

Edited by Sylvie De Buck, Ivan Ingelbrecht, Marc Heijde and Marc Van Montagu





Innovative farming and forestry across the emerging world: the role of genetically modified crops and trees

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Important acronyms

AATF African Agriculture Technology Foundation

ABS African Biofortified Sorghum

ANB Agence Nationale de Biosécurité / National Biosafety Agency

ANPEl National Research and Development Association of Innovative Companies

AP Agronomic Performance

APROCOB Association Professionnelle Des Sociétés Cotonnières du Burkina

ASBP-II Agricultural Biotechnology Support Project II

BASF Badische Anilin- und Soda-Fabrik

BARI Bangladesh Agricultural Research Institute

BCC Biosafety Core Committee

Bc+ BioCassava Plus

BNDES Brazilian Development Bank

Bt Bacillus Thuringiensis

BXW Bacterial Xanthomonas Wilt

CAFTA-DR Central American-Dominican Republic Free Trade Agreement

CAPES Brazilian Federal Agency for Support and Evaluation of Graduate Education

CEO Grupo Consultores en Economía Organización

CFDT Compagnie Française pour le Développement des fibres Textiles

CFS Committee on World Food Security

CONABIA Argentinean Government of the National Advisory Commission on Agricultural Biotechnology

CONARGEN National Committee on GMO Risk Analysis

CIBio International Commissio of Biosafety

CINVESTAV-IPN Centro de Investigación y de Estudios Avanzados del Instituto Politécnico Nacional

CNBS National Council on Biosafety

CNPg National Counsel of Technological and Scientific Development

CTNBio Brazilian National Biosafety Technical Commission

CYMMYT International Maize and Wheat Improvement Centre / Centro Internacional de

Mejoramiento de Maíz y Trigo

DBT Department of Biotechnology
DDPSC Danforth Plant Science Center

DGPSA General Direction for Animal and Plant Health Protection

EMBRAPA Empresa Brasileira de Pesquisa Agropecuária

EPA Environmental Protection Agency

ES Earth System

EWI Department of Economy, Science and Innovation of the Flemish Government

FAO Food and Agriculture Organization of the United Nations
FDA-USA Food and Drug Administration United States of America

FINEP Brazilian Innovation Agency

FPAC Forest Products Association of Canada
FPIC Free, Prior and Informed Consent

FSB Shoot and Fruit Borer
FSC Forest Stewardship Council
GA Glyphosinate ammonia

GAIN Global Agricultural Information Network

GDP Gross Domestic Product

GEAC Genetic Engineering Appraisal Committee
GM Genetic Modification / Genetically Modified

Gt Gigaton

HT Herbicide Tolerance / Herbicide Tolerant

IBC Institutional Biosafety Committee
 IBSC Institutional Biosafety Committee India
 IFPRI International Food Policy Research Institute
 IIBN International Industrial Biotechnology Network

IICA Inter-American Institute for Cooperation in Agriculture

IITA International Institute of Tropical Agriculture
INTA National Institute of Agricultural Technology
IPBO International Plant Biotechnology Outreach

IPRs Intellectual Property Rights

IR Insect Resistance / Insect Resistant
IRRI International Rice Research Institute

ISAAA Service for the Acquisition of Agri-biotech Applications
ISID Inclusive and Sustainable Industrial Development

KALRO Kenya Agricultural and Livestock Research Organization

LBR Late Blight Resistant
LMO Living Modified Organism

MAGFOR Ministry of Agriculture and Forestry

MARENA Ministry of the Environment and Natural Resources

MINSA Ministry of Health

MOA Ministry of Agriculture of Bangladesh

MOAI Ministry of Agriculture and Irrigation of India
MOEF Ministry of Environment and Forest of India

MOEF&CC Ministry of Environment, Forests and Climate Change of Bangladesh

NARO National Agricultural Research Organization
NCB National Committee on Biosafety Bangladesh

NBC National Biosafety Committee / National Biosafety Centre

NBT Novel Breeding Techniques
NE Nutritional Enhancement

NEWST Nitrogen Use Efficiency, Water Use Efficiency and Salt Tolerance
NIBGE National Institute for Biotechnology and Genetic Engineering

NSC National Seed Committee of Myanmar

NTBC National Technical Biosafety Commission of Costa Rica
NTCCB National Technical Committee for Crop Biotechnology

NTF No-Till Farming

NUE Nitrogen Use Efficiency

NUCS Neglected Underutilized Crop Species

Pak EPA Pakistan Environmental Protection Agency

PEFC Programme for the Endorsement of Forest Certification

PPP Public Private Partnerships

PQ Product Quality

PRRI Public Research and Regulation Initiative

PSC Punjab Seed Council

Research and Development

RCGM Review Committee on Genetic Manipulation

RNAi Ribonucleic Acid Interference

RR Roundup Ready

SABC South Asia Biotechnology Centre
SAG Ministry of Agriculture and Livestock

SAGENE South African Committee for Genetic Experimentation

SDG Sustainable Development Goals

SENASA National Service of Plant and Animal Health
SIGMA Simulation Graphical Modeling and Analysis

SOCOMA Société Cotonnière du Gourma

SOFITEX Société Voltaïque/Burkinabé des Fibres Textiles

ST Salinity Tolerance

TAC Technical Advisory Committee
TPF Total Productivity Factor
UCA University of Central America

UN United Nations

UNA National Agrarian University

UNEP United Nations Environment Programme

UNEP GEF Global Environment Facility of the United Nations Environment Programme

UNESCO United Nations Educational, Scientific and Cultural Organization

UNIDO United Nations Industrial Development Organization

UNPCB Union Nationale des Producteurs de Coton du Burkina Faso

USDA United States Department of Agriculture

VGGT Voluntary Guidelines on the Responsible Governance of Land Tenure

WBCSD World Business Council for Sustainable Development

WEMA Water Efficient Maize for Africa

Foreword

Marc Van Montagu and Philippe Scholtès

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The launching of the Sustainable Development Goals (SDG) by the United Nations (UN) in 2015 has provided a strong signal from the world's governments that sustainable development must happen at global scale without leaving anyone aside. The post-2015 Development Agenda has the ambitious challenge of empowering all of us to achieve healthy and stable economies, fair and well-governed societies, respect for human rights, respect for the environment, and consequently world peace.

Reaching the SDG targets will not be possible without a strong and sustainable global agriculture. Beyond their direct impact on hunger and malnutrition, agriculture and biomass-based industry are the common thread connecting together the SDGs, from poverty alleviation to education, gender equality, water use, energy use, economic growth and development, sustainable consumption and production, climate change, and ecosystem management.

Sustainable agriculture and downstream processing industry are knowledge based. We have technologies and know-how to succeed, and UN organizations such as FAO (Food and Agriculture Organization of the UN), UNESCO (United Nations Educational, Scientific and Cultural Organization) and UNIDO (United Nations Industrial Development Organization) are engaged to bring all knowledge and tools made available by science and technology to individuals and institutions of civil society that can play a vigorous part in the development of sustainable value chains.

Technological innovation is dependent on the iterative process of science, under amazingly fast evolution. Since the beginning of the 21st Century, plant sciences have dramatically progressed in understanding the structure, function and regulation of the mechanisms that translate the plant genome into phenotypes. The latest discoveries have shown that genomes are much more dynamic entities than ever expected. Tapping into the very complex and intriguing RNA regulatory mechanisms have unravelled how epigenetics can be regulated in a tissue and even cell-specific manner by the gene expression. This fundamental knowledge has led to the development of novel genome-editing technologies, which adjust genomic sequences at a high degree of precision. The new tool for *in vivo mutagenesis* (CRISPR/Cas) can be used not only in plants but in their symbionts and pathogens as well. The application will foster the development of novel crops adapted to an intensified and sustainable production of food, feed and biomass.

Scientific progress is making it possible to design new hybrid plants to address some of the challenges our world is facing today. This includes, among others, crops resilient to abrupt changes in environmental con-

ditions, crops able to perform well in no-tilling agriculture (to prevent soil erosion), and through improved efficiency in nutrient use, crops that are less dependent on agro chemicals and their collateral damage on the soil microbiome. Such developments can impact crop productivity in some of the most densely-populated and vulnerable regions of the world.

Even though technological innovations are promising, their applications are not straightforward. This has been the case for Genetically Modified (GM) crop biotechnology. Its discovery in the 80s led to a series of technological inventions that opened a wide spectrum of agricultural and industrial applications. The innovation has triggered one of the largest changes in the history of agriculture, yet it has faced an extremely hostile response to commercialization. The persistent lobbying and dissemination by ongovernmental organizations of alarming, though not supported by scientific evidence, information on the potential risks of GM crops has raised public suspicion and a general reluctance to adopt this novel technology. Plant scientists have not been able to effectively balance this misinformation with science-based facts probably due to weak science communication strategies and poor exchanges with specialists in social, political, economic sciences and with the civil society. A major consequence for Europe is that legislators have established a discouraging, complex and costly regulatory system. By the same token, investment in GM technology was limited to companies with strong financial and human power. Small and medium enterprises and the public sector were set aside. Meanwhile, low-income economies are facing challenges in establishing a regulatory framework and in building sufficient capacity along the innovation chain. These different factors have led to a situation where only a few multinational corporates are able to propose a limited number of GM crops.

Nevertheless, in recent years several Public Sector research institutions in low-income countries and in emerging economies have made enormous efforts and progress to bring adapted GM crops in their agricultural systems. Banana resistant to parasitic nematodes and weevils, potato resistant to blight, water-efficient maize, drought-tolerant groundnuts, rice, and sugarcane, Bt eggplant, cassava resistant to brown streak disease and cassava mosaic disease to name but a few, are public sector or public-private partner-ship initiatives on field trial. These examples show that low- and middle-income countries can develop their own tailored GM crops and become major actors in the world market.

This book, through its introductory overview chapter and selected country studies, explores the experience and achievements obtained by integrating GM technology in agricultural systems of developing countries and emerging economies. The emphasis is on the potential and concerns encountered with the adoption of these new technologies. The lessons learned over the last quarter century of experience should serve in the current debate on the challenges of sustainable agriculture intensification. The experiences of agricultural biotechnology provide a unique perspective on how to harness existing and future innovations to preserve the pristine nature still remaining on our planet, to cope with rapid population growth and to spread the benefits of science and technology to communities around the world.

Key innovations in plant biotechnology and their applications in agriculture, industrial processes, and healthcare

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Abstract

The Sustainable Developmental Goals aim to secure immediate human needs, such as adequate food supply and healthcare and provision of clean, affordable, and accessible energy. These achievements have to be imbedded in a sustainability concept. Bioeconomy is at the core of this concept in which agricultural (plant) biotechnology plays a major role in delivering biomass for food, feed, and industry. Modern plant biotechnology comprises the genetic modification technology and various molecular biological tools which enhances the plant breeding potential. It results in increased food supplies, increased farm income worldwide, and reduced environmental damage. Here we review the innovations in plant biotechnology that are available on the market or at the late developmental stages and their application to agriculture, agroforestry, industrial processes, and pharmaceutical industry. Special emphasis is given to approaches adapted to meet heterogeneous local needs and help support more inclusive growth in low and middle-income countries.

Introduction

In the 21st century, humanity is faced by a myriad of socioeconomic and resource challenges to supply diverse emerging and recurrent global needs to feed, clothe, and fuel a population growing in size, age, and wealth. Pressure on resource competition and scarcity as well as the identification, evaluation, and quantification of the impact of the human pressure on the planet have catalysed a global concern on the sustainability of the continuous development of human societies. The Holocene – the warm period of the past 10-12 millennia – is the only state of the planet that we know for sure to support contemporary human societies and is now being destabilized. Indeed, since the later part of the 18th century, the effects of humans on the global environment have grown so dramatically that a new geological era, the Anthropocene, has been proposed (Crutzen, 2002). There is an urgent need of a paradigm shift to maintain the Earth System (ES) in a safely operating space for humanity. Sustainable developmental goals have to be implemented to guarantee immediate human needs, such as food supply, healthcare, and energy, alongside measures for a stable ES functioning. Nine critical processes/ features have been proposed to regulate the ES functioning: climate change, biosphere integrity, land system change, freshwater use, biochemical flows, ocean acidification, atmospheric aerosol loading, stratospheric ozone depletion, and novel entities. Scientifically based planetary boundary levels of human perturbation have been established for these ES processes/features, beyond which the ES functioning may be substantially altered (Steffen *et al.*, 2015).

Embedded in this emerging ES thinking, the new bioeconomy proposes a global transition toward sustainability through a bio-based industry that integrates the use of renewable aquatic, and terrestrial resources and biological processes to create energy, materials and products with an environmentally friendly footprint. Besides bioindustry, bioeconomy also encompasses research, climate, environment, and development policies.

The deployment of bioeconomy relies on technological developments, among which biotechnology plays a key role. Biotechnology-based industry is an emerging reality that generates economic opportunities for agriculture, healthcare, chemical, and manufacturing sectors, with far-reaching potential impacts on socio-economic developments and environment. According to the Biotechnology Global Industry Guide (www.researchandmarkets. com/reports/41522/biotechnology_global_industry_guide), the total revenues of the global biotechnology industry were US\$ 323.1 billion in 2014, representing a compound annual growth rate of 7.2% between 2010 and 2014. The biotech industry is revolutionary beyond industrial growth because it offers opportunities for society to walk a different path toward multiple sustainable goals. In the energy and chemical sectors, biotech innovation reduces dependence on petroleum and fossil fuels and, consequently, cleans the environment and fights global climate change. In the healthcare sector, the biotech industry has developed and commercialized drugs, vaccines, and diagnostics with significant impact on length and quality of life. In the agricultural field, biotech innovations simultaneously increase food supplies, reduce environmental damage, conserve natural resources of land, water, and nutrients, and increase farm income in economies worldwide.

The future of the biotech industry, more specifically, the industrial and agricultural sector, holds considerably in biomass production. Although biomass has since long been used as feedstock, e.g. wood-based materials, pulp and paper production, biomass-derived fibers, the transition toward the modern bioeconomy requires the sustainable raw material production and efficient biomass use, implying a set of principles that should be strived for: (i) increased yields for food, feed, and industrial feedstock with as minimal as possible increases in land, water, fossil fuels, and minerals for fertilizer production; (ii) flowing use of biomass as food, feed, material, and, finally, energy; and (iii) cyclic reaction in which products should be designed for disassembly and reuse, consumables should be returned harmlessly to the biosphere, durables should maximise their reuse or upgrade, and renewable energy should be used to energize the process (Mathijs et al., 2015).

Agriculture is central for global development promotion within the biophysical limits of a stable ES. The conventional tools of intensive agricultural growth, i.e., mechanization, plant breeding, agrochemicals, and irrigation, diminish returns and threaten the ES resilience. Four ES features transgress the proposed planetary boundary levels: climate change, biosphere integrity, biogeochemical flows, and land system changes (Steffen et al., 2015). As agriculture is the anthropogenic perturbation with the most prominent impact, it is challenged to produce sustainable yields. Of the novel technologies of several kinds needed to achieve sustainably high-yield agriculture, one of the most important implementation is modern plant biotechnology, i.e. genetically modified (GM) technology and various molecular biological tools, that enhances the plant breeding potential and reduces the negative impact both within fields and surrounding lands.

Plant GM technology originated back in the 1980s, when the first GM plant, resistant to the

antibiotic kanamycin, had been developed (Van Montagu, 2011 and references therein; Angenon et al., 2013). In the 1970s, Jeff Schell, Marc Van Montagu, and colleagues at the Ghent University (Belgium), who studied the tumor-inducing principle of Agrobacterium tumefaciens, discovered that a large plasmid was responsible for the formation of crown galls on infected plants and that part of its DNA was transferred to plant cells (Zaenen et al., 1974; Van Larebeke et al., 1975; Depicker et al., 1978). After it had become clear that Agrobacterium could be used as a vector to transfer foreign DNA to plant cells, fertile transgenic tobacco (Nicotiana tabacum) plants were generated that expressed and transmitted the chimeric antibiotic resistance genes to their progeny. A first company on plant genetic engineering, Plant Genetic Systems (Ghent, Belgium), was founded (Van Lijsebettens et al., 2013 and references therein) and the GM technology was soon employed worldwide both in fundamental science to study gene function and in agriculture to produce transgenic crops with useful agronomic traits. The commercialization of GM crops started in 1996. Since then, the acreage of GM crops cultivated worldly has increased steadily to up to 100-fold the area planted. The average agronomic and economic benefits of GM crops are large and significant (Klümper and Qaim, 2014) as is evidenced both in developed and developing countries. The agricultural sector is probably the segment of biotech industry that provides more benefits to the middle and low-income economies. In this introductory chapter we give an overview of the innovations in plant biotechnology that have been approved for commercialization or are at the late stages of development and their application to agriculture, agroforestry, industrial processes, and pharmaceutical industry.

Global GM crop plants

Genetic engineering has the potential to address the critical constrains of sustainable agriculture and the need for sufficient quantity of healthy food, feed, and biomass feedstock for the industry as well, but GM crops have delivered only a limited range of agronomic traits for the agriculture production. Of the possible GM crop options that have ever been commercialized in the world, only nine GM crops are grown commercially worldwide, among which soybean (Glycine max), maize (Zea mays), cotton (Gossypium hirsutum), and canola (Brassica napus) account for 99% of the worldwide GM crop acreage. In 2014, the largest share (50%) was for GM soybeans, followed by maize (30%), cotton (14%), and canola (5%) (James, 2014). Other crops that account for 1% of global GM planting are alfalfa (Medicago sativa), sugar beet (Beta vulgaris), papaya (Carica papaya), squash (Cucurbita pepo), and eggplant (Solanum melongena). Only three traits, herbicide tolerance (HT), insect resistance (IR), and hybrid vigor have been generated and introduced in almost all GM crops grown commercially over the past 20 years. In 2014, 57% of the world's land surface of GM crops was HT, 15% IR, and 28% both HT and IR, called stacked traits, whereas other traits, such as virus resistance and drought tolerance, collectively account for less than 1%. The drought-tolerant biotech corn varieties are cultivated since 2013 only in the USA (James, 2014).

In Africa, where the GM technology is most needed to foster agricultural transformation, the output is deceiving. Only three African countries cultivate GM crops: South Africa with 2.7 million ha of maize, soybean, and cotton; Sudan with 0.1 million ha of cotton; and Burkina Faso with 0.5 million ha of cotton (James, 2014).

Despite this quite unsatisfying output in terms of crops and traits, farmer's acceptance as well as global income, production, and environmental impacts of these biotech crops are impressive. Farmers who have been granted the opportunity, quickly adopted GM crops. By 2014, millions of farmers in 28 countries worldwide have chosen to plant GM crops over 181.5 million ha and grow almost half of the global plantings of soybean, maize, cotton, and canola. The GM traits have provided logistical advantages, risk reductions, and economic benefits.

Brookes and Barfoot (2015a) analyzed the changes in farm income thanks to the impact of GM

technologies on yields, key production costs, notably seed cost and crop protection expenditure, but also impact on energy and labor costs where data were available, and the prospect of planting a second crop in one season. At the global level, GM technology has had a significant positive impact on farm income. The net economic benefits of the four major GM crops (soybeans, maize, canola, and cotton) at the farm level amount to US\$ 133.4 billion for 18 years of commercialization between 1996 and 2013. Approximately 70% of these gains have derived from yield and production gains and 30% from cost savings, such as less ploughing, fewer pesticide sprays, and less labor. In 2013, the direct global farm income benefit was US\$ 20.5 billion, which is equivalent to a 5.5% addition to the global production value of the four main crops. As expected, US farmers have been the largest beneficiaries of increased

incomes, because they adopted the GM technology early on and more than 80% of the four crops are GM since several years. More relevant is that farmers in developing and emerging economies got approximately 50% of the economic gains. The additional income benefits for soybean and maize farmers in South America (Argentina, Bolivia, Brazil, Colombia, Paraguay, and Uruguay) and cotton farmers in Asia (China and India) were US\$ 31.1 billion and US\$ 32.9 billion respectively. Table 1 summarizes the economic impact of GM crops since their first commercialization year to 2013.

GM technology has also contributed to reduce the agriculture's environmental footprint by facilitating environmentally friendly farming practices (Brookes and Barfoot 2015b). The GM IR traits replaced insecticides used to control pest. Since

Table 1. Farm level economic benefits of GM crops

Biotech crop	Total cumulative farmer's income benefit 1996-2013 (US\$ billions)	Biotech trait	Type of benefit	Country
Soybean	14.8	HT soybeans (1st gener- ation)	Lower production costs	Brazil, USA, Canada, Uru- guay, South Africa
			Lower production costs + second crop gains	Argentina, Paraguay
			Lower production costs + yield gains	Mexico, Bolivia, Romenia
		HT soybean (2nd gener- ation with higher yield potential)	Lower production costs + yield gains	USA, Canada
		HT/IR soybean	Cost savings as 1st generation HT soybean + insecticide savings + yield gains	Brazil, Argentina, Paraguay, Uruguay
Maize	7.36	HT maize	Lower production costs	USA, Canada, South Africa, Colombia
			Lower production costs + yield gains	Argentina, Brazil, Philip- pines
	37.2	IR maize (resistance to corn boring pests)	Yields gains	USA, South Africa, Hondu- ras, Argentina, Philippines, Spain, Uruguay, Colombia, Canada, Brazil, Paraguay
		IR maize (resistance to rootworm pests)	Yield gains	USA, Canada
Cotton	1.49	HT cotton	Lower production costs	USA, South Africa, Aus- tralia, Argentina, Uruguay, Paraguay
			Lower production costs + yield gains	Brazil, Mexico, Colombia
	40.78	IR cotton	Yield gains	USA, China, South Africa, Mexico, Argentina, India, Colombia, Burkina Faso, Pakistan, Burma
Canola	4.3	HT canola (tolerant to glyphosate)	Mostly yield gains where replacing triazine-tolerant canola	Australia
		HT (tolerant to glufosinate)/ hybrid vigor canola	Mostly yield gains	USA, Canada
Sugarbeet	0.14	HT sugarbeet	Mostly yield gains	USA, Canada

Adapted from Brookes and Barfoot (2015a).

1996, the active insecticide ingredient use in cotton and maize was reduced by 239 million and 71.7 million kg, respectively, with the highest benefits for cotton, because its culture requires an intensive treatment regime with insecticides. The adoption of GM IR cotton in China and India resulted in a cumulative decrease in insecticides of over 192 million kg for the period 1996-2013. IR soybeans were first grown commercially in 2013, mostly in Brazil, and the savings in active insecticide amounts in that year was above 0.4 million kg, corresponding to 1% of the total soybean insecticide use.

The environmental gains associated with the use of GM HT traits are related to the application of more environmentally friendly products and to simplified changes in farming systems. The adoption of conservation tillage has led to additional soil carbon sequestration and a reduction in tractor fuel use that amounted to 7,012 million liters between 1996 and 2013 (Carpenter, 2011). Less fuel, associated with fewer insecticide and herbicide sprays and less or no ploughing, corresponded to 28,005 million kg of CO_2 eliminated from the atmosphere or, in terms of car equivalents, to 12.4 million cars off the road for a year (Brookes and Barfoot 2015b).

The higher productivity of the currently commercialized GM crops alleviates the pressure to convert additional land for agriculture. To achieve the same tonnage of food, feed, and fiber obtained during the 1996-2013 period, 132 additional million ha would have been needed with conventional crops only (James, 2014).

GM crops approved for commercialization in the world

In contrast to the limited number of GM crops on the market, an important number of crops, events, and traits have received approval for commercialization. As of 11th October 2015, a total of 40 countries granted regulatory approvals to 29 GM plants and 383 GM events, covering 36 GM traits for use as food, feed and/or for cultivation (www.isaaa.org/gmapprovaldatabase). The

fast-growing number of approved GM trait-containing varieties and hybrids shows that GM technology does not narrow the genetic diversity of the crop plant. In addition to the commercial HT and IR GM traits used to construct the vast majority of GM crops on the market, GM traits have been also approved for abiotic stress tolerance, altered growth/yield, disease resistance, modified product quality, and pollination control systems. Table 2 summarizes the GM traits approved per GM plant. Remarkably, 13 different GM traits aim to change product quality in 13 different crops.

A number of noteworthy biotech crops/traits have been recently approved. In November 2014, the US Department of Agriculture (USDA) endorsed commercial planting of two crops employing an RNA interference (RNAi) approach: a transgenic alfalfa with reduced lignin for improving fiber digestibility via RNAi of caffeoyl coenzyme 3-Omethyltransferase gene involved on the synthesis of guaiacyl lignin subunit and a potato (Solanum tuberosum) with reduced levels of several enzymes, among which one that produces the potentially carcinogenic metabolite acrylamide. This Innate[™] potato (J.R. Simplot, Boise, Idaho) also suffers less wastage from bruising (Waltz, 2015). The Enlist™ Duo for maize and soybean (Dow AgroSciences, Indianapolis, IN, USA) that contains two stacked genes to confer tolerance to the herbicides glyphosate and 2,4-D-choline was approved in Canada in April 2014 and in the USA in September 2014 (James, 2014). Approval of the Arctic Apples, genetically engineered to resist browning associated with cuts and bruises by reduction of the browning-causing enzyme levels was granted by the USDA in February 2015 and by the Food and Drug Administration (USA) in March 2015.

Developing countries also generated and approved novel biotech plants. In 2013, Indonesia ratified the environmental certificate for cultivation of drought-tolerant sugarcane (*Saccharum* spp.). In Brazil, a virus-resistant bean (*Phaseolus vulgaris*) was approved in 2011 and is due for commercialization in 2016 and a GM *eucalyptus*

Table 2. Global status of GM technology: GM crops approved for commercialization in at least one country

Commercial trait	GM trait	GM Plant
Abiotic Stress Tolerance	Drought stress tolerance	Maize
		Sugarcane
Altered Growth/Yield	Enhanced photosynthesis/yield	Soybean
	Volumetric wood increase	Eucalyptus
Disease Resistance	Black spot bruise tolerance	Potato
	Viral disease resistance	Bean
		Papaya
		Plum
		Squash
		Sweet pepper
= .	21.5	Tomato
Herbicide Tolerance	Glufosinate herbicide tolerance	Argentine canola
		Cotton
		Maize
		Polish canola
		Rice
		Sugar beet
	Glyphosate herbicide tolerance	Cotton
	- ургания по	Creeping bent grass
		Maize
		Polish canola
		Potato
		Soybean
		Sugar beet
		Wheat
	Isoxaflutole herbicide tolerance	Soybean
	Mesotrione herbicide tolerance	Soybean
	Oxynil herbicide tolerance	Argentine canola
		Cotton
		Tobacco
	Culfonduras harbicida talaranca	Carnation
	Sulfonylurea herbicide tolerance	
		Cotton
		Flax
		Maize
		Soybean
Insect Resistance	Coleopteran insect resistance	Maize
		Potato
	Lepidopteran insect resistance	Cotton
		Eggplant
		Maize
		Poplar
		Rice
		Soybean
		Tomato
	Multiple insect resistance	Cotton
		Maize
		Poplar
Modified Product Quality	Altered lignin production	Alfalfa
	Non-browning phenotype	Apple
	Modified oil/fatty acid	Argentine canola
	· ·	Soybean
	Phytase production	Argentine canola
	Thytase production	Maize
	NA I'C I G	
	Modified flower color	Carnation
		Petunia
		Rose
	Modified amino acid	Maize
	Modified alpha amylase	Maize
	Delayed ripening/senescence	Melon
		Tomato
	Delayed fruit softening	Tomato
	Modified starch/carbohydrate	Potato
	-	
	Reduced acrylamide potential	Potato
	Anti-allergy	Rice
	Nicotine reduction	Tobacco
Pollination control system	Fertility restoration	Maize
	Male sterility	Argentine canola
		Chicory
		Cilicoly

(Eucalyptus sp.) in 2015 (James, 2014; www.isaaa. org/gmapprovaldatabase). FuturaGene, owned by the Brazil-based Suzano Pulp and Paper company and the second largest producer of eucalyptus pulp globally, developed the transgenic eucalyptus that contains a gene encoding an Arabidopsis thaliana protein that facilitates cell wall expansion and accelerates growth. According to FuturaGene, the GM tree produces 20% more wood than the conventional variety and is ready for harvest in five and a half years instead of seven.

There is a growing interest in GM forest trees due to the increasing global trend for timber production from plantations and bioenergy applications. Since forests can be grown on marginal lands, competition with land resources suitable for agricultural production can be avoided. At the same time, the increased productivity from bioengineered forests will provide an option to protect native forests.

A few GM forest trees have been produced commercially. In China, poplar (Populus sp.) trees are cultivated for uses in furniture, boat making, paper and chopsticks, because of their flexibility and close wood grain. (ISAAA, 2015). Since 2000, China produces GM poplars to fight Asian longhorn beetle that devastated 7.04 million ha of poplar. Three clones of *Populus nigra* were developed with the Bacillus thuringiensis (Bt) gene cry1Aa and a hybrid white poplar (Populus alba) was transformed by fusion of cry1Aa and the gene coding for a proteinase inhibitor from Sagittaria sagittifolia. In the transgenic poplar plantations, the fast spread of the target insect pests was inhibited effectively and the number of insecticide applications was significantly reduced. The performance of the Bt black poplar plantations is significantly better than that of the clones deployed locally, resulting in a substantial 90% reduction in leaf damage. In 2014, GM poplar was cultivated in 543 ha in China (James, 2014).

ArborGen Inc. (Ridgeville, SC, USA), a tree seedling company, has developed a GM loblolly pine (*Pinus taeda*) cultivar with enhanced density. Lobloblly

pines are used for lumber, plywood, and paper (ISAAA, 2015). As none of the inserted genes are derived from plant pests, the USDA deregulated the GM loblolly pine that can be cultivated without undergoing environmental studies (http://www.capitalpress.com/Timber/20150128/usda-can-not-restrict-gmo-pine).

Near-term innovations

Regulatory constraints, with delaying approvals and increasing costs, have discouraged biotech innovations, except in big corporations. The cost of discovery, development, and authorization of a new biotech crop or trait has been estimated to be approximately US\$ 136 million (Prado et al., 2014). Notwithstanding, good Research and Development projects continue to be pursued both in developed and developing countries. A wide variety of plants are being generated for resilience to biotic and abiotic stresses, increased water or nitrogen use efficiency (NUE), and nutritional improvements (Ricroch and Hénard-Damave, 2015). The major multinational agribusiness corporations often collaborate with public institutions, private entities, and philanthropic organizations in the least developed countries, particularly in Africa. Other relevant innovations for nonfood purposes, such as pharmaceutical, biofuel, starch, paper and textile industries are being pursued in developed countries.

Sustainable trait management

Management of several sustainable biotech traits is quickly becoming available. The main multinational seed corporations continue to develop GM traits directed to broad-spectrum herbicides and resistance to chewing insects on a wide range of species. Most of these innovations are related to stacking different HT and/or IR genes. Gene stacking simplifies and enhances pest management as demonstrated by IR and weed HR based on a single gene technology (Que *et al.*, 2010).

Nonetheless, research continue to focus on other kinds of sustainable agronomic traits and several traits and crops in the pipeline resulting from both private and public endeavors that target the developing world are about to be commercialized. Some case studies are listed below.

Water-Efficient Maize for Africa (WEMA)

Agriculture requires more water than any other human activity. Drought is a threat to farms around the world and in Africa drought is one of the major factors that prevent good yields. The Food and Agriculture Organization of the United Nations estimates that by 2025 approximately 480 million Africans could be living in areas of water scarcity. To face this challenge, plant scientists are developing drought-tolerant traits. The WEMA project is a public-private partnership that aims to improve food security and livelihoods for small farmers in Sub-Saharan Africa by finding ways to double the maize yields. In this project, GM and non-GM technology, including marker-assisted breeding, are combined to generate hybrid maize seeds with increased water use efficiency and resistance to insect pests. To this end, the Bt gene will be stacked with the drought-tolerance biotech trait (MON87460) that expresses the Bacillus subtilis cold-shock protein B (cspB), licensed from Monsanto. (http://wema.aatf-africa.org).

Centro de Investigación y de Estudios Avanzados del Instituto Politécnico Nacional (CINVESTAV-IPN)

In Mexico, the biotech maize CIEA-9 was developed with enhanced adaptation to severe drought and extreme temperatures. The antisense RNA expression was used for silencing trehalase in the popular maize inbred line B73 (derived from Iowa Stiff Stalk Synthetic). This biotech maize requires 20% less water, endures high temperatures (up to 50°C), and the seeds germinates at 8°C, demonstrating their ability to withstand cold at early development stages (Ortiz *et al.*, 2014). In 2012, the Government of Mexico granted 4 ha for experimental release of CIEA-9 in Sinaloa (Mexico). This permit was the first delivered to a Mexican public research center since the biosafety law was authorized (Wolf and Otero, 2015).

Centro Internacional de Mejoramiento de Maíz y Trigo (CYMMYT; International Maize and Wheat Improvement Center) Over the past five years, this Mexican center has analyzed experimental releases of genetically engineered drought-resistant wheat (*Triticum* sp.). All the different events tested in experimental trials on 0.1-ha plots at the Tlaltizapan Morelos site were drought resistant (Wolf and Otero, 2015).

ArborGen Inc.

This Brazilian company developed a GM *eucalyptus* tree that can withstand extremely low temperature. It contains a cold-inducible promoter driving a C repeat-binding protein from *A. thaliana*. This biotech tree combines the fast-growing and highly desirable fiber quality characteristics of a known Brazilian eucalyptus variety that can withstand freezing temperatures. Transgenic freeze-tolerant eucalyptus can grow up to 52.4 feet (15.97 m) at 16.80F (-8.4°C), compared to the control trees that grew only 0.3 feet (9 cm) (Hinchee *et al.*, 2011). This freeze-tolerant tropical *eucalyptus* product (AGEH427) is currently going through the government review process for deregulation in the USA (www.arborgen.com).

Arcadia Biosciences Inc. (Davis, CA, USA)

The NUE trait contributes to improve yields in N-limited environments and reduces fertilizer costs and N fertilizer pollution (Hirel et al., 2011). Among the various genetic engineering strategies for NUE enhancement in crops, the overexpression of the gene coding for alanine aminotransferase that increases N uptake at early growth stages is a very promising candidate for commercialization. The intellectual property associated with this invention has been licensed to Arcadia Biosciences Inc. The company possesses the rights to use this gene technology in major cereals, such as wheat, sorghum (Sorghum bicolor), rice, maize, and barley (Hordeum vulgare), as well as in sugarcane. Field trials have been executed for rice in China, for rice and wheat in India. Its value for maize and rice is being assessed in Sub-Saharan Africa through private-public partnerships. Rice with NUE/water use efficiency and salt tolerance (NEWST) is on field trial in Uganda. The National Agricultural Research Organization (NARO), African Agriculture Technology Foundation (AATF), and Arcadia Biosciences cooperate on this research (Ortiz *et al.*, 2014; James 2014).

Laboratorio Nacional de Genómica para la Biodiversidad at CINVESTAV

The National Laboratory of Genomics for Biodiversity at the Irapuato campus (Mexico) and a private Mexican company are developing GM plants that will be able to absorb and optimize the use of phosphorus. The GM plants absorb phosphites rather than phosphates and so improve the use of fertilizers and weed control that compete for the phosphorus element. According to the developers, the trait can reduce the required amount of fertilizer by 30% to 50%, eliminates or reduces the use of herbicides, and is harmless to humans and animals. The group is developing a GM tobacco as first crop and, if successful, the trait will be introduced into maize for Africa in the near future (Wolf and Otero, 2015).

Examples of transgenic plants resistant to fungal disease

(1) Late blight of potato, one of the most devastating diseases caused by a pathogen similar to fungi, Phytophthora infestans, accounts for 20% of potato harvest failures worldwide, translating into 14 million tons and valued at EURO 2.3 billion (Ortiz et al., 2014 and references therein). Several lines of transgenic potato containing R genes identified in wild relatives with high resistance to late blight have been produced (such as resistant genes from the wild Mexican relative Solanum bulbocastum, was used to breed the Fortuna cultivar and the Rpi-vnt1.1 gene isolated from Solanum venturii had been introduced into the potato variety Désiree). As these R genes had been identified in wild potato species, the use of the so-called cisgenic technology facilitated the rapid transfer of these genes into cultivated potato varieties without linkage drag. These plants have been shown to be resistant to late blight in several years of field tests (Gaffoor and Chopra, 2014 and references therein; Ortiz et al., 2014, Jones, 2015).

(2) In wheat, one of the most damaging fungal diseases is powdery mildew. Transgenic wheat lines

harboring different versions of a powdery mildew resistance gene (*Pm3 R*) have gone through field tests. Two years of field trials have revealed that the GM plants were more resistant to powdery mildew than the nontransgenic control plants (Gaffoor and Chopra, 2014).

(3) The chestnut blight fungus secretes several toxic compounds, such as oxalic acid that lowers the pH of the surrounding plant tissue, with death of the infected tissue as a consequence. Plants transformed with a wheat gene encoding oxalate oxidase were able to detoxify the oxalic acid, thereby starving the fungus and restricting it to the bark of the tree (*Castanea* sp.). These plants were tolerant to the disease and have undergone rigorous laboratory testing and several years of successful field trials (Gaffoor and Chopra, 2014).

(4) Banana (Musa sp.) plants have been engineered to control a bacterial disease Xanthomonas wilt, better known as BXW. The transgenic plants containing genes from sweet pepper (Capsicum annuum) encoding a hypersensitive response-assisting protein (Hrap) or a ferredoxin-like protein (Pflp) were evaluated over two successive crop cycles in a confined field trial in Uganda (Tripathi et al., 2014). Approximately 20% of the 40 Hrap lines and 16% of the 26 Pflp lines, for a total of 11 transgenic lines, showed 100% resistance and retained the resistance in the ratoon crop. As elicitor-induced resistance is not specific against particular pathogens, this transgenic approach may also provide effective control of other bacterial diseases of banana, such as moko or blood disease in other parts of the world. Nearly 15 million people either rely on bananas for their income or consumption, making it an important food and cash crop in the Great Lakes region of East Africa. Food security studies revealed that in Uganda, Rwanda, and Burundi, bananas constitute >30% of the daily per capita caloric intake, rising to 60% in some regions (Tripathi et al., 2014).

Other ongoing biotech crop research activities for sustainable management that are on field trials in Africa include: (i) IR cowpea (*Vigna unguicula-*

ta) in Burkina Faso (L'Institut pour l'Etude et la Recherche Agronomique, AATF, Network for the Genetic Development of Cowpea, and The Commonwealth Scientific and Industrial Research Organization), Ghana (AATF and Savanna Agricultural Research Institute), and Nigeria (AATF and Institute of Agricultural Research); (ii) virus-resistant cassava (Manihot esculenta) in Nigeria (National Root Crops Research Institute), Kenya (Kenya Agricultural and Livestock Research organization [KALRO], International Institute of Tropical Agriculture [IITA], Danforth Plant Science Center [DDPSC], and Masinde Murilo University of Science and Technology), and Uganda (NARO, DDP-SC, and IITA); (iii) Fungal resistance and drought/ salt-tolerant wheat in Egypt (Agricultural Genetic Engineering Research Institute); (iv) Virus resistant sweet potato Ipomoea batatas) in Kenya (KALCRO and DDPSC), (vi) IR sweet potato in Uganda (NARO and DDPSC); and (vii) nematode-resistant banana (NARO and University of Leeds, UK) (James, 2014).

Output traits for food and feed

Nutritionally enhanced food crops

A few nutritionally enhanced food crops have undergone safety approval, namely maize with increased lysine content and canola and a number of GM soybeans with improved fatty acid profile, including high stearidonic acid, an intermediate of omega-3-Fatty Acid. However, the last decade witnessed great progress in R&D to generate nutritionally improved biotech food crops specifically for targeting low-income families. Addressing nutritional deficiencies by gene engineering would lead to decreased healthcare costs and increased economic performance. Biofortified staple crops harboring essential micronutrients to benefit the world's poor and new functional GM food crops for enhancing human health are under development. Several of these GM crops are currently being tested in developing countries. Some relevant examples are given below.

(1) Golden Rice, named for its golden color due to its high β -carotene content, is one of the first examples of a GM staple crop that was specifical-

ly designed to combat malnutrition and vitamin A (VitA) deficiency, because it is an essential nutrient needed for the visual system, growth, development, and a healthy immune system. Golden Rice was generated by the research group of Ingo Potrykus (ETH Zürich, Switzerland) (Ye et al., 2000) to offer a viable solution for eye damage of three million preschool-aged children due to VitA lack. The GM rice (GR1) was engineered with two genes from other organisms (daffodil [Narcissus poeticus] and the bacterium Erwinia uredovoia) that reconstitute the carotenoid biosynthetic pathway within the rice genome (Tang et al., 2009). The current Golden Rice version, known as GR2, utilizes genes from two distinct proVitA pathways, including the maize phytoene synthesis gene instead of the analogous daffodil gene used in the GR1 rice. Golden rice can produce β-carotene amounts that were up to 35 µg/g dry rice. Bioavailability testing has confirmed that Golden Rice is an effective source of VitA in humans (Hefferon, 2015 and references therein).

- (2) Transgenic biofortified rice has also been engineered to combat iron and folate deficiency, with improved mineral bioavailability, and with high content to essential amino acids, such as lysine (Blancquaert *et al.*, 2015; Hefferon, 2015).
- (3) The BioCassava Plus (BC+) program genetically engineered cassava with increased levels of iron and proVitA. Retention and bioavailability of transgenic cassava are similar to the findings on conventional biofortification research. The first field trials for a proVitA-biofortified cassava began in 2009, followed by trials for high-iron cassava, and delivery of the biofortified crops is expected in 2017. Additional traits included in BC+ are increased shelf life, reduced cyanide levels, and improved disease resistance (Tohme and Beyer, 2014). The National Root Crops Research Institute of Nigeria is performing field trials with proVitA-rich cassava (James, 2014).
- (4) Transgenic bananas with proVitA and iron are being developed by the NARO Uganda and the Queensland University of Technology. The per

capita consumption of bananas is estimated to be 0.7 kg per day in Uganda. Scientists applied the pro-Vitamin A genes used in Golden Rice to a popular local variety. Bananas with up to 20 ppm proVitA have been generated and trials have started in Uganda. The ProVitA bananas are expected to be released in 2020. A human bioavailability study began in late 2013 (Waltz, 2014).

(5) Sorghum biofortified with VitA and bioavailable zinc and iron is tested by the Africa Harvest and Pioneer Hi-Bred in Nigeria (in collaboration with the National Biotechnology Development Agency) and in Kenya (in collaboration with KALRO) (James, 2014).

(6) Nutritional fatty acids associated with reducing coronary heart disease risks can be introduced into oilseed crops to improve human health. So far, 10 transgenes that have led to the accumulation of high-value fatty acids in plants (Ortiz et al., 2014). High oleic acid GM soybeans produced by Pioneer Hi-Bred International, Inc. (Pioneer), a DuPont Company (Johnston, IA, USA), was the first biotech soybean product of this kind (Plenish™). RNAi technology was used to decrease the expression of the endogenous soybean gene encoding fatty acid desaturase (gm-fad2-1) that produced seeds with an increased concentration of oleic acid (C18:1) and a correspondingly reduced concentration of linoleic acid (C18:2). The purpose of this change in fatty acid profile is to provide a stable vegetable oil that is suitable for frying applications without the need for hydrogenation (De Maria, 2013).

(7) To synthesize Omega-3 long-chain polyunsaturated fatty acids found routinely in fish oils, scientists of the Rothamsted Research Institute (Harpenden, UK) have metabolically engineered camelina (*Camelina sativa*) plants. The metabolic pathway to produce this fatty acid was reconstituted in camelina by substituting synthetic versions of up to seven genes from marine algae (Betancor *et al.*, 2015). The levels of eiosapentaenoic acid and docosahexaenoic acid *obtained* were economically reasonable, thus representing

a tangible success. Therefore, GM oilseeds can be a novel source of this essential oil. Omega-3 long-chain polyunsaturated fatty acids are of great interest due to their dietary benefits, such as improvements to brain function and development as well as for cardiovascular health. The camelina plants with a high content of these omega-3 oils in the laboratory/glasshouse are being evaluated for their performance in the field. Other beneficial fatty acids have also been made in plant seed oils, including y-linolenic and stearidonic acid, as well as arachidonic acid (Hefferon, 2015).

(8) Transgenic tomato (Solanum lycopersicum) fruits with threefold enhanced hydrophilic antioxidant capacity have been obtained through metabolic engineering. The "purple" tomato contains genes from two snapdragon (Antirrhinum majus) transcription factors Delila and Rosea1 that control anthocyanin biosynthesis (Butelli et al., 2008). Anthocyanins, compounds found in blueberries (Cyanococcus sp.) and cranberries (Vaccinium sp.) are believed to fight cardiovascular diseases and exhibit anti-inflammatory properties. Tomatoes were chosen because they are quite affordable antioxidant sources. The GM tomato with an as much as 30% significantly extended life span in the cancer-prone mice (Mus musculus), is currently being tested on heart patients in Britain (Hefferon, 2015). A recent study shows that the purple tomato not only is more healthy, but also has a longer shelf life and is more resistant to diseases than not GM tomatoes (Zhang et al., 2013).

(9)Transgenic tomato plants that accumulated trans-resveratrol and trans-resveratrol-glucopyranoside have been obtained by transformation with the stilbene gene from grape (*Vitis vinifera*). These GM tomato lines showed a significantly increased antioxidant capability and ascorbate content. The GM tomato extracts were able to counteract the pro-inflammatory effects of phorbol ester in a culture of monocyte-macrophages (Hefferon, 2015).

Nutrionally enhanced feed crops

GM feed crops have been developed to improve the nutritional value of animal feed as well as to produce more environmentally friendly manure. Biotech crops engineered with increased levels of amino acids are an alternative to the direct addition of supplemental amino acids in animal diets. Examples of these types of crops include GM maize with enhanced production and accumulation of free lysine in the corn kernel; protein-enriched GM soybean with more digestible lysine, methionine, threonine, and valine; high-methionine GM lupine (*Lupinus* sp.); high-tryptophan GM rice; and GM alfalfa with increased levels of cysteine, methionine, aspartate, and lysine (ISAAA, 2012; Hefferon, 2015).

GM feed crops with phytase enzyme have been shown to improve phosphorus availability. Non-ruminants cannot efficiently absorb phosphorus stored in plants as phytate salts. The undigested phosphates excreted by these animals can accumulate in the soil and water, leading to phosphorous pollution and organic matter accumulation. In addition, phytic acid forms insoluble salts with zinc and other cations that reduce the bioavailability of trace minerals. GM corn, soybean, canola, and wheat expressing phytase transgenes have shown a positive effect on performance, phosphorus retention, and excretion. Other antinutritive factors that have been tackled by plant gene engineering include GM soybeans with reduced levels of the antinutritive oligosacharides raffinose and stachyose and GM cotton seeds with low contents of the phenolic pigment gossypol (ISAAA, 2012).

Production of pharmaceuticals in biotech plants

Plants can be genetically engineered to harness endogenous metabolic pathways and the protein biosynthesis machinery to produce complex small-molecule compounds and recombinant biologicals. A number of plant species have been genetically engineered in several metabolic pathways to produce defined secondary metabolites of high pharmaceutical value, including paclitaxel,

tropane, morphine, and terpenoid indole alkaloids either as whole plants or cultured organs/cells. Several advances are being implemented in terms of quality, purity, and yield, as well as procedures to meet regulatory requirements to move from these products from proof-of-principle to commercial production (Fisher *et al.*, 2015).

One of the key features of plant-based production platforms that distinguish them from other biological manufacturing concepts is the lack of a single biotechnological basis or a standardized platform. The technologies encompass stable transgene integration and transient expression in plants by means of bacterial, viral, or hybrid vectors (Chen and Lai, 2015). The platforms range from plant cells or simple plants, growing in bioreactors containing fully defined synthetic media, to whole plants growing in soil or in hydroponic environments. Whereas transient expression can produce very large amounts of the protein of interest within a short time, transgenic plants are preferable when the transgenic seed production is needed. Many pharmaceutical products can be improved and made in a shortened time or on an enlarged scale in plant-based systems. These features are relevant when products can be produced with a superior quality and/or with plant specifications or when production scale and costs are important factors.

The production of recombinant pharmaceutical proteins by means of using GM plants, often described as molecular farming, originated from the need for safe and inexpensive biopharmaceuticals in developing countries. Plants synthesizing expressing vaccine proteins can be grown using local farming techniques, only need to be partially processed, are easily transportable, and do not require refrigeration. Vaccines produced in food or feed crops effectively elicit an immune response to a particular pathogen when consumed fresh, dried, or lyophilized into a powder and reconstituted as a juice when needed. Therefore plant made vaccines could be easily available at low costs at remote regions of the planet (Hefferon, 2015).

These developments open interesting opportuni-

ties for low-income countries and investment in manufacturing pharmaceuticals in plants increases globally. When production needs to be scaled up, the capital investments on plant-manufacturing platforms in special molecular farming are expected to be considerably lower than with mammalian cell culture platforms. Companies in the USA and Europe have invested in the establishment of new currently good plant-manufacturing practice facilities (Lössl and Clarke, 2013).

In 2012, an important breakthrough was achieved when the first plant-made pharmaceutical product was approved for use in humans, namely ELELY-SO® (taliglucerase alfa) (Pfizer, New York, NY, USA), a recombinant form of human glucocerebrosidase produced in transgenic carrot (Daucus carota) root bioreactors for the treatment of the lysosomal storage disorder Gaucher's disease (Stoger et al., 2014). Another product gained global attention because of its role in an experimental Ebola therapy. The monoclonal antibody ZMapp, developed by Mapp Pharmaceuticals (Mountain View, CA, USA), was produced in tobacco plants at Kentucky Bioprocessing, a unit of Reynolds American. The drug was first successfully tested in humans during the 2014 West Africa Ebola virus outbreak, but has not yet been subjected to a randomized controlled trial (Zhang et al., 2014). This spectacular example of molecular farming proved it to be a fast and cheap way to produce novel biologicals.

Besides these success stories, a number of plant-derived pharmaceutical products are currently on the market or undergoing clinical development for several clinical applications, including antibiotic-associated diarrhea, inflammatory bowel disease, osteoporosis, HCV HSV/HIV, vaccine, anti-caries antibody, and microbicide (Sack *et al.*, 2015). Moreover, several pharmaceutical companies with plant-based production facilities established commercial platforms for nonpharmaceutical products, such as cosmetics, veterinary pharmaceuticals, technical enzymes, research reagents, and media ingredient, as a manner to generate revenue during costly clinical studies (Sack *et al.*, 2015).

It is important to be aware that, as for all medi-

cal interventions, safety and legal issues are required for production and usage of plant-made pharmaceuticals. Depending on the plant production system, different biosafety rules apply. Metabolites produced in cell suspension cultures based on medicinal plants are treated as natural products, whereas recombinant proteins produced in plants are considered products of GM organisms and, therefore, follow different regulations. The development of plant cell suspension cultures as a platform for plant-made pharmaceuticals have been encouraged, partly because of the lack of a coherent regulatory framework for whole plant-derived pharmaceuticals (Fisher et al., 2015). Consequently, the first plant-derived recombinant pharmaceutical protein approved for human use was produced in plant cells. Notwithstanding, there are impressive efforts to incorporate the latest regulatory innovations of industry-like platforms into whole plant-based manufacturing processes and to define updated guidelines (Fischer et al., 2015). With innovative and optimized production processes that can be scaled up and appropriate regulatory and biosafety frameworks, plant-derived recombinant proteins may offer high-volume and cost-effective delivery systems for many medical applications in this century (Mangan, 2014).

Examples of veterinary pharmaceuticals produced in feed include GM seeds for antibiotic replacement in animal farming, such as rice grains with human lactoferrin and/or lysozyme as antibacterial and immunity-stimulating agents in chickens and pigs (Humphrey et al., 2002; Hu et al., 2010). Recently, Arabidopsis seeds have been transformed with an antibody against enterotoxigenic Escherichia coli and used as a proof of concept for a passive oral immunization-based approach for piglets (Virdi et al., 2013).

Plant biotechnology for industrial applications

Innovations on output traits aiming at supporting sustainable processes in the chemical and fuel industry are lagging behind other plant biotech developments. To our knowledge, the only prod-

uct approved for commercialization is the Amflora potato produced by BASF Plant Science (http:// www.sciencemag.org/news/2013/12/eu-court-annuls-gm-potato-approval). This GM potato produces starch composed almost exclusively of amylopectin because the gene coding for starch synthase, involved in the synthesis of amylose had been switched off by RNAi strategy. As for certain industrial uses of starch only the thickening properties of amylopectin are required, the gelling amylose component is undesirable in many products and can interfere with certain processes. The chemical modification or separation of these two components is associated with increased consumption of energy and water. The European Commission approved the Amflora potato for industrial use in 2010 and cultivation started on a small scale in the Czech Republic, Sweden, and Germany. However, in January 2012, BASF Plant Science decided to stop marketing the Amflora potato in Europe due to lack of acceptance of GM crops in Europe and relocated its headquarters from Germany to the USA. In 2013, the European Union annulled the approval for BASF's Amflora potato.

Potato has also been engineered to produce high-amylose starch by suppression of the starch-branching enzyme SBE1 and SBE2 through RNAi. Still at R&D stage, the production of high-amylose starches can be used in the production of packaging material as well as film and coating from natural resources (Menzel *et al.*, 2015).

Other biochemical pathways for the production of molecules for the chemical industry are actively engineered, but most are still at R&D stage, including the tailoring of oil composition for use as biofuel and bio-based lubricants in camelina and *Jatropha curcas* (Kim *et al.*, 2014; Kim *et al.*, 2015); altered lignin content and composition to develop more efficient biofuels and biomaterial conversion processes in poplar, sorghum, and sugarcane (Fu *et al.*, 2011; Bottcher *et al.*, 2013; Van Aker *et al.*, 2014). Sugarcane has also been transformed with microbial genes that produce cellulose-degrading enzymes to produce self-processing plants (Harrison *et al.*, 2011).

Plant biotechnology for phytoremediation

There are a rapidly increasing number of scientific publications relating to phytoremediation and an expanding number of ways in which plants can be used for effective remediation of contaminated soil, sludge, sediment, ground water, surface water, and wastewater. Several case studies have demonstrated that GM technologies have successfully enabled phytoremediation to be tailored towards specific pollutants. Examples include model plants developed to degrade 2,4,6-trinitrotoluene (TNT), hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX), trichloroethylene (TCE), and polychlorinated biphenyls (PCBs) (Rylott et al., 2015). Focus is now turning from model plant systems to the transfer of this technology into plant species suitable for remediation in the field. One example is the transfer of rabbit cytochrome P450, 2E1 into poplar trees (Doty et al., 2007), based on the pioneering approach of expressing a single human 2E1 in tobacco for increased degradation of TCE, vinyl chloride, carbon tetrachloride, chloroform and benzene (Doty et al., 2000; James et al., 2007).

Conclusion

Biotechnology provides to many of the challenges that our world faces today, from feeding and fuelling a growing population, tackling a worldwide epidemic of neglected and chronic diseases, to mitigating the environmental impact of modern human societies. Plant biotechnology with focus on seed-varietal improvement, such as GM technology and molecular-assisted breeding, has generated products that help agriculture to achieve enhanced yields in a more sustainable manner. GM technology has brought significant improvements to earned income, life quality, and per acre productivity. The global value of transgenic seed alone has been estimated at US\$ 15.7 billion, representing 35% of the approximately US\$ 45 billion commercial seed market (James, 2014), which is a formidable achievement, considering the very limited number of commercialized crops and traits. Relevant is also that farmers in developing countries touched approximately 50% of the economic gains of the GM technology and that GM crops generated a provisional benefit of US\$ 68.21 billion between 1996-2013 (Brookes and Barfoot, 2015a) for growers of which 94.1% or more than 16.9 million were smallholder and resource-poor farmers from developing countries (James, 2014).

Although impressive, these figures are less remarkable when challenged with the statistics of 800 million people around the world, or 78% of the world's poor people, who live in rural areas and rely on farming, livestock, aquaculture, and other agricultural work for their subsistence (www. worldbank.org/en/news/feature/2014/11/12/ for-up-to-800-million-rural-poor-a-strong-worldbank-commitment-to-agriculture) and for whom the GM technologies do not satisfactorily reach the needs in the least developed countries. Although more than half of the global GM crop area is located in developing countries, the major GM crops commercialized today, i.e. soybean, maize, and canola, except cotton, are grown on large farms in Latin America and do not match the interests of most smallholder farmers in the least developed countries. Crops of relevance to marginal environments, such as millet (Pennisetum glaucum), groundnut (Arachis sp.), cowpea, common bean (Phaseolus vulgaris), chickpea (Cicer arietinum), pigeon pea (Cajanus cajan), cassava, yam (Dioscorea batatas), and sweet potato, to name a few, have been mostly ignored by GM technology.

Because of their restricted trade, these so-called neglected underutilized crop species (NUCS) present little economic interest for commercial seed companies, but they have the potential to play an important role in the improvement of food security by contributing to food quality and dietary diversity. NUCS may also increase sustainability of agriculture, because they are believed to be well adapted to niche-specific environments, such as marginal and harsh lands, and to need a low input. As such, NUCS can help mitigate the impact of climate change on food production. However, these crops have been abandoned by researchers and farmers in favor of major crops that are sometimes promoted even in less suit-

able areas (Chivenge et al., 2015). Moreover, the limited information on the genetic potential, agronomy, water requirements, and nutrition of NUCS remains a hindrance to their development and competitiveness. Therefore, actions have to be taken to overcome the constraints and obstacles for the cultivation of NUCS in regions where the uncertain climatic future can hamper food security, including acceleration of research to improve genetics and management as well as cultural acceptability and marketing.

Biotechnology tools can quicken the genetic improvement of NUCS. The GM approach can be used to introduce directly the desired sustainable management and the valuable output traits into varieties well adapted to local growing conditions. A major technological constraint is plant transformation that is critical for the development of biotech crops, for which GM techniques, such as transgenics, cisgenics, or by precision breeding, are required in the developmental process. The lack of efficient transformation protocols and breeding programs for geographical niche crops is in blatant contrast with the continuous striving for simpler, more robust, and more efficient transformation protocols for crop species for intensive agriculture.

There have been significant advances in the development of GM crops that can deliver food with health benefits beyond basic nutrition and in targeting small-market crops and a few NUCS for quality traits. These so-called second-generation traits will soon reach the market. The innovations coincide with an increasing consumer demand for healthy and nutritious food. The public sector shares a great deal of the research done in this field and public-private partnerships excel in translating the proof-of-concept to a marketable product.

Plant-made pharmaceuticals have become a major focus point since 2010, when realistic opportunities for commercial development emerged. Plant-manufacturing platforms for pharmaceuticals or molecular farming open interesting prospects for low-income countries, where large

quantities of medicines need to be provided on a regular basis. Cost-effective local focus and needle-free deployment can be of great help for the treatment of tropical diseases.

In the industrial sector, plant biotechnology has the potential not only to generate more productive biomass feedstocks and minimize inputs, but also to develop more efficient biofuels, chemicals, and bio-material conversion processes. A number of nonfood crops improved with sustainable management have gone through the regulatory process. Additionally several biochemical pathways are currently being explored for the development of quality traits for the chemical industry and for phytoremediation (Ricroch and Hénard-Damave, 2015).

Of the greatest technological gaps in the commercialization of second-generation biofuels along with chemicals are the conversion processes that are costly, environmentally threatening, and time consuming. Advanced nonfood feedstocks have to be developed that can grow on marginal lands and simultaneously can decrease the costs of lignocellulosic biomass pretreatments. Numerous projects are under consideration that aim at engineering lignin content and monomer composition to optimize lignin degradation (Harfouche *et al.*, 2014).

Examination of the fast uptake of biotech crops on millions of hectares globally and of the current R&D pipelines impacting numerous plant species indicates that plant biotechnology will be a major tool to overcome the challenges of sustainability and development. Developing and emerging economies have taken the lead in terms of adoption of biotech crops and also in approvals of new transgenic crop varieties (James, 2014). As more actors become involved in R&D and more technologies are adapted and applied to new regions and local crops, the more developing countries will play a leading role in agricultural biotechnology. In the near term, most of the developing world will continue to rely on development assistance and innovations, as well as on technology partnerships and joint ventures with companies from developed countries that look for access to large developing markets. However, as research capacities increase, public sector institutes and private firms in emerging and low-income economies are likely to develop new biotech crops on their own. In the not too distant future, agricultural biotech research in developed countries could be surpassed in the same manner that production has already been.

The opportunities offered by plant biotechnology have never been greater, but neither have the challenges been, among which the most daunting is public perception and its influence on the regulation of biotech crops. All GM crops are submitted to a rigorous battery of tests and regulatory scrutiny prior to commercialization. Typically, the properties of the GM crops are compared to those of the corresponding non-GM variety with respect to various potential risk factors. Such comparative analyses include agronomic, molecular, compositional, toxicological, and nutritional assessments. Regulatory systems must ensure that all steps are in place to guarantee biosafety, but they must also ensure that none of these steps is unnecessary. Currently, the biggest constraint to commercialization of transgenic products is the regulatory delay, including, among others, test repetition, slow review time, and requests by regulators for additional information, often not necessary to demonstrate safety, and lack of clarity with respect to the regulatory requirements. Another source of delay is political interference in the biosafety regulatory process that hampers technologies developed by public-sector institutions or small private firms that, compared to large multinational corporations, have less financial flexibility to absorb the costs until the regulatory authority finally renders its decision (Bayer et al., 2010). Thus, the extensive time needed to complete a regulatory file may significantly reduce the net benefits of GM products.

The costs of compliance with biosafety regulation also deter low-income and emerging economies from considering GM technologies as a solution to agricultural problems. Biotech developers must take into account not only the countries where the cultivation of the new biotech crops could take place, but also where the consumption of such crops might ultimately occur. So, an emerging country that wants to export GM food to the developed world is confronted with regulatory frameworks that do not give it much latitude. Moreover, low-income and emerging economies will not be able to keep pace with the ever-changing regulatory requirements of the developed world and will clearly restrict their decision to apply GM technology.

Public perception of GM crops and food is influenced by numerous factors, including access to information or misinformation, commercial actions by corporations, moral and ethical beliefs, and perceptions of personal benefit from the technology. Anti-GMO activists diffuse misinformation to uphold the belief that harm will come to those who consume foods made up of GM ingredients, heightening anxiety with the mass public as well as with public authorities (Blancke et al., 2015). This concerted opposition to GM crops resulted in a number of complex legal and regulatory issues that have halted cultivation and stymied plant research in Europe with disastrous consequences to the development of new crops varieties and their introduction to markets worldwide. The best example is Golden Rice that has still not been approved for release in spite of its urgent need and readiness for well over a decade. Should concerns of this nature persist, R&D efforts will probably be restricted to large agribusiness corporations that will continue to focus on major intensive agriculture crops.

Nevertheless, there is no time to waste. The world's overpopulation and the pressures on the Earth system require all the ingenuity human beings can deliver. To ensure that the biotechnologies live up to the expectations, they will have to focus on the priorities that could slow, limit, or halt research and development, including negative public opinion and the lack of regulatory harmonization. Needless to say that markets and

technology alone cannot promote the sustainable development of human societies. A deep transformation of societal values in a holistic manner will be required that can only be achieved with strong political will.

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Biotechnology and GM Crops in Brazil

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Abstract

Since the 1970s, biotechnology has influenced to the economic growth of many countries. In Brazil, the development of a national biotechnology policy occurred only in 2007. To date, the greatest biotechnological contribution in the country has undoubtedly been in the agribusiness sector, which is responsible for approximately 23% of Brazil's Gross Domestic Product. Genetically modified (GM) crops, particularly soybean (Glycine max), maize (Zea mays), and cotton (Gossypium hirsutum), are the best examples of this biotechnological application that increased between 3% and 4% in 2014 (exceeding 42 million hectares), which is 4.6% higher than in 2013 and is the equivalent of 1.9 million hectares. Brazil harbors the second largest cultivated acreage of GM crops worldwide and a substantial growth is projected in the next few years. Currently, 50 transgenic events are authorized for commercialization in Brazil, of which two, an imidazolinone-tolerant soybean and a golden mosaic virus-resistant common bean, are the direct outcome of national technology and public sector. Maize became the crop plant with the largest number of transgenic traits released in Brazil, accounting for 29 events and others in the pipeline for approval and commercialization, followed by cotton (12 events), and soybean (7 events). The rapid increase in the adoption of GM crops results from the technical commission responsible for biosafety in Brazil, which is one of the most effective worldwide. Pest control, among other constraints in the agricultural sector, has been the subject of intense investigation by the Brazilian biotech sector and has received support from the public sector through the creation of programs for leveraging government and industry partnerships.

Keywords: biotech crops, agribusiness, transgenic plants, cotton, soybean, maize

Introduction

In the past two decades, innovation has played a pivotal role in economic development. The build-up of innovative technologies has been of foremost importance for successful and dynamic growth in developing countries (Organization for Economy Co-operation and Development, 2012). Advances and investments in biotechnology, including those focused on health, agriculture, industry and the environment, are now crucial for any country to thrive on the global market.

Consequently, the application of biotechnology to various sectors and industries has increased exponentially. In 2014, 181.5 million hectares were grown with genetically modified (GM) crops worldwide in 28 countries, of which 20 developing countries and eight industrialized countries (James, 2014). Notably, approximately 53% (93.1 million hectares) of GM crops were produced in developing and emerging markets from Latin America, Asia, and Africa. The most cultivated transgenic crop in the world is soybean (*Glycine max*), representing over 50% of the to-

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tal transgenic crop area, followed by maize (*Zea mays*) and cotton (*Gossypium hirsutum*) (James, 2014). A particular meta-analysis of the impacts of 147 commercialized transgenic crops over the last 19 adoption years (1995 to 2014) emphasized the multiple significant benefits generated by biotechnological (biotech) crops, including their contribution to a 37% reduction in chemical pesticide use, an 22% increase in crop yields, and a 68% increase in farmer profits (Klümper and Qaim, 2014).

Since the beginning of the 1970s, government institutions and agencies in Brazil, including Brazilian Development Bank (BNDES), Brazilian Innovation Agency (FINEP), National Counsel of Technological and Scientific Development (CNPq), and Brazilian Federal Agency for Support and Evaluation of Graduate Education (CAPES), have invested in and provided support for the development of innovative products and processes in the country. An important step was the release of the National Innovation Law in 2004 (Brasil, 2004). This legislation sought to encourage innovation within the public sector (particularly at universities) and to incite partnerships between academic institutions and the private sector. Another initiative to coordinate the biotechnology policy was the creation of the National Biotechnology Committee to manage the implementation of government's biotechnology policies (Brasil, 2007).

Recently, the Scientific American Worldview (http://www.saworldview.com/scorecard/2015-scientific-american-worldview-overall-scores/) has released an overview of the performance of 54 nations in Biotechnology Innovation, in which was aggregate performance in seven categories - Productivity, Intellectual Production Protection, Enterprise Support, Intensity, Education/Workforce, Foundations, and Policy & Stability. Overall, Brazil is in second position among the Latin America's countries, behind only the Chile, but even so several biotechnological sectors must be better exploited, such as the related to biopharmaceutical products, once the country imports the great majority of medicines.

Indeed, in the last two decades, Brazil has been a leader in the use of GM crops and in the development of agricultural biotech products. In 2014-2015, approximately 42.2 million hectares of biotech crops were under cultivation, uncluding three major crops, maize, soybean and cotton, at an adoption rate of 89.2% in the three cultures analyzed (Céleres, 2014; James, 2014; Céleres, 2015). Since 2009, the country ranks second worldwide regarding the GM planted area, losing out to only the United States (73.1 million hectares), but Brazil was ahead of other BRIC countries, such as Russia and India, in terms of biotechnological advances.

Development of GM crops in Brazil

By 2020, the global population will reach approximately 7-8 billion people. Providing adequate nutrition for all these people will be a great challenge, particularly in Asia, Africa, and Latin America, where the majority of the population is located. The intensification of food production and distribution, associated with an increase in productivity and a reduction in agricultural costs, are key factors to meet this challenge (www.worldometers.info/world-population).

Despite the production growth over the last 30 years, pests continue to be the major causes of yield losses during the pre- and post-harvest periods (Carlini and Grossi-de-Sa, 2002; Ferry et al., 2006). Annually, the world average yield loss reaches approximately 42% (Paoletti and Pimentel, 2000), resulting in a damage of up to US\$ 250 billion (Oerke et al., 2012). Even though more than 2.5 million tons of pesticides are applied worldwide, over 40% of the entire production is still lost prior to harvest by several pests, including insect pests and other phytopathogens (Grube et al., 2011; Ceresana Research, 2012). In contrast, the use of tolerant/resistant crop cultivars is considered the most efficient, cost-effective, and least environmentally damaging pest control method available.

Genetic engineering has enabled the generation of technologies that reduce losses and increase

crop yields. GM varieties provide improved farming practices and enhance the quantity and quality of agricultural commodities, boosting the farmers' income and promoting economic growth. In the case of transgenic plants tolerant to herbicides or resistant to insects, management of invading plants and insects is facilitated and the application of pest-controlling substances is reduced. The available plants on the market that harbor both characteristics represent an efficient alternative for farmers. In addition to their agronomic advantages, these varieties also favor the preservation of biodiversity.

The Brazilian Trade Balance in agribusiness has increased by 320% from US\$ 25.90 billion in 2003 to US\$ 75.1 billion in 2015 (MAPA, 2015; Figure 1). This increase is higher than the overall Brazilian Trade Balance that went through many variations during the last decade, from US\$ 46.46 billion in 2006 to a deficit of US\$ 3.9 billion in 2014 (MDIC, 2013; MAPA, 2015). In 2014, the Brazilian Trade

Balance closed with a surplus of US\$ 5.5 billion for the agribusiness sector and in 2015, the agribusiness sector represented more than US\$ 391 billion of the country's Gross Domestic Product (GDP) (www.comexdobrasil.com/brasil-projeta-aumentar-em-us-20-bilhoes-as-exportacoes-do-agronegocio-ate-2018). The contribution of agribusiness to the Brazilian Export Balance is higher than any other sector in the country. In 2013, 41.24% of the income from exports was related to agribusiness products (MDIC, 2013). Agribusiness is also responsible for the employment of approximately 35% of the working population of Brazil (Riedel, 2013; http://www.canaldoprodutor.com.br/print/69844). Currently, Brazil holds 7% of the global market for agricultural products and is expected to retain 10% of the global sector in 2018.

In the early 1990s, the first examples of the utilization of GM crops in Brazil were controversial. At the time when farmers in the south of the country

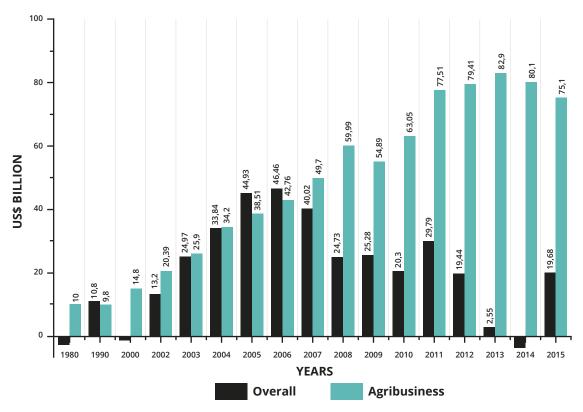


Figure 1. Brazilian trade balance from 1980 to 2015. Black and green bars correspond to the overall amount of Brazilian Trade Balance and the amount represented by the agribusiness in Brazil, respectively. Values are given in US\$ Billion. Adapted from (MDIC, 2014; MAPA, 2015).

started planting the first transgenic soybean, all transgenic seeds came from Argentina, because the cultivation and commercialization of GM crops in Brazil was approved only in 1995. However, three years later, a "moratorium" on GM crop commercialization was established and upheld until 2003-2004. In 2005, after a broad political and social debate, a new regulatory framework resolved the legal conflicts, resulting in a new phase of plant biotechnology in Brazil. In fact, the number of commercial releases of transgenic crops has significantly increased in Brazil after endorsement of this efficient and science-based approval system, known as the Biosafety Law.

In 2014-2015, approximately 42.2 million hectares of GM crops were cultivated in Brazil, representing a 4.6% increase compared to 2013 and an adoption rate of 89.2%, more specifically, of 93.2% for GM soybean, 72.6% for GM summer maize, 90% for GM winter maize, and 65.1% for GM cotton (Céleres, 2014; James, 2014). Of the 42.2 million hectares of the GM crop area, GM soybean was cultivated on 29.1 million hectares (68%)

of the total area), followed by GM maize (summer and winter) covering 12.5 million hectares (29.6%) and by GM cotton with 0.6 million hectares, an increase of 25.1% over 2013 (Céleres, 2014, 2015; James, 2014) (Figure 2). According to projections, the GM planted crop area will increase by 3.9% in 2015-2016 compared to that in 2014-2015, reaching 44.2 million hectares and an adoption rate of 90.7% for three products, soybean, maize, and cotton (Céleres, 2015). The high growth of the biotech crop area in Brazil represents a consolidated adoption and a large contribution to the Brazilian GDP, equivalent to more than US\$ 0.5 trillion.

Biotech maize is responsible for the greatest increase in farmers' income (58%), followed by soybean (39%) and cotton (3-4%) (Céleres, 2012). Considering the enhanced demand for agricultural products, it is clear that expansion of the agricultural production will be needed and that GM crops will play a major role. Brazil is expected to cultivate 16.2 million hectares of GM cotton, 178.4 million hectares of GM maize and 293.0 million hectares.

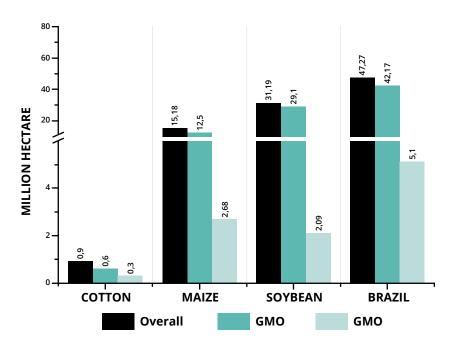


Figure 2. Biotech Cultivation area in Brazil. Black, green, and light-green bars correspond to the total area used for agriculture in Brazil, for GM crops, and for non-GM crops in Brazil, more specifically for the plantation of cotton, maize, and soybean, respectively. In more than 89% of the total agricultural area transgenic plants are cultivated. Approximately 93.2%, 82.4%, and 65.1% of all soybean, maize, and cotton planted in Brazil are transgenic, respectively. (Adapted from CONAB, 2014; Céleres, 2014).

lion hectares of GM soybean within the next ten years, reaching a production worth of US\$ 118.2 billion (Céleres, 2012). Furthermore, a high adoption rate is foreseen for GM crops with combined traits (such as insect resistance [IR] and herbicide tolerance [HT]) that has recently been welcomed by Brazilian farmers. The use of single-trait technology is rapidly decreasing compared to stacked traits, with a considerable contribution from the IR/HT soybean commercialization. From the technological data farmers will obviously prefer the stacked traits to the single feature due to their significant benefits.

The potential offered through the adoption of GM soybean, maize, and cotton crops clearly show important economic and environmental gains for both farmers and society. The economic benefits of biotech crops in Brazil were evaluated to be US\$ 24.8 billion for the periods from 1996-1997 and 2012-2013 and US\$ 6.3 billion for the 2013 year alone (Céleres, 2013, 2014). Additionally, based on provisional data, an annual economic assessment of the value of the use of GM crop technology in agriculture at the farm level, covering the benefits from biotech crops over a 10-year period (2003-2013) revealed that Brazil gained US\$ 11.8 billion and, of which US\$ 3.4 billion in 2013 alone (Brookes and Barfoot, 2015).

Soybean

In Brazil, soybean cultivation is intense and agriculture is often associated with utilization of advanced technology and modern cropping systems. Hence, the first transgenic event authorized in Brazil was Roundup Ready (RR) from Monsanto, a GM soybean with tolerance to the herbicide glyphosate, conferred by the transgenic event GTS 40-3-2 (CT-NBio, 1998). Since the release of soybean RR for planting and commercialization in Brazil in 2003-2004, the GM crop adoption rate rapidly increased and is currently approximately 93.2% with approximately 85% of all soybean cultivars grown representing the RR technology.

Two other transgenic soybean events that were approved for commercial planting in 2010 are

also herbicide resistant (A2704-12 and A5547-127 [Liberty Link] of Bayer SA) and show tolerance to glyphosinate ammonia (GA) (Table 1), with the advantage of high degradability and low toxicity to animals and the environment. Soil microorganisms rapidly degrade the glyphosate herbicide by using the molecule as a nitrogen source and releasing phosphorus and CO2 (CTNBio, 2010a, 2010b).

In the same year, the MON87701 & MON89788 (Monsanto) event, which confers both tolerance to the herbicide glyphosate and resistance to insects, was approved for commercial planting. Both features were derived from crosses obtained by classical breeding by means of already genetically modified parentals containing either of the transgenic events (CTNBio, 2010c). In 2011, 15 different cultivars that contained this event were planted in the country.

In 2009, a new IR GM soybean event (BPS-CV127-9, known as Cultivance™), developed through a partnership between the Brazilian government company (Empresa Brasileira de Pesquisa Agropecuária [EMBRAPA]) and the private company Badische Anilin- und Soda-Fabrik (BASF) was approved for commercialization. This transgenic event was obtained by insertion into soybean of the Arabidopsis thaliana csr1-2 gene. This csr1-2 gene encodes an acetohydroxy acid synthase protein conferring tolerance to imidazolinone herbicides due to a point mutation that results in a single amino acid substitution; the serine residue at position 653 was replaced by asparagine (S₆₅₃N). The Cultivance™ soybean event is the first GM soybean developed in partnership with a national research institution and is expected to be commercialized in Brazil in 2016. Recently, another soybean event has been approved, DAS-68416-4 from Dow Agrosciences, with both IR and HT traits (CTNBio, 2015a). Currently, at least two other events are in the pipeline that contain genes coding for HT proteins and/or stacked traits (Coelho, 2013, 2015; CTNBio, 2015a).

The release of different events for the same trait is a strategic measure, because it contributes

Table 1. Genetically Modified Crops Approved for Commercialization in Brazil.

Plant	Company	Event	Commercial Name	Regulatory Approval (Year)	Transgene Product	Insect Resistance	Herbicide Resistance	Other Features
Soybean	Monsanto Company	GTS-40-3-2	Roundup Ready™ Soybean	1998 / 2003	CP4 EPSPS*		Х	
		MON87701 & MON89788	Intacta™ RR™ 2 Pro	2010	CP4 EPSPS*; Cry1Ac	Х	Х	
	BASF & Embrapa	BPS-CV-127-9	Cultivance™	2009	CSR-1-2*		Х	
	Dow Agroscience	DAS68416-4	Enlist™ Soybean	2015	AAD-12*; PAT*	Х	Х	
	Bayer CropScience	A5547-127	Liberty Link™ Soybean	2010	PAT*		Х	
		A2704-12	Liberty Link™ Soybean	2010	PAT*		Х	
Maize	Monsanto Company	MON810	YieldGard™, MaizeGard™	2007	Cry1Ab	Х		
		NK603	Roundup Ready™ 2 Maize	2008	CP4 EPSPS*		Х	
		NK603 & MON810	YieldGard™ CB + RR	2009	CP4 EPSPS*; Cry1Ab	Х	Х	
		MON89034	YieldGard™ VT Pro	2009	Cry1A.105; Cry2Ab2	Х		
		MON89034 & NK603	Genuity® VT Double Pro™	2010	CP4 EPSPS*; Cry1A.105; Cry2Ab2	Х	Х	
		MON88017	Yield Gard™ VT™ Rootworm™ RR2	2010	CP4 EPSPS*; Cry3Bb1	Х	Х	
		MON89034 & MON88017	Genuity® VT Triple Pro™	2011	CP4 EPSPS*; Cry1A.105; Cry2Ab2; Cry3Bb1	Х	Х	
		NK603 & T25	Roundup Ready™ Liberty Link™ Maize	2015	CP4 EPSPS*; PAT*		Х	
	Bayer CropScience	T25	Liberty Link™ Maize	2007	PAT*		Х	
	Syngenta Seeds, Inc.	Bt11	Agrisure™ CB/LL	2008	PAT*; Cry1Ab	Х	Х	
		GA21	Roundup Ready™ Maize, Agrisure™ GT	2008	mEPSPS*		Х	
		Bt11 & MIR162 & GA21	Agrisure™ Viptera™ 3110	2010	mEPSPS*; Cry1Ab; Vip3Aa20*	Х	Х	
		Bt11 & GA21	Agrisure™ GT/CB/LL	2009	PAT*; mEPSPS*; Cry1Ab	Х	Х	
		MIR162	Agrisure™ Viptera™	2009	Vip3Aa20*	Х		
		MIR604	Agrisure™ RW	2014	mCry3A*	Х		
		Bt11 & MIR162 & MIR604 & GA21	Agrisure™ Viptera™ 3111, Agrisure™ Viptera™ 4	2014	Cry1Ab; mCry3A*; Vip3Aa20*; mEPSPS*; PAT*	Х	Х	
	Dow Agrosciences	DAS-40278-9	Enlist™ Maize	2015	AAD-1*		Х	
	DuPont	TC1507 & NK603	Herculex™ I RR	2009	CP4 EPSPS*; PAT*; Cry1F	Х	Х	
		MON810 & TC1507 & NK603	Power Core™	2011	CP4 EPSPS*; PAT*; Cry1Ab; Cry1F	Х	Х	
		TC1507 & MON810	TC1507Xmon810	2011	PAT*; Cry1Ab; Cry1F	Х	Х	
		TC1507 & MON810 & MIR162	Not available	2015	Cry1Ab; Cry1F; Vip3Aa20*; PAT*	Х	Х	
		MON810 & MIR162	Not available	2015	Cry1Ab; Vip3Aa20*	Х		
		MIR162 & NK603	Not available	2015	Vip3Aa20*; CP4 EPSPS*	Х	Х	
		MIR162 & TC1507	Not Available	2015	Cry1F; Vip3Aa20*; PAT*	Х	Х	
		TC1507 & MIR162 & NK603	Not available	2015	Cry1F; Vip3Aa20*; PAT*; CP4 EPSPS*	Х	Х	

Plant	Company	Event	Commercial Name	Regulatory Approval (Year)	Transgene Product	Insect Resistance	Herbicide Resistance	Other Features
		TC1507 & MON810 & MIR162 & MON603	Not available	2015	Cry1Ab; Cry1F; Vip3Aa20*; CP4 EPSPS*; PAT*	Х	Х	
		TC1507 & MON810 & NK603	Optimum™ Intrasect	2015	Cry1Ab; Cry1F; CP4 EPSPS*; PAT*	Х	Х	
	DuPont & Dow Agrosciences	TC1507	Herculex™ I, Herculex™ CB	2008	CP4 EPSPS*; Cry1Ab	Х	Х	
		TC1507 & DAS- 59122-7	Herculex™ XTRA	2013	PAT*; Cry1F; Cry34Ab1; Cry35Ab1	Х	Х	
	Monsanto & Dow Agrosciences	MON89034 & TC1507 & NK603	Power Core PW/Dow	2010	CP4 EPSPS*; PAT*; Cry1A.105; Cry2Ab2; Cry1F	Х	Х	
Cotton	Monsanto Company	MON531	Bollgard™ I	2005	Cry1Ac	Х		
		MON1445	Roundup Ready™ Cotton	2008	CP4 EPSPS*		Х	
		MON531 & MON1445	Bollgard™ I Roundup Ready™ Cotton	2009	CP4 EPSPS*; Cry1Ac	Х	Х	
		MON15985	Bollgard™ II	2009	Cry1Ac; Cry2Ab	Х		
		MON88913	MON88913-8	2011	CP4 EPSPS*		Х	
		MON15985 & MON88913	Bollgard™ II Roundup Ready™ Flex™ Cotton	2012	CP4 EPSPS*; Cry1Ac; Cry2Ab2	Х	Х	
	Bayer CropScience	LLCotton25	Fibermax™ Liberty Link™ Cotton	2008	PAT*		Х	
		GHB614	GlyTol™	2010	2mEPSPS*		Х	
		T304-40 & GHB119	TwinLink™	2011	PAT*; Cry1Ab; Cry2Ac	Х	Х	
		GHB614 x T304- 40 & GHB 119	GlyTol™ TwinLink™	2012	2mEPSPS*; Cry1Ab; Cry2Ac	Х	Х	
		GHB614 & LLCot- ton25	GlyTol™ Liberty Link™ Cotton	2012	2mEPSPS*; PAT*		Х	
	Dow Agrosciences	281-24-236 & 3006-210-23	WideStrike	2009	PAT*; Cry1Ac; Cry1F	Х	Х	
Bean	Embrapa	Embrapa 5.1	Embrapa 5.1	2011	AC1 (sense and anti- sense) *			X ¹
Eucalyptus	FuturaGene	H421	Not Available	2015	CEL1*			X ²

^{*} Abbreviations: 2mEPSPS: 5-enolpyruvyl shikimate-3-phosphate synthase enzyme (double mutant version); AAD-1: aryloxyalkanoate dioxygenase 1 protein; AC1: sense and antisense RNA of viral replication protein, i.e., no functional viral replication protein is produced; CEL1: CEL1 recombinant protein; CP4 EPSPS: 5-enolpyruvylshikimate-3-phosphate synthase enzyme from CP4 Agrobacterium tumefaciens strain; CSR-1-2: modified acetohydroxyacid synthase large subunit (AtAHASL); mCry3A: modified Cry3A; mEPSPS: modified 5-enolpyruvylshikimate-3-phosphate synthase enzyme; PAT: phosphinothricin N-acetyltransferase enzyme; Vip3Aa20: vegetative insecticidal protein.

¹ Resistance to virus

² Volumetric increase of wood.

to both increased food security and agronomic productivity. The use of HT varieties with different action mechanisms provides farmers with an improved way to manage resistant weeds due to selective pressure.

Maize

Brazil is the third largest producer and exporter of maize worldwide, after the United States and Argentina, but is only the fourth in terms of cultivation area of GM maize, surpassed by the United States, Canada, and Chile (www.gmo-compass. org/eng/agri biotechnology/gmo planting/341. genetically modified maize global area under cultivation.html). In Brazil, the main insect pests of maize are caterpillars, including the fall armyworm (Spodoptera frugiperda), the corn earworm (Helicoverpa zea), and the sugarcane borer (Diatrea saccharalis), which is also a corn pest. These insect pests cause crop losses of up to 35% and require dozens of insecticide applications for effective control during a culture cycle (Gallo et al., 2002; Caccia et al., 2014).

As protection against these typical losses, Monsanto, Bayer, and Syngenta released three GM maize events in Brazil in 2007 (Table 1). MON810 (YieldGuard™) from Monsanto of Brazil Ltd. was developed with a *cry1Ab* gene derived from the bacterium *Bacillus thuringiensis* that encodes the Cry1Ab protein (Bt protein) that is toxic to insects of the order Lepidoptera (CTNBio, 2007a). In 2011, Brazil recorded 113 cultivars modified with the MON810 event.

The Bayer Company released the event T25 (Liberty Link™) with the pat gene that provides transgenic maize crops with tolerance to herbicides, but a court ruling temporarily annulled the commercial approval. In 2010, a new ruling definitively confirmed the approval for the whole country (CT-NBio, 2007b) (Table 1).

In 2008, Syngenta Seeds Ltd. obtained approval for the commercial launch of the BT11 event, an IR maize obtained by the introduction of a genetic construct containing an insecticidal *Btk* gene and

the pat gene as a selection marker. The *Btk* gene was obtained from *B. thuringiensis* var. *kurstaki* that encodes the Cry1Ab protein and confers resistance to *S. frugiperda, H. zea,* and *D. saccharalis* (CTNBio, 2008a).

The need to increase the insect resistance with the pyramiding strategy while keeping the herbicide tolerance led Dow Agrosciences Seeds & Biotechnology of Brazil to partner with DuPont of Brazil to release improved transgenic corn events. In 2008, the commercial maize HerculexTM (TC1507) was approved in Brazil. The previous event included the *pat* and *cry1f* genes that provide tolerance to herbicides and resistance to insects, respectively (CTNBio, 2008b).

In 2013, the GM maize, commercially denominated Herculex™ XTRA (TC1507 & DAS-59122-7), included the produced PAT protein, responsible for the increased in herbicide tolerance and three Bt toxins (Cry1F, Cry34Ab1, and Cry35Ab1). Whereas Cry34Ab1 and Cry35Ab1 were involved in plant defense against coleopteran insects, Cry1F controlled lepidopteran pests (CTNBio, 2013). This event was approved for commercialization after the successful partnership between Dupont and Dow Agrosciences.

The partnership between Dow Agrosciences and Monsanto of Brazil created MON89034 & TC1507 & NK603 (Power Core PW/Dow). Released in 2010, it included the produced CP4 EPSPS and PAT proteins to increase tolerance to glyphosate, together with three Bt toxins (Cry1Ac.105, Cry2Ab2 and Cry1F) that significantly enhanced the resistance against *S. frugiperda* (CTNBio, 2010d) (Table 1).

In 2014, Syngenta Seeds Inc. released two transgenic corn events in Brazil: MIR604 and a combination of Bt11 & MIR162 & MIR604 & GA21 (CTNBio, 2014). Whereas MIR604 (commercially known as Agrisure™ RW) displayed resistance against insects by expressing the mCry3A protein, the other event showed both herbicide tolerance and insect resistance by expressing five foreign proteins, Cry1Ab, mCry3A, Vip3Aa20, mEPSPS, and PAT (Table 1).

By 2015, maize is the crop with the largest number of transgenic traits released in Brazil, totaling 29 different events. Until 2014, Monsanto in Brazil Ltd. had the largest number of approved events, but in 2015, Brazilian DuPont (a division of Pioneer Seeds) released seven new events, all involving insect resistance and herbicide tolerance (CTNBio, 2015b, 2015c). In the same year, Monsanto of Brazil Ltd. issued only one new event for herbicide tolerance (Table 1) (CTNBio, 2015d) and Dow Agrosciences a new GM corn, DAS-40278-9, commercially known as Enlist™, with increased tolerance to herbicides (CTNBio, 2015e).

Cotton

In terms of planted area, cotton is the third biotech crop in Brazil, covering an estimated area of 0.6 million hectares that represent over 65% of a total planted area of the 0.9 million hectares in 2014-2015 (www.abrapa.com.br/estatisticas/Paginas/area-producao-produtividade-brasil.aspx; James, 2014; Pispini *et al.*, 2014). Approximately 23.6% of the transgenic cotton cultivated in Brazil is tolerant to herbicides, 31.2% is resistant to insects, and 10.3% contains both traits. Most cotton cultivation is located in the Midwest (approximately 60%) and northeast (approximately 60%) regions of the country, particularly in the states of Mato Grosso, Bahia, and Goiás (Céleres, 2014; James, 2014; Pispini *et al.*, 2014).

The first approved transgenic cotton was the variety Bollgard™ I (event MON531) in 2005 that confers resistance to the leaf worm (*Alabama argillacea*), the pink bollworm (*Pectinophora gossypiella*), and the apple caterpillar (*Heliothis virescens*). By means of the commercial variety Coker 312, Monsanto introduced the gene encoding the Bt toxin Cry1Ac into the vector PV-GHBK04 and transformed cotton plants via *Agrobacterium tumefaciens*. The produced protein provided increased resistance against the three pests (CTNBio, 2005).

Three years later, Monsanto released the event MON1445 (Roundup Ready™), while Bayer simultaneously created LLCotton25 (Liberty Link), both of which are herbicide-tolerant GM cotton (Table

1) (CTNBio, 2008c, 2008d). In 2009, events with both traits - tolerance to herbicide and resistance to insect pests – arrived on the market with two different releases: Bollgard™ I + Roundup Ready™ (RR) from Monsanto and WideStrike from Dow Agrosciences (Table 1) (CTNBio, 2009a). Whereas Monsanto fused both proteins used in Bollgard™ I and RR (Cry1Ac and CP4 EPSPS) cotton, Dow Agrosciences introduced the first transgenic cotton with Cry1F protein, in addition to Cry1Ac and PAT proteins. Pyramiding of the Cry toxins allowed an extension of the activity against insect pests, because the attacks of additional pests, such as Helicoverpa zea, Spodoptera frugiperda, Spodoptera exigua, Spodoptera eridania, Pseudoplusia includens, and Trichoplusia ni, could be controlled as well (CTNBio, 2009b).

To date, 12 events of transgenic cotton have been approved for cultivation and commercialization in Brazil (Table 1), two of which provide insect resistance, five increase herbicide tolerance, and the other five present both traits. Since 2005, cotton production and productivity have increased (although varying over the years) and are expected to keep growing, because the amount of cultivated GM cotton continues to expand in Brazil.

Common beans

Brazil is the largest producer of beans in the world, with a production of 3.3 million tons per year, ahead of India (3.0 million tons), China (1.9 million tons), and Mexico (1.3 million tons) (CON-AB, 2013; www.almanaguedocampo.com.br/ verbete/exibir/89). The most common species cultivated in Brazil are Phaseolus vulgaris (common bean), which is found all over the Brazilian territory, and Vigna unguiculata (cowpea), which is mainly cultivated in the Amazon and northeast regions. Bean cultivation extends to all states of Brazil as a single system or intercalated with other crops. Previously considered a subsistence crop in small properties, the common bean is now adopted in production systems that require the use of intensive technologies, such as irrigation, pest control, and mechanical harvesting (Salvador, 2012).

As a traditional food, beans are one of the main components of the Brazilian diet and are consumed in large quantities. The grains of this legume represent an important source of protein, iron, and carbohydrates, particularly for populations from developing tropical and subtropical countries (http://www.agricultura.gov.br/vegetal/culturas/feijao/saiba-mais).

In addition to this high demand, another reason for the increase in bean import is the supply maintenance due to the losses caused by pathogens and pests. Many diseases affect the common bean that, in addition to yield reduction, also depreciate the quality of the product. These diseases may be of fungal, bacterial, or viral origin. The golden mosaic virus is one of the most devastating diseases of the common bean in several Brazilian states. It is economically important in the south of Goiás and Minas Gerais, as well as in the northern part of Paraná and Mato Grosso do Sul. This virus is capable of causing 100% yield losses, depending on the region and infection time. The symptoms become apparent in the infected plants when two to four of the trifoliate leaves start to develop a yellowish color (Wendland, 2011).

Although a number of techniques have been tested and used to control the virus, there is an urgent need to develop more efficient strategies for disease control. Hence, in 2011, EMBRAPA created the world's first GM common bean. It was also one of the world's first examples of a transgenic crop that was completely developed by a public institution (CTNBio, 2011). Ten institutions contributed, including four universities, six EMBRAPA units from four different states, and the Federal District. The GM event, designated Event 5.1, was generated with the RNA interference (RNAi) strategy and was obtained through the insertion of transgenes into the nuclear genome of the bean through a biolistic technique (Aragão et al., 1996). The cultivation of transgenic beans will be an important tool for the control of the golden mosaic virus, not only in Brazil, but also in other countries that suffer from the disease, including India, Myanmar, China, the USA, and Mexico.

Eucalyptus

In Brazil, 7.6 million hectares were used for plantingtrees, a 2.8% increase compared to 2012 (7.39 million hectares). Eucalyptus (Eucalyptus) species represent 72% of all trees planted in Brazil and 20.7% correspond to pine (Pinus sp.) trees. Approximately 81% of the eucalyptus produced in the country, or more than 180 million m³, is converted into cellulose and paper (ABRAF, 2010; Indústria brasileira de árvores [www.iba. org]). The commercialization of eucalyptus for the production of cellulose, paper, laminate flooring, and charcoal contributed to 6% of the Brazilian Sectorial GDP in 2013 (approximately US\$ 20.7 billion) (www.iba.org). Several areas are dedicated to eucalyptus plantations and 2% of all of the locally planted area are found in the State Minas Gerais. The city of Itamarandiba is one of the largest eucalyptus producers in Brazil (ABRAF, 2010). Considering the global market, Brazilian participation in forestry production represents 2%. The country occupies the 11th position in global paper production, representing 2.2% of this market (http://bracelpa.org.br/bra2/?q=en/node/228) and the 7th position in the global cellulose production market, corresponding to 4.2% of the country's participation in this sector. However, Brazil's largest market in the eucalyptus sector is in the lumber trade. With a participation of 4.3% in the global production, the country occupies the 5th position in this sector (http://bracelpa.org.br/bra2/?q=en/node/228).

Brazilian eucalyptus presents a strong potential for expansion in the international market over the next few years. Therefore, in 2015, the first GM eucalyptus (H421) from FuturaGene Brazil Technology, a company associated with the National Research and Development Association of Innovative Companies (ANPEI) was approved in Brazil. The new eucalyptus event aims at improving wood production by producing a protein capable of enhancing the volume of tree trunks (CTNBio, 2015f). This approval provided a new vision for Brazil as a pioneer in the release of GM eucalyptus for commercial purposes.

Biosafety risk assessment the Brazilian case

The use of GM crops in agriculture has exponentially increased during the last decade. The high adoption rate is thought to reflect the growing benefits and satisfaction for the whole food production chain, but public and scientific concerns have arisen regarding the environmental impact and safety of GM crops. Therefore, each country has created a legal framework to evaluate the biosafety and, sometimes, other possible effects of commercialization, including social and economic issues. Thus, in many countries, including Brazil, before GM crops are authorized for commercial purposes, national authorities conduct risk analysis procedures, which vary from one country to another.

Risk analysis includes three main components: risk assessment, risk management, and risk communication (Figure 3). Risk assessment can be defined as the identification of potential health or environmental hazards (adverse effects) and the

determination of the probability that an identified hazard will occur (Organization for Economy Co-operation and Development, 2012). Therefore, biosafety, comprising health and environmental issues, is evaluated by risk analysis.

Risk management can be defined as the measures that must be taken to minimize or mitigate a potential hazard or adverse effect that has been identified in the risk analysis (including monitoring/surveillance) (Organization for Economy Co-operation and Development, 2012). Risk management also includes the process of weighing policy alternatives in the light of the risk assessment results and other relevant evaluations (Johnson *et al.*, 2007). Risk communication is the interactive exchange of information and science-based opinions concerning risk among risk assessors, risk managers, consumers, and other stakeholders (Johnson *et al.*, 2007).

Therefore, risk analysis constitutes an ample activity that considers the information concerning

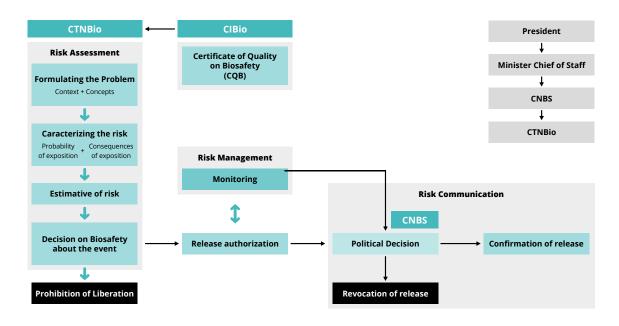


Figure 3. Risk analysis flowchart, including risk assessment, management, and communication (adapted from Wolt *et al.*, 2010). The biosafety risk assessment for commercial release of GM organisms is conducted by the Brazilian Technical Council of Biosafety (CTNBio), the Internal Commission of Biosafety (CIBio), and the National Council of Biosafety (CNBS). The members of CIBio and CTNBio are chosen by the Minister Chief of Staff, under major authorization by the President of Brazil (upper right corner).

the risks to health and the environment (obtained during the risk assessment), as well as the economic, political, moral, and ethical issues. In Brazil, risk assessment is conducted exclusively by the Brazilian National Biosafety Technical Commission (CTNBio), whereas the social and economic aspects of the commercialization are analyzed separately by a Council of Ministers, the National Council on Biosafety (CNBS) (Brasil, 2005; Nordström, 2015), because the social and economic impacts related to the commercialization of GM products often require evaluations that are different from those involving risks to health and the environment.

In Brazil, CTNBio is composed of scientific specialists with Ph.Ds in biosafety, biotechnology, environment, biology, and human or animal health, whereas CNBS comprises only ministers, who have the state legitimacy to assess issues that may have socio-economic impacts in the country. This separation minimizes the eventual ideological influenc-

es on the decision-making process and makes the Brazilian biosafety system pragmatic and efficient.

As a matter of fact, since this regulatory framework was approved in 2005 by the 11.105 Law (Brasil, 2005), approval for the use of GM events in Brazil has rapidly increased, with 50 varieties of GM maize, cotton, soybean, common bean, and eucalyptus authorized for commercialization to date (Figure 4). Consequently, with the adoption of biotechnology in the field, more than 89% of the cultivars are now represented by transgenic plants (Figure 2). In addition to the use of transgenic plants for agriculture, Brazil is also investing in GM vaccines, diagnostic tests, and the production of enzymes, hormones, and biofuels, some of which are produced as recombinant proteins in transgenic plants.

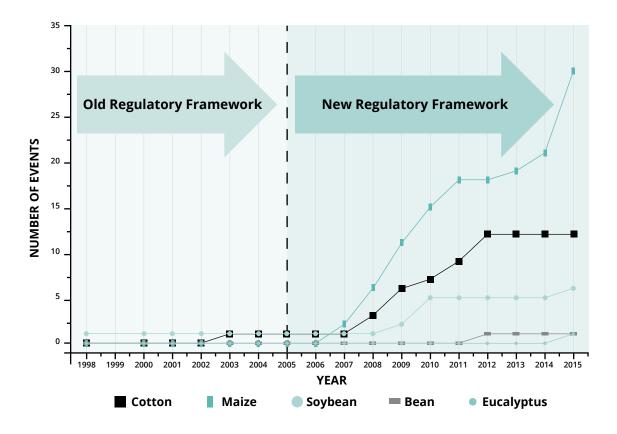


Figure 4. Number of events of GM crops approved by CTNBio for commercial release in Brazil. After the Biosafety Law (Brazil, 2005), the number of authorized varieties started to increase. (Adapted from Paes de Andadre *et al.*, 2012; CTNBio, 2015).

Conclusions

The 2013-14 season marks the 10th anniversary of the use of the first GM seeds in Brazil. The country's farmers now cultivate 50 biotech crop varieties, including soybean, maize, cotton, common bean, and eucalyptus. Following the commercial release of the golden mosaic virus-resistant bean developed by researchers from EMBRA-PA, the Institution is now working in partnership with other countries, including Japan, on several drought-tolerant cultivars, such as soybean, cotton, sugarcane (Saccharum officinarum), maize, and common beans (Ruane, 2013). EMBRAPA plays an important role in the development and future release of GM crops in Brazil, in collaboration with international private companies and research institutions.

Moreover, other GM crop plants with different traits, including GM rice (*Oryza sativa*) with increased yield, GM wheat (*Triticum* sp.) with drought stress tolerance (MAPA, 2013), and GM cotton with insect and nematode resistance, are also being developed in Brazil. Field trials of IR and HT GM sugarcane and GM *Sorghum* (*Sorghum* sp.) with increased sugar accumulation and biomass production will also be approved for cultivation in Brazil within the next few years.

In the last decade, the adoption of GM crops has produced considerable advances in crop management and productivity, which have been accompanied by a remarkable change in the agricultural sector in Brazil that makes it a very competitive market, due to the arrival of large corporations. Consequently, a scaffold of knowledge protection and an enhanced openness of public institutions toward the private sector have become necessary (Lopes *et al.*, 2012).

The majority of the Brazilian territory lies in the tropics, with unique soil and climate characteristics, intense biotic and abiotic stresses, complex farming structures, and diverse patterns of technological infrastructure and logistics. Thus, innovation in genetics and plant breeding to develop improved seeds and adapted production systems

will be crucial for the country, particularly considering the increase in food demand in the predicted scenarios of climate change (Assad *et al.*, 2008; Lopes *et al.*, 2012).

Thus far, the interrelationship between Brazilian entrepreneurial farming and agricultural research has resulted in the rapid implementation of transgenic crops, with clear benefits of their use. Over the next decade, new varieties of sugarcane, citrus (*Citrus* sp.), eucalyptus, and GM crops with traits such as resistance to both nematodes and insects, tolerance to other herbicides, and tolerance to water stress and saline soils are expected to arrive on the market. The future also points toward the creation of transgenic plants harboring enhanced nutritional properties or producing drugs. A prerequisite for these advances will be the continued strengthening of the strategic partnerships between public and private institutions.

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Genetically Modified Crops in Argentina

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Abstract

The story of genetically modified (GM) crops in Argentina is still unfolding and is one the world has paid close attention for over the last 18 years. Currently, the country ranks third, behind the United States of America and Brazil, in GM crop area at the world level. The economic impacts of the introduction of GM technologies in Argentina have been very important. A key factor has been the occurrence of a strong synergy between herbicide-tolerant soybean (Glycine max) and no-till farming practices. The cumulative gross benefits resulting from the use of GM crops from 1996 to 2010 have been estimated at US\$ 72.65 billion. During that same period, 1.8 million jobs have been created as an indirect consequence of the introduction and adoption by farmers of agricultural GM technologies. Thanks to the implementation of these new technologies, the global supply has been estimated to increase by 216.1 million tons over these 15 years. The benefits from this supply shock have spilled over to world consumers, generating savings in food expenditures estimated at US\$ 89.0 billion. The case of GM crops in Argentina has been, undoubtedly, one of success. Long-term sustainability of these production systems as well as a number of institutional issues need to be assessed if the country is to consolidate this achievement.

Introduction

Research and Development (R&D), defined as new knowledge created and applied to increase the quantity and/or quality of biomass produced by human intervention, has driven progress in agriculture throughout history. In many countries with a long-standing tradition as export of agricultural commodities, productivity gains attributable to changes in technology have been higher in agriculture than in any other sector for a good part of the 20th century. That has been the case, for instance, in the United States of America (USA), until the advent of the digital era with computer, communication, and information technology.

The unavoidable increase in the demand for safe and good-quality food of a growing population, which is foreseen to reach 9 billion in 50 years, will challenge science and technology applied to agriculture. Both the attention and hopes of the world are focused on countries and regions with large food surpluses, that is, the biggest players in the international market of agricultural products. Nevertheless, in the less developed nations, the key factors that determine the advances in agricultural development, have implications in the very sensitive issue of food security for urban consumers, in the improvement of the farmers' income, and in an overall prospect of poverty alleviation thanks to the availability of more affordable and safe food. As farmers are price takers, their income is tied directly to the yield of the products under their control. It is in this context that the role of genetically modified (GM) crops in reshaping the world agriculture will be described in this chapter. Argentina's experience offers concrete evidence of the full expression of its potential and of the key role played in this story by a responsible and effective institutional environment. This chapter is based on two reports (Trigo et al., 2009; Trigo, 2011) and looks into the impacts of availability and adoption of GM crops in that country, emphasizing both the benefits for the domestic economy and for the global consumers. In addition, some of the noneconomic advantages will be analyzed, resulting from the adoption of the GM technology by the farmers of Argentina, and some of the underlying drivers behind this process will be discussed briefly.

Evolution of the Argentinean agriculture

The history of agriculture in Argentina over the last century is one that shows a positive long-term trend regarding the area planted with grains and oilseeds (Figure 1). Between 1900 and 2008, this area increased more than five-fold, from 5 to almost 28 million hectares. A strong growth took place in the first three decades, driven mostly by mechanization, which implied a capital-driven process. Both the Great Depression and the restrictive domestic policies induced later a de-

crease in investments in the sector, all severely reducing the cultivated land from 18 million hectares in 1940 to approximately 10 million in 1950. In the 1960s, thanks to the Green Revolution, the improved dwarf wheat (Triticum sp.) varieties and the high-yielding hybrid maize (Zea mays) turned out to be two major technological milestones that steered a renewed innovation-based productivity growth cycle unabated ever since. In 1991, no-till farming (NTF) started to be massively adopted. NTF consists basically on sowing of seeds at the required depth with a minimum disturbance of the soil structure. This is achieved through the use of specially designed machinery to eliminate the need for plowing and other previously required tillage practices. In 1996, the first GM herbicide-tolerant (HT) soybean (Glycine max) varieties were available. These GM crops induced a synergy with NTF of such a magnitude that it surpassed all expectations, vastly outperforming even its counterparts in the USA, the center of origin of both technologies.

As further evidence of the importance of innovation and technology in the history of agriculture in Argentina, Figure 2 shows how both labor and land productivity have evolved between 1908 and 2007. In 1908, Argentina was already a ma-

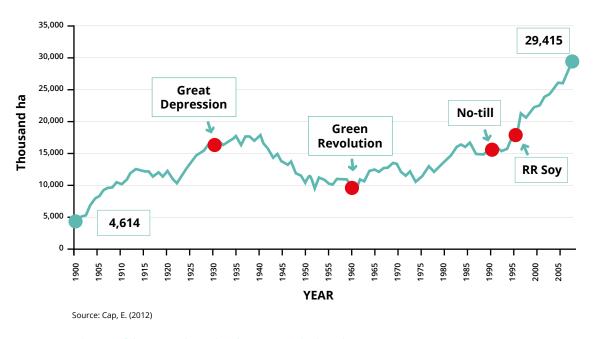


Figure 1. Evolution of the area planted with grains and oilseeds in Argentina (1900-2008) (Cap, 2012).

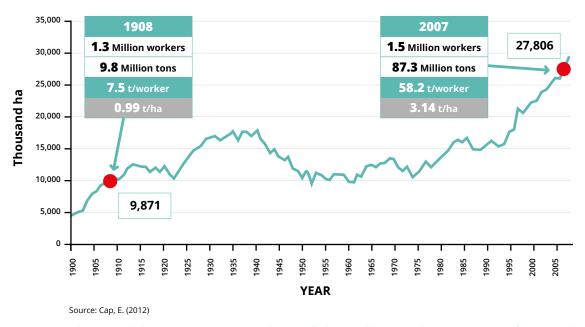


Figure 2. Technological change in Argentina: evolution of labor and land productivity in Tons of grains+oil-seeds per worker and per hectare (1908-2007) (Cap, 2012).

jor player in international agricultural commodity markets: each farm worker produced 7.5 tons of grains and oilseeds and one hectare of land yielded one ton of products. A century later, 58.2 tons of grains and oilseeds were produced per farm worker with a yield of 3.14 tons per hectare.

A study on the sources of the growth in the Argentinean farm sector (Lema, 2010) has confirmed the overwhelming preeminence of technical change among them (Figure 3). From 1963, approximately the start of the second wave of

sustained expansion, to 2009, the agricultural sector recorded a growth of over two-thirds due to increases in the total productivity factor (TPF), the ratio of output and input quantities, a figure rarely seen in farm sectors of Argentina's size. There is one caveat that should be brought up: the reported contribution of land to this process (20%) is most likely an overestimation, because land use expansion cannot always be regarded as linearly independent of technical change. In other words, at least a fraction of that 20% should be credited to innovation, and thus the TPF contribu-

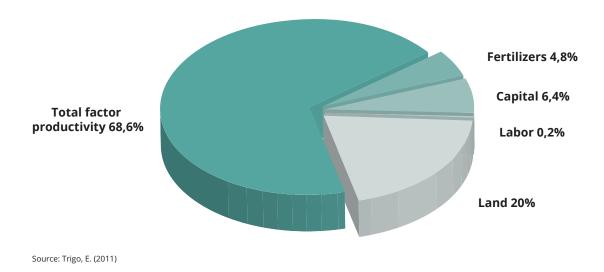


Figure 3. Increase in grains and oilseeds (1968-2008) (Lema, 2010).

tion would even be higher than 68.3%. However, in the current econometric tools used to estimate the TPF, special situations, such as the one described, are not built into the formulas used in the calculations. Theoretical econometricians should probably look into how to remove such methodological restrictions like this in order to improve the existing tools.

Gm crops in Argentina

The story of GM crops in Argentina is still unfolding and is one that the world has been paying close attention to over the last 18 years. This was partly because a number of variables that played a role in this story were simply not found anywhere else. Unexpected synergies took place on a scale never seen before. The sheer magnitude of the figures involved has shaken the foundations of traditional econometric analytical tools. Traditional agricultural economics were at a loss when trying to track and model the causal relationships using those same tools. Prices have not driven this unprecedented shift in the supply of grains and oilseeds, but technological change has and still does, which is one of the reasons why this story has attracted so much attention. In the next sections, we will deal briefly with most of the issues mentioned above.

The first GM crops introduced in the Argentinean agriculture were soybean varieties tolerant to the herbicide glyphosate. These HT varieties were released by the national regulatory authority and, subsequently, made commercially available in the 1996/1997 crop season. Since then, 20 additional events have been approved for commercialization, planting, and consumption as food, feed, or fiber, including 15 HT, insect-resistant (IR), and HT-IR maize varieties, three HT, IR, and HT-IR cotton (Gossypium hirsutum) varieties, and two soybean varieties resistant to herbicides other than glyphosate. Since the creation in 1991 by the Argentinean Government of the National Advisory Commission on Agricultural Biotechnology (CONABIA), 1,721 applications for field trials have been granted. Maize, soybean, cotton, and sunflower (Helianthus ...) are the crops with the greatest number of implemented field trials, followed by wheat, rice (Oryza sativa), potato (Solanum tuberosum), and alfalfa (Glycine sativa). In terms of traits, there has been an important evolution from single traits (HT and IR) to combined or stacked traits that clearly prevail, a trend also observed elsewhere around the world (James, 2010). The vast majority of technologies subjected to field trials were of foreign origin. In the 2010/2011 crop season, the technologies were applied on nearly 22.9 million hectares, of which 19 million were cultivated with HT soybean; 3.5 million hectares with GM maize, of which 1.6 million with IR traits, 300,000 with HT ones, and 1.6 million with both traits stacked; and 614,000 hectares with GM cotton, of which 56,000 HT, 8,000 IR, and 550,000 with both traits stacked (Consejo Argentino para la Informacíon y el Desarrollo de la Biotecnología; www.argenbio.org). These figures represent approximately 100%, 86%, and 99%, of the total area planted with soybean, maize, and cotton, respectively (Figure 4).

These numbers place Argentina third, behind the USA and Brazil, in GM crop area at the world level, followed immediately by India and Canada (James, 2010). This adoption dynamic is almost unprecedented in the history of the world agriculture and it is only comparable to the path followed by the adoption of hybrid maize into the State of Iowa (USA) in the 1930s. Even within the boundaries of the Argentinean experience, the evolution of the use of GM technologies by its farmers parallels very positively with other innovative plant materials, such as wheat with Mexican germplasm, developed by the Center for the improvement of Maize and Wheat (CIMMYT), and that gave rise to the "Green Revolution" and hybrid maize. Both events took place a few decades earlier (Figure 4). It took 27 years for Argentinean farmers to adopt hybrid maize at the level reached for GM maize after only 13 years and 12 years were needed to adopt Mexican wheat 12 years, whereas in just four planting seasons the same adoption level was reached at the farm level for soybean, i.e. 90% of total planted area. It is worth noting, however, that none of the major technologies involved was a product of the local R&D system. All the GM technologies that received approval for commercial use were created by multinational seed companies and introduced into the local genetic pool. The predominance of foreign technologies has remained unchanged since the first HT soybean varieties were introduced for field testing during the early 1990s. Still no applications for field test permits have been filed for locally developed innovations in any of the major crops. This caveat notwithstanding, there is a wide consensus that the strength of local breeding programs and the existence of a consolidated seed industry have played a key role in the rapid diffusion and adoption of these new technologies.

The impact of GM technologies on the economy of Argentina

The economic impact of the introduction of GM technologies – HT soybean in particular – in Argentina has been very important, not only due to the reduction of production costs, but also because they provided a renewed thrust to a

growth cycle in agriculture. That started some years before thanks to economic incentives, such as elimination of export taxes and reduction or elimination of import duties on farm machinery, which made investment in a new technology easier and more affordable for farmers. Another key factor was also the strong synergy between HT soybean and NTF practices. Indeed, shortening the idle time between harvests of wheat and sowing of soybean enabled double cropping through the use of short-cycle soybean varieties in regions where this land productivity-enhancing management system had not been feasible until then. This real example lends support to the hypothesis of the implicit assumption that the expansion of cultivated land on the one hand and changes in factor productivity on the other hand are linearly independent. The net effect of this synergy has been the emergence of a significant "virtual" growth in total planted acreage without an actual increase in the available of arable land. This expansion in cultivated land has been estimated in the range of 3.5 million hectares and has been

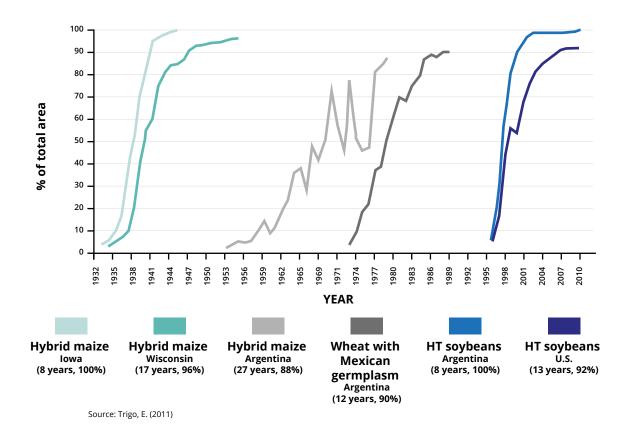


Figure 4. Adoption rate of the different GM technologies versus other technological milestones (Trigo, 2011).

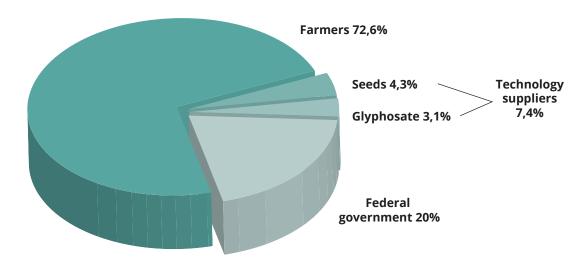
undoubtedly one of the main economic determinants in the farmers' adoption of the new technologies. This favorable shift has been reinforced by the free fall in the price of glyphosate from US\$ 10/liter by the end of the 1990s to less than US\$ 3/liter in 2000, as a direct effect of the patent expiration and the occurrence of new suppliers on the market. At the same time, these new technologies made soybean strongly competitive with other crops, such as maize and sunflower. In turn, livestock production (beef and milk) induced an intensification process that, in the end, increased productivity in these other farm activities that compensated for the area reduction and sustained the output levels achieved before the soybean expansion had occurred. During the 1996-2005 period, the area with pastures (both natural and planted) has been estimated to have suffered a reduction of more than 5 million hectares while the supply of beef and milk remained stable (Trigo and Cap, 2006). These productivity increases have not been recorded in the statistics because the yield indicators commonly used, namely the slaughtered beef heads/year and the volume of milk for dairy, are computed without reference to the area on which that output is produced.

In this context, the cumulative gross benefits for Argentina resulting from the use of GM crops during the period 1996/1997-2010/2011 have been evaluated to amount to US\$ 72.65 billion, of which US\$ 65.44 billion from HT soybean (US\$ 3.52 billion from the reduced production costs and US\$ 61.92 billion from the expanded cultivated acreage), US\$ 5.38 billion from the use of IR and HT maize (single and combined events), and US\$ 1.83 billion from the use of IR and HT cotton (single and combined events). The bulk of these benefits (72.67%) went to the farmers, whereas the input industry received approximately 7.38% of the grand total and the Federal Government - thanks to revenues from export duties - the remaining 19.95% (Figure 5). Regarding the crops, the benefit distribution follows a similar pattern, namely farmers cultivating soybean and maize captured 72.4% and 68.2% of the grand total, respectively. However, the benefits of the supplier sector differ mostly in the plant propagation patterns of each crop – open-pollinated soybean and cotton varieties versus maize hybrids - and the status concerning the intellectual property rights (IPRs). The original HT genes were not granted patents in Argentina: ASGROW, the seed company that held those IPRs at the time of the commercial release of the GM soybean varieties, failed to file an application with the regulatory authorities. For an extensive discussion on the situation regarding IPRs, see Trigo et al. (2002). Moreover, the farmers had the opportunity to save grain by using an open-pollinated plant species, such as soybean, as seed in the following planting season. This right had been granted by the provisions of the 1978 International Convention for the Protection of New Varieties of Plants, to which Argentina adheres. Thus, the lack of patents and the grain saving became a strong incentive for an illegal seed market, both for soybean and cotton seeds, but not for maize. Indeed, hybrid seed production results from crossing genetically homogenous parent lines that are not available outside the seed company itself and, thus, precludes the option available to soybean and cotton farmers. The effect of the differences among these GM crops was that seed companies gained 19% of the total benefits in the case of maize, but only 3.2% and 3% in the case of soybean and cotton, respectively (Trigo, 2011).

In addition to the direct economic benefits reported above, the introduction of GM crops into Argentinean agriculture has also had, through a set of multipliers, a significant economy-wide impact, particularly in terms of job creation. During the 1996-2010 period, 1.8 million jobs were created as an indirect effect of the introduction and adoption by farmers of agricultural GM technologies in Argentina (Trigo, 2011). For the job creation estimates, each additional dollar in goods generated by the adoption of GM materials (valued at border price, i.e., FOB prices at Argentine Ports) was supposed to generate another dollar in the services sector (transportation, storage, etc), according to a procedure based on the actual "cost" of adding one job to the economy for each year during the

period under analysis in terms of GDP. For this exercise, a baseline stock was assumed of 10 million jobs in 1996 (when GM soybean was released) with annual cumulative increases or subtractions to account for the evolution of GDP along the different stages of the economic cycle (for details on the procedure and the complete estimation, see Trigo, 2011). This figure in itself is impressive, considering the relatively small size of the economy of Argentina, which has a workforce estimated at 17 million in 2010. Its relevance is further empha-

sized when one considers that the period under analysis includes the crisis years of 2001-2003, in which the fixed peso-dollar exchange rate that was pegged at a value of one was abandoned, the public debt was 100 billion dollar, the economy shrunkened by 10.9% in 2002, and the unemployment rate skyrocketed to 21.5% (Instituto Nacional de Estadística y Censos; www.indec.mecon.ar).



Total Benefits 1996-2010: 72,4 Billion US\$

Source: Trigo, E. (2011)

Figure 5. Soybeans: distribution of the cumulative benefits (1996-2011) attributable to the adaption of GM HT technology in Argentina. (Trigo, 2011)

The analytical tool used to estimate the economic impacts of GM events is based on a dynamic Simulation Graphical Modeling and Analysis (SIGMA) model, developed by the Instituto Nacional de Tecnología Agropecuaria (INTA). The model replicates situations that occur in the field in countries with a great diversity in technological and productive realities not due to agro-ecological differences but mainly to socio-economic factors. The key component of the model is the replication of the farmers' adoption process of innovations that introduce changes into the production function, inducing a more efficient use of resources, in turn, increasing crop yields, and/or reducing costs, and/or improving the product quality, and/or expanding the potentially suitable area for its commercial production. The model may be used for ex-ante and ex-post studies. The final result is an estimate of the effects of alternative technology generation and adoption scenarios (regional or national) on the total aggregate output. SIGMA calculates the social rather than the private benefits, namely how much more (both in volume and value) when compared to the baseline can be produced due to the adoption of technologies already available on the market or to be generated in the future by the R&D system (for details, see Appendix I; Trigo. 2011).

Noneconomic benefits

The expansion of GM crops in Argentina has moved along with an impressive acreage increase under NTF. This NTF is particularly meaningful for its environmental impacts since, on the one hand, it has enabled to partially reverse the negative effects (externalities) of conventional tilling and plowing practices on the physical structure of Pampean soils (Viglizzo *et al.*, 2010) and, on the other hand, to significantly improve the energy balance in the agricultural sector (Pincen *et al.*, 2010).

NTF began to be utilized in Argentina by the end of the 1980s, because the cumulative effects of both water and wind erosion were already manifest in many of the most fertile areas of the Pampas. Continuous farming based on traditional tilling practices and without pasture rotations due to their low profitability (Secretaría de Agricultura, Ganadería y Pesca y Consejo Federal Agropecuario, 1995) resulted in decreased yields. Therefore, the impact on the economic viability of farming, together with an enhanced availability of state-of-the-art no-till sowing equipment, thanks to the deregulation and opening of the economy, and

the reduction in direct costs due to the elimination of tillage practices, were ideal to launch the diffusion of NTF that, in turn, led to an increased productivity that made up for a portion of the losses incurred until that time. However, it was not until the introduction of HT soybean that the process gained momentum and NTF consolidated itself as the predominant soil management strategy in farms all across the country (Figure 6). The NTF are evolved from approximately 300,000 hectares in 1990/1991 to nearly 25 million hectares at the present time (for an in-depth discussion on this process, see Trigo et al., 2010). The combination of NTF and HT soybean integrates two technological concepts: one that consists of new mechanical technologies that modify the soilcrop interaction and one that is based on the use of a total herbicide (glyphosate), which is highly effective in eliminating a wide array of weeds virtually without residual effect. Glyphosate persists in the soil between 12 and 60 days, it carries a low polluting risk of underground waters, it is mildly toxic on animals, and it does not accumulate in animal tissues (Pincen et al., 2010). The combined use of mechanical technologies and total herbicides imply an increase in the use of inputs, gen-

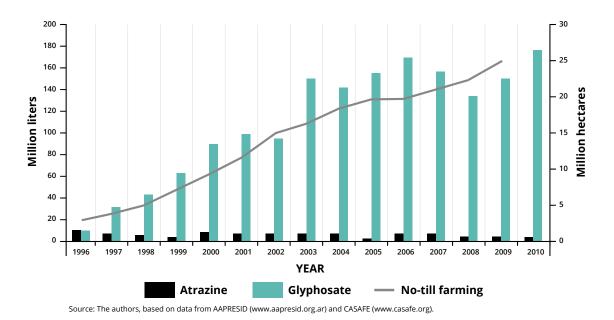


Figure 6. Evolution of planted area with NTF and type of herbicide used.

Based on data from the Asociación Argentina de Productores en Siembra Directa (www.aapresid.org.ar) and the Cámara de Sanidad Agropecuaria y Fertilizantes (www.casafe.org).

erally described as "hard" intensification (Figure 6), but this intensification is, at the same time, environmentally friendly because it has resulted in a parallel reduction in the use of other herbicides with high residual effects, such as atrazine. Although the benefits of the synergy between HT soybean and NTF are difficult to quantify, the potentially positive effects cannot be ignored on soil fertility and, thus, on present and future land productivity as well as other promising effects, such as contribution to the mitigation of the so-called "greenhouse effect" (thanks to reduced emission levels NO₂). Regarding the organic matter content of soils, in NTF systems with crop rotations, including wheat, maize, or sorghum, the annual soil losses are under 2 ton/hectare, a value much lower than the tolerable maximum of 10 ton/hectare and below the levels recorded under other soil management practices (Casas, 2006).

Between 1996 and 2009, the total fuel consumption in soybean farming in Argentina increased by 201.3 million liters (95.1%), from 211.6 to 412.9 million liters/year, but the average consumption per hectare dropped by 38%, from 35.8 to 22.2 liters/hectare, implying a decrease in carbon dioxide emission of 5.19 million tons when compared to what would have been emitted if soybean cropping had been based on conventional tillage practices (Brookes and Barefoot, 2011). On an annual basis, this figure represents a reduction of 13.5 million liters of fuel. Similar effects have been reported regarding the carbon sequestration impact, resulting from the use of reduced or no-till soil management practices: the total cumulative amount of carbon sequestered over the 13-year period was estimated at 13.82 million tons (Brookes and Barefoot, 2011). Impacts of the same nature have been described for maize and cotton, but with a lower magnitude, because the planted area planted and the time elapsed since these technologies had been made available to farmers differ significantly from the values recorded for soybean.

Sustainability issues associated with the soybean expansion

The above mentioned synergies and benefits do not necessarily mean that one should ignore the potential risks associated with the massive transformation of farming systems that appears to have been triggered by the introduction of GM crops into Argentina during the mid-1990s. Particularly important are the extensive losses of soil nutrients, as a consequence of the increasing predominance of monoculture (especially in the case of soybean) and the relatively low fertilization levels recorded in Argentina. Moreover, the potential negative effects of the more fragile ecosystems of the new agricultural frontier in the Northeastern and Northwestern sub-humid areas that have gradually become suitable for growing soybean and, thus, have increased the acreage of arable land. The environmental effects due to changes in land use patterns are a pertinent issue that falls beyond the scope of this chapter. It is worth pointing out that, even though soybean represents a core component of present-day cropping systems without pasture rotations, this process had started long before soybean became predominant in the farming scene of Argentina. Most of the areas where soybean is grown now had previously been planted with other crops. Changes in rainfall patterns that enabled crop cultivation on land where was not possible before, have been identified as one of the probable drivers in this process (Grau y Gasparri, 2005). Regardless of these facts, which should be further analyzed and discussed, sustainable farming strategies are highly relevant, given the magnitude of the figures involved. The key issue that needs to be addressed is the long-term effect of the continued "export" of soil nutrients, particularly phosphorus, because replacement is either nonexistent or insufficient. Recently, soybean has been found to positively respond to phosphorus fertilization with an increase of 500 to 730 kg per hectare. The cumulative amount of phosphorus "exported" between 1996 and 2010 has been estimated at more than 14 million tons of triple super phosphate and the restocking cost for this particular nutrient for the entire 15-year period

under study at US\$ 7.95 billion (Trigo, 2011). This obviously large figure accounts only for 8.41% of the total cumulative benefits accrued for the 1996-2010 period.

Contributions to global food security

Argentina is one of the main players in the international soybean market - it is the third largest producer, exporting almost 100% of its production; thus, in addition to the impact on the country's own economy, positive effects can also be identified at the global level through contributions to the enhancement of food security. The implementation of the new technologies by Argentinean farmers has been evaluated to result in an increase in global supply of 216.1 million tons over a 15-year period, which would account for 22.53% of the world's cumulative increase in soybean production for the same period (Trigo and Cap, 2006; Trigo, 2011). In turn, it leads to international market price levels that were significantly lower than those that would have prevailed without them (Trigo and Cap, 2006; Trigo, 2011). The estimation was based on the supply price flexibility of soybean that measures the response of prices to changes in output with 0.80, using as a starting point for the supply price elasticity of soybean in the USA, the world's biggest producer, implying (given that certain assumptions hold) a price flexibility value of 1.25 (for a more complete discussion of the methodology and calculation process, see Trigo and Cap, 2006). In these terms, the total benefits to world consumers - had Argentina not adopted the new technologies and had its farming patterns remained unchanged - represent savings in consumer expenditures of US\$ 89.0 billion for the 1996-2010 period. Whether these savings have effectively been passed to the consumers or have been captured totally or partially as rent by the other links in the value chain remain to be seen. Notwithstanding, GM technologies have a considerable potential with implications concerning issues of welfare economics.

Conclusion

The parallel story of GM crops and NTF soil management technologies in Argentina has been, undoubtedly, one of success, but it also highlights a set of issues that should be addressed. The economic benefits obtained by the farmers, either directly or indirectly, by many other players in multiple value chains, and by the federal government (generating funding for a potential increase in the supply of public goods) have crossed over the geographical boundaries to overflow onto world consumers. This complex web of impacts has resulted from the adoption of these technologies by the Argentinean farmers, but it also identifies some of the necessary conditions that should be met by a country to be able to benefit from their availability, which may have little to do with its own R&D capacities. A key feature in this story is the fact that Argentina has adopted very early on the available innovations. This behavior was possible because the institutions were already in place that allowed almost immediately diffusion and transfer of these technologies to the farmers. By the early 1990s, both the biosafety regulations and the infrastructure required to assess effectively the GM technologies existed; furthermore, a very proactive and efficient seed industry enabled the rapid introduction of the new traits into commercial varieties that were already well adapted to the multiple agro-ecological conditions in the different growing areas and contributed to their rapid diffusion. Had these particular features not have been present, this story would, most likely, have been less successful. The bottom line of this case leads us to conclude that, at least at the present state of GM technologies, biosafety institutions and a well-functioning seed market in place seem to be more important than a well-endowed local R&D apparatus to generate innovations. As GM technologies seem to "travel well", it is essential for any country to have the right tools in place at the time of their availability to extract the maximum benefits.

Another relevant issue deals with the noneconomic implications of the introduction of these technologies. The synergies between GM tech-

nologies and no-till practices have contributed to generate a "win-win" outcome, combining increases in productivity and output with positive microand macro-environmental impacts. Nevertheless, there is still need to recognize that alongside this virtuous cycle, there are other not so clear-cut issues merit a closer look, given the magnitude of the changes described. The dramatic expansion of the area planted with soybean and the increase in output of grains and oilseeds as a whole have brought about important benefits, but have also induced a shift in land allocation that raises questions about the long-term sustainability of the current farming system, due to the detrimental effects on soil nutrient levels and the potentially negative impact on fragile ecosystems. Although these concerns are legitimate, they do not detract from the clearly positive net balance of the first 15 years of GM crops in Argentina. However, they do highlight the need for appropriate policy responses aimed at optimizing the management of this particular kind of innovations. GM technologies are groundbreaking events and for a successful implementation at the farm level they require adequate biosafety and IPR frameworks for a successful implementation at the farm level.

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Genetically Modified (GM) Technology for Sustainable Agriculture in Central America

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Abstract

The use of genetically modified (GM) crops has exploded over the last decade worldwide. In 2012, developing countries increased their share of the global cultivation of biotechnology crops to more than 50% of the total, a trend expected to persist in the future. In Latin America, farmers in 11 countries planted more than 70 million hectares of GM crops in 2014. The technology has been embraced wholeheartedly by the largest and wealthiest countries, such as Brazil and Argentina, but the adoption rates and policy approaches to GM crops within the less-developed Central American countries differ and can provide a window into the future of the GM Revolution. Whereas Costa Rica has embraced various projects, Nicaragua and Honduras, the two countries with the largest land areas in Central America are on opposite ends of the spectrum when it comes to growing GM crops. Furthermore, anti-GM groups have expended great energy to ban biotechnology crop production in the Central American region. Here, we give an overview of the GM experiences in Costa Rica, Honduras, and Nicaragua and propose recommendations for improving public and private Research and Development (R&D) to enhance the contribution of GM technology to support sustainable agriculture in the region. In addition, we discuss the challenges that hamper the abilities to create food security while protecting the environment. We also stress the need for scientists to create awareness among the public about the scientific facts regarding GM organisms.

Introduction

Over the course of thousands of years, agricultural practices have developed a broad spectrum of food options. Scientific advances in molecular biology and, more recently, the application of modern biotechnology into agriculture, have steadily improved plant yield and product quality. This result has been accomplished by means of both traditional plant breeding and so-called genetically modified (GM) technology. Unlike traditional plant breeding methods, in which hundreds of unknown genes are often transferred from one plant to another, GM technology allows the precise and efficient transfer of known genes that confer resistance to pests, diseases, herbicides, and environmental stress to an otherwise unprotected host. It offers opportunities for improving the overall nutritional characteristics of food by controlling quality traits, such as superior post-harvest storage and nutritional content (Nap et al., 2003). Yet, surprisingly, anti-GM groups insist that the precision of GM technology is inherently more dangerous than the wholesale transfer of

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unknown genes between hosts. Modern biotechnology now plays a crucial role in food production and it is progressively considered a key instrument for increasing and improving sustainable agricultural production, decreasing poverty and hunger, and boosting food security. GM technology is desperately needed in the developing world, but much less so in developed countries where hunger is less of a problem.

Since the first commercial release of a GM crop in 1996, more and more farmers have adopted the technology annually. GM crops are planted in 28 countries, covering 181.5 million hectares worldwide. Twenty years later, developing countries grow more hectares of GM crops than developed countries (James, 2014) and the GM crop fraction is projected to increase dramatically, especially in developing countries (Wieczorek and Wright, 2012). Argentina and Brazil are among the world's largest developing countries producing GM crops. As of 2014, eleven countries in Latin America have approved GM crops for various purposes, namely Argentina, Brazil, Bolivia, Chile, Colombia, Costa Rica, Cuba, Honduras, Mexico, Paraguay, and Uruguay.

Below we describe the GM situation in Central America, focusing on the regulatory rules and policies implemented in Honduras, Costa Rica, and Nicaragua and propose recommendations for improving public and private Research and Development (R&D) to increase the contribution of GM technology toward improving sustainable agriculture in the region.

The situation in Central America

Nicaragua

There is no commercial production of GM crops in Nicaragua. However, for a number of years Nicaragua has authorized the import of GM soybean (*Glycine max*) meal and GM corn (*Zea mays*) for animal feed. According to a United States Department of Agriculture (USDA) report from the Global Agricultural Information Network (GAIN), in 2014, Nicaragua imported over 154,500 met-

ric tons (MT) of GM yellow corn from the United States with a total value of US\$ 40.7 million and the GM soybean meal imports in the same year reached over 80,000 MT with a total value of US\$ 39.6 million (http://gain.fas.usda.gov/Recent GAIN Publications/Agricultural Biotechnology Annual_Managua_Nicaragua_7-14-2015.pdf). There are no known reports on Nicaraguan imports of other biotechnology or "biotech" crops from the US or other countries.

The import of GM grains was first approved officially in 2005. The Ministry of Agriculture and Forestry (MAGFOR) issued a ministerial resolution (no. 034-2005, now expired) in response to a request from grain importers. The resolution was granted with the specific objective of allowing the import of 15 GM corn events for animal feed, renewable on a yearly basis.

From 2005 on, the Nicaraguan government started requiring notification of imports of GM organisms to comply with the provisions of the Cartagena Protocol on Biosafety (Secretariat of the Convention of Biological Diversity, 2000), of which Nicaragua is a signatory. Among the new requirements, companies interested in importing biotech crops are obliged to apply and file a risk analysis of a GM event prior to its import. In 2010, the Nicaraguan Parliament approved Law 705 on "The Prevention of Risks from Living Modified Organisms through Molecular Biotechnology". Its application, however, has been restricted due to a lack of procedural norms necessary for its implementation. Indeed, although the Nicaraguan Government approved the import of GM corn in 2005 through the ministerial resolution 034-2005, the legal framework for Law 705 for the regulation of GM plants and animals has yet to be completed.

Law 705 introduces a wide-ranging, science-based platform for regulating the use of living GM organisms in a broad spectrum of instances, including confined use, research, release into the environment, commercialization, propagation and evaluation of field production, transportation, transit, import, and export, that are all destined for hu-

man consumption or for processing and animal feed. This law not only controls the usage of GM crops for all agricultural purposes, but also for bio-medication, conservation, preservation, and other uses linked to biological diversity.

In keeping with Law 705, the National Committee on GMO Risk Analysis (CONARGEN) was created to regulate entry of GM crops and to determine their possible presence in the country. CONARGEN includes officials from MAGFOR, specifically the Chief Director of the General Direction for Animal and Plant Health Protection (DGPSA) and from the Ministry of the Environment and Natural Resources (MARENA). In 2014, DGP-SA was renamed as the Institute of Agricultural Health and Protection (IPSA). The presidency of CONARGEN alternates each year between these two government agencies. Other members are representatives from the Nicaraguan Institute for Agricultural Technology (INTA), the Ministry of Health (MINSA), various universities, such as the National Agrarian University (UNA) and the University of Central America (UCA). There is one representative from the private sector and one from the environmental nongovernmental organizations.

Costa Rica

Since 1992, Costa Rica has been cultivating biotech crops for seed production, specifically cotton (Gossypium hirsutum) and soybean with all seeds destined for export, although there are currently no central government restrictions on planting GM crops for domestic seed production. The acreage for biotech crops peaked in 2009 at 1,697 ha, including approximately 1,500 ha of soybean alone. However, it is estimated that in 2015 only 300 ha were planted with GM crops (USDA GAIN report; http://gain.fas.usda.gov/Recent GAIN Publications/Agricultural Biotechnology Annual_San Jose_Costa Rica_7-15-2015.pdf), of which a large majority was planted with GM cotton destined for propagation of planting seeds and export to the United States. Costa Rica produces GM cotton and soybean seed entirely for export and not for local consumption.

Overall, in Costa Rica the procedures for obtaining authorization from the government to plant GM varieties are uncomplicated and do not obstruct production. Projects and events are approved on a case by case basis without specific legislation for biotech products for food consumption, animal feed, or food processing. Costa Rica runs projects to bring to market the red-fleshed GM "Rosé" pineapple (*Ananas comosus*) of Del Monte (patent pending).

Imports of GM grains and soybeans for animal feed production are evaluated with the same procedures used for the importation of any other agricultural product and follow the technical requirements established by the Cartagena Protocol on Biosafety, a supplementary agreement to the United Nations Convention on Biological Diversity of 1993 (Mackenzie *et al.*, 2003).

However, in 1990, Costa Rica established the National Technical Biosafety Commission (NTBC) under the leadership of the Ministry of Agriculture. Under the law, the NTBC has the power to regulate import and cultivation of biotech crops, including export, research, testing, movement, propagation, industrial production, marketing, and use of transgenic and other GM organisms for agricultural use (Animal and Plant Health Protection Law 7664 of April 1997). Nevertheless, new legislation is under consideration that may pose a threat to future developments in biotech agriculture.

Honduras

Since 1998, Honduras has planted GM maize. Although the country produces only a minor fraction of the global biotech crop yield (0.001%), its positive GM experience illustrates the potential value of GM technologies for developing countries, in general, and for Central America, in particular. Honduras was the first country in Central America and one of only five countries in Latin America to allow field trials and commercial production of GM crops (USDA GAIN report; http://gain.fas.usda.gov/Recent GAIN Publications/Agricultural Biotechnology Annual_Tegucigalpa_Hon-

duras_7-8-2015.pdf). In 2014, Honduras planted 34,000 ha for the commercial production of GM corn, including several field trials of new GM varieties. GM corn is commercialized within the domestic market and exported to various countries, including the US, Colombia, and Argentina. Honduras also imports GM soybeans and corn to supply poultry, livestock, and fishery enterprises.

Honduras has a science-based agricultural biotechnology regulatory system that is increasingly used as a good example for biotechnology policy and regulations by other countries in the region. The current administrative policy is empowered by the Phytozoosanitary Law of the Ministry of Agriculture and Livestock (SAG), modified as part of the Central American-Dominican Republic Free Trade Agreement (CAFTA-DR), and regulated by the Biosecurity Regulation with Emphasis in Transgenic Plants. Additionally, Honduras ratified the Cartagena Protocol in 2008 and has established specific regulations concerning the intellectual property protection of plant varieties as of 2012.

The National Service of Plant and Animal Health (SENASA) within SAG is responsible for designing the regulatory framework for agricultural biotechnology. SENASA relies on advice from the National Committee of Biotechnology and Biosecurity whose members are experts from the public and private sectors.

Biotechnology can be used as a developmental tool in Central America

In less developed countries, such as those in Central America, the success of agricultural biotechnology will depend on sufficient institutional support to foster private sector investments and on stimulation of public efforts, mainly at universities, to assess and adapt the technology to the specific regional needs.

In 1998, the Honduran government introduced a concerted strategy to promote agricultural biotechnology, facilitating commercial production and field testing. The high adoption rate of GM

crops in Honduras may be interpreted as a reflection of farmer satisfaction and benefit for the whole production chain. Data from a study comparing non-GM corn (traditional or hybrid) with closely-related GM corn revealed a significant increase in yield for the GM corn. The maximum yield per hectare was 2.7 MT for traditional corn, 3.6 MT for hybrid corn, and 8.0 MT for GM corn.

Corn is an important food staple in Central America and is cultivated for local trade within each country. For a large majority of farmers, however, it is intended for household consumption. The average yield of approximately 2 MT per hectare in Central America is one of the lowest in Latin America. This low yield has various causes, including poor soil fertility and insect damage. Therefore, insect-resistant GM corn would present an alternative to chemical controls, especially benefiting small farm holders.

Costa Rica is the only Central-American country that has engaged in the development of locally designed GM crops, carrying out laboratory and glasshouse-based research for this purpose. Currently, Costa Rican scientists are involved in research aimed at the development of GM rice resistant to virus and herbicides, banana (*Musa* sp.) resistant to black Sigatoka, and pineapple with increased antioxidant content. It has been reported that field testing of biotech pineapples, bananas and rice are at the confined-field trial phase.

This progress in agricultural research, which may be explained by governmental commitment to education, science, and innovation, however, conflicts with the slow adoption of commercially cultivated GM crops when compared to Honduras. Although Costa Rica appears at the forefront of domestic GM product development in Central America, the farmers seem to benefit the most in Honduras.

In the late 1990s, Nicaragua took the lead in efforts to develop biotechnology. Since 2000, the UCA at Managua has been organizing and hosting international biotechnology conferences in the

region with world-renowned scientists, informative presentations, and networking opportunities for the scientific, nonscientific, and student communities as well as coordinating field trips to local sites of scientific interest. The keynote speaker of the 2008 Conference was Professor Marc Van Montagu (Ghent University, Belgium), who, together with Jeff Schell, discovered a natural vector for plant transformation and created a procedure to produce transgenic plants. The Molecular Biology Center at the UCA collaborates with Professor Van Montagu, now at the International Plant Biotechnology Outreach (IPBO) (Ghent, Belgium), to enhance human capacities, training, and education in plant molecular biology and biosafety in Central America.

Similarly, and more recently, Honduras has also been promoting agricultural biotechnology through a series of seminars focused on scientific studies regarding the use of biotechnology. In 2012, Honduras hosted a regional biotech outreach program focusing on food security, biosafety, and agricultural development. This event, attended by officials and scientists from all Central-American countries, was aimed at strengthening the development and safe use of agricultural biotechnology as a strategic platform for increasing productivity and competitiveness in agriculture. One of the key commitments from this meeting was to develop a common vision between agricultural and environmental policies in the region. A number of regional and international institutions collaborate in these efforts, including the Public Research and Regulation Initiative (PRRI), the International Food Policy Research Institute (IFPRI), the Service for the Acquisition of Agri-biotech Applications (ISAAA) and the Inter-American Institute for Cooperation in Agriculture (IICA).

Improving public and private R&D to boost sustainable agriculture in the region

A framework for improving public and private R&D (capacity building) in Central America would greatly enhance sustainable agriculture and food security

in the region. Biotechnology is a sine qua non of the modern knowledge society. Developing countries create capacities in biotechnology as part of their growth strategies. In Central America, a sizable share of research and innovation is conducted within public institutions. Strengthening the scientific and technical capacities of universities and institutes will enable them to play a more important role in GM research relevant to the needs of the countries and to assimilate new technologies that otherwise offer limited incentives for the international private sector. Public institutions are in an advantageous position, because they are often closely linked to end-users of agricultural technology products, such as farmers and local rural government agencies. Furthermore, by facilitating the participation of publicly funded research institutions in the GM crop development process, the developing countries will probably reap the benefits of agricultural biotechnology rapidly and efficiently and with a more sustainable development approach.

Foreign donors and lending institutions (such as the World Bank and the Inter-American Development Bank) could provide support for the development of GM varieties and traits in Central America via public-private partnerships to address strategic development needs, including those of resource-poor farmers. At the same time, the governments of the developing nations should also contribute their own funds to reduce the dependence on industrialized countries and to retain decision-making control regarding fundamental agricultural research and development priorities.

Biotechnology R&D is an expensive enterprise. Placing a new GM product on the market can cost in the range of US\$ 1.5-4.5 million and even up to US\$ 15 million (Traxler, 2001). This large financial investment represents a major limitation for less developed countries. Therefore, it might be advisable to establish international cooperations with large corporations as a regional block to profit from this technology. This strategy could create the foundation of a continuous local biotech development.

Most developing countries have limited or no research experience with GM organisms and agricultural research in general is mostly inadequate. One way around this dilemma would be to identify and employ existing new technologies with the intention of developing local capacity to innovate new products. Honduras and Argentina have been doing this successfully. In the case of Argentina, genes generated in the US were introduced into the local germplasm base for both soybeans and corn (Burachik and Traynor, 2001).

Stimulating biotechnology R&D in the developing world is an arduous task. Countries must balance, among others, between a complex set of economic, social, and political goals with insufficient resources and a host of environmental and scientific needs. Relevant priorities in terms of policy can be identified through technology assessment that contemplates different biotechnology options, while establishing core economic and social goals. The channeling of biotechnological development toward sustainable growth and food security must take into account the wider environment available to facilitate the technology, as well as the possible impacts of specific GM crops on rural livelihoods. Moreover, for biotechnology to succeed in enhancing food security in Central America, governments may want to establish guidelines requiring that new GM varieties introduced into the country demonstrate direct benefits for rural development, such as enhanced crop yields; along with research on agronomic and soil conditions in the areas where new GM crops are planned.

Ideally, developing countries would design a comprehensive plan to support not only the regulatory framework and implementation, but also the development of biosafety and biotech policy. National Academies of Sciences have been shown to play an important role by facilitating debates and building consensus among various stakeholders, because they are trusted institutions that address contentious GM issues (Aerni and Bernauer, 2006).

In Central America, the development of agricultural biotechnology and specifically of GM crops must be carried out via a sustainable approach to agriculture that faces the specific challenges and opportunities brought about by these modern technologies. The appropriate methodology would be strengthened by considering economic benefits within a broader framework of sustainability. Indeed, agricultural biotechnology has remarkable potential to lower the environmental impact of farming through limitation of chemical treatments on farms, stimulation of no-tillage farming practices, reduction of soil erosion, and efficient intensification by producing more food on less land.

Appropriate policies should be established through good governance, ensuring that they act as a tool for sustainable development to conserve the environment for future generations. For instance, governments could provide funding for public universities to support public-interest research on crops considered crucial for society (Huffman *et al.*, 2006) and they could endorse institutional mechanisms to facilitate access to information and critical knowledge, while addressing intellectual property protection (Graff and Zilberman, 2001; Atkinson *et al.*, 2003).

Agricultural biotechnology could also be used to improve additional crops beyond the traditional herbicide- and insect-resistant GM traits, including plants with reduced water requirements, plants that fix nitrogen, and plants that reduce fertilizer-caused pollution. Crops could also be tailored to assess global food insecurity by the incorporation of enhanced nutritional qualities or resilience to a changing climate (National Research Council, 2010).

Anti-GM activism may obstruct development in small countries

Despite the positive legal framework in Costa Rica, some anti-GM actions could prevent the potential development of the agricultural biotech sector. Environmental activist groups have been implementing a decade-long campaign against the cultivation and commercialization of GM crops and they have

recently called for legal banning of the import of transgenic grains and for establishing a labeling system for transgenic foods. In Honduras, consumer groups have also been influenced by widespread negative information. This same anti-GM activism has been quite pronounced in Nicaragua to the point that government is now very cautious about promoting agricultural biotechnology. For the same reason, the government has not implemented the official regulations for GM approvals. As Nicaragua has a reasonable biotech law and strong intellectual property right protections, stimulation of private sector investments in modern technologies seems plausible. However, hesitation and ambiguity on the part of the government may deter large investments in GM crop production and discourage biotech companies from introducing new GM crops into Central America.

The use of biotechnology and, specifically, the genetic modification of plants to increase yield, to protect against pest invasions, and to confront issues resulting from climate change is not without conflict. As with many other scientific innovations when they had first been introduced, GM products for animal and human consumption have met varying degrees of acceptance, suspicion, skepticism, and, frequently, outright rejection. There are many reasons why this spectrum of responses has been and remains in many communities in Central America.

The desire to prevent international mega-corporations from controlling local seed production and supply is, of course, paramount in the minds of many members of the anti-transgenic movement led by local and international nongovernmental organizations. The regulation, or lack thereof, of local seed supplies is directly related to power and ownership issues, even of sovereignty, and self-determination in developing nations and their communities of small, independent farmers (Pearson, 2012). Unfair seed production agreements in favor of large multinational corporations and tactics by these corporations, seen as "bullying", may have a detrimental effect on small farmers. The struggles of the small seed producers are

shared within the community and beyond, creating doubt and fear among an increasing number of farmers and their supporting organizations.

Fear, ignorance of the science behind GM food production, and negative reputation of foreign multinationals, coupled with genuine concerns for safety, are all used by large and small actors in the movement against GM import, production, and consumption in Central America and elsewhere. Many American and European anti-GM organizations actively support local initiatives in the region.

Concluding remarks

Agricultural biotechnology is a key technological platform to foster sustainable economies in developing countries and to enhance food security in the fight against global hunger. Some new varieties may also be developed to increase the resilience to climate change. In addressing all of these challenges, less-developed countries, such as those of Central America, need to make use of all available tools. In particular, it would be foolish to exclude GM methods because of specious political arguments that have been promulgated in Europe. Such arguments against GM crops have no direct consequences in Europe because increase of its food production is not required. In contrast, the developing countries need GM crops desperately if they are to feed their expanding populations.

Governments should adopt appropriate pro-agricultural biotechnology policies and laws based on sound science and should promote a rigorous public relations campaign to improve the acceptance of GM technology. Speaking from their own experience, science academies and universities could provide independent advice to policy-makers and the public. As the Central-American region is still in the early stages of biotechnology diffusion, capacity building should be strengthened, specifically in the area of applied research. New crops should be judged by their contribution to the needs of the Central-American countries, particularly those related to food requirements of low-income populations, and not be arbitrarily banned because of the production method.

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Genetically Modified Crops in South Africa

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Abstract

South Africans have been growing genetically modified (GM) crops since 1999 and the area under cultivation has steadily increased since. Insect-resistant cotton (Gossypium hirsutum) was introduced in 1997 as the first GM crop grown by both commercial and smallholder farmers. In recent years cotton plantings, whether GM or not, have decreased for economic reasons. In 2013, some 96% of commercial maize (Zea mays) cultivation was GM carrying either Bacillus thuringiensis-mediated insect resistance, herbicide resistance, or both. This included white maize for human consumption and yellow maize for animal feed. The crops are grown by both commercial and smallholder farmers. Herbicide-resistant GM soybean (Glycine max) is also cultivated. The adoption of GM insect-resistant maize has resulted in increased yields and reduced pesticide use with associated environmental and economic benefits. There is also anecdotal evidence of reduced mycotoxin contamination in food products from GM insect- resistant maize. Aflatoxins have been implicated in oesophageal cancer, a disease widespread in parts of Africa where homebrewed maize beer is widely consumed. Recommendations for future cultivation of GM crops include improving access to seed by smallholder farmers, provision of extension services, implementation of appropriate integrated pest management practices, and implementation of selective labeling. New GM crops in the pipeline need to be expedited to allow field trials to occur.

Introduction

The area planted to genetically modified (GM) crops in South Africa has steadily increased since they were first introduced in 1997. Currently, the maize (*Zea mays*) crop covers some 2.5 million hectares, of which 2.14 are GM (86% adoption). Soybeans (*Glycine max*) are grown on 600,000 hectares, of which 552,000 are GM (92% adoption), whereas cotton (*Gossypium hirsutum*) is a small crop cultivated on 8,000 hectares, all of which is GM (James, 2014).

The Genetically Modified Organisms Act was promulgated in May 1997, but could not be implemented until the Regulations were approved. As approval only happened in November 1999, during the intervening period, applications for trial or commercial releases were handled by the South African Committee for Genetic Experimentation (SAGENE).

To give an idea of the number of applications SAGENE handled during 1997 alone, of a total of 27, 13 were introduced for maize, four for cotton, two for soybeans, one each for canola (*Brassica napus*), strawberry (*Fragaria* × *ananassa*), eucalyptus (*Eucalyptus obliqua*), and apple (*Malus domestica*), and four for microorganisms (Thomson,

2013a). The GMO events approved for commercial release in South Africa from 1997 until 2014 are listed in Table 1.

The adoption of currently approved traits is seemingly reaching saturation because not all plantings require *Bacillus thurigiensis (Bt)* insect resistance. Indeed, in many cases cost savings can be achieved by applying fungicide and insecticide simultaneously through overhead irrigation when needed. In addition, some regions are not subject to severe stalk borer pressure (James, 2014). However, new traits in the pipeline, such as fungal resistance and drought tolerance, may serve to further enhance adoption levels.

Cotton production has declined in recent years due to movement away from risky dryland regions to regions under irrigation, where it has to compete with maize or soybeans. Additionally, there have been problems with cotton gin closures. Therefore, only approximately 9,000 hectares were planted with GM cotton in 2014 compared with 11,000 hectares in 2012, of which 95% contained the stacked *Bt* and herbicide resistance genes, whereas the remaining 5% was herbicide resistant used as refugia (James, 2014).

In addition to GM crops grown for commercial releases, permits were also issued for commodity clearance of imported GM crops. The approved commodities from 2012 to 2014 are listed in Table 2, showing that food producers in South Africa use imported GM crops as well as those produced locally.

There are a number of reasons why South Africa led the way among countries in Africa in introducing GM crops. One was the existence of SAGENE, the body which, prior to the introduction of the

Table 1. GMO general release approvals under the GMO Act

Event	Crop	Trait	Company	Year approved
TC1507xMON810 xNK603	Maize	Insect resistance	Pioneer	2014
		Herbicide tolerant		
TC1507xMON810	Maize	Insect resistance	Pioneer	2014
		Herbicide tolerant		
TC1507	Maize	insect resistance	Pioneer	2012
		Herbicide tolerant		
BT11xGA21	Maize	Insect resistance	Syngenta	2010
		Herbicide tolerant		
GA21	Maize	Herbicide tolerant	Syngenta	2010
MON89034xNK603	Maize	Insect resistance	Monsanto	2010
		Herbicide tolerant		
MON89034	Maize	Insect resistance	Monsanto	2010
Bollgard IIxRR flex (MON15985x MON88913)	Cotton	Insect resistant	Monsanto	2007
		Herbicide tolerant		
MON88913 (RR flex)	Cotton	Herbicide tolerant	Monsanto	2007
MON810xNK603	Maize	Insect resistant	Monsanto	2007
	Maize	Herbicide tolerant		
Bolgard RR	Cotton	Insect resistant	Monsanto	2005
	Cotton	Herbicide tolerant		
Bollgard II, line 15985	Cotton	Insect resistant	Monsanto	2003
Bt11	Maize	Insect resistant	Syngenta	2003
NK603	Maize	Herbicide tolerant	Monsanto	2002
GTS40-3-2	Soybean	Herbicide tolerant	Monsanto	2001
RR lines 1445 & 1698	Cotton	Herbicide tolerant	Monsanto	2000
Line 531/Bollgard	Cotton	Insect resistant	Monsanto	1997
MON810/Yieldgard	Maize	Insect resistant	Monsanto	1997

Source: www.daff.gov.za/doc/GeneralRelease Approvals.pdf

GMO Act, facilitated early on farm trials and subsequent commercial releases. Furthermore, an organization, AfricaBio aided information dissemination about GM crops and held regular farmers' meetings to help spread farmer-to-farmer experiences. Finally, the fact that South Africa is home to many highly sophisticated commercial farmers facilitated GM crop adoption (Thomson, 2013b).

Hereafter, the various GM crops will be discussed based on their traits. As most of these crops are grown by commercial and smallholder farmers (less than 2 hectares), the experiences of both types will be covered.

Insect resistance

Bt cotton

Bt cotton has been grown commercially in South Africa since 1999. An analysis of the benefits of adoption by both small- and large-scale farmers (Gouse et al., 2004) revealed that the yield increase was 18.5% for large-scale farmers who irrigated, 13.8%, for large-scale farmers under rainfed agriculture, and 45.8% for small-scale farmers. Besides the yield benefits, the adoption of Bt cotton also caused a decrease in the volume of insecticides sprayed, with associated cost and health benefits. As small-scale farmers do most of their spraying by hand, this reduction usually

meant more time for weeding and other farm management activities.

According to Gouse *et al.* (2004), "a high percentage of large-scale farmers have indicated that peace of mind about bollworms is a very important benefit of *Bt* cotton." This confidence gave farmers managerial freedom to devote time to other crops or general farming activities. These farmers also noticed increased populations of beneficial insects, such as ladybirds and lacewings, in *Bt* cotton fields, indicating a possible environmental advantage due to reduced insecticide applications.

The area in South Africa where most of the *Bt* cotton is grown by small-scale farmers is the Makhathini Flats of KwaZulu-Natal. This region is rich in indigenous plants and weeds that act as natural host plants for all the bollworm species. Therefore, they act as alternative refuges for the moths and have helped to prevent the build-up of *Bt*-resistant insects (Green *et al.*, 2003), in contrast to *Bt* maize

In recent years, plantings of cotton, whether *Bt* or not, have decreased partly due to the world-wide drop in cotton prices. The yields of 12 to 15 tons per ha of dryland cotton that is produced predominantly by small-scale farmers are not competitive. How-

Table 2. GMO commodity clearance approvals under the GMO Act

Event	Crop	Trait	Company	Year approved
BT11x59122xMIR604xTC1507xGA21	Maize	Insect resistant Herbicide tolerant	Syngenta	2014
BT11xMIR604xTC1507x5307xGA21	Maize	Insect resistant Herbicide tolerant	Syngenta	2014
BT111xMIR162xMIR604xTC1507x5307	Maize	Insect resistant Herbicide tolerant	Syngenta	2014
MIR162	Maze	Insect resistant	Syngenta	2014
MON89034xMON88017	Maize	Insect resistant Insect resistant	Monsanto	2014
MON87701xMON89788	Soybean	Herbicide tolerant Insect resistant	Monsanto	2013
MON89788	Soybean	Herbicide tolerant	Monsanto	2013
DAS-44406-6	Soybean	Herbicide tolerant	Dow AgroSciences	2013
DAS-40278-9	Maize	Herbicide tolerant	Dow AgroSciences	2012
CV127	Soybean	Herbicide tolerant	BASF	2012
MON89034xTC1507xNK603	Maize	Insect resistant	Dow AgroSciences/ Monsanto	2012

Source: www.daff.gov.za/doc/CommodityClearanceApprovals.pdf

ever, all the cotton planted in 2014 was expected to be GM, mostly carrying the *Bt* gene together with herbicide resistance (James, 2014). The decrease in *Bt* cotton cultivation by small-scale farmers, such as those in the Makhathini Flats area, is due to the above economic reasons and not to a failure of the technology.

Bt maize

Maize, although technically a grain, is used in cooking as a vegetable or starch. In many African countries it is the staple food that people can eat three times a day. White maize is consumed by humans, yellow maize is fed to livestock and poultry. South Africa is the only African country growing commercial GM maize that is mostly consumed locally by commercial farmers producing approximately 96% of the crop.

GM maize was introduced in 1997, but only became commercially adopted on a major scale in 2000. Since then, GM maize plantings have increased dramatically. Maize can be severely damaged by the larvae of the maize stalk borer, *Busseola fusca*, and, as with cotton, genes coding for *Bt* toxin varieties can be introduced into this crop to protect it. In a 2009 study of 80 farmers planting *Bt* maize, it was found that the two greatest advantages associated with these plantings were convenient management (88%) and increased productivity (42.5%), whereas 42.5% indicated that they perceived *Bt* technology to be environmentally friendly (Kruger *et al.*, 2009).

In 2014, some 86% of commercial maize plantings were estimated to be GM, of which 28% carried the single *Bt* gene and the remainder comprised either herbicide resistance or both traits stacked. The adoption was very similar for white and yellow maize and is now reaching saturation because not all plantings are subject to severe stalk borer pressure and, hence, do not require *Bt* insect resistance. Over 92% of commercial maize samples tested were positive for GM traits, either pure GM or co-mingled. Some traders import or contract farmers for non-GM grain for certain customers (James, 2014).

The first report on resistance of the maize stem borer to *Bt* occurred in 2007. In order to limit such resistance, farmers are required to plant refugia. Refuges are defined as habitats in which the target pest is not under selection pressure because of the toxin and, therefore, provide a sustainable environment for pest development. The principle underlying the high-dose and refuge strategy is that any resistant insect emerging from the *Bt* crop is more likely to mate with one of the much larger number of susceptible pest insects from refugia than with each other, thereby decreasing the selection of *Bt* resistance alleles (Bourguet, 2004).

Initial levels of refuge compliance were low and, even though farmers were obliged to plant a refuge area for each *Bt* maize field, only 77.7% did so during 1998. However, this number increased to 100% during 2008 (Kruger *et al.*, 2009). Although the evolution of resistance of *Buscola fusca* can probably be ascribed to several factors, including rainfall and humidity, the low initial levels of compliance to refuge requirements probably played an important role (Kruger *et al.*, 2011a). Interestingly, farmers remain positive about the technology in spite of resistance development (Kruger *et al.*, 2011b).

A different story appeared when small-scale farmers were surveyed. Of the 78 farmers interviewed, only 59% had more than 10 years of experience in cultivating maize and were well aware of the key production constraints. Their knowledge of GM maize production practices was very poor and knowledge of the risks associated with this technology was completely lacking. None of the farmers interviewed properly understood the refuge strategy. In addition, most were illiterate and were, therefore, unable to read and understand the information on the user guides (Assefa and van den Berg, 2010). Clearly, this issue needs to be addressed if small-scale farmers are to cultivate *Bt* maize.

Remedial actions taken in South Africa have included the release of pyramided maize hybrids that combine two different toxin-producing transgenes,

Cry1A.105 and Cry2Ab2, replacing the ineffective single transgene. However, it remains to be seen whether cross resistance will occur between the Cry1A.105/Cry2Ab2 and the closely related Cry1Ab toxin. In hindsight, the survival of *Buscola fusca* larvae noted in 1988 should have triggered actions to address the issue and to monitor compliance with refuge requirements. This retrospection also emphasizes that *Bt* crops should not be seen and used in isolation from other insect resistance management measures (Van den Berg *et al.*, 2013).

Post-harvest fungus resistance

Smallholder farmers in South Africa often store their annual maize crop in storage cribs that are open to the air. If the cobs have been "nibbled" by insect borers, holes will occur in their kernels. These kernels are perfect breeding grounds for fungi under rainy and sunny conditions alike. Many fungi are Aspergillus species that produce aflatoxins, a known human carcinogen that has been linked to liver cancer (http://ehtrust.org/factsheets-facts-about-aflatoxin/). Instead of using such infected maize directly for food, many women will ferment it to form beer. As aflatoxins have also been implicated in oesophageal cancer, it is little wonder that this disease is widespread in parts of Africa where homebrewed maize beer is widely consumed. One indirect benefit of Bt maize adoption that has been observed in different countries is reduced mycotoxin contamination (F. Wu, 2006). Mycotoxins are secondary metabolites produced by fungi that colonize crops such as maize. Insect damage is one factor that predisposes maize kernels to fungus contamination. There is strong field evidence that Bt maize has significantly lower levels of mycotoxins that non-Bt isolines. Hence Bt maize is an important genetic tool for reducing mycotoxin contamination.

Herbicide resistance

Maize

Weeds compete with crops for moisture, nutrients, and light. Uncontrolled weed growth can thus result in significant yield losses. Therefore, farmers have been spraying herbicides on their

crops for decades. As with insecticidal sprays, spraying is often done by means of airplanes, with the result that a great deal of the spray drifts away from the target sites.

The best known example of transgenic herbicide resistance is Monsanto's RoundupReady®. The active ingredient in the herbicide Roundup is glyphosate which acts on an enzyme found in many plants, including maize and its weeds. Using Roundup on conventional maize fields is a tricky operation because the herbicide must not make contact with the crop. RoundupReady® maize produces a naturally occurring form of the target enzyme, 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) that is resistant to glyphosate and, hence, to the herbicide. The gene encoding the glyphosate resistant form of EPSPS was derived from Agrobacterium tumefaciens, coincidentally the bacterium that is used to genetically manipulate plants.

In 2014, 19% of the GM maize crop in South Africa was herbicide tolerant, whereas 53% was planted to stacked Bt and herbicide-tolerant traits (James, 2014). South Africa is the only country in the world where smallholder farmers have been producing a GM subsistence crop for a relatively long period of time. A study that followed the farmers' experience for eight seasons in KwaZulu-Natal (Gouse, 2012) revealed that both Bt and herbicide-tolerant maize seeds were valued. Interestingly, the farmers were more willing to pay for the weed control convenience than for insect borer control. The reason is that weeds are always present and the herbicide-tolerant seeds are a labor-saving device, whereas insect infestations come and go from season to season. Therefore, the option of planting seeds with stacked genes for both traits would apparently be preferred.

However, smallholder farmers have experienced practical problems related to obtaining crop credit, signing of contracts to comply with refuge planting, enforcing refugia, and obtaining small aliquots of GM seeds (James, 2013). However, in 2013, marketing of GM seeds in packets of 2 to 25 kg saw

planting of 6,308 hectares of GM white maize (8% insect resistant, 61% herbicide tolerant and 31% stacked), as well as 7,180 hectares of GM yellow maize (0.9% insect resistant, 78% herbicide tolerant and 21% stacked). This successful smallholder adoption is expected to increase (James, 2013). In the Gauteng region, where much of the country's maize is grown, the number of smallholder farmers cultivating GM maize has increased from 10 to 33 with the number of hectares increasing from 20 to 1275 in 2011 to 2014, respectively (AfricaBio, personal communication).

One of the positive environmental impacts of herbicide-resistant maize is the use of no-till cultivation or conservation tillage. With conventional maize, farmers till the soil to allow weeds to grow, spray with herbicides, and then wait a sufficient time for their degradation before planting. Now, they can allow weeds and maize to grow together before spraying. This results in reduced soil erosion and better moisture retention in the soil. In addition, Roundup is more readily degradable by bacteria than many other herbicides (Balthazor and Hallas, 1986).

Soybean

Soybeans are not a major crop in South Africa, with a planted area of approximately 600,000 hectares in 2014 (James, 2014). However, 92% of the crop is GM herbicide tolerant.

Traits in the pipeline

A number of different GM crops specific for (South) Africa have been developed by the public sector in South Africa. These include improved sugarcane (Saccharum officinarum), eucalyptus, and grapevine (Vitis sp.) varieties, post-harvest damage-protected potato (Solanum tuberosum), and virus-resistant cassava (Manihot esculenta). Maize resistant to the African endemic maize streak virus, one of the major threats to this crop in Africa, and tolerant to drought, a condition that is becoming increasingly important due to climate change, has also been produced (Thomson et al., 2014). However, no field trials have taken place for any of these crops. The reasons include lack

of funding, complicated regulatory environment, and market uncertainties.

Another crop being developed is vitamin A-enriched sorghum (Sorghum bicolor), similar to the Golden Rice (Oryza sativa) variety (Ye et al., 2000). In 2005, the Bill and Melinda Gates Foundation funded the African Biofortified Sorghum (ABS) project, run by an international consortium under the leadership of Africa Harvest, an African-based international non-profit organization. This engineered sorghum contains the gene for a high-lysine storage protein from barley (Hordeum vulgare) and has increased levels of Vitamin A, iron, and zinc. In 2013, the ABS initiative received a "Patents for Humanity Award" from the USA Patent and Trademark Office for its efforts to improve nutrition, production, and availability of sorghum in Africa (http://biosorghum.org).

Recommendations

GM crops are clearly popular with growers, commercial and smallholder alike, because of the agronomic advantages they offer. To quote one farmer from the Mpumulanga province: "On average, with GM maize I get 5 tons/hectare on dryland, which is 0.5 tons better than conventional maize and under irrigation 10 tons/hectare, which is 1 ton better than conventional, equivalent to 2,000 rand (US\$ 200) plus 60 rand per hectare for better quality" (James, 2013). Another farmer in the Free State province, who grows 3,000 hectares of GM maize as well as 340 hectares of soybeans, ascribes his success in crop production to GM varieties (James, 2013).

The mandatory labeling of GM/GMO "goods", ingredients, or components, as prescribed in Regulation 7 of the Consumer Protection Act of 2008 should have entered into force in 2011. It has elicited ongoing criticism from stakeholders in the food chain due to its ambiguity and complexity. There has been little effort on the side of the Department of Trade and Industry to proceed with the enforcement of this regulation that might be seen by trading partners as a technical barrier (James, 2013). My recommendations regarding currently ap-

proved GM crops are the following:

- 1. Improve access to small amounts of seed by smallholder farmers.
- 2. Provide farmers with agricultural extension services to help them understand how to handle new and improved cultivars, enabling them to realize the importance of planting refugia (in the case of *Bt* crops) and to encourage them to operate in cooperatives to better implement appropriate agronomic and integrated pest management practices.
- 3. Implement the labeling requirements by including the words "may contain ingredients derived from GM crops", where appropriate. This wording is necessary because South Africa does not require the segregation of GM and non-GM crops post-harvest. When producers can prove conclusively (in a court of law if required) that items contain less than the prescribed limit of GM crop-derived ingredients (1% per total mass or volume), then the words "does not contain ingredients derived from GMOs" should be mentioned.

My recommendations regarding GM crops in the pipeline are the following:

- Developers are needed to bring these crops to field trials and beyond. Many potential investors view crops that are important to Africans only as unable to make a return on their investment.
 I challenge this view as the resultant increase in food security could help to turn around the economies of many African countries.
- Governments should also realize that by supporting this technology they can improve food security, nutritional security, and add to economic growth.
- 3. The South African regulatory authorities should rethink their current tendency to view any "home-made" GM crop as representing a greater risk than imported ones because of the lack of international biosafety data. Government authorities need to realize that African scientists are just as capable of developing safe and valuable GM crops as their international counterparts and they also need to build their confidence in their own abilities to assess risk effectively.

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The success story of Bt cotton in Burkina Faso: a role model for sustainable cotton production in other cotton-growing countries?

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Abstract

The West-African cotton (Gossypium hirsutum) industry has a huge economic potential. In particular, Benin, Burkina Faso, Ivory Coast, and Mali play an important role as exporter on the world market. Still, the cotton sector is also subject to a number of risks that can threaten the sustainability of the cotton production in West Africa. This chapter overviews the challenging pest problems and assesses how biotechnology and, more specifically, insect-resistant cotton (Bt cotton), overcome these problems. Introduction of Bt cotton in Burkina Faso and South Africa resulted in important benefits regarding yield, farmer income, pesticide use, and environmental and health impacts. When structural and institutional limitations are suppressed to realize its full potential, Bt cotton can clearly contribute both to the economic and environmental sustainability of the cotton production.

Introduction

Cotton (Gossypium hirsutum) is an important industrial crop worldwide and the predominant natural fiber in the textile industry. Despite competition with artificial fibers, cotton remains important and accounted for 30% of the more than 82 million tons of textile fibers processed in 2013 (www.icac.org/tech/Overview/100-facts-aboutcotton). In 2000, the world production of cotton was twice that of 1960. Even though the production is subject to fluctuations, it still increases (http://faostat3.fao.org/home) (Figure 1). Farmers produce seed cotton that is processed into cotton lint, mainly for the textile industry to produce fabrics for clothing, furniture applications, or money bills. From the seeds derived from the seed cotton less than 1% is used to plant cotton again (www.icac.org/tech/Overview/100-facts-aboutcotton). Cotton seeds are mainly applied in food and feed. The protein-rich seeds can be used as feed for ruminants, but, because they contain the toxic gossypol, they are not suited for consumption as such by humans and monogastric animals. Processing of the cotton seeds yields an edible oil that is suitable for cooking and human consumption as well as additional byproducts utilized in soaps and cosmetics (www.vib.be/en/about-vib/plant-biotech-news/Documents/BackgroundReport_BT_Cotton.pdf).

Cotton is a subtropical crop and is grown either under irrigation or in sub-humid and semi-arid locations with an annual rainfall between 50 and 150 cm (ECOWAS-SWAC/OECD, 2006). Because of the high vulnerability to insect infestations, cotton is currently grown in a few tropical locations only. In 2013, the top producers of seed cotton were China (18.93 million tons [Mt]), India (18.91 Mt), USA (7.63 Mt), and Pakistan (6.24 Mt) (http://faostat3.fao.org/home). The West-African production levels are quite low (2.35 Mt). Nevertheless, the four main cotton-producing countries in West Africa, Benin, Burkina Faso, Ivory Coast, and Mali, play an important exporter role on the world market. Export of high-quality cotton accounts for approximately 80% of the total production of the entire region. The cotton industry is seen as an important source of economic growth as well as a social safety net for the region, especially in rural areas because it secures farmers' income and generates employment. As a result, cotton is often referred to as 'white gold' (Redifer et al., 2014; Vitale and Greenplate 2014; http://faostat3.fao.org/home).

Despite its economic potential, the cotton indus-

try is also subject to a number of risks, such as price fluctuations of inputs (i.e. fuel, fertilizers, and pesticides) and cotton on the world market, changing weather conditions, and emergence of pests and/or pesticide resistance. All these can threaten the sustainability of the cotton production in West Africa (Redifer et al., 2014, Vitale and Greenplate, 2014). In this chapter, we look at the pest problems that challenge the cotton production and how biotechnology and, more specifically, insect-resistant cotton (Bt cotton), can play a role to overcome these problems. Furthermore, we aim to evaluate the contribution of Bt cotton to sustainable cotton production in Burkina Faso and South Africa. Specifically reviewing the introduction of Bt cotton into these countries, we will take into account the lessons learned and analyze whether it can serve as a role model in other cotton-growing countries in West Africa to increase the sustainability of the cotton sector.

Cotton production sustainability and the role of *Bt* cotton

Cotton production is subject to a number of risks, among which its susceptibility to a wide range of insect pests, such as the caterpillars *Helicoverpa armigera* (cotton bollworm), *Pectinophora gossypii* (pink bollworm), and *Heliothis virescens* (tobacco bollworm), was responsible for the largest eco-

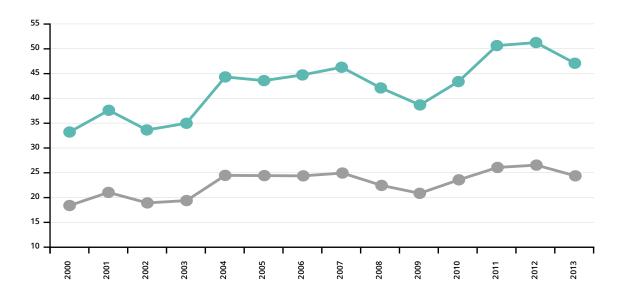


Figure 1. Global production of cotton seed (green) and lint cotton (grey) (M tonnes) (source: FAOSTAT, 2015)

nomical losses before efficient management strategies were put in place (www.cottoninc.com/fiber/Agricultural Disciplines/Entomology/). For West Africa, the cotton bollworm has been reported to be the main threat and to be able to cause up to 90% damage when untreated (Vitale and Greenplate, 2014). The larvae feed on cotton terminals, small squares, such as blooms, large squares, and bolls, provoking important losses (Boyd *et al.*, 2004). As traditional pest control measures have become less efficient, other alternatives have been explored.

The common Gram-positive soil bacterium Bacillus thuringiensis (Bt) produces crystal (Cry) proteins with an insecticidal activity. Large-scale screening of different Bt strains has revealed over 700 cry gene sequences, of which some without known invertebrate target, but many effective against insect pests (Palma et al., 2014). More importantly, these Cry proteins that are specific to a limited number of insect species belonging to the orders of Lepidoptera, Diptera, Coleoptera, Hymenoptera, Homoptera, Othoptera, and Mallophaga, are not toxic to humans (Bravo et al., 2012). The Cry proteins are ingested as protoxins and processed in the insect gut into Cry toxins, which recognize and bind specific receptors in the insect gut wall, with pore formation (Bravo et al., 2012) or apoptosis (Zhang et al., 2006) as a result. Eventually, the insect dies due to starvation and to bacterial or other infections (www.vib.be/en/about-vib/plant-biotech-news/ Documents/BackgroundReport_BT_Cotton.pdf).

As Cry proteins of *B. thuringiensis* are highly effective as well as specific against a number of insect pests, they were used as bioinsecticides already at the end of the 1930s (Schnepf *et al.*, 1998; Bravo *et al.*, 2012), but these commercial preparations that often contained a mixture of spores and crystals were not widely adopted. Inefficiency was high because of the non-optimal spray coverage and because rain showers washed off the pesticides. Moreover production costs were relatively high and the formulation was sensitive to UV degradation (Krattiger, 1997). The plant genetic trans-

formation technology triggered the interest in Bt applications because they can bypass these disadvantages: spraying is no longer required, because the crops produce the Cry proteins themselves and, thus, are protected throughout their life cycle (www.vib.be/en/about-vib/plant-biotech-news/ Documents/ BackgroundReport_BT_Cotton.pdf). Biotechnology can greatly contribute to agricultural challenges. Bt-mediated insect resistance was one of the first commercialized traits, namely in 1995, when the Bt potato (Solanum tuberosum) resistant to the Colorado potato beetle (Leptinotarsa decemlineata) was the first Bt crop approved for commercialization in the USA (James and Krattiger, 1996). Since then, the Bt trait has been successfully introduced into a number of crops, such as maize (Zea mays), brinjal or eggplant (Solanum melongena), poplar (Populus sp.), potato, and cotton and has resulted in a worldwide adoption. In 2014, 55 million hectares of insect-resistant Bt crops were planted (James, 2014). In 1996, Bt cotton was grown for the first time in the USA on 1.7 million acres (approximately 688,000 ha). BollgardTM (Monsanto, St. Louis, MO, USA) cotton produced one Cry protein (Cry1A[c]) that conferred resistance against Helicoverpa armigera (cotton bollworm), Pectinophora gossypii (pink bollworm), Bucculatrix thurberiella (cotton leaf perforator), Trichoplusia ni (cabbage looper), and Estigmene acrea (Drury) (saltmarsh caterpillar) (Krattiger, 1997). Since this first successful introduction, biotech cotton has been adopted by many cotton-growing countries and new biotech cotton varieties have been developed, such as herbicide-tolerant (HT) cotton or biotech hybrid cotton that produces two or more Bt toxins with different action modes or combined with herbicide tolerance (James, 2014). BollgardII cotton synthesizes two proteins from Bacillus thuriengiensis: Cry1Ac and Cry2Ab and was developed by introducing the cry-2Ab gene into transgenic cotton that already contained the cry1Ac gene. These two Cry toxins are recognized by different receptor sites on the midgut wall of the insects. Cry1Ac is effective against Helicoverpa armigera and Helicoverpa punctigera (Australian bollworm) as well as against Earias vittella (rough bollworm), Pectinophora gossypii, and

some other *Lepidoptera* spp. The addition of Cry-2Ab increases the efficacy by extending the period in which it effectively controls *Helicoverpa* spp. (www.monsanto.com/global/au/products/documents/bollgard-ii-technical-manual.pdf). An additional advantage is that the possibility that a target insect develops resistance simultaneously against the two different Cry toxins will be extremely rare (www.vib.be/en/about-vib/plant-biotech-news/Documents/BackgroundReport_BT_Cotton.pdf).

In 2014, 15 countries, namely India, USA, China, Pakistan, Australia, Burkina Faso, Brazil, Argentina, Paraguay, South Africa, Myanmar, Mexico, Colombia, Sudan, and Costa Rica, grew a total of 25.1 million hectares of Bt cotton, constituting 68% of the global cotton planted area (James, 2014). In Africa, Bt cotton had already been introduced in 1998 (Gouse et al., 2004), when it had been approved for commercialization in South Africa. It took another 10 years for the first commercial release in Burkina Faso and in 2012, Sudan was the third African country to adopt Bt cotton (James, 2014). To date, 73.8% of the cotton planted in Burkina Faso and 80% in Sudan is Bt cotton. Even though South Africa grows a relatively low acreage of cotton, the adoption rate of Bt cotton is high and reached 95%, whereas the remaining 5% is HT cotton planted as refuge area to manage insect resistance development (James, 2014).

The wide-scale adoption of insect-resistant (IR) cotton has resulted both in a positive environmental and economic impact when compared to conventional farming practices. In 2012, the global farmer income gains from the use of IR cotton have been estimated at US\$ 5.3 billion. These gains resulted mainly from increased yields thanks to reduced crop damage, especially in developing countries, but also from decreased input costs, mostly in developed countries (Brookes and Barfoot, 2014). The number of insecticide sprays could be reduced significantly, corresponding to important savings in insecticide-active ingredients: 205.4 million kg cumulatively from 1996 to 2012 or a reduced environmental impact of 28.2% (as measured by the Environmental Impact Quotient). An additional positive effect from using biotech IR cotton is the decreased fuel usage, namely 17 million liters in 2012 (Barfoot and Brookes, 2014).

The cotton industry in Burkina Faso

Cotton was already produced in West-Africa during the colonial period at the beginning of the 20th century. In 1949 under the French administration, the Compagnie française pour le développement des fibres textiles (CFDT) was founded and contributed to the development of the cotton industry (Perret, 2009). The CFDT applied the parastatal industry model: a vertical coordination between producers and company. Under a parastatal structure, the company provides inputs, such as seeds, pesticides, and fertilizers, and technical advice to the farmers. After the growing season, the company buys the yield at fixed prices from the farmers, who in this manner pay off their input credit, and takes up transportation, ginning, and marketing (Theriault and Serra, 2014; Tumusiime et al., 2014).

After independency in the early 1960s, stateowned enterprises set up the parastatal model and promoted cotton production (Theriault and Serra, 2014; Tumusiime et al., 2014). After the independence of Haute-Volta, renamed Burkina Faso in 1984, the CFDT partnered with the government and private investors to found the Sociéte Voltaïque/Burkinabé des Fibres Textiles, abbreviated SOFITEX (Redifer et al., 2014). The cotton production increased as producers gained access to chemical fertilizers, insecticides, herbicides, and improved cotton seeds. Land expansion also contributed to intensify the cotton production (Vitale and Greenplate, 2014), namely from 74,000 ha in 1981 to 406,000 ha in 2003 (Redifer et al., 2014). This was of great importance for the economic development and rural livelihoods.

However, in the late 1990s, the world prices collapsed and the sector faced an economic crisis. The sector was also subject to bad governance and mismanagement. Input credits were given also to non-cotton farmers, even though cotton revenue

remained the principal mean to cover the loans. In addition, some farmers sold their inputs on the black market without repaying their loans (Theriault and Serra, 2014). The economic crisis led to structural and market-oriented reforms. The sector was partially liberalized and two new additional ginning companies, Faso-Coton and Société Cotonnière du Gourma (SOCOMA) were established. This however did not result in a price competition between the three companies (Tumusiime et al., 2014) because they each manage their own production zone and retained a parastatal structure. SOFITEX controls the West and approximately 80 to 90% of Burkina Faso's total cotton production, SOCOMA the East, and Faso-Coton the center (Bassett, 2014; Redifer et al., 2014). Market coordination and contract enforcement were improved by installing regional cooperatives restricted to cotton farmers only, whereas a national inter-professional association grouped the unions of the farmers, the Union Nationale des Producteurs de Coton du Burkina Faso (UNPCB; the national cotton producer association or growers' union) and the ginners, Association Professionnelle Des Sociétés Cotonnières du Burkina (APROCOB, the professional association of cotton companies of Burkina) (Theriault and Serra, 2014; Redifer et al., 2014; Vitale and Greenplate, 2014). As a consequence, the involvement of the producers in the companies increased, while the government's role in decision making was reduced (Tumusiime et al., 2014).

Despite these reforms, the cotton production level decreased between 2006 and 2011 (http://faostat3.fao.org/home). One reason is that the costs for fertilizers had increased and simultaneously the cotton prices dropped, imposing a serious pressure on the sector. To tackle these short-term risks, two publicly managed schemes were installed: the "Stabilization Fund" in 2007 and the "Input Fund" in 2012. In short, farmers receive subsidies from the Stabilization Fund when cotton prices are low and funds are returned in years with high cotton prices. The Input Fund ensures that input costs, in particular fertilizers, are affordable by supplying credits at reduced costs (Redifer et al., 2014).

In the last years, Burkina Faso's cotton production has recovered, reaching 766,000 tons in total in 2013 (http://faostat3.fao.org/home), representing 3.5% of Burkina Faso's gross domestic product in real terms. Cotton accounted for 18% of the export earnings in 2013 and 15-20% of the labor income is estimated to derive directly from it (Redifer et al., 2014). Nevertheless on the long term, cotton prices might still continue to drop. Currently, there is a production surplus, resulting in significant stock volumes. The International Cotton Advisory Committee predicts that "Even assuming reasonably lower production and higher consumption in the next few years, it will take several seasons for the significant volume of stocks to reach a more sustainable level, and low cotton prices are likely to persist while the market adjusts" (www.icac.org/Press-Release/2015/PR-1-Low-Cotton-Prices-A-Long-term-Problem#zoneTop-Wrap). This situation could threaten the sustainability of the cotton sector in Burkina Faso and concerns raise that under continuing low prices producers might shift away to other crops.

Bt cotton introduction in Burkina Faso

Input costs arise not only from the acquisition of seeds and fertilizers, but also from pesticides. In conventional cotton cultivation, farmers typically spray 6 times throughout the season and in Burkina Faso annually the aggregate insecticide costs can roughly be as high as US\$ 60 million. In addition, insecticide resistance had emerged in Burkina Faso, with, as a consequence, not only an intensified insecticide use, but also a shift towards broad-spectrum, more toxic insecticides that pose significant health hazards. The decreasing efficiency of the conventional pest control measures triggered the interest of Burkina Faso in biotechnological applications as a new pest control option. In collaboration with Monsanto, two regional Bolgard II varieties were generated. In parallel, the government developed a legal framework to regulate field testing and commercialization of genetically modified (GM) crops. After several years of field trials (2003-2007), the National Biosafety Agency authorized the two Bt cotton varieties for seed production and commercialization

in 2008 (Vitale and Greenplate, 2014), which were distributed that year by the three cotton-producing companies and planted on approximately 8,500 ha for seed multiplication. One year later, the adoption rate already increased to 29% and reached 70% in 2014 or a total of 454,124 ha, demonstrating the success of *Bt* cotton in Burkina Faso (Figure 2) (James, 2009, 2014).

The parastatal structure of the cotton industry in Burkina Faso facilitated the introduction of Bt cotton (Vitale and Greenplate, 2014). The large number of smallholders, approximately 300,000, who grow cotton would result in numerous contracts and agreements under the typical marketing model, but the vertical coordination through APROCOB allowed the upstream introduction of the technology and reduced the number of agreements to enforce the legal compliance and prevent resale and reuse of the Bt cotton seeds. In addition, the legal burden was shifted from the producers to the company. The royalties were set up in such a manner that the fee for the Monsanto technology depended on the farmer's income. The gross income is calculated as the value of increased yield plus savings in insecticides and is divided between the farmers (two-thirds) and Monsanto and the seed companies (one-third) (James, 2014). Burkina Faso continues to support Bt cotton and a new authorization for 10 years for

Bollgard II has been issued in 2013. Meanwhile, other cotton biotech varieties are explored: for example, Roundup Ready® Flex cotton (Monsanto) was in its fourth year of field trials in 2014 and field trials have started with the stacked Bollgard II x Roundup Ready® Flex cotton (ABNE, 2015).

The introduction of *Bt* cotton into Burkina Faso in 2008-2009 has also created a research pool regarding socioeconomic, environmental, and health impacts. Several studies have been conducted over a period of five years (2009-2013) and annually reported to the Agence Nationale de Biosécurité, the National Biosecurity Agency (ANB). The following paragraphs summarize the main findings of these reports (I.R.E. Sanou, G. Vognan, J. Vitale and I. Brants, personal communication).

Yield performance (kg ha⁻¹)

In the 2013 growing season, the yield of growers of *Bt* cotton was 14.3% higher than that of conventional cotton growers (Figure 3). Moreover, such yield gain has been observed for each agricultural campaign from 2009 to 2013, albeit with yearly variations that may be essentially due to two factors, namely raining season fluctuations and fertilizer mixtures. Nevertheless, it is clear that cultivation of *Bt* cotton created a substantial yield gain of at least 14%.

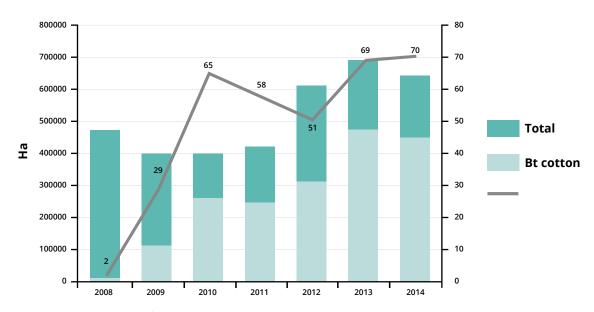


Figure 2. Adoption rate of Bt cotton in Burkina Faso.

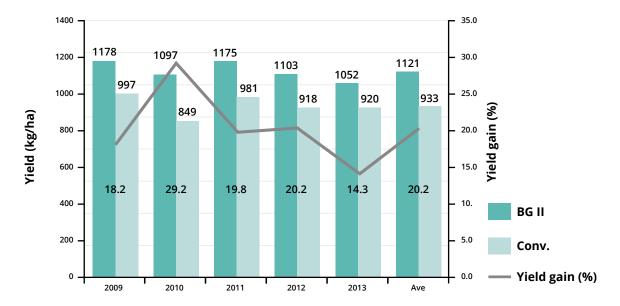


Figure 3. Yield performance (Kg.ha⁻¹); BG II: BGII, Bollgard II (*Bt* cotton); conv., conventional cotton.

Bt cotton profitability (US\$ ha-1)

In 2013, analyses indicated that farmers derive the majority of their income from growing Bt cotton (on average 63.1%), implying that Bt cotton is an economically important crop for the country. For the yearly reports to the ANB, the profitability of Bt and conventional cotton has been analyzed by comparison of net incomes, by taking into account the gross income based on yield, the sale price of cotton, as well as the average input costs for seeds, fertilizers, insecticides, herbicides, and labor. The average costs are considered because, besides seed cost, each cost is able to change from one agricultural campaign to another in Burkina Faso. In fact, during each campaign, a dialog framework is instituted between the government and the farmer's organization UNPCB that fixes all prices considering the cotton currency on the international market.

At the end of an agricultural campaign, a *Bt* cotton grower experiences on average a production cost quasi equivalent to a conventional cotton grower (US\$ 319 ha-1 to US\$ 312 .ha-1) (Figure 4). This insignificant difference in production costs is due to the fact that even though *Bt* cotton farmers have a relevant gain in insecticides treatments, they incur higher seed costs. As a result, the sum of seeds and insecticide costs is approximately the same for *Bt* cotton (US\$ 78 ha-1) and conventional cotton (US\$ 75 ha-1). Nevertheless, farmers grow-

ing *Bt* cotton have a 65.1% higher net income than conventional cotton growers that could be attributed to the yield gains and concurrently increased gross income.

Environmental impact

Bt cotton has been discredited at its adoption time due to the perception of possible environmental risks, but field observations show a clearly positive impact. Since its introduction in 2008, a significant reduction in the insecticide use has been observed (Figure 5) (http://faostat3.fao.org/home) with a beneficial impact on the environment. This reduction results from the reduced annual numbers of sprays from 6 to 2 as recommended to control sucking insects present in the field.

The yearly reports to the ANB also assessed the behavior of *Bt* cotton farmers regarding this recommendation. On average, 1.1% of the farmers do not spray their fields at all, 18.9% once a year, and 80% report to faithfully respect the two sprays. Nevertheless, disregard of the recommended number of sprays is not without consequences on yield performance (Figure 6). Indeed, two insecticide sprays to deal with the secondary insect pests improve yields on average by 17.9% and even 40.7% compared to one and no treatment, respectively.

Specific interviews under the research framework from 2011 to 2013 focused mostly on the identi-

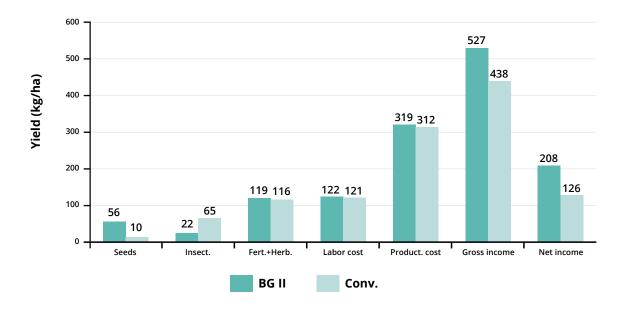


Figure 4. Average *Bt* cotton profitability (US\$ ha⁻¹) from 2009-2013. BG II, Bollgard II (*Bt* cotton); conv., conventional cotton; insect., insecticides; fert., fertilizers; product., production.

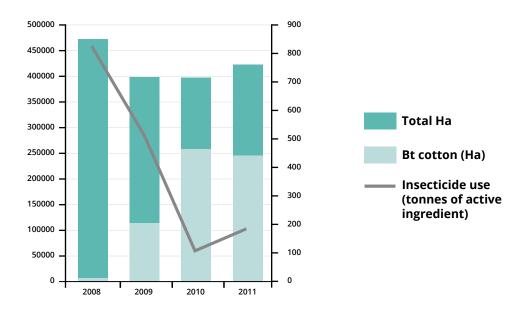


Figure 5. Use of insecticides in Burkina Faso since the introduction of Bt cotton in 2008.

fication of beneficial species present in *Bt* cotton fields, such as termites, bees, and ants that have a role in the agroecosystem equilibrium. All farmers interviewed certified the presence of these species. These results match outcomes of *Bt* cotton trials before commercialization, indicating that reduction of insecticide treatments would increase the presence of beneficial organisms.

Health impacts

Field surveys of the Institut National pour l'Etude et la Recherche Agronomiques indicated that over seven growing seasons (2004-2010), 50.8% of the cotton farmers experienced at least one pesticide poisoning incident, despite the extensive services in good management practices provided by the seed companies. Approximately 80.3% of these incidents could be attributed to the application of *Lepidoptera*-targeting insecticides. These incidents have se-

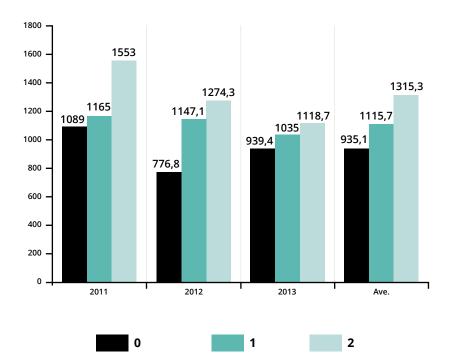


Figure 6. Yield performance (kg ha⁻¹) according to the insecticides sprays in *Bt* cotton fields.

rious health impacts, from symptoms ranging from dizziness to difficult breathing and vomiting and, additionally, they lead to economic losses as well due to medical costs and a loss of income, which have been estimated at US\$ 39.22 per incident. However, with the introduction of *Bt* cotton, farmers were able to reduce the number of sprays. The 2011 survey showed a 75% decreased pesticide use for *Bt* cotton farmers, translating into a projected reduction of 30,380 poisoning incidents and a positive economic impact of US\$ 1.09 million per year.

In conclusion, both the farmers and the environment have benefitted from the introduction of *Bt* cotton in Burkina Faso, not only by improving the safety of the working conditions but also by an increased net income from the yield gains. The 2011 survey indicated that the reduced pesticide use combined with the enhanced yields were perceived by 63.5% of the farmers as the most important motivation to adopt *Bt* cotton, whereas for an additional 16% the limitation in health risks was the single most important reason.

Bt cotton introduction in South Africa

South Africa planted *Bt* cotton for the first time in 1998. The adoption rate continued to increase and the *Bt* cotton coverage reached 95% in 2007

(with the remaining 5% HT cotton planted as refuge area) (James, 2007). Bt cotton was not only adopted by large-scale farmers, but also by smallholders. In the 1998/1999 season, 12% of the cotton-growing farmers in the Makhathini region planted Bt cotton. This grew to 40% in 1999/2000, 60% in 2000/2001, and 90% in 2001/2002 (Ismael et al., 2002; Gouse et al., 2005). Studies indicated that the yield increases had the highest impact on the income of both large-scale and small-scale farmers, with the largest yield increases obtained by the large-scale farmers who use irrigation. Furthermore, the reduced number of insecticide sprays additionally result in decreased application costs. Large-scale farmers save on diesel costs and tractor hours, whereas small-scale farmers benefit from labor savings that can be reinvested into other agricultural management practices, such as weeding and harvesting. Together, these benefits generate increased farming income for both groups, despite the high seed costs and additional technology fee (Gouse et al., 2004). Of course, yield benefits can differ from one season to another, because they are also influenced by weather conditions and insect pressure. Analysis indicates that the yield increase from Bt cotton is higher during a wet season when insect pressure is higher and the pesticides are washed off

by rain than in a dry year without significant yield advantage. Even so, the overall impact is positive and weather-related variation is reduced (Gouse *et al.*, 2005). Besides the economic benefits, the number of insecticide sprayings related to *Bt* cotton plantings had decreased between 1998 and 2001 with a beneficial impact on the environment (Morse *et al.*, 2006). Surprinsingly, this decrease resulted from a reduction not only in pesticides targeting *H. armigera*, but also in the highly toxic pesticides targeting secondary pests. The advantage would be less clear, when the applications of the latter would increase again.

The issue of field-emerging Bt resistance and its solution

The main threat to the success of the Bt applications would be the development of insect resistance in the field. In the past, the cotton bollworm has been able to adapt to the chemical pesticides, hereby reducing their efficiency. The large-scale exploitation of Bt cotton increases the selective pressure and Bt-resistant insects have already been observed in the field (www.vib.be/en/about-vib/plant-biotech-news/ Documents/BackgroundReport BT Cotton.pdf). Field-evolved resistance to Cry1Ac with reduced crop efficacy has been reported in cotton fields in the USA (in 2002) and India (in 2009), both within less than 10 years after their commercialization. In 2005, only 2 years after the commercialization of Cry1Ac and Cry2Ab hybrid cotton, Cry2Abresistant insect populations have been detected in the USA, possibly caused by Cry1Ac crossresistance. Experiments have indeed indicated that resistance to plants that produce two Cry toxins evolves faster when they are grown alongside single-toxin plants (Tabashnik et al., 2013).

It is widely recognized that the level of pest resistance to *Bt* crops will determine their long-term efficacy. Hence, proactive measures have been set up to delay and manage the evolution of pest resistance (Tabashnik *et al.*, 2013; www.vib.be/en/about-vib/plant-biotech-news/Documents/BackgroundReport_BT_Cotton.pdf). The United States Environment Protection Agency

imposed a number of IR management practices, with planting of refuge areas as a key component (http://www3.epa.gov/pesticides/chem_search/reg_actions/pip/regofbtcrops.htm). Other measures include monitoring for resistance development or for increased tolerance to the *Bt* protein; education of and increased communication among growers, producers, researchers, and the public; development of a remedial action plan in case of identified resistance.

The refuge approach is based on the assumption that inheritance of resistance is recessive and that mating between susceptible and resistant insects will result in progeny susceptible to the Bt toxin(s). The success of this strategy does not only depend on the recessive nature of the resistance, but also on a low initial frequency of resistance alleles and the abundant presence of non-Bt host plant refuges. For example, Australia applies a very strict refuge requirement, namely 70% for one-toxin and 10% for two-toxin Bt cotton. The resistance frequency in Australia remained below 1% for Helicoverpa armigera and Helicoverpa punctigera after more than a decade since its first release. In addition, the dose of Cry toxins in Bt crops has to be high enough to eliminate more than 99% of susceptible insects under field conditions. This strategy is referred to as 'the high-dose rule' (Tabashnik et al., 2013; www.vib.be/en/about-vib/plant-biotech-news/ Documents/BackgroundReport BT Cotton.pdf). Indeed, studies on Bt maize in South Africa have shown that resistance development to Busseola fusca (maize stalkborer) has been enhanced because the crop did not conform with the highdose requirement. Moreover, this was aggravated by the low compliance to refuge requirements by South-African farmers during the first 5-7 years after release (Kruger et al., 2012; van den Berg et al., 2013).

In theory, combining different *Bt* toxins targeting the same pest into one plant, the so-called pyramids or stacks, significantly lowers the chance of resistance development, but the example described above indicates that resistance develops

faster when pyramids are grown alongside single-toxin plants. Resistance can emerge already after two years in the absence of appropriate insect resistance management practices and suboptimal design of the resistance gene(s) (Tabashnik *et al.*, 2013). Nevertheless, under optimal circumstances and when all factors influencing the development of insect resistance are taken into account, *Bt* crop efficiency can be sustained for 15 years or more. Even with the use of *Bt* pyramids, it is absolutely imperative that farmers are informed on and comply with insect resistance management practices when they adopt *Bt* crops to ensure their sustainability.

Bt cotton for the West-African cotton production

Before considering the introduction of Bt cotton into other West-African cotton production systems, it will be important to introduce the trait into local varieties adapted to the regional climatic conditions to fully gain the benefits observed for Burkina Faso and South Africa. In addition, the local farmers will need to be trained to implement resistance management practices to ensure a durable crop protection and to avoid or delay the development of insect resistance. When these important factors are taken into account, the examples described above clearly indicate that Bt cotton adoption into the cotton production systems is beneficial with regard to yield and farm income, pesticide use, and environmental and health impact.

However, it should be considered that the South-African farmers have been confronted with some limitations, such as difficult climatic conditions, failing credit system, and monopsonistic cotton companies, which can all put pressure on the sustainability of the cotton economy (Gouse et al., 2005; Morse et al., 2006; Witt et al., 2006). Although Burkina Faso reformed its cotton sector, it did not create competition. As a result, world market prices are not always translated into producer prices which in 2011, led even to farmer protests (Bassett, 2014). In contrast, studies have shown that in the absence of a well-functioning credit

market, parastatal structures improved growth in the cotton sector (Tumusiime *et al.*, 2014). In Burkina Faso, the reforms tackled the challenges on a global level by establishing a funding mechanism to balance the impacts of seasonal variations in input and/or international cotton prices (Redifer *et al.*, 2014).

In conclusion, it is clear that *Bt* cotton presents important benefits that contribute both to economic as well as environmental sustainability, but the structural and institutional limitations should be addressed appropriately to realize its full potential.

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Genetically Modified Crops in South Asia

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Abstract

Comparable to the rapid adoption of the high-yielding crop varieties during the Green Revolution, four agriculturally important countries of South Asia are at the forefront in implementing genetically modified (GM) crops to reduce production cost and increase food production. India, Pakistan, and Myanmar were the first to approve the commercial cultivation of the first generation of insect-resistant Bt cotton (Gossypium hirsutum). Likewise, Bangladesh was the first country in the world to commercialize insect-resistant Bt brinjal or eggplant (Solanum melongena) varieties to increase domestic vegetable production. Approximately 1.7 billion people live in South Asia, with the majority depending on agriculture for livelihood, employment, and economic activity. India, Bangladesh, and Pakistan are also home to the poorest people in the world. Furthermore, South Asia suffers from malnutrition and hunger that are rampant in the rural areas. These countries are also vulnerable to climate change and seasonal weather disturbances that often result in severe losses in crop production and decreased income for farm communities. These four South Asian countries have either set up or are in the process of setting up policies and regulatory frameworks and have adopted GM crop technologies to help address agricultural constraints and improve their farmer's livelihoods in the 21st century.

Overview of agriculture in South Asia

Agriculture is at the heart of employment, livelihood, and economic activities in the South Asian regions, including the countries of the South Asian Association for Regional Cooperation and Myanmar. Agriculture contributes to one-third to twothirds of the gross domestic production and employs two-thirds of the population. In the 1970s, the introduction and rapid adoption of semidwarf and high-yielding crop varieties and hybrids enabled smallholder farmers to achieve breakthroughs in yield and production, helping these countries to feed the ever growing population. Of the approximately 1.7 billion people in 2015, the populations of India, Pakistan, Bangladesh, and Myanmar are estimated to be 1,250 million, 182 million, 156 million, and 53 million, respectively. In these countries 42% of the world's population is estimated to earn less than US\$ 1.25 per day (http://www.worldbank.org/en/news/feature/ 2014/03/24/south-asia-regional-brief), with the Eastern States of India and Bangladesh as the dark spots of rural poverty. In addition to extreme poverty, malnutrition, and hunger are rampant in these rural parts. The South Asian countries are also vulnerable to climate change and seasonal weather disturbances that put a tremendous pressure on agriculture for meeting food security. As noted in Table 1, India has to feed its 1.25 billion people from the ever shrinking arable land of 157 million hectares and the

Table 1. Key Agriculture Indicators in South Asia

Country	Population (millions)	Total arable (Mha)	Arable land (ha/person)	Rural population (% of total population)	Employment in agriculture (% of total employment)	Small farms (millions)
India	1250	157	0.13	68	51	93
Pakistan	182	21	0.12	62	45	-
Bangladesh	156	8.7	0.05	67	-	17
Myanmar	53	10.4	0.20	67	-	-

Table 2. Area and Yield of Major Crops in South Asia

Country	Wheat (Mha)	Rice (Mha)	Maize (Mha)	Soybean (Mha)	Cotton (Mha)	Cereal* Yield (kg/ha)
India	29	42	9.0	10	12	2,962
Pakistan	8.5	2.5	1.0	-	3.0	2,722
Bangladesh	0.4	11	0.2	0.04	0.05	4,357
Myanmar	0.1	7	0.45	-	0.35	3,641

^{*}Cereal: wheat, rice, maize and millets

availability of arable land per person has decreased to 0.05 hectare per person in Bangladesh (http://data.worldbank.org/region/SAS). On the contrary, the demand for food in terms of calories increases in each country, because food consumption shifts toward non-vegetarian food with an increasing income (Table 1). At the national level, the productivity of the major crops is either stagnant or decelerating, thus widening the gap between demand and supply in the food production system. In recent years, the availability of food grains, pulses, edible oil, vegetables, and fruit has decreased (Choudhary et al., 2014a). Similarly, the average cereal yields in the major Asian countries are among the lowest in the world (Table 2). With the exception of maize (Zea mays) and cotton (Gossypium hirsutum), the yields of other crops, including rice (Oryza sativa), wheat (Triticum sp.) and millets are stagnant and need to increase to maintain the food supply. Many countries are at risk of crop damage due to pests and diseases and sometimes crop failures result from the effects of climate change. The South Asian region often registers significant yield decreases that require the introduction of improved crop varieties and farming practices. These new crops should not only withstand biotic and abiotic stresses, but also help smallholders to create more resource-efficient and resilient farming sys-

tems. The adoption of improved crop varieties is indispensable for competitive agriculture, which remains at the heart of rural transformation.

Globally important GM Crops

In 2014, GM crops were planted over 181 million hectares in 28 countries, spanning from North and South America, Africa, Europe, Asia, and Oceania. More than 18 million farmers benefited by planting crops that were resistant to insects and/ or tolerant to herbicides. Of these 28 countries, four of them are South-Asian countries, namely India, Pakistan, Bangladesh, and Myanmar (James, 2014). The insect-resistant (IR) and herbicide-tolerant (HT) traits are two of the major innovations that are effectively utilized by smallholder farmers in both industrial and developing countries. Notably, the IR and HT traits are the most advanced technologies in the agricultural sector that are packaged into the simplest form of crop inputs known as seed. Firstly, the familiarity to seed makes this technology preferred by the smallholder farmers, leading to a rapid uptake of GM crops in both industrial and developing countries. Secondly, both IR/HT traits are accessible in local crop varieties that are grown and known for decades. The IR trait, which is available in single and double genes, tackles effectively the major insect pests of crops, such as cotton, maize, and

Table 3. Approval of insect resistant (Bt) Crops in South Asia

Country	Biotech crop	Approval	Biotech area in 2014	Total area	Adoption	Date of signature	Date of entry into force
India	Cotton	2002	11.6 Mha	12.25 Mha	95%	01/23/2001	09/11/2003
Pakistan	Cotton	2010	2.85 Mha	3.2 Mha	88%	01/04/2001	05/31/2009
Myanmar	Cotton	2010	318,000 ha	360,000 ha	88%	05/11/2001	05/13/2008
Bangladesh	Brinjal	2013	12 ha	50,000 ha	<1%	05/24/2000	05/05/2004
Nepal						03/02/2001	09/11/2003
Bhutan						-	09/11/2003
Maldives						-	09/11/2003
Sri Lanka						05/24/2000	07/26/2004
Afghanistan						-	05/21/2013

brinjal or eggplant (Solanum melongena). The first generation of the single-gene IR trait (cry1Ac gene) imparts effective resistance to the American bollworm Helicoverpa armigera in cotton and Leucinodes orbonalis, known as the Shoot and Fruit Borer (FSB) of brinjal. The double-gene IR trait controls both Helicoverpa armigera and Spodoptera pests in cotton. Uniquely, GM crops are also available with stacked traits of IR/HT. In addition to controlling the insect pests through the IR trait, the HT trait helps farmers to kill weeds by spraying herbicides on HT crops without damaging the crop. Stacking of the IR and HT traits offers farmers an advanced and environmentally friendly alternative to tackle multiple constraints, such as effective control of specific insect pests and efficient management of weeds.

Approval and adoption of GM crops in South Asia

In 2002, India was the first South Asian country to approve the commercial planting of *Bt* cotton (Table 3). It was a breakthrough to revive the ailing cotton sector in the country that was then characterized by a stagnation in terms of production, a decelerating yield trend with consequently overreliance on import for many decades. Before 2002, Indian cotton farmers suffered considerable losses due to the heavy infestation of *Helicoverpa armigera*, thus requiring often numerous insecticide sprays. Half of the total amount of insecticides used in the country was consumed for cotton alone before the commercial approval of *Bt* cotton in 2002 (Kranthi, 2012). Figure 1 shows percent reduction of insecticides on cotton with

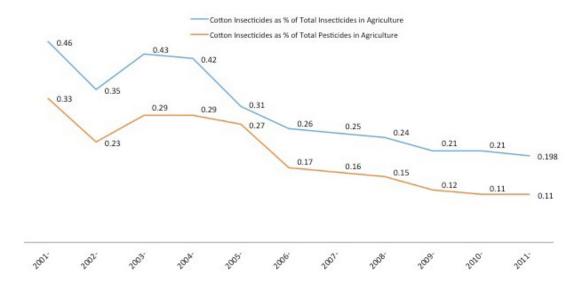


Figure 1. Percent reduction of insecticides on cotton with respect to total insecticides and pesticides used in agriculture in India, 2001 to 2012. Source: Kranthi (2012); Choudhary, et al. (2014).

respect to total insecticides and pesticides used in agriculture in India, 2001 to 2012. A large number of insect-resistant Bt cotton varieties that express single cry genes were successfully developed and released between 2002 and 2006. In 2006, the Government of India released the double-gene Bt cotton hybrids that contained the cry1Ac and cry2Ab genes. In subsequent years, double-gene Bt cotton hybrids were approved that controlled both Helicoverpa armigera and Spodoptera. These hybrids were widely adopted by cotton farmers across the country. In the meantime, four other events of Bt cotton that express different variants of the cry gene(s) were approved as well. However, the smallholder cotton farmers preferred the double-gene Bt cotton hybrids over the other Bt cotton events. In the 2002-2014 period, cotton farmers, irrespective of farm size and income, replaced the commonly used chemical-based crop protection methods for the insect-resistant Bt cotton method that is a more efficient and cost-effective crop protection (Choudhary et. al., 2014a). In the same period, farmers grew Bt cotton over a very large acreage, covering irrigated, rainfed, and semi-irrigated areas of the country. By 2014, the area under Bt cotton cultivation had increased to over 11.6 million hectares, corresponding to 95% of the total cotton area in the country (Table 3). Approximately 7 million smallholder farmers representing more than 95% of the total cotton farmers in the country adopted Bt cotton in the 10 cotton-growing states (James, 2014). Thus, Bt cotton has become an integral part of the cotton cultivation in India.

Following the success of *Bt* cotton in India, the neighbouring country Pakistan, became the second South Asian country to approve the commercial cultivation of the single *cry* gene-based *Bt* cotton varieties in 2010 (Table 3). Eight *Bt* cotton varieties expressing the *cry1Ac* gene, including the Mon531 event developed by Monsanto and one *Bt* cotton hybrid expressing the fused *cry1Ac* and *cry1Ab* genes (GFM event) developed by Pakistani public-sector institutes and local seed companies, received approval for commercial cultivation by the Punjab Seed Council (PSC).

Later, the former federal Ministry of Food and Agriculture and the federal National Biosafety Committee (NBC) of the Pakistan Environmental Protection Agency (Pak EPA) endorsed the PSC decision for commercial release of Bt cotton (at http://environment.gov.pk/national-biosafety-center-nbcs-directorate/). In the subsequent years, the PSC approved additional varieties of Bt cotton, totalling 30 Bt cotton varieties and two Bt cotton hybrids in 2014. Notably, in the fifth year of cultivation of Bt cotton varieties and hybrids, Bt cotton was cultivated in 2.85 (88%) out of 3.2 million hectares of cotton and approximately 700,000 smallholder cotton farmers planted and benefited from Bt cotton in 2014. It is noteworthy that Bt cotton occupied almost the entire cotton crop acreage in the Punjab and Sindh provinces and a substantial part in Baluchistan and Khyber Pakhtunkhwa – four important cotton-growing provinces of Pakistan.

In 2010, Myanmar (formerly known as Burma) officially released the commercial cultivation of a long-staple Bt cotton variety, designated "Silver Sixth" and popularly known as "Ngwe chi 6", that had been developed, produced, and distributed by the State-owned Myanmar Industrial Crops Development Enterprise. In the same year, the National Seed Committee of the Ministry of Agriculture and Irrigation officially registered "Ngwe chi 6" for commercial cultivation and it was used unofficially for the first time by farmers in 2006-2007. During this period, this Bt cotton variety became very popular in all major cotton-growing regions, including Western Bago, Mandalay, Magwe, and Sagaing. At the time of official release, the "Ngwe chi 6" Bt cotton was estimated to be grown by 375,000 farmers on approximately 270,000 hectares (an average of 0.7 hectares of Bt cotton per farm) (Choudhary and Gaur, 2010), whereas in 2014, it occupied the entire long-staple acreage of 318,000 hectares (88%) of 360,000 hectares of cotton in Myanmar (Table 3). Approximately 454,000 smallholder farmers planted the Bt cotton variety in 2014. Until now, "Ngwe chi 6" is the only long-staple Bt cotton variety released in Myanmar (James, 2014) and has been approved

in the absence of a national biosafety system, of which the formulation is being processed and considered by the national assembly in the near future.

In contrast to the approval of feed and fiber GM crops in the world, Bangladesh - the most densely populated country in South Asia - took a historical decision on 30 October, 2013 to approve the official release of four GM varieties of Bt brinjal (eggplant) for a limited commercial cultivation. As such, Bangladesh became the first country in the world to approve the cultivation and consumption of Bt brinjal, namely resistant to FSB. Brinjal is grown over approximately 50,000 hectares throughout the year, and suffers regular and heavy yield losses due a very destructive insect pest, the FSB that is difficult to control by conventional insecticides. However, during heavy infestation, farmers have no other option than to apply insecticides, sometimes every other day, up to a total of 80 applications per season. This has serious implications for producers, consumers, and also the environment. The Government of Bangladesh through its National Committee on Biosafety of the Ministry of Environment and Forests approved the release of four Bt brinjal varieties produced by the Bangladesh Agricultural Research Institute: Bt Brinjal-1 variety, popularly known as Uttara, for planting in the Rajshahi region; Bt Brinjal-2 (Kajla) in the Barisal region; Bt Brinjal-3 (Nayantara) in the Rangpur and Dhaka regions; and Bt Brinjal-4 variety, known as Iswardi/ ISD006, for planting in the Pabna and Chittagong regions (Choudhary and Gaur, 2014). On 22 January 2014, the seedlings of these four Bt brinjal varieties were distributed by the Honorable Minister of Agriculture, Ms. Matia Chowdhury, to 20 smallholder farmers, who became the first Bangladeshi farmers to plant Bt brinjal over 2 hectares in four representative regions, namely Gazipur, Jamalpur, Pabna, and Rangpur in the spring. Subsequently, the Bangladesh Agricultural Research Institute distributed seedlings to 100 additional farmers in the winter of 2014. In total, 120 farmers planted Bt brinjal varieties over 12 hectares in four intensive brinjal-growing areas of Bangladesh (James, 2014) (Table 3). The Government of Bangladesh is expected to release five additional *Bt* brinjal varieties in the near future to provide a wider choice to brinjal growers also in other areas of the country and plans to bring 20,000 hectares (approximately 40%) of the total 50,000 hectares across 20 districts under nine *Bt* brinjal varieties in the next five years.

Biosafety and regulatory system of GM crops in South Asia

Nine countries of the South Asian region have ratified the Cartagena Protocol on Biosafety (Secretariat of the Convention of Biological Diversity 2000) from 2003 to 2013 (Table 3). The Convention of Biological Diversity of 1993 recognizes the potential of modern biotechnology to contribute to human well-being, while taking cognizance that modern biotechnology could have negative effects on environment and human health. It emphasizes the need to regulate the risks associated with the use of living modified organisms (LMOs) and calls for the legally mandatory international instrument on biosafety in the form of the Cartagena Protocol on Biosafety that came into force in 2003. The Protocol focuses on the transboundary movement of the LMOs and seeks to lay down an internationally acceptable framework to provide an adequate level of protection against the possible adverse effects of LMOs on biodiversity and human health. The Cartagena Protocol mandates the parties to establish an advanced informed agreement procedure to ensure that countries can take informed decisions regarding the importation of such organisms into their territory. The Cartagena Protocol also establishes a Biosafety Clearing House to facilitate the exchange of information on LMOs and to assist countries in the implementation of the Protocol. India was the first country in the South Asian region to ratify the Protocol in 2003 and Afghanistan the last that assented in 2013.

Although many South Asian countries have adopted the protocol (Table 3), only a few have recognized biosafety and regulatory systems for testing,

commercial approval, and import and export of the LMOs. India, Pakistan, and Bangladesh are the three South Asian countries that have established a working biosafety and regulatory system on GM crops (Table 4). Prior to joining the Cartagena Protocol on Biosafety, India notified the Environmental Protection Agency Rules on "the manufacture, use, import, export, and storage of hazardous micro-organisms, genetically engineered organisms, or cells 1989", commonly referred as the EPA Rules 1989. The EPA Rules 1989 provides the legal and institutional framework for granting approvals for testing and commercialization of GM crops from the research stage to large-scale commercial use. The Ministry of Environment and Forest administers the apex biotech regulatory committee, the Genetic Engineering Appraisal Committee (GEAC), whereas the Review Committee on Genetic Manipulation functions under the supervision of the Department of Biotechnology. The EPA Rules 1989 mandates each institute to have an Institutional Biosafety Committee before projects are undertaken that involve recombinant DNA technology. Bt cotton is the only GM crop evaluated and approved for commercial cultivation by GEAC in 2002. Although the GEAC thoroughly evaluated Bt brinjal and declared it safe for environmental release in 2009, a moratorium had been imposed on its commercial release in 2010 (MOEF, 2010). The GEAC-led Indian regulatory system has successfully evaluated the safety, efficacy, and performance of numerous GM crops that involved many traits, including insect resistance, herbicide tolerance, nitrogen use efficiency, hybrid vigor, salinity, and drought tolerance.

Similarly, tthe Pak-EPA of the Ministry of Climate

Change administers the National Biosafety Committee, an apex regulatory committee with the mandate to approve the commercial release of GM crops in Pakistan. Other regulatory committees include the Technical Advisory Committee and the Institutional Biosafety Committees (Table 4) that were set up with the notification of the Pakistan Biosafety Rules 2005, issued under the Pakistan Environmental Protection Act 1997 of the Ministry of Climate Change. Accordingly, the National Biosafety Guidelines 2005 were developed and notified to provide a roadmap, procedures, and protocols to evaluate the safety and efficacy of GM crops in Pakistan. The Pak-EPA also institutionalizes the National Biosafety Centre to coordinate the evaluation process among different committees. In 2010, Pakistan approved the commercial release of its first GM crop, Bt cotton.

In recent years, Bangladesh has created a unique biosafety regulatory system under the Bangladesh Biosafety Rules 2012 and the Biosafety Guidelines of Bangladesh 2007, comprising key biosafety committees led by the National Committee on Biosafety that is administered by the Ministry of Environment and Forests. Another committee is the National Technical Committee on Crop Biotechnology of the Ministry of Agriculture that evaluates and recommends decisions to the National Committee on Biosafety on GM crops and to the Biosafety Core Committee of the Ministry of Environment and Forests. This provides the obtained technical comments and recommendation on GM crops and informs the Institutional Biosafety Committees of the respective institutes that assess and monitor the research and development activities of GM crops at the

Table 4. Regulatory agencies on GM crops in key South Asian countries

Country	Regulatory Agency	Administrative Ministry	Approved GM crops
India	Genetic Engineering Appraisal Committee (GEAC) Review Committee on Genetic Manipulation (RCGM)/Institutional Biosafety Committee (IBSC)	Ministry of Environment, Forests and Climate Change (MOEF&CC)/Department of Biotechnology (DBT)	Cotton
Pakistan	National Biosafety Committee (NBC)/Technical Advisory Committee (TAC)/Institutional Biosafety Committee (IBC)	PAK-EPA/Ministry of Climate Change	Cotton
Bangladesh	National Committee on Biosafety (NCB)/National Technical Committee for Crop Biotechnology (NTCCB)/Biosafety Core Committee (BCC)/ Institutional Biosafety Committee (IBC)	Ministry of Environment and Forest (MOEF)/Ministry of Agriculture (MOA)	Brinjal
Myanmar	National Seed Committee (NSC)	Ministry of Agriculture and Irrigation (MOAI)	Cotton

institute level (Hussain and Lagos, 2014). These committees coordinate the biosafety assessment of GM crops from laboratory experiments all the way to approval for commercial release. NCB is the apex decision making body on approving the commercial release of GM crops in the country. In October 2013, the NCB approved the commercial release of the country's first GM insect-resistant Bt brinjal. Bangladesh is an exemplary model for the successful public-private partnership and delivery of the benefits of Bt brinjal to resource-poor farmers in South Asia. Bt brinjal was developed by the Bangladesh Agricultural Research Institute in collaboration with the private Indian seed company Mahyco and had been facilitated by the Agricultural Biotechnology Support Project, funded by the United States Agency for International Development. It was the first collaborative project on GM crops between India and Bangladesh.

The biosafety regulatory framework of other Asian countries is either at the draft or conceptual stage. Myanmar is the only country in South Asia that approved the commercial cultivation of a GM crop, a long staple Bt cotton variety "Ngwe Chi 6", without a national biosafety system in place. However, this Bt cotton variety "Ngwe Chi 6" was approved by the National Seed Committee of the Ministry of Agriculture and Irrigation in 2010. In the past, the Ministry of Agriculture and Irrigation with the help of the Global Environment Facility of the United Nations Environment Programme (UNEP GEF) drafted the Myanmar National Biosafety Framework 2006 that aims at balancing the use of biotechnology with ensuring human health and biodiversity (www.unep.org/biosafety/files/MMNBFrep.pdf). In the meantime, Myanmar has benefited from the large-scale planting of Bt cotton from 2006 to 2014. At national level, cotton production has more than doubled from 271,069 MT in 2006-07 to 618,220 MT in 2012-13 (James, 2014). Yields of the long staple cotton increased to 2,100 kg per hectare as compared to the yield of 450 kg per hectare for short staple cotton. Brookes and Barfoot (2014) estimated an enhanced farm income at US\$293 million for the period 2006 to 2013 and the benefits for 2013 alone at US\$28 million. In this context, therefore, the draft biosafety framework needs a critical revision for developing a cost- and time-effective regulatory system to officially introduce double gene Bt cotton varieties in the country. Similarly, the UNEP GEF assisted Sri Lanka to draft its National Biosafety Framework 2005 and the Guidelines for the Safe Use of Recombinant DNA Technology in the Laboratory 2005 (LKNBFrep.pdf). The biosafety framework was prepared to ensure that potential risks resulting from modern biotechnology applications and its products would be minimized and that biodiversity, human health, and environment would be protected in a maximum way (Gupta et al., 2014). Meanwhile, the Government of Sri Lanka notified the Food (Control of Import, Sale, and Labeling of Genetically Modified Foods) Regulation 2006 to ensure the proper regulation of the transboundary movement of GM crops. The Government of Sri Lanka is also drafting the National Biosafety Act to create a workable framework for experimentation, export, import, and commercial release of GM crops. Other South-Asian countries, including Bhutan, Afghanistan, and Maldives have very limited activities involving GM crops.

Impact of GM crops in South Asia

Four South Asian countries have harnessed enormous benefits from GM crops as evidenced by the rapid uptake and expansion of GM crop cultivation. India achieved a near 95% adoption of Bt cotton at the national level between 2002 to 2014 and similarly of 88% in both Pakistan and Myanmar between 2010 and 2014 (Table 3). Notably, the adoption of Bt cotton was distributed evenly among all the cotton-growing areas in these countries, irrespective of farm size and status of farmers in the society. Empirical studies show significantly reduced cultivation cost and increase in cotton production due to the wide-scale adoption of Bt cotton. Further, the adoption of Bt cotton allowed farmers to reduce insecticide sprays for the management of Helicoverpa armigera from on average more than 24 to only 2-3 sprays per season. Uniquely, the market share for cotton insecticides as a percentage of total insecticides decreased from 46% in 2001 to 20% in 2011 and, more specifically, from 71% in 2001 to 3% in 2011 for the insecticide against cotton bollworm (Choudhary *et al.*, 2014a). The same trend was observed in *Bt* cotton areas of Pakistan and Myanmar. In Pakistan, a *Bt* cotton study noted important health and environmental advantages in terms of reduced incidence of acute pesticide poisoning and increased higher farmland biodiversity with reduced soil and groundwater contaminations, respectively (Kouser and Qaim, 2013).

On the production side, *Bt* cotton contributed not only to an increase in productivity at farm level, but also in doubling the cotton production in India and Myanmar. In Myanmar, farmers increased the long-staple cotton yield by 125% from 2006-2007 to 2013-2014, resulting in a net income estimated at US\$ 138 million for the period 2006 to 2013 and at US\$ 28 million benefits for 2013 alone (Winn and Vasquez, 2011). In India, the acreage expanded rapidly from 9 million hectares to 12 million hectares, thus developing non-traditional cotton areas in the semi-arid tropics. Consequently, the national cotton production

increased from 13.6 million bales in 2002-2003 to 39 million bales in 2013-2014, almost a tripling of cotton production in twelve years. Figure 2 shows a strong correlation between the large-scale adoption of *Bt* cotton and a positive trend in cotton production, regardless of yearly fluctuations in cotton yield (Choudhary and Gaur, 2015).

As a result, the South Asian input to the global cotton production improved from 20% in 2001 to 33% in 2014. In India, the average cotton yield evolved from 308 kg lint per hectare in 2001-2002 to more than 500 kg lint per hectare in 2013-2014. Bt cotton enhanced farm income by US\$ 16.7 billion in the twelve year period 2002 to 2013 and US\$ 2.1 billion in 2013 alone. Hence, farmers across the countries preferred to grow Bt cotton because it became comparatively more profitable than other crops, such as millets and legumes.

In Pakistan, the gains from the large-scale cultivation of *Bt* cotton were limited to the production costs and were not observed on cotton productivity, largely due to a lack in proper supply of *Bt* cotton varieties, adverse weather conditions, and infestation by the cotton leaf curl virus in the ma-

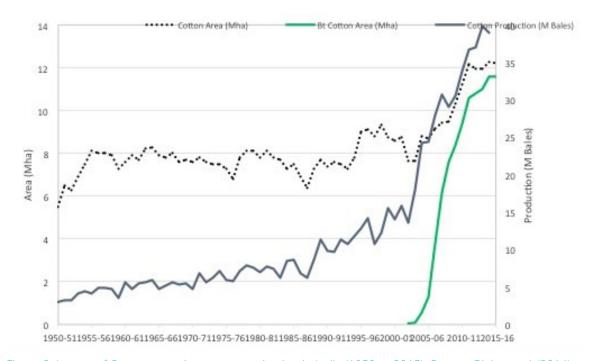


Figure 2. Impact of *Bt* cotton on the cotton production in India (1950 to 2015). Source: Blaise *et al.* (2014); adapted from James (2014).

jor cotton-producing Punjab province. Notably, at the national level, *Bt* cotton had been estimated to deliver a total benefit of US\$ 701/hectare, including the health and environmental benefits of US\$ 195/hectare (Kouser and Qaim, 2013). Translation of these benefits into gross benefits would have provided economic gains from *Bt* cotton varieties for Pakistan of US\$ 615 million for 2010-2013 and US\$ 368 million for 2013 alone (Brookes and Barfoot, 2014).

The commercial approval of Bt brinjal in Bangladesh, although limited to 12 hectares and grown by 120 farmers in 2014, demonstrated the effectiveness of the Bt technology in the field also for brinjal. In line with the data generated during the field experiments, Bt brinjal substantially reduced insecticide sprays, namely by 70-90%, diminishing the production cost of unblemished fruits, enhancing yield (by at least 30%) and fruit marketability, and thus increasing income and return from the local market. In terms of value, farmers spent less on pesticide sprays resulting in a net economic benefit of US\$ 1,868 per hectare over non-Bt brinjal (Choudhary et al., 2014b). Empirical results suggest that the large-scale cultivation of Bt brinjal could generate a substantial economic benefit for approximately 150,000 brinjal growers in Bangladesh.

Experiences from four GM crops growing countries in South Asia indicate a rapid adoption and acceptability of GM crops by smallholder farmers. It has been demonstrated that the *Bt* technology is scale neutral and has delivered similar benefits, if not more, to smallholder farmers in developing countries as to the large scale farmers of industrial countries. Figure 3 captures the trend in adoption of Biotech cotton by large scale farmers in USA from 1996 to 2015 as compared to the smallholder *Bt* cotton farmers in India from 2002 to 2015.

Future prospects of GM crops in South Asia

Crop improvement by integrating the best biotechnological traits and optimal germplasm remains the key priority for most of the South Asian region. Biotechnological traits have opened an enormous opportunity to complement conventional selection and mutation breeding. From the vast experience of growing GM crops in India, Pakistan, Myanmar, and Bangladesh, GM crops obviously offer the possibility to tackle challenges rou-

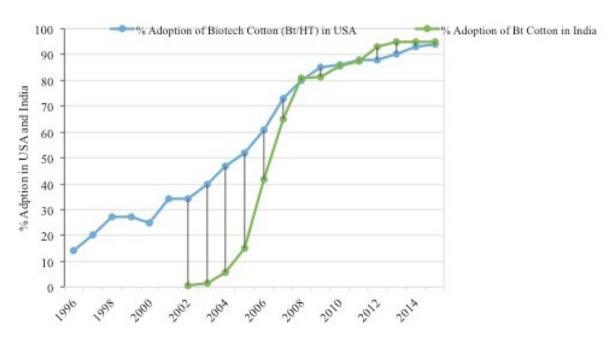


Figure 3. Adoption of biotech cotton by famers in the USA and India, 1996 to 2015. Source: Analyzed by Bhagirath Choudhary, 2015

tinely encountered by farmers and, therefore, to help improve crop productivity, enhance income and ensure livelihood. As of now, the countries in South Asia have only experienced the IR benefits of GM crops. The opportunities of promising commercial GM traits cultivated in other parts of the world need to be explored to advance the crop improvement paradigm. These traits include HT, virus resistance, drought tolerance, quality traits, and above all multiple trait stacking to optimize resource utilization and to maximize inputoutput return.

Ongoing field experiments in South Asia (Table 5) of GM crops include IR/HT, but also nutritional enhancement, disease resistance, nitrogen use efficiency, and salinity tolerance. A dozen crops with these GM traits have either been analyzed in laboratories or are at the event selection and confined-field trial stages in India, Pakistan, and Bangladesh. These crops and traits are likely candidates for commercial approval in the South Asian region in the near (1-3 years) to medium term (2-5 years).

The continuation of field experiments and possible commercial approval hinge on multiple factors that differ from country to country. Bangladesh forges ahead with great emphasis on GM crops developed preferably by public-sector institutes. Besides Bt brinjal, Bangladesh is testing Asia's first late blight-resistant (LBR) potato (Solanum tuberosum) varieties, developed by the public sector institute Bangladesh Agricultural Research Institute and the Potato Research Centre and facilitated by the United States Agency for International Development led the Agricultural Biotechnology Support Project. This LBR potato carries a resistance gene from a wild-type potato (Solanum bulbocastanum) species that would significantly reduce the amount of fungicides and result in increased potato yield and quality. Golden rice is another public-sector product developed by the Bangladesh Rice Research Institute in collaboration with the International Rice Research Institute and has been field-tested in the last couple of years. Recently, Bangladesh field tested the IR cotton variety developed jointly by Supreme Seed (Dhaka) in association with the Hubei Provincial Seed Group Co. (China) in the field. This Bt cotton variety was

Table 5. Status of GM field trials in key South Asian countries, 2015

Country	Crop	Gene/Traita	Organizationb	Status
Bangladesh	Brinjal (5 additional varieties)	IR	BARI	Final stage
	Cotton	IR	Supreme-Hubei Seeds	Import approval and field testing
	Potato	LBR	BARI/ABSP-II	Confined field trials
	Golden Rice	NE	BARI/IRRI	Confined field trials
India	Cotton	IR and HT	Mahyco/Monsanto	Pending commercial approval
	Maize	IR/HT	Monsanto	Biosafety research level 2 stage
	Mustard	PQ	Delhi University	Final Stage
	Brinjal	IR	Mahyco	Under moratorium
	Brinjal	IR	Bejo Sheetal/Ankur/Rasi	Biosafety research level 1 stage
	Chickpea	IR	Sungro Seeds	Biosafety research level 1 stage
	Rice	NUE	Mahyco	Biosafety research level 1 stage
	Rice	ST	Mahyco	Biosafety research level 1stage
	Rice	AP	BASF	Event selection trial
Myanmar	Cotton	IR (double gene)	MOAI	Final stage
Pakistan	Cotton	IR and HT	Monsanto	Import permit granted; no trials yet
	Maize	IR and HT	Monsanto, Pioneer, Syngenta	Advanced field trials
	Sugarcane	-	NIBGE	Field trials
	Wheat	-	NIBGE	Field trials

^a AP, Agronomic Performance; IR, Insect Resistance; HT, Herbicide Tolerance; LBR, Late Blight Resistance; NE, nutritional enhancement; NUE, nitrogen use efficiency; PQ, product quality, ST, salinity tolerance.

^b ASBP-II, Agricultural Biotechnology Support Project II; BARI, Bangladesh Agricultural Research Institute; BASF, Badische Anilin und Soda Fabrik; IRRI, International Rice Research Institute; MOAI, Ministry of Agriculture and Irrigation; NIBGE, National Institute for Biotechnology and Genetic Engineering.

field tested in the Kharif (monsoon) 2015 season for evaluating the safety, efficacy, and agronomic performance. Bangladesh aims at increasing cotton production to offset the huge import of raw cotton from India and China and to sustain the growing textile industry in the country.

Pakistan suffered an enormous opportunity cost in not taking full advantage of Bt cotton due to the absence of a comprehensive policy on GM crops, protection of plant variety system, and uncertainty surrounding biosafety regulation. The policy and regulatory uncertainty compounded when the Federal Government of Pakistan enacted the 18th Amendment in pursuant of the Constitution (18th Amendment) Act 2010 that devolved many federal subjects, including environment, to the Provinces in April 2010. Subsequently, agriculture, environment, and biosafety matters were reorganized between the Federal level and the Provinces and also among various ministries at the Federal level. At present, the National Biosafety Centre (NBC) functions under the Environmental Protection Agency (EPA) and is administered by the Ministry of Climate Change. For the last two years, NBC is working without any permanent staff and the EPA officials are temporarily looking after the NBC affairs with a very limited technical capacity to handle cases related to field trials and commercial approval of GM crops. In 2016, two important GM crops that await commercial approval include Bt/HT cotton and Bt/HT maize.

Myanmar drafted a National Biosafety bill in 2006, but realized that it needs to be reviewed and enacted by the parliament before other GM crops can be introduced into the country.

Bhutan maintains its GM-free status as far as cultivation is concerned, following the decision in April 2011 to ban GM crops issued by the Ministry of Agriculture and Forestry. However, the country allows the import of processed and semi-processed GM products that are incapable of reproduction and of which the safety assessment has been conducted in the country of origin (Yangzom, 2014). As of 2015, Bhutan is considering the

enactment of the Biosafety Bill 2014 that should clear the way for experimentation, commercial release, and import and export of GM foods in the future.

The future prospects of GM crops in India remain unclear after the moratorium on Bt brinjal imposed by the Ministry of Environment and Forests in February 2010, although it had been approved in October 2009. However, after the moratorium period, the regulatory system has become indecisive, causing delays and discontinuation of field testing of GM crops. The additional requirement of the "no objection certificate" from (the) State(s) prior to conducting field trials has further complicated the regulatory system. In 2014, the country has made significant strides on the regulatory front by granting approval for field trials of IR/HT maize in Maharashtra in the kharif 2014 season and of GM mustard (Brassica juncea) in Punjab and New Delhi in rabi (spring) 2014 season. Other GM crops, such as brinjal, rice, and chickpea (Cicer arietinum) that received permission to undergo field trials are awaiting the "no objection certificate" from the respective States. In the same year, GEAC also approved four biotech events of soybean (Glycine max) for import and use as feed. In 2016, India is expected to consider the commercial approval of GM mustard (Brassica juncea) with enhanced heterosis. Table 5 presents a comprehensive list of GM crops that are under field trials and nearing commercial approval in India.

In 2016, India is likely to either approve or reject the commercial release of *Bt/HT* cotton developed by Mahyco, GM mustard by Delhi University, and *Bt/HT* maize developed by Monsanto. These three GM crops have completed the required tests for safety, efficacy, and agronomic performance. These crop developers are expected to submit the final biosafety dossiers for commercial release to GEAC in 2016. Therefore, it is important for the country to overcome the bottlenecks in the current regulatory system and critically evaluate the potential of GM crops in improving production and productivity of important crops.

Finally, it is noteworthy to recognize that the farmers in India, Bangladesh, Pakistan, and Myanmar have adopted GM crops, including Bt cotton and Bt brinjal. Although the experience of growing GM crops has been remarkable, but limited to cotton and brinjal only, a large number of GM crops and traits are being field tested in the South Asian region. GM crops, such as Bt/HT cotton, Bt/Ht maize, Bt chickpea, Bt brinjal, Golden rice, LBR potato, and GM mustard are important crops for smallholder farmers in South Asia. These GM crops and other crops in the pipeline will only be cultivated provided the governments in the respective South Asian countries show strong political will and support that are essential to ensure that these GM crops reach the South Asian farmers. The way forward for the South Asian counties is to develop South-South collaborations to avoid "reinvention of the wheel" and promote the Public-Private Partnerships to quickly deliver GM crops to those who need them the most.

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Greening the Supply Chain: The potential for a forest biomass-based bio-economy*

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Abstract

Advances in forest biotechnology have the potential to deliver step changes in woody biomass productivity and process efficiency and an expansion of quality, scope, and scale of forest products and services. Well-placed, well-managed plantations of yield-enhanced, yield-protected tree varieties could deliver far more than simply meeting market fiber demand. By using degraded land, above- and belowground carbon sequestration and avoided deforestation impacts would be considerable. Transfer and uptake of best practices to developing countries could help address rural development, food security, and poverty alleviation objectives of the Post-2015 Development Agenda of the United Nations. Driven by appropriately designed supply chain transformation initiatives, responsible procurement policies, and consumer-driven awareness, investments in biomass-based chemicals and fuels could be part of means to ease fossil-fuel dependency, uncouple growth from emissions, and open a new era for sustainable materials. Advances in imaging and mapping technologies, coupled with progress in field-sensing technologies will allow precision agriculture and forestry to be deployed effectively in ways that spare high conservation value areas and identify areas for ecosystem restoration. Underpinning all these aspects will provide new standards for incorporation of the free prior and informed consent of local communities and forest-dependent populations, including transparency and verification.

Introduction

To prevent natural resources from becoming binding constraints for development, the world economy must be better reconciled within the finite global ecosystem. With limited scope for sustainable resource throughput, ensuring well being within planetary boundaries will require transformational changes in resource use efficiency to meet increasing, diversifying, and shifting demands. In practical terms, step changes in productivity and process efficiency will be required as well as expansion in quality, scope, and scale of products and services.

The social, economic, and environmental dimensions of forests and forestry will permeate every aspect of this transformation – from driving new energy solutions and supporting rural development,

^{*} This paper is dedicated to the memory of Eugenio Ulian, Vice President for Regulatory Affairs, who died tragically in a cycling accident on May 24, 2015 in Brazil.

to mitigating climate change and safeguarding the ecosystems on which future generations will depend. Sustainable production practices coupled with novel woody biomass utilization have the potential to steer the transition toward a low-carbon development trajectory - a bioeconomy - that would reduce dependency on fossil fuels and uncouple growth from emissions. In June 2012, during a side event of the Food and Agriculture Organization of the United Nations (FAO), International Council of Forest and Paper Associations, Associação Brasileira de Celulose e Papel, and partners at Rio +20 entitled "Forests: the heart of a green economy", we presented a systems-based view of the needs to attain this goal (available at: http://www.futuragene.com/en/presentations.aspx).

This proposal of doing more with less outlined the building blocks of an innovation-driven, technology-rich trajectory for the forestry sector toward a world in which 9 billion people will live well in 2050 within planetary boundaries. In this change theory, there are three critical assumptions. Firstly, a fundamental prerequisite is to bring together an interdependent clustering of forest and forestry stakeholders (private sector, non-government organizations, government, the United Nations system, finance, and research community) to design and implement a bioeconomy based on sustainable production, trade, and consumption of forest products. Secondly, scientific and technological innovations will be implemented that will drive biomass productivity and process efficiency and expand the quality and scope of products and services on scale and time. Thirdly, mechanisms for technology transfer and enhanced international cooperation will be required to enable conveying biomass-based industrial development tools and practices to developing countries. Implicitly, the mechanisms are to favor uptake of advanced technology by smallholders and enhancement of their access to local and international markets.

All assumptions, addressing the political, social, economic, and technological barriers to the implementation of a forest biomass-based bioeconomy would need to be adopted in unison. Therefore, the immediate requirement is a new vision

on forest policy cohesion, local and international cooperation, and scientific collaboration.

In our opinion, the potential for this vision to emerge is real, based on the premise that investment in a forest biomass-based bioeconomy is the cheapest, most accessible, and durable option for simultaneously achieving climate change mitigation and sustainable development agendas. The experience of the Brazilian planted forest sector provides insights into a possible forest biomass-based solution and the required impact-delivering conditions. The priority areas are intensification of sustainable plantation management, increase in downstream products and services based on woody biomass, frameworks to direct research to meet productivity challenges and to provide technology governance, diffusion and uptake, down to the local level, and mechanisms to guide consumer acceptance of scientific and technological innovations for sustainable intensification. This chapter takes a critical look at this vision viability, convergence of the individual components of the trajectory, validation of the assumptions made, and assessment of the influences of recent trends in the political landscape.

The productivity challenge

The ways in which strategies for transforming land, water, and energy use are designed and implemented will be decisive in determining future well-being within planetary boundaries. Currently, the patterns of land and resource use and scale and intensity of changes in land use threaten the ecological infrastructure of the planet. From a climate perspective alone, agriculture, forestry, and other land use account for just under 15% of anthropogenic greenhouse gas emissions (approximately 10-12 gigaton (Gt) CO₂ equivalent/ year) (Smith et al., 2014). There is robust evidence and high levels of agreement that "Leveraging the mitigation potential in the [forest] sector is extremely important in meeting emission reduction targets" (Smith et al., 2014). Forests, sustainably managed forestry operations, and forest products are carbon sinks: whereas forests cover only 12% of the planet, they store 66% of all terrestrial carbon, providing 30% of the total mitigation capacity needed to abate the rise in atmospheric carbon over the next 20 years (Dobbs et al., 2007), absorbing roughly 50% of fossil fuel-based greenhouse gas emissions in 2009 (Stevens et al., 2014). Any realistic climate change attenuation or adaptation strategy must invoke a comprehensive forest protection plan. Prevented deforestation would provide 5.8 of the estimated 17 Gt CO₂ equivalents necessary to keep atmospheric carbon concentrations below 450 ppm, of which planted forests could provide 1.5 Gt CO₂ equivalents (Dobbs et al., 2007). By halving deforestation, net benefits of approximately US\$ 3.7 trillion over the long term (Eliasch, 2008) (counting only the avoided damage costs of climate change) could be generated, taking advantage of the 2 billion hectares of degraded land that are available for reforestation, of which 75% in Africa (Minnemeyer et al., 2012). A coordinated effort is imperative to slow, halt, or reverse deforestation and forest degradation from 13 million hectares per year.

Leadership is required to successfully integrate the future role of forests, sustainable forestry, and forest product trade and consumption in this complex agenda, because wood harvesting could triple to approximately 10 billion m³ in 2050 (WWF, 2011a/b/c/d, 2015). As market demand for food, fiber, and fuel will increase in the coming decades, so will the impact on the planet's natural resources. The costs of inaction are not acceptable: the global economic cost of climate change caused by deforestation is estimated to possibly reach US\$ 1 trillion a year (net present value) by 2100 (Eliasch, 2008). Therefore, actions to halt or slow deforestation by responsible investment in agriculture are needed, conceivable, and effective.

What is needed is a step change in the efficiency of production that can only be achieved through a technological upgrade to intensify existing practices for agricultural commodity production. The development of appropriate technologies and standards to guide development and use will be an essential prerequisite for ensuring a sustainable and general next innovation wave.

Sustainable intensification of woody biomass productivity

The forest sector faces the significant challenge of reducing logging pressure on natural forests, while meeting growing, diversifying, and shifting demands. Plantations are increasingly being seen as part of the solution (Forest Stewardship Council [FSC], 2012), because they produce more wood on less land than natural forests and, hence, could spare land for other uses. In 2006, whereas tree plantations comprised only 7% of total forest area, they provided 50% of industrial roundwood (Jagels, 2006). These "Intensively Managed Planted Forests" provided 40% (Kanowski and Murray, 2008), yielding far more wood per hectare than natural forests, especially close to the equator.

However, to meet future demands and avoid logging of natural forests, the plantation area will need to double by 2050: roughly 250 million hectares of new plantations (WWF, 2011a/b/c/d 2015). The Forests Solutions Group of the World Business Council for Sustainable Development (WBCSD, 2012) defined a set of clear forestry sector deliverables to ensure the transition to a world in which "9 billion people live well and within the limits of the planet", including increasing forest carbon stocks by 10% (239 Gt CO₂ or 6.8 Gt CO₂/ year between 2015 and 2050) by: (i) significantly reducing tropical deforestation by 5 million hectares per year (savings of nearly 5 Gt CO₂/year); (ii) reducing harvest in modified natural forests by 4 million hectare per year (for instance by decreasing fuel wood harvesting with savings of 0.7 Gt CO₃/year), and (iii) tripling yield and harvest of planted forests from 800 million m³ to 2.7 billion m³ from 7% to 11% of the world's forests to meet demands for wood, paper, and biomass (savings of 2.35 Gt CO₃/year and a net gain of 1.5). Enhancement and protection of yields of planted forests would be achieved "through genetic improvements that emphasize a mix of plant traits (drought tolerance, insect resistance, product characteristics) and adaptation to different forest types and locations" (WBCSD, 2012).

How does sustainable plantation management work in practice? The example of the Brazilian Planted Forest sector

The experience of the planted forest sector in Brazil provides a striking example of how a blend of policy measures, voluntary actions, adoption and diffusion of technology, and multi stakeholder engagement can transform plantation productivity from a situation of environmental and social crisis. Twenty years ago, plantation-based production was considered with concern and opposition, including from conservationists and social nongovernmental organizations. Their worries were real, particularly where deep failures of forest governance systems and land-tenure issues contributed to social deprivation, inequality, and environmental degradation.

In Brazil, the development of principles and criteria for sustainable forest management by FSC coincided with social and environmental policies of the government and plantation strategies of companies to increase intensity, efficiency, and quality of pulp production. This convergence provided a strong incentive for companies and plantation owners to plant on degraded land and to save and restore protected reserves, all under guidance of international conventions and guidelines, such as the Convention on Biological Diversity, the International Labour Organization declaration on Fundamental Principles and Rights at Work, the FAO Voluntary Guidelines for Responsible Management of Planted Forests, and the Committee on World Food Security (CFS) Voluntary Guidelines on the Responsible Governance of Land Tenure (VGGT).

As soon as policy and governance frameworks for plantation management are in place, they can drive the investments that underpin a globally competitive industry that, in turn, can restore degraded lands, conserve biodiversity, and support rural livelihoods. To date, the experience in Brazil has shown that such a goal can be been achieved without transferring the additional costs to consumers with the following key impacts. (i) For each hectare of forest planted, an average of 0.6

hectares of natural forest is restored, thus establishing ecological corridors and mosaics on lands that were previously degraded and representing a net positive gain of almost 3 million hectares of secondary forest and a significant contribution to ecosystem functions, such as biodiversity preservation and carbon storage, absorbing roughly 64 million metric tons of CO₂ from the atmosphere every year. (ii) Brazilian plantations-based companies work with local communities to agree collectively on best practice and integrate roughly 13,000 families into the forestry industry chain through outgrower programs in over 1,000 municipalities in some of the poorest and most remote areas of the country. In 2013, Brazilian plantations-based companies invested US\$ 64 million in social programs, adding multiple values to the quality of life of local communities. (iii) Production outsourcing is common practice: Suzano Pulp and Paper Company sources up to 30% of its fiber from outgrowers, mostly smallholders, and has helped groups to become certified, covering 22,400 hectares of plantations and 13,000 of natural forest to date, thus, providing outgrowers a price premium, making income per hectare four fold higher than ranching, which is the main rural activity in most of the production regions. (iv) Today, 100% of the market pulp is produced from only 0.7% of all arable land, creating more than 4.4 million direct and indirect jobs and significantly reducing the pressure to bring natural forest areas into production. The joined livestock and forestry programs of the Ministry of Agriculture targets 70 million hectares of land for integrating productivity-enhancing approaches in agriculture and forestry.

In Brazil today, the process of developing and implementing policy and standards for plantation management has created a framework for an on-going dialog around the topic of plantations. Although a great deal remains to be achieved, some interim findings of significance are that (i) deep-rooted conflict can be overcome when leadership on performance standards and cooperation on actions has an impact on common objectives; (ii) a sympathetic approach to ecosystems,

local communities, and small forest owners can be a viable business strategy, without additional costs for the consumers; and (iii) mechanisms to distribute and share the benefits of research (improvements via conventional breeding) into plantation productivity with smallholders can be a win-win situation for business and communities.

The Brazilian experience shows the power of what can be achieved through guarantee convergence between Government and company policies. This collaborative framework has fuelled substantial investments of plantation companies in improved forestry practices, enhanced breeding, rational landscape-scale forest zoning, perfected technologies, ameliorated governance, including strong social safeguards, and sound policies. These direct and indirect social and environmental indicators demonstrate the potency of voluntary commitments in creating a system in which targeted extraction of natural resources can have a net positive impact on social standards and environmental protection.

Market transformation: responsible commodity production and trade

Where and how commodities are produced, processed, consumed, and financed present a mosaic of opportunities and challenges that require systemic transformational changes. Forests and the sustainable production and consumption of forest products are at the centre of this concern.

Sustainable productivity intensification is necessary to meet the increasing demand while moving to net zero deforestation and degradation (Godfrey et al., 2010). Climate resilience and carbon neutrality could be achieved by enhancing plantation yield and developing strategies that provide protection against future pest and disease outbreaks. The exploitation of new low-volume, high-value pathways for the utilization of plantation biomass could generate options for relieving dependence on fossil fuel use in the carbon-based chemical, specialized fiber, and polymer sector (a bio-economy). The Forest Products Association of Canada (FPAC) Biopathways study estimated a mar-

ket value of over US\$ 200 billion for biomass-based products (FPAC, 2011).

However, to achieve an intensified productivity, the existing performance standards that were designed to manage linear incremental changes will not suffice. Future standards must take the complexity of systemic transformational changes into account with a governance framework for the highly disruptive process of further intensification. Such a framework must be conceived to provide social safeguards and effective stewardship and to stimulate preferential procurement and increased consumer awareness. To this end, the Market Transformation Initiative (http://wwf.panda.org/what_we_do/how_we_work/ businesses/transforming markets/) has been created, offering a collaborative approach toward climate resilience and zero net deforestation and degradation through responsible agricultural commodity production. The created coalitions capture 40-50% of demands through leveraging 25% of producers.

To incorporate forest productivity into this new matrix, scientific and technological innovations for enhanced plantation productivity will have to be integrated into zoning and land management under local social license. The Brazilian experience of the plantation sector in internalizing the costs of ecosystem protection and social license could provide an invaluable guidance on what can be produced, by whom, and how.

The forest sector, the forest certification bodies, governments, and civil society have the opportunity to be precompetitive, collectively setting new targets for plantation management that will feed the supply chains of the future. The creation of a governance system with resilience and ambition to meet these challenges will depend on dialog that addresses the stakeholder concerns over the implications of sustainable intensification, thus resulting in a unity of baseline criteria. Not only would such an alliance deliver credible solutions, but it would also have the legitimacy to guide and influence global policy arising from the Post-2015 Development Agenda of the UN.

The rationale for productivity gain: the need for scientific and technological innovation

The rationale for intensifying plantation productivity is based on the formulation of principles, criteria, and indicators. This process is governed by the following framework. (i) The world economy must be reconciled in a finite global ecosystem, if natural resources are not to become binding development constraints. (ii) Enhanced resource use efficiency will be required to ensure well-being within planetary boundaries, while meeting increasing demand. (iii) In practical terms, step changes in productivity and process efficiency will be necessary as well as enhanced quality, scope, and scale of products and services. (iv) Improved process efficiency and scope of products can only be achieved by increased dependence on scientific and technological innovation. If the principal means to achieve resource use efficiency is to produce more from less through an intensification of existing practices and, in turn, relies on an increased dependence on scientific and technological innovation, then frameworks will be needed to direct research to meet productivity challenges and to provide governance for technology utilization, diffusion, and implementation, down to the local level, and local users.

Therefore, the fundamental challenge and opportunity of our time are to develop leadership in the formulation of a framework that will master production efficiency in transformative ways and that stimulates preferential acquisition and increased consumer awareness, in which the physical challenge is the elaboration and use of science and technology for the sustainable intensification of forest commodity production and the social challenge has to ensure that technology reaches those who need it the most. Furthermore, a behavioral transformation is required as well to create a governance framework for the highly disruptive and controversial process of further intensification.

Risk perception: common objections to genetically modified trees

Today, the position concerning genetically modified (GM) trees is similar to that regarding plantations 20 years ago. The debate on GM trees is intimately linked with that on plantations because of its relevance to productivity enhancement. In 2000, worries over GM trees have led to the adoption of policies that prohibit their growth on land certified both by the FSC and Programme for the Endorsement of Forest Certification (PEFC). At present, the FSC Policy on GM organisms bans the use of GM trees, but under the Policy of Association permits field trials of GM trees outside the certified areas. Many of these concerns were catalogued in 2007 by the United Nations Environment Programme (UNEP, 2007) and a subset can be found in the FSC Policy for Association.

The vast body of scientific knowledge accumulated through fundamental research carried out since 2000 and through the experiences and data from the field tests on GM trees carried out around the world have provided answers to the apprehension against GM trees. A study from the European Commission Directorate-General (2010) reported that between 2001-2010, a total of 50 projects involving more than 400 research groups and representing European research grants of roughly EUR 200 million had been focused on GMO safety alone and the funding on GMO safety since 1982 was more than EUR 300 million, involving research on environmental impacts of GMOs, GMO and food safety, and risk assessment and management. The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs are not per se more risky than e.g. conventional plant breeding technologies".

A sector-wide interest in the development and use of GM trees is primarily to provide the step changes needed for yield enhancement and yield protection. Before a widespread deployment of GM trees, there is a window of opportunity for

the FSC and GM tree-developing institutions to establish a common framework for the criteria that would govern development and utilization.

Safe use of GM technology: more than 700 field trials since 1988

A summary of the global status of field tests with GM trees in different countries has been published (FAO, 2004). Since 1988, more than 700 approved field trials for GM trees are reported, of which 28 species and 32 traits were tested in the European Union and 37 species and 36 traits in the USA. The large number of species and traits, of which many were aimed at environmental benefits, can be attributed to the fact that until 2004, the bulk of all trial applications were from public sector institutes, representing public sector interests, and curiosity-driven, non-commercial objectives, including species conservation (American elm [Ulnus americana] and American chestnut [Castanea dentata]), and phytoremediation. A large body of data was obtained that allowed the analysis of many of the technology-related concerns, such as gene flow and gene stability, and provided a track record of biosafety and risk assessment.

Productivity and technology: producing more from less

Productivity has to be considered historically to understand how research priorities can be built to support the objectives of sustainable productivity intensification. At FuturaGene, the initial focus has been on yield enhancement to provide a step change to the incremental improvements obtained over 40 years of conventional breeding at Suzano Pulp and Paper Company. Thanks to breeding for improved tree varieties, plantation productivity has been doubled since the 1970s, meaning that the amount of land required to feed a 1 million ton per year of pulp mill has decreased from 171,500 to 73,500 hectares. If the 1970s productivity levels were in practice today, the eucalyptus plantation of Brazil would be 9.9, rather than 5.1, million hectares. Clonal development and breeding provide continuous improvements in quality and supply, while maintaining genetic

diversity. Suzano has a collection of 15,000 clones in its breeding programs that offer a robust genetic base for yield improvement, fiber quality, and resilience. If enhancing plantation productivity requires a continued emphasis on increasing technical efficiency, then genetic modification could be part of the solution. The technology has an important relevance in Brazil, where yield improvements of eucalyptus through conventional breeding are now limited and where the emergence of various pests and diseases demand urgent solutions to adequately protect yields.

Yield-enhanced GM eucalyptus: laboratory and field studies

To increase the improvements obtained over 40 years of conventional breeding at Suzano, the present strategic focus is on yield enhancement. The most advanced GM trees in the pipeline are transformed with the endoglucanase-encoding gene from the plant Arabidopsis thaliana. This gene is present in all plant species and its product is part of normal plant development processes, facilitating relaxation of the crystalline matrix of the rigid plant cell wall during cell growth, thereby enhancing overall plant growth. The results obtained in field trials under different agroecological conditions at a variety of locations in Brazil show an average yield enhancement of 20% compared to conventional varieties, almost half of the entire yield gain achieved over the last 40 years of breeding.

Brazilian biosafety regime: general considerations

Laboratory and field-testing of the yield-enhanced eucalyptus of FuturaGene in Brazil have been conducted under the 2005 Brazilian Biosafety law 11.105 and Normative 5 – GM event characterization, environmental testing, and health and safety testing. The principles of the Brazilian Biosafety law and Normative 5 are based on the provisions of the Cartagena Protocol on Biosafety (Secretariat of the Convention of Biological Diversity, 2000), the Codex Alimentarius, and the precautionary principle (1992)⁴. The Brazilian Biosafety law conforms to decision IX/5(1) taken at the 9th Confer-

ence Of the Parties to the Convention on Biological Diversity in 2008 and created the National Biosafety Council, the National Biosafety Commission (CTNBio), the Internal Biosafety Commission, and the Biosafety Quality Certificate. CTNBio establishes all normatives required to perform work with GMOs, including Normative 5, for biosafety of commercial approvals.

The Brazilian Biosafety law is very strongly comparable with other national and regional regimes. A comparison with the European biosafety risk assessment procedures that are widely acknowledged to be the most stringent in the world reveals the two to be essentially equivalent in terms of regulatory framework, risk assessment, decision process, and accompanying measures.

Under this framework, the regulatory field trials of FuturaGene have established field performance criteria and allowed the collection of biosafety data. The design of the studies formulated under the directives of the Brazilian Biosafety law addresses many of the commonly raised concerns and directly the decision IX/5(1) of the United Nations Convention on Biological Diversity⁵.

A dossier was submitted to CTNBio in January 2014, and in September 2014 at a public audience in Brasilia, and finally approved for commercial use in April 2015. Approval was based on a rigorous examination of the data presented that showed a substantial equivalence to conventional trees, no risks to animal or human health, and

no detrimental environmental impact. Indeed, in the GM event, an Arabidopsis protein is produced, representing a protein family present in all plants without homology to known allergens or toxins. The GM trees show no visible changes in structure, other than faster growth rate, without modifications in fiber, wood, or chemical properties nor in pollen morphology or viability. The environmental impact of these GM trees has also been rigorously tested without changes in decomposition rate, nor impact on other organisms, including aquatic species, microorganisms, insects, and bees. Gene flow studies have been conducted, tending to zero at <700 m and the invasive potential of the trees is unchanged, because, as an exotic species, the trees cannot cross with wild species in Brazil. A number of studies carried out under a variety of agroecological conditions in different seasons indicate that water usage by the GM trees is similar to that of conventional varieties, in spite of the faster growth rate. Two of the most important insights into the impact of the trees on the biophysical soil characteristics are provided by studies on soil arthropod diversity and population dynamics as well as on the molecular assessment of the diversity of soil bacteria and fungi. No differences in the arthropod, bacterial and fungal populations occurred when the soils of conventional and yield-increased GM eucalyptus were compared. Considering that the diversity and abundance of these organisms are highly dependent on the physical, chemical, and hydrological properties of their environment, and that any change in water use due to the increased

⁴ Article 1 of the Brazilian Biosafety Law states: "This Law provides for safety norms and inspection mechanisms for the construction, culture, production, manipulation, transportation, transfer, import, export, storage, research, marketing, environmental release and discharge of genetically modified organisms – GMOs and their by-products, guided by the need for scientific development in the biosafety and biotechnology area, the protection of life and human beings, of animal and plant health, and in compliance with the precautionary principle."

⁵ (r) Reaffirm the need to take a precautionary approach when addressing the issue of genetically modified trees;

⁽s) Authorize the release of genetically modified trees only after completion of studies in containment, including in greenhouse and confined field trials, in accordance with national legislation where existent, addressing long-term effects as well as thorough, comprehensive, science-based and transparent risk assessments to avoid possible negative environmental impacts on forest biological diversity; (t) Also consider the potential socio-economic impacts of genetically modified trees as well as their potential impact on the livelihoods of indigenous and local communities;

⁽u) Acknowledge the entitlement of Parties, in accordance with their domestic legislation, to suspend the release of genetically modified trees, in particular where risk assessment so advises or where adequate capacities to undertake such assessment is not available;

⁽v) Further engage to develop risk-assessment criteria specifically for genetically modified trees;

⁽z) Provide the available information and the scientific evidence regarding the overall effects of genetically modified trees on the conservation and sustainable use of biological diversity to the Executive Secretary for dissemination through the clearing-house mechanism;

productivity of the GM eucalyptus would necessarily result in changes in the populations of these indicator organisms, we conclude, that, based on the studies carried out so far, the GM eucalyptus does not affect the soil hydrology.

Technology diffusion and future social impact

One of the major concerns raised against the development of GM trees is the consolidation of corporate control over land and use of natural resources and the deterioration of smallholder rights. Will smallholders have access to GM tree technologies and will the presence of GM tree plantations impact the livelihoods of local communities? In the case of Suzano, the company strategy, voluntary agreements with landowners (including smallholders), and national legislation will determine the rate of technology utilization and the diffusion level to other landowners. Suzano has specific written procedures for engagement with indigenous people, local communities, and smallholders within social responsibility policies and guidelines. Under these provisions, Suzano works closely with local communities and, depending on the region, indigenous people whether directly as outgrowers, or not. The company considers that the use of GM trees can bring substantial benefits in the regions in which it operates. Approximately 31% of the pulp is derived from over 1,000 forest outgrowers, of which 80% are smallholders, who have currently access to the company's genetic material (clones) to produce eucalyptus wood. Furthermore, the GM trees under development would be made available for planting in the company's own plantations and to the outgrowers under arrangements similar to the existing proprietary non-GM varieties, in continuation of the policy of providing access to the best available planting material. Free, Prior and Informed Consent (FPIC) is part of this process and Suzano already follows the certification rules regarding FPIC and will maintain them regarding GM tree use. The Brazilian Planted Forest sector as a whole has evolved through close relationships with local communities to collectively agree on best practice and by integrating roughly 20,000 families in the supply chain through outgrower programs.

The relevance of the Post-2015 Development Agenda

A milestone for intergovernmental policy development (UN, 2014) is the year 2015. The sustainable development goals, the Post-2015 Development Agenda, and the outcomes of the 2015 Climate Change negotiations will all be critical for determining how forests and forestry can contribute to future well-being within planetary boundaries (Milledge *et al.*, 2014). The fundamental consideration that runs through the proposed outcomes is that unprecedented cohesion, cooperation, and collaboration on enhanced efficiency in natural resource use will be required to alter the trajectory of global development toward a "safe operating space for humanity" (Rockström *et al.*, 2009).

Cooperation and governance

At the heart of the common interests is the promotion of mechanisms to develop, introduce, and ensure sustainable forest management practices in an environment of constantly increasing fiber demand. Technology and innovation are core elements in this equation as well as the open dialog with all stakeholders regarding appropriate governance frameworks to increase forest productivity. Currently, we strongly believe in a real and practical opportunity for developing, in a collaborative manner, the governance of technologies that would guide research and ensure management and diffusion of the technology to those who could benefit the most.

By embedding such a framework within existing standards for plantation management, the impact of GM trees under consideration for participatory and negotiated land-use planning, emphasis on strengthening smallholder benefits, and biodiversity protection would be addressed. Hence, productivity intensification could free land for other use, such as food production for local markets and biodiversity, further decreasing the logging pressure on natural forests and their associated

communities, ecosystem services, and biodiversity. Conditions that promote diffusion and transfer of the technology could benefit the communities of outgrowers who currently access genetic material and clones to produce wood. Such a framework would fully support the findings that set forward the need for sustainable intensification of smallholder productivity (FAO, 2014).

The certification bodies could lead this process, as they did for plantations, creating a framework that is sector wide, but built on case-by-case assessment protocols and relevant national and international laws, conventions, and voluntary standards. For the scientific and technological innovation a similar leadership is needed as the one that generated the governance frameworks for the principles and criteria of plantation management.

Thus, GM trees as a feedstock for a bioeconomy are part of the solution for market transformation. The GM tree debate and plantations are linked by the need for sustainable intensification and, like plantations, not all GM trees are equal and their impact needs to be assessed on a case-by-case basis. The forest sector understands the need for productivity enhancement and yield protection and is open for cooperation with the civil society in a constructive debate on scientific and technological innovation. Creation of public support to accept the social and environmental impact of sustainable intensification will depend on the debate quality on the subject. Clearly, convergence on governance is needed to ensure sound forest management and sustainability in the face of increasing demand and environmental constraints.

Existing dialog platforms provide input for decision making

Important concerns over the negative impact of both plantations and GM trees persist. However, to meet the challenge of finding an acceptable way forward on plantations, the New Generation Plantations Platform (www.newgenerationplantations.org) established by WWF in 2007 brought together companies, government forest agencies, and civil society

from around the world to explore, share, and promote improved ways of planning and managing plantations. The experience of the last seven years clearly shows that carefully designed and managed plantations in the right places can benefit people and nature when they are developed through an effective stakeholder participation that maintains the ecosystem integrity, protects high conservation values, and contributes to inclusive green growth.

In parallel, The Forests Dialogue, (www. theforestsdialogue.org) is a platform and process that is pioneering new standards in multistakeholder partnership and international dialog to resolve current and future conflicts and to define solutions for some of the key fracture lines that divide opinion – such as FPIC, Intensively Managed Planted Forests, GM trees, and the Food, Fuel, Fiber, and Forests.

These forums provide a means to create inputs for an informed debate on both plantations and GM trees within the certification bodies, for governments and for policy makers. Indeed, precisely agreement on these issues will determine how quickly and how effectively the world is able to make a transition toward economic, social, and environmental renewal. Given that the environmental issues of plantation forestry are well known and that well-developed tools are available, multistakeholder processes are the new frontier to evaluate the process-based technological advances and to ensure inclusive local economic development, hence, reconciling stakeholder perspectives and priorities and bringing innovation to the local level and the family farmer.

Conclusions

An inclusive, low-carbon development model is required to uncouple growth from gas emissions, substitute fossil fuel dependency, and halt or reverse present cycles of deprivation, degradation, and inequality. In short, a revolution in resource use efficiency is necessary (Enkvist *et al.*, 2007). The collectively faced challenges are complex and so are the solutions. Through vision and action,

sustainable intensification of plantation forestry provides an opportunity to enhance the quality of human livelihoods, while maintaining and protecting the natural resources, biodiversity, and ecosystems. The way forward is improved and constructive dialog on technology, enabling policies that stimulate the flow of needed technology and investment and the international cooperation in technology development and deployment. A rational debate on two critical aspects of this model is essential, namely on the supply-side interventions that are vital for sustainable intensification of biomass supply to fuel development, transfer, and uptake of the model, and on the multistakeholder convergence that is mandatory for understanding, acceptance, and, ultimately, governance of the model. The three most important conclusions are that clearly identified solutions and benefits for increasing the production efficiency exist, platforms for dialog are available, and frameworks to deliver timely impact on scale are emerging in the Post 2015 Agenda of the UN. The key action point is the creation of a space for stakeholder convergence to collectively promote a cohesive policy environment and to enable the switch for a transformational change. Progress toward a bioeconomy will be determined by how well collective resistance to transformational change can be overcome.

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Concluding remarks

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Agriculture and the agribusiness sector are fundamental to the livelihoods and food security of populations worldwide and form the backbone of the economies of many developing countries. The sustainable growth of the sector is key in attaining the United Nations Sustainable Development Goals (SDGs) particularly Goals 1 and 2 to end poverty and zero hunger. These goals are as important as challenging because the countries facing extreme poverty and hunger are also often the ones with the highest expected demographic growth. In addition, climatic change and variability is expected to result in further losses in food production and decreased incomes of the people whose livelihoods depend on agriculture. This is especially true in the poorest regions of the world, where smallholder farmers and landless households dominate the agriculture sector. This book highlights the adoption of biotechnology GM crops in agricultural systems of some developing and emerging countries, in Africa, Asia, Central and South America. Although the adoption rate, speed and extent was shown to be very diverse over the different countries there are similarities regarding success, bottlenecks and concerns.

From the second half of the twentieth century on, agriculture has undergone extreme changes and exponential growth - thanks to initiatives led and encouraged by people like Norman Borlaug (Nobel Peace Laureate 1970) - with the development of high-yielding crops, modernization of farming techniques, the use of hybrid seeds, synthetic fertilizers, and pesticides by farmers. Even though

this so called "Green Revolution" has allowed millions of people to be saved from starvation and has ensured food security in many regions of the world, some of the poorest countries to date, have not benefited to the highest extent from these breakthroughs in agriculture production. Biotechnological techniques have further opened up an enormous opportunity to complement conventional selection and mutation breeding in introducing new traits into the genetic background of an existing crop variety. If not encouraged, it might well be that these same countries will not benefit from what is today named the second green revolution. This new step in agriculture is based on the use of genetic engineering technologies and marker-assisted selection to develop new crops and foods that will take the lead in producing increased crop yield and nutritional value.

During the last 20 years, the adoption rate of GM crops has been remarkable but, remains limited to a few crops (mainly maize, soyabean, cotton and canola) and traits (mainly herbicide tolerance and insect resistance), which are appealing to growers and investors because of the agronomically and economically added value they offer. Currently, a number of new GM crops and traits are being field tested in different parts of the world, including major food crops, such as rice and potato, but also crops such as chickpea, mustard, and cassava that are important food crops in Asia, South America or Africa. These crops are gaining importance on the global markets as export commodities of the producing countries that

are developing. The new upcoming crops and traits are the result of multiple international research initiatives started under public, private or public private partnerships. These research and development initiatives are being conducted to produce not only improved GM crops using a combination (stack) of existing traits, but also new types of GM plants. Newly developed crops aim at providing an added value not only to growers, but to the consumer as well (vitamin A, iron or folate enriched), or present a clear environmental benefit (e.g. nitrogen- or water-efficient plants) with the potential to optimize resource utilization and to maximize input-output return. The continuous advancement of technologies, as for example the currently heavily discussed Novel Breeding Techniques (NBTs), and the increase of biological knowledge and comprehension, promises to further extend the possibilities for the development of crops and traits of high quality.

The cultivation of GM crops is still very much polarized to a few countries with the largest areas of cultivation in the USA, Brazil, Argentina, India, Canada and China. Although only five European countries (Spain, Portugal, Czech Republic, Slovakia and Romania) grow GM maize, Europe is a substantial importer of GM crops for its livestock industry. In the last years, different African countries conducted field trials with biotech/GM staple crops, including rice, maize, wheat, sorghum, banana, cassava, cowpea, potato and sweet potato. However, currently only three countries namely Burkina Faso, Sudan and South Africa, are commercially growing GM crops. The reason can be attributed to different factors, including the low availability of GM crops adapted to regional conditions and regulatory systems that are not yet fully operational in every country. Both issues are arguments for investors and companies to stay away from this market.

Indeed, the regulatory systems concerning GM crop cultivation pose a major bottleneck for potential expansion. Laws regulating GM crop cultivation are still under development in some cases or display a high level of complexity, making com-

mercialization of GM crops difficult. In addition, a lack of homogeneity in regulation at an international level is hindering commercialization in the global market as well.

To consolidate the successful adoption of GM crops worldwide and ensure the long-term sustainability of the production systems, a number of institutional issues need to be considered, based on the successes, challenges and lessons learned from current producers of GM crops. For example, Argentina and other countries producing GM soybean, have experienced dramatic expansion of land allocated to production, as well as the increase in output of grains and oilseeds as a whole. This did not only bring significant economic benefits to these countries, but it also induced a shift in land allocation raising questions about the longterm sustainability of the current farming system due to detrimental effects on soil nutrient levels and the potential negative impact on fragile ecosystems. While these concerns are legitimate, the cultivation of GM cultivars cannot be incriminated as the sole culprits, because it might be more the effect of a general and essential need for agriculture intensification. Upcoming GM crops with novel traits allowing cultivation under higher crop densities or using less water and nutrients, support sustainability in that, increased productivity can be achieved without further exploiting the scarce water and land resources. This would go a long way in amplifying the positive net balance of 20 years of GM crops. It is therefore important to highlight the need for appropriate policy responses aimed at optimizing the management of these innovations with adequate biosafety and regulatory frameworks and at establishing sustainability of agricultural systems. Finally, to ensure every country in need benefits from the transfer of technology and investment, international cooperation in technology development and deployment is essential. Although investors might view crops important for developing countries as unable to make a return on investment, it could be argued that supporting the expansion of local crops in developing countries, would invariably lead to increased food security, improved livelihoods and

better incomes. This would especially be the case for the farming communities, who will then be in a better position to afford new technologies and inputs for their farming and off-farming activities. It is therefore also of major importance that the adoption of technologies is accompanied by development of the entire value chains including processing industries and marketing in order to create an added value for agricultural production and development.

Although nobody should claim that one technology can solve by itself major issues such as hunger and poverty, adoption of GM technology combined with an efficient soil, water and pest management is a promising component for a sustainable intensification of agriculture in many regions of the world.

Innovative farming and forestry across the emerging world: the role of genetically modified crops and trees

This book makes the "business case" for the role of biotechnology innovations for sustainable development in emerging and developing economies. It seeks to support the factual debate on biosciences and technology for developing and emerging economies. The book argues that careful applications of biosciences and technology to clearly identified development challenges can result in positive outcomes for communities, farmers and enterprises, environment and society at large. The book provides a compilation of selected studies from different emerging and developing countries that each illustrate either the potential or demonstrated value of a particular biotechnology application for sustainable agricultural innovation and/or industrial development.



The International Industrial Biotechnology Network (**IIBN**) was established in 2010 as a joint inititiave of UNIDO, the Flemisch Government (EWI) and IPBO. IIBN serves as a catalyst for advancing sustainable applications of agricultural and industrial biotechnologyin developing and emerging economies in cooperation with Flanders and other international partners. IIBN is being developed along three tracks: (1) engage in advocacy to raise awareness for the development potential of esp. agricultural biotechnology by providing science-based information and case studies; (2) establish a formal network of like-minded institutions and organizations, and (3) forster R&D cooperation and capacity building in biosciences that addresses the needs of developing and emerging economies, in cooperation with stakeholders in Flanders and beyond



IPBO (International Plant Biotechnology Outreach), a group within VIB, was founded in 2000 by Prof. Marc Van Montagu with the support of the Flemish Government and the Seghal Foundation. The mission of IPBO is to stimulate applications of agricultural biotechnology for inclusive and sustainable development of developing and emerging economies. IPBO's activities include advocacy to raise awareness and improve understanding of the sustainability benefits of biotechnology, training and education of students from developing countries to empower local biotech applications, and fostering international R&D cooperation in the area of aplied agricultural biotechnology oriented towards the needs of developing and transition economies.



VIB Basic research in life sciences is VIB's raison d'être. On the one hand, we are pushing the boundaries to what we know about molecular mechanisms and how they rule living organisms such as human beings, animals, plants and microorganisms. On the other hand, we are creating tangible results for the benefit of society. Based on a close partnership with five flemish universities – Ghent University, KULeuven, University of Antwerp, Vrije Universiteit Brussel and Hasselt University – ans supported by a solid funding program, VIB unites the expertise of 75 research groups in a single institute. VIB's technology transfer activities translate research results into new economic ventures which, in time, lead to new products that can be used in medicine, agriculture and other applications. VIB also engages actively in the public debate on biotechnology by developing and disseminating a wide range of science-based information about all aspects of biotechnology. More information: www.vib.be



Ghent University After more than twenty years of uninterrupted growth, Ghent University is now one of the most important institutions of higher education and research in the Low Countries. Ghent University yearly attracts over 41,000 students, with a foreign student population of over 2,200 EU and non-EU citizens. Ghent University offers a broad range of study programs in all academic and scientific fields. With a view to cooperation in research and community service, numerous research groups, centers and institutes have been founded over the years. For more information: www.UGent.be



The department of Economy, Science and innovation (**EWI Department**) of the Flemish Government prepares, monitors and evaluates policy in the Economy, Science and Innovation Policy area. The aim is to develop Flanders into one of the most advanced and prospercous regions of the world. Their driving forces are the promotion of (1) Excellence in scientific research, (2) an attractive and sustainable business strategy and (3) a creative, innovative and entrepreneurial society.



The United Nations Industrial Development Organization (**UNIDO**) aims to eradicate poverty through inclusive and sustainable industrial development (ISID). UNIDO advocates that ISID is the key driver for the successful integration of the economic, social and environmental dimensions, required to fully realize sustainable development for the benefit of our future generations.

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