC submitted information in relation to the request for scientifically sound information on the identification of LMO's 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. This submission included a lengthy bibliography of references on environmental risk assessment.

The available scientific literature, as described in the current and previous GIC submissions on Risk Assessment and Risk Management, supports the conclusion that there are no confirmed adverse effects detected.

Transgenic Crops

Environmental Risk Assessment for Field Trials of GM Crops in Select Countries

Argentina: Since 1991, over 1700 experimental field trials have been permitted in Argentina. The majority of these were in corn, followed by soybean, cotton, sunflower and rice. Information on risk assessments for field trials is available at: http://64.76.123.202/site/agricultura/biotecnologia/50-EVALUACIONES/index.php.

Australia: Since 1995, 93 licenses for intentional release have been issued in Australia, most frequently for cotton which accounts for 40 licenses. The next most commonly tested crops were canola, wheat and barley. Information on the risk assessments that were conducted prior to issuing licenses for deliberate release is available at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1.

Canada: From 1989 to 2011, 9669 field trials of plants with novel traits, which may include products of mutation breeding, have been conducted in Canada. Information about field trials in Canada is available at: http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/field-trials/eng/1313872595333/1313873672306.

European Union: Field testing began in the European Union in 1991. As of April 2012, over 2500 field trials had been conducted with over 80 different plant species. Figure 2 shows the number of deliberate releases in the EU for field trials by crop for the top ten most frequently tested crops. Information on deliberate releases in the EU for field trials is available at: http://mbg.jrc.ec.europa.eu/deliberate/gmo.asp.

India: Field trials have taken place in India since 1995. Detailed information is available on field trials conducted since 2007, across a range of crops including cotton, corn, rice, potato, brinjal (eggplant), okra, tomato, watermelon, sorghum, mustard, sugarcane and others at: http://igmoris.nic.in/multiLocReTrail.asp.

United States: The first field trials of GM crops were conducted in 1985 in the U.S. Since then, nearly 18,000 field trials have been conducted in the U.S. under permit or notification involving potentially millions of different transformation events. Figure 1 shows the number of releases by crop for the top ten most frequently tested crops. Information on the environmental risk assessments that have been done prior to the issuance of field trial permits or acknowledgments of notification is available at: http://www.aphis.usda.gov/brs/biotech_ea_permits.html.

Environmental Risk Assessment for Commercial Release of GM Crops

It has been 20 years since the first biotechnology-derived (GM) crop was granted deregulated status for environmental release in the United States[2]. Over this time, significant experience has been gained pointing to the safety of the GM crops assessed and approved for environmental release. The GM Crop Database (CERA, 2012) contains comprehensive records on regulatory approvals for regulated crops. This database currently shows that 125 unique products have been granted environmental release[3]. (See Table 1.) The environmental approvals encompass 20 species of plants, most of which are considered highly domesticated. According to the GM Crop Database, 313 separate environmental risk/safety assessments have been completed by regulatory authorities globally. The majority of these assessments have been conducted in the U.S. (82), Canada (72) and Japan (56).

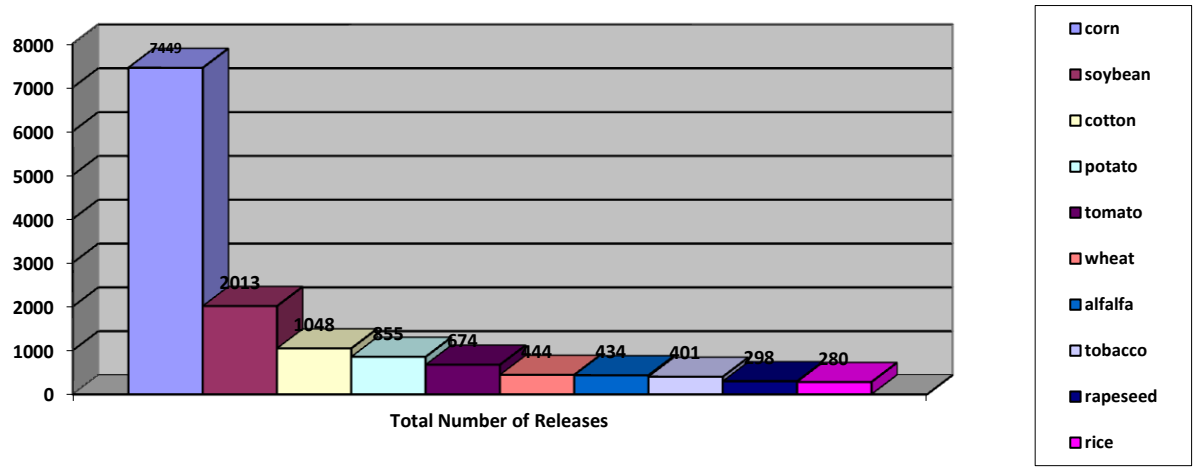
Several of these products have been subject to multiple environmental assessments in the course of seeking approvals in various countries. A total of 14 products have been granted at least five environmental approvals (Table 2), including four products which have been granted approvals by 9 countries: MON531/757/1076 (Bollgard® Cotton), GTS 40-3-2 (Roundup Ready® Soybean), BT11 (X4334CBR, X4734CBR) (Agrisure CB Advantage®) and MON810 (Yieldgard®) maize.

Detailed information on the risk assessments that have been done by regulatory authorities in various countries is available on the following websites:

Australia: www.ogtr.gov.au
Brazil: www.ctnbio.gov.br/index.php
European Union: gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx
United States: www1.usgs.gov/usbiotechreg/

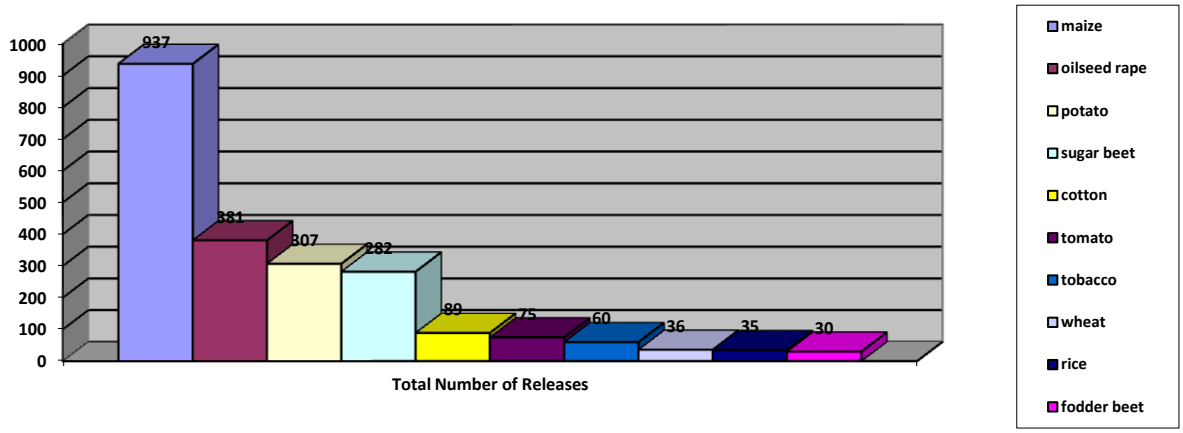
[2] The first GM crop to be approved for environmental release was the FlavrSavr Tomato, which was granted deregulated status in 1992 by the USDA APHIS. The product was not commercialized until 1996.
[3] The database includes information for all approvals including non-GM plants with novel traits in Canada. This database does not include information on other reviews and approvals that have occurred in countries like China and Iran who have reviewed and approved products in rice, cotton, poplar and tobacco.

Figure 1. Total number of field trial releases for top 10 crops in the United States



Source: http://www.isb.vt.edu/release-summary-data.aspx

Figure 2. Total number of field trials releases for top 10 crops in the European Union



Sources: mbg.jrc.ec.europa.eu/deliberate/dbplants.asp up to September 8, 2008 and gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx September 9, 2008 to April 4, 2012

Table 1. Number of environmental assessments conducted globally by crop

Crop	# of Products Approved for Environmental Release[a]	# of Environmental Assessments (approvals)	Trait(s) HT-herbicide tolerance IP-insect protected MS-male sterility QUAL-quality VR-virus resistant	Notes
Alfalfa	1	2	HT	
Canola	15	39	HT, MS, QUAL	*Brassica napa and B. rapa*
Carnation	3	5	HT, QUAL	
Chicory	1	2	HT, MS	
Cotton	17	48	HT, IP	Includes 5 stacked event products
Flax/Linseed	1	2	HT	
Lentil	1	1	HT	Product of mutagenesis
Maize	48	144	HT, MS, QUAL, IP	3 products of mutagenesis; 18 stacked event products
Papaya	2	2	VR	
Plum	1	1	VR	
Potato	4	8	IP, VR	4 different approvals for 20 unique events
Rice	2	2	HT	Does not include Bt rice from China and Iran
Soybean	10	33	HT, QUAL	
Squash	2	2	VR	
Sugar Beet	3	6	HT	
Sunflower	1	1	HT	Product of mutagenesis
Tobacco	1	1	QUAL	
Tomato	6	8	IP, QUAL	5 delayed ripening products
Wheat	6	6	HT	Products of mutagenesis
TOTAL	125	313		

Source: CERA. (2010). GM Crop Database. Center for Environmental Risk Assessment (CERA), ILSI Research Foundation, Washington D.C. http://cera-gmc.org/index.php?action=gm_crop_database

[a] Products may include more than one event.

Table 2. Products with 5 or more environmental assessments (approvals)

Crop	Product	Trait	# of Approvals	Countries
Cotton	MON15985	IP	6	Australia, Brazil, Burkina Faso, India, South Africa, United States
	MON1445/1698	HT	7	Argentina, Australia, Brazil, Colombia, Japan, South Africa, United States
	MON531/757/1076	IP	9	Argentina, Australia, Brazil, Colombia, India, Japan, Mexico, South Africa, United States
Corn/Maize	176	IP	5	Argentina, Canada, European Union, Japan, United States
	Bt11	IP	9	Argentina, Brazil, Canada, Colombia, Japan, Philippines, South Africa, United States, Uruguay
	GA21	HT	7	Argentina, Brazil, Canada, Japan, Philippines, United States, Uruguay
	MON810	IP	9	Argentina, Brazil, Canada, European Union, Japan, Philippines, South Africa, United States, Uruguay
	Bt11xGA21	IP x HT	5	Argentina, Brazil, Canada, Japan, Uruguay
	MIR162	IP	5	Argentina, Brazil, Canada, Japan, United States
	MON89034	IP	5	Argentina, Brazil, Canada, Japan, United States
	NK603	HT	8	Argentina, Brazil, Canada, Japan, Philippines, South Africa, United States, Uruguay
	NK603xMON810	IP x HT	7	Argentina, Brazil, Canada, Japan, Philippines, South Africa, Uruguay
	T14, T25	HT	6	Argentina, Brazil, Canada, European Union, Japan, United States
	TC1507	IP, HT	6	Argentina, Brazil, Canada, Japan, United States, Uruguay

Source: CERA. (2010). GM Crop Database. Center for Environmental Risk Assessment (CERA), ILSI Research Foundation, Washington D.C. http://cera-gmc.org/index.php?action=gm_crop_database

Transgenic Trees

Environmental Risk Assessment for Field Trials

The most comprehensive review of the status of trasgenic trees was prepared by the Food and Agricultural Organization, which conducted a survey in 2003. At that time, 27 countries reported approved field trials of transgenic trees of either forest or tree species. (See Table 3.) An updated summary of the status of field tests with transgenic trees for select countries is provided in Table 4.

Environmental Risk Assessment for Commercial Release

Two countries, the United States and China, have approved the commercial release of transgenic trees, as follows.

China is the only country to approve commercial planting of transgenic forest trees. It is reported that 1.4 million Bt poplar trees have been planted on an area of 300-500 hectares, with an associated refuge for insect resistance management. The oldest trees are now more than 15 years old (Walter, et al. 2010). In addition, it is estimated that 99% of papaya on over 5000 hectares are planted with virus resistant papaya (ISAAA).

Two transgenic tree species have completed the necessary regulatory reviews in the U.S.: virus resistant papaya and virus resistant plum. Virus resistant papaya was commercially deployed in 1998, protecting the Hawaiian papaya industry from the threat of papaya ringspot virus. A second virus resistant papaya variety for cultivation in the state of Florida completed regulatroy review in 2009. Virus resistant plum is not yet commercialized, as the plum pox disease to which it is resistant has not become established in the U.S. Information on the risk assessments that were conducted for these two technologies are available at: www1.usgs.gov/usbiotechreg/.

Table 3. Summary of reported field trials of transgenic trees from 2003 FAO Survey

Field Trials Reported	Genus/Species Assessed	Traits Involved
Australia	Forest Trees:	Reporter and marker genes
Belgium	Eucalyptus	Fruit ripening
Brazil	Populus	Viral resistance
Canada	Picea	Fungal resistance
Chile	Pinus	Herbicide resistance
China	Betula	Lignin modification
Finland		Nitrate reductase synthesis
France	Fruit Trees:	Metabolites
Germany	Carica papaya	Heavy metal phytoremediation
India	Malus	Bacterial resistance
Indonesia	Olea	Salt resistance
Ireland	Prunus	Rooting
Israel	Cyphomandra	Altered ethylene production
Italy	Juglans	Plant development
Japan	Belladonna	Altered sugar alcohol levels
Mexico	Citrus	Metabolism of halogenated hydrocarbons
Netherlands	Persea	Sterility
New Zealand	Castanea	Altered fruit ripening
Norway		Altered gene expression
Portugal		Altered polyphenol oxidase levels
South Africa		Changes in reproduction (not sterility)
Spain		Insect resistance
Sweden		Sugar content
Thailand		
United Kingdom		
United States		
Uruguay		

Source: FAO, 2004, Preliminary review of biotechnology in forestry including genetic modification, Forest Genetic Resources Working Paper 59. (http://www.fao.org/docrep/008/ae574e/ae574e00.htm)

Table 4. Summary of field trials for transgenic trees and other woody perennials in selected countries

Country	# of Permits	Species
Argentina	7	orange
Australia	8	banana, rose, grape, papaya
Canada	72	poplar, spruce, grape, cherry
EU	>80	>25 species
US	>750	>50 species

Sources: Argentina: 64.76.123.202/site/agricultura/biotecnologia/50-EVALUACIONES/___historica/index.php; Australia: www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1; Canada: www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/field-trials/eng/1313872595333/1313873672306; EU: gmoinfo.jrc.ec.europa.eu/gmp_browse.aspx; US: www.isb.vt.edu/search-release-data.aspx.

Plant-Made Pharmaceuticals

Since 2004, USDA has issued over 100 permits for the confined release of plants genetically engineered to produce pharmaceuticals, industrials, value added proteins or for phytoremediation (Table 5)[4]. An annex to the GIC's 2009 submission on environmental risk assessment provided an overview of how some selected countries have adapted existing risk management practices for the conduct of confined field trials to enable the safe production of PMP's under confined, or closed-loop, production systems. Table 5 provides up to date information on release permits issued by the US Department of Agriculture Animal and Plant Health Inspection Service for Pharmaceuticals, Industrials, Value Added Proteins for Human Consumption or for Phytoremediation, as of April 5, 2012.

Transgenic Animals, Including Fish

Also in an annex to the GIC's 2009 submission on environmental risk assessment was an overview of the regulatory and review procedures of selected countries as they apply to the environmental risk assessment of transgenic animals including fish. Since that submission, the US Food and Drug Administration completed an environmental assessment of a goat genetically engineered to produce recombinant human antithrombin III (rhAT), a therapeutic protein for treatment of congenital Antithrombin III deficiency, a life-threatening condition causing clot formation during high risk situations such as surgery and obstetrical procedures. Information on the environmental approval is available at: http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM163814.pdf

In September 2010, the US Food and Drug Administration held a public meeting to review data relevant to the safety and effectiveness concerning a genetically engineered salmon intended to grow faster than conventional bred Atlantic salmon. In conjunction with this meeting, the US Food and Drug Administration released an environmental assessment submitted by the sponsor of the application. It is available at: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224760.pdf.

[4] It is likely that plant made pharmaceuticals will remain regulated, requiring a permit for environmental release in the United States, even for commercial production.

Table 5. Number of release permits issued by USDA for plants genetically engineered to product pharmaceutical and industrial compounds

Year	Pharmaceuticals, Industrials and Value Added Proteins	Phytoremediation
2004	11	5
2005	13	1
2006	11	1
2007	11	1
2008	8	2
2009	10	1
2010	11	1
2011	10	1
2012[a]	6	1
Totals	91	14

[a] As of April 5, 2012. Includes permits that are issued or pending.

References

Recent Publications Relevant to Environmental Risk Assessment of GM Crops

ALBAJES, R., LUMBIERRES, B., MADEIRA, F. & PONS, X. 2012. Field trials to assess risks of transgenic crops for non-target arthropods: power analysis and surrogate arthropods in Spain. *IOBC/WPRS Bulletin,* 73**,** 1-7.

ALBAJES, R., LUMBIERRES, B. & PONS, X. 2009. Responsiveness of Arthropod Herbivores and Their Natural Enemies to Modified Weed Management in Corn. *Environ Entomol,* 38**,** 944-954.

ALBAJES, R., LUMBIERRES, B. & PONS, X. 2010. Managing weeds in herbicide-tolerant GM maize for biological control enhancement. *GMOs in Integrated Plant Production IOBC/wprs Bulletin,* 52**,** 1-8.

ÁLVAREZ-ALFAGEME, F., ORTEGO, F. & CASTAÑERA, P. 2009. Bt maize fed-prey mediated effect on fitness and digestive physiology of the ground predator Poecilus cupreus L. (Coleoptera: Carabidae). *J Insect Physiol,* 55**,** 144-150.

ASANUMA, Y., JINKAWA, T., TANAKA, H., GONDO, T., ZAITA, N. & AKASHI, R. 2011. Assays of the production of harmful substances by genetically modified oilseed rape (Brassica napus L.) plants in accordance with regulations for evaluating the impact on biodiversity in Japan. *Transgenic Research,* 20**,** 91-97.

AVIRON, S., SANVIDO, O., ROMEIS, J., HERZOG, F. & BIGLER, F. 2009. Case-specific monitoring of butterflies to determine potential effects of transgenic Bt-maize in Switzerland. *Agriculture, Ecosystems & Environment,* 131**,** 137-144.

BALOG, A., KISS, J., SZEKERES, D., SZÉNÁSI, Á. & MARKÓ, V. 2010. Rove beetle (Coleoptera: Staphylinidae) communities in transgenic Bt (MON810) and near isogenic maize. *Crop Prot,* 29**,** 567-571.

BHATTACHARJEE, R. 2009. Harnessing Biotechnology for Conservation and Increased Utilization of Orphan Crops. *ATDF Journal,* 6**,** 24-32.

BINDRABAN, P. S., FRANKE, A. C., FERRARO, D. O., GHERSA, C. M., LOTZ, L. A. P., NEPOMUCENO, A., SMULDERS, M. J. M. & WIEL, C. C. M. V. D. 2009. GM-related sustainability: agro-ecological impacts, risk and opportunities of soy production in Argentina and Brazil. *In:* UR, W. (ed.) *Wageningen : Plant Research International, 2009.* Wageningen: Wageningen University and Research Centre.

BOHM, G. M. B. & ROMBALDI, C. V. 2010. Genetic transformation and the use of glyphosate on soil microbial, biological nitrogen dixation, quality and safety of genetically modified soybean. *Ciencia Rural,* 40**,** 213-221.

BROOKES, G. & BARFOOT, P. 2010. Global Impact of Biotech Crops: Environmental Effects, 1996-2008. *AgBioForum,* 13**,** 76-94.

BUCHANAN, G., HERDT, R. W. & TWEETEN, L. G. 2010. Agricultural Productivity Strategies for the Future: Addressing U.S. and Global Challenges. Ames, Iowa: Council for Agricultural Science and Technology.

CARPENTER, J. 2011. Impacts of GM crops on biodiversity. *GM Crops,* 2**,** 1-17.

CARPENTER, J. E. 2010. Peer-reviewed surveys indicate positive impact of commercialized GM crops. *Nat Biotech,* 28**,** 319-321.

CARRIÈRE, Y., ELLERS-KIRK, C., CATTANEO, M. G., YAFUSO, C. M., ANTILLA, L., HUANG, C.-Y., RAHMAN, M., ORR, B. J. & MARSH, S. E. 2009. Landscape effects of transgenic cotton on non-target ants and beetles. *Basic Appl Ecol,* 10**,** 597-606.

CERDEIRA, A. L., GAZZIERO, D. L. P., DUKE, S. O. & MATALLO, M. B. 2010. Agricultural Impacts of Glyphosate-Resistant Soybean Cultivation in South America. *Journal of Agricultural and Food Chemistry,* 59**,** 5799-5807.

CHEN, J., JIANG, X. F., LUO, L. Z. & HU, Y. 2010. Influences of feeding artificial diet containing different concentrations of Cry1Ac toxin by early-instar larvae of Spodoptera exigua (Hubner) (Lepidoptera: Noctuidae) on its larval development and adult reproduction. *Acta Entomologica Sinica,* 53**,** 1119-1126.

DAI, P.-L., ZHOU, W., ZHANG, J., CUI, H.-J., WANG, Q., JIANG, W.-Y., SUN, J.-H., WU, Y.-Y. & ZHOU, T. 2012. Field assessment of Bt cry1Ah corn pollen on the survival, development and behavior of Apis mellifera ligustica. *Ecotoxicology and Environmental Safety,* 79**,** 232-237.

DANA, G. V., KAPUSCINSKI, A. R. & DONALDSON, J. S. 2012. Integrating diverse scientific and practitioner knowledge in ecological risk analysis: a case study of biodiversity risk assessment in South Africa. *Journal of Environmental Management,* 98**,** 134-146.

DHILLON, M. K. & SHARMA, H. C. 2009. Effects of Bacillus thuringiensis δ-endotoxins Cry1Ab and Cry1Ac on the coccinellid beetle, Cheilomenes sexmaculatus (Coleoptera, Coccinellidae) under direct and indirect exposure conditions. *Biocontrol Sci Techn,* 19**,** 407 - 420.

ELLIOTT, L. M., MASON, D. C., ALLAINGUILLAUME, J. & WILKINSON, M. J. 2009. Use of airborne remote sensing to detect riverside Brassica rapa to aid in assessment of transgenic crops. *Journal of Applied Remote Sensing,* 3**,** 033562.

FLIESSBACH, A., MESSMER, M., NIETLISPACH, B., INFANTE, V. & MÄDER, P. 2012. Effects of conventionally bred and Bacillus thuringiensis (Bt) maize varieties on soil microbial biomass and activity. *Biology and Fertility of Soils,* 48**,** 315-324.

FRISVOLD, G. B., BOOR, A. & REEVES, J. M. 2009. Simultaneous Diffusion of Herbicide Resistant Cotton and Conservation Tillage. *AgBioForum,* 12**,** 249-257.

GIVENS, W. A., SHAW, D. R., KRUGER, G. R., JOHNSON, W. G., WELLER, S. C., YOUNG, B. G., WILSON, R. G., OWEN, M. D. K. & JORDAN, D. 2009. Survey of Tillage Trends Following The Adoption of Glyphosate-Resistant Crops *Weed Technol,* 23**,** 150-155.

GRESSEL, J. 2010. Gene flow of transgenic seed-expressed traits: Biosafety considerations. *Plant Science,* 179**,** 630-634.

GUO, J.-Y., WU, G. & WAN, F.-H. 2010. Activities of digestive and detoxification enzymes in multiple generations of beet armyworm, Spodoptera exigua (Hübner), in response to transgenic Bt cotton. *Journal of Pest Science,* 83**,** 453-460.

HAN, P., NIU, C.-Y., LEI, C.-L., CUI, J.-J. & DESNEUX, N. 2010a. Quantification of toxins in a Cry1Ac + CpTI cotton cultivar and its potential effects on the honey bee Apis mellifera L. *Ecotoxicology,* 19**,** 1452-1459.

HAN, P., NIU, C.-Y., LEI, C.-L., CUI, J.-J. & DESNEUX, N. 2010b. Use of an innovative T-tube maze assay and the proboscis extension response assay to assess sublethal effects of GM products and pesticides on learning capacity of the honey bee Apis mellifera L. *Ecotoxicology,* 19**,** 1612-1619.

HARRIGAN, G. G., LUNDRY, D., DRURY, S., BERMAN, K., RIORDAN, S. G., NEMETH, M. A., RIDLEY, W. P. & GLENN, K. C. 2010. Natural variation in crop composition and the impact of transgenesis. *Nat Biotech,* 28**,** 402-404.

HIGGINS, L. S., BABCOCK, J., NEESE, P., LAYTON, R. J., MOELLENBECK, D. J. & STORER, N. 2009. Three-Year Field Monitoring of Cry1F, Event DAS-Ø15Ø7-1, Maize Hybrids for Nontarget Arthropod Effects. *Environ Entomol,* 38**,** 281-292.

HÖNEMANN, L. & NENTWIG, W. 2009. Are survival and reproduction of Enchytraeus albidus (Annelida: Enchytraeidae) at risk by feeding on Bt-maize litter? *Eur J Soil Biol,* 45**,** 351-355.

HÖSS, S., NGUYEN, H. T., MENZEL, R., PAGEL-WIEDER, S., MIETHLING-GRAF, R., TEBBE, C. C., JEHLE, J. A. & TRAUNSPURGER, W. 2011. Assessing the risk posed to free-living soil nematodes by a genetically modified maize expressing the insecticidal Cry3Bb1 protein. *Science of The Total Environment,* 409**,** 2674-2684.

HUANGFU, C.-H., QIANG, S. & SONG, X.-L. 2011. Performance of hybrids between transgenic oilseed rape (Brassica napus) and wild Brassica juncea: An evaluation of potential for transgene escape. *Crop Protection,* 30**,** 57-62.

HUTCHISON, W. D., BURKNESS, E. C., MITCHELL, P. D., MOON, R. D., LESLIE, T. W., FLEISCHER, S. J., ABRAHAMSON, M., HAMILTON, K. L., STEFFEY, K. L., GRAY, M. E., HELLMICH, R. L., KASTER, L. V., HUNT, T. E., WRIGHT, R. J., PECINOVSKY, K., RABAEY, T. L., FLOOD, B. R. & RAUN, E. S. 2010. Areawide Suppression of European Corn Borer with Bt Maize Reaps Savings to Non-Bt Maize Growers. *Science,* 330**,** 222-225.

JENSEN, P. D., DIVELY, G. P., SWAN, C. M. & LAMP, W. O. 2010a. Exposure and Nontarget Effects of Transgenic Bt Corn Debris in Streams. *Environmental Entomology,* 39**,** 707-714.

JENSEN, P. D., DIVELY, G. P., SWAN, C. M. & LAMP, W. O. 2010b. Exposure and Nontarget Effects of Transgenic Bt Corn Debris in Streams. *Environ Entomol,* 39**,** 707-714.

JHALA, A. J., BHATT, H., TOPINKA, K. & HALL, L. M. 2011. Pollen-mediated gene flow in flax (Linum usitatissimum L.): can genetically engineered and organic flax coexist[quest]. *Heredity,* 106**,** 557-566.

JØRGENSEN, R., HAUSER, T., D'HERTEFELDT, T., ANDERSEN, N. & HOOFTMAN, D. 2009. The variability of processes involved in transgene dispersal—case studies from Brassica and related genera. *Environmental Science and Pollution Research,* 16**,** 389-395.

KNISPEL, A. & MCLACHLAN, S. 2010. Landscape-scale distribution and persistence of genetically modified oilseed rape Brassica napus) in Manitoba, Canada. *Environmental Science and Pollution Research,* 17**,** 13-25.

KNOX, O. G. G., WALKER, R. L., BOOTH, E. J., HALL, C., CROSSAN, A. N. & GUPTA, V. V. S. R. 2012. Capitalizing on deliberate, accidental, and GM-driven environmental change caused by crop modification. *Journal of Experimental Botany,* 63**,** 543-549.

KRAMARZ, P., DE VAUFLEURY, A., GIMBERT, F., CORTET, J., TABONE, E., ANDERSEN, M. N. & KROGH, P. H. 2009. Effects of Bt-maize material on the life cycle of the land snail Cantareus aspersus. *Appl Soil Ecol,* 42**,** 236-242.

KRISHNA, V., ZILBERMAN, D. & QAIM, M. 2009. Transgenic Technology Adoption and On-Farm Varietal Diversity. *International Association of Agricultural Economists Conference.* Beijing, China.

KRUGER, G. R., JOHNSON, W. G., WELLER, S. C., OWEN, M. D. K., SHAW, D. R., WILCUT, J. W., JORDAN, D. L., WILSON, R. G., BERNARDS, M. L. & YOUNG, B. G. 2009. U.S. Grower Views on Problematic Weeds and Changes in Weed Pressure in Glyphosate-Resistant Corn, Cotton, and Soybean Cropping Systems. *Weed Technol,* 23**,** 162-166.

KWIT, C., MOON, H. S., WARWICK, S. I. & STEWART, C. N. 2011. Transgene introgression in crop relatives: molecular evidence and mitigation strategies. *Trends in Biotechnology,* 29**,** 284-293.

LAWHORN, C. N., NEHER, D. A. & DIVELY, G. P. 2009. Impact of coleopteran targeting toxin (Cry3Bb1) of Bt corn on microbially mediated decomposition. *Appl Soil Ecol,* 41**,** 364-368.

LAWO, N. C., WÄCKERS, F. L. & ROMEIS, J. R. 2009. Indian Bt Cotton Varieties Do Not Affect the Performance of Cotton Aphids. *PloS ONE,* 4**,** e4804.

LETOURNEAU, D. K. & HAGEN, J. A. 2009. Plant fitness assessment for wild relatives of insect resistant crops. *Environmental Biosafety Research,* 8**,** 45-55.

LI, Y. & ROMEIS, J. 2010. Bt maize expressing Cry3Bb1 does not harm the spider mite, Tetranychus urticae, or its ladybird beetle predator, Stethorus punctillum. *Biol Control,* 53**,** 337-344.

LIU, B., WANG, L., ZENG, Q., MENG, J., HU, W., LI, X., ZHOU, K., XUE, K., LIU, D. & ZHENG, Y. 2009. Assessing effects of transgenic Cry1Ac cotton on the earthworm Eisenia fetida. *Soil Biol Biochem,* 41**,** 1841-1846.

LONDO, J. P., BAUTISTA, N. S., SAGERS, C. L., LEE, E. H. & WATRUD, L. S. 2010. Glyphosate drift promotes changes in fitness and transgene gene flow in canola (Brassica napus) and hybrids. *Annals of Botany,* 106**,** 957-965.

LU, Y., WU, K., JIANG, Y., XIA, B., LI, P., FENG, H., WYCKHUYS, K. A. G. & GUO, Y. 2010. Mirid Bug Outbreaks in Multiple Crops Correlated with Wide-Scale Adoption of Bt Cotton in China. *Science***,** science.1187881.

MANN, R. S., GILL, R. S., DHAWAN, A. K. & SHERA, P. S. 2010. Relative abundance and damage by target and non-target insects on Bollgard and Bollgard II cotton cultivars. *Crop Prot,* 29**,** 793-801.

MEISSLE, M. & ROMEIS, J. 2009a. Insecticidal activity of Cry3Bb1 expressed in Bt maize on larvae of the Colorado potato beetle, Leptinotarsa decemlineata. *Entomologia Experimentalis et Applicata,* 131**,** 308-319.

MEISSLE, M. & ROMEIS, J. 2009b. The web-building spider Theridion impressum (Araneae: Theridiidae) is not adversely affected by Bt maize resistant to corn rootworms. *Plant Biotechnology Journal,* 7**,** 645-656.

MINA, U., CHAUDHARY, A. & KAMRA, A. 2011. Effect of Bt cotton on enzymes activity and microorganisms in rhizosphere. *Journal of Agricultural Science,* 3**,** 96-104.

MÜLLER, A. K., SCHUPPENER, M. & RAUSCHEN, S. 2012. Assessing the impact of Cry1Ab expressing corn pollen on larvae of Aglais urticae in a laboratory bioassay. *IOBC/WPRS Bulletin,* 73**,** 55-60.

NATIONAL RESEARCH COUNCIL 2010. The Impact of Genetically Engineered Crops on Farm Sustainability in the United States. Washington, DC: National Academies.

PERRY, J. N., DEVOS, Y., ARPAIA, S., BARTSCH, D., EHLERT, C., GATHMANN, A., HAILS, R. S., HENDRIKSEN, N. B., KISS, J., MESSÉAN, A., MESTDAGH, S., NEEMANN, G., NUTI, M., SWEET, J. B. & TEBBE, C. C. 2012. Estimating the effects of Cry1F Bt-maize pollen on non-target Lepidoptera using a mathematical model of exposure. *Journal of Applied Ecology,* 49**,** 29-37.

PERRY, J. N., DEVOS, Y., ARPAIA, S., BARTSCH, D., GATHMANN, A., HAILS, R. S., KISS, J., LHEUREUX, K., MANACHINI, B., MESTDAGH, S., NEEMANN, G., ORTEGO, F., SCHIEMANN, J. & SWEET, J. B. 2010. A mathematical model of exposure of non-target Lepidoptera to Bt-maize pollen expressing Cry1Ab within Europe. *Proc R Soc Lond B Biol Sci* 277**,** 1417-1425.

PRIESTLEY, A. & BROWNBRIDGE, M. 2009. Field trials to evaluate effects of Bt-transgenic silage corn expressing the Cry1Ab insecticidal toxin on non-target soil arthropods in northern New England, USA. *Transgenic Res,* 18**,** 425-443.

RAUBUCH, M., BEHR, K., ROOSE, K. & JOERGENSEN, R. G. 2010. Specific respiration rates, adenylates, and energy budgets of soil microorganisms after addition of transgenic Bt-maize straw. *Pedobiologia,* 53**,** 191-196.

RAUSCHEN, S. 2010. A case of "pseudo science"? A study claiming effects of the Cry1Ab protein on larvae of the two-spotted ladybird is reminiscent of the case of the green lacewing. *Transgenic Res,* 19**,** 13-16.

RAUSCHEN, S., SCHAARSCHMIDT, F. & GATHMANN, A. 2010. Occurrence and field densities of Coleoptera in the maize herb layer: implications for Environmental Risk Assessment of genetically modified Bt -maize. *Transgenic Research,* 19**,** 727-744.

RAUSCHEN, S., SCHULTHEIS, E., PAGEL-WIEDER, S., SCHUPHAN, I. & EBER, S. 2009. Impact of Bt-corn MON88017 in comparison to three conventional lines on Trigonotylus caelestialium (Kirkaldy) (Heteroptera: Miridae) field densities. *Transgenic Res,* 18**,** 203-214.

RAYBOULD, A. & VLACHOS, D. 2011. Non-target organism effects tests on Vip3A and their application to the ecological risk assessment for cultivation of MIR162 maize. *Transgenic Research,* 20**,** 599-611.

ROLA, A. C., CHUPUNGCO, R. A., ELAZEGUI, D. D., TAGARINO, R. N., NGUYEN, M. R. & SOLSOLOY, A. D. 2010. Consequences of Bt cotton technology importation. *Philippine Agricultural Scientist,* 93**,** 9-21.

ROMEIS, J., HELLMICH, R., CANDOLFI, M., CARSTENS, K., DE SCHRIJVER, A., GATEHOUSE, A., HERMAN, R., HUESING, J., MCLEAN, M., RAYBOULD, A., SHELTON, A. & WAGGONER, A. 2011. Recommendations for the design of laboratory studies on non-target arthropods for risk assessment of genetically engineered plants. *Transgenic Research,* 20**,** 1-22.

ROMEIS, J. & MEISSLE, M. 2011. Non-target risk assessment of Bt crops – Cry protein uptake by aphids. *Journal of Applied Entomology,* 135**,** 1-6.

ROMEIS, J., MEISSLE, M., RAYBOULD, A. & HELLMICH, R. L. 2009. *In:* FERRY, N. & GATEHOUSE, A. M. R. (eds.) *Environmental impact of genetically modified crops.* Wallingford; UK: CABI.

SANVIDO, O., ROMEIS, J. & BIGLER, F. 2009. An approach for post-market monitoring of potential environmental effects of Bt-maize expressing Cry1Ab on natural enemies. *Journal of Applied Entomology,* 133**,** 236-248.

THE ROYAL SOCIETY 2009. Reaping the benefits: science and the sustainable intensification of global agriculture. London, England: The Royal Society.

TOTHOVA, T., SOBEKOVA, A., HOLOVSKA, K., LEGATH, J., PRISTAS, P. & JAVORSKY, P. 2010. Natural glufosinate resistance of soil microorganisms and GMO safety. *Central European Journal of Biology,* 5**,** 656-663.

TOWERY, D. & WERBLOW, S. 2010. Facilitating Conservation Farming Practices and Enhancing Environmental Sustainability with Agricultural Biotechnology. West Lafayette, Indiana: Conservation Technology Information Center.

TRIGO, E., CAP, E., MALACH, V. & VILLARREAL, F. 2009. The Case of Zero-Tillage Technology in Argentina. Washington, DC: International Food Policy Research Institute.

WANG, J. & YANG, X. 2010. Application of an atmostpheric gene flow model for assessing environmental risks from transgenic corn crops. *International Journal of Agricultural and Biological Engineering,* 3**,** 36-42.

WANG, Z.-J., LIN, H., HUANG, J.-K., HU, R.-F., ROZELLE, S. & PRAY, C. 2009. Bt Cotton in China: Are Secondary Insect Infestations Offsetting the Benefits in Farmer Fields? . *Agricultural Sciences in China,* 8**,** 101-105.

WOLT, J. D. & PETERSON, R. K. D. 2010. Prospective formulation of environmental risk assessments: Probabilistic screening for Cry1A(b) maize risk to aquatic insects. *Ecotoxicology and Environmental Safety,* 73**,** 1182-1188.

WU, G., HARRIS, M. K., GUO, J.-Y. & WAN, F.-H. 2009. Response of multiple generations of beet armyworm, Spodoptera exigua (Hubner), feeding on transgenic Bt cotton. *J Appl Entomol,* 133**,** 90-100.

ZEILINGER, A. R., ANDOW, D. A., ZWAHLEN, C. & STOTZKY, G. 2010. Earthworm populations in a northern U.S. Cornbelt soil are not affected by long-term cultivation of Bt maize expressing Cry1Ab and Cry3Bb1 proteins. *Soil Biol Biochem,* 42**,** 1284-1292.

ZURBRÜGG, C. & NENTWIG, W. 2009. Ingestion and excretion of two transgenic Bt corn varieties by slugs. *Transgenic Research,* 18**,** 215-225.

Recent Scientific Literature Relevant to Environmental Risk Assessment of Transgenic Trees

AXELSSON, E., HJÄLTÉN, J., LEROY, C., JULKUNEN-TIITTO, R., WENNSTRÖM, A. & PILATE, G. 2010. Can Leaf Litter from Genetically Modified Trees Affect Aquatic Ecosystems? *Ecosystems,* 13**,** 1049-1059.

BOYD, E. 2010. Societal Choice for Climate Change Futures: Trees, Biotechnology, and Clean Development. *BioScience,* 60**,** 742-750.

DIFAZIO, S. P., LEONARDI, S., SLAVOV, G. T., GARMAN, S. L., ADAMS, W. T. & STRAUSS, S. H. 2012. Gene flow and simulation of transgene dispersal from hybrid poplar plantations. *New Phytologist,* 193**,** 903-915.

FAO 2010. Forests and Genetically Modified Trees. Rome: Food and Agriculture Organization of the United Nations.

HU, J., YANG, M. & LU, M. 2010. Advances in biosafety studies on transgenic insect-resistant poplars in China. *Biodiversity Science,* 18**,** 336-345.

MEIRMANS, P. G., LAMOTHE, M., GROS-LOUIS, M.-C., KHASA, D., PÉRINET, P., BOUSQUET, J. & ISABEL, N. 2010. Complex patterns of hybridization between exotic and native North American poplar species. *American Journal of Botany,* 97**,** 1688-1697.

SCHNITZLER, F. R., BURGESS, E. P. J., KEAN, A. M., PHILIP, B. A., BARRACLOUGH, E. I., MALONE, L. A. & WALTER, C. 2010. No Unintended Impacts of Transgenic Pine (Pinus radiata) Trees on Above Ground Invertebrate Communities. *Environmental Entomology,* 39**,** 1359-1368.

STEFANI, F. O. P. & HAMELIN, R. C. 2010. Current state of genetically modified plant impact on target and non-target fungi. *Environmental Reviews,* 18**,** 441-475.

TYSON, R. C., WILSON, J. B. & LANE, W. D. 2011. A mechanistic model to predict transgenic seed contamination in bee-pollinated crops validated in an apple orchard. *Ecological Modelling,* 222**,** 2084-2092.

WALTER, C., FLADUNG, M. & BOERJAN, W. 2010. The 20-year environmental safety record of GM trees. *Nat Biotech,* 28**,** 656-658.

ZHAO, J. H., HAN, J. & ZHAO, D. G. 2010. Bioinformatic prediction of marker protein allergenicity in transgenic crops. *Acta Tabacaria Sinica,* 16**,** 76-79.

Recent Scientific References Relevant to Environmental Risk Assessment of Transgenic Animals

AHRENS, R. M. & DEVLIN, R. 2011. Standing genetic variation and compensatory evolution in transgenic organisms: a growth-enhanced salmon simulation. *Transgenic Research,* 20**,** 583-597.

DUAN, M., ZHANG, T., HU, W., GUAN, B., WANG, Y., LI, Z. & ZHU, Z. 2010. Increased mortality of growth-enhanced transgenic common carp (Cyprinus carpio L.) under short-term predation risk. *Journal of Applied Ichthyology,* 26**,** 908-912.

MADIN, E. M. P. 2011. Genetically Engineered Salmon Pose Environmental Risks That Must Be Considered. *BioScience,* 61**,** 6.

MUMFORD, J. D. 2012. Science, regulation, and precedent for genetically modified insects. *PLoS Neglected Tropical Diseases,* 6**,** e1504-e1504.

REEVES, R. G., DENTON, J. A., SANTUCCI, F., BRYK, J. & REED, F. A. 2012. Scientific standards and the regulation of genetically modified insects. *PLoS Neglected Tropical Diseases,* 6**,** e1502-e1502.

SANTOS, M., NOGUEIRA, P., DIAS, F., VALLE, D. & MOREIRA, L. 2010. Fitness aspects of transgenic Aedes fluviatilis mosquitoes expressing a Plasmodium -blocking molecule. *Transgenic Research,* 19**,** 1129-1135.

SCOLARI, F., SICILIANO, P., GABRIELI, P., GOMULSKI, L., BONOMI, A., GASPERI, G. & MALACRIDA, A. 2011. Safe and fit genetically modified insects for pest control: from lab to field applications. *Genetica,* 139**,** 41-52.

SMITH, M. D., ASCHE, F., GUTTORMSEN, A. G. & WIENER, J. B. 2010. Genetically Modified Salmon and Full Impact Assessment. *Science,* 330**,** 1052-1053.

STEINKRAUS, H. B., ROTHFUSS, H., JONES, J. A., DISSEN, E., SHEFFERLY, E. & LEWIS, R. V. 2012. The absence of detectable fetal microchimerism in nontransgenic goats (Capra aegagrus hircus) bearing transgenic offspring. *Journal of Animal Science,* 90**,** 481-488.

WISE DE VALDEZ, M. R., NIMMO, D., BETZ, J., GONG, H.-F., JAMES, A. A., ALPHEY, L. & BLACK, W. C. 2011. Genetic elimination of dengue vector mosquitoes. *Proceedings of the National Academy of Sciences*.

K. CENTER FOR INTEGRATED RESEARCH IN BIOSAFETY

Centre for Integrated Research in Biosafety

Tel: +64 3 354 2500, Fax: + 64 364 2590
Email: jack.heinemann@canterbury.ac.nz

UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

Ref. SCBD/BS/MPDM/jh/67587 - Submission of 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.

This is a submission from the Centre for Integrated Research in Biosafety (INBI)[1] on paragraph 12 of decision BS-V/12 as per the request of Mr. Ahmend Djoghalf (25 January 2012):

"The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP), in paragraph 12 of its decision BS-V/12, requested Parties and invited 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."

In reply to (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:

We note that this hypothetical category of LMOs is relevant only for the purposes of Article 7(4)[2]. We further note that Article 15 requires risk assessments of LMOs to be undertaken in accordance with Annex III which states in part 6: "Risk assessment should be *carried out on a case-by-case basis*. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the *likely potential receiving environment*" (emphasis added).

After a thorough reflection of the scientific literature on risk assessment of LMOs, we can find no examples of case-by-case risk assessments based on scientific data of adequate quality[3] that would in our opinion assist Parties in identifying LMOs that could be

---

[1] The Centre for Integrated Research in Biosafety (INBI) is a multidisciplinary research centre located at the University of Canterbury, New Zealand. We are composed of primarily academic teaching and research staff. Our mission is to provide advice on the safe implementation of biotechnology, including conducting risk assessment research and performing evaluations of risk assessments. Our core audience is the public and public sector with an emphasis on those who could otherwise not access the resources to address their questions.

[2] "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."

[3] For terms, please refer to AHTEG. Guidance Document on Risk Assessment of Living Modified Organisms. http://www.cbd.int/doc/meetings/bs/mop-05/official/mop-05-12-en.pdf: United Nations

considered to not likely "have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health" in environments that were not explicitly considered in the case-by-case assessment.

By their very nature, case-by-case risk assessments are not suited to making global or universal assessments. This is for various reasons. Case-by-case assessments:

- include case-specific protection goals; these protection goals vary from area to area, country to country and region to region;
- will have used assessment endpoints and measurements of these endpoints that were specific to the potential receiving environment and society; "[d]ue to the complexity and variability of environmental relations, it is not possible to predict all potential effects for all regions where a GMO might be exposed. Thus it remains uncertain whether the results of risk analysis obtained on a temporally and spatially limited basis, actually hold under conditions of commercial use on larger spatio-temporal scales"[4];
- different jurisdictions require different methods to inform their case-by-case risk assessments. For example, the European Union requires a general surveillance monitoring plan[5] and risk assessments that are not informed by such a plan will not provide the information necessary to determine whether an LMO, assessed using different procedures for different potential receiving environments, is not likely to cause an unanticipated adverse effect in the countries of the EU.
- are compatible with all articles of the Protocol, but a global assessment would not be. For example, Article 23(a)[6] of the Protocol sets requirements for "safe transfer and handling" which by necessity will be country-specific and intended use-specific for the following reasons:
    - the potential to cause an adverse effect may in part be deemed unlikely because of specific transfer and handling procedures;
    - these procedures will be informed by knowledge of the capacity and familiarity of the public and/or users of the LMO and this capacity and familiarity will differ from country to country and intended use.

In summary, it was not possible to find credible evidence to support the contention that existing case-by-case assessments are demonstrated transferable to all other, much less all, potential receiving environments, or that case-by-case assessment is compatible with the notion that they would be transferable. We are unaware of any existing LMOs that have benefited from a globally comprehensive set of case-by-case risk assessments. Without even a single such case to draw experience from, we find it premature to consider the premise that there could be a reason to expect that any particular case-by-case assessment would provide evidence that any LMO or trait derived from modern biotechnology is "not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."

In reply to (ii) the criteria that were considered for the identification of such living modified organisms:

Do criteria exist that could be adopted to identify LMOs that are not likely to have an adverse effect? Given the nature of the case-by-case risk assessment process, this

---

Environment Programme Convention for Biodiversity; http://www.cbd.int/doc/meetings/bs/mop-05/official/mop-05-12-en.pdf; 2010.

[4] p. 72 of Breckling, B. and Reuter, H. (2006). General surveillance of genetically modified organisms – the importance of expected and unexpected environmental effects. J. Verbr. Lebensm. *1 Supplement 1*, 72-74.

[5] Directive 2001/18/EC Annex VII.

[6] "Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health."

question is in our opinion unproductive because it is too open ended to inform a scientifically credible risk assessment process. Any given LMO would have to benefit from an environment-specific risk assessment for all potential receiving environments and then be retrospectively confirmed to not have caused an adverse effect in any potential receiving environment. Conversely, different potential receiving environments would have to be determined to be alike in all relevant ways to transfer the conclusions from one to the other. Neither of these is at present a scientific or practical possibility.

If there were LMOs which had already been evaluated by a comprehensive, or at least objectively representative, range of case-by-case risk assessments, then it would be possible to *begin* a discussion of whether any one or combination of case-by-case assessments were predictive of a global outcome. Of course, this type of discussion would not likely be productive until a statistically informative number of comprehensively assessed LMOs and traits existed.

In summary, it was not possible to find evidence of any scientifically plausible criteria for identifying LMOs not likely to cause an adverse effect.

Notwithstanding our assertion that there is no evidence of any scientifically plausible criteria for identifying LMOs not likely to cause an adverse effect, should the Parties come to form the view that they would be satisfied that such identifications could be made in some generic way, then we would suggest two criteria that should be mandatory.

Any such products should have such a high level of confidence that they can cause no adverse effects that developers of such products:

(1) assume and maintain liability for unanticipated adverse effects and bear the costs of ongoing monitoring, and
(2) assume liability for any subsequent adverse effect resulting from its intended use which results in a loss of efficacy (e.g., loss of use of a herbicide that was overused in conjunction with the LMO[7]).

In summary, it was not possible to identify any scientific basis for establishing criteria that would assist Parties in identifying LMOs "not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health." Attempts to categorise LMOs this way would be fundamentally at odds with case-by-case risk assessment.

Sincerely yours,

Dr. Jack A. Heinemann
Professor of Genetics and Molecular Biology
School of Biological Sciences
and
Director, Centre for Integrated Research in Biosafety
University of Canterbury

[7] It is clear, for instance, that the intended use of Roundup (or glyphosate-based herbicides) on Roundup Ready crops has uniquely lead to the development of glyphosate-tolerant weeds that threaten the use of glyphosate-based herbicides on LMOs and conventional crops. For references, see Heinemann, J. A. and Kurenbach, B. (2008). Special threats to the agroecosystem from the combination of genetically modified crops and glyphosate (Kuala Lumpur, Third World Network).

L. PUBLIC RESEARCH AND REGULATION INITIATIVE

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

M. THIRD WORLD NETWORK

Submission by Third World Network (TWN)

Information on 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

1. The context: Article 7(4)

The request for information on the identification of living modified organisms (LMOs) that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, is made in the context of Article 7(4) of the Cartagena Protocol on Bisoafety.

Article 7(4) states:

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.

Based on the current knowledge and experience gained on biosafety of LMOs, TWN is of the opinion that it is not possible to identify LMOs 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 is due to various reasons, the need for case-by-case risk assessment being the most obvious one (see the elaboration in Point 3 below). Notwithstanding this opinion, TWN would like to emphasize that any identification of such LMOs **is only relevant to the application (or not, as the case may be) of the advance informed agreement procedure.**

Thus, if any such identification is agreed to by a decision of the COP-MOP in accordance with its rules and procedures, this cannot be taken to imply a blanket assurance of 'safety', nor should it be extrapolated as such.

2. Other applicable and/or relevant provisions of the Cartagena Protocol

This also means that if any such identification is agreed to by a decision of the COP-MOP in accordance with its rules and procedures, the other obligations and rights in the provisions of the Cartagena Protocol still continue to apply and/or are relevant to LMOs that have been identified as not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

The applicable and/or relevant provisions of the Cartagena Protocol and the key elements include, *inter alia*:

- Article 1 - the precautionary approach

- Article 2(4) – the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in the Protocol
- Article 15 – the right of a Party to subject all LMOs to risk assessment prior to the making of decision on import
- Article 16 – the obligation of Parties to establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks
- Article 16(3) – the obligation of Parties to take appropriate measures to prevent unintentional transboundary movements of LMOs, including such measures as requiring a risk assessment to be carried out prior to the release of a LMO
- Article 18(1) – the obligation of Parties to take necessary measures to require that LMOs that are subject to intentional transboundary movement are handled, packaged and transported under conditions of safety
- Article 18(2)(c) – documentation requirements accompanying LMOs that are intended for intentional introduction into the environment of the Party of import and any other LMOs within the scope of the Protocol
- Article 20 – information sharing and the Biosafety Clearing House
- Article 23 – public awareness, education and participation, including access to information
- Article 25 – the obligation of Parties to prevent and, if appropriate, penalize illegal transboundary movements
- Article 26 – the right to take into account socio-economic considerations
- Article 27 and the provisions of the Nagoya- Kuala Lumpur Supplementary Protocol on Liability and Redress – the application of liability and redress rules and procedures in the event of damage caused by a LMO.

TWN also emphasizes that if there is damage caused by a LMO, liability and redress applies regardless of whether that LMO has been identified 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.

3. The need for case-by-case risk assessments and consideration of the LMO concerned, its intended use and the likely potential receiving environment

Article 15 of the Cartagena Protocol requires risk assessments to be undertaken in accordance with Annex III (Risk assessment).

Paragraph 1 of Annex III states:

The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the ***likely potential receiving environment****, taking also into account risks to human health.* (emphasis added)

Paragraph 5 of Annex III states:

Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the ***likely potential receiving environment****.* (emphasis added)

Paragraph 6 of Annex III states:

Risk assessment should be carried out on a ***case-by-case*** *basis. The required information may vary in nature and level of detail from case to case,* ***depending on the living modified organism concerned, its intended use and the likely potential receiving environment***. (emphasis added)

Paragraph 8(a), 8(b) and 8(f) of Annex III state:

To fulfil its objective, risk assessment entails, as appropriate, the following steps:
(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the ***likely potential receiving environment****, taking also into account risks to human health;*
(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the ***likely potential receiving environment*** *to the living modified organism;*
(f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the ***receiving environment***. (emphasis added)

Paragraph 9(h) of Annex III states:

9. ***Depending on the case****, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:*
(h) Receiving environment*. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the* ***likely potential receiving environment***. (emphasis added)

It is clear from the reading of the above provisions that the risk assessment process set out in the Cartagena Protocol on Biosafety should be carried out on a case-by-case basis and that the specific LMO concerned, its intended use and the likely potential receiving environment are all important considerations. The latter criteria mean that the potential adverse effects of a LMO are dependent on its specific characteristics, how it is used and where it is released. These will vary in different ways and would be influenced also by environmental, health and socio-economic factors.

Therefore, case-by-case risk assessments cannot be transferable to all potential receiving environments. It follows that any generic identification of LMOs 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, is not possible. In fact, such a move would seriously undermine the case-by-case principle of risk assessment that is enshrined in the Cartagena Protocol. Accordingly, the identification of any criteria for the identification of such LMOs is not possible.