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).

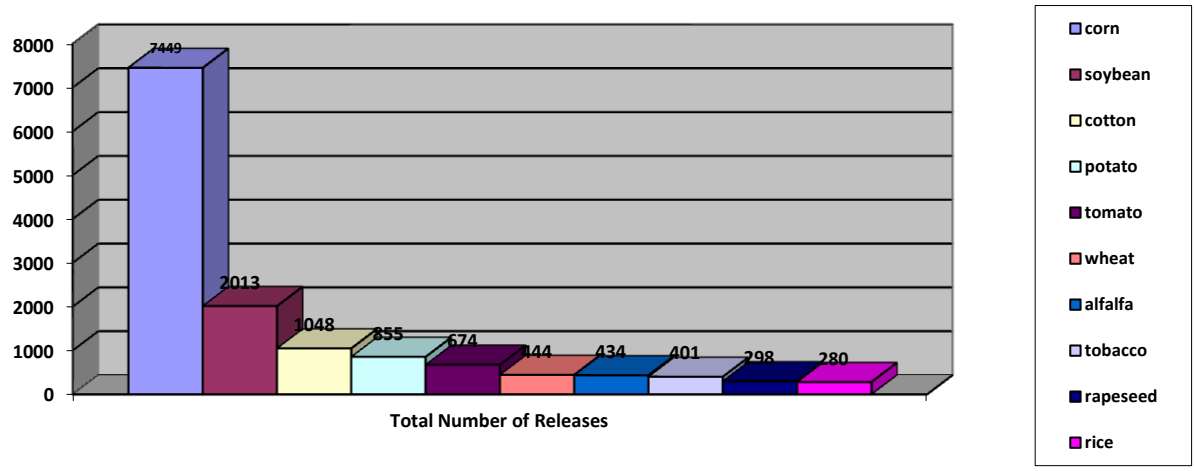
Several of these products have been subject to multiple environmental assessments in the course of seeking approvals in various countries. A total of 14 products have been granted at least five environmental approvals (Table 2), including four products which have been granted approvals by 9 countries: 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/

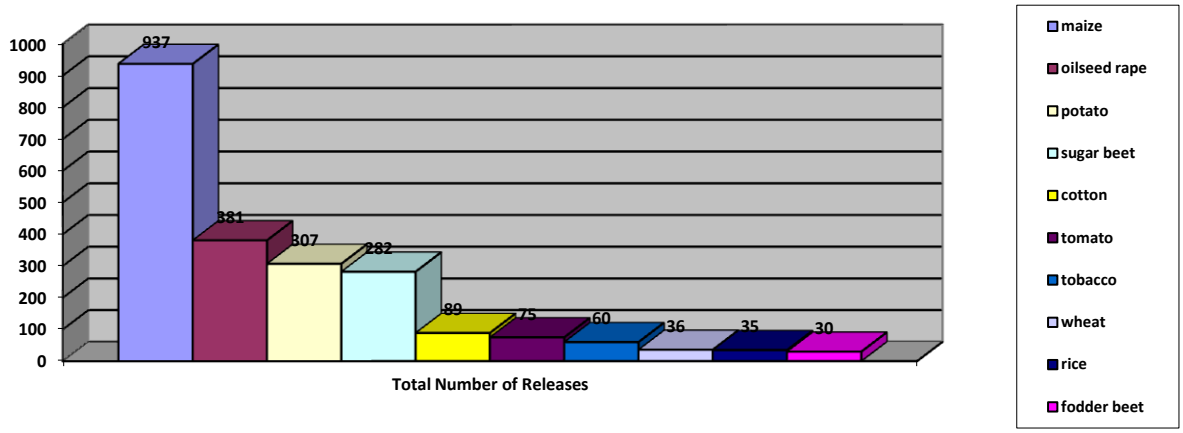
[2] The first GM crop to be approved for environmental release was the FlavrSavr Tomato, which was granted deregulated status in 1992 by the USDA APHIS. The product was not commercialized until 1996.
[3] The database includes information for all approvals including non-GM plants with novel traits in 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*.