SGRP

Biotechnology and Biosafety Related Policies and Activities of the Consultative Group on International Agriculture Research (CGIAR)

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INTRODUCTION

The International Agriculture Research Centres of the Consultative Group on International Agriculture Research (CGIAR) are located around the world.[1] They engage in agricultural science to reduce poverty, foster human well-being, and protect the environment. Their work is divided into five areas:

- Sustainable production of crops, livestock, fisheries and forests.
- Enhancing national agricultural research systems.
- Germplasm improvement.
- Germplasm characterization and conservation.
- Research and capacity strengthening, concerning policies that impact upon agriculture's potential contribution to livelihoods.

The aim of this paper is to present the policies of the Centres concerning biotechnology development and use, as well as to provide an overview of the Centres' work on the development of modified organisms (LMOs) and their biosafety practices.

The paper is divided in two sections. The first section contains the Centres' common policies with regards to the following issues:

- biotechnology in general;
- genetic use restriction technologies (GURTs); and
- unintentional presence of transgenes in *ex situ* collections.

The second section of the paper is a summary of the Centres' activities in relation to the development of LMOs and the adoption of biosafety measures. In particular:

- LMO development activities engaged in by CGIAR Centres;
- Centres' research relevant to assessing the potential impacts of LMOs;
- Centres' biosafety practices and efforts to ensure regulatory compliance; and
- Centres' capacity-building activities in the field of biotechnology and biosafety.

COMMON PRINCIPLES OF THE CENTRES OF THE CONSULTATIVE GROUP ON INTERNATIONAL AGRICULTURE RESEARCH

Centres' Position Statement on Biotechnology

Biotechnology has taken up an important place in both the research and policy agendas of the Centres of the CGIAR. The Genetic Resources Policy Committee of the CGIAR has dealt with biotechnology issues since its establishment in 1995, and its discussions and recommendations have facilitated the adoption of common principles which currently guide the activities of the Centres on LMOs and biosafety.

In 1998, the CGIAR Centres adopted the following common position statement on biotechnology:

"*Given the immensity of the long-term food security and environmental conservation challenges confronting countries of the South, the Centres firmly believe in the following propositions:*

- *Biotechnology must be viewed as one of the critical tools for providing*

[1] The CG Centres include: Centro Internacional de Mejoramiento de Maiz y Trigo (CIMMYT), Centro Internacional de Agricultura Tropical (CIAT), Centro Internacional de la Papa (CIP), International Rice Research Institute (IRRI), International Food Policy Research Institute (IFPRI), World Agroforestry Centre (ICRAF), WorldFish Center, Center for International Forestry Research (CIFOR), International Livestock Research Institute (ILRI), West African Rice Development Association (WARDA), International Water Management Institute (IWMI), International Institute of Tropical Agriculture (IITA), International Center for Agricultural Research in the Dry Areas (ICARDA), International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) and Bioversity International (Bioversity)

food security for the poor.

- *The Centres advocate the prudent application of the full range of biotechnology tools to achieve substantial and sustainable growth in agricultural productivity in poor countries. These tools include, but are not limited to, molecular markers, genetic engineering, and recombinant vaccines.*
- *The Centres view biotechnology as an important means for ensuring environmental protection over the long term.*
- *The Centres have a clear comparative advantage in ensuring access by the countries of the South to the advanced tools of biotechnology. This advantage accrues by virtue of its present credible mass in biotechnology, its global network of partnerships within and among countries of the South, and its increasingly close linkages to advance research institutions of the north, both public and private.*
- *Given the extremely rapid pace of new developments in biotechnology, the Centres are committed to increasing their partnerships with ARIs, both public and private, north and south, to ensure ready access of Centre scientists and our partners in the south to advanced technologies.*
- *The Centres make adequate investments in the arena of biotechnology in order to: 1) maintain their own credible scientific mass, 2) be proactive in assisting countries of the South to establish effective biosafety regulations, and 3) contribute substantially to developing the human capital needed to ensure the judicious application of appropriate biotechnology tools to important food security and environmental problems.*
- *The Centres are firmly committed to the application of genomics (molecular genetics, molecular markers) for immediate use in better understanding and manipulating the genomes of plants, animals, and their pathogens and pests.*
- *The development and deployment of transgenics (via genetic engineering), is seen by the Centres to provide important options for meeting the food security and environmental challenges of the future.*
- *The Centres will carry out all of their activities in the arena of biotechnology under high standards of appropriate and approved biosafety regulatory frameworks, both within individual countries and institutions. The Centres will seek partnerships with institutes that have such frameworks in place (thus our commitment to policy and capacity building in this area).*"[2]

Within the frame of these common principles, the Centres have developed their own principles or guidelines on genetically modified organisms[3].

CGIAR Policy Statement on Genetic Use Restriction Technologies

Also in 1998, following the recommendations of the Genetic Resources Policy Committee, the Centres adopted the following policy statement on Genetic Use Restriction Technologies (GURTs):

"The International Agricultural Research Centres supported by the Consultative Group on International Agricultural Research system, which are engaged in breeding new crop

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[2] System-wide Genetic Resources Programme (SGRP), CGIAR Genetic Resources Policy Committee, *Booklet of CGIAR Centre Policy Instruments, Guidelines and Statements on Genetic Resources, Biotechnology and Intellectual Property Rights*. Version II. Rome, July 2003. URL: www.cgiar.org/corecollection/docs/sgrp_policy_booklet_2003.pdf

[3] These can be found in the following URLs:
Bioversity International: http://www.bioversityinternational.org/About_Us/Guiding_Principles/GMO/index.asp
CIMMYT: http://www.cimmyt.org/english/wps/transg/gmo_stmt.htm
ICRISAT: http://www.icrisat.org/gt-bt/Genetic_Engg.htm
IFPRI: http://www.ifpri.org/about/aboutbio.asp

varieties for resource poor farmers, will not incorporate into their breeding material any genetic systems designed to prevent seed germination."[4]

Guiding principles for the development of CGIAR Centres' policies to address the possibility of unintentional presence of transgenes in *ex situ* collections

Based on the outcomes of a workshop organized by the GRPC and the Science Council in 2004, and protracted consultations with a wide range of stakeholders, the GRPC drafted a set of Guiding Principles for the development of CGIAR Centres' policies to address the possibility of unintentional presence of transgenes in *ex situ* collections, for wide dissemination and discussion. Those Guiding Principles were adopted by the Alliance Executive and considered by the Commission's Intergovernmental Technical Working Group on Plant Genetic Resources for Food and Agriculture (in October 2005) and the Commission on Genetic Resources for Food and Agriculture (in June 2007), which welcomed the Guiding Principles and noted their potential importance for a wide range of users worldwide. The International Wheat and Maize Improvement Centre (CIMMYT) is currently coordinating a system-wide process, through the SGRP-coordinated Global Public Goods 2 project (GPG2), to develop model guidelines for rice, maize and potato.

"Guiding Principles for the development of the CGIAR Centres' policies to address the possibility of unintentional presence of transgenes in ex situ collections

Background

1. *In the management of germplasm, the CGIAR Centres embrace the following overarching principles: ethics, transparency, accountability, risk analysis and quality control.*
2. *The purpose of genebanks is to collect, conserve and make genetic resources available. The maintenance of the genetic identity of the accessions is an overriding objective of genebanks. The Centres take proactive steps that aim to prevent the unintentional introgression of exotic genes, including transgenes, not already present into samples conserved in their genebanks. Proper germplasm management procedures and genebank practices and protocols to ensure quality and integrity of accessions must be followed.*
3. *Transgenes and conventional genes are subject to the same underlying biological processes of mutation, geneflow, introgression, recombination and natural selection. Therefore, best practices for preventing introgression of conventional genes provide an appropriate basis for preventing introgression of transgenes.*
4. *Germplasm management procedures and practices should conform to best practices. Best practices and appropriate technologies vary with the crop, influenced, for example, by its breeding system, pollination system, and whether it is an annual/perennial. These best practices include procedures and practices that aim to prevent the transfer of genes from sources other than the accession in question. Routes for transfer by other sources include admixture of seeds and pollination.*
5. *It is recognized that available technical means do not permit the complete exclusion of unintentional presence of exotic genes, including transgenes, in genebank accessions. It is also recognized that available testing techniques do not provide an absolute guarantee, without testing every single seed or plant that any given accession is free*

[4] System-wide Genetic Resources Programme (SGRP), CGIAR Genetic Resources Policy Committee, *Booklet of CGIAR Centre Policy Instruments, Guidelines and Statements on Genetic Resources, Biotechnology and Intellectual Property Rights*. Version II. Rome, July 2003. URL: www.cgiar.org/corecollection/docs/sgrp_policy_booklet_2003.pdf

of transgenes. However, best practices in genebanks will achieve a high degree of statistical probability that an accession does not include unintentionally present transgenes.

Guiding Principles

6. *The Centres should take proactive steps to determine the risk of the unintentional presence of exotic genes, including transgenes, in their ex situ collections.*
7. *The Centres should develop, document and communicate crop-specific guidelines for best gene bank management practices. These guidelines should include crop-specific risk analysis procedures (i.e., risk assessment, management, and communication) addressing critical control points.*
8. *The major genebank operations that need to be evaluated are collecting, acquisition, regeneration, characterization, delivery, conservation, testing health and viability, evaluation and documentation (genebanks are most open to unintentional introduction of transgenes at the collecting and acquisition stage, because germplasm may have been exposed to geneflow outside the control of the genebank).*

The guidelines must aim to minimize geneflow at these stages, for transgenes and for conventional genes.

9. *As part of their risk analysis, when collecting or acquiring new accessions by other means, Centres should consider the following regarding testing:*
   a. *whether transgenic events (commercial and research) in the relevant taxa are likely to be present in the area of collecting or acquisition;*
   b. *the distance between the collecting site and areas where transgenic events (commercial and research) are situated; or*
   c. *whether germplasm providers can provide adequate documentation of their germplasm management practices with respect to the material in question.*
10. *With respect to existing accessions, Centres' testing procedures should be guided by the following criteria:*
    a. *No testing would be required when:*
       i. *there are no transgenic events (commercial or research) in the relevant taxa at the present time;*
       ii. *there were no transgenic events (commercial or research) in the relevant taxa at the time of acquisition (e.g., maize prior to 1996);*
       iii. *it is determined that, unless there are other factors, there is no presence of transgenic events within a distance that would allow for introgression; or*
       iv. *there are transgenic events (commercial or research) present, however, proper management practices have been followed and documented in the management of the accession,*
    b. *Tests should be undertaken when there are transgenic events (commercial or research) present and good management practices cannot be demonstrated.*
    c. *Once an accession has been determined to either not require testing or has tested negative, the Centre will follow best practice regeneration and maintenance procedures to maintain the genetic integrity, as for all accessions.*
11. *If and when transgenes are detected in an accession, in following best practice management procedures, the Centres will take appropriate steps to prevent introgression of those transgenes to other accessions.*
12. *The Centres should establish and maintain a database on the global status of GM research and development for the crops within their collections in order to facilitate*

risk analysis. The database should be posted on a publicly accessible website.

13. *The Centre should bear the costs of the procedures, including tests when necessary, set out above. Requests for additional assurances above those established by the Centre should be met through additional funds on a case-by-case basis from outside sources.*
14. *Upon request by the recipients of materials, the Centre will provide information describing procedures and tests that the Centre has followed for the accession concerned.*
15. *All data resulting from any testing should be properly documented and made publicly available as soon as it is considered scientifically reliable (e.g., by posting on the Centre's web site). All procedures and supporting information should be presented at the same time. The Centre will also inform the relevant authority of the country of collecting or acquisition of the material in question when transgenes are found; the Centre will also inform the relevant authority of the country in which the Centre is located."*

SUMMARY OF BIOTECHNOLOGY AND BIOSAFETY RELATED ACTIVITIES COORDINATED BY THE SCIENCE COUNCIL OF THE CGIAR

The Science Council of the CGIAR has long recognized the importance of addressing issues related to biosafety within the CGIAR System. In 2003 the interim Science Council (a precursor body of the current Science Council) commissioned a strategic study of biosafety across the CGIAR System, in order to shed light on current policies, procedures and practices, and to make recommendations on future biosafety policies and practices.

The Panel's report[5] was based on the analysis of a questionnaire and a review of case studies on living modified organisms provided by the Centres. The report highlighted a number of findings and made 12 specific recommendations on strategy, policy and practices. These recommendations, with additional comments, were endorsed by the Science Council and the Executive Committee of the CGIAR. One of the recommendations was to review the actual implementation of the report's suggestions and to identify areas where further work might be necessary.

As a follow-up to the 2003 report, a workshop entitled "*Biotechnology, Biosafety, and the CGIAR: Promoting best practice in science and policy"*, was held at IRRI headquarters, Los Baños, Laguna, Philippines, on 22-24 April 2008. This workshop was co-organized by IRRI and the Science Council, in close consultation with Bioversity International. The aim of the workshop was to bring together the scientific and policy issues that the CGIAR Centres must consider when conducting biotechnology research with the purpose of producing international public goods. More specifically, this initial meeting explored the following actions:

- Establish a network of Centres and national agricultural research systems (NARS) that are engaged in LMO research, which will facilitate a meaningful exchange of experiences, including through possible common regional mechanisms;
- identify modes of collaboration between Centres and NARS that ensure the outcomes of Centres' research meet the needs of partners;
- discuss research needs in emerging areas (fisheries, livestock, trees); and
- identify means by which the CGIAR Centres could coordinate their representation at international scientific and regulatory fora.

[5] Report of the Biosafety Panel to the CGIAR Science Council on biosafety policy and practices of the CGIAR Centres - May 2007 (February 2004), available at http://www.sciencecouncil.cgiar.org/publications/index.html

Participants in the meeting included CGIAR scientists who are involved in biotechnology research, representatives of selected NARS (some of whom work closely with Centres on LMO projects), an original author of the 2003 report, other research and development partners, and Civil Society / Farmers' organizations. The report of this workshop is due later in 2008.

SUMMARY OF THE CGIAR CENTRES' ACTIVITIES IN RELATION TO LMOs AND BIOSAFETY

LMO development activities engaged in by CGIAR Centres

The Centres and their partners are using LMOs to get the desired combination of traits in a wide variety of species. All are in the research phase and have yet to be the subject of regulatory approval for commercial release.

An overview of past and current activities of the Centres is provided below:

Bioversity International

- Development of a transient transformation system of banana protoplasts via electroporation.
- Stable transformation of banana and plantain after particle bombardment and Agrobacterium-mediated transformation of embryogenic cell suspensions.
- Banana transformed with different rice chitinase genes. Chitinases are involved in defense mechanisms because of their anti-fungal properties. At this moment, transgenic lines are being field-tested under confined conditions in Uganda, at the National Agricultural Research Organization (NARO).
- T-DNA tagging method employed to identify promoters directly from the banana genome. Large populations of independent transgenic cell colonies via highly efficient Agrobacterium-mediated transformation of embryogenic cell suspensions generated. The tagged lines have been screened for responsiveness to cold/chilling stress.
- Transient Agrobacterium-mediated transformation of tobacco utilized to obtain insights into the function of the ARF1 gene, possibly involved in non-host resistance.
- Co-transformation technology for gene stacking developed.

CIAT

- Agrobacterium used to transform recalcitrant indica rice varieties into rice varieties adapted to flooded conditions, poor acid soils or high elevation hill-side Andean ecosystems. Viral genes of rice Hoja Blanca Virus cloned and introduced in Cica 8, grown by small farmers and used in breeding. The best transgenic lines outperform commercial varieties in the field. Yield trials carried out; results ready for assessment by farmers.
- Genetic resistance to sheath blight studied for rice (currently only field tolerance exists).
- Transgenic work on drought tolerant genes of rice carried out in collaboration with CIMMYT, IRRI, the National Institute of Agricultural Sciences (NIAS) and RIKEN (Japan), and funded by the Japan International Research Center for Agricultural Sciences (JIRCAS).
- Agrobacterium tumefaciens used to genetically transform cassava clones used by small farmers, in order to introduce resistance to cassava stem borer, Chilomina clarkei, focusing on the introduction of insecticide proteins.
- The development of transgenic cassava with novelty starch qualities, retarded senescence, early flowering and with increased ß-carotene content.

- Cassava field trials conducted at headquarters since 2003; rice field trials conducted since 2000.
- Particle bombardment and Agrobacterium mediated transformation carried out on the wild species Phaseolus acutifolius. Current efforts focus on the use of a congruent backcross scheme to introgress higher regeneration response from P. acutifolius into P. vulgaris, while preserving desirable bean agronomic traits.
- Transgenic beans with marker genes generated and in evaluation under biosafety greenhouse conditions.
- Generic permit, independent of agronomic and food quality traits, granted for cassava and rice in March 2008.

CIMMYT-Kenya *(insect resistant maize for Africa project)*

- Lab experiments carried out to determine which Bt genes in maize express resistance to which stem borer;
- Maize lines transformed at CIMMYT-Mexico used to convert several CIMMYT and KARI (Kenya Agricultural Research Institute) maize inbred lines through conventional backcrossing in biosafety containment and confinement facilities.

CIMMYT-Mexico, *(transformation laboratory)*

- Evaluation of transgenic wheat lines, with the gene encoding transcription factor (DREB1A) under the stress-inducible promoter (rd29A) for their tolerance to drought conditions, and for their water use efficiency, carried out.
- Production of transgenic plants for the assessment of other regulatory genes (genes involved in signaling pathways) as well as stress-inducible genes in wheat for their tolerance to water-stress conditions.
- Production of transgenic plants for the assessment of different combinations of gene encoding transcription factors and inducible promoters for conferring drought tolerance in wheat.
- Genetic and Molecular analysis of the transgenic wheat for the integration, segregation and transmission of transgenes, as well as the expression of transgenes at the transcriptional and functional level.
- Development of an Agrobacterium-mediated transformation system for different varieties or advanced lines of wheat which are important to breeders, agronomists and pathologists.

CIP-Peru

- Bt potato varieties with resistance to the potato tuber moth (Phthorimaea operculella) developed, with excellent results.
- Eight Bt potato field trials carried out, between 1994 and 1998, by CIP in collaboration with Peruvian universities. CIP has ten Bt varieties with resistance to three distinct PTM species.
- Research conducted, from 1992 to 2000, aimed at increasing resistance to bacterial wilt in potato using lytic peptides from insects and lysozyme. The research failed to produce satisfactory levels of resistance and has been abandoned.
- Development of three gene technology approaches to enhance resistance to potato or late blight (Phytophthora infestans) since 2000. Despite promising results, field trials impeded by the Peruvian biosafety law.
- Potato leaf roll virus resistance in the variety Desiree developed in 2006, through post-transcriptional gene silencing.
- Development of several sweet potato varieties expressing viral genes for testing research hypotheses on their function in virus resistance.

- Identification of at least four Bt proteins in sweet potato with activities against African weevils (Cylas spp.), in cooperation with the National Agricultural Research Organization (NARO), Uganda.
- Development of modified sweet potato starch. Field trials for high molecular weight glutenin gene from wheat in sweet potatoes to be conducted in China in 2008. Development of starch-modified sweet potato plants with high amylose (since 2006).

ICARDA- Syria

ICARDA explores the possibility of using genetic engineering to achieve improved tolerance to fungal, drought and other abiotic stress resistance. Activities in this area include:

- Chickpea and lentil transformation carried out in cooperation with the University of Hannover/DSMZ (the German Resource Centre for Biological Material).
- Cereal transformation carried out in cooperation with the Agricultural Genetic Engineering Research Institute (AGERI), Egypt and the Centre de Biotechnologie de Sfax (CBS), Tunisia.
- Gene encoding research into improvement of salt and drought tolerance in wheat carried out in cooperation with CBS, Tunisia.
- Abiotic stress resistant wheat and barley developed in cooperation with AGERI, Egypt.
- Development of drought and heat tolerant cereal germplasm, by ICARDA in cooperation with the Arid Land Research Centre of Tottori University, for use in Central and West Asia and North Africa.

ICRISAT-India

- Development of in-vitro tissue culture for the production of transgenic plants, based on Agrobacterium mediated gene transfer for groundnut, pigeonpea, chickpea and for sorghum.
- Research carried out on transgenic groundnuts for resistance to the Indian peanut clump Virus (IPCV), and on transgenic pigeonpea.
- Contained field tests carried out for groundnut, for resistance to IPCV; and for pigeonpea and chickpea, for resistance to the legume pod borer, using cry1Ab and cry1Ac genes.
- Development of transgenic plants carrying genes for resistance to viruses, insect pests, fungal pathogens, tolerance to drought stress and nutritional enhancement.

IITA-Nigeria

Research carried out on the development of transgenic cowpea for resistance to *Maruca vitrata*

ILRI - Kenya

Research carried out on East Coast Fever (ECF):

- Development of a diagnostic process for LMOs.
- Production of a P67 vaccine, using transformed bacteria.
- Production of Schizont vaccine candidates using transformed E.coli and pox viruses.
- Research by partners, at the ILRI-hosted BecA platform, on transgenic plants for disease resistance and other adaptive traits.

IRRI-Philippines

Development of several transgenic rice varieties with useful genes for resistance to diseases and insects, e.g. Xa21 gene for bacterial blight resistance inserted in rice cultivar IR 72 through transformation.

IRRI-China and India

- Case study on transgenic rice with several Bt genes (cryIAb/cryIAc) driven by tissue-specific and constitutive promoters.
- Transgenic rice varieties evaluated (eg. MH63, Azucena, IR72, Mot Bui, IR68899B, Tulasi, Vaidehi, Basmati 370 and Dinorado). High resistance to stem-borer found. Bioassay data and molecular data were systematically recorded and correlated with phenotypic data and the best lines were selected based on all positive results.
- Transgenic rice varieties MH63 and IR732 field evaluated against several insect pests in China and India; Bioassay data and non-targeted insects' pests monitored, showing excellent results with good agronomic performance. MH63 (a CMS line) crossed with Restorer line to develop the Hybrid Bt rice, Shan You 63, showing excellent plant protection and yield advantage. All studies published in refereed journals.

World Fish

Commercially important aquatic species targeted by genetic improvement programmes, eg. tilapias, African catfish, giant freshwater prawn (*Macrobrachium rosenbergeii)*.

Research relevant to assessing the potential risk/impacts of LMOs

Many Centres have conducted gene flow studies to analyze potential introgression of genes between different populations. In some cases, studies on natural gene flow from cultivated to wild species have been taken as a reference to predict the level of introgression from transgenes into wild populations of the same species (ICRISAT, WorldFish Center, CIAT). Several Centres have conducted studies on gene flow from genetically modified crops to non-modified crops, and on the impact of biotechnologies on the ecosystems, particularly on insects and non-target species (CIMMYT, CIAT). In addition to providing evidence about the impacts of LMO on genetic diversity, these studies constitute the basis for the elaboration of management practices for those farmers that will cultivate genetically modified varieties. The assessment of the potential impacts of LMOs on biodiversity has an important place in the current and future research agenda of the CGIAR Centres, particularly in those that are more involved in biotechnology research (CIAT, CIMMYT, CIP, IRRI). Some of the research conducted by the Centres is described in more detail below.

Bioversity International

A transgenic banana field has recently been established in Uganda. This will, among other things, provide information on the dispersal of banana transgenes over the coming years. Most cultivated banana cultivars are male sterile. Dispersal of a genetic construct via pollen will therefore not occur. In a plantation the plants are seedless and infertile, even under the most favorable conditions, i.e. hand-pollination with highly fertile pollen, does not exceed three seeds per bunch.. Such seeds are mostly non-viable (ca. 90%) and any germination requires embryo rescue technologies which must take place under sterile culture conditions. Therefore, natural cross hybridization in the field with other species or wild relatives to produce a new generation of plants does not occur[6].

[6] see also: http://www.bioversityinternational.org/publications/pdf/1210.pdf

CIAT

Environmental biosafety research has targeted crop landraces and their wild relatives, using the so-called mandate crops[7] as models for the case studies. The topics of the research include:

- Documentation of genetically compatible species, and their range of natural distribution, including modern crop cultivars, traditional landraces and wild relatives. This part also includes geographic information systems (GIS) tools and methodologies to make this information readily available to users. This dates back to part of the so-called institutional memory and expertise (specially after 1995) in CIAT breeding programmes, biotechnology, genetic resources, and geography/land science, and paved the way for CIAT's involvement in biosafety research.
- Documentation of gene flow events (from transgenic and non-transgenic plants) towards landraces, compatible weedy and wild relatives, in terms of frequency, range of distribution, spatial distance, involvement of several species and time persistence of alien alleles. This has been done mainly on the rice and bean models in Colombia, Costa Rica, Peru and Venezuela since year 2001, through two grants from BMZ of Germany. Key partners are: University of Hannover, Federal Institute of Environmental Research (BBA Institute, Braunchweig), University of Costa Rica, Instituto Colombiano Agropecuario (ICA) of Colombia, Universidad Central of Venezuela. In 2006 a new component on maize gene flow was introduced applying and adapting simulated gene flow models developed in Europe to the tropics, in collaboration with German partners. Gene flow analysis relies heavily on the molecular marker tools developed at CIAT since the 1990s for crop models from a variety of funding sources, and CIAT adapted their use for tracking and monitoring gene flow / introgression at landscape level (farmers' fields).
- Effect of transgenic crops on non-target associated biota. This research was supported by the United States Agency for International Development (USAID) and, with input by Cornell University, has been under way since 2003 by monitoring the effects of Bt crops on non-target aerial insects, soil arthropods and nematodes.

An important component of CIAT's work consists of socio-economic impact assessment, namely how transgenic crops may affect production (positive/negative/neutral), consumers' preferences, and special niches for landraces. A simulation study has already been performed by CIAT using cassava tolerant to herbicide as a model.

CIMMYT

- Gene flow studies conducted by CIMMYT in all major maize growing environments in Kenya in order to provide information to farmers on the management of Bt maize fields, for when Bt varieties will be available.
- Extensive studies carried out on the impact of Bt-maize on the populations of major non-target arthropods (predators), and on the general arthropod diversity and to create data bases that include identities and quantities of non-target arthropods of Bt o-endotoxins in Bt maize confined field trials and in all major maize growing ecologies in Kenya.
- Reference collection of the arthropods found in the confined field site and in the maize growing environments established for use together with the database to determine the impacts of Bt maize and to be used during the monitoring phase when Bt maize will be commercially available in Kenya.

[7] The so-called mandate crops of the CGIAR are: Andean roots and tubers, barley, cassava, chickpea, coconut, cowpea, finger millet, forages, groundnut, lentil, maize, Musa, pearl millet, Phaseoulus, pigeon pea, rice, sorghum, soybean, sweet potato, wheat and yam.

- Studies carried out in the biosafety greenhouse and biosafety laboratory on the impacts of Bt maize on the development of stem borers; and on the bionomics of key parasitoids of stem borers, Cotesia flavipes and C. sesamiae, to study tri-trophic effects of Bt o-endotoxins on the natural enemies of stem borers.
- Extensive studies carried out to develop appropriate insect resistance management strategies for small holder maize farmers in Kenya.
- Field surveys conducted in several districts in Kenya to find out whether natural refugia for wild species and alternative species from intercrops could be used in Kenya and in China.

CIP

- Demand for transgenic potato assessed and the impact of transgenic varieties on the environment included in research programme for potato.
- Survey implemented by CIP established that Andean farmers are willing to try to purchase new potato varieties with insect resistance at a higher price.
- Naturalized experiment to test the ability of cultivated potatoes and hybrids to survive without human intervention, and in contact with wild relatives, carried out in collaboration with the Peruvian National Agriculture Research Institute in Puno, Peru, in 2004. Although incomplete, the experiment does not demonstrate a significant rate of survival of particular cultivars or wild hybrids, but instead the tendency of hybrids to disappear more often in comparison with wild plants.
- Examination of past occurrences of gene flow that might have come from exotic genes present in the introduced modern potato varieties and not present in the Andean germplasm.
- Tests to identify unintentional presence of transgenes in CIP genebank carried out. Research scientists screened a third of the potato genebank accessions (selected randomly) in 2001 and did not find transgenes resulting from laboratory mixtures.
- Research on the impact on human health conducted for potential products only, because of the high costs involved. The Bt potato developed at CIP is using gene technology with previously established safety records produced by a private company.
- Allergenicity database searches for two sweet potato Bt proteins that are candidates for the engineering of sweet potato weevil resistance carried out in anticipation of future Bt sweet potato products. CIP is currently considering developing toxicity testing for the candidate Bt proteins for gastric fluid digestibility.

ICARDA

- Regional Workshop, entitled “Risk assessment and risk management of GM crops in the Central Asia Sub-region”, planned for 16-20 June 2008, at ICARDA, in collaboration with FAO.

ICRISAT

- Three-year project (funded by the UK Department for International Development (DFID)) undertaken to study the diversity of pigeonpea in cultivars and landraces and possible gene flow in southern Andhra Pradesh in India. While this project did not employ any transgenic material, it was evident that there was no natural gene flow from cultivated to wild species, and the loss of biodiversity was mainly due to human intervention and various biotic and abiotic constraints.
- Gene flow study on non-genetically modified sorghum ongoing in Mali and Kenya. Its objectives are: i) to identify the biological, environmental and human factors that might favour or limit sorghum crop-to-wild genetic introgression in traditional ecosystems characteristics of semi-arid Sub-Saharan Africa; ii) to measure the

adaptive value of crop/wild sorghum hybrids relative to their wild and cultivated parents; iii) to train national scientists on environmental risk assessment methodologies and provide scientific information to help biosafety regulators to make science-based decisions.

IFPRI

- Eleven environmental risk assessment research projects supported by IFPRI, through the Biotechnology Biodiversity Interface (BBI) grants mechanism, as part of the Program for Biosafety Systems (PBS) (see Annex 1). BBI focuses on the need to better understand the interaction among transgenic crops and animals, agriculture, and biodiversity.
- Scientific leadership for the 11 projects is with developing-country research institutes.
- Findings from the BBI projects reviewed through regional technical review meetings and international conferences.

IITA

- Gene flow studies between non-transgenic cowpea and wild cowpea lines carried out. The results show that gene exchange does occur at very low frequency. These results will be used to determine isolation distance.
- Studies on longevity of hybrid seed of cowpeas conducted in the field.
- Effects of insecticidal genes of cowpea on non target organisms, e.g. parasitoids of Maruca vitrata, analyzed. The risk assessment has been conducted by the developer of the LMO and an independent institution.

IRRI

- Toxicological studies conducted on transgenic Bt rice. Preliminary data showed no difference between control and transgenic rice.
- Several homozygous Bt rice lines developed in different backgrounds are ready for detailed food-safety studies and may be deployed in experimental field trials for further monitoring of risk assessment and cost/benefit studies.

WorldFish Center

- Assessment of ecological (environmental, biodiversity and economic) impacts of the dissemination and use of aquatic LMOs, in partnership with national agriculture research systems (NARS) in Africa (Malawi, Zambia, Ghana, Cameroon) and Asia (China, Thailand), and with agriculture research institutions (ARI) in USA (University of Minnesota, Notre Dame University. Specifically, the WorldFish Center supports a USAID-funded project in Zambia on the spread and impact of the alien tilapia Oreochromis niloticus on indigenous O. andersonii, and is collaborating with scientists at the University of Minnesota and Kassetsart University, Thailand, in assessing the ecological risks posed by genetically improved tilapias.
- Major contributions to a new multi-authored state-of-the-art publication entitled *Environmental Risk Assessment of Genetically Modified Organisms: Methodologies for Transgenic Fish* (CABI, 2007), made by WorldFish Center staff members. The Centre has agreed to purchase and distribute 150 copies of the book to developing country NARS, libraries and scientists.

Centres biosafety practices and efforts to ensure regulatory compliance

Biosafety measures regarding the work of the CGIAR Centres are generally taken at two levels: institutionally and nationally. At the institutional level, the practical enforcement and implementation of these measures in the CGIAR Centres is carried out by so-called

'Institutional Biosafety Committees' (IBC's). At the national level, the implementation and enforcement of biosafety measures is carried out by National Biosafety Committees.

The Report of the Biosafety Panel to the CGIAR Science Council on Biosafety Policy Practices of the CGIAR Centres (2007)[8] listed its findings as follows:

"1. Most of the Centres using gene technologies have formally constituted Institutional Biosafety Committees whose duties and responsibilities (though they vary from Centre to Centre) have been defined. Some Centres have appointed specific Biosafety Officers while in others a Principal Investigator acts as the nodal, coordinating person.

2. As criteria for action, most Centres have prepared Institutional Biosafety Guidelines, primarily developed by Centre staff, in accordance with the requirements of their respective host country national regulatory authorities.

3. The Institutional Biosafety Committees are charged with implementing good laboratory practices for biotechnology-related research in laboratories and greenhouses and the required biosafety regulations in trials of LMOs under containment.

4. These Institutional Biosafety Committees also oversee the preparation of risk assessments reports.

5. Recommendations of the Centre's institutional biosafety committee are advisory, with final decisions entrusted to the Centre Director General, with approval of the National Biosafety Committee.

6. Applications for approval of biotechnology-related research involving the use of LMOs generally follow the route of: Investigator/Developer of LMO, to Institutional Biosafety Committee, to National Biosafety authority for clearance and approval to proceed with laboratory, greenhouse, and /or field evaluations of LMOs".

The aforementioned report also provides an overview of the findings regarding biosafety practice in terms of biosafety science, research and capacity building. Some of them are listed here:

> *"1. All Centres meet or exceed the capacity and requirements of their host country to govern the biosafety of LMOs. Some host countries are still developing their biosafety governance frameworks. […].*
>
> *2. Most of the Centres are actively helping their host country to develop its biosafety governance frameworks and most identified multiple biosafety capacity needs for the host country and other countries they work in.*
>
> *3. The Centres are currently focused on containing and confining LMOs within projects underway in labs, glass/screen houses or field tests, using apparently adequate containment and confinement practices. The main objectives of the current research projects are to develop LMOs and measure their agriculturally important traits. These projects generally involve little or no specific biosafety related research objectives. In some instances, the Centres are able to draw on biosafety-related work conducted elsewhere (e.g. resistance management in relation to Bt genes). However, in other cases, environmental impact assessments are being initiated by some Centres to assess risks associated with LMOs in particular environments.*
>
> *[…]*

[8] CGIAR Science Council (2007) Report of the Biosafety Panel to the CGIAR Science Council on Biosafety Policy and Practices of the CGIAR Centres. Rome, Italy: Science Council Secretariat. P. 20 and 24. The Panel's report is based on an analysis of a questionnaires and review of case studies on LMOs provided by the Centres.

6. In relation to marker genes, CIP has undertaken research on identifying non-antibiotic, selectable marker genes for use in potato and sweet potato. CIAT is moving its safety design of genetic constructs to "precision genetic engineering" involving tissue-specific expression. This is an example of good safety design because it should reduce variability in transgene expression, which should reduce variability in overall LMO behavior and, in turn, improve the predictability of biosafety tests. IRRI has developed marker-free Bt and Golden indica rice that may have added value and public acceptance of LMOs.
[…]"

In the following section, the situation of each individual CGIAR Centre, with regards to those specific biosafety measures and policies that apply to them, is described briefly:

Bioversity International
The Katholieke Universiteit Leuven (KULeuven) follows the relevant European and Belgium legislation, which require different types of risk assessments and the adoption of measures to ensure environmental and public safety as well as the protection of scientists working with LMOs[9].

At this moment a field trial is being conducted in Uganda in collaboration with the National Agricultural Research Organization (NARO). For this, approval to field trial the genetically modified plants was determined following a review of the application by the Ugandan National Agricultural Research Organization (NARO), Institutional Biosafety Committee (IBC) and subsequently by the Ugandan National Biosafety Committee (NBC). The NBC is the administrative body for biosafety within the Ugandan National Council for Science and Technology (UNCST). Statute No. 1 of 1990; Sec. 3 & 4, designates the UNCST as the competent authority to supervise the testing and introduction of genetically engineered organisms, as specified in Document 38: Revised Draft Biosafety Regulations, October 2003. Importation, movement and quarantine procedures required for the transgenic bananas were determined by the Phytosanitary Service of the Ministry of Agriculture, Animal Industry and Forestry (MAAIF). Upon obtaining the required approvals, the European Commission and the Belgian Federal Public Service for Health, Food Chain Security and Environment were notified according to Regulation (EC) No 1946/2003 on transboundary movements of genetically modified organisms, thereby fulfilling the obligations of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

The laboratory of Tropical Crop Improvement is now looking into systems for the removal of selectable markers from genetically modified banana plants.

CIAT
CIAT first issued its Biosafety Guidelines in July 1991. These guidelines were reviewed and complemented with the CIAT Biopolicy ("A Pact with Society") approved by the Board in December 2002. The Biosafety Committee is located at CIAT headquarters (Cali,

[9] See Heading 51 of Vlarem I and II - the Flemish environmental regulations. The Belgium legislation is based on European directives (90/219/EEG and amendments), translated into national legislation, and European regulations that apply directly in the member-States. In Europe an environmental permit is required before LMOs can be used in laboratories. In Belgium an additional permit, related to the check of risk assessments by the government, is required. If work is to be done with LMOs that could make people ill, the conditions of the Royal Decree of 4 August 1996 must be complied with in order to protect the scientists. Vlarem and the Royal Decree both adopt the same principles.

COLOMBIA), and comprises expertise in botany, genetics of genepools, plant breeding, plant pathology, animal science, food chemistry, cell and molecular biology, molecular virology, intellectual property rights (IPR) and socio-economics.

CIAT has been granted a registration and permit by the Colombian National Biosafety Council, authorizing CIAT to generate and import transgenic plants for research. This permit entitles CIAT to conduct research on, and evaluation of, transgenic plants in the laboratory and biosafety greenhouse, with notification to the Colombian authorities. For the field trials, first the CIAT Biosafety Committee reviews all the applications. Once the CIAT Biosafety Committee approves the application, a recommendation is forwarded to the Director General for legal consent to be issued by the Colombian Biosafety Council. Only after obtaining approval by this Council, can field trials be conducted.

Particular containment measures in force include: the use of a biosafety greenhouse; restricted entry to areas under development; seed storage under restricted conditions; bagging of panicles; autoclaving of soil before use and disposal; strict phytosanitary conditions; and the incineration of organic disposal. Rice field trials have been conducted under controlled conditions, such as screens used to prevent contact with birds; incineration of plant residues; isolation of fields; field rotation; and gene flow analysis. CIAT experiments are monitored by the Colombian National Biosafety Council.

CIAT is moving its safety design of genetic constructs to “precision genetic engineering” involving tissue-specific expression. This may reduce the variability in transgene expression, which should reduce variability in overall LMO behaviour and, in turn, improve the predictability of biosafety tests.

CIMMYT

CIMMYT has established a Biosafety and Bioethics Committee. CIMMYT-Kenya worked with the government of Kenya to develop biosafety guidelines which were ultimately developed into the Kenya Biosafety Bill (2007). This bill is in Parliament awaiting debate and enactment. In Mexico, the adherence of CIMMYT to the strictest internal and external protocols and regulations has resulted in the adoption of CIMMYT standards by its partners.

In CIMMYT-Mexico, wheat transgenic plants are maintained in the restricted containment area, where pollen movement is strictly controlled by bagging all heads. The seeds harvested are immediately placed into sealed marked envelopes, transported in sealed boxes and then stored in locked containers in a biosafety facility. All other plants tissues, soil and waste materials are autoclaved before disposal. Nevertheless, field testing of Bt maize in Mexico stopped due to a moratorium that was imposed in 1999. Despite public limitations, the development and evaluation of LMO-related activities continues in CIMMYT’s biosafety greenhouse

CIP

Through several years of collaboration with the International Service for National Agriculture Research (ISNAR), CIP established internal guidelines on biosafety which, in 1992, were approved by the Peruvian Ministry of Agriculture. These included the creation of a CIP Biosafety, Biotechnology and Bioethics Committee. The CIP internal guidelines on biosafety were endorsed by the Ministry in 1994. This endorsement led to permission by the Ministry for CIP to conduct field experimentation under the supervision of the national plant phytosanitary agency, SENASA.

Among other tasks, CIP contributed to establishing a regulatory norm on terminology for LMO, and the Biosafety law (October 2002) and its regulations, which are still under revision by the Ministry's legal office.

CIP is currently developing an original sterilizing gene technology system which would make gene flow concerns in sweet potato obsolete. The technology has the potential for use in other crops. CIP is also developing an intragenic vector for sweet potato, based on its own genome sequence in order to minimize consumer concerns as well as reduce regulatory constraints. Biosafety measures adopted in CIP include confined experiments; flower removal; and use of sterile varieties.

In response to the contentious issue of CIP working on transgenic potatoes in the genetic centre of diversity, CIP commissioned an external review, "CIP Strategies on Development and Deployment of Genetically Engineered Potatoes and Sweet Potatoes" in 2005. This review helped CIP establish a new policy prohibiting the deployment of transgenic potatoes in Andean countries at least until social and cultural acceptance has improved and a reliable biosafety regulatory system is in place.

ICARDA

In July 2007 the Arab Fund for Economic and Social Development (AFESD) approved the "Establishment of a Containment Facility at ICARDA" Improvement of the current infrastructure through the development of a containment facility at ICARDA would provide the basis for a regional approach to the testing of, and advanced research on, genetically modified organisms (GMO) in the Arab world. National agricultural research and crop improvement programmes would use the facilities at ICARDA to test their material until national facilities are developed or until the materials can be tested in field trials in National programmes not located in the centre of diversity. The facilities would also be used by visiting scientists from national programmes to conduct joint research at ICARDA on the development of improved germplasm, and to provide specialized workshops and training courses.

ICARDA has actively promoted the development and establishment of national and regional biosafety regulations in dry areas and especially in West Asia and North Africa (WANA). Together with other national and international organizations and donors, ICARDA organized a regional workshop on developing and harmonizing biosafety regulations for countries in WANA, 11-13 September 2000, at ICARDA, Aleppo, Syria, in collaboration with Egypt's Agricultural Genetic Research Institute (AGERI), the Food and Agriculture Organization of the United Nations (FAO), the United States Department of Agriculture (USDA), and the Syrian Atomic Energy Commission, and with financial support from the Arab Fund, Kuwait, the "Emerging Markets Program" of the Foreign Agricultural Service of USDA, FAO, and GTZ. The objectives of the workshop were to assess the current situation related to biosafety in WANA countries and to formulate national action plans for the development of biosafety regulations for the region.

ICRISAT

ICRISAT has established biosafety guidelines. Research activities are carried out in laboratories and in (P2 level) safe storage glasshouses. Other biosafety measures include sterilization before disposal; autoclaving of instruments; incineration; monitoring of containment facilities; and the carrying out of field trials under controlled conditions.

At ICRISAT key issues such as biosafety regulations, risk assessment and management, Intellectual Property Rights (IPRs) and other scientific, technical, environmental,

regulatory and policy-making issues are dealt with using a great deal of sensitivity. In developing its strategy concerning the genetic modification of its mandate crops, ICRISAT has emphasized the need for partners at the international level, and the biosafety of LMOs at the farmer level. The safety of transgenic material is a major concern, and in order to address public concerns with regards to genetically modified food, utmost importance is being given to the established regulatory systems. ICRISAT will pursue active research in collaboration with NARS and ARIs on biosafety and the deployment of genetically engineered crops (GECs). Briefly, ICRISAT adopts a balanced perspective, when conducting biotechnology research, undertaking activities within the framework of existing national and global research agendas and priorities. Field evaluation and risk assessment are performed according to the biosafety guidelines of the host country under the immediate guidance and supervision of the Institute's Biosafety Committee.

ILRI

ILRI has an institutional biosafety committee and collaborates with national plant and animal health regulatory authorities. Work with Vaccinia and Salmonella is conducted under containment. Work with pox viruses is being carried out under BL2 containment. No field trials have been conducted yet with LMOs.

IRRI

Biosafety measures adopted by IRRI include containment; bagging of panicles; and the autoclaving of soils before disposal. Transgenic seeds are stored under strict conditions, with regular monitoring. Vegetative plant parts are burned, stubbles are buried and entry to the sites is restricted. All experiments are regularly monitored by the Institute's Biosafety Committee. These practical measures are the fruit of IRRI's policy on GMOs, which requires that a risk assessment be carried by both an independent agency and the developer of the LMO. Applications for LMOs must be approved by Institute of Biosafety and by the National Committee on Biosafety of the Philippines; similar applications are submitted and duly approved by the National Biosafety Committees in China and India.

WARDA

WARDA has established an internal Biosafety Committee and has developed a draft framework for guidelines on GMOs. The Centre has collaborated with national authorities in the preparation of a national policy for the implementation of biosafety regulations. Confinement facilities are almost ready for use.

WorldFish Center

The WorldFish Center always complies with national/regional legislation and regulations in any transfer or use of alien aquatic species or LMOs. The Centre follows guidance and practices (the details of which are set out in a number of documents (see footnote[10], and has implemented a Policy and an associated Code of Practice in relation to the transfer of genetically improved tilapias to Africa.

10 FAO (1997). Aquaculture Development. FAO Technical Guidelines for Responsible Fisheries. No. 5, ftp://ftp.fao.org/docrep/fao/003/W4493e/W4493e00.pdf
ICES (2004) Code of Practice on the Introductions and Transfers of Marine Organisms http://www.ices.dk/reports/general/2004/ICESCOP2004.pdf
Hewitt, C.L., Campbell, M.L. & Gollasch, S. (2006). Alien Species in Aquaculture. Considerations for Responsible Use. http://www.iucn.org/dbtw-wpd/edocs/2006-036.pdf
IUCN, Gland, Switzerland; (v) WorldFish Center (2002) Nairobi Declaration on aquatic Biodiversity and Use of Genetically Improved and Alien Species for Aquaculture in Africa.
http://www.worldfishcenter.org/cms/list_article.aspx?catID=39&ddlID=109.

Capacity building, outreach and communication[11]

The Centres are engaged in strengthening institutional and human capacity in the area of biosafety, through training; technical advice; public awareness; the generation of models for analyzing the potential flows of transgenes through populations, and measuring the socioeconomic impact of the introduction and use of LMOs.

Two Centres (Bioversity International and IFPRI) and the CGIAR System-wide Genetic Resources Programme (SGRP), recently published a module for the training of trainers, entitled Law and Policy of Relevance to the Management of Plant Genetic Resources; Learning Module with Review of Regional Policy Instruments, Developments and Trends. The module includes training materials addressing, among other areas, phytosanitary and biosafety regulations designed to assist genetic resource managers with understanding relevant global and regional laws. In 2006 six regional and/or national workshops were held in Asia, Latin America and Sub-Saharan Africa, using the module. In 2006 the module was made available in both French and Spanish.

Five of the Centres are partners in the consortium "Program for Biosafety Systems" (PBS), a project funded by USAID and managed by IFPRI[12]. PBS seeks to increase ability of countries to implement national biosafety systems and make biosafety decisions based on scientific evidence. Its mission is to support partner countries in Africa and Asia in the responsible development and safe use of agricultural biotechnology. PBS has five main components: (1) Supporting risk assessment research in Africa and Asia; (2) Policy development and implementation; (3) Regulatory advisory services for biotechnology product development; (4) Education/training in biosafety and food safety; and (5) Communication strategies and outreach. PBS assists national governments in designing and implementing the policies and procedures necessary to evaluate and manage the potential harmful effects of modern biotechnology on the environment and human health.

CG Centres are increasing their participation in regional biosafety capacity development initiatives. Currently CIAT, together with CIP and the Brazilian Agricultural Research Corporation (EMBRAPA)[13,] is preparing a regional initiative to further strengthen the biosafety technical capacity of countries (Mexico, Costa Rica, Colombia, Brazil and Peru) regarding the safe deployment of transgenic crops. This is being supported by the Global Environmental Facility (GEF) /World Bank

IRRI, CIAT, IFPRI and IITA have participated in activities organized by the Public Research and Regulation Initiative (www.pubresreg.org), an alliance of public sector researchers that seek to represent public research interests in the ongoing activities concerning the implementation of the Cartagena Protocol on Biosafety and to provide scientific expertise and training for Parties and other participants in COP/MOP[14] meetings and Ad Hoc Committees.

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11 Most of this information included in this section was reported to the Third Coordination Meeting for Governments and Organizations implementing and/or funding Biosafety Capacity-building Activities, held in Lusaka, Zambia, 26 - 28 February 2007.

12 Detailed information about this programme can be found in the document UNEP/CBD/BS/CM-CB/3/INF/1 of the Third Coordination Meeting for Governments and Organizations implementing and/or Funding Biosafety Capacity-building Activities, held in Lusaka, Zambia, 26 - 28 February 2007, entitled *Update on the Ongoing Biosafety Capacity-Building Projects and Other Initiatives: A compilation of submissions from Governments and Organizations*.

13 Empresa Brasileria de Pesquisa Agropecuária

14 The Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Protocol

The following section presents some examples of capacity building efforts by the CG Centres individually:

Bioversity International

A module entitled "Law and Policy of Relevance to the Management of Plant Genetic Resources", featuring a section on biosafety and policy issues was developed by Bioversity. A second edition, "Learning Module with Review of Regional Policy Instruments, Developments and Trends" was subsequently produced.

KULeuven, together with the other Flemish universities and the Flanders Institute for Biotechnology (VIB), have published the booklet "Biosafety in the laboratory". In addition to this, a PowerPoint presentation is used as an introduction to the legislation for foreign scientist and students. Scientists contribute to the debate over transgenic crops and publish their results. KULeuven has had several PhD students, from developing countries, working on banana transformation, and trains about five MSc students from abroad annually.

In Collaboration with the Agricultural Biotechnology Support Project II (ABSP-II), PBS and NARO (Uganda), a GM banana field trial has been set up in Uganda. All appropriate procedures were followed and where skills were lacking specific training has been given.

CIAT

Since 1999 and with the support of the Federal Ministry for Economic Cooperation and Development of Germany (BMZ), USAID, the Rockefeller Foundation and CIAT core resources, CIAT has organized workshops and courses on biosafety (20 in total). Capacity-building has focused on researchers from NARS (breeders and non-biotechnology specialists from the Latin American and Caribbean region), some of them being directly hired in CIAT by the respective projects. Another target audience has been the national authorities responsible for regulating the introduction and management of transgenic crops (members of Technical Biosafety Council), and other government officials (i.e. senators, members of Ministry of Environment, Health and Agriculture). A high priority has been media coverage (radio, newspapers), TV programmes/videos (4 workshops). Since 2003, CIAT has been participating in a Global Environmental Facility (GEF)/World Bank funded project for the implementation of the Cartagena Protocol in Colombia by giving Colombia technical assistance and training, and establishing research capacity on environmental safety. In March 2008, CIAT got approval for the GEF/World Bank project on Enhancing Technical Capacity on Biosafety for Implementation of the Cartagena Protocol in Brazil, Colombia, Costa Rica and Peru.

CIP

CIP management and research scientists approved guiding principles for the development and deployment of genetically engineered organisms in 2001. CIP developed and distributed information pamphlets on biosafety and biotechnology research in 2002 and 2003. In 2000 CIP established, and continues to maintain, a communication and information website on potato genetic engineering PotatoGENE (www.potatogene.org). Finally, in collaboration with the communication department, CIP held an event on genetically engineered crops for the Peruvian press journalists and communicators in 2007.

Participation and contribution to the debate over transgenic crops has been an important activity of CIP scientists involved with biotechnology research, as part of the Latin American network REDBIO. CIP, together with the United Nations Industrial Development

Organization (UNIDO), the Canada-Latin America Initiative in Biotechnology for Sustainable Development (CAMBioTech), and the Peruvian Ministry of Foreign Affairs, convened an important international conference in 2001, to discuss the potential of modern biotechnology for food and agriculture. During the Generation Challenge Program meeting in Nairobi in 2004, CIP organized and led a workshop, involving CG Centres, NARS, and ARIs, on gene technology. More recently, CIP organized a seminar, with support from the Rockefeller, McKnight and Syngenta Foundations, to discuss bottlenecks and solutions to make the benefits of biotech crops available to resource-poor farmers in Africa. These conferences and seminars have been important elements to develop the global strategy for CIP's research programme and product development for transgenic technologies.

ICARDA

ICARDA has actively promoted the development and establishment of national and regional biosafety regulations in dry areas and especially in West Asia and North Africa (WANA). Together with other national and international organizations and donors, ICARDA has organized a number of regional workshops on biosafety, which include:

- A workshop on biosafety, 29 August – 1 September 2003, Damascus, organized in collaboration with the General Commission for Scientific Research (GSCAR), Syria, and the Syrian Atomic Energy Commission (SAEC), and with the financial support of FAO. This was followed by another three day workshop at ICARDA, Aleppo, for selected participants to demonstrate practical detection of GMOs using a variety of methodologies.
- A policy dialogue meeting, entitled Harnessing Biotechnology and Genetic Engineering for Agricultural Development in the Near East and North Africa (NENA), 12-14 February 2006, Cairo, Egypt. This meeting was attended by a number of eminent scientists as invited speakers and country representatives from NENA countries.
- A Third Country Training Programme (TCTP), entitled 'Genetic transformation of plants and detection of GMOs', 28 May - 8 June 2006 at ICARDA, Aleppo. This was a practical, 'hands-on' training course involving 15 scientists and administrators dealing with the development, introduction and testing of transgenic crops in their respective countries.
- A training course, entitled "Genetic Transformation and DNA Markers Application for Crops Improvement", 2-13 March 2008, at ICARDA Headquarters, organized by the Hanover University, Germany, and ICARDA. The course was financially supported by the German Agency for Technical Cooperation (GTZ).
- A training course, entitled "Genetic transformation and biosafety", 2-10 September 2008, Karaj, Iran, jointly organized with the Agricultural Biotechnology Research Institute (ABRII), in Karaj, Iran.

ICRISAT

Training activities for NARS scientists and students from several universities have received major attention at ICRISAT. Interactions with media personnel in the form of media workshops have been very productive and have created a positive impact in the news media (both print and television). Media workshops, organized by ICRISAT, were carried out in India, Bangladesh and Niger, in 2005 and 2006. The aim of the workshops was to create greater awareness and understanding in the media of technical issues concerning GM crops. Another workshop is planned for Kenya in the future. ICRISAT, in collaboration with the Southern Asian Biosafety Program (SABP) and the Asia Pacific Consortium on Agricultural Biotechnology (APCoAB), also conducted training of trainers workshops in 2005, and a workshop on "Biosafety regulations for transgenic crops and

the need for harmonizing them in the Asia-Pacific region" in 2006. These activities have also resulted in the publication of a sourcebook for journalists entitled "Genes are Gems: Reporting Agri-Biotechnology" in 2006.

IFPRI

The IFPRI-managed Program for Biosafety Systems (PBS) contributes to the implementation of the Cartagena Protocol by supporting partner countries as they develop the policy and legal framework, administrative procedures, technically qualified personnel and outreach mechanisms integral to their national biosafety systems. PBS work emphasizes sound science-based decision making and research, while also addressing socioeconomic considerations. PBS works with partner countries in Africa (Ghana, Mali, Nigeria, Kenya, Uganda, Malawi, Mozambique, South Africa) and Asia (the Philippines, Indonesia) to develop and implement a program of activities tailored to biosafety needs identified by local collaborators. In addition, PBS works with regional policy-making bodies on subjects of common interest, such as GM commodity trade and the development of regional technical guidelines. The scope of activities includes the following:

Policy and regulatory development through stakeholder participation: The PBS policy component analyzes the implications of different country and regional regulatory approaches for genetically modified organisms and develops new decision models to assist regulatory agencies. Choices regarding biosafety policies and objectives are evaluated for their implications for agricultural growth, trade, and food security.

Technical training in environmental and food risk assessment: PBS maintains an active program of training and outreach activities. The overall aim of such activities is to ensure that the people involved in biosafety decision-making are competent and confident to assess planned releases of GMOs and GM food products using the best available science.

Strategic planning for communications and outreach: Clear and consistent communications about biotechnology and biosafety are key to the success of biosafety capacity development in partner countries. Improving the understanding of biotechnology and biosafety in a wide array of audiences is essential to achieving this goal.

Grants for scientific research on environmental risk issues: The focus of the Biotechnology-Biodiversity Interface (BBI) grant program, managed by PBS, is on the need to better understand the interaction between genetically engineered crops, agriculture, and the environment. Environmental risks and benefits, and their applicability to the agricultural realities of different ecological regions, must be assessed on a case-by-case basis. Through BBI, competitive grants fund biosafety research aimed at addressing the effects of agricultural biotechnology, particularly genetically engineered crops, on natural biodiversity as it occurs in developing countries.

Assistance with regulatory documentation for proposed field testing: For the benefits of agricultural biotechnology to reach farmers and consumers in developing countries, specific agricultural products must be developed, tested, and deployed. Each step along this process must be carried out following good biosafety practices and in conformity with national biosafety regulations. This component of PBS aims to help public sector R&D institutions to incorporate biosafety into their product development efforts and to comply with regulatory requirements. It also aims to help regulatory agencies to carry out their roles effectively in the review, approval, and inspection processes.

ILRI

ILRI is hosting Biosciences eastern and central Africa (BecA), an initiative which forms part of the New Partnership for Africa's Development (NEPAD), African Biosciences Initiative, based in Nairobi. BecA is a capacity-building and research platform for Africa to enhance the application of biosciences, including biotechnology and biosafety, and address agricultural constraints in Africa. As part of the design of BecA, a comprehensive environmental impact assessment (EIA) was conducted leading to an environmental management plan approved by both the Kenyan regulators (National Environment Management Authority) and the Canadian government. This process included a unique strategic environmental assessment, in which regional biosafety concerns were addressed. Applications for the research work have been made to the regulators in Kenya thus the Kenya Plant Health Inspectorate Services (KEPHIS) – for plant related research; the Department of Veterinary Science – for livestock related research; and the National council of Science and Technology – for research related to genetic engineering (GE) and genetic modification (GM). The regulators have approved the design of the facilities, which has been judged to be appropriate for the research proposed. ILRI has also re-established a fully functional Biosafety Committee, whose task is to review the risk assessment forms related to any work involving genetic modifications among other biological research activities taking place in the institute. The membership of the Committee includes scientists from a number of CG Centres working with plants and animals as well as micro-organisms. These reviews provide ILRI management with on-going information on biosafety issues associated with the research programme on the ILRI campus.

IRRI

IRRI continues to participate in regional deliberations, including: the The Association of Southeast Asian Nations (ASEAN) – United States Roundtable on Agricultural Biotechnology Policy and Strategy; the Asia Pacific Economic Cooperation (APEC) Biosafety Conference; the APEC Working Group on Research, Development and Extension on Agricultural Biotechnology; and the APEC High Level Policy Dialogue on Agricultural Biotechnology. Within the Philippines, IRRI has continued its longstanding role in helping the development of local biosafety rules and regulations, and to this end, IRRI was an active participant in the national consensus for the Philippine National Biosafety Framework; providing advice to the Senate Foreign Relations Committee, by invitation, during its deliberations prior to the ratification of CBD and the CBP; and has engaged in the national consensus led by the Department of Agriculture to revise the application forms and dossier requirements for field testing, propagation approval and for deregulation approvals of transgenic crops. In addition, IRRI provided an instructor for the course entitled "Commercialization of Biotechnology Crops in Asia", in 2006, which included participants from the Philippines, Malaysia, and Vietnam. As part of its ongoing research and in special bilateral relationships, IRRI routinely hosts junior and other scientists from other countries in its biotech labs and projects and provides on the job training on local and relevant international biosafety requirements as part of this experience. IRRI has been asked by Vietnam to help train its scientists in agricultural biotechnology.

WorldFish Center

With partners, the WorldFish Center has been a leading voice in promoting biosafety measures in the development and use of aquatic alien species and LMOs[15]. WorldFish

[15] For example, see the following publications: WorldFish Center (2003) Dhaka Declaration on Ecological Risk Assessment of Genetically Improved Fish, http://www.worldfishcenter.org/Pubs/Dhaka%20booklet/Dhaka_booklet.pdf.

Center staff members have been major contributors to a new multi-authored state-of-the-art publication, '*Environmental Risk Assessment of Genetically Modified Organisms: Methodologies for Transgenic Fish*' (CABI, 2007). The Centre has agreed to purchase and distribute 150 copies of the book to developing country NARS, libraries and scientists.

The Centre continues to support workshops where such matters are debated, including the next International Symposium on Tilapias in Aquaculture that will be held in Egypt in 2008. Biosafety issues are highlighted in all genetic improvement training courses and materials that the WorldFish Center delivers.

CONCLUSIONS

- In carrying out LMO development activities, the CGIAR Centres meet or exceed the requirements and standards of national and international law. In most of the cases, LMO development is accompanied by gene flow studies and other research (including socio-economic research) relevant to assessing the potential impacts of LMOs. The results of these studies are made publicly available to the international community and can be taken into consideration by national governments and international fora when designing biosafety policies.
- The CGIAR Centres are increasing their levels of involvement in capacity-building with respect to the development of biosafety policies and regulations. Most of this work is firmly grounded in the biological and socioeconomic scientific expertise of the Centres and their experiences as international public sector research organizations dedicated to the production and distribution of public goods. The Centres look forward to further strengthening their work in this field by forging connections with other organizations and placing their capacity-building work within the larger global framework.

WorldFish Center (2002) Nairobi Declaration on aquatic Biodiversity and Use of Genetically Improved and Alien Species for Aquaculture in Africa.
http://www.worldfishcenter.org/cms/list_article.aspx?catID=39&ddlID=109.

Annex 1. Projects supported by the Biotechnology-Biodiversity Interface (BBI) competitive grants mechanism under the Program for Biosafety Systems (PBS)

Project title (year awarded)	Objectives	Investigators
Investigation of Secondary Ecological Effects of Bt Corn in the Philippines (2004)	▪ To study the direct effect on indicator species using the maximum hazard dose approach. ▪ To study the long term effect on indicator species using exposure characterization in the greenhouse. ▪ To conduct on-farm studies of indicator species abundance and species composition. ▪ To study the use of riparian areas by indicator species.	**E. Alcantara**, Nat. Inst. of Mol. Bio. and Biotech., University of the Philippines. **B. Lavina-Caoili**, Dept. of Entomology, University of the Philippines. **P.A. Javier**, National Crop Protection Center, University of the Philippines. **M. Dulce J. Mostoles**, Camarines Sur State Agricultural College, the Philippines.
Baseline Susceptibility and Genetic Diversity among Eggplant Shoot and Fruit Borer (ESFB) Populations in India (2004)	From sites throughout India: ▪ To study baseline susceptibility of ESFB using laboratory selections of ESFB on a Bt diet. ▪ To study baseline genetic diversity and population structure of ESFB using DNA fingerprinting techniques. ▪ To conduct observations/survey on alternate/wild hosts and parasites found on ESFB larvae.	**S. Parimi and U.B. Zehr**, MAHYCO Ltd, India. **B.D. Siegfried**, University of Nebraska, Lincoln, NE, USA.
Risk Assessment and Management Options for Stacked-Gene Transgenic Crucifers in India and Indonesia (2004)	▪ To test the efficacy of this dual gene system in delaying the development of resistance to Bt in Diamond Back Moth (DBM), using the Bt plants and/or simulated Bt spray formulations. ▪ To compare the relative impact on selected target and non-target arthropods of Bt transgenic crucifers, foliar Bt products, and the most commonly used synthetic insecticide.	**G.T. Gujar**, Indian Agricultural Research Institute, New Delhi, India. **A. Rauf**, Institut Pertanian Bogor (IPB), Bogor Agricultural University Bogor, Indonesia. **A.M. Shelton**, Cornell University, Ithaca, NY USA. **R.T. Roush**, UC Davis, Davis, CA USA. **D.A. Russell**, LaTrobe University, Vic Australia.
Environmental Risk Assessment of Genetically Engineered Sorghums in Mali and Kenya (2004)	▪ To identify and characterize a number of wild sorghum populations in Mali and Kenya. ▪ To estimate crop-to-wild gene flow parameters and introgression rates at different distances and successional stages, using micro-satellite DNA markers. ▪ To characterize the habitats/ecological requirements and the demographic processes that control the dynamics of wild populations. ▪ To test the fitness of F1 and BC progeny from crosses between wild sorghums and disease or insect resistant landraces.	**F. Sagnard and E. Weltzien-Rattunde**, ICRISAT-Mali. **A. Toure and M. Karembe**, Institut d'Economie Rurale du Mali, Mali. **O. Koita**, Faculte des Sciences et Techniques, Universite de Bamako, Mali. **R. Folkertsma**, ICRISAT-University of Hohenheim and ICRISAT-Nairobi, Kenya. **B. Kanyenji**, Kenya Agricultural Research Institute (KARI), Embu Station, Kenya.
Post Commercialization Monitoring of Asian	▪ To determine the initial frequency of Cry1Ab resistance alleles in ACB.	**B.F. Cayabyab,** College of Agriculture, University of the

Project title (year awarded)	Objectives	Investigators
Corn Borer *Ostrinia furnacalis* Resistance to Bt Corn in the Philippines and the Impact of Pollen Dispersal on Non-target Lepidoptera (2005)	▪ To determine the number of receptor classes in different populations of ACB. ▪ To clone the ACB receptor and study its Cry1Ab binding kinetics. ▪ To measure the extent of dispersal and density of Bt corn pollen deposition on the host plant of the non-target lepidopteran *H. bolina..* ▪ To determine the susceptibility of the non-target lepidopteran *H. bolina* to Cry1Ab protein.	Philippines, Los Banos. **E.P. Alcantara,** BIOTECH, University of the Philippines, Los Banos. **A.C. Sumalde,** Dept. of Entomology, University of the Philippines, Los Banos. **W.R. Cuaterno**, Crop Protection Division, Bureau of Plant Industry, San Andres, Manila. **B.D. Siegfried**, University of Nebraska, Lincoln, NE, USA. **Ma. Charisma T. Malenab**, College of Agriculture, Univ. of the Philippines, Los Baños .
Ecosystems Approach in the Assessment of the Environmental Impacts of Herbicide-tolerant (Ht) Corn on Wild Biodiversity in Corn Production Systems in Luzon, Philippines (2005)	▪ To assess and compare the dynamics of plant succession in HT corn fields, conventional farm areas, and adjacent marginal areas or forest edge taking into consideration the type of corn production system. ▪ To assess and monitor spatial and temporal changes in avifauna associated with corn. ▪ To assess the effect on arthropods of HT corn in relation to the changes in plant species composition. ▪ To assess and compare the soil characteristics associated with the use of conventional and HT corn.	**C.I. Villamor** and **V.O. Sinohin** Ecosystem Research and Development Bureau (ERDB), Department of Environment and Natural Resources (DENR) College, Laguna, Philippines.
Gene Flow from Cultivated Rice (Oryza sativa) to its AA Genome Wild Relatives in the East African Region: Key Research for Transgene Risk Assessment (2005)	▪ To investigate eco-geographic areas with the potential for gene flow from cultivated rice to wild rice in Tanzania, Ethiopia, and Kenya. ▪ To investigate the frequency of crop-to-wild hybridization in experimental plots and the relative fitness of hybrid progeny from these crosses. ▪ To investigate whether the genetic diversity of wild populations has been reduced by crop-wild hybridization and, if so, whether novel transgenes might exacerbate this problem.	**S. Kiboi**, Dept. of Botany, University of Nairobi, Kenya. **M. Nkya**, National Plant Genetic Resources Centre, Arusha, Tanzania. **T. Haileselassie**, Dept. of Biology, Addis Ababa University, Ethiopia. **A. Snow**, Ohio State University, Columbus, OH, USA. **D. Kiambi**, Plant Science Dept. McGill University, Quebec, Canada.
Can Bt-Cowpea be Deployed in Africa without Incidence on Wild Cowpea Biodiversity and Demography? (2005)	▪ To assess the diversity of wild cowpea in the Eastern part of its range as well as the genetic structure of its populations and assess the current genetic swamping of wild/weedy cowpea in West Africa by gene flow from domesticated types. ▪ To identify and assess the importance of cowpea predators. ▪ To assess whether wild cowpea populations are currently seed limited.	**R.S. Pasquet**, ICIPE, Nairobi, Kenya. **J.T. Ouedraogo**, CREAF de Kamboinse, INERA, Burkina Faso. **S. Demissew**, Addis Ababa University, Ethiopia. **P. Gepts**, University of California, Davis, CA, USA.
Baseline Biodiversity Impact Studies of Transgenic Bt Cotton on Wild Ecosystems in the East African Region (2006)	▪ To study and evaluate the ecological consequences of gene flow between transgenic Bt cotton and feral cotton populations and wild cotton relatives in Kenya, Uganda, and Tanzania. ▪ To assess the impact of transgenic Bt cotton on arthropod diversity in Kenya, Uganda, and Tanzania.	**W.C. Hamisy**, Tropical Pesticides Research Institute (TPRI), Arusha, Tanzania. **C.N. Watura**, Kenya Agricultural Research

Project title (year awarded)	Objectives	Investigators
		Institute (KARI), Thika, Kenya. **S. Byabagambi**, District Agricultural Officer, Kiboga Uganda. **R. Abdallah**, Tropical Pesticides Research Institute (TPRI), Arusha, Tanzania. **J.M. Pleasants** and **J.F. Wendel**, Iowa State University, Ames, IA, USA. **N.C. Stewart**, University of Tennessee, Knoxville, TN, USA.
Modeling the Impacts of Bt Transgene Flow on Lepidopteran Food Web Structure and Stability on Wild Rice in Vietnam (2006)	▪ To document the diversity and abundance of non-target Lepidoptera and their natural enemies in wild rice ecosystems. ▪ To assess variation in non-target lepidopteran susceptibility to Bt crop/wild hybrids. ▪ To determine the structure of a model lepidopteran-based food web. ▪ To characterize lepidopteran-based food webs to predict how the Bt gene may impact arthropod food webs.	**N.L. Cuong**, Cuu Long Rice Research Institute, Can Tho, Vietnam. **Y.H. Chen**, International Rice Research Institute, Manila, Philippines. **A.T. Barrion**, PhilRice Los Banos, College, Laguna, Philippines. **G. Langellotto**, Fordham University, Armonk, NY, USA. **B. Lu**, Fudan University, Shanghai, China. **N.V. Tuat**, Food Crops Research Institute, Vietnam.
Continued US-Africa Research and Capacity Building on Risk Assessment of Crop-Wild Gene Flow in Sorghum (2006)	▪ Determine the potential for co-occurrence of wild and cultivated sorghum in major sorghum growing regions of Ethiopia, Niger, and South Africa, and provide information on the wider distribution of wild sorghum species in these countries. ▪ Study the population ecology of wild sorghum species to determine their potential to occur as weeds in agricultural and natural habitats, and predict whether specific transgenic traits are likely to exacerbate any existing weed problems.	**Dr. Allison A. Snow**, Ohio State University, Columbus, OH, USA. **Dr. Tesfaye Tesso**, Ethiopian Institute of Agricultural Research, Nazareth, Ethiopia. **Dr. Issoufrou Kapran**, Institut National de la Recherche Agronomique du Niger(INRAN), Niamey, République du Niger. **Mr. Gurling Bothma**, ARC-Roodeplaat, Pretoria, South Africa. **Dr. Gebisa Ejeta** and **Dr. Cécile Grenier**, Dept. of Agronomy, Purdue University, West Lafayette, IN , USA. **Dr. Jeffrey F. Pedersen,** USDA, ARS, University of Nebraska, Lincoln, NE, USA.