Agricultural Biotechnologies in Developing Countries: Options and opportunities in crops, forestry, livestock, fisheries and agro-industry to face the challenges of food insecurity and climate change (ABDC-10)

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LATIN AMERICA AND THE CARIBBEAN PARALLEL SESSION

Generation, adaptation and adoption of appropriate biotechnologies in the Latin America and the Caribbean Region: Concrete actions for the near future

3 March 2010

BACKGROUND DOCUMENTS[1]

The scope of each regional session is to address the potential role of biotechnologies for agricultural development in the region and to cover the entire range of biotechnologies across all the food and agricultural sectors and not just to focus on any one aspect. The Latin America and the Caribbean (LAC) Region Parallel Session of the ABDC-10 will focus in two major pillars of such endeavor.

First, it is necessary to assess which biotechnologies are already available and suited for application to food/feed crop production and their status in the Region. The creation, screening and selection of new or "orphan" genetic variation in the present production and management systems considering also sustainable crop production intensification and climate change is a must. This analysis may be focused in smallholders and family agriculture to consider national and/or sub regional biotechnology institutional capacity for R&D and on-farm participatory plant breeding programmes issues including regional and sub regional operating networks. There are key unsolved critical problems as biotic and biotic stresses, genetic base narrowing and yield gap, nutritional enhancement and sustainable and environmental friendly crop production that are of first order consideration.

Second, and not last, the parallel session will need to consider the needed biosafety regulations and the corresponding perspectives, needs and actions to strengthening at national level. As countries differ in their biological diversity they harbor (some are mega-diverse), the size and suitability of agricultural areas, and the balance between agro-ecosystems and protected ecosystems, these facts give the region its rich and diversified character at the same time they demand particular environmental considerations for each particular case, as a result, different environment protecting goals will reflect on biosafety criteria. In particular, the parallel session may focus in the need for harmonization and coordination efforts on biosafety regulations. The on-going FAO and REDBIO sub regional project TCP/RLA/3109: "*Development of reference technical tools for Biosafety Management in Extended Mercosur Countries*," is a critical example for national capacity reinforcement. Harmonization also entails the recognition of areas in which work is still needed to achieve the desired status.

The set up of the Latin America and the Caribbean parallel session have been coordinated by REDBIO/FAO Network, IICA and The REDBIO International Foundation. For the perspective of the crops sector, two background documents have been prepared as follow:

1) Biotechnology-assisted crop genetic improvement for food security and sustainable agriculture: perspectives for the Latin American and Caribbean Region and,
2) Biosafety regulations and perspectives at the Latin America and the Caribbean Region: Status, needs and actions.

Note: The following documents presented herein reflects the opinions of the authors and does not represent any official position of the institutions to which they belongs or either FAO, IICA or REDBIO.

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[1] This document was produced for the FAO international technical conference on Agricultural Biotechnologies in Developing Countries (ABDC-10), held in Guadalajara, Mexico 1-4 March 2010. The views expressed in this information product are those of the author(s) and do not necessarily reflect the views of the Food and Agriculture Organization of the United Nations.

Biotechnology-assisted crop genetic improvement for food security and sustainable agriculture: perspectives for the Latin American and Caribbean Region [2]

Rodomiro Ortiz [3]

Summary

This article highlights some crop biotechnology advances that are relevant to Latin America and the Caribbean as well as suggest further actions for building regional platforms to share such advances in this region. The challenges for agriculture in Latin America and the Caribbean are noted and the potential of agro-biotechnology to address them as well as lessons learnt from both transgenic- and genomic- led crop breeding are provided It appears agro-biotechnology contributes to sustainable agriculture by conserving plant genetic resources (by providing better insights into crop endowments), preserving the environment (e.g. by reducing pesticide use or facilitating conservation agriculture practices), responding to social requirements (by targeting improvement of traits to meet end user demands), and being economically competitive and profitable as shown by the use of some agro-biotechnology products (including knowledge therein) by farmers in the Region. This article also gives some examples of advanced biotechnology (such as crop genome sequencing) in which labs in the Region are participating. The article ends with some thoughts regarding public-private partnerships to boost agro-biotechnology in the Region, and how platforms or networks could assist in developing further biotech approaches for improving crops in Latin America and the Caribbean.

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A. Introduction

Latin America and the Caribbean are expected to experience stable growth rates, though slightly higher than for developed regions —between 3.5 and 4.5% yr^{-1}. As a result this Region should notice a significant increase on the availability of calories for consumption as food per day and per capita, and the greatest decline (51%) worldwide for children malnutrition towards this mid-century (Hubert *et al.*, 2010). There will be a sharp increase of net meat exports though the per capita demand for cereals will fall by 11 kg. Nevertheless, there will be a slight annual average grain yield growth of about 1.25 yr^{-1} and total cereal area may expand by 9%. One hectare of land should feed 1 person in 2050 whereas it fed 0.7 and 0.5 persons in 2000 and 1965, respectively (James French, IICA, personal comm.). There are however significant contrasts between sub-regions and countries in Latin America and the Caribbean (IICA, 2007), e.g. there was agricultural growth in Latin America, particularly in the Southern Cone, but not in the Caribbean island states (except Dominican Republic) in the last 1.5 decades. The strong growth in agriculture seems to be associated to export markets, which are being influenced by the integration and transnationalization of production chains and trade.

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[2] Paper to be given at ABDC10 [Guadalajara, Mexico, 1-4 March 2010] on Generation, adaptation and adoption of appropriate biotechnologies in the Latin America and the Caribbean Region: concrete actions for the near future

[3] Ph.D.; Consultant, Martín Napanga 253, Apt. 101, Miraflores, Lima 18, Perú, rodomiroortiz@gmail.com, Tel. + 51 1 358 5530

There are at least 15 million farms and over 100,000 agricultural small-to-medium size plants that process food and agricultural products or produce inputs in this Region (Pomareda and Hartwich, 2006), which also hosts also some of the most challenging agro-ecosystems of the world due to their altitude, climate, or topography, as well as because of the huge inequality in land distribution; i.e., the bottom 60% of landowners —those with the smallest landholdings— own only 4% of all land and income inequality (with an average Gini index score of 53.29) irrespective of its high average economic growth of the last two decades (IFPRI, 2009). Since the late 1980s Latin America and the Caribbean went through significant reforms by controlling (hyper-) inflation, selling off state enterprises, lowering tariffs, signing free trade agreements within and outside the region, opening capital markets, reforming tax systems, deregulating financial markets, and reducing government deficits. Nonetheless, there are still at least 60% of the Region's poor living in rural areas, where they suffer from slow economic growth, unequal distribution of assets, inadequate public investment and public services, and vulnerability to natural and economic shocks. Revitalizing agriculture and rural areas could improve the overall development and wellbeing of this continent (Berdegué *et al.* 2006). For example, as noticed by the International Food Policy Research Institute (IFPRI, 2009), agricultural growth has had a broad effect on rural and urban populations by increasing incomes, reducing the cost of living, and increasing tax revenue for the government's social programs in Brazil. Furthermore, agriculture contributes significantly higher to the GDP when considering a wider sector definition, e.g. between 20 to 35% for the latter instead of the known 4 to 11% for some of the largest crop producers in the Region (James French, IICA, personal comm.). It will be therefore important to advocate a smallholder's food and agriculture system innovations that should focus on nutritious, healthy and safe diets in Latin America and the Caribbean.

The Inter-American Institute for Cooperation in Agriculture (IICA, 2007) points out that agriculture and rural life in the Region face four challenges, namely, making agriculture more competitive, achieving greater equity in agriculture and the rural milieu, adopting a more sustainable paradigm, and promoting governance in rural territories. Furthermore, the 5th Foro de las Américas para la Investigación y Desarrollo Tecnológico Agropecuario (FORAGRO, 2008) agreed on promoting a knowledge-led agriculture following an innovation systems perspective, which needs to consider innovating technology, policy and institutions in Latin America and the Caribbean. Such an approach should allow reaching food security, reducing both urban and rural poverty, improving both quantity and quality of produce output, enabling equity in benefits arising from agriculture, minimizing negative impacts on the environment by conserving natural resources, and addressing new challenges for agriculture and rural development in the continent. This regional forum supports institutional innovations that promote inclusive, participatory research and extension with both the public and private sectors considering the agro-ecosystem heterogeneity (both physical and social) of the Region. New investments, particularly from the private sector, are needed to overturn the low resource allocation to science and technology at large and especially for agriculture in Latin America and the Caribbean for innovations systems to succeed in improving its agriculture and rural livelihoods.

This article highlights some agro-biotech innovations that are already delivering, or will soon become available and suited to contributing more, safe, healthy and nutritious food in Latin America and the Caribbean while considering sustainable intensification of agriculture by smallholders under a changing climate. It also provides a brief overview on how biotech-aided crop breeding can contribute to sustainable and environmental friendly crop production.

B. The potential of transgenics and genomics for crop genetic betterment

Agro-biotechnology includes several technology options used in food and agriculture, e.g. micro-propagation of clean planting materials, the genetic enhancement of crops and livestock, characterization and conservation of genetic resources, pathogen and pest diagnosis, vaccine development, and improvement of feeds. This article concentrates on the use of crop genetic modification (or genetic engineering) and molecular markers for aided germplasm characterization and assisted crop breeding (genomics) rather than on today's routine tissue culture in crops for mass propagation of pathogen-tested propagules, *in vitro* seed germination (often after inter-specific hybridization), haploidy, chromosome doubling, mutagenesis, somaclonal variation or DNA-recombinant technology for diagnostics of pathogens and pests.

Crop genetic engineering refers to introducing into a new cultivar one or more genes into its genetic material from another organism using DNA-recombinant technology rather than conventional cross-breeding. The genes may be from a different kingdom or a different species within the same kingdom (transgenesis) or even from the same species (cisgenesis). The use of transgenic crops remains controversial worldwide after 1.5 decades of introducing them into the agro-ecosystems using specific frameworks to regulate their release and commercialization. While conventional plant breeding that utilizes non-transgenic approaches will remain the backbone of crop improvement strategies, transgenic crop cultivars (popularly called genetically modified crops or GM-crops) should not be excluded as products capable of contributing to development goals. For example, the net economic benefits of transgenic crops —grown in 125 million ha in 2008 (James, 2008) — amounts to US$ 10.1 billion in 2007 and US$ 44.1 billion for the 1996-2007 period at the farm level (Brookes and Barfoot, 2009). The farm income gains alone for 2007 was equivalent to adding 4.4% to the value of global production of the four main transgenic crops: soybeans, maize, canola and cotton. A recent analysis by Brookes *et al.* (2010) suggests that world prices of soybean, maize and canola would probably be, respectively, 9.6%, 5.8% and 3.8% higher, on average, than 2007 baseline levels if transgenic crop technology was no longer available to farmers. Their modeling research further suggests that average global yields would fall for soybeans, maize and canola, and there would be a net fall in global production of the three crops of 14 million t irrespective of their additional plantings. The first generation of commercial transgenic crops include traits such as delayed ripening, herbicide tolerance, host plant resistance to viruses and insect pests, or male-sterility, whereas the second generation of transgenic crops aims new cultivars for abiotic stress-prone environments (especially affected by limiting water) and better product quality (crop composition traits such as fatty acids, starch, amino-acids, b-carotene and enzymes for producing food, feed, fuel and industrial inputs, as well as improved shelf-life). Stein and Rodríguez-Cerezo (2010) estimate 120 different transgenic events in commercialized GM-crops worldwide by 2015 — compared with around 30 transgenic events in commercially cultivated GM-crops in 2008. Moreover, they expect that about 50% of the new transgenic events that could be brought to market until 2015 may be developed mostly in Asia (particularly China and India) but also in Latin America, whereas the remaining half by the transnational private seed sector in the United States and the European Union.

Molecular markers are identifiable DNA sequences found at specific locations of the genome that follow Mendelian inheritance. A broad range of molecular markers are available and they rely on specific DNA assays. They differ in their technical requirements, time, money and labor needed, as well as and the numbers that can be detected for each of them throughout the genome. Marker-aided breeding consists on using DNA markers —which are physically located within or nearby genes of interest— to select desired alleles, e.g. for host plant resistance, quality or yield. DNA marker maps facilitated the use of marker-aided breeding because many markers of know location are interspersed at relative short intervals throughout the genome. Subsequent association analysis using statistics allows linking marker types to traits of interest. This breeding method was restricted initially to a few economically important temperate crops but expanded to many crops due to lowering costs, efficiency and easiness of the enhanced DNA marker technology. Today marker-aided breeding is applied to a broad range of crops and could facilitate domesticating entirely new crops. Genomics is the study of the entire genome of any organisms with the aid of DNA markers, and includes both DNA sequencing and fine-scale genetic mapping. Genomics has been improving in the last 10 years and today there are faster and cheaper systems that are increasingly used in genebanks, genetic research and crop breeding, e.g. for studying interactions between loci and alleles such as heterosis, epistasis and pleiotropy, or analyzing genetic pathways. Advances in crop genomics are providing useful data and information for identifying DNA markers can be further used for both germplasm characterization and marker-aided breeding. Genomics-assisted breeding approaches along with bioinformatics capacity and metabolomics resources are becoming essential components of crop improvement programs worldwide.

Agro-biotechnology country assessments for some Latin American countries are available elsewhere (Ávila and Izquierdo, 2006; Diamante and Izquierdo, 2004; Morales, 2006; Pastor, 2004; Schuler and Orozco, 2006; Solleiro, 2007; Wendt and Izquierdo, 2004). Argentina, Brazil, Chile, Colombia, Cuba and Mexico are regarded as having the largest, advanced and diversified biotech industry in the Region. Falck-Zepeda *et al.* (2009) indicated that Argentina, Brazil, and Mexico have the capacity to perform transgenic crop breeding whereas Chile, Colombia, Costa Rica, Perú and Uruguay have the capacity to use conventional and modern breeding techniques. However, the remaining countries in Central America as well as Bolivia, Dominican Republic and Paraguay have very low capacity for conventional breeding techniques and almost no capacity to perform modern agro-biotechnology applications. The level of human resources and funding for agro-biotechnology by each country may explain such heterogeneity as well as accounts for a notable dilution of agro-biotechnology innovation capacity in many countries of the Region. Moreover, Izquierdo and de la Riva (2000) indicated that many small research university or national research institute teams are poorly connected or integrated, have a high dispersion of facilities and qualified labor force. They further pointed out that agro-biotechnology in Latin America and the Caribbean seems to be somewhat repetitive and follows an academic model whose objectives sometimes do not respond to the needs of sustainable crop production and food security of this Region. The involvement of the private sector in agricultural research in the Region is higher than Africa and the Middle East, but lower than in some countries of the Asia-Pacific Region (Stads and Beintema, 2009). Multinational seed and agrochemical producers —such as BASF, Dupont, Monsanto, Pioneer, and Syngenta—actively conduct agricultural research and development in the region, as do multinational fruit growers such as Chiquita, Del Monte, and Dole. CamBioTec (2003) indicated that there were in excess of 400 private biotechnology enterprises in Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, Guatemala, México, Perú, Paraguay, Uruguay and Venezuela in 2002. They were working in various sectors: agriculture, food, human and animal health, environment and industry. The most important agro-biotechnology products in Latin America and the Caribbean are pathogen-tested plantlets ensuing from micro-propagation (or tissue culture), DNA markers for characterizing germplasm and diagnostics, transgenic crops, and to lesser extent marker-aided crop breeding. The broad agro-biotechnology range and crops reflects the wide genetic resources diversity in the Region and how organizations address respective country needs for crops and traits.

C. Transgenic crops in the Latin America

Although transgenic crops were originally developed for industrialized agriculture, genetic engineering has the potential to address some of the most challenging biotic and abiotic constraints faced by farmers in Latin America and the Caribbean, which are not easily addressed through conventional plant breeding alone (Ortiz and Smale, 2007). These constraints include insect pests and viruses, as well as to providing traits for adapting crops to global warming and water scarcity due to climate change (Ortiz, 2008, Ortiz *et al.*, 2007a). A second advantage of genetic transformation is that it can add an economically valuable trait while maintaining other desirable characteristics of the host cultivar. Enhanced product quality or micronutrients can be added to a well-adapted cultivar that already yields well under local conditions. This feature is particularly attractive for semi-commercial, smallholder farmers in non-industrialized agriculture, who are more likely to consume as well as sell their farm products. The poor in Latin America and the Caribbean should benefit from the deployment of desirable transgenic crops that follows scientifically-sound biosafety and food safety standards and appropriate intellectual property management and stewardship (Ortiz and Smale, 2007). The use of transgenic crops should be also the result of social consensus considering that any new cultivars must be tested before it is released to farmers while keeping in mind the risks of not releasing it at all. The involvement of well-informed stakeholders throughout the potential transgenic crop chain will be needed to succeed in this endeavor. Furthermore, as suggested very recently by Glover (2010), any agro-biotechnology that aims to benefit poor farmers should incorporate their requirements, capacities, priorities and constraints into its technology's design and performance.

The cultivated area with transgenic crops increased fast in Latin America and the Caribbean: it was in excess of 41 million hectares in 2008 (James, 2008)—although only for soybeans, maize and cotton with herbicide tolerance and insect resistance or combinations of both in Argentina (21 million ha), Bolivia (0.6 million ha), Brazil (15.8 million ha), Colombia (< 50,000 ha), Honduras (< 50,000 ha), México (0.1 million ha), Paraguay (2.7 million ha) and Uruguay (1.7 million ha). The multinational private seed sector developed all the commercially grown transgenic crops in the Region while public national innovations systems are yet to transfer any transgenic crop to farmers in Latin America and the Caribbean. Nonetheless, national researchers are producing transgenic crops that are now in the regulatory pipeline prior their future approval for commercialization. IICA (2005) indicate that the Region also grows transgenic crops for off-season seed production and exports those seeds mainly to the US market.

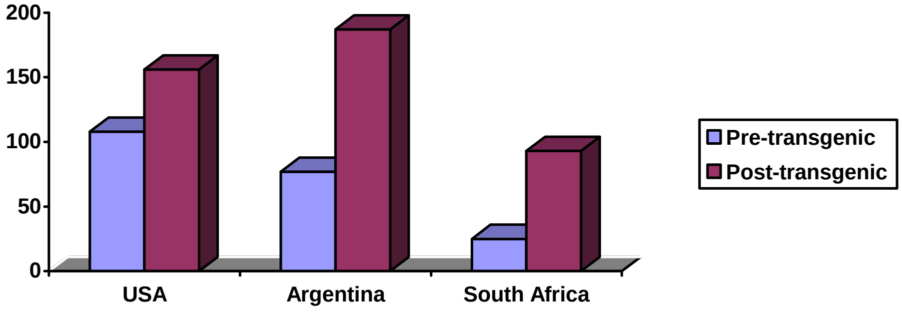

Fig. 1. Annual growth rates of maize grain yield (kg ha^{-1}) in the United States of America, Argentina and South Africa before and after introducing transgenic maize in 1997, 1998 and 2000, respectively (Source: Mezzalama *et al.*, 2010)

The use of transgenic maize in recent years has been associated with significant increases of maize yield rates in Argentina (Fig. 1). Transgenic maize with borer resistance —grown in 41.9% of the 23.5 million ha— in 2006 had an average impact of + 7.6% on yield (or 0.49 t ha^{-1}) that translated on 4.8 million t of additional grain after introducing in 1998 this gene technology in Argentina (Brookes *et al.*, 2010). Maize production could fall by 3.1% (~ 0.7 million ha) in Argentina without transgenic maize with insect resistance. The total accumulated benefits of transgenic maize with insect resistance for the 19982005 period were US$ 481.7 million in Argentina (Trigo and Cap, 2006). They were distributed among farmers (43.19%), seed suppliers (41.14%) and the National Government (15.67%). The average yield effect of herbicide tolerant maize was + 9% —thereby adding + 0.36 t ha^{-1} of grain— in Argentina in 2005, when this new transgenic maize was first used commercially (Brookes *et al.*, 2010). There were additional 30,559 t of grain due to 6.1 % yield gain (or 0.31 t ha^{-1}) after growing 100,000 ha (or 54.3% of country area for this crop) this transgenic maize with borer resistance in Uruguay in 2004.

The vast majority of soybean output in South America is transgenic and is grown on commercial farms (James, 2008). Transgenic tolerant Roundup Ready® soybean impact in Argentina was estimated at US$ 19.7 billion for the period 19962006 (Trigo and Cap, 2006). The total accumulated benefits were distributed as follows: 77.5% to the farmers, 3.9% to seed suppliers, 5.2% to herbicide suppliers and 13.4% to the National Government (revenues collected through an export tax, imposed in 2002). Furthermore, Brookes *et al.* (2010) indicated that transgenic herbicide tolerant soybean facilitated the adoption of no-tillage in the Southern Cone of the continent, thereby shortening the crop cycle and allowing a second crop that added 53.1 t of soybeans in Argentina and Paraguay from 1996 to 2006 (11.6 million t alone in 2006). The average yield/production effects of transgenic soybean area were for the second crop in each country + 20% and 7.6%, respectively. Soybean growers in Chiapas (Mexico) were able to harvest transgenic herbicide tolerant soybean yielding up to 3.3. t ha^{-1} , reducing their costs by 60% and having an economic benefit above 35% in the region of Soconusco (Solleiro and Saad, 2007). This performance of transgenic herbicide tolerant soybean explains the high level of adoption in the State of Chiapas: above 60% of total area seven years after introducing this gene technology. Transgenic cultivars have one or a few exogenous genes whereas the background genotype is still the product of non-transgenic (or conventional) crop breeding. For example, Roundup Ready® soybeans grown in South America have improved yield and quality traits due to previous decades of plant breeding using mutagenesis and inter-specific hybridization. Furthermore, soybean farmers in Argentina use genetically-engineered cultivars (> 95% of total area) because of many useful traits —such as host plant resistance to pathogens or heterosis that were bred using non-transgenic methods— rather than just due to their transgenic traits.

The total accumulated benefits for insect-resistant cotton in Argentina between 1998 and 2005 were estimated by Trigo and Cap (2006) at US$ 20.8 million (86.19% to farmers, 8.94% to seed suppliers and 4.87% to the National Government). The initial adoption rate of *Bt*-cotton was low (5.4%) because of this proprietary technology costs: 4- to 6-times higher than non-transgenic cultivars (Qaim and de Janvry, 2003). However, as noted by Qaim and Traxler (2005), black market *Bt*-cotton seed became available after few years at 1/3 the price and rights of this proprietary technology became virtually unenforceable in Argentina. Traxler and Godoy Avila (200) calculated annual benefits of US$ 2.7 million for *Bt*-cotton in Mexico, where it was introduced in 1996. Adopting farmer —with an average holding of 14 ha— spent below US$ 100 on pest control and their net revenue was US$ 295 ha^{-1} than non-adopting farmers. As a result of this transgenic technology, cotton profitability and competitiveness increased and crop failures risks reduced in Mexico. At the time of their assessment, the national adoption in Mexico was about 33% because *Bt*-cotton protects only for some insects pests. Solleiro and Saad (2007) further stated that *Bt*-cotton also brings a benefit to the environment by decreasing up to 80% the pesticide sprayings, as well as improving fiber quality because it lacks any spots owing to reducing insect attacks to cotton plants. Qaim (1998) using an *ex-ante* analysis also predicted a profit of US$ 288.8 acre^{-1} for virus-resistant potato in Mexico.

One main concern on using crop genetic engineering in biodiversity-rich Latin America and the Caribbean could be the unintentional spread of transgenic traits into conventionally-bred crop or landrace gene pools of the same species, particularly in a Region that includes centers of diversity or origin for many crops. The transgenic plant might breed with another and perhaps forever alter the other plants' genetic identity**.** This gene flow is not something peculiar to transgenic plants because it happens at any time one organism breeds with a related species, thus passing along their combined DNA to the offspring. Selection rather than the overall rate of gene flow is the most important factor governing the spread of favorable alleles as noted by population genetics research. Local knowledge of resource-poor farmers will be needed to avoid such gene flow to hamper the efforts for maintaining distinct cultivars for the marketplace (Ortiz and Smale, 2007). Nevertheless, crop diversity is not static but changes constantly as a result of biological and social processes, e.g. maize gene flow in Mexico should be seen both as biological and human phenomenon because some farmers deliberately mix seed from different sources with the express purpose of hybridizing them (Bellon and Berthaud, 2004). As indicated by Bellon and Berthaud (2006), farmers' or consumers' perceptions that transgenes are ''contaminants'' and that landraces containing transgenes are ''contaminated'' could however cause these landraces to be rejected and may trigger a direct loss of their diversity. Appropriate measurements should be therefore taken when transgenic and conventional crops of the same species coexist in the same locations if some farmers wish to grow crops for transgenic-free markets or avoid transgene flow to other crop genetic resources. For example, Scurrah *et al.* (2008) suggest the use of sterile cultivars with scarce flower production and lacking seed production to minimize the risk of gene flow from transgenic potato in the Andean region of Perú —the center of origin of this crop (Spooner *et al.*, 2005) — because gene flow occurs to landraces and wild relatives growing near potato crops (Celis *et al.* 2004). The extensive spread of transgenic cultivars and any rate of out-crossing have also significant implications for maintaining the integrity of landraces in farmers' fields, conventional breeding material and cultivars during seed multiplication, and genetic resources during regeneration. Thus, genebank curators and plant breeders must take significant precautions during distribution of seed for research trials, breeding programs, genebank operations and germplasm exchange (see Mezzalama *et al.*, 2010 for maize). In short, decisions, policies and procedures about monitoring transgenic crops should be science-based, and this approach requires education. Hoisington and Ortiz (2008) conclude that there will be continuing assessment on the need for, and type of monitoring as new (and unique) products are developed and released to agro-ecosystems.

D. Genomics to unlock crop diversity in Latin America and the Caribbean

Genebank curators have interest in the conservation of plant genetic resources because of the potential uses of this germplasm (Ortiz, 2002). Genebanks are therefore biodiversity reservoirs and sources of alleles for sustainable genetic enhancement of plant crops. Genetic resources available in genebanks are still the best source for an easy gene discovery.

This search will be facilitated by gene databases assembled with the aid of applied plant genomics, which can also accelerate the utilization of available genes through transformation or meiotic-based plant breeding methods.

Molecular markers are descriptors that offer reproducible results for characterizing genotypes; i.e., the environment and the genotype-by-environment interaction should not affect them. In Latin America and the Caribbean, most countries are using molecular markers mostly for characterizing genebank accessions, farmers' landraces and bred cultivars. DNA markers can be also used for identifying duplicate genebank accessions, determining out-crossing rates and effective population sizes, and revealing population structure of the crop and its wild species, or elucidating crop domestication. For example, research by Spooner *et al.* (2005) with amplified fragment length polymorphism genotyping supports a monophyletic origin of potato landrace cultivars in Perú rather than from multiple independent origins from various northern and southern locations of the Andes from Central Perú to northern Argentina. Likewise, cloned DNA sequences provide means for determining genomics origins of any crop species and their wild relatives. This information will be useful for designing crossing schemes to incorporate wild species germplasm into the cultigens. The targeted use of landraces and wild species held in genebanks will be facilitated by integrating whole-genome mapping approaches and DNA-marker analyses along with cloning of quantitative trait loci and EcoTILLING —which is a high throughput, low cost technique for rapid discovery of natural nucleotide diversity in natural populations using reverse genetics.

Sequencing of crop genomes has opened new frontiers in biodiversity conservation and genetic enhancement as well as gaining new insights into genomic diversity (Ortiz 1998). For example, the Laboratorio Nacional de Genómica para la Biodiversidad at the Centro de Investigación y de Estudios Avanzados del Instituto Politécnico Nacional (CINVESTAV, Irapuato, Mexico, http://www.ira.cinvestav.mx/) sequenced the EDMX-2233 accession of the Palomero Toluqueño landrace —a highland popcorn from San Lorenzo Teotuitlán, Mexico— and compared its features with the genome of the US inbred B73 (Vielle-Calzada *et al.*, 2009). Their data suggest that environmental factors related to the metal contents of local soils, possibly relating to volcanic activity 8500 to 10,500 years ago, could be important in maize domestication. The information of the Palomero landrace genome offers means exploring allelic variants selected during early maize cultivation. Advances in gene isolation and sequencing in plant species also offer the possibility that within a few years, gene bank curators could replace their large cold stores of seeds with crop DNA sequences, which will be electronically stored and easily accessed by any users. This characterization of plant genomes will create true genebanks, which should possess a large and accessible gene inventory of today's non-characterized crop gene pools. Of course, seed banks of comprehensively investigated stocks should remain because geneticists and plant breeders —the main users of genebanks— will need this germplasm for their work (Ortiz, 2002). Characterization of crop genetic resources at the DNA level could also assist on ensuring ownership and equitable benefit sharing.

E. Marker-aided selection for smart crop breeding in Latin America

DNA markers and genetic maps are available for most important food crops. Marker-trait associations have been established for a diverse array of traits in these crops, and research on marker/quantitative trait loci (QTL) validation and refinement is increasingly common (Dwivedi *et al.*, 2007). Candidate gene-based mapping and genome-wide linkage disequilibrium (LD) and association analysis are routinely used in addition to classical QTL mapping to identify markers broadly applicable to breeding programs. In contrast to linkage mapping, LD mapping relies on surveys of natural variation. The LD is determined by their physical distance across chromosomes and has proven to be useful for dissecting complex traits because it offers a fine scale-mapping due to historical recombination. In this regard, Crossa *et al.* (2007) used diversity array technology markers to find associations with resistance to stem rust, leaf rust, yellow rust, and powdery mildew, plus grain yield in five historical wheat international multi-environment trials from the International Maize and Wheat Improvement Center (CIMMYT, Mexico, http://beta.cimmyt.org/). The historical phenotypic data used in this study were recorded by national program partners worldwide, which led to genotype-by-environment effects being observed for all traits. The Food and Agriculture Organization of the United Nations (FAO) and International or Regional Agriculture Research Centers facilitate multi-environment testing of crop genetic resources, thereby enabling the sharing of newly bred germplasm with national public and private seed sectors that can use them directly on as sources in their breeding programs. For example, CIMMYT distributes improved germplasm to a network of maize and wheat research and breeding cooperators across the world who evaluate this material in many different agro-ecosystems and crop husbandry practices. Phenotypic data from these multi-environment trials are cataloged, analyzed, and made available to the network. The data allows CIMMYT to identify parents for future crosses and to drive the strategic incorporation of new genetic variation into advanced lines and populations that are consequently able to cope with the dynamics of abiotic and biotic stresses.

Genomics tools have become a routine component of most private-sector maize breeding programs where they are used to dissect the genetic structure of relevant germplasm to understand gene pools and germplasm (heterotic) groups, provide insights into allelic content of genetic resources for potential use in breeding, screen early generation breeding populations to select segregants with desired combinations of marker alleles associated with beneficial traits (to reduce the scale of costly phenotypic evaluations), and to establish genetic identity (fingerprinting) of their products (Ortiz *et al.*, 2010). Routine integration of molecular markers from introducing new genetic resources to releasing new elite breeding lines in public-sector breeding programs should be a primary strategic goal for international and national breeding undertakings in Latin America and the Caribbean. Large-scale marker-aided breeding programs for crops such as rice, maize, wheat, barley, sorghum, pearl millet and common bean have already been initiated worldwide. Although MAS is becoming progressively cheaper, it is still often relatively expensive compared to alternative approaches for many crops grown in Latin America and the Caribbean.

Marker-aided breeding is also practiced by the centers of the Consultative Group on International Agricultural Research (CGIAR) Consortium for enhancing various host plant resistances to pathogens and pests, several quality traits, and a number of abiotic stress tolerances in many crops (Dwivedi *et al.*, 2007). For example, the International Rice Research Institute (IRRI, The Philippines, http://beta.irri.org/) incorporate the *submergence 1* (*sub1*) gene into popular cultivars, which can be immediately use by farmers, to allow the rice crop to survive prolonged periods of submergence due to increased rainfall and flooding that will be brought by climate change in many parts of Asia. Likewise, the International Crop Research Institute for the Semi-Arid Tropics (ICRISAT, India, http://www.icrisat.org/) used marker-aided breeding for developing a new downy mildew resistant pearl millet hybrid whose F_1 hybrid seed was produced to sow at least 300,000 ha in 2008 (Hash, 2009). CIMMYT uses DNA markers for incorporating resistance to nematodes and some root pathogens wheat materials bred for drought-prone environments (Ortiz *et al.*, 2007b). Likewise, simple polymerase chain reaction marker systems are being developed at CIMMYT for selecting parental combinations with optimal combinations of favorable lycopene epsilon cyclase (*lcyE*) alleles to enhance the pro-vitamin A levels in maize grain, which is an important target trait for tropical maize breeders as large areas of the developing world have dietary vitamin A deficiency causing eye disease in millions of children while placing many millions of people at risk of other health disorders (Ortiz *et al.*, 2010). The Centro Internacional de Agriculture Tropical (CIAT, Colombia, http://www.ciat.cgiar.org) along with national partners in Central America, Colombia and Eastern Africa tagged simple traits with easy-to-use DNA markers for the *bgm*-1 gene for bean golden yellow mosaic virus resistance and the *bc*-3 gene for bean common mosaic virus resistance (Blair *et al.*, 2007). Marker-aided breeding was effective for reducing breeding costs for both traits as land and labor savings resulted from eliminating susceptible individuals. CIAT and the International Institute of Tropical Agriculture (IITA, Nigeria, http://iita.org/) have been using DNA markers for mapping host plant resistance to cassava mosaic disease (CMD) that is the most important virus affecting cassava in Africa and a potential threat for Latin America —where it is still unknown but most of its cassava germplasm is very susceptible to CMD— especially after finding a widespread new biotype of the whitefly vector with a broad host range, including cassava, in the continent. Akano *et al.* (2002) mapped a dominant gene (*CMD2*) conferring host plant resistance to CMD in cassava using microsatellite markers and bulk segregant analysis. This collaborative intercontinental research uses markers linked to *CMD2* marker-aided breeding for pre-emptive host plant resistance to this virus in Latin America and for increasing the cost-effectiveness of resistance breeding in Africa. DNA markers are also increasingly used to transfer yield or quality-enhancing QTL alleles from wild relatives to elite cultivars.

Dwivedi *et al.* (2007) indicated that today's challenge is to translate and integrate ensuing knowledge from the use of DNA markers into appropriate tools and methodologies for plant breeding programs. The role of computational tools in achieving this task is therefore becoming increasingly important. For example, the recently launched Wheat Phenome Atlas initiative aims for enabling technologies to link genotype to phenotype across a wide range of agronomic traits of high priority to wheat farmers across the world. This Wheat Phenome Atlas will facilitate more rapid development of molecular breeding tools, increased understanding of genotype-by-environment interaction, and will lead to increased precision and scope of targeted breeding impacts (Ortiz *et al.*, 2008). A Phenome Map is a representation of all the regions of a genome that influence heritable phenotypic variation for a trait, and a Phenome Atlas consists of the integration of all available phenome maps with a description of the methodologies that were used to produce the maps, whereas the Phenome Atlas Toolbox is a set of tools and methodologies for producing the Phenome Atlas (DeLacy *et al.*, 2009).The Phenome Atlas Toolbox is being developed as an open source resource for wheat genetics, breeding, pathology, physiology, and biological research The initiative is based on a unique database (amongst crop plants) developed by CIMMYT and national partners over the past half century, based on the field evaluation of more than 15,000 elite breeding lines in more than 100 locations across the world—at a cost of about US$ 0.5 billion. All seed from these breeding lines has been preserved in the CIMMYT genebank and could be the subject of whole genome genotyping.

F. Genome-sequencing in Latin America

Advances in crop genome sequencing, high resolution genetic mapping and precise phenotyping will accelerate the discovery of functional alleles and allelic variation that are associated with traits of interest for plant breeding. Genome sequencing and annotation include an increasing range of species such as banana/plantain (Lescot *et al.* 2008; www.genoscope.cns.fr/spip/September-8th-2009-Banana-genome.html), cassava (www.phytozome.net/cassava), citrus (http://www.citrusgenomedb.org/node/19**)**, coffee (http://www.coffeegenome.org/communications/report/Minutes_ICGN_meeting_Campinas_Sept08.pdf), grape (Travis, 2008), model legumes (Sato *et al.*, 2007), maize (Schnable *et al.*, 2009; Vielle-Calzada *et al.*, 2009), potato (Visser *et al.*, 2009), rice (Matsumoto *et al.*, 2005), sorghum (Paterson *et al.* 2009), sugarcane (http://fapespbioen.org/index.php?option=com_content&view=article&id=106&Itemid=95&lang=en), soybean (Schmutz *et al.*, 2009), and the wheat relative *Brachypodium distachyon* (The International *Brachypodium* Initiative, 2010), among other crops. Perhaps further research on the sorghum genome may assist to breeding more hardy and water efficient maize, rice and wheat due to gene synteny among cereals. National labs from Argentina, Brazil, Colombia, Chile, Mexico and Perú are participating actively in most of these genome sequencing projects. For example, Brazil launched some years ago animal and plant genomics networks and today this country leads sugarcane genomics while some of her small-medium enterprises are working on the application of the ensuing knowledge or how to market the results elsewhere (Sasson, 2005). Likewise, Chile has "Genoma Chile" that include grape genomics among other plants, whereas Argentina in cooperation with Spain built a new plant genomics institute in Rosario —the center of soybean cultivation in this country. Mexico invested in CINVESTAV for researching on maize genomics, whose results should be regarded as a milestone in the genetics of this crop.

G. The role of public-private agro-biotechnology partnerships

> "*Biotecnología es producto y es negocio; antes es laboratorio e investigación, pero si no desemboca en algo que mejora la vida de los ciudadanos no es biotecnología, y no es bioindustria y no es bioeconomía.*" (Sasson, 2005)

Private resources —particularly of the multinational seed sector— seldom invest in research that is directly or intentionally for poor smallholders (Spielman and von Grebmer, 2004). Most of the private sector investment in agricultural research is directed toward crops, traits, and technologies that benefit farming in the developed world and are profitable enough to guarantee adequate returns on investment in research. Research collaboration between the public and private sectors in which each sector contributes to the planning, resources, and activities needed to accomplish a mutual objective are referred as public-private partnerships. They combine often the resources of government with those of private agents — either businesses or civil society organizations— to deliver societal goals (Martinez Nogueira, 2006). This type of partnerships should be participative and of multi-stakeholder nature to ensure all key players around a development issue are mobilized for developing and implementing actions to address this issue. By being participative the partnership builds a great commitment and could create a legitimate and sustainable solution, whereas its exchange of resources, competency combination and new ways for activity coordination ensues from it multi-stakeholder nature. Nonetheless, misunderstandings and conflicts can arise due to the diverse goals, values and perspectives of the partners involved. Public-private partnerships require therefore building structures, skills, and processes that will bring structural flexibility, resilience, ability to make and sustain own rules and to adapt goals, which along with partners' values and capacities plus funding and a leader who can motivate all partners and resolve conflicts are the "ingredients" for succeeding in this endeavor. Spielman and von Grebmer (2004) further emphasize that public-private partnerships can enhance the production of goods, services and technologies that would not otherwise be produced by either sector acting alone.

Partnerships between technology providers and the productive sector seems to be promising for pooling scarce human and financial resources for innovation and collectively develop solutions that respond to the needs of farmers, consumers, and agro-industry in Latin America (Pomareda and Hartwich, 2006). They further indicate that the most successful partnerships include pest diagnosis to ensure product quality, processed fruit and vegetable protocols, and cereal improvement for local environments. Public-private agro-biotechnology partnerships in the Region may allow the public sector to access new, cutting-edge scientific know-how and ensuing technology own by the private sector, mechanisms for developing, marketing and distributing final products, and financial resources that are increasingly difficult to obtain, whereas the private sector benefits by accessing farmers in new markets, influencing constructively the development of legal and regulatory systems, participating in fora addressing smallholder research, and improving their corporate profile and reputation.

High price differentials between publically available and private sector patented technology (or its license fees) can drive farmers to black-market seed or to refuse fee payments as happened with herbicide tolerant soybean in South America (Murphy, 2007). For example, farmers in Southern Brazil widely planted Roundup Ready® after smuggling seeds from Argentina, which pushed Monsanto to devise an innovative delivery-based value capture program (Bell and Shelman, 2006). Under this point-of-delivery system, farmers paid a postharvest fee for soybean grains grown from transgenic soybean seed for which royalties has not been paid. The grain companies collected the fee on behalf of Monsanto and in the first year 97% of the farmers self-declared the use of Roundup Ready®. Another possible solution could be developing indigenous proprietary seed technology, which can be made available to farmers at low cost (Cohen, 2005). For example, the Empresa Brasileira de Pesquisa Agropecuária (EMBRAPA, Brazil, http://www.embrapa.br/) and BASF established a public-private partnership for developing locally adapted herbicide tolerant soybean cultivars, which are planned for release to farmers in 2011. Such partnership allows Brazil to develop its own proprietary biotechnology as well as dealing with restricted access due to intellectual property rights of the Roundup Ready® technology. Likewise, new user-led philanthropy-private-public partnerships in the Latin America and the Caribbean may allow the development and deployment of agro-biotechnology solutions for sustainable agriculture and food security. In such endeavor with funding from available philanthropic resources in the Region, an "honest broker" contributes its leadership, unique experience in public-private partnership management, technology stewardship and project management expertise, whereas the public sector provides locally adapted crop germplasm and expertise in plant breeding and its field testing network, and the private sector brings proprietary germplasm, advanced breeding tools and expertise, and desired transgenes. Such a partnership needs to agree from the onset on tasks such as seed multiplication and distribution ensuing from this joint undertaking as well as on profit sharing from seed sales.

H. Outlook: Agro-biotechnology regional networking and platforms

Agro-biotechnology implies a direct relationship between entrepreneurs, government, university and national institute researchers because human resources, technology and accumulated expertise should be rationalized and optimized both nationally and through regional integration, thereby enhancing national capacity and savings both in funding and time (Sasson, 2005). In this regard, the continent benefits from REBDIO/FAO —Red de Cooperación Técnica en Biotecnología Agropecuaria para América Latina y el Caribe (www.redbio.org/) — which is a regional agro-biotechnology network launched in 1990 under FAO sponsorship. REDBIO/FAO included 5,467 researchers of 738 labs from 32 countries in Latin America and the Caribbean at the end of 2008. It promotes, among public and private sector researchers, knowledge, technology and biological material sharing, and encourages agro-biotechnology innovation training, rational use and capacity building, as well as the conservation of plant genetic resources in the Region. In 2002, the Fundación REDBIO Internacional (FRI) was created as a not-for-profit non-governmental organization to act as the executing branch of priority activities identified by REDBIO/FAO. Among its main tasks are the triennial regional conference for information exchanges, proposal development and capacity building on basic and applied agro-biotechnology.

Member states with the sponsorship of the Inter-American Development Bank and IICA established in 1998 The Fondo Regional de Tecnología Agropecuaria (FONTAGRO, http://www.fontagro.org/index_es.htm) as a consortium to promote regional strategic agricultural research with the direct participation of Latin American and Caribbean countries in securing priorities and financing research projects. The consortium membership includes 14 countries in the Region and Spain, and funds projects that are approved after submitting proposals to the regular bi-annual thematic calls or extraordinary requests for proposals. FONTAGRO has funded agro-biotechnology projects in its first decade, e.g. marker-aided breeding for cold tolerance in rice for the Southern Cone, genomics tools for adapting coffee to climate change, identification of molecular markers for host plant resistance to bud rot in oil palm, or durable resistance in barley. The projects promote knowledge-based regional partnerships among participating labs to address issues affecting agriculture in Latin America and the Caribbean. Researchers in the Region also benefits from partnerships with advanced labs in North America, Japan, Europe and Australia, with whom they can access other funding sources (e.g. national research councils or alike) to implement collaborative agro-biotechnology undertakings.

The CGIAR launched in 2008 a major Change Initiative to identify how best to adapt to and anticipate global changes and challenges as well as to ensure the continued supply of international public goods to help address them. This initiative culminated in the CGIAR's decision in December 2008 to adopt a new business model that should enable the CGIAR do more and do better, as it fulfills its mandate to fight poverty and hunger while conserving the environment (http://cgiar.org/changemanagement/index.html). The Strategy and Results Framework and Mega-programs are key elements of the new CGIAR (Alliance of CGIAR Centers, 2009). The expected changes should bring clear strategic focus; increased research output, outcome and impact; greater efficiency, effectiveness and relevance; simplicity and clarity of governance; enhanced decentralized decision making; and active subsidiarity to capitalize on complementarities between the Centers and partners. The latest Strategy and Results Framework proposal considers implementing research through mega-programs. For example, Mega-Program 3 (Genomics and Global Food Crop Improvements) may establish a networked Molecular Discovery and Enhancement Program to provide CGIAR researchers and partners with relevant technology, which can also be developed locally because many of the crops require particular breeding conditions. The principal users and partners of this mega-program's products and services are public and private sector plant breeders in the developing world. Similarly, CIAT has recently proposed to establish with partners in the Region an agro-biotechnology research platform for Latin America and the Caribbean (CIAT, 2009). This platform will exploit both genomics and transgenic approaches for improving its mandate crops (bean, cassava, rice, tropical forages and pastures) as well as other crop species of high priority for the regional partners. The scientific community platform will include CIAT researchers along with colleagues from the region who deal with a broader array of crops and traits. The research will be implemented both at CIAT and other labs in the Region [e.g. of its sister centers CIMMYT and Centro Internacional de la Papa (CIP, Perú, http://www.cipotato.org) and of the Centro Agronómico Tropical de Investigación y Enseñanza (CATIE, Costa Rica, www.catie.ac.cr/), CINVESTAV or EMBRAPA among others] or in advanced research institutes outside Latin America and the Caribbean but all with links to the platform, which will focus on problem-solving research that yields clear impacts in the field and marketplace.

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Biosafety regulations and perspectives at the Latin America and the Caribbean Region: Status, needs and actions[4]

Dr. Moisés Burachik[5]

History and Current Status

The history of harmonization efforts on biosafety regulations in the Latin American (LA) countries started in 1992 with the Workshop "“Biosafety Harmonization in the South Cone: Oversight of Transgenic Plants,” organized by the Inter-American Institute for Cooperation in Agriculture (IICA) and the International Service for the Acquisition of Agri-biotech Applications (ISAAA), in Buenos Aires, Argentina. At these early days of agricultural biotechnology in the region, scientists and regulators across the Latin America (LA) Region recognized harmonization as a worthwhile goal and significant efforts were devoted to that end.

Since then, several similar meetings and workshops have been held, which ultimately led to the ongoing two-year Project FAO TCP/RLA/3109: “*Development of reference technical tools for Biosafety Management in Extended Mercosur Countries,”* which started in Jan. 2008. Within this project, which is operating under the umbrella of REDBIO/FAO and the Fundación REDBIO Internacional (FRI), several workshops, training and document-generating activities have been organized addressed to paving the way and provided concrete instruments and concensed agreed documents for regional harmonization for the biosafety regulation of genetically modified (GM) crops. These documents are available at www.redbio.org (bioseguridad).

As a result of these efforts several issues have been identified.

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[5] Biotechnology Directorate, Ministry of Agriculture, Livestock and Fisheries, ARGENTINA

Countries differ in several environment-related issues: the biological diversity they harbor (some are mega-diverse), the size and suitability of agricultural areas, and the balance between agro-ecosystems and protected ecosystems just to mention a few. While these facts give the region its rich and diversified character at the same time they demand particular environmental considerations for each particular case, as a result, different environment protecting goals will reflect on biosafety criteria. For example, adherence to the Cartagena Protocol on Biosafety (CP) to the Convention of the Biological Diversity has direct incidence on regulations. By raising concerns about the safety of GM crops and food/feed derived from them, regulatory policies tend to be exceedingly restrictive, resulting in an increased regulatory burden.

In addition, it is assumed that the CP seeks a balance between the protection of biological diversity in a commodity importing country and the economic benefits of the exporting partner. Therefore, membership to this instrument is connected with differences in commodity trade flows, which are also important when considering harmonization. Additionally, the import/export status on commodity trade touches relevant questions regarding country's economy and food security, which are determined by national policies. Consequently, harmonizing positions for negotiations at international forums regarding the environment also remain a relevant goal. Membership as Parties to CP is, in fact, a dividing issue, as not all countries in the region have ratified this instrument and/or have different views over it. Therefore, this is a very distinctive challenge for the region.

Policies regarding the different agricultural practices may differ. Conventional or GM crops and organic production are alternatives that entail considering other issues such as co-existence, traceability and regulations for land use.

Environmentally-oriented NGOs' activities have impact on the adoption rate of GM crops, which usually reflects on regulations. While the issues raised by these organizations are essentially similar worldwide, the societal impact and consumers' reactions may be different among the countries of the region, what poses additional challenges.

Why Harmonization?

In order to tackle all these problems, reaching a consensus on key specific areas may be an approach. It is clear that harmonization has the potential to bring important benefits:

a) It will facilitate intra- and extra- regional trade, avoiding asynchronous approvals, which are likely to occur because of differences in the species and in the relevance of GM crops each country will adopt and also because of the increasing number of new events in the pipelines of developers;

b) It will help to integrate regionally the adoption of the new technologies. There are several reasons supporting this. MERCOSUR (Argentina, Brazil, Paraguay and Uruguay) plus Bolivia and Chile (the expanded MERCOSUR countries) represent a significant portion of the total world area in which GM crops are commercially grown. Argentina and Brazil are major exporters of GM food/feed commodities and they have strong national R&D agriculture programs involved at developing and releasing new GM crops appropriate for their agro-ecological conditions. Therefore, harmonized regulatory instruments are then also key factors for innovation. There are additional benefits derived from this, as countries in the region may be interested in developing GM crops other the commodities produced by the big players (i.e., orphan crops), which are of local interest. As in many cases these crops are consumed within the region, harmonization will facilitate trade.

c) It will make possible to test and grow GM crops across boundaries.

d) It may establish cooperation channels for research, regulations and policies, leading to a better use of human and physical resources.

What to Harmonize?

Considering national specificities, a reasonable goal is not to aim at the detailed regulatory guidelines but to a set of basic biosafety criteria which are embedded in a common framework. This is an appropriate goal, considering that consensus on these basic criteria opens a greater common ground and thereby the way to more detailed documents. For instance, countries may engage in comparative exercises, by which the different regulatory processes, the information requirements for risk assessments, the criteria and guides to risk management and post-marketing monitoring (if applicable) can be compared. Active exchange of knowledge and views among the countries on these issues may help to harmonize other areas beyond the above-mentioned technical matters such as administrative instruments and regional risk communication (in fact a part of risk analysis).

As agricultural biotechnology has the potential to make significant positive contributions to global challenges, like how to deal with climate change and how to work towards the UN's Millennium Goals, a concerted activity in this area may led to relevant synergies among the countries.

Reaching a consensus in these areas will ultimately help the region have a more unified position before the international community, what will give the region the tools and power to play a visible role and have more weight at international agreements.

Harmonization: Needs

To accomplish this task, two kinds of needs may be identified: those connected with human resources and capacity-building and those related to the instrumentation of such needs.

Regarding human resources, they are essential to implement a biosafety regulatory framework. Training is crucial to achieve this, as well as the definition of a common framework. To that aim, consensus must be reached about the criteria underlying said framework.

On the more practical side, infrastructure is crucial, as well as focal points and communication channels. All these aspects require funds to sustain and coordinate activities. Financial resources are also needed to allow for exchange visits, face-to-face meetings and workshops and the mobility of experts. These are essential to participate jointly at international forums in which negotiations relevant for the region are being held.

Harmonization: Actions

Biosafety research is a rapidly evolving field. It is also a field in which journals are often misled by flawed "scientific" reports. Active exchange and information sharing, as well as discussions about pertinent literature could be a possible action that will tend to build a rational approach and to harmonize views on conflictive issues. This may in turn impact on regulatory harmonization as results of biosafety research are relevant to regulators for their day-to-day work and also for conceptual reshaping regulations when needed. Joint regional projects would be a way of achieving this.

Another issue to consider is the "asynchronous" approval of GM crops in the region. A very useful instrument in the area of recording the regulatory status around the world is the Biosafety Clearing House of the CP. Perhaps a similar initiative can be envisaged within the region, which will collate not only the approved varieties but also the dossiers under ongoing reviews. Along these same lines, building mechanisms for consultation on regulatory matters which appear not only at reviewing the dossiers but also in the decision–making process would be very advantageous.

Essential to the above are the on going activities under the Project conducted under the umbrella of REDBIO/FAO and FRI mentioned earlier. These include:

i) Harmonization in areas of technical management of biosafety (identification of minimum information requirements, identification in consensus of a set of regional criteria for decision-making, setting-up a virtual consultative group to exchange information and a shared information system);

ii) A shared system for training communication, including a website (www.redbio.org) with links to pertinent databases. This site will contain also other relevant information, like current issues of interest, human resources, case studies, recent literature, development of communication skills, and food safety courses; and

iii) Promotion of collaborative research toward biosafety strategic areas. These include identification of the most important gaps, the design of joint projects and the help for increased participation of the regional scientists in biosafety-related meetings and in international publications.

Major Challenges

Fortunately, these major challenges are based on some common grounds, which constitute a good base for harmonization of biosafety regulations in the LA region. For example, countries agree in several basic principles that must be included in the regulatory framework. There are coincidences in that this framework must be science-based, case-by-case, continuously updated with new knowledge and that information provided by developers must have peer-reviewed quality. The best available scientific information should be used in risk assessment to inform decision-makers. There is also agreement in the scope and focus of the scientific information required for decision-making. To achieve this and due to the increasing complexity of products, such as the incorporation complex phenotypes and multiple stacked events, updating with cutting edge knowledge, familiarity with scientific methodology, academic links and knowledgeable means to assess the quality of the information in the approval process are essential and the region should work on this. Pertinent training would be required. In fact, the REDBIO/FAO and FRI Project has designed a series of activities to this end, which have been mentioned above.

Another area of regional coordination should be risk communication, a component of risk analysis, which is related to stakeholders' inputs and transparency. It may be expected that workable coincidences can be built, which may then reflect in harmonized policies pertaining these issues.

Another aspect to consider is research. There is agreement on the importance of biosafety research as a fundamental input to sound regulatory criteria. For this purpose, relevance of the research objectives should be carefully analyzed and the experience gained since the first placing on the market of GM products should be capitalized accordingly. Countries' specificities may command a dedicated set of research goals, but at the same time this would bring opportunities for fruitful cooperation and for the establishment of research groups across national borders.

Harmonization also entails the recognition of areas in which work is still needed to achieve the desired status. There is agreement on the scope of the scientific requirements for the safety assessment. Molecular characterization, phenotypic expression (including a comparative analysis on composition, toxicology, allergenicity, nutritional value, agronomic characteristics) and adequacy to uses are recognized as essential elements of the risk assessment. Nonetheless, the challenges posed in this are connected with the relevance and place of socio-economic considerations in the decision making process as well as with views on the protecting goals for biological diversity. The later derives into two main closely-connected features: the status with regard to the CP and the situation with regard to local biological diversity. Consistency between regulations and the CP has been a template input for some national biosafety frameworks and indeed, countries differ in the biological diversity they harbor. These, then, represent another challenge.

Information exchange, channels for cooperation and regional training workshops are already operative. REDBIO/FAO and Fundación Redbio Internacional have organized training workshops where common grounds are built in wide areas, and harmonization can be perceived as an attainable goal. We are working to pave the way to a fruitful and productive harmonization.

Paving the Road towards Harmonization

When biosafety regulation is understood as a scientific process, human resources are essential and their proficiency and expertise to accomplish this task are crucial. When considering the whole region, this process requires defining common regulatory processes, that is, harmonization, which would include all the most relevant aspects that are within the region's best interests. This very ample approach would take into consideration not only region-specific challenges but also some country-specific concerns. To be strong as a region it is important to make some concessions. Last but not least, reaching a workable consensus before the international community and international forums as a region is also important. Regional harmonization of GM biosafety frameworks would not only benefit the LA region but also would facilitate its participation in the worldwide efforts to cope with relevant global challenges.