Agricultural Biotechnology and Global Competitiveness

ASIAN PRODUCTIVITY ORGANIZATION

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Report of the APO Asian Food and Agribusiness Conference 2013:
Biotechnology and Global Competitiveness, 15–18 July 2013, Republic of China

Dr. Paul Piang Siong Teng, Singapore, served as the volume editor.

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CONTENTS

FOREWORD

Asian agriculture faces challenges arising from low productivity, climate change, natural resource constraints, food security needs, and sustainable development. Biotechnology has wide applications in agriculture and offers tremendous potential for enhancing productivity and developing niche products. Several multinational companies in developed countries have been engaged in the production and commercialization of agricultural biotechnology products and are reaping great benefits.

Those attempting to apply biotechnology on a commercial scale in many Asian countries, however, must deal with inadequate policy measures and regulatory mechanisms; insufficient investment in R&D, especially by the private sector; ecosystem and food safety concerns; and a lack of intellectual property protection. There is also a paucity of knowledge on the part of entrepreneurs of the tremendous business potential of biotechnology in the production of more valuable horticultural crops as well as forest and fishery products. Another issue is how to enable resource-poor, small-scale producers to benefit from biotechnological innovations.

To provide a platform for deliberating on the latest scientific advances and future directions of agricultural biotechnology and assess niche areas where Asian SMEs in food and agribusiness could be competitive, the APO organized its first Asian Food and Agribusiness Conference in Taipei, the Republic of China, 15–18 July 2013. The conference focused on the theme Biotechnology and Global Competitiveness.

This volume is a compilation of the papers and proceedings of the conference covering global trends in biotechnology applications, commercialization of agricultural biotechnology, risk management by agricultural/biotechnology-based SMEs for sustainable business, and roles of biotechnology in enhancing Green Productivity and the global competitiveness of agriculture. I hope that this publication will serve as a useful reference on the subject in APO member countries and elsewhere.

The APO is grateful to the Government of the Republic of China for hosting the conference and to the China Productivity Center, Food and Fertilizer Technology Center, and Council of Agriculture of the Executive Yuan for implementing the program. Special thanks are due to all contributors for their commitment to the project and publication, especially chief resource person Dr. Paul P.S. Teng, who oversaw the entire process and edited this volume.

Mari Amano
Secretary-General
Tokyo
June 2015

ABBREVIATIONS

2,4-D	2,4-Dichlorophenoxyacetic Acid
10-DAB	10-deacetylbaccatin
AAAT	Agency for the Assessment and Application of Technology
ABDC	Agricultural Biotechnologies in Developing Countries
ABIM	Annual Biocontrol Industry Meeting (Switzerland)
ABRII	Agricultural Biotechnology Research Institute of Iran
ACCase	AcetylCoA carboxylase
ACIAR	Australian Centre for International Agricultural Research
ADB	Asian Development Bank
AFMA	Agriculture and Fisheries Modernization Act, Philippines
AFR	Altered Fruit Ripening
AgriTI	Agricultural Technology Industry
AHRI	Australian Herbicide Resistance Initiative
AIATs	Assessment Institute for Agricultural Technology
AO	Administrative Order
APAARI	Asia-Pacific Association of Agricultural Research Institutions
APCoAB	Asia-Pacific Consortium on Agricultural Biotechnology
APEC	Asia-Pacific Economic Cooperation (Forum)
APHIS	Animal and Plant Health Inspection Service
AP	Argonomic Phenotype
APP	Anticipation, Preparation, and Practice
APQA	Animal Plant Quarantine Agency
AR	Abiotic Resistance
ARC	Australian Research Council
AREEO	Agricultural Research, Education and Extension Organization
ARS	Agricultural Research Service (of the USDA)
ARTI	Agrarian Research and Training Institute, Sri Lanka
ASEAN	Association of Southeast Asian Nations
ASR	Asian Soybean Rust
ATIT	Animal Technology Institute Taiwan
BAAC	Bank for Agriculture and Agricultural Cooperatives, Thailand
BAC	Bacterial Artificial Chromosome
BARI	Bangladesh Agricultural Research Institute
BASF	Badische Anilin und Soda Fabrik
BAU	Bogor Agricultural University

BBS	Biogas Biofilter System
BDC	Biotechnology Development Council, Islamic Republic of Iran
BIOTEC	National Center for Genetic Engineering and Biotechnology, Thailand
BIOTECH	(or NIMBB) National Institute of Molecular Biology and Biotechnology, Philippines
BOD	Biochemical Oxygen Demand
BOF	Bio-organic Fertilizer
BPPT	Agency for Assessment and Application of Technology, Indonesia
BQ	Blackquarter Disease
BR	Bacterial Resistant
BSE	Bovine Spongiform Encephalopathy
BST	Bovine somatotropin
Bt	*Bacillus thuringiensis* (a bacterium)
CABB	Center of Agricultural Biochemistry and Biotechnology, Pakistan
CABI	CAB International (formerly Centre for Agriculture and Biosciences International, formerly Commonwealth Agricultural Bureau International)
CBD	Convention on Biological Biodiversity
CCAFS	CGIAR Research Program on Climate Change, Agriculture and Food Security
CCAP	Center for Chinese Agricultural Policy
CDM	Clean Development Mechanism
cDNA	Complementary Deoxyribonucleic Acid
CERA	Center for Environmental Risk Assessment, USA
CFT	Confined Field Trials
CGD	Center for Global Development
CGIAR	Consultative Group for International Agricultural Research
CGMP	Current Good Manufacture Practice
CIMMYT	International Maize and Wheat Improvement Center (Mexico)
CIRAD	French Agricultural Research Centre for International Development
CLSU	Central Luzon State University
CMS	Cytoplasmic Male Sterile
cms-T	Texas Cytoplasm of Maize
CMV	Curly Mosaic Virus
COA	Council of Agriculture Executive Yuan, Republic of China

COD	Chemical Oxygen Demand
COP13/ MOP3	The 13th Conference of the Parties to the United Nations Framework Convention on Climate Change and the Third Meeting of the Parties to the Kyoto Protocol
CP	Coat Protein
CPTI	Cowpea Trypsin Inhibitor
CR	Corn Rootworm
CSCAP	Council for Security Cooperation in the Asia Pacific, Malaysia
CSIRO	Commonwealth Scientific and Industrial Research Organisation, Australia
CSR	Center for Strategic Research, Islamic Republic of Iran
CSSA	Crop Science Society of America
CTC	Centro de Technologia Canaviera (or Sugarcane Research Center), Brazil
CTNBio	Comissão Técnica Nacional de Biossegurança (or National Technical Commission for Biosecurity), Brazil
CVPD	Citrus Vein Phloem Degeneration Virus
DA-BPI	Department of Agriculture-Bureau of Plant Industry, Philippines
DBT	Department of Biotechnology, India
DFS	Division of Food Safety (of the TFDA), Republic of China
DNS	Determination of Non-regulated Status
DOA	Department of Agriculture
DOST	Department of Science and Technology, Philippines
DP	DuPont Pioneer
DPIAB	Development Program for Industrialization of Agricultural Biotechnology
DRA	Division of Research and Analysis (of the TFDA), Republic of China
DSSAT	Decision Support System for Agrotechnology Transfer (A biophysical crop model)
DST	Department of Science and Technology, India
DT	Drought Tolerant
DTMA	Drought-Tolerant Maize for Africa
EASAC	European Academies' Science Advisory Council
ECNCST	Executive Committee of the National Commission on Science and Technology, Pakistan

EGFR	Epidermal Growth Factor
EFSA	European Food Safety Authority
EIA	Environmental Impact Assessment
EIQ	Environmental Impact Quotient
EIS	Environmental Impact Statement
ELISA	Enzyme-linked Immunosorbent Assay
eQTLs	Expression Quantitative Trait Loci
ERDB	Ecosystems Research and Development Bureau
EST	Expressed Sequence Tag
ETS	Excellence Through Stewardship
EU	European Union
FAO	Food and Agricultural Organization of the United Nations
FAO-RAP	Food and Agricultural Organization of the United Nations-Regional Office for Asia and the Pacific
FC	Fowl Cholera
FDA	Food and Drug Administration, USA
FDI	Foreign Direct Investment
FMD	Foot and Mouth Disease
FOPs	Aryloxyphenoxy propionate
FR	Fungal Resistant
FTO	Freedom to Operate
GAIN	USDA Global Agricultural Information Network
GATT	General Agreement on Tariffs and Trade
GCARD	Global Conference on Agricultural Research for Development
gDNA	Genomic Deoxibonucleic Acid
GEF	Global Environment Facility
GHG	Greenhouse Gas
GM	Genetically Modified
GMFAC	Genetically Modified Food Advisory Committee, USA
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practice
GRDC	Grains Research and Development Corporation, Australia
GT	Glyphosate Tolerant
GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit, Germany
HEC	Higher Education Commission, Pakistan

HIV	Human Immunodeficiency Virus
HPPD	4–Hydroxyphenylpyruvate dioxygenase inhibitor
HS	Haemorrhagic Septicaemia
HT	Herbicide Tolerant
IAARD	Indonesian Agency for Agricultural Research and Development
IAEA	International Atomic Energy Agency
IBC	Institutional Biosafety Committee, National Institute of Health, USA
IBD	Infectious Bursal Disease
ICABIO-GRAD	Indonesian Center for Agricultural Biotechnology and Genetic Resources Research and Development
ICAFS	International Conference on Asian Food Security
ICAR	Indian Council of Agricultural Research International Committee for Animal Recording
ICGEB	International Centre for Genetic Engineering and Biotechnology, Sri Lanka
ICR	Center for Rice Research
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
ICRR	Indonesian Center for Rice Research
ICT	Information and Communication Technology
IFAD	International Fund for Agricultural Development
IFNG	Human Interferon Gamma
IFPRI	International Food Policy Research Institute
IIS	Indonesia Institute of Science
IITA	International Institute of Tropical Agriculture
ILSI	International Life Sciences Institute
IMPACT 2009	A global agricultural supply-and-demand projection model
INIA	Instituto Nacional De Investigaciones Agrarias, Spain
INR	Indian Rupee
INRA	Institut National De La Recherche Agronomique, France
IP	Intellectual Property
IPB	Bogor Agricultural University, Indonesia
IPCC	Intergovernmental Panel on Climate Change
IPO-PAK	Intellectual Property Organization of Pakistan
IPR	Intellectual Property Right
IR	Insect Resistant

IRIEC	Indonesian Research Institute for Estate Crops
IRIN	United Nations Integrated Regional Information Network
IRRI	International Rice Research Institute
ISAAA	International Service for the Acquisition of Agri-biotech Applications
ISB	Information Systems for Biotechnology
ISRIC	International Soil Reference and Information Centre
ISTWG	APEC Industrial Science and Technology Working Group
ITB	Bandung Institute of Technology
ITOFCRI	Indonesian Tobacco and Fiber Crops Research Institute
IVEGRI	Indonesia Vegetables Research Institute
KAPE	Korea Institute for Animal Products Quality Evaluation
KNIH	Korea National Institute of Health
KRW	Korean Won
LAMP	Loop Mediated Isothermal Amplification
LFA	Lateral Flow Assay
LIPI	Indonesian Institute of Sciences
LL	Liberty Link®
LLP	Low-Level Presence
LMO	Living Modified Organisms
MAFRA	Ministry of Agriculture, Food and Rural Affairs, Republic of Korea
MAHYCO	Maharashtra Hybrid Seed Company, India
MARDI	Malaysian Agricultural Research and Development Institute
MAS	Marker-Assisted Selection
MAT	Microscopic Agglutination Test
MC	Modified Color
MDV	Marek's Disease Virus
MENR	Ministry of Environment and Natural Resources
MINFAL	Ministry of Food, Agriculture and Livestock (now renamed as Ministry of National Food Security and Research), Pakistan
MMT	Million Metric Tons
MNC	Multinational Corporation
MO	Modified Oil Composition
MOE	Ministry of Education
MOEA	Ministry of Economic Affairs
MOHW	Ministry of Health and Welfare, Republic of China

MVD	Mutant Variety Database
NAFTA	North American Free Trade Agreement
NAIF	National Animal Industry Foundation, ROC
NAM	Non Aligned Movement
NAQS	National Agricultural Products Quality Management Service
NARC	National Agricultural Research Centre, Pakistan
NBC	National Biosafety Committee
NBER	National Bureau of Economic Research
NBF	National Biosafety Framework
NCBP	National Committee on Biosafety of the Philippines
NCHU	National Chung Hsing University
NCSD	National Council for Sustainable Development
NCST	National Commission on Science and Technology
NGO	Non-Governmental Organization
NGS	Next Generation Sequencing
NIH	National Institutes of Health
NPV	Nucleopolyhedrosis Virus
NSC	National Science Council, ROC
NSF	National Science Foundation
NSTP/AB	National Science and Technology Program for Agricultural Biotechnology, Republic of China
NTS	Non-Traditional Security
NUWEST	Nitrogen Use Efficient-Water Use Efficient and Salt Tolerant
ODM	Original Design Manufacturer
OECD	Organisation for Economic Cooperation and Development
OEM	Original Equipment Manufacturer
OGTR	Office of the Gene Technology Regulator, Australia
OO	Other Quality Traits
ORIC	Office of Research, Innovation and Commercialization
P5C5	Proline-5-Carboxylate Synthase
PABIC	Pakistan Biotechnology Information Center
PABP	Pingtung Agricultural Biotechnology Park
PAEC	Pakistan Atomic Energy Commission
PARC	Pakistan Agricultural Research Council
PC	Pollination Control

PCAARRD	DOST's Philippine Council for Agriculture, Aquatic and Natural Resources Research and Development
PCR	Polymerase Chain Reaction
PG	PG Economics
PHP	Philippine Peso
PMRC	Pakistan Medical Research Council
PNCM	Philippine National Collection of Microorganisms
PPP	Purchase Power Parity
PPRV	Pestes des Petites Ruminants
PQ	Product Quality
PR	Public Relations
PRRS	Porcine Reproductive and Respiratory Syndrome
PSC	Punjab Seed Company
PTPNXI	Perkebunan Nusantara X
PVC	Polyvinyl Chloride
R&D	Research and Development
RDA	Rural Development Administration
RDV-F	Ranikhet Disease Vaccine, F-strain
RFID	Radio Frequency Identification
ROC	Republic of China
ROK	Republic of Korea
RR	Roundup Ready®
RRG	Reduced Representation Genomic
RRI	Royan Research Institute
RSIS	S. Rajaratnam School of International Studies
SAARC	South Asian Association for Regional Cooperation
SABRAO	Society for the Advancement of Breeding Researches in Asia and Oceania
SARS	Severe Acute Respiratory Syndrome
SBR	Sequencing Batch Reactor
SCN	Soybean Cyst Nematode
SEA-EU-NET	A project between Southeast Asia and EU to expand scientific collaboration
SEAMEO	Southeast Asian Ministers of Education Organization
SEARCA	Southeast Asian Regional Center for Graduate Study and Research in Agriculture

SLCARP	Sri Lanka Council of Agriculture Research and Policy
SME	Small and Medium Enterprise
SNPs	Single Nucleotide Polymorphisms
SPS	Sucrose Phosphate Synthase
SSRs	Simple Sequence Repeats
STRP	Scientific and Technical Review Panel
SUB1A	Submergence Tolerance Gene
TAC	NBC, Technical Advisory Committee
TAGS	Test accuracy in the Absence of a Gold Standard
TANUVAS	Tamil Nadu University of Veterinary and Animal Sciences
TATM	Taiwan Agriculture TechnoMart
TAVC	Ta Foong Veterinary Company
tCO_2	Tonnes of Carbon Dioxide Emissions
TCOA	Taiwan Council of Agriculture
TEPA	Taiwan Environmental Protection Administration
TFDA	Taiwan Food and Drug Administration
TFP	Total Factor Productivity
TIB	Temporary Immersion Bioreactor
TIOS	Taiwan International Orchid Show
TISTR	Thailand Institute of Scientific and Technological Research
TOP	Taiwan Orchid Plantation
tPA	Tissue Plasminogen Activator
TPWT	Three-step Piggery Wastewater Treatment
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TRPVB	Translational Research Platform for Veterinary Biologicals, India
TYLCV	Tomato Yellow Leaf Curl Virus
UGM	Gaja Mada University
UNCDD	United Nations Convention to Combat Desertification
UNEJ	University of Jember
UNEP	United Nations Environment Program
UNIBRAW	University of Brawijaya
UNUD	Udayana University
UPLB	University of the Philippines Los Baños
USB	United Soybean Board, USA
USD	United States Dollar
USDA	United States Department of Agriculture

VC	Venture Capital
VCS	Verified Carbon Standard
VIB	Vlaams Instituut voor Biotechnologie, Belgium
VNN	Viral Nervous Necrosis
VR	Virus Resistant
WEMA	Water Efficient Maize for Africa
WFP	World Food Programme
WHO	World Health Organization
WTO	World Trade Organization
YTOCA	Yaitai Operational Center for Aquaculture, Republic of China

1

RECOMMENDATIONS

THE FIRST ASIAN FOOD AND AGRIBUSINESS CONFERENCE 2013: BIOTECHNOLOGY AND GLOBAL COMPETITIVENESS

15–18 July 2013, Taipei

PREAMBLE

The APO in collaboration with the Council of Agriculture, China Productivity Center, and Food and Fertilizer Technology Center organized the Asian Food and Agribusiness Conference: Biotechnology and Global Competiveness in Taipei, the Republic of China (ROC), 15–18 July 2013. Inaugural remarks were given by the Deputy Minister of the Council of Agriculture Executive Yuan, Wen-Deh Chen.

Seventy-four participants from 13 APO member countries (ROC, India, Indonesia, IR Iran, Republic of Korea, Malaysia, Mongolia, Nepal, Pakistan, the Philippines, Sri Lanka, Thailand, and Vietnam) attended. Sixteen resource persons from the Asia-Pacific Association of Agricultural Research Institutions/Asia-Pacific Consortium on Agricultural Biotechnology; Asia BioBusiness Pte. Ltd. Singapore; CropLife Asia Singapore; International Service for the Acquisition of Agribiotech Applications Philippines; *Journal of Commercial Biotechnology*, USA; Malaysian Biotechnology Corporation; Nanyang Technological University Singapore; the Southeast Asian Regional Center for Graduate Study and Research in Agriculture Philippines; US Soybean Export Council; and five organizations of Taiwan shared their expertise through thematic presentations on biotechnology-related topics. The conference consisted of thematic sessions, open forums, panel discussions, poster exhibition, and a visit to the Bio Taiwan 2013 exhibition.

One important outcome of the conference was the widespread view among the experts and participants that biotechnology is one important tool to help APO countries meet the challenges arising from climate change, natural resource constraints, food security, and sustainable development. Additionally, experts shared experience in the many varied, proven, safe, effective applications of biotechnology ranging from biopesticides and biofertilizers to biotech (genetically modified [GM]) crops. The participants agreed on the following recommendations:

RECOMMENDATIONS

A. Policy/Regulatory Enablers

1. Many countries lack the biosafety regulatory frameworks for application of biotechnology and commercialization of biotech products to benefit all stakeholders. Governments should put in place appropriate biosafety regulatory frameworks for promoting biotech applications in the food, agriculture, forestry, fishery, aquaculture, livestock, and health sectors. These regulations should be science based and in line with international conventions. The regulatory process must be well defined with deadlines to ensure timely review and processing of applications.

2. Commercialization of biotech products faces challenges. In particular, asynchronous international approvals, high regulatory costs, and adverse public perception remain the major challenges in developing and commercializing GM products. There is a need to synchronize international approvals, lower regulatory costs, and create favorable public awareness of the socioeconomic benefits of biotech products and services in order to accelerate acceptance by the public.

3. Biotechnology is innovation based. It requires a set of enablers like intellectual property protection, a sizable market for products, and R&D investment for development of the sector. Countries should learn from the experience of those that have been successful in harnessing biotechnology through using cross-national metrics to benchmark progress and through the sharing of initiatives and experiences, whether successful or unsuccessful.

4. To encourage biotech innovations and commercialization, governments should provide basic support such as financial incentives, a supportive policy environment, and infrastructure (e.g., Pingtung Agricultural Biotechnology Park in ROC). Such support will help attract further investments in biotechnology, establish agrobioindustrial SME clusters, and develop academia-industry cooperation, all vital contributors to innovation and revenue generation.

B. Risk Management and Risk Communication

5. There are risks in starting and sustaining agricultural biotech enterprises. Specialized expertise is required to identify and manage such risks. A full understanding of these risks and the stakeholders concerned is needed with reference to the entire spectrum of biosafety regulatory and commercialization requirements for biotech products.

6. There are still some concerns raised by the general public on the cultivation of biotech/GM crops. Experience has shown that it is important to treat all such concerns seriously. There is a need to address those concerns directly through appropriate communication strategies including the use of risk communication tools. Both public and private groups in charge of biotech commercialization need to develop proactive strategies and plans to foster public acceptance and promote constructive dialogue on biotechnology. Communication strategies based on science-based positive messages and using the APP (anticipate, prepare, and practice) paradigm is recommended.

7. One of the leading countries in Asia to approve a GM food crop for planting by farmers was the Philippines. The approval was made possible through a science-based regulatory system and by addressing myths and misconceptions about GM crops. Considerable expertise now resides in the national system within the Philippines. This experience should be tapped to conduct communication activities aimed at both internal and external stakeholders during R&D, product development, and commercialization. Such activities should be carefully designed to recognize stakeholders' perceptions, build trust, and be flexible and effective even under high-risk situations.

C. Investment

8. Many Asian countries have invested heavily in public-sector biotech R&D in anticipation of the growing demands to remain food secure. Biotechnology as a relatively new agricultural technology has seen high returns on investment. However, in order for the benefits of biotechnology to be realized fully, a key structural requirement is the existence of science-based biosafety regulatory frameworks and their operational implementation.

9. Agriculture requires continuous innovations to keep up with the needs of the marketplace, farmers, and consumers. But agricultural technologies require significant investments in funding and time, especially potentially "game-changing" technologies such as biotechnology. While the private sector has large investments in biotech R&D, this is dwarfed collectively by public investments, especially in Asia. There is a great need to optimize and synergize, at the country level, biotech applications emanating from both the private and public sectors and to explore ways for both sectors to work toward expediting the delivery of biotech benefits to farmers and consumers.

10. Many Asian countries face common challenges in meeting food and feed security needs. Biotech applications are the solution to address both challenges. A significant barrier to the use of biotechnology is the heavy investment required, especially by governments. Countries such as Malaysia and IR Iran have announced national biotechnology policies and established institutionalized entities to spearhead and attract foreign direct

investment. Special business-friendly investment terms offered by governments such as the Malaysian government have demonstrated their attractiveness for joint-venture business entities to apply biotechnology in food production. Asian countries need to learn from one another and share experiences as well as coordinate efforts between governments, academic communities, local private companies, and foreign investors to offer a modality to accelerate the growth of the biotech sector.

D. Biotechnology for Green Productivity/Technology Solutions

11. "Green food production" has become essential given declining water, energy, labor, and land resources to grow more food to meet increasing demand. The growth in crop yields has slowed down or stagnated over the past two decades or so. Such trends are more pronounced in rice and wheat, two key crops that have not benefited from biotechnology, than in biotech-enhanced maize and soybeans. In the coming decades, countries will have to use biotechnology for green food production in order to deter food insecurity and to address the anticipated effects of climate change.

12. Animal waste is a growing problem in Asia due to the increased demand for protein. It is a major source of greenhouse gas emissions. Livestock biogases include methane, nitrous oxide, hydrogen sulfide, and carbon dioxide. Strategies to address biogas emissions such as biodesulfurization technology using bacterial biofilters as used in ROC can be utilized to treat the large amounts of livestock biogas before it is used as clean energy in farming and other sectors.

E. Strategies for Sector Advances

13. Non-GM biotech applications are much easier to commercialize and receive public acceptance than GM biotech applications. Many non-GM biotech applications, such as biofertilizers, biopesticides, and tissue culture, are already accepted in Asian countries. Countries are urged to use the experience gained from public acceptance of such non-GM applications to support GM biotech applications.

14. Biotech applications are varied, with a very broad scope, such as production inputs (biofertilizers, biopesticides, and animal vaccines), technologies (bioreactors, tissue culture, GM), and target crops and animals. Countries need to prioritize biotech applications appropriately to meet their needs, as has been done by ROC, and provide adequate policy, financial, and logistical support to ensure success. Support mechanisms include basic research in selected areas, industry–university cooperation, industrialization promotion programs, and product marketing.

15. Biotechnology has considerable potential to produce additional food from declining water and land resources while mitigating climate change impact, but its commercialization is constrained by unfounded perceptions of risk. International organizations (e.g., the APO), regional organizations (e.g., ASEAN and SAARC), NGOs, and agribiotech companies should continue to sensitize policymakers and planners to the potential contribution biotech applications can make to ensure national food security and socioeconomic development of the farming community.

At the end, the participants resolved that they would do their utmost to contribute to advances in biotech applications with due safeguards for achieving national food and nutrition security in their countries through utilizing and disseminating the lessons learned from this conference.

2

GLOBAL TRENDS IN BIOTECHNOLOGY APPLICATIONS

GLOBAL DEVELOPMENTS IN BIOTECHNOLOGY CROPS

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INTRODUCTION

The 2012 Food and Agricultural Organization of the United Nations (FAO) report on food insecurity in the world and the resulting impact on poverty and malnutrition, highlighted that 870 million people suffer from hunger and malnutrition today [1]. Notably, the report concludes that, "Agricultural growth is particularly effective in reducing hunger and malnutrition. Most of the extreme poor depend on agriculture and related activities for a significant part of their livelihoods. Agricultural growth involving smallholders, especially women, will be most effective in reducing extreme poverty and hunger when it increases returns to labor and generates employment for the poor." [1]

In addition, by 2100 the global population is expected to reach 10.1 billion, almost 50% more than today's 7 billion [2]. Increased population is expected to occur in high fertility developing countries such as those in Africa. The population of sub-Saharan Africa could increase from the current 1 billion (15% of global population) to 3.6 billion in 2100, which would be 35% of the global population. This high population growth in Africa is due to high-fertility countries: Nigeria, whose population is expected to increase more than five-fold from 135 million today to 730 million, and Kenya, whose population is expected to quadruple from 40 million today to 160 million by 2100. In Asia, the Philippines is expected to double its population from the current 85 million to 179 million. India will have replaced PR China as the most populous country in the world with 1.5 billion and PR China with 940 million. Three of the 20 most populous countries today are from Africa. This will triple to nine in 2100 and will include Tanzania with 316 million, the Democratic Republic of Congo with 212 million, Uganda with 171 million, Ethiopia with 150 million, Zambia with 140 million, Niger with 139 million, Malawi with 130 million, and Sudan with 128 million.

Generally, the population of most industrial countries will decline between now and 2100, but the high-fertility countries will more than compensate for the decline in population in most industrial countries. However, the USA is expected to grow by about 50% from 300 million today to 478 million in 2100 [2]. The 50% increase in global population between now and 2100, plus a change in lifestyle (the creation of an enormous new middle class) and consumption of more meat, presents a formidable challenge to increase crop production (the main source of food and animal feed) to achieve food, feed, and fiber security in 2100. It is noteworthy that, currently, Africa cannot even feed its 1 billion people, a population that is only one-third of the projected 3.6 billion in 2100.

Food producers have continued to improve agricultural systems to meet food demand. The number of conventional agricultural practices that has evolved over time includes: ways to develop new germplasm (such as the use of wild crop relatives); the application of heterosis in the production of hybrids; tissue culture; mutation breeding; and others. Crop culture strategies have also improved with the application of fertilizers, improved irrigation, and crop protection technologies. The combination of these strategies had efficiently provided enough food a couple of decades ago, but this will not be sufficient for current and future food requirements.

There is thus a need to utilize new technologies, such as biotechnology, for a more efficient, productive and sustainable strategy of food production. Research shows that biotechnology can contribute more than the 1% incremental increase in food production, which is the historical improvement in crop production over the past 30 or 40 years. A significant increase can be obtained by using molecular marker technology, and even more so with the use of modern biotechnologies such as genetic engineering. It is important to know and understand that, when put in the proper context, modern biotechnology is just an additional tool to the many innovative tools that are currently available to agriculturists. It is not by itself the most important technological tool, but it serves as the foundation for modern agriculture.

The aim of this paper is to present global developments in biotech crops and forthcoming biotech crops, and to discuss challenges to biotech crop adoption and trade.

GLOBAL ADOPTION OF BIOTECH CROPS

Currently, biotechnology is the most-adopted new farming technology in the world. In 17 years of commercialization from 1996 to 2013, biotech crops' global area increased more than 100-fold from 1.7 million ha in 1996, to 175.2 million ha in 2013 (Table 1). This rate of adoption is the highest for any crop technology in the modern agricultural era. It also reflects the continuing and growing acceptance of biotech crops by both large farmers in industrial countries, and resource-poor farmers in developing countries. In the same period, the number of countries growing biotech crops more than quadrupled, increasing from six in 1996 to 29 countries in 2010 and 2011, declined to 28 in 2012, and to 27 in 2013. Poland did not plant in 2012 due to regulatory problems in the EU, and neither did Egypt in 2013 due to political instability [3].

In 2013, 27 countries (developing and industrial) planted biotech crops and there is a strong indication that several new countries will join in the near term. There has been notable and significant continuing progress in Africa, with three African countries (South Africa, Burkina Faso, and Sudan) collectively planting more than 3.5 million ha in 2013. Significant increases in area of "new" biotech crops, such as biotech maize in Brazil, have also been recorded. From 1996 to 2013, the accumulated area under biotech crops reached 1.6 billion ha (4 billion acres). Developing countries in 2013 grew 54% of the global biotech crop area, and for the second time, developing countries exceeded industrial countries by 5.6 million ha [3]. This trend of higher adoption by developing countries is likely to continue in the future as more countries from the South adopt biotech crops.

Table 1. Global area of biotech crops

	Country	2012		2013		+/–*	%
		Million Hectares	%	Million Hectares	%		
1	USA†	69.5	41	70.1	40	+0.6	+1
2	Brazil†	36.6	21	40.3	23	+3.7	+10
3	Argentina†	23.9	14	24.4	14	+0.5	+2
4	India†	10.8	6	11.0	6	+0.2	+2
5	Canada†	11.6	7	10.8	6	–0.8	–7
6	PR China†	4.0	2	4.2	2	+0.2	+5
7	Paraguay†	3.4	2	3.6	2	+0.2	+6
8	South Africa†	2.9	2	2.9	2	0	0
9	Pakistan†	2.8	2	2.8	2	0	0
10	Uruguay†	1.4	1	1.5	1	+0.1	+7
11	Bolivia†	1.0	1	1.0	1	0	0
12	Philippines†	0.8	<1	0.8	<1	0	0
13	Australia†	0.7	<1	0.6	<1	–0.1	–
14	Burkina Faso†	0.3	<1	0.5	<1	+0.2	–
15	Myanmar†	0.3	<1	0.3	<1	<0.1	–
16	Spain†	0.1	<1	0.1	<1	<0.1	–
17	Mexico†	0.2	<1	0.1	<1	–0.1	–
18	Colombia†	<0.1	<1	0.1	<1	<0.1	–
19	Sudan†	<0.1	<1	0.1	<1	<0.1	–
20	Chile	<0.1	<1	<0.1	<1	<0.1	–
21	Honduras	<0.1	<1	<0.1	<1	<0.1	–

(...continued)

	Country	2012		2013		+/–*	%
		Million Hectares	%	Million Hectares	%		
22	Portugal	<0.1	<1	<0.1	<1	<0.1	–
23	Cuba	<0.1	<1	<0.1	<1	<0.1	–
24	Czech Republic	<0.1	<1	<0.1	<1	<0.1	–
25	Costa Rica	<0.1	<1	<0.1	<1	<0.1	–
26	Romania	<0.1	<1	<0.1	<1	<0.1	–
27	Slovakia	<0.1	<1	<0.1	<1	<0.1	–
	Total	**170.3**	**100**	**175.2**	**100**	**+5.0**	**+3**

Source: James, C. 2013 [3].
Notes:
* Percentage increase (+) or decrease (–) in hectarage from 2012–13.
† Countries planting 50,000 ha or more.

GLOBAL STATUS OF REGULATORY APPROVALS

In 2012, there were newly approved biotech crop products, such as the stacked insect-resistant (IR)/herbicide-tolerant (HT) soybean, approved for Brazil and the USA. The USA also resumed planting Roundup Ready®Alfalfa, while Brazil approved the planting of a virus-resistant soybean. Additionally, there was continued growth in stacked traits in cotton and maize (increased deployment by 13 countries worldwide), and new second-generation events with quality traits such as Golden Rice enriched with vitamin A, as well as soybean with healthier omega-3 oil [4].

In 2013, new events of maize, soybean, eggplant (brinjal) and sugarcane were approved for cultivation for the first time. The maize stacked event 4114 (DuPont), simultaneously expressing three different Bt *cry* genes and the *pat* gene for glufosinate herbicide tolerance was approved for food/feed use and cultivation in Canada and the USA. The USA also approved for food/feed use and cultivation, the glyphosate-herbicide-tolerant maize events HCEM485 (Stine Seed Farm, Inc.), and VCO-01981-5 (Genective S.A.) expressing modified *epsps* genes. The soybean event DAS44406 (Dow AgroSciences) expressing triple modes of herbicide tolerance (glyphosate, glufosinate and 2,4-D tolerance), was approved in Canada for food/feed use and cultivation. Australia, New Zealand, and South Africa have also approved this event for import for food/feed use. The USA has also approved for cultivation four new events, following Canada's approvals in 2012: canola events 73496 and MON88302, maize event MON87427, and soybean event FG72 [3].

In Asia, Bangladesh and Indonesia have achieved major milestones with the approvals of two new biotech crops for environmental release. The drought-tolerant sugarcane event NXI-1T, expressing a bacterial *betA* gene for the production of anti-water stress compound glycine betaine, was finally approved for cultivation in Indonesia by the Biosafety Commission for Genetically Engineered Product.

The NXI-1T event, developed by a government-controlled corporation, was given food safety clearance in 2011. In Bangladesh, the government has approved the release of four varieties of eggplant, expressing the Bt *cry1Ac* gene for commercial cultivation. The four Bt eggpant varieties are based on the Bt eggplant event EE1 originally developed by the India-based Maharashtra Hybrid Seed Company (MAHYCO), which was later transferred to the Bangladesh Agricultural Research Institute (BARI) through a public–private partnership agreement. These new eggplant and sugarcane events add to the growing number of biotech crops developed through public–private partnership, or by government institutions [3].

A total of 36 countries (35 + EU-28) have granted regulatory approvals for biotech crops for food and/or feed use, and for environmental release, or planting from 1994 (as of 30 November 2013). In these 36 countries, a total of 2,833 regulatory approvals involving 27 genetically modified (GM) crops and 336 GM events have been issued by competent authorities, of which 1,321 are for food use (direct use or processing), 918 for feed use (direct use or processing), and 599 for environmental release or planting. Japan has the most number of events approved (198), followed by the USA (165 not including stacked events), Canada (146), Mexico (131), Republic of Korea (103), Australia (93), New Zealand (83), European Union (71 including approvals that have expired or under renewal process), the Philippines (68), Republic of China (65), Colombia (59), PR China (55) and South Africa (52). Maize has the most number of approved events (130 events in 27 countries), followed by cotton (49 events in 22 countries), potato (31 events in 10 countries), canola (30 events in 12 countries) and soybean (27 events in 26 countries) [3].

The events with the most number of approvals are the herbicide-tolerant soybean event GTS-40-3-2 (51 approvals in 24 countries + EU-28), followed by the insect-resistant maize event MON810 (49 approvals in 23 countries + EU-28), herbicide-tolerant maize event NK603 (49 approvals in 22 countries + EU-28), insect-resistant maize event Bt11 (45 approvals in 21 countries + EU-28), insect-resistant maize event TC1507 (45 approvals in 20 countries + EU-28), herbicide-tolerant maize event GA21 (41 approvals in 19 countries + EU-28), herbicide-tolerant soybean event A2704-12 (37 approvals in 19 countries + EU 28), insect-resistant maize event MON89034 (36 approvals in 19 countries + EU-28), insect-resistant cotton event MON531 (36 approvals in 17 countries + EU-28), herbicide-tolerant and insect-resistant maize event MON88017 (35 approvals in 19 countries + EU-28), and insect-resistant cotton event MON1445 (34 approvals in 15 countries + EU-28) [3].

In 2013 alone (as of 30 November 2013), a total of 77 biotech events in six biotech/GM crops (canola, cotton, eggplant, maize, sugarcane, and soybean) have been approved for food/feed use and/or cultivation in 19 countries (including Argentina, Bangladesh, Brazil, Canada, Indonesia, Japan, Paraguay, and the USA). A total of 70 GM events were approved for food and/or feed use, with 25 biotech events approved for cultivation.

A country approves a biotech crop for food/feed use when it cannot produce the crop domestically, but can allow import for subsequent food/feed use. Out of the 127 approvals issued in 2013, 27 are for cultivation, and 100 are for food and or feed use. Of the 100 food/feed approvals, 85 are for imported food/feed or processed products containing the event, and 15 are for direct use of cultivated biotech crop as food/feed [3].

Of the 77 events approved, 22 are single-trait events and 55 are stacked-trait events. Stacked traits of herbicide tolerance and insect resistance dominate in terms of number of events, or globally issued regulatory approvals. This is followed by single traits of herbicide tolerance and insect resistance. 6% of the approved events have stress tolerance trait (drought tolerance), and 5% have product quality traits (modified oil, starch amylase) [3].

Continuous development of biotech crops is expected as farmers and consumers demand improved agronomic traits and nutritional traits. Such development entails a long process of product development that includes the following stages [5]:

1. *Early research and development stages*: This is the initial proof of concept stage which involves identifying and isolating the gene in the laboratory; there may as yet, be no plan for commercialization;

2. *Advanced research and development*: Selected transformation events have gone through confined field tests for one location and is anticipating multiple location field trials;

3. *Regulatory pipeline*: Agronomic data and expression-level data of introduced genes in the advanced GM line are collected from multiple location field trials as prerequisites to commercialization; and

4. *Commercial pipeline*: GM event is authorized in at least one country for food/feed/processing, but not yet marketed.

5. *Commercial GM crops*: The approved GM event is marketed and sold.

Herbicide tolerance has consistently been the dominant trait during the 18-year commercialization of GM crops. In 2013, herbicide-tolerant soybean, maize, canola, cotton, sugar beet, and alfalfa occupied 99.4 million ha or 57% of the 175.2 million ha of biotech crops planted globally. Herbicide tolerance decreased by a net 1.1 million ha from 100.5 million ha in 2012 to 99.4 million ha in 2013. Several events contributed to this reduction including: the displacement in Brazil of 2.2 million ha of herbicide-tolerant soybean by the stacked product, the reduction of close to 1 million ha of HT canola in Canada, and a reduction of about 100,000 ha of HT canola in the USA [3].

Farmers in all countries favor stacked traits for all crops. Stacked traits increased from 43.7 million ha in 2012 to 47.1 million ha, an increase of 3.4 million ha equivalent to an 8% increase from 2012 to 2013. In 2013, areas featuring insect resistance traits also increased by 10% from 26.1 million ha to 28.8 million. Generally the increases and decreases for various traits were mainly due to changes in the key countries of Brazil, USA, Argentina and to a lesser extent, to more modest gains in countries like Paraguay. The stacked traits for herbicide tolerance and insect resistance are deployed in cotton and soybean (Bt/HT), and maize (Bt/Bt/IR, Bt/HT, and Bt/Bt/HT), but not in sugar beet and alfalfa. The Bt/Bt/IR stack refers to different Bt or other IR genes that code for different traits. In terms of year-over-year increases, the highest growth was for the insect resistance trait at 10%, followed by stacked products at 8%, with herbicide tolerance recording a marginal decrease of 1% [3].

The deployment of stacked traits of different Bt genes and herbicide tolerance is becoming increasingly important and is most prevalent in the USA, which had approximately 66% of the 47.1 million ha as “stacked traits” in 2013. The relative percentage in the USA is expected to decline proportionally over time as leading emerging developing countries like Brazil plant more stacks generally, and when new stack products like HT/Bt soybean become available and adopted. HT/Bt in Brazil and neighboring countries are expected to increase adoption very rapidly.

PRIVATE SECTOR GM CROPS IN THE PIPELINE

The private sector has sustained the development of new biotech crops and traits in order to address various agricultural problems: insect pests, weeds, diseases, and climate change effects. The many years of wide adoption of glyphosate-herbicide-tolerant crops in the USA and other countries has resulted in an increase of resistant weed species. In 2012, Green and Owen cited Heap’s 2011 survey of herbicide-resistant weeds, which recorded 21 weed species that have evolved resistance to glyphosate [6–7].

Hence, seed and agrichemical industries have responded with existing herbicide mixtures and multiple HR crops.

In a similar manner, the many years of wide Bt crop adoption in maize and cotton may result in resistant pests. However, industrial and developing countries have benefited tremendously from this technology, which should be nurtured and further cared for. Hence, saving the technology entails its incorporation into an integrated pest-management program and the development of new and multiple insect-resistant traits.

On 5 June 2014, CropLife released a list of crops and traits being developed by five major seed industries [8]. With the need to intensify development of biotech maize to address concerns on herbicide tolerance and insect resistance, the next 5–7 years will see Monsanto and Dow AgroSciences releasing new and stacked herbicide tolerant traits (Table 2). There will also be more diverse traits targeting above-ground pests, new versions of stacked traits for lepidopteran and coleopteran pests from Monsanto, DuPont Pioneer, and BASF. Higher yielding maize from the collaboration of Monsanto and BASF will also be released in due time. Continuing developments are in herbicide tolerance, insect resistance, fungal resistance, nitrogen use efficiency, and new generation drought tolerance.

Table 2. Private sector pipeline for maize

Advanced Development (Next 5–7 Years)		
Trait	**Commercial Name/Trait**	**Developer**
Herbicide tolerance	Third-generation herbicide tolerance	Monsanto
Herbicide tolerance	Enlist™, 2,4-D & FOP	Dow AgroSciences
Insect resistance	Third-generation above-ground insect protection	Monsanto
Insect resistance	SmartStax® Pro	Monsanto
Insect resistance	Optimum® Leptra™	DuPont Pioneer
Insect resistance	Lepidopteran/Coleopteran DP4114	DuPont Pioneer
High yielding		Monsanto, BASF
Early Development		
Herbicide tolerance	Fourth-generation herbicide tolerance	Monsanto
Herbicide tolerance	Multiple mode	DuPont Pioneer
Insect resistance	Fourth-generation below-ground insect protection	Monsanto
Insect resistance	Fourth-generation above-ground insect protection	Monsanto
Insect resistance	New modes of action Coleopteran III	DuPont Pioneer
Insect resistance	New modes of action Lepidopteran III	DuPont Pioneer

(...continued)

Advanced Development (Next 5–7 Years)		
Trait	**Commercial Name/Trait**	**Developer**
Insect resistance	Second-generation CRW control	Syngenta
Insect resistance	Novel insect traits	Syngenta
Fungal resistance		BASF
Nitrogen use efficiency		DuPont Pioneer
Nitrogen use efficiency		Syngenta
Stress tolerance	Drought tolerance II	DuPont Pioneer
Stress tolerance	Yield & stress maize II	Monsanto, BASF
Stress tolerance	Yield & stress maize III	Monsanto, BASF

Source: CropLife, June 2014 [8].
Notes: 2,4–D, 2,4-Dichlorophenoxyacetic acid; CRW, corn rootworm; DP, DuPont; FOP, Aryloxyphenoxy propionate.

With the increasing problem of glyphosate-tolerant weeds in large soybean fields, herbicide-tolerant traits involving glyphosate, glufosinate, dicamba, 2,4-D and 4-hydroxyphenol pyruvate dioxygenase (HPPi), will abound in single, double, and multiple combinations in soybeans for the next 5–7 years (Table 3). Auxins (dicamba and 2,4-D) in very small quantities and HPPi were used in monocot crops to control broadleaf weeds [6]. Hence, GM auxin resistant and HPPi-resistant soybeans need to be developed. The stacked HT and IR soybean could provide another means to reduce production cost in soybean farms.

Monsanto will soon release second-generation GM soybeans with omega-3 and low unsaturated zero-trans fat oil. Continuing research in herbicide tolerance, resistance to insects, nematode, disease, and fungal pathogens, as well as improved yield and improved nutrition, are also being actively pursued.

Table 3. Private sector pipeline for soybean

Advanced Development (Next 5–7 Years)		
Herbicide tolerance	Roundup Ready® Xtend	Monsanto
Herbicide tolerance	Third-generation herbicide tolerance: Roundup Ready® Xtend (Glyphosate + Dicamba tolerances) + third mode of action	Monsanto
Herbicide tolerance	Multiple mode	DuPont Pioneer
Herbicide tolerance	HPPDi + glufosinate	Syngenta Bayer CropScience

(...continued)

Advanced Development (Next 5–7 Years)		
Herbicide tolerance	Enlist™: 2,4-D + glufosinate	Dow AgroSciences
Herbicide tolerance	Enlist E3™: 2,4-D + glyphosate + glufosinate	Dow Agrosciences, M.S. Technologies
Herbicide tolerance	Balance™ GT/LL: glyphosate + HPPDi + glufosinate	Bayer CropScience, MS Technologies
Herbicide tolerance	Balance™ GT: glyphosate + HPPDi	Bayer CropScience, M.S.Technologies
Herbicide tolerance	Cultivance: imidazolinone	BASF, Embrapa/ Brazil
Herbicide tolerance/insect resistance	Enlist E3™ + 2-Bt Trait: 2,4-D + glyphosate + glufosinate + 2 Bt Traits	Dow AgroSciences
Insect resistance	Second-generation insect protection	Monsanto
SDA omega-3		Monsanto
Vistive Gold	Low unsaturated, zero-trans-fat oil	Monsanto
Early Development		
Herbicide tolerance	Fourth-generation herbicide tolerance	Monsanto
Insect resistance	Third-generation insect protection	Monsanto
Insect resistance	Hemiptera/stink bug	DuPont Pioneer
Insect resistance	Lepidopteran	DuPont Pioneer
Nematode resistance	SCN	Syngenta
Nematode resistance	SCN	Bayer CropScience
Nematode resistance	SCN	BASF, Monsanto
Disease resistance	ASR II	DuPont Pioneer
Disease resistance		Syngenta
Fungal resistance		BASF
Higher yielding	Next-generation higher yielding	Monsanto, BASF
Increased oil & improved feed efficiency		DuPont Pioneer

Source: CropLife, June 2014 [8].
Notes: ASR, Asian soybean rust; GT, glyphosate tolerent; HPPDi, 4-Hydroxyphenylpyruvate dioxygenase inhibitors; LL, Liberty Link® (glufosinate); SCN, soybean cyst nematode.

Tables 4 and 5 provide information on GM crops at the advanced-development stage in cotton and canola, respectively. In cotton, combinations of new-stacked herbicide-tolerant traits are featured, in combination with insect-resistant traits. New versions of Bollgard by

Monsanto, and Widestrike by Dow AgroSciences are also in the offing. Bayer CropScience is developing their next-generation herbicide-tolerant cotton, while Monsanto has embarked on Lygus control, and its fourth-generation Bollgard (Table 4).

Advanced development in rapeseed oil is focused on herbicide tolerance with combinations of glyphosate- and glufosinate-resistant traits from Monsanto, DuPont Pioneer, and Bayer CropScience. At early stages of development are dicamba-tolerant soybeans by Monsanto, traits for healthy fatty acids by BASF jointly with Cargill, and oil quality from Bayer CropScience (Table 5).

Table 4. Private sector pipeline for cotton

Advanced Development (Next 5–7 Years)		
Herbicide tolerance	Bollgard® II XtendFlex™	Monsanto
Insect resistance/herbicide tolerance	GlyTol® TwinLink™ Plus: glufosinate + glyphosate + expanded insect resistance	Bayer CropScience
Insect resistance/herbicide tolerance	Bollgard® III	Monsanto
Insect resistance	WideStrike® 3	Dow AgroSciences
Early Development		
Herbicide tolerance	Next-generation herbicide tolerance	Bayer CropScience
Insect resistance	Lygus control	Monsanto
Insect resistance	Fourth-generation Bollgard®	Monsanto

Source: CropLife, June 2014 [8].

Table 5. Private sector pipeline for canola

Advanced Development (Next 5–7 Years)		
Herbicide tolerance	TruFlex™ RR	Monsanto
Herbicide tolerance	Optimum® GLY	DuPont Pioneer
Herbicide tolerance	LL	DuPont Pioneer
Herbicide tolerance	LL	Monsanto, Bayer CropScience
Herbicide tolerance	RR + LL	Bayer CropScience
Herbicide Tolerance	TruFlex RR + LL	Bayer CropScience, Monsanto

(...continued)

Early Development		
Herbicide tolerance	Dicamba tolerance	Monsanto
Healthy fatty acids		BASF, Cargill
Oil quality		Bayer CropScience

Source: CropLife, June 2014 [8].
Notes: LL, Liberty Link®; Optimum® GLY, DuPont Pioneer's glyphosate-tolerant canola; RR, Roudup Ready®.

Rice is one of the world's most important staples, being consumed by 60% of the global population. Only the USA and Brazil commercialize HT rice produced by Bayer CropScience. Although Bt rice has received a biosafety certificate in PR China, its large-scale commercialization is yet to be realized. Beta-carotene-enriched Golden Rice is undergoing multiple location trials in the Philippines, and is expected to be commercialized in three years. Following the initial success of Bt rice in the Islamic Republic of Iran, and in some parts of PR China (though not officially documented), seed developers have pursued the development of insect-resistant rice using Bt genes, and other genes with different modes of action against lepidopterans. Table 6 provides a listing of the advanced GM lines featuring new generation herbicide-tolerant (glyphosate) rice and Golden Rice. Early developments in GM rice include herbicide-tolerant and insect-resistant rice by DuPont Pioneer, insect-resistant rice by Bayer CropScience, and its high-yielding rice in partnership with BASF (Table 6).

Table 6. Private sector pipeline for rice

Advanced Development (Next 5–7 Years)		
Herbicide tolerance	LL	Bayer CropScience
Golden Rice 1	Beta-carotene content	IRRI/Philippines
Golden Rice 2	Beta-carotene content	IRRI/Philippines
Early Development		
Herbicide tolerance		DuPont Pioneer
Insect resistance	Dual mode of action Lepidopteran	DuPont Pioneer
Insect resistance		Bayer CropScience
High yielding		BASF, Bayer CropScience

Source: CropLife, July 2014 [8].
Notes: IRRI, International Rice Research Institute; LL, Liberty Link®.

Non-major crops such as alfalfa, bean, eggplant, potato, sugar beet, sugarcane, and wheat are being improved for disease and insect resistance, as well as nutritional quality for humans and livestock. Notable of these are the Gemini virus resistant bean developed by the public institution Embrapa in Brazil, and alfalfa with reduced lignin for livestock feed, which are both in advanced stages of development. High-yielding alfalfa, sugar beet, sugarcane, and wheat are in the early stages of development (Table 7).

Table 7. Private sector pipeline in other crops

Early Development		Advanced Development	
Alfalfa			
High yielding	Monsanto, Forage Genetics International	Reduced lignin	Monsanto, Forage Genetics International
Bean			
		Virus resistance (Gemini virus)	Embrapa/Brazil
Eggplant			
		Insect resistance (Bt)	Maharashtra Hybrid Seeds Company
Potato			
		Virus resistance (Potato Virus Y)	Tecnoplant/Argentina
Sugar beet			
Higher yielding	BASF, KWS Saat		
Sugarcane			
Insect resistance/ herbicide tolerance (Insect protected + Roundup Ready	Monsanto		
Higher yielding	BASF, CTC		
Wheat			
Herbicide tolerance I	Monsanto		
Herbicide tolerance II	Monsanto		
Yield & Stress	Monsanto, BASF		

Source: CropLife, June 2014 [8].
Note: CTC, Centro de Tecnologia Canavieira (Sugarcane Research Center, Brazil).

GM PRODUCTS IN THE PIPELINE IN LEADING DEVELOPING COUNTRIES

Brazil ranks second only to the USA in biotech crop area in the world. With 40.3 million ha, it is emerging as a global leader in biotech crops. For the fourth consecutive year, Brazil was the global engine of growth in 2013, increasing its area of biotech crops more than any other country, a record 3.7 million ha increase, equivalent to an increase of about 10% [3]. Brazil grows 23% of the global area of 175.2 million ha. A fast track approval system allows Brazil to approve events in a timely manner. Brazil has already approved the first stacked soybean with insect resistance and herbicide tolerance, which was commercialized in 2013. Embrapa, a public sector institution gained approval to commercialize a homegrown biotech virus-resistant bean. Also in the pipeline are important crops and traits, including the stacked HT, IR and DT maize, soybean, and cotton; single HT, IR, DT and low lignin in sugarcane; IR and yield enhancement in eucalyptus; and the virus-resistant bean. The homegrown virus-resistant bean was approved for commercialization in 2011 and is completing variety certification trials to be in farmers' fields by 2015.

India cultivated a record 11 million ha of Bt cotton in 2013, 11% of the global area with a 93% adoption rate. The OECD/FAO Global Agricultural Outlook for 2013–2023 report projected that India will become the world's largest cotton-producer by 2017/2018 [9]. Vegetables are considered staples in the country, hence, GM crops in the pipeline include mostly vegetables and some grains such as IR eggplant, cabbage, cauliflower, chickpea, okra, sorghum, sugarcane, and tomato; single and stacked trait IR/HT maize, cotton, rice, tomato, and sorghum; DT chickpea, rice, groundnut, mustard, sorghum and tomato; and virus resistance in papaya, potato, watermelon, and tomato. As of October 2013, 79 applications for field trials were forwarded for cotton, rice, castor, maize, wheat, sugarcane, eggplant, potato, chickpea, mustard, and sorghum [3].

In 2013, PR China successfully grew approximately 4.2 million ha of Bt cotton, about 5,800 ha of virus resistant papaya in Guangdong province and Hainan Island, and 543 ha of Bt poplar. PR China is actively developing GM crops with traits that include HT, high-lysine and low-phytase maize, canola, rice, soybean, and wheat; IR rice and poplar; flood resistant wheat; and high-yielding poplar [3].

The growth momentum for GM/biotech crops in Africa was maintained in 2013, as exemplified by increased area, additional multi-location trials for important cash and food crops, as well as policy pronouncements. In 2012, biotech crops had already been reported in four countries: South Africa, Burkina Faso, Egypt, and Sudan. However, due to political instability, Egypt was not able to continue planting Bt maize for 2013. For the first time, Ghana's National Biosafety Committee granted approval for confined field trials (CFT) of GM crops in the country. They include: multi-location trials of Bt cotton (Bollgard II), Bt cowpea CFT by the Savannah Agricultural Research Institute, Nitrogen Use Efficient-Water Use Efficient and Salt Tolerant (NUWEST) rice by the Crops Research Institute and high-protein sweet potato (Table 8) [3]. Nigeria also commenced multi-location trials for Bt cowpea to evaluate the efficacy of the pod borer-resistant cowpea lines under different ecological zones, having tested the same in CFT in Zaria since 2010. The multi-location trials are being carried out by the Institute for Agricultural Research within its research farm stations in the city of Zaria, Talata Mafara in Zamfara State, and Minjibir in Kano State. In addition, Cameroon entered its second year of CFT on insect-resistant and herbicide-tolerant traits of GM cotton in three locations. This is representative of Cameroon's growing conditions after a successful first season CFT in 2012. For the other countries, Table 8 provides a self-explanatory summary of those that continued to conduct field trials with biotech crops in 2013. These countries are Egypt, Burkina Faso, Cameroon, Ghana, Kenya, Malawi, Nigeria, South Africa, and Uganda, with the following key crops at various stages of experimentation in both confined and open trials: banana, cassava, cotton, cowpea, maize, rice, sorghum, wheat, and sweet potato. More importantly, most of the on-going trials focus on traits of high relevance to challenges facing Africa such as drought, nitrogen use efficiency, salt tolerance, and nutritional enhancement, as well as resistance to tropical pests and diseases.

Table 8. Field trials of GM crops in Africa

Country	Crop	Trait: Stage of Field Trial
Burkina Faso	Cowpea	IR: CFT, fourth season
Ghana	Cotton	Bt: Multi-locational trials in six sites
	Rice	NUWEST: first CFT
	Cowpea	Bt: first CFT
Egypt	Wheat	DT: CFT approved 2010, updated 2013
		Fungal resistance: third season, approved 2010, updated 2013
Nigeria	Cassava	Beta-carotene: CFT, second season completed
	Cowpea	Bt: multi-locational trials in three sites
	Sorghum (ABS)	Beta-carotene: third CFT, and back-crossing with local varieties
Cameroon	Cotton	IR and HT: second season, CFT in three sites
Kenya	Maize	DT (WEMA): fourth season FT completed, ongoing fifth season
		IR: first season CFT completed, second season planted
	Cotton	IR: CFTs completed, awaiting submission of application for commercial release
	Cassava	Mosaic virus resistance: CFT, first season completed

(...continued)

Country	Crop	Trait: Stage of Field Trial
Kenya	Cassava	Brown streak disease resistance: first season completed, preparing for second season
		Beta-carotene: CFT, first season completed CFT
	Sweet potato	Virus disease: mock trial CFT completed, Actual CFT approved by IBC
		IR: lab and Greenhouse approved 2013
	Sorghum	Biofortified for Beta-carotene, zinc, iron: greenhouse trial completed, second season CFT completed
	Pigeon pea	IR: lab and greenhouse approved 2013
	Gypsophila flowers	IR: CFT Applications approved by IBC and submitted to NBA
Uganda	Maize	DT: fifth season CFT planted
		IR: first season CFT planted
	Banana	Bacterial wilt resistance: first CFT completed, replanting commended 2013
		Biofortified iron and beta carotene: third season CFT
	Cassava	Virus resistance: third season CFT
		Brown streak virus resistance; multi-locational CFT application submitted to IBC
	Rice	NUWEST: first CFT completed, application for second CFT submitted 2013
Malawi	Cotton	IR and HT: first season CFT harvested
South Africa	Maize	DT: fifth season CFT
		Sterility/fertility: second season CFT
		Stacked IR: fourth season CFT
		Stacked IR/HT: second and fourth seasons multiple CFT repeats
	Cotton	Stacked IR/HT: second and fourth seasons multiple CFT repeats
	Soybean	Modified oils/HT: CFT approved

Source: James, C. 2014 [3].
Notes: Bt, Bacillus thuringiensis; CFT, confined field trial; DT, drought tolerant; HT, herbicide tolerant; IBC, institutional biosafety committee; IR, insect resistant; NUWEST, nitrogen use efficient-water use efficient and salt tolerant; WEMA, water efficient maize for Africa.

GM PRODUCT PIPELINE IN LEADING INDUSTRIAL COUNTRIES

In the USA, consistent with the demand for new herbicide-tolerant traits in major crops, the US Animal and Plant Health Inspection Service (APHIS) is already processing applications for the environmental impact assessment (EIS) of both new and combinations of herbicide-tolerant traits (Table 9) [10]. Noteworthy, are the presence of the auxin-based herbicide-tolerant trait and acetylcoA carboxylase (ACCase), inhibitor-tolerant genes in maize, soybean and cotton, as well as freeze-tolerant eucalyptus for climate change effects. Applications for second-generation genetic modification with improved product quality in apples and potatoes, as well as alfalfa for biofuels are already being reviewed. New generation HT and IR traits in cotton and maize are also under study for deregulation [10].

Table 9. USA pipeline for GM crops

Crop	Trait	Developer
USA Petitions for Environmental Impact Statements (APHIS, 2014)		
Creeping bentgrass	Glyphosate tolerant	Scotts
Maize	2,4-D and ACCase-Inhibitor tolerant	Dow
Soybean	2,4-D and Glufosinate tolerant	Dow
	Dicamba tolerant	Monsanto
	2,4-D, Glyphosate and Glufosinate tolerant	Dow
Eucalyptus	Freeze tolerant	Arborgen
Cotton	Dicamba and Glufosinate tolerant	Monsanto
USA Pending Petition for Determination of Non-Regulated Status (APHIS, 2014)		
Apple	Non-browning	Okanagan Farms
Alfalfa	Reduced lignin	Monsanto/Forage Genetics
Potato	Low acrylamide, reduced black spot bruise	JR Simplot
Cotton	2,4-D and Glufosinate tolerance	Dow
Maize	Rootworm resistant/Glyphosate tolerant	Monsanto

Source: APHIS, 2014 [10].
Notes: 2,4–D, 2,4-Dichlorophenoxyacetic acid; ACCase, Acetyl-CoAesterase; APHIS, animal and plant health inspection service; environmental impact statements.

According to the Information Systems for Biotechnology (ISB), from 2013 up to 28 July 2014, field trials of 26 crops with traits such as HT, IR, and stacks thereof (nutritionally enhanced; virus, bacterial, and disease-resistant; DT; enhanced nutritional content; and improved product quality) have been issued approval permits (Table 10) [11].

A total of 158 new GM crop and trait combinations have been approved with soybean having the most approvals for herbicide tolerance followed by maize and alfalfa.

Table 10. Field trials of GM crops in the USA from 2013 to 28 July 2014

	Crops	**Number of Field Trials**
1	Soybean	58
2	Maize	36
3	Alfalfa	16
4	Coyote Tobacco/Tobacco	6
5	Cotton	5
6	Sugarcane	3
7	Cassava	3
8	American chestnut	3
9	Falsefax	3
10	Tomato	2
11	Apple	2
12	Loblobby pine	2
13	*Populus deltoides x Populus nigra*	2
14	Citrus	2
15	Sorghum	2
16	Poplar/Hybrid poplar	2
17	Switchgrass	2
18	Banana	1
19	Rapeseed	1
20	Rice	1
21	Camelina	1
22	Potato	1
23	European palm	1

(...continued)

	Crops	Number of Field Trials
24	Sweet gum	1
25	Papaya	1
26	Peanut	1
	Total	**158**

Source: Information Systems for Biotechnology, 2014 [11].

In Australia, the Office of the Gene Technology Regulator (OGTR) has approved field trials of crops with improved nutritional quality in canola, wheat, and barley, as well as herbicide tolerance in cotton and lupin (Table 11) [12]. Public research institutes and universities take the lead in some of the advanced GM research in Australia. Development of new sources of herbicide tolerance have been studied by the Australian Herbicide Resistance Initiative (AHRI), and funded by both the Grains Research and Development Corporation (GRDC) and the Australian Research Council (ARC) [13]. Studies on resistance evolution, mechanisms, management, and resistance surveys are being undertaken.

Table 11. Field trials in Australia from 2013 to 28 July 2014

Crop	Trait	Developer
Cotton	IR/HT	Monsanto Australia
Canola	Altered oil content	Nuseed Pty Ltd
Wheat	Abiotic stress and yield	Victorian Government of environment and Primary Industries
	Altered grain composition (nutrient utilisation efficiency)	CSIRO
Safflower	Altered oil profile	CSIRO
Narrow-leafed lupin	Herbicide tolerance	University of Western Australia
Barley	Altered grain composition (nutrient utilisation efficiency)	CSIRO

Source: Office of the Gene Technology Regulator, Australia, 2014 [12].
Notes: CSIRO, Commonwealth Scientific and Industrial Research Organisation; HT, herbicide tolerant; IR, insect resistant.

As reported by the Joint Research Centre (JRC) [14], approved field trials in the EU for 2013–14 include GM maize with IR, HT, or the stacked traits. These are mainly in Spain, including one trial in the Czech Republic (Table 12). Sugar beet production in the EU has also become a prime agricultural product with HT and bacterial-resistant traits. Field trials were also approved in Sweden, Slovakia, Spain, and Belgium. GM poplar in Europe was improved for wood composition, as well as bioenergy production in Belgium and France. Four events of HT cotton have been included in field trials as reference materials.

Table 12. Field trials approved in the EU for 2013–14

Crop	Trait	Developer
Maize	HT	Limagrain Iberica, Spain
	IR/HT	Limagrain Iberica, Spain
	Vitamin enhancement	University of Leida, Spain
	HT (NK603)	Czech University of Live Sciences, Czech Republic
	IR/HT	INIA, Spain
Sugarbeet	Rhizomania-resistant and HT sugarbeet	Syngenta Seeds SAS, Sweden
	HT sugarbeet	Plant Production Research Center Piestany, Slovakia
	HT sugarbeet	SESVanderHave N.V., Spain
Poplar	Modified wood composition	IB, Belgium
	Wood properties and bioenergy production	INRA, France
Cotton	Four HT events	Bayer CropScience SA-N.V., Spain

Source : Joint Research Centre, European Commission 2014 [14].
Notes: HT, herbicide tolerant; IB, Vlaams Interuniversitair Instituut voor Biotechnologie (Belgium); INIA, National Institute for Agricultural and Food Research and Technology (Spain); INRA, National Institute for Agricultural Research (France); IR, insect resistant; NK603, one of Monsanto's Roundup Ready® corn (maize) events.

GM PRODUCTS IN THE GLOBAL PIPELINE

Based on the 2009 JJRC, 2015 will see the release of an estimated total of 124 new GM events from both the private and public sectors (Table 13) [5]. Most releases will be for cotton, maize, and soybean. Insect tolerance is expected to lead in terms of trait, followed by herbicide tolerance and composition (Table 14). With the decrease in the price of global cotton, together with the recent shift in some countries to soybean and maize in place of cotton, and the need for new sources of HT traits, this estimate may change slightly [3].

Table 13. Number of GM events in the global pipeline by crop

Crop	Commercial (2008)	Commercial Pipeline (2009–15)	Regulatory Pipeline (2009–15)	Advanced Development (2009–15)	Total by 2015
Soybean	1	2	4	10	17
Maize	9	3	5	7	24
Canola	4	0	1	5	10
Cotton	12	1	5	9	27
Rice	0	1	4	10	15
Potato	0	0	3	5	8
Others	7	0	2	14	23
All crops	33	7	24	60	124

Source: Stein and Cerezo, 2009 [5].

Table 14. Number of GM events in the global pipeline by trait

Crop	Commercial (2008)	Commercial Pipeline (2009–15)	Regulatory Pipeline (2009–15)	Advanced Development (2009–15)	Total by 2015
Insect resistance	21	3	11	22	57
Herbicide tolerance	10	4	5	13	32
Composition	0	1	5	10	16
Disease resistance	5	0	3	7	15
Stress tolerance	0	0	0	5	5
Others	2	0	0	12	14

Source: Stein and Cerezo, 2009 [5].

PUBLIC–PRIVATE SECTOR PARTNERSHIPS IN THE DEVELOPMENT OF NEW PRODUCTS

The first generation biotech crops were mostly developed and deployed by private seed companies for crops meant to solve the major problems of food and feed sufficiency. With the emergence of public institutions in developing countries capable of conducting biotech/ GM crops, partnerships among public and private research institutions have become more prevalent. This contributes to the acceptance of biotech crops and biotech capability building in developing countries. Among the noted partnerships are:

- Research and future deployment of Golden Rice falls under control of the Humanitarian Board, who was given permission for use and commercialization without royalty by the relevant patent holding private sector parties. In addition, the International Rice Research Institute, in partnership with public research institutes in the Philippines, Indonesia, and Bangladesh, are in the process of developing Golden Rice in local varieties [15].

- Research and development of IR cabbage and cauliflower have been made through collaboration between public research institutes in India (Indian Agricultural Research Institute and University of Delhi) with the University of Ottawa, Canada, and CIRAD Aventis (private sector) in Montpellier, France [16].

- Drought Tolerant Maize for Africa (DTMA) is a project led by the International Maize and Wheat Improvement Center (CIMMYT) and International Institute of Tropical Agriculture (IITA). It aims to develop and disseminate drought tolerant, high-yielding, locally adapted maize varieties and to reach 30–40 million people in sub-Saharan Africa in 10 years. The project is supported by the Bill and Melinda Gates Foundation and the Howard G. Buffet Foundation [17]. The DTMA project has already released more than 100 conventional varieties to national programs in 13 African countries, and more than 7,000 tons of drought tolerant maize seeds were produced in 2012.

- The BioCassava Plus program is funded by the Bill and Melinda Gates Foundation, and is considered to be the largest coordinated research development and deployment program funded for cassava. The project brings new innovative technologies to solve problems in cassava biology by more than 25 research investigators located on five continents. The overall objectives of the program were to provide the complete minimum daily requirements of protein, iron, zinc, vitamin E, and provitamin A in a 500 g meal for an adult, or a 250 g meal for a child [18].

- Seed company BASF and Brazil's Embrapa partnered in the development of HT GM Cultivance soybeans. The GM soybean is the result of more than 10 years of successful cooperation between Embrapa and BASF. The product combines HT soybean varieties with BASF's broad-spectrum imidazolinone class of herbicides, tailored to regional conditions [19].

CHALLENGES IN COMMERCIALIZATION

Successful commercialization of GM crops in biotech crop planting countries has been possible by overcoming challenges faced by seed developers and farmers, and also in the regulatory system. Stakeholders also face other challenges that affect the approval process, trade, consumer acceptance, and eventual commercialization of biotech crops.

These challenges include:

1. *Lack of regulatory and biosafety legal frameworks in many countries*

   For many countries seeking to build acceptance and adoption of biotech crops, the major hindrance is the lack of regulatory and biosafety legal frameworks. It may be observed though that some countries started commercializing biotech crops unofficially. Biotech crops were only adopted through farmers' insistence and active lobbying. Such is the case in Brazil and Pakistan. It is essential for a country to set up a regulatory and biosafety framework for biotech crops in order to protect the technology, guide the farmers on the proper use of the technology, and develop a science-based appreciation for the benefits of the technology.

2. *Asynchronous approvals across countries*

   GM approvals for planting since 1996 have increased from six to 29 countries in 2011, 28 countries in 2012, and 27 countries in 2013. Once these countries start commercializing biotech crops, succeeding approvals may come depending on each country's economic and trading needs. Similarly, approval for imports of GM food and feed does not occur simultaneously across adopting countries. Hence, this could affect commodity trade for processing and manufacturing industries in the country. Thus, exporters of GM products should make sure that the GM events contained in the shipment are approved to enter the importing countries.

3. *Negative public perception and political opposition*

The perennial problem of biotech advocates is, of course, rising negative activism. This is felt by both industrialized and developing countries. Fully funded and equipped with emotional and non-scientific allegations, these groups are harassing scientists, policy makers, consumers, and even medical practitioners. Countries facing such activism have a difficult time moving forward in commercialization of biotech crops. Developing countries are currently facing this problem in the commercialization of Golden Rice and Bt eggplant.

4. *High regulatory cost prevents products in early research and development stage from advancing*

To ensure the food, feed, and environmental safety of GM crops, many countries have enforced strict and onerous regulations. GM opponents have affected regulators so that compliance with these rules has become expensive. Thus, in some developing countries that are just starting to develop their publicly owned products, commercialization has become even more difficult. This also affects advancement of new products.

FUTURE OUTLOOK OF GM CROPS

First-generation input traits such as HT, disease and insect resistance, which were first released in 1996, are expected to continue their dominance of the market until 2025. It is anticipated that the first-generation input traits will soon become available for non-major GM crops (major GM crops being soybean, cotton, maize, and canola). Second-generation input traits, including stacks of these traits (such as Intacta™ soybean released in 2013) and traits to address problems associated with climate change (drought, salt, and cold tolerance), will likely be deployed in major GM crops. The second-generation input traits have been released since 2010 and are expected to continue until 2025, including nitrogen-use efficiency and high-yield traits [5]. Third-generation output traits for crop composition and quality such as modified oil, omega-3 modified starch/sugar, low-lignin, non-browning fruit, beta-carotene, ferritin, and Vitamin E in major staple crops will be released in 2014 and successively until 2025.

In soybean, various output traits are being developed, such as a high-oleic soybean that reduces trans fats, low-phytate soybean to reduce phosphorous levels in animal manure and improve mineral absorption by the human body, high omega-3 soybean for human health benefits, and high-stearic acid soybean to improve food processing and reduce harmful fats.

Third-generation GM crops for biopharmaceuticals are vaccines for major human and animal diseases, therapeutic proteins and polymers. These are expected to be in the market from around 2017 to 2025 [5]. In the next five years, maize, soybean, cotton, and canola will still be the dominant GM crops where stacked and new input traits (new generation IR and HT, drought tolerance, as well as nutritional enhancement) will be deployed.

The private sector determines the global commercial potential of these major crops. Emerging crops include rice, sugarcane, wheat, and horticultural crops with the public sector leading R&D with some private sector partnerships.

GM livestock may have a small likelihood of commercial release. GM carp and Atlantic salmon, which have been modified to contain growth hormones, may also be considered for commercialization.

SUMMARY AND CONCLUSION

Biotech crops have initially been developed for major crops of maize, soybean, cotton, and canola with the input traits of IR and HT. Stacked traits developed in these major crops are now dominating the global GM market.

The next wave of GM crops that target stress-tolerant traits such as climate change has become a reality. DT maize and sugarcane, as well as new traits for disease and insect resistance, have subsequently been developed. Field trials of these crops show good progress in Africa and Asia. Output trait GM crops such as improved soybean oil/omega-3, modified potato starch, and beta-carotene-enriched rice will enter the market within the next 3–5 years. These output trait crops as well as other products being developed through public-private partnerships and government-funded projects are likely to be marketed in the next 5–10 years. There are also biotech crops developed to provide plant-derived vaccines, therapeutic proteins, and biopolymers for human diseases. These, and second-generation biofuel crops (grasses and trees), will be in the regulatory pipeline in 5–10 years.

Thus, with the upcoming wave of new traits and modern biotechnology-improved crops, challenges that revolve around the lack of or incomplete regulatory framework in developing countries, asynchronous approvals across countries, negative public perception, and high regulatory costs need to be addressed immediately. These challenges may not be easily solved but strategic steps taken in the soonest possible time would increase biotech crop adoption by many poor farmers.

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USING BIOTECHNOLOGY TO MEET DEMANDS FOR FOOD, FEED, AND FUEL

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INTRODUCTION

One of the prevailing concerns today is how the ever-rising and unlimited global demands for food, feed, fiber, and fuel can be met to sustain the daily needs of human lives. This concern is further deepened given that existing natural resources are not unlimited. Additionally, other resources are also in rapid decline. These demands are continuously increasing due to various factors such as population growth and economic prosperity. The complexity of this topic is further challenged as the world confronts a number of concurrent problems like climate change, food shortages, and the shortage of energy resources. Therefore, securing food supply, increasing agricultural productivity, providing safe food/feed for consumption, and developing alternative energy resources have gained great attention worldwide, prompting the urgent need to seek a resolution.

Biotechnology can be adopted as one of the tools to tackle this global concern. It has been employed in the R&D of animal and plant breeds, improvement of crop production, detection and diagnosis of animal and plant diseases and pests, development of biopesticides, biofertilizers and animal vaccines, and development of biofuels, etc. Examples are genetically modified (GM) maize, soybean and cotton, orchid virus detection kits, and ornamental fluorescent fish, etc. [1–2]. In order to cope with the global challenges and to advance the agricultural sector, the Republic of China (ROC) has invested in manpower, increased its budget allocations for agriculture, and promoted cooperation among research institutes and private industries towards using biotechnology for scientific research and technological development. Many achievements have been made, helping to solve the problems of agricultural production and to facilitate agricultural development in ROC.

GLOBAL ISSUES

The world is currently confronted by a number of alarming issues. Some of the issues are of great concern to the agriculture sector, and have not only affected our environment, but also considerably impacted the world's resources, putting them at risk.

Climate Change

Climate change has become a well-recognized global environmental issue that has attracted great attention and raised much concern. Over the last century, the average world temperature has increased by approximately 0.6 °C. As a consequence, changes in climate were witnessed in the form of floods, droughts, heat and freezing, and even severe natural disasters including hurricanes and tsunamis. Agriculture is particularly vulnerable to climate change due to its reliance on regular climate patterns. As a result, the sector has inevitably been affected not only with regard to crop production, but also in livestock rearing and fishery production. The sector is also negatively affected as a result of devastation by animal and plant diseases, as well as pests, which are also influenced by climate.

Food Security

According to the universal definition given by United Nations World Health Organization (WHO), food security is when "all people are able to have access to basic supply of food at all times" [3]. However, sources from the 2010 World Food Program showed that there were 870 million people in the world living in hunger without access to sufficient food supplies. About 15% of the population of developing countries has been classified as "malnourished." At the time this paper was written, UN statistics counted the world population at 7.2 billion. It is further expected to reach 8.1 billion by 2025 and 9.6 billion by 2050 [4]. While global resources are limited, our world is facing the challenge of increasing demand for food to cope with population growth. Nevertheless, the impact of climate change on agriculture and the decrease of natural energy resources have put constraints on food supply. This situation makes food security a global issue that requires more attention and effort to meet the demand for food to feed an increasing population, as well as the present numbers of hungry people.

Food/Feed Safety

While some areas of the world are experiencing food shortages and food insecurity, those which do have access to food supply are not without problems. Animal and plant diseases, as well as pests, cause severe damage to crops and livestock, resulting in a great deal of economic loss in agricultural production. It may even affect human or animal health due to zoonosis or toxins produced by harmful organisms. Chemical residues resulting from the inappropriate application of chemical pesticides, chemical fertilizers, animal drugs or food additives, as well as industrial wastes, may also affect food/feed safety. Exposure to and consumption of chemical residues not in compliance with regulations cause considerable harm to human health and the environment. Thus, safe food and feedstuff is currently an important issue of concern to consumers.

Agricultural Productivity

Agricultural productivity is a ratio that measures the value of output to the value of inputs. A perpetual increase in demand resulting from population growth, as well as from increasing economic wealth in some countries, means there is a need to produce more outputs through increasing agricultural productivity. Furthermore, favorable agricultural productivity not only denotes sufficient quantity of supply, but also good quality of products.

According to the World Bank's Global Food Production Index, food productivity increased from 34.21 to 116.55 between 1961 and 2011 [5]. The productivity improvement started with the Green Revolution in the 1940s when innovations and new technologies for agricultural production were developed. However, this positive trend should not mislead us to an optimistic conclusion because the rate of population growth far exceeds the rate of the world's food productivity. Furthermore, the latter has been slowing in recent years. This can be evidenced by the world grain output. Between the 1950s and 1980s, world cereal yield increased 2.6 fold [6]. But from 2003 to 2011 it increased only from 3,125 kg/ha to approximately 3,700 kg/ha [7]. In addition, the world's decreasing arable lands and impact of climate change have contributed to a reduced world agricultural productivity rate. More effective measures are required to improve agricultural productivity to meet the growing population's increased demands.

Energy Shortage

The world is facing an increasing demand for energy due to economic boom in certain regions. Presently, fossil fuels such as coal, oil, and natural gas, are the world's common sources of energy. The world's supply of fossil fuels is limited and is significantly depleting over time. Furthermore, when countries work to spur their economy toward industrialization and increase their productivity, they add to the existing demand for fossil fuels. As fossil fuels are non-renewable energy sources, it is clear that the world has to find alternative sources to avoid energy shortages in the future. Biofuels may play an important role if the world is to reduce reliance on fossil fuel. The International Energy Agency data show that global production of biofuels (liquid and gaseous fuels derived from biomass) has been growing steadily over the last decade from 16 billion L in 2000 to more than 100 billion L in 2011 [8].

Measures to be Taken

To face the challenges of these global issues in order to meet the demands of an increasing world population, a resolute course of action is urgently needed.

The following are the recommended measures that should be taken:

1. Breeding of animals and plants that:
   a. Are resistant to environmental stress (excess of water, drought, cold/freeze, heat, salinity, etc.)
   b. Are resistant to diseases and pests
   c. Have specific traits (nutrition, growth rate, functional foods, etc.)

2. Improving cultivation or rearing technology for:
   a. Efficient use of water
   b. Rational use of fertilizers
   c. Efficient use of feed stuff
   d. Efficient use of energy

3. Improving disease- and pest-control measures:
   a. Accurate and rapid diagnosis
   b. Monitoring and early warning of outbreaks
   c. Development and improvement of control technologies
   d. Use of integrated pest management

4. Monitoring or testing of chemical residues:
   a. Development of testing technology
   b. Monitoring or testing in the fields or in the markets

5. Application of non-chemicals:
   a. Biofertilizers
   b. Biopesticides
   c. Natural enemies
   d. Animal vaccines
   e. Microbial feed additives

6. Organic farming

7. Reuse of animal, crop or food waste

8. Development and use of biofuels (such as grains, sugarcane, and algae)

APPLICATION OF BIOTECHNOLOGY IN AGRICULTURE

Biotechnology can be employed to facilitate R&D for these measures. It can be applied in many ways such as:

- Improving conventional breeding by using selected DNA markers
- Artificial insemination or cloning/replication of livestock
- Using genomics knowledge to facilitate breeding and disease and pest control
- Developing identification, detection, and diagnosis technologies for animals, plants, and microorganisms
- Developing microorganisms to facilitate agricultural production: biofertilizers, biopesticides, animal vaccines, feed additives (probiotics)
- Developing GM animals, plants or microorganisms with desired traits
- Using bioreactors
- Molecular farming

According to the International Service for the Acquisition of Agri-biotech Applications, the planting area of GM crops has increased from 1.7 million ha in 1996 to 170.3 million ha in 2012 [1]. Maize, soybean, canola, and cotton accounted for most of the GM crops in the world. Among these four crops, 35% of the 159 million ha of maize, 81% of the 100 million ha of soybean, 81% of the 30 million ha of cotton, and 30% of the 31 million ha of canola were GM crops. The benefits of planting GM crops include increases in production, decreases in losses due to pest infestation, reductions in chemical pesticide use, and increases in small farmers' income. Although research has been employed to develop transgenic animals such as cattle, chickens, goats, pigs, sheep and fish, none are commercially produced for the market yet. According to BCC Research Inc., biopesticides had USD2.1 billion product value in 2012, and is expected to increase to USD3.7 billion by 2017 [9]. Most of the biopesticides are thuricide (bacterial insecticide). The benefits of application of biopesticides include reducing chemical pesticide usage, facilitation for environment safety, and organic farming.

AGRICULTURAL BIOTECHNOLOGY IN ROC

ROC benefits from its geographical and climatic characteristics, which are suitable for agriculture. It is located in tropical and subtropical regions that are characterized by high temperatures and heavy rainfall. ROC has a land area of 36,000 sq km, of which 66% is made up of mountains or sloping land, and cultivated land accounts for about 22%. While it is rich in biological resources, its environmental and geological features inevitably accommodate the breeding of diseases and pests as well. Although ROC has these advantages for agricultural development, agriculture only comprised 1.75% of its GDP in 2011, and the value of agricultural production was about USD16.1 billion (TWD475.5 billion) [10].

ROC's accession to the World Trade Organization (WTO) in 2002 has created new opportunities for investment and trade. However, international competitiveness and the global tendency toward free trade have also put great pressure on ROC's agricultural sector. In addition, climate change has caused much damage to agricultural production and added more threats to it as well. Therefore, to overcome these threats to agriculture, the traditional model of agricultural development has to change and various measures adopted. Agricultural biotechnology is one of the elements for spurring ROC's agricultural sector to make the necessary transformation and face international competition. ROC's policy is to employ biotechnology for agricultural R&D and to implement efficient management of living GM organisms to ensure biosafety and biosecurity.

Research and Development

The Council of Agriculture (COA) has 16 research institutes and extension stations tasked with the development and extension of innovative technologies, as well as methods in different domains including crops, livestock, fisheries, forestry, animal health, and plant protection. The institutes have made many contributions to ROC's agricultural success over the years through transfers of technology to farmers and the private sector. For the past two decades, the COA has been financially supporting these institutes and stations, universities, and the private sector in research and technological development for the promotion of the agricultural biotechnology industry. The targeted areas of R&D consist of eight categories: plant seedling biotech, aquaculture biotech, livestock biotech, food biotech, biofertilizers, biopesticides, animal vaccines, and tests and diagnosis. As of 2011, there were 92 companies in the agricultural biotechnology industry, together producing total revenue of approximately USD213 million (TWD6.39 billion). Two significant developments that have contributed to promoting the industry are the implementation of the Development Program for Industrialization of Agricultural Biotechnology (DPIAB), and the establishment of the Pingtung Agricultural Biotechnology Park (PABP).

Development Program for Industrialization of Agricultural Biotechnology

Recognizing the private sector's important role in the development and commercialization of agricultural products, the COA implemented a five-year program (DPIAB 2009–13) to advance cooperation among government agencies, academia, and industry to promote commercialization and industrialization of biotechnology research results [11].

The program set six development strategies:

1. Setting up an intergovernmental task force;
2. Forming demand-oriented science and technology policy;
3. Linking the industry-academia R&D system;
4. Building up a commercialization platform;
5. Training business talent; and
6. Speeding up agricultural transformation.

The program is supported by multiple agencies, including the COA, Department of Health, Ministry of Education, National Science Council, Academia Sinica, and Industry Bureau of Ministry of Economic Affairs, with the COA as the major agency in charge of administrative coordination. The missions shared by the different agencies in the program are shown in the following scheme (Figure 1). Based on global trends in biotechnology development, and the niches and favorable factors already existing in ROC, DPIAB has selected priority areas to which most of the resources and efforts are towards obtaining valuable outcomes. These areas include aquaculture, livestock and poultry, plant seedlings, orchid, biopesticide, biofertilizer, Chinese herbs, and health food. From 2009 to 2012, the expenditure for the program totaled USD67.46 million (TWD2.02 billion), of which more than one-third was supported by the COA.

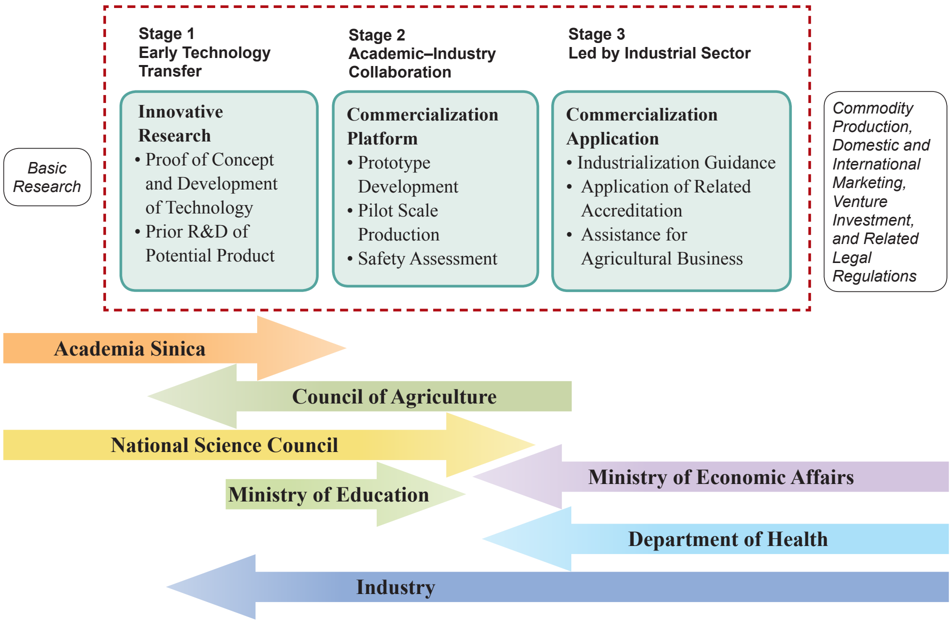

Figure 1. Development Program for Industrialization of Agricultural Biotechnology (DPIAB) Planning Scheme.

Pingtung Agricultural Biotechnology Park

Pingtung Agricultural Biotechnology Park (PABP) is currently the only science park dedicated to agricultural biotechnology in ROC. With an area of 233 ha, it was established by the COA in 2003 and came into operation in 2006 [12]. PABP provides integrated support and incentives to companies in the park, and has combined agricultural biotechnology resources in the neighboring areas to create an agricultural biotechnology industry cluster. The goal of PABP is to promote the agricultural biotechnology industry and to facilitate the transformation and sustainability of agriculture in ROC. PABP provides a one-stop service, which includes various governmental administration, R&D funding, factory licensing, and international marketing aid.

PABP already has 78 applications from companies for residency, covering several areas of agriculture and biotechnology, including plant seedlings, animal breeding and specific pathogen-free animals, fish breeding and aquaculture products, functional foods, modern Chinese medicine and medicinal cosmetics, biopesticides, biofertilizers, animal vaccines, animal and plant test reagents, animal and plant molecular farms, and biotechnological services. PABP companies are gradually developing supplementary and upstream/downstream supply relationships among themselves. Furthermore, they are forming an extensive supply chain with companies or business resources outside the park, thus creating powerful cluster synergies. Currently PABP companies have formed six industrial clusters, as shown in Table 1 [12].

Table 1. Industrial clusters in Pingtung Agricultural Biotechnology Park (PABP)

Industrial clusters	**Products**
Natural health and cosmetics	Functional foods, modern Chinese medicine, biotech cosmetics, edible and medicinal mushrooms, etc.
Fisheries and aquaculture biotechnology	Ornamental fish, aquaculture products, aquatic accessories, etc.
Bioagricultural materials	Biofertilizers, biopesticides, plant nutrients, etc.
Animal biotechnology industry	Animal vaccines, feed additives, livestock probiotics, etc.
Biotech testing and OEM/ODM service	Animal and plant virus testing, food safety testing, biotech OEM/ODM services, etc.
Environmental control device and agricultural facilities industry	Environmental control facilities for aquaculture, etc.

Source: Pingtung Agricultural Biotechnology Park [13].
Notes: ODM: Original Design Manufacturer; OEM: Original Equipment Manufacturer.

In addition, two special facilities were constructed by PABP, including a customized Current Good Manufacture Practice (cGMP) plant for animal vaccines and an operational center for aquaculture focusing on ornamental fish. The center offers several functions such as R&D, breeding, quarantine and inspection, export, packaging, and logistics.

Achievements of Agricultural Biotechnology in ROC

For the past decade in ROC, many efforts have been devoted to R&D in agriculture by employing biotechnology, which has resulted in many achievements. The following are examples of these achievements [2, 14].

- A new rice variety “Tainan 16” was bred by marker-assisted selection and approved for release in 2012.

- Using the Agrobacterium-mediated transformation method, transformed callus and regenerated transgenic seedlings of *Phalaenopsis* were obtained.

- Orchid virus detection kits were developed with advantages such as fast diagnosis, high specificity for the cymbidium mosaic and odontoglossum ringspot viruses, high sensitivity, and easy result interpretation.

- The first somatic cell-cloned dairy cow calf and goat were achieved in 2001 and 2002, respectively.

- Pigs were used as bioreactors to produce transgenic recombinant human factor IX (rhFIX).

- The baculovirus was used in silkworm systems to serve as the platform for producing feed additives and vaccines.

- A new variety of Taiwan yew was used for anti-cancer drug production.

- A transgenic *eucalyptus* species was developed with high cellulose and low lignin, which improved pulp production and increased the benefit to the pulping industry.

- A bio-desulfurization system was developed to facilitate pig farms in generating electrical energy by using farm waste produced by pigs.

- The world’s first medium-sized fluorescent fish (angelfish and convict cichlid) were developed in 2010, and the first pink fluorescent angelfish was developed in 2012.

CONCLUSION

Biotechnology provides useful tools for facilitating food, feed, fiber, and biofuel production, minimizing the impact of disease and pest attack, reducing the hazards of chemical residues, and meeting the challenges of climate change, all of which are helpful in the supply of food/feed to meet global demand and sustaining our daily needs.

GM organisms have long been a main concern of the public in relation to human health, environmental safety, and biodiversity. Hence, it is important to establish laws and regulations to properly govern the application of biotechnology and the commercialization of GM products. It is further important to communicate scientific aspects to the consuming public to cater to their concerns.

ROC will continue to employ biotechnology in agriculture and promote the biotechnology sector's development.

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INNOVATION TRENDS IN THE GLOBAL BIOTECHNOLOGY INDUSTRY

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Journal of Commercial Biotechnology
USA

INTRODUCTION

Biotechnology holds special importance for many countries. As with other technologies, biotechnology can be used to develop valuable products that generate revenues for citizens, subsequently improving a country's GDP and tax base, thereby providing numerous financial benefits. However, the benefits of biotechnology also extend into other realms.

Biotechnology products can be broadly divided into therapeutic, agricultural, and industrial applications. These products can respectively improve the quality and duration of citizens' lives, improve their nutrition and health, and reduce the environmental impact of industrial processes. This paper reviews some of the benefits and challenges of biotechnology innovation, and provides an overview of the *Scientific American Worldview* project.

CURRENT STATUS, MAIN CHALLENGES AND PRINCIPAL TRENDS

The concept of innovators and followers is important in evaluating the opportunities to benefit from biotechnology. Innovators have the ability to develop novel products and countries with strong innovation capacity can benefit by having products directed at domestic needs. Followers generally leverage knowledge gained from innovators and focus on extending the applications of these innovations, or reducing their cost.

A drawback for countries having poor innovation capacity is a reduced capability to develop solutions for local needs. They are therefore reliant on foreign innovators to develop domestic solutions. A challenge for emerging economies with poor innovation capacity is developing that capacity, but there are no clear solutions. The current world leader in biotechnology innovation is the USA, which is expected given the concentration of its biotechnology companies.

However, even in the USA, that strength is not evenly distributed. The greatest concentration of innovation capacity is concentrated in just a few states, with the others struggling to match.

Most countries have made significant efforts over the past decades to develop domestic biotechnology innovation capacity. The lesson from these failures to increase biotechnology innovation capacity is that it is difficult. Building innovation capacity requires sustained and substantial investments of time and money; elements that are at odds with the short-term requirement to acquire needed innovations.

So, what are the alternatives? One is to pay foreign parties to produce these innovations. Another method is to produce needed innovations through compulsory licensing of patents or direct infringement of patents. While the former solution is expensive in the short-term, the latter solution can have far-reaching consequences. By preventing innovators the opportunity to profit from their innovations, a country may be perceived as presenting a weak opportunity market. Therefore, foreign innovators would lack motivation to develop new innovations that could be of use to that market.

Country-level Data – The *Scientific American Worldview* Project

The objectives of the *Worldview* study are to provide comprehensive comparative data on a global level, identify countries that are global leaders in individual categories, and provide a framework to guide progress in other countries. The *Scientific American Worldview* project provides an ideal opportunity to measure and compare biotechnology innovation capacity in individual countries.

The *Worldview* project has tracked global biotechnology since 2009 and comprises the following:

- An objective innovation capacity scorecard
- A series of shorter data-driven narratives on various themes
- A collection of subjective magazine-style articles profiling individual innovators countries, and biotechnology-related themes [1]

The *Worldview* scorecard uses numerous data sets to derive an innovation capacity score for each country. These are shown in Table 1.

Table 1. Criteria for *Scientific American Worldview* scores

Intellectual property	Scope and strength of IP protection
Intensity	• Public biotechnology company employees per capita • Public biotechnology company revenues per GDP • Biotechnology patents per total patents • Biotechnology VC per GDP • Biotechnology R&D per total R&D • Proportion of public companies
Enterprise support	• Business friendly environment • Biotech venture capital • VC availability • Capital availability
Education/Workforce	• Post-secondary science graduates per capita • PhD graduates in life sciences per capita • R&D personnel per thousand employment • Talent retention • Brain gain
Foundations	• Biotechnology R&D spending • R&D business expenditures per GDP • Government support of R&D per GDP • Infrastructure quality • Innovation and entrepreneurship opportunity
Policy and stability	• Political stability and absence of violence/terrorism • Government effectiveness • Regulatory quality • Rule of law

Source: Scientific American Worldview Scorecard [2].
Notes: IP, intellectual property; VC, venture capital.

For example, the Republic of China received an average score for intellectual property protection, a very low score for intensity, an average score for enterprise support, an average score for education/workforce, a relatively high score for foundations, and a high score for policy/stability. This information can be used to guide further research into appropriate country specific interventions.

Recognizing that the scorecard is constrained by its need to provide robust comparisons in a broad set of countries, *Worldview* also contains data-driven narratives on various themes. These smaller narratives may only compare a smaller set of countries. Some of the themes investigated include university/industry collaboration, agricultural biotechnology plantings (in both absolute and relative measures), field trials of genetically modified crops, research output, the influence of drug prices on access to therapeutic drugs, and corruption.

As data alone cannot adequately describe opportunities and challenges in biotechnology, *Worldview* also includes a rich series of articles focusing on individual countries and special themes of great importance. A wide spectrum of countries is profiled: Australia, Egypt, Russia, and Denmark are profiled in the 2013 issue. The themes are also diverse, including big data, biosimilars, and improving regulations.

SUMMARY AND CONCLUDING REMARKS

Biotechnology offers numerous benefits, and each country is encouraged to build a strong innovation capacity to facilitate the development of innovations directed at domestic needs. A comprehensive study of the successes and failures of development efforts in other countries and in the USA can help in the formulation of strategic plans. *Scientific American's Worldview* can further be used as a tool to measure progress and to communicate case studies and progress.

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ENHANCING BIOTECHNOLOGY TRADE: UNITED STATES SOYBEANS

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INTRODUCTION

As the world's largest oilseed crop, soybeans annually supply 44 million metric tons (MMT) of oils for edible and industrial uses, as well as 188 MMT of vegetable protein meals for animal production worldwide. The importance of soybeans in the food supply chain can easily be seen from its production compared with other major oilseeds as shown in the following graph (Figure 1):

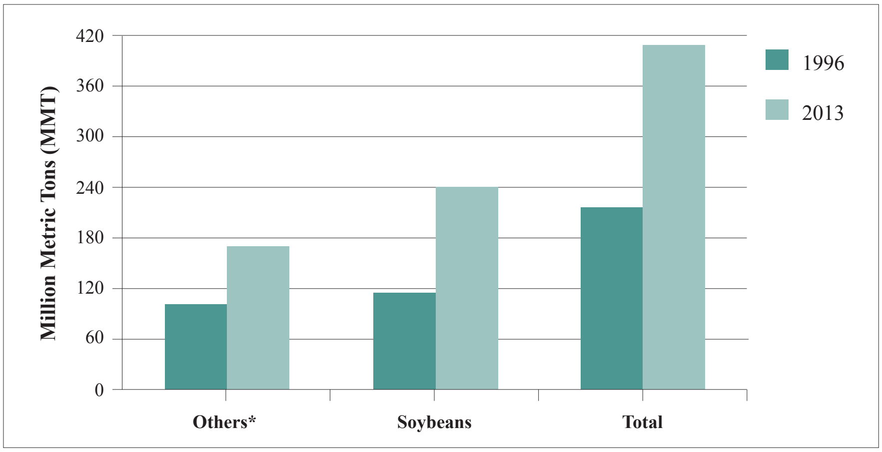

Figure 1. Global crush (MMT): 1996 versus 2013.

Source: Data consolidated from two reports by the Office of Global Analysis, Foreign Agriculture Services, and United States Department of Agriculture (USDA) [1, 2].
Note: *Others: copra, rapeseed, sunflower, cottonseed, palm kernel, and peanut.

In 17 years, global crush volume has increased from 217 MMT in 1996 to 408 MMT in 2013, representing 188% growth mainly due to the drastic increase in demand for edible oil in Asian markets such as PR China, the Association of Southeast Asian Nations (ASEAN) countries, and India. The growth is even larger in soybeans that have dual functions. Sharing 68% of the world demand for vegetable protein meals, soybean meal is the most economical alternative for converting vegetable protein into animal protein, such as chicken, pork, eggs, beef, milk, and even aquaculture, to feed the rapidly growing middle-class population in the region. However, with the world facing decreasing land and water resources, as well as increasing environmental protection concerns, growth in soybean volume could not have been achieved without applying biotechnology to soybean production in the USA and other major producing countries.

IMPORTANCE OF BIOTECHNOLOGY TRADE FOR ASIAN COUNTRIES

Of the 285.5 MMT of global annual soybean production, over 80% are produced by farmers in the USA, Brazil, and Argentina, with only 10% produced in Asia. With less than 30 MMT produced in the region, Asian countries rely heavily on importation to satisfy their demands for whole soybeans, soy oil, and meal that combined are equivalent to 106 MMT of soybeans (Figure 2). The trend keeps growing as the region's economy grows stronger along with the significant growth of the middle-class populations in PR China, India, and ASEAN countries.

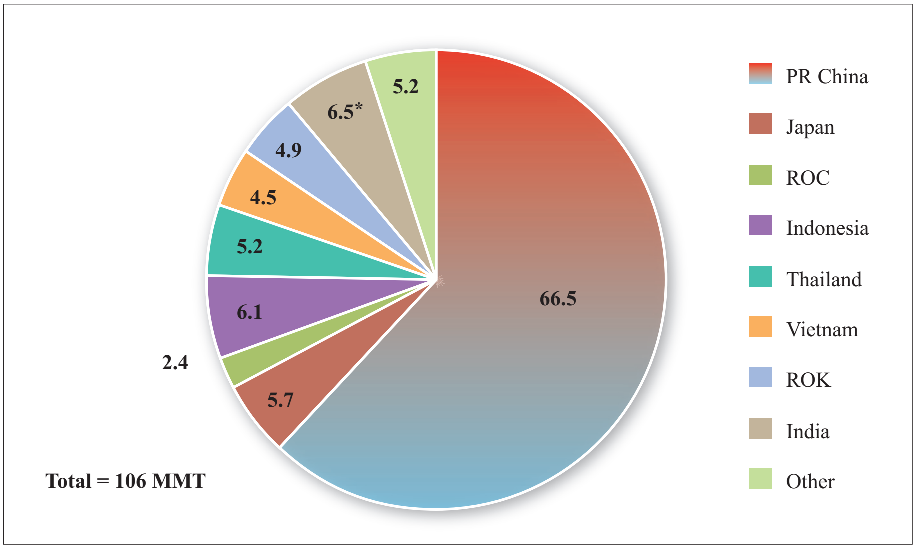

Figure 2. 2013 Imports by countries in Asia in soybean equivalent† (MMT). ROC, Republic of China; ROK, Republic of Korea; MMT, million metric tons.

Source: Office of Global Analysis, Foreign Agriculture Services, USDA [3].

Notes:

* 6.5 MMT of soybeans is the equivalent of 1.17 MMT of soy oil that India imports.

† Including soybean quantities equivalent to soy oil and meal imported.

While demand for imported soybean is sharply increasing in Asia, available arable land in major soybean-exporting countries, e.g., the USA, Brazil, and Argentina, are not growing at the same pace. Global supply would be much lower and much more expensive than it is today if biotechnology had not been developed and applied to soybean production. In the past 10 years, production costs have increased significantly due to the high cost of land, fertilizers, and investments for meeting environmental protection needs. With the availability of biotechnology crops, farmers in the USA have become better able to control their production costs through savings in energy costs, herbicide expenses, and better field management, all of which contribute to yield performance.

Growing soybeans seems simple. Farmers plant the seeds, the plants grow, then farmers harvest the mature soybeans and ship them to country elevators for processing or distribution down the marketing channels. However, farmers will point out that growing the crop is much more difficult than it looks. There is soil health to consider, diseases and insects to handle, and also unexpected weather conditions.

In the USA, all soybeans and maize are treated with herbicides and insecticides to maintain healthy fields. Here, farmers have historically controlled weeds through plowing (which buried weed seeds) and tilling during the growing season. These practices deplete topsoil, cause soil erosion, and release carbon dioxide. To pursue sustainable production, no-till planting is encouraged [4]. However, use of no-till planting was not popular until the late 1990s when Roundup Ready® soybean (the first biotech event introduced in the USA with the glyphosate-resistant trait), produced by Monsanto, was commercialized.

While all soybeans are tolerant to some herbicides, until now, they could not withstand glyphosate, a herbicide widely known for its very favorable environmental profile. Biotechnology helped make weed management easier so that farmers are better able to increase the practice of no-till planting. With the introduction of the Roundup Ready® trait, farmers now may substitute Roundup for all other weed control herbicides. Furthermore, these farmers may use up to one-third less total herbicides in their soybean fields.

Biotechnology crops are not only grown in the USA, but also in Brazil, and Argentina. Farmers in these countries rapidly accepted biotechnology because of the improved agronomic benefits they received from the new events. According to CropLife Asia, percentages of biotechnology-derived soybeans being grown in the USA, Brazil, and Argentina are 93%, 88% and 100%, respectively [5]. A similar situation is seen in global maize production.

The trend of increasing biotechnology use in global agricultural production is expected. Currently, most of the biotech-derived crops in production have modified crop-protection characteristics, mainly in protection against specific insects or tolerance to specific herbicides.

There have also been stacked events developed that carry more than two agronomic traits, which will help to make soybean farming even more efficient. In addition to improving agronomic traits, biotechnology has moved one huge step further to enhancing crop value. In the foreseeable future, there will be biotech crops with improved nutritional value, functionality, and the combined benefits of both, that can be used for processing better foods such as OPTIMUM® high-oil maize, low-phytate-phosphorus maize, low-oligosaccharide soybeans, high-lysine soybeans, and high-oleic soybeans.

In the USA, high-oleic soybeans were introduced into the production chain in late 2011. With high-oleic soybeans coming into the production pipeline, farmers now have an opportunity to meet the needs of a long-term market demand for healthy and better-functioned soy oil.

In the 1990s, the United Soybean Board (USB) identified trans fats as a threat to soybean demand and started investing in research to resolve this threat. This was long before a law requiring the labeling of trans-fat foods went into effect in 2006. These efforts identified high oleic as the most important trait for resolving the problem. Research efforts funded by USB, including mapping the soybean genome and identifying naturally occurring high-oleic mutations in soybeans, played a key role in the commercial development of high-oleic soybean events. Two major crop biotechnology companies, Monsanto and DuPont-Pioneer, used these discoveries to develop their high-yielding high-oleic soybean varieties [6].

Success is encouraging development of other new traits to meet the market needs for specific purposes in the future. These high-value soybean events have been introduced in the market and highly accepted by food companies due to their health benefits and better functionality without needing hydrogenation. It is expected that production of high-oleic-acid soybeans will expand rapidly and represent 30% of total US soybean production by 2023.

As a result, a smooth and unhindered trade environment for biotechnology crops is extremely important for Asian countries to maintain sufficient supplies of soybeans and products, as well as foods that are made better with use of biotech ingredients. Governments, researchers, food companies, and consumers in the region should prepare to accept this new technology and develop sound policies to encourage their use to provide long-term food supply stability to their countries.

CURRENT SITUATION

In North Asian countries, governments are basically pro-biotechnology. They already have regulations in place to govern biotechnology-derived foods.

The basic principles of the regulations are:

- All biotechnology foods, including crops, are required to be registered for importation, production, distribution, and marketing.

- All biotech-derived foods are required to be labeled.

Relevant requirements for registration in individual countries are posted on the websites of relevant governments in this region.

Since its first launch in 1996, imports of Roundup Ready® soybeans into PR China, Japan, Republic of Korea (ROK), Republic of China (ROC), and ASEAN countries have been smooth. With average annual imports of 60 MMT in soybeans and products, total imported quantities of biotech soybeans into major Asian countries in the last 12 years are estimated at 720 MMT. The annual imports in the last five years were even higher than the 12-year average due to the rapid growth for soybean demand in PR China and soy oil in India [7]. In 2013, these imports were forecasted at 106 MMT. Soybean imports, together with maize imports, will contribute at least USD75 billion to biotechnology trade in Asia.

As abstracted from the statement made by the United States Department of Agriculture (USDA), safe and appropriate use of science and technology, including biotechnology, will help the world meet agriculture's challenges and consumers' needs for food in the 21st century.

Again, governments, researchers, food industries, and consumers in the region should be prepared for accepting this new technology, and governments should develop sound policies to cope with the change for ensuring the long-term stability of food supplies for their country and people. Currently, soybean and maize prices have increased almost 200% in comparison with those in the early 1920s. Without using biotechnology, these prices would be even higher today.

Challenges

In spite of all the benefits contributed from biotechnology, there are still challenges that need to be addressed for the long-term development of biotech crop production and trade. On the production side, there have been concerns about the resistance developed by certain weeds to glyphosate herbicide (glyphosate being Roundup's active ingredient). This occurrence implies that continuing R&D for new events, stacked events, and farming practices is required to further improve crop production and quality towards sustaining sufficient long-term food supplies in the global markets. In other words, there is no one event that can be used forever. It is fortunate that there are US seed companies investing large amounts of funds into R&D. These investments go towards developing new events that are beneficial towards expanding production and improving the quality of soybeans and maize needed by the global market [8].

Low-Level Presence of Biotech Events

While the numbers of commercialized biotech events are increasing, they are authorized at different rates in different countries, raising the chance of commingling. These asymmetric authorizations interrupt trade if importing countries reject cargoes containing non-approved events that were already approved by the exporting country. To avoid trade interruption, it is therefore important to harmonize understanding about the concept of low-level presence (LLP) among importing countries and establish a workable LLP for new biotech events as defined. This is urgently needed.

An academic definition made by Dr. Nicholas Kalaitzandonakes, Professor of Agriculture Economics & Biotechnology at the University of Missouri, USA, is considered the best description of LLP and quoted for readers' reference: "*LLP* has been adopted to describe the accidental presence of small amounts of biotech events that *have undergone full safety assessment and have received regulatory approval* for all possible uses in one or more countries but are still unauthorized in others due to regulatory asynchronicity or expiration of their approvals" (emphasis added) [9].

As with many new technologies and innovations, some groups have expressed opposition to agricultural technology, or have called for the removal of biotech-derived foods from their diets. These kinds of activities that are based on incorrect and misleading information are never-ending. As a result, anti-biotechnology campaigns from consumer groups or non-governmental organizations continue to be a major challenge in the region. By using falsehoods and unscientific materials, these groups attack biotechnology and seed companies through press conferences, seminars, lobbying, and all kinds of published material whose only purpose is to halt the further development of biotechnology.

These campaigns always catch the eyes of the media. As a result, in today's media environment where negative incidences are always much more newsworthy and popular, most consumers are misinformed. Besides, it is a common-enough trend for society to generally sympathize with a weak minority, even without good reasons. Although there are thousands of reports concerning the benefits and safety of biotech-derived crops, the media is simply not keen or interested in reporting them. Whenever there is a negative report on biotech food in the press, journalists will rush to publish it, even if they are not quite aware of the facts or whether the story is even true.

With limited access to scientific information, consumers generally believe them and eventually refuse to buy foods made from biotech-derived crops. In ROC for example, a consumer group along with an extreme agronomy professor is trying to eliminate use of biotech soybeans for food uses through a series of programs including press conferences, television interviews, and seminars, claiming that biotech-derived soybeans are grown for feed use. They have made further attacks, telling consumers that they are feeding their children animal feed if they purchase soy products made with transgenic soybeans. This trend will slow down the development and application of biotechnology in Asia, continue the imbalance in trade of soybean and maize between Asia and exporting countries that use biotechnology, as well as the world. That is not a preferred situation.

Anti-biotechnology activities are not expected to stop in the foreseeable future. To cope with this, the biotechnology industry and parties believing in "science and facts" should devote stronger efforts to spread facts on the safety, value, and benefits of biotechnology to the world as the crucial solution for sustaining sufficient food supplies to the global population in the face of scarce resources and increasing environmental issues.

Currently, seed companies are working with local governments and researchers to build capacity and improve regulation of new biotechnology events. These approaches are working well as these partners are well-trained and knowledgeable about the importance of the technology. Partly due to their effort, registration of new biotech-derived events in key Asian countries such as PR China, Japan, ROK, and ROC has been approved within reasonable timeframes. However, the scope should be widened to include consumers who do not normally have access to the right information. They are easily influenced by anti-biotech campaigns using non-scientific evidence to scare people about the safety of biotech-derived foods.

CONCLUSION

As the world population keeps growing, demand for food and high-quality protein such as pork, eggs, and chicken will increase accordingly. For Asian countries that rely heavily on importation to satisfy food demands, including feed ingredients for producing high-quality animal products, maintaining a sound trade policy that ensures the smooth importation of biotechnology-derived commodities, such as feed grains and soybeans, is a must.

As biotechnology continues to be developed, there will be more biotech crops, including nutritionally improved soybean, maize, and wheat events introduced into the development pipeline. Seed companies and major producing countries should exert their efforts to keep importing countries informed of the introduction of new events and ensure that these new events will be legal for importation in the future. These efforts should include educational campaigns for consumers in the region to understand the safety and importance of biotechnology in stabilizing food supplies in the region and its contribution to the environment.

It is important for consumers to understand that biotechnology will facilitate more accurate and efficient food protection methods. They need to be educated that biotechnology in the broad sense is, in fact, not a discrete technology. It refers to a group of useful enabling techniques that includes, but is not limited to, genetic modification with wide applications in research and commerce. While irrational and non-scientific anti-biotech campaigns will continue and be more vigorous, it is the responsibility of the entire biotech industry, including seed companies and commodity groups (such as the US Soybean Export Council, US Grain Council, and soy food processors) to provide correct and scientific information to the world, so that biotechnology development can continue to contribute to ample and high-quality supplies of food to the increasing world population of the foreseeable future.

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3

COMMERCIALIZATION OF AGRICULTURAL BIOTECHNOLOGY: INVESTMENT, POLICY, INSTITUTIONAL, AND REGULATORY FRAMEWORKS

MULTINATIONAL INVESTMENTS IN AGRICULTURAL BIOTECHNOLOGY

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INTRODUCTION

By 2050, the Food and Agricultural Organization of the United Nations (FAO) estimates that the world's population will reach 9.1 billion, with nearly all of the population increase occurring in developing countries [1]. As such, investments in agriculture need to increase to meet the looming food security challenge.

Timmer noted that a new resurgence of interest in agriculture has recently started, stemming from, among others, a new understanding that economic growth is the main vehicle for reducing poverty and furthermore, that growth in the agricultural sector plays a major role in overall growth, and in connecting the poor to growth [2]. After several decades of under investment for the agricultural sector in developing countries, the late 2000s witnessed a surge in foreign direct investment for primary agricultural production [3]. The reasons for this surge are diverse and complex, but the main drivers can be linked to the steep rise in commodity prices in 2007–08 and the realization that demand for finite natural resources is set to continue increasing significantly in the next four decades. Although investment in agricultural R&D continues to be one of the most productive investments, with rates of return between 30% and 75%, it has been neglected in most low income countries [1]. The FAO added that investing in agriculture is one of the most effective strategies for reducing poverty, hunger, and promoting sustainability [4].

Indeed, after two decades of neglect, interest in agriculture is returning with new international initiatives, signalling strong commitment to agriculture and food security. Donor commitments of aid for the agricultural production sector roughly doubled from USD4 billion in the mid-2000s to a little more than USD8 billion in 2010, but the amount was still just 5% of total official development assistance commitments [5]. While aid to agriculture grew relatively rapidly in the last few years, in real terms, it remains well below the levels of the 1970s. For its part, the Asian Development Bank committed USD2 billion a year for the Operational Plan for Food Security in Asia and the Pacific. It calls for a multisector approach to improve the productivity, connectivity, and resilience of food supply chains; enhanced partnerships; and increased but focused support for agricultural research [6].

Timmer also recognized that there is a relatively stagnant shelf of available agricultural technologies that can be easily borrowed and widely adopted by farmers [2]. Unless modern genetic technologies are brought to bear on the problem, there is little promise of a radical breakthrough in the foreseeable future.

Indeed, biotechnology enables diverse applications in agriculture, health, industry, and the environment. Biotechnological tools such as tissue culture, genetic engineering, and molecular breeding (marker-assisted selection) continue to provide promising opportunities for achieving greater food security, while improving the quality of life. Biotechnology, however, is only one among several tools available to complement conventional agriculture. Effectively addressing the challenges faced by agriculture requires a multitude of approaches that include good governance, improved infrastructure, farmer education, improved seed quality and delivery systems, inputs, market access, fair trade, and appropriate technologies that integrate proven indigenous knowledge practices with emerging technologies, such as modern biotechnology [7].

For its part, the plant science industry continues its role of improving the efficiency and effectiveness of crop production around the world by making available high quality seeds, improved biotechnology-derived crops, and crop protection products. The technologies offered by the industry have a critical role to play in meeting the challenges of a growing world; from increasing yields and reducing soil erosion, to crops that can grow in saline soils, and crops that require less water.

FOOD SECURITY

The FAO defined food security as a situation that exists “when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life” [4]. Based on this definition, four food security dimensions can be identified: food availability, economic and physical access to food, food utilization, and stability over time. The current world food and agricultural situation is characterized by continued high and volatile international food prices and the persistence of hunger and malnutrition in many parts of the world [4].

Muhammad Yunus, Nobel Peace Prize Winner, was quoted as saying, “In the 21st century, the world has no excuse for tolerating the existence of a billion people going without food.” It was in 1990–92 when one billion people were estimated to be undernourished, equivalent to 18.6% of total world population. The State of Food Insecurity in the World 2012 reported that a total of 868 million people in 2010–12, or 12.5% of all people in the world, were estimated to be chronically undernourished [8]. Undernourishment or chronic hunger is a state, lasting for at least one year, of inability to acquire enough food, defined as a level of food intake insufficient to meet dietary energy requirements [4].

Out of the world's 868 million undernourished population, a total of 563 million (13.9% of total population) is found in Asia, down from 739 million (23.7%) in 1990–92 [8]. This means that in 2012, Asia is home to almost 65% of the undernourished in the world, of which 29.1% of the global total is in southern and eastern Asia. The number of people suffering from chronic undernourishment is still unacceptably high, especially in Asia, and eradication of hunger remains a major global challenge. While it is clear that improving Asia's food security would improve global food security, the region is faced with daunting challenges that include population growth, demographic changes, high and volatile food prices, natural resource constraints, and climate change [9].

It is generally acknowledged that Asia is exposed to the world's supply and demand of food, and to the international market. In the case of soybeans and the grain trade, for example, Asia is a major importing region. In 2011–12, Asia imported 71 million metric tons (MMT) of soybean, 40 MMT of wheat and 40 MMT of maize [10]. In the case of rice, Asia has historically been both its biggest producer and consumer. In 2007, the region accounted for almost 91% of world's rice production. Timmer noted, however, that while the overall importance of rice to Asian consumers as a source of calories is gradually declining, the total size of rice demand remains important because rice remains the largest single source of calories for a significant majority of Asian consumers [11]. Also, Asia's food marketing system, particularly for rice and potato in Bangladesh, PR China, and India, is transforming rapidly, and modernized value chains coexist with, while apparently displacing, traditional value chains [12]. With its remarkable population increase and economic growth, Asia greatly influences the food supply and demand situation in the world. As such, the coexistence of economic development and environmental protection is important.

It appears that closing the gender gap in agriculture would help address this problem significantly. The FAO estimates that if women had the same access to productive resources as men, they could increase yields on their farms by 20%–30% percent, raising total agricultural output in developing countries by 2.5%–4%, which could in turn reduce the number of hungry people in the world by 12%–17% [13]. Gains of this magnitude could, therefore, equate to 100–150 million fewer people living in hunger. As it is, children bear the brunt of the malnutrition problem in the world. Childhood malnutrition is an underlying cause of death in an estimated 35% of all deaths among children under the age of five [8]. In 2010, more than 100 million children under the age of five in developing countries were still underweight.

To quote Jacques Diouf, director-general of the FAO, “Defeating hunger is a realistic goal for our time, as long as lasting political, economic, financial, and technical solutions are adopted.” But while the number of undernourished has gone down, it should be noted that most of the progress was achieved before the 2007–08 price spikes. Since then, global progress in reducing hunger has slowed and levelled off. In its 2012 Global Food Policy Report, the International Food Policy Research Institute announced that if the Millennium Development Goal of reducing poverty and hunger is not achieved, more than 800 million people may suffer from hunger in 2015.

Moreover, the global food system remained fragile in 2012, affected by weather, climate change, food prices, productivity growth, and competition from biofuels. Vulnerable food systems, if left unchecked, will reduce the availability, access, and utilization of safe and nutritious food [6].

Climate change puts poor people who depend on agriculture in a most vulnerable position. Rosegrant et al. noted that agriculture is inherently risky, and may be even more so in the future with an increasing frequency of extreme climate events [14]. The flux of agroclimatic conditions can alter the length of growing seasons, planting and harvesting calendars, water availability and water usage rates, along with a host of plant physiological functions including evapotranspiration, photosynthesis and biomass production, and land suitability. The complex interactions between agroclimatic conditions and technological drivers such as nutrient application, irrigation, and seed selection determine food availability and quality. Warming across the Asian continent will be unevenly distributed, but will certainly lead to crop yield losses in much of the region and subsequent impacts on prices, trade, and food security, disproportionately affecting poor people. Most projections indicate that agriculture in South, Central, and West Asia will be hardest hit [14]. It is also estimated that developing countries could experience a decline of between 9% and 21% in overall potential agricultural productivity as a result of global warming [1].

After declining in real terms throughout the 1980s and 1990s, international food prices began rising in 2002 in an apparent reversal of this long-term trend. By 2011, the FAO Food Price Index reached more than double its level during 2000–02 [4]. Perhaps more significant is the fact that real prices have remained above their previous low for more than 10 consecutive years. This is the longest sustained cyclical rise in real prices experienced in the last 50 years. While international food prices have come down slightly from their 2011 peak, they still remain well above historical averages and cereal prices increased again in mid-2012. The OECD-FAO estimates that prices will rise over the medium term. In the near term, crop prices should fall as production rebounds, while low livestock products are set to rise with meat, fish and biofuel prices projected to rise more strongly [3].

The OECD-FAO also announced in the 2013 outlook, that global agricultural production for commodities is projected to grow at 1.5% annually, on average, compared to 2.17% in the previous decade [15]. This slower growth is expected to be exhibited by all crop sectors and livestock production. These trends reflect rising costs, growing resource constraints, and increasing environmental pressures, which are anticipated to inhibit supply response in virtually all regions.

Rapidly growing demand for biofuel feedstocks has contributed to higher food prices, threatening the food security of poor net food buyers in both urban and rural areas [16]. This may have led Timmer to warn that the growing of biofuels has two alternative futures: it could spell impoverishment for much of the world's population because of the resulting high food prices, or it could spell dynamism for rural economies and the eventual end of rural poverty [2]. It depends fundamentally on the technology, economics, and politics of biofuel production.

In 2007–08, total usage of coarse grains for the production of ethanol reached 110 MMT, about 10% of global production, posing serious implications for food security [1]. By 2022, biodiesel production is projected to consume 28% of total world production of sugarcane, 15% of vegetable oils, and 12% of coarse grains [15]. In order to feed the expected 9.1 billion population by 2050, food production (net of food used for biofuels) must increase by 70%. Annual cereal production will need to rise to about 3 billion metric tons from 2.1 billion today and annual meat production will need to rise by more than 200 MMT to reach 470 MMT [1]. Fan recommended halting the expansion of biofuel production from food crops through policies that remove subsidies encouraging the use of food crops for fuel production, and support for the use of second-generation technologies to sustainably produce biofuels from non-food crops [9].

ROLE OF TECHNOLOGY

Historically, the level of agricultural production per unit area in developed countries is much higher than in developing countries. Among others, this difference is attributed to soil and climatic factors, farm management practices, crop varieties used, and the technologies available and adopted by farmers.

The situation is much pronounced in the case of maize production by major growing regions (Figure 1). Maize growers in the developed countries of North America and Western Europe achieve yields five times higher than their counterparts in Africa. However, there is potential to narrow the yield gap, and this is where technology plays an important part, particularly biotechnology. Crop yield increases have been achieved due to advancements in agricultural technologies. Between 1996 and 2011, genetically engineered crops were responsible for the production of an additional 110 MMT of soybeans, 195 MMT of maize, 15.8 MMT of cotton lint, and 6.6 MMT of canola [17]. Also, with modern crop protection technologies, global rice yields have more than doubled since 1961 [18].

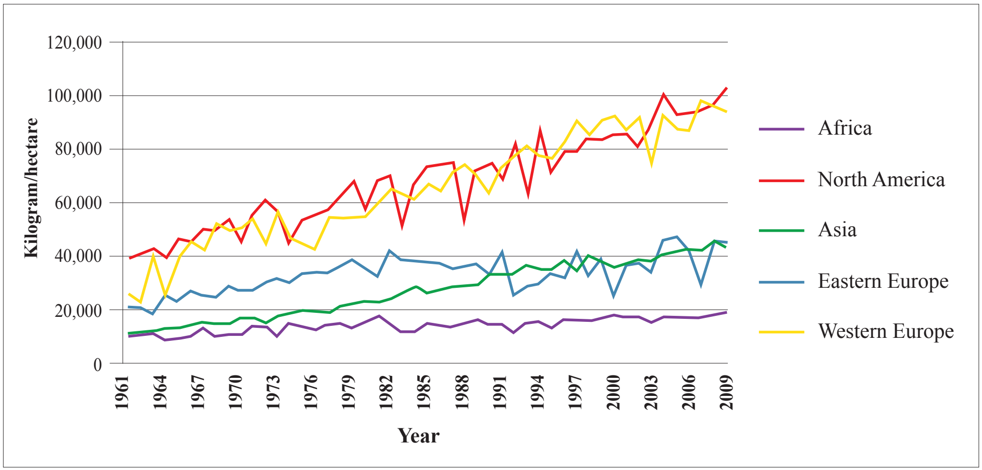

Figure 1. Yield gap in maize production (kilogram/hectare).

Source: USDA-FAS. Maize Production by Major Growing Regions [19].

Major landmarks in the history of genetic engineering can be traced as scientists embarked on the manipulation of genes to produce modified plants. In 1973, Herbert Boyer and Stanley Cohen transferred DNA from one organism to another to create the world's first recombinant DNA organism. Advances have allowed scientists to manipulate and introduce genetic material to a target crop species from the same or different plant species, or in many cases, unrelated organisms and induce a range of different effects.

The 1980s was marked by geneticists proving that genes can be transferred between plant species with the aid of *Agrobacterium tumefaciens*, the discovery of the polymerase chain reaction in DNA, and thousands of applications for the field testing of genetically engineered varieties. From then on, transgenic crops were developed and commercialized, starting in tomato with delayed ripening traits, and other crops such as canola, cotton, maize, and soybean rendering them with traits such as herbicide tolerance, and virus and insect resistance. Genetic modification has been occurring since humans first domesticated plants. One of the benefits of biotechnology and genetic engineering is dramatically reducing the time taken to create new types of plants with the desired traits that breeders want. While it took 10,000 years of artificial selection for man to develop the modern-day maize from its wild-type predecessor, teosinte, it has taken only 15 years to come up with insect-resistant Bt maize.

One of the major investments by the plant science sector and public institutions continues to be R&D, in order to address challenges that may seriously affect crops, especially the major staples, vegetables, and fruit crops. Currently, the key goals for plant breeders and biotechnology are in the following fields: insect pest protection; multiple herbicide tolerance; disease resistance; hybrid production; nutrient use efficiency; carbon sequestration; salinity tolerance; cold and frost tolerance; drought tolerance; oil, starch and amino acids; and nutrient quality [20]. Achieving these goals will require traditional breeders' skills but will be accelerated by the use of novel molecular techniques and genetic engineering.

Varshney et al. showed how next-generation sequencing technologies (Figure 2) could accelerate crop improvement [21]. They outlined important areas such as the large-scale development of molecular markers for linkage mapping, association mapping, wide crosses and alien introgression, epigenetic modifications, transcript profiling, population genetics, and *de novo* genome/organellar genome assembly. Crop biotechnology's future and the next-generation biotech product development will rely on activities in various fields, such as genomics and bioinformatics. These will help unravel the interaction of genes and metabolic pathways leading to traits of interest that can facilitate the development of new crop varieties.

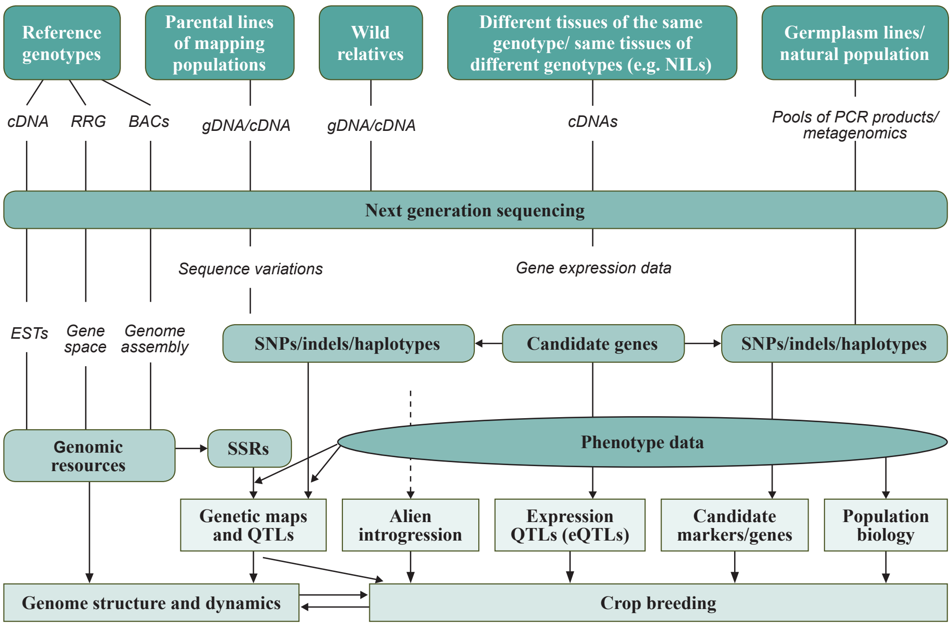

Figure 2. Technologies involved in accelerating plant biotechnology. BAC, Bacterial Artificial Chromosome; cDNA, complementary deoxyribonucleic acid; eQTL, expression quantitative trait loci; EST, expressed sequence tag; gDNA, genomic deoxribonucleic acid; PCR, polymerase chain reaction; QTL, quantitative trait loci; RRG, reduced representation genomic; SNP, single base-pair site inside the human genone; SSRs, simple sequence repeats.

Source: Varshney, R.K., Nayak S,N., May G.D., et al. [21].

In addition to the development of biotech crops and products, the past two decades ushered additional applications of biotechnology and molecular biology in plants with the potential to further enlarge the plant breeder's toolbox for accelerated breeding techniques.

Lusser et al. reviewed a total of 187 relevant scientific publications and classified them according to one of seven new plant breeding techniques: zinc finger nuclease technology; oligonucleotide directed mutagenesis; cisgenesis and intragenesis; RNA-dependent DNA methylation; grafting; reverse breeding; and agricultural infiltration [22]. They found that while the plant science industry conducts considerable amount of R&D, public institutions are the ones engaged in publishing their outputs, with 84% of publications on these techniques coming from public institutions in the European Union, North America, Asia, and other countries (Figure 3).

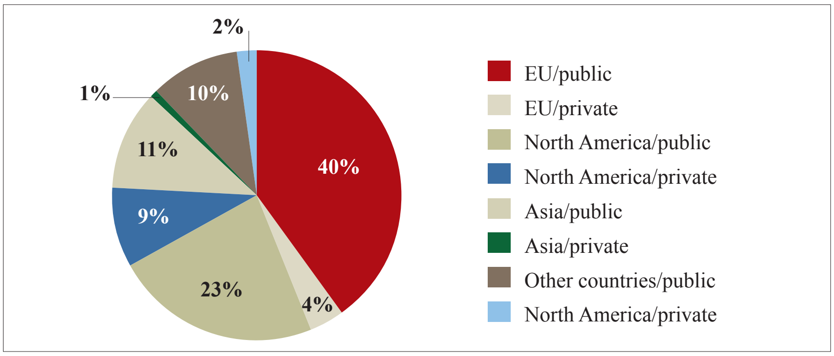

Figure 3. Country of origin and sector (public or private) of institutions authoring scientific publications on new plant breeding techniques.

Source: Lusser, M. Parisi C., Plan D., et al. [22].

THE ROLE OF CROPLIFE

CropLife International is the global federation representing the research-based plant science industry that develops, manufactures, and sells products and services designed to improve the global production of food, feed, fiber, and fuel in a sustainable way. As a global network, CropLife International acts as an ambassador for the plant science industry, encouraging understanding and dialogue whilst promoting sound science and agricultural technology in the context of sustainable agriculture and development. CropLife International is led by the major R&D-driven plant science companies such as BASF, Bayer CropScience, Dow AgroSciences, DuPont, FMC, Monsanto, Sumitomo Chemical, and Syngenta. These companies represent approximately 80% of total global sales of crop protection products.

CropLife International represents a 15-member network of regional and national associations in 91 countries that include CropLife regional networks in Africa/the Middle East, America, Asia, Canada, and Latin America, and other like-minded organizations in Africa, Brazil, Mexico, Argentina, Japan, and Europe. These member associations cover all major markets and are located in both developed and developing regions. More than 1,000 international, national, regional, and local companies are represented by the global CropLife network of associations. As a regional unit of CropLife International, CropLife Asia envisions a region where productive food and agricultural systems, enabled through innovative crop science and technologies, contribute to improving food security and the living standards of all in an economically, socially, and environmentally sustainable manner.

CropLife Asia traces its beginnings back to 1996 when it was established as the Asia Pacific Crop Protection Association, and in 2002 when it changed its name to CropLife Asia [23]. It was the time when the agriculture sector was experiencing an unprecedented adoption of transgenic crops benefiting both large and small farmers in developed and developing countries. From originally focusing on crop protection technologies, CropLife Asia has widened its outreach efforts to include plant biotechnology. In doing so, the association believes that through biotechnology, farming communities can directly increase their income and food supply.

CropLife Asia works with three major stakeholders: government (regulatory bodies), society (general public), and members of the food value chain, including its international trading partners. Its programs focus on capacity building and public education and implementation of these programs by forging networks, partnerships, and collaborative working arrangements. It engages stakeholders through conferences, seminars, workshops, training, on-farm projects, and farmer exchanges [23].

INVESTMENTS IN AGRICULTURAL BIOTECHNOLOGY R&D

Developing biotech crops requires considerable resources in the form of human resources, facilities and equipment, and R&D funds. In 2011, the plant science companies BASF, Bayer CropScience, Dow AgroSciences, DuPont, Monsanto, and Syngenta invested a total of USD5.9 billion in R&D, equivalent to 10.4% of their aggregate sales [24]. They spent USD2.5 billion for agrochemicals and USD3.4 billion for seeds and traits R&D. As of 2009, it appeared that future investment in seeds and traits R&D would continue to outpace agrochemicals [25]. For seeds and traits R&D, the biggest investment in 2011 was made by Monsanto amounting to USD1.4 billion, followed by DuPont with more than USD0.7 billion, and Syngenta with USD0.4 million [24].

Similarly, global companies in other sectors invest huge sums in R&D to remain competitive. In 2012, Apple allocated a total R&D investment of USD3.4 billion or 2% of total sales and Microsoft used USD9.8 billion or 13% of sales. In 2011, Nokia spent USD7.3 billion or 14.5% of sales, Amazon used USD2.9 billion or 6.1% of sales, HP spent USD3.3 billion or about 3% of sales, Samsung had USD9.1 billion or 6% of sales, and Google spent USD5.2 billion or 13.6% of sales [26].

Since 2000, the agrochemical market has grown by 3.5% per annum, while the total seed market grew at an average annualized rate of 5.5% per annum. During the same period, R&D expenditure by the 15 leading agrochemical companies grew at a compound annual growth rate of 5% [25]. However, before a new agrochemical product can be introduced into the market, a plant science company has to spend approximately USD256 million, of which 33.3% goes to research, 57% to development, and 9.7% for registration [25]. On the other hand, a new plant biotechnology trait requires approximately USD136 million to support R&D and registration before it reaches the market. The combined cost associated with regulatory science, and registration and regulatory affairs is USD35.1 million [24].

It takes an average of 13.1 years to introduce a new biotech crop from the discovery of the trait to first commercial sale: 11.7 years for canola, 12 years for maize, 12.7 years for cotton, and 16.3 years for soybean. It should be noted that the time associated with registration and regulatory affairs took a mean of 44.5 months for an event introduced before 2002, but has taken substantially longer (65.5 months) for an event introduced in 2011 [24].

Despite the long history of innovation in agriculture, more R&D than ever before is needed to meet future demands for food. This can be facilitated if innovators and product developers are rewarded for their developments through effective intellectual property protection, and then encouraged to invest the necessary resources required for long-term R&D to continuously produce new technologies and products that benefit farmers, consumers and the environment [27]. This is especially true for plant science innovation where R&D is intensive and costly. Intellectual property protection helps to ensure that industry has the ability to continually invest in developing new technologies that will help farmers protect and expand food supply.

GLOBAL ADOPTION OF BIOTECH CROPS

Since the first transgenic crop was commercialized, the areas planted to biotech crops have steadily increased through the years. In the 17th year of commercialization, James reported that 170.3 million ha of biotech crops were grown globally in 2012 [28].

With an annual growth rate of 6%, the increase amounted to 10.3 million from 160 million ha in 2011. The hectarage marked a 100-fold increase from 1.7 million ha in 1996, making biotech crops the fastest adopted crop technology in recent history. Of the 28 countries that planted biotech crops in 2012, 20 were developing and eight were industrial countries. A total of 17.3 million farmers grew biotech crops, more than 15 million of whom were small resource-poor farmers in developing countries. The year 2012 was also the first time that developing countries grew more (52%) of global biotech crops equivalent to 88.5 million ha than industrial countries (48%) or 81.8 million ha. Five Asian countries planted a total of 18.7 million ha led by India (10.8 million) and PR China (4 million), while only the Philippines and Myanmar have commercial plantings of biotech crops in ASEAN, which combined, total at 1.1 million ha [28]. Overall, the global value of biotech seeds in 2012 had reached USD15.7 billion [24].

Benefits from Biotech Crops

Based on the findings of PG Economics [17], the net economic benefit from biotech crops at the farm level in 2011 was USD19.8 billion, equal to an average income premium of around USD131.6 per hectare. For the 16-year period 1996–2011, the global farm income gain was USD98.2 billion. Of the total farm income benefit, 49% (USD48 billion) was due to yield gains resulting from lower pest, weed pressure, and improved genetics, with the balance arising from reductions in the cost of production.

According to the PG Economics analysis, genetically engineered crops offer important benefits in addition to improvements to the bottom line. First, their use has obviated the need to cultivate vast additional amounts of arable land. Between 1996 and 2011, genetically engineered crops were responsible for the production of an additional 110 MMT of soybeans, 195 MMT of maize, 15.8 MMT of cotton lint and 6.6 MMT of canola. If modern genetic engineering had not been available to the 16.7 million farmers using the technology in 2011, maintaining global production levels at the 2011 levels would have required additional plantings of about 5.3 million ha of soybeans, about 6.6 million ha of maize, about 3.3 million ha of cotton and 198,295 ha of canola. This total area requirement is equivalent to 9% of the arable land in the USA.

Second, the cultivation of genetically engineered crops has significantly reduced the release of greenhouse gas emissions from agricultural practices. This is due to less fuel use and additional carbon sequestration from reduced tillage with the cultivation of genetically engineered crops, as compared to conventional varieties. In 2011, this was equivalent to removing 23 billion kg of carbon dioxide from the atmosphere or to removing 10.2 million cars from the road for a year.

Third, the cultivation of pest-resistant genetically engineered crops reduced pesticide spraying by 474 million kg between 1996 and 2011. This decreased the environmental impact associated with herbicide and insecticide use on the area planted to genetically engineered crops by 18.1%.

Success stories abound on the benefits derived from growing biotech crops. To cite an example, the Philippines has experienced success with biotech maize as its farmers benefited from higher yields (+3.5 metric tons/ha), doubling in farm income, and reduced plowing and weeding needs [29]. The Philippines has the distinction of being the first and only Asian country to grow a major biotech crop for food, feed, and processing – that of Bt maize MON 810 approved for commercialization in 2002 [30]. From 2006 to 2011, Philippine farmers growing Bt maize achieved yield gains of 18.6% [17].

In the Philippines, biotech maize is now planted on 0.8 million ha in the country [28], a huge increase from the 10,000 ha planted in 2003 [30]. It should be noted, however, that getting the biotech crop approved for commercialization took almost 10 years from laboratory to farmers' fields and required crucial key elements for the technology to be accepted and adopted. These included strong political support, a vigilant scientific community, a well-informed media, and a dynamic collaboration among public and private sectors [30].

GLOBAL BIOTECH PIPELINE

The plant science industry is committed to developing superior plant biotech varieties, which can adapt to a wide range of farming conditions. CropLife-member companies are developing the next generation biotech crops, and traits in the pipeline cover interest areas such as pest management, increased yield, nitrogen utilization, stress tolerance (i.e. drought), and improved crop composition.

These pipeline products are in the early to advanced development stages. Early development includes products in their research, discovery, and proof of concept phases, as well as early product development. Advanced development products are in late stages of development and have an expected launch date within the next five to seven years, subject to regulatory approvals [20]. These products cover soybean, maize, cotton, canola, rice, and other crops such as alfalfa, beans, eggplant, potatoes, sugarbeet, sugarcane, and wheat.

The new biotech applications in the R&D pipeline (such as drought- and stress-tolerant crops) offer additional opportunities to get the most out of the land being cultivated and increasing global food security, while protecting the environment. Biotech plants that use nitrogen more efficiently can reduce the need for added fertilizer, reducing greenhouse gas emissions from agriculture. With the development and adoption of herbicide-tolerant crops, farmers are able to switch to conservation or no-till systems (growing crops with minimal or no soil cultivation). These methods help conserve water and minimize run-off by increasing moisture penetration and retention in the soil. Growing insect-resistant biotech crops would require less amount of pesticides to control damage due to insects, and therefore, less chemicals released into the environment.

These next generation biotech crops will likely be deployed in developing countries, particularly in Asia, where half of the world's population and majority of the poor and impoverished people live. Eventually, these biotech crops will contribute to poverty and hunger reduction and help attain global food, feed, fiber, and energy security.

CONCLUSION

The world faces the challenge of providing enough food and other requirements to a population that is expected to reach 9.1 billion in 2050. Asia is home to the majority of the world's poor and undernourished.

Agriculture as a global industry must respond to the challenges of feeding the expanding population and satisfying demands of growing affluence. In order to meet this future demand, farmers will need innovative tools and technologies that enable them to grow and produce what the world needs. Governments, public institutions, and the plant science industry must be able to harness the opportunities offered by modern science and biotechnology to help the agriculture industry. Biotechnology is not a magic bullet, however, and is only offered to serve as a complementary approach with other forms of agriculture.

The plant science industry has a long history of collaborating with stakeholders from the agriculture and food value chain to consistently provide farmers with innovative technologies. It is committed to play a role by investing in new technologies and putting these technologies into the hands of farmers. Considerable investments in R&D are needed to make this possible and, as such, the industry banks on the freedom to operate under smart regulations and social responsibility that will allow a sustainable approach to food security.

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WHAT DOES IT TAKE TO SELL BIOTECHNOLOGY PRODUCTS?

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INTRODUCTION

This paper presents a unique perspective on biotechnology commercialization. While there are many excellent resources explaining how to assemble a business plan, and the central need for strong science, management, and intellectual property protection, a central issue that is often ignored is the need to build adaptability into plans. This paper will focus on addressing business risks.

This paper focuses on business risks in the following categories: reaching markets; post-launch; general management; and political and social impediments.

Reaching Markets

The concept of "freedom to operate" is key to reaching markets. While many innovators may see R&D as the primary challenge to reaching markets, it is also important to gauge the impact of non-technical factors that may affect commercialization. This section focuses on intellectual property (IP), but it is also important to consider political and regulatory issues. Unlike IP, these issues vary substantially depending on a company's location and the location of the target market. Many innovators have an incomplete understanding of patents. This section will briefly describe some of the issues related to patent protection as an example of the pitfalls of being insufficiently prepared. Because patent laws vary significantly across jurisdictions, interested readers are encouraged to seek professional advice early in project development.

The notion of "upstream" and "downstream" patents is important in evaluating freedom to operate. Patents confer upon inventors the ability to exclude others from adopting an invention. This "exclusion" is an important concept: patents provide a negative right upon others; they do not confer the right to practice an invention. Consider the example of an inventor who develops a gene-based crop improvement to produce valuable plant biomaterials. While the inventor may have rights to the modified plants containing the gene of interest, she may be impeded from practicing her invention by upstream patents such as those on the isolated gene, or methods to introduce the genes and express their products in plants. Examples of downstream patents include methods used to extract the biomaterials from mature plants. Accordingly, to practice her invention, the inventor will need to license or work around the upstream and downstream patents.

It is also important to consider that despite performing a comprehensive freedom to operate analysis at the outset of a project, new patents may emerge during development or after commercialization that may require licensing. The case of Monsanto's use of bovine somatotropin (BST) to increase milk production in cows provides an example of late-emerging patents. Nearly a decade after the commercial introduction of BST in 1994, the University of California obtained patents on the technology (based on filings initiated in 1990). To continue selling BST technology, Monsanto was forced to license the patents at an estimated cost of USD185 million.

Post-Launch

A key consideration for biotechnology products is maintaining regulatory clearance. As a highly regulated industry, falling afoul of regulators can prevent a company from commercializing its products and lead to significant financial losses. There are numerous cases in the therapeutic space of companies having to recall drugs due to manufacturing problems or due to serious side effects emerging after launch. Agricultural biotechnology producers should learn from these lessons and be prepared for post-launch issues.

A common issue in biotechnology commercialization is the development of products for which a profit-enabling market does not exist. Calgene Fresh's Flavr Savr tomato provides an excellent example. Despite overcoming numerous technical challenges, the company produced a tomato that addressed a need (long shelf life) for which customers were not willing to pay premium prices. Comprehensive market research conducted early in product development would have been able to assess if a market opportunity had existed.

General Management

The history of Dyadic provides an excellent example of management issues that can derail a company. Briefly, Dyadic was founded to leverage transportation arbitrage, capitalizing on container vessels such as trains, barges, and trucks, which were returning empty after delivering their loads. Dyadic commissioned these vessels to collect stones from quarries, which it then sold for landscaping. With a glut of pumice, Dyadic entered the denim jean stonewashing industry. On noticing that cellulases started displacing pumice in stonewashing, Dyadic began to search for a way to undercut other cellulase producers by developing a lower-cost manufacturing method. Following a successful collaboration with a Russian partner, Dyadic found a Chinese partner to further commercialization. Accounting irregularities in the Chinese partner led the board to ask Dyadic's founder to step down so that they could investigate the incident. The founder acquiesced and transferred control of the company to the board, however, after completing their investigation, they failed to reinstate him [1]. After an extended battle the founder was able to regain control, but the value of the company's stock had been decimated (it was 90% off its 52-week high), challenging the company to amass the resources to continue commercial development [2].

Political and Social Impediments

Many new technologies face political and social impediments, and agricultural biotechnology is exemplary in this regard. *Scientific American's Worldview* contains myriad stories on challenges faced in attempting to advance biotechnology, including Greenpeace's activities to prevent the use of ringspot virus resistance technology to save papaya crops in Thailand [3]. Additionally, concerns over biopiracy are impeding access by well-intentioned researchers and holding back basic scientific research. Social resistance to genetically modified crops is also blocking cultivation of crops with improved characteristics. All these elements should be considered, and ideally, plans to address them should also be initiated early in the product development process.

SUMMARY AND CONCLUDING REMARKS

Many companies view others in their space as competitors and attempt to isolate themselves from their peers. This parochial view ignores the reality that similar companies can work together to realize synergies. Successful industry clusters with global impact, such as Hollywood, Silicon Valley, and others, have thrived because of non-competitive sharing between companies. It is recommended that agricultural biotechnology companies form associations to leverage common and complementary non-competitive assets, including positive and negative case studies, as a guide for progress.

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OVERCOMING HURDLES TO COMMERCIALIZE BIOTECHNOLOGY

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INTRODUCTION

There are many projections of expected global population growth in the coming decades. While projections may vary by the hardly trivial 1 billion people, the reality is that more food will have to be produced than before on a dwindling area of land, whilst coping with extreme weather conditions resulting from climate change. Some of the countries most likely to be impacted by climate change are in the Asian region (e.g., Vietnam and Bangladesh), and efforts must be made now to ensure that widespread hunger does not develop beyond what currently exists.

Biotechnology has the capacity to positively impact all four dimensions of food security as outlined in Figure 1. Biotechnological approaches have already been seen to impact the production phase, improving yield by reducing losses through biotic stresses. In the coming years, biotech will be seen to help overcome losses in yield due to increased temperature, reduced water availability, and elevated carbon dioxide levels (abiotic stresses). Biotechnology can also help reduce post-production losses and ensure that food is available at an affordable price. Just as important, biotechnology can ensure that foods are safe (e.g., reduced mycotoxin levels or pesticide residues) and are more nutritious through the development of grains with a better balance of oils, elevated vitamin or pro-vitamin levels, and micronutrients.

As Figure 2 shows, there has been a steady adoption of biotechnology-derived crops since their recent inception, with cultivation areas in developing countries exceeding those in developed nations. Despite this, many countries, especially in Africa and Asia where food security is a pressing issue, are still not growing these crops or importing from producer countries.

THE COMMERCIALIZATION PROCESS

The commercialization of a product is not an easy task, and a biotechnology crop costs a considerable amount of money and can take as long as 10–15 years to cultivate. It is important to understand the complexity of the process. While we may think of the process as linear, anyone engaged in the process should understand that there may be times when one steps back, and times when one must look considerably farther forward than the step being negotiated at any one time. It is important that the inventor never lose sight of the market, as it will only be then that the invention truly becomes an innovation. It should also be realized that there are many skills required at different stages in the product development process and rarely are these skills present in one individual. It is thus vital for a team of appropriately skilled people to be engaged in the process. Satisfying regulations relevant to the new product is a vital component of the commercialization process. This is often not well understood by researchers and not anticipating these regulatory demands wastes considerable amounts of time and money.

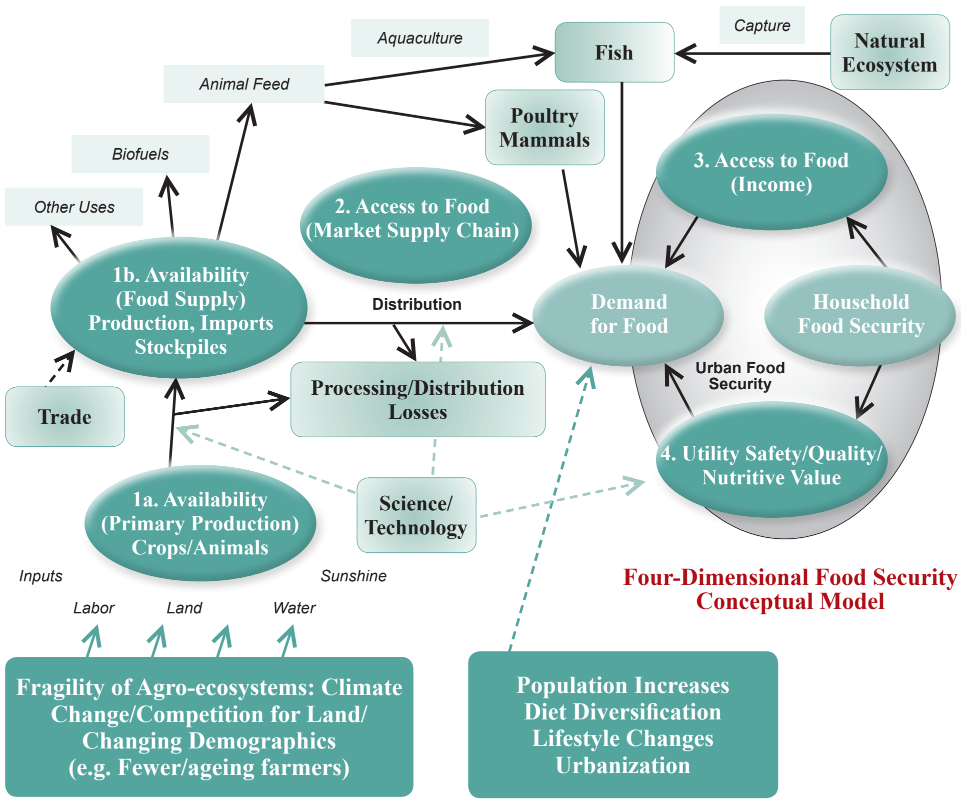

Figure 1. Schematic showing the four dimensions of food security.

Source: Teng and Escalier [1].

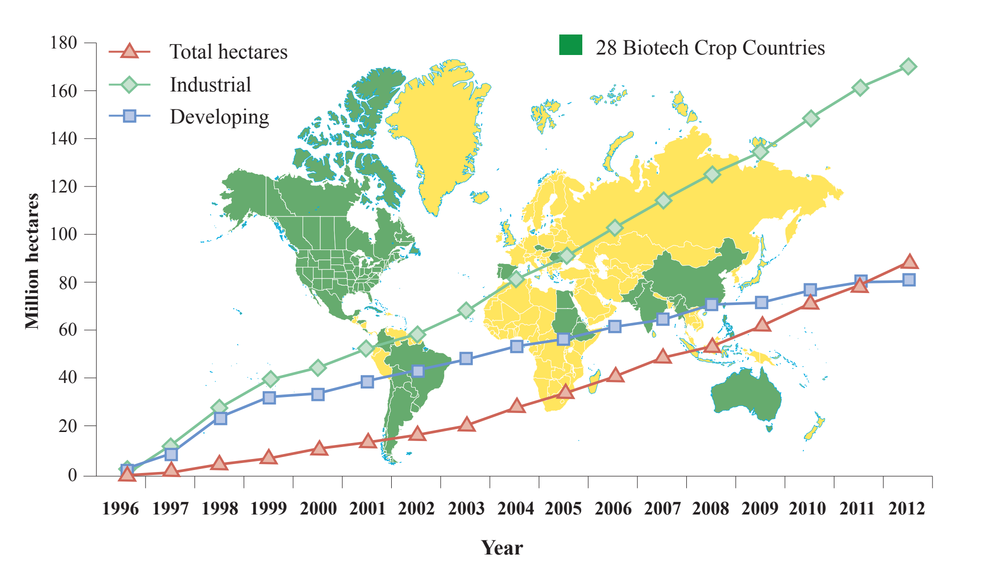

Figure 2. Global area of biotech crops (million hectares), 1996–2012.

Source: James, W.C. [2].

These regulations need to be scientifically sound, consistent with other international regulations, and not overly restrictive and costly. Unfortunately, in a number of countries this is not the case and often where regulations do exist, they are implemented inconsistently or not implemented at all. In some countries, appropriate regulations have not been developed and the regulatory process is made complicated by the fact that multiple agencies, often at odds with each other, oversee the process. All of these are leading to delays in commercializing both local and internationally developed technology.

Specifically, there are wide variations in the way countries respond to the Cartagena Protocol on Biosafety [3]. There are countries that are biotech crop producers but are non-parties to the protocol; non-biotech crop producers that are parties to the protocol; biotech crop producers that are parties to the protocol; and non-biotech crop producers that are not parties to the protocol. All of this leads to a highly confused environment that discourages commercialization and trade of biotech crops.

There are also differences in the types of regulatory processes that are put in place. Some countries have an individual product-based regulatory system, while others follow a process-based system. In one case, permission for the conduct of field trials requires the approval of the country's cabinet, which has more than 30 members!

The treatment of technology also varies in countries in Asia and around the world. Where multiple (stacked) traits are introduced into a new plant, some countries require this plant to be treated as a totally new plant even though all the introduced genes were already shown to be safe when they were introduced as single traits in previously approved plants. Other countries allow the data from previously introduced traits to be used in the regulatory process.

Some countries extend the scope of biosafety review and include non-safety related considerations that are totally beyond the bounds of a safety assessment. These countries include socio-economic considerations in the safety assessment. Some countries are including public discussions into the regulatory process which, though desirable in principle, often lead to delayed decision-making by the regulators and often serve as fora for minorities to generate considerable outrage about the technology.

The issue of labeling of biotech-derived foods is also an area of inconsistency both within the region and around the world. There is considerable variation in the percentages at which a product should be labeled as containing an ingredient derived from a genetically modified plant (0.95%–5%). Some countries require labeling even though no recombinant DNA is present in the food ingredient (e.g., canola oil).

One area of regulation causing considerable concern is the issue of how low-level presence (LLP) is being addressed around the world [3]. LLP is a result of the unintentional or inadvertent mixing of a grain commodity with small, insignificant quantities of another (transgenic) variety of grain (this means that an approved biotech crop may, through this unintentional mixing, contain another biotech crop that has not been approved).

There are two types of LLP approvals:

1. *Asynchronous approval*: Biotech events approved in the exporting country, but not currently approved in the importing country, become mixed in with grain approved in both exporting and importing countries.

2. *Asymmetric approval*: Biotech events approved in the exporting country, but for which approval is not being sought in the importing country, become mixed in with grain approved in both exporting and importing countries.

As with labeling, there are differences as to what percentage levels countries define an LLP and at which point the movement of grain from one country to another may be stopped. Clearly, if there is a possibility that a shipment of grain may be rejected due to a low-level presence of an unapproved event, this substantially increases the financial risk to the shipper. The LLP situation is likely to become more serious given that by 2015, there will be more than 120 genetically modified events worldwide (30 now) with rice likely to come on board, adding to maize, canola, soybean, and cotton. Further stacking of traits will exacerbate the issue and more players from both public and private sectors will become involved (44% of events will come from Asia). More biotech crops will be developed in Asia for local markets and so it is unlikely that they will be submitted for approval overseas.

Clearly there is considerable complexity and variability in the regulatory environment around biotech crops. Some of the challenges exist to the product developer in that they must ensure biosafety by satisfying the demands of the regulators. Other challenges exist much further down the commercialization pathway, indeed some long after the product has gone to market. But wherever this issue exists, it is a problem for the agricultural biotechnology sector. A confusing or poorly defined regulatory environment is a barrier to investment wherever it may be in the product development pathway. To ensure that the benefits of biotechnology accrue to all stakeholders, including the farmer and the people sitting around the dinner table, a consistent, science-based, transparent, and fair regulatory environment is essential.

COMMUNICATION AND THE CONSUMER

It is one thing to have a sound regulatory environment but there must also be a market for the biotech-derived product. The reality is that many consumers have become uneasy about this technology. As a result, the media and anti-technology activists have exacerbated this disquiet.

Typically, this uneasiness about biotech-derived crops and food has been addressed by filling the perceived information void in the minds of the public. There have been many campaigns to tell the consumer about the technology, what it is, what it does, how crops are produced, and what benefits will accrue from growing and eating these new foods.

This has not worked! If one examines the various initiatives through the years, this “deficit model” is based on the premise that if we teach the public about the technology, they will understand and accept it, and then all will be fine in the world. Sadly this approach is flawed. Awareness does not bring about acceptance. In fact, awareness seems to make things worse!

Research indicates that facts about risk appear to play little or no role in determining public perceptions and concerns about risks. In fact, this research suggests that facts actually only contribute about 5% towards influencing how risk is perceived by audiences. The 95% in any risk dialogue concerns the social, moral, ethical, and most importantly, the personal aspects of risk. This is not to say that the facts do not matter, but that the primary focus should be on addressing these more personal aspects of risk perception [4].

In short, risk is personal, and we must understand that people who are concerned about risk are completely different from those who understand the technology and any risks, albeit small, associated with it. Natural scientists or regulators of these sciences need to learn from communications studies about how people perceive risk. With this understanding, they must learn how to communicate better.

Understanding the concept of "outrage" will help inform why facts play so small a role in influencing how risk is perceived. Dr. Peter Sandman first described this concept of "outrage" in 1993 [5]. He sought to distinguish between the risks that worry experts as opposed to the risks that worry the public. He chose to describe the risks that concern experts as "hazard," with "outrage" representing citizens' preoccupations when looking at risk issues.

When risk assessors (experts) assess risk they equate risk as equaling hazard (the probability that something bad will happen) at any given time. The public, however, sees risk differently. They equate risk as equal to hazard plus outrage.

In essence:

For risk assessors: Risk = Hazard
For the public: Risk = Hazard + Outrage

Researchers in risk communication like Dr. Peter Sandman and Dr. Vincent Covello talk about outrage factors [6]. Sandman focuses on 12 principal components of outrage. Each of these factors has the capacity to alter perceptions in varying degrees of magnitude. The level of risk perception will determine the level of concern that changes attitudes and behavior. In general, people with low levels of outrage will see things as safe, whereas those with high outrage will see things as risky.

Outrage is a powerful and universal force, overriding hazard in all cultural perceptions of risk. It leads to audiences resisting data and hanging onto their risk perceptions unless outrage is addressed. What this means is that even if there is substantial and convincing data on a particular concern that should dispel someone's argument, their outrage may increase. This is seen time and time again when people simply deliver data about an issue that generates high outrage. Awareness does not bring about acceptance, further proving that the deficit model clearly does not work.

The risk perception factors may be narrowed down to four key ones:

1. Trust
2. Benefit
3. Fairness
4. Control

Trust is the most important outrage factor. If a person or organization is not seen to be trustworthy then risk perception and outrage increases. If a person sees no benefit to them, their outrage will increase. The response is the same if they see a situation as lacking fairness or where they feel they have no control. An understanding of how these factors affect risk perception is essential. From a communication standpoint, our own personal perceptions of risk should not influence how we interact with those who need to be reassured or those who are being asked to accept a particular risk. It is important that the outrage factors be addressed.

Communication about risk faces quite a few challenges. There are few (risky/controversial) entities (public and private) that have developed even a basic risk communication strategy. Risk communication techniques also need to be culturally sensitive. There is a great need for research on risk perception and how messages are crafted in different cultures, especially in Asia.

More on Trust

Trust is important in how the risk is perceived, but also in how the message itself is received (i.e., how the message deliverer is perceived). Covello did much work in this area in the 1990s and saw how trust factors change considerably in high-concern situations [7].

The left-hand pie chart in Figure 3 below shows the key factors that affect trust when we engage in a normal conversation in which normal levels of trust or concern exists. Competence/expertise is the most important factor that determines whether we will trust a person. Things change considerably, however, in situations of low trust/high concern. In these situations, what is most important is that caring and empathy are shown; only then may the person take on board a risk that they may face. Other important factors that increase their relevance are honesty, openness, dedication, and commitment. Competence/expertise decreases in importance when compared to a low concern situation. Covello sums this up as, "people need to know that you care, before they care about what you know [6]!"

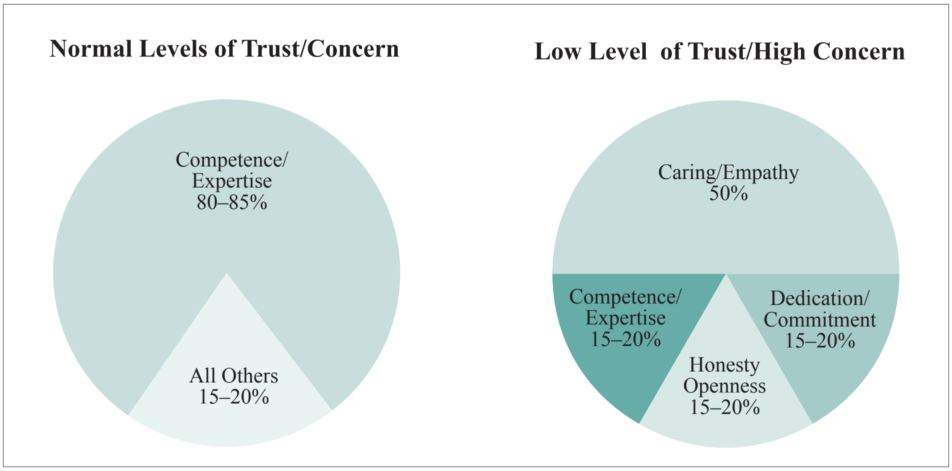

Figure 3. Trust factors in environmental risk communication.

Source: Peters, R.G., Covello, V.T., McCallum, D.B. [7].

Some comments may be made on trust and the biotech sector's handling of communication. All biotech stakeholders work in a trust ecosystem, as illustrated in Figure 4. If any one person, company, or organization in this ecosystem erodes the trust that is inherent in the system, then the system breaks down and all suffer. There are groups that erode this system all the time with their behavior and their communication strategies.

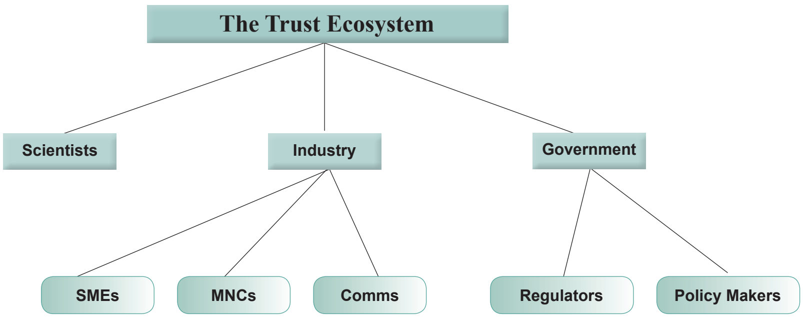

Figure 4. The trust ecosystem. Comms: Communicators; MNCs: Multinational companies; SMEs: Small and medium enterprises.

All in the biotechnology sector should appreciate the importance of risk factors and look beyond hazards to more empathetic and personal views of risk. Currently, risk communication relies on purely technical and hazard-based advocacy (public relations (PR)) tactics. Risk communication effectiveness is being harmed by perceptions of lack of control, personal benefits, and fairness. In other words, trust is compromised.

Many biotech businesses use the same people to assist in risk communication as they do for media, government relations, and advertising. In the view of this paper, this is a mistake. The existing public relations propaganda model is the antithesis of effective risk communication. Industry is seen to be hiding behind third parties (trust breach) and the public is often treated as uninformed and as irrational risks, requiring manipulation (showing lack of empathy, misalignment of interests, failure to engage).

Denial of Risk and Uncertainty

PR companies want to be positive in tone, never talk about risks, and deny any uncertainty. In any risk management framework looking to long-term business sustainability, transparency and trust, this position is completely untenable. As an industry, much will be gained by acknowledging risk.

Many of the techniques used in PR are outdated and actually erode trust. The PR strategies of yesterday need to be replaced by knowledge gained from modern social science research, research that gives an improved insight into the communication of risk.

CONCLUSIONS

The challenges faced in addressing the four dimensions of food security are daunting [1]. Plant biotechnology is just one technology that can help in meeting these challenges. For this to happen however, there needs to be a greater understanding of the commercialization process so that policies addressing biosafety, biosecurity, and trade issues are developed to allow the technology to deliver solutions. Failure to develop policies that are science-based, easy to implement, and transparent will cause reduced investment in agricultural biotechnology. It is also important that the science of communication be applied to the communication policies around the issue of agricultural biotechnology. The deficit model thinking in the communication process must be replaced by communication that takes into account outrage factors and the different values that exist in the public at large.

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RISK MANAGEMENT BY AGRICULTURAL/ BIOTECHNOLOGY-BASED SMES FOR SUSTAINABLE BIOTECHNOLOGY

RISKS IN THE AGRICULTURAL BIOTECHNOLOGY BUSINESS

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INTRODUCTION

Getting to market is quite simple, right? You have an idea. You make it or grow it. Sell it (lots of it), and then you buy a car (a VERY fast or VERY big car). No problem!

Er…. Not really. So many things impact on the commercialization process that they can often mean that a venture simply does not move from the discovery or idea phase to become a true innovation.

In agricultural biotechnology, a number of challenges are faced that may impact heavily on the ability to commercialize a product. These include:

- Dealing with the many patents held in agricultural biotechnology, the so-called patent "thicket"
- Expensive inputs at R&D level
- Long lead time from R&D to market
- Some areas of agricultural biotechnology (e.g., genetic modification) are very heavily regulated
- Some areas have high start-up or scale-up costs
- Financing for start-ups is limited
- Exit strategies for venture capitalists are limited
- Public perceptions of new technologies are often negative

RISKS

Risk is inherent in life and everything we do involves risk of some kind or another. A business owner chooses to take risks every day and often relies on experience and intuition to manage these risks. However, the more complex the business, the more important it is to both identify the risks that could prevent a business from realizing its potential, and to manage them in order to minimize adverse outcomes and maximize positive outcomes.

But what exactly is meant by risk? According to The Business Dictionary, risk is "the probability of loss inherent in an organization's operations and environment that may impair its ability to provide returns on investment." [1]

It may also be expressed as:

Risk = probability x harm, i.e., Risk = Hazard

Risk management is a broad-based framework for managing assets and relevant risks to those assets. When risk is managed effectively, the business owner is able to avoid losses, maximize potential of opportunities and, ultimately, achieve the company's goals. Small and medium-sized enterprise owners and managers face both <u>business</u> (application of technology, skills, pricing, packaging, distribution choices, competitive positioning, etc.) and <u>non-business</u> (compliance, legal, disasters, liability, product warranty, etc.) risks. Proactive management to anticipate any risk is absolutely essential for a company to achieve its goals.

Risk management is not a trivial task and must include identification, analysis, evaluation, and treatment of the risks. All of this is done within the context of the business itself and requires communication, consultation, and assessment. It is a continuous process and requires constant review and monitoring. Risk management needs to be integrated into all aspects of a company's business including human resources, contract management, financial management, business planning, occupational health and safety, client relationships, management compliance, quality assurance, etc. [2].

Risks can take various forms. They may be "hazard-based" risks that can be managed by safety and hazard management tools, techniques and methods; "opportunity-based" risks that are managed by assessing the upside or downside of the risk; and "uncertainty-based" risks that are managed by disaster and emergency planning and business continuity planning.

Three kinds of risk impacting agricultural biotechnology businesses are discussed in this paper: technical risk, financial risk, and marketing risk. Specifically, the following will be discussed:

- Freedom to operate: Intellectual Property (Technical Risk)
- Burn rates: use of funding (Financial Risk)
- Regulatory compliance (Marketing Risk)
- Communication with stakeholders (Marketing Risk)

Freedom to Operate (FTO)

FTO means the ability to proceed with research, development and/or commercial production, marketing, or use of a new product or process without infringing the intellectual property rights of another party [2].

Is FTO needed? In a word, "yes!" If an enterprise proceeds without FTO it risks wasting research dollars, very expensive lawsuits, and even destroying the business altogether. Ensuring that an enterprise has FTO is not easy and requires considerable skill. It is advisable that a patent agent or attorney be engaged. It will be worth the expenditure in the long term and this expenditure should be viewed as an investment to assure success.

The assessment of FTO goes beyond just patents. It will include:

- Possible pertinent patents, including their prosecution and/or litigation status
- Patent applications
- Third-party trade secrets, including whether they might have been misappropriated
- All third-party rights
- All research tools used to make the ag-biotech product or innovation
- Any agreement (for example, trade secret licenses, material transfer agreements, bag-tag [shrink-wrap], or technology-use licenses, etc.)

If the patent agent finds that there is FTO, then the enterprise may have something that is patentable. If not, it may be the end of the development of that particular idea, but there may still be other avenues that can be pursued.

Patents may not have been applied for in many countries; the claimed matter is protected only where there is a patent issued. If the enterprise is working in a country where the patent is not issued, there may be other options. In addition, patents may not have been granted in some of the countries where applications were made; laws about what is patentable vary between countries. Patents that were issued may not still be in force if the patentee has not made regular payments due.

It is worth remembering that patents are a limited monopoly and they do expire (check expiration dates!). Some countries have exemptions for certain actions around those patents. Patents that were issued in different countries may have broader or narrower claims, it is very important to look at these claims to see what they apply to. What an enterprise wants to apply the patent to may not be covered in the target country or territory.

But in a worst-case scenario where FTO does not exist, what can be done? It may be feasible to obtain a written authorization from the patent holder to use the patented technology for specified acts, in specified markets, and for a specified period of time. A cost-benefit analysis will need to be conducted to determine whether the costs associated with this licensing are justifiable. One option is to consider cross-licensing. In this instance, two companies exchange licenses in order to be able to use certain patents owned by the other party. This requires that the enterprise have its own patent portfolio that is of value to potential licensing partners. Another option to obtain FTO is to look at how the enterprise can "invent around." For this, changes to the product or process would have to be made to avoid infringing on the patent(s) owned by others. This will avoid payment of licensing fees but could delay commercialization.

Financial Risk – Money Matters

Agricultural biotechnology can be very costly and it takes a long time to get a product to market. There are many examples of companies that run out of money before they have executed their business plan.

"Burn rate" is a synonymous term for negative cash flow. This is a measure for how fast a company uses up its shareholders' capital [3]. If the shareholders' capital is exhausted, the company will either have to start making a profit, find additional funding, or close down. Early stage companies often focus too much on their product development and lose sight of burn rate and the final marketing of the product. Of course the company must be focused, but not to the exclusion of other possibilities that may reduce the burn rate.

Burn rate can be reduced by:

- Developing multiple revenue streams
- In-licensing, i.e., the enterprise uses another company's IP and pays a fee for that use
- Looking at secondary revenue streams from the enterprise's key product
- Looking at alternative applications of the enterprise's core assets (e.g., provide a service for a fee to generate cash flow)
- Outsourcing during product development, e.g., diagnostic kit manufacturing

Regulatory Compliance

Start-ups often often lack understanding of the regulatory environment prevailing in the sector that their new venture hopes to serve. Agriculture and agricultural biotechnology is rife with regulations that attempt to mitigate risks inherent in the technology or product.

The enterprise may need to satisfy or comply with:

- Food and feed safety requirements, e.g., fermentation products for animal feed, ingredients from genetically modified (GM) plants
- Environmental biosafety, e.g., bioremediation, biofertilizers, GM plants
- Biosecurity requirements, e.g., fermentation products
- Phytosanitary requirements, etc., for plants exported
- Multilateral environmental agreements, etc.

Communication – Stakeholder Engagement

This is a major area that is often ignored in start-ups. Just because the enterprise considers its product or technology to be fantastic, it does not logically follow that others will think the same! Time and resources need to be spent to manage communication, an often-neglected marketing risk. It cannot be left to just before the product enters the market, otherwise there is a risk for potential rejection of the product at the last stage of the commercialization process.

There is a great need to manage stakeholder perceptions in the process of managing risks. The enterprise needs to understand that there are both internal and external stakeholders. Internal stakeholders will include staff and subcontractors. External stakeholders include clients and customers, the community as a whole, the media, regulators, contractors, suppliers and insurers. Effective communication with all of these stakeholders is essential. The enterprise may need to use risk communication strategies.

Risk communication is a different kind of communication, which recognizes that where a perception of risk (real or imagined) exists, the mind works differently to times when regular communication is engaged. This change in the way the mind works in these "high risk perception scenarios" has major implications for entrepreneurs, and business and market development.

Risk communication is a science-based strategy for communicating effectively in different situations, examples bring: high concern (outrage); low trust; sensitive; or controversial situations [3]. It has broad applications for those engaged in entrepreneurial activities. It can assist in ensuring that regulators understand the product, help to gain customer desire for the product, and help in gaining investor support. An appreciation of risk communication will help a company to develop messages that are believable and understandable; convincing; clear and concise; and positive.

The key to communication success is anticipation, preparation, and practice (APP). APP is the central risk communication strategy. It requires an in-depth analysis of the risks faced; development of messages that will be delivered effectively by the right people for the job using the appropriate channels of communication; and carrying out considerable practice before execution of the strategy. Without this practice, there is considerable potential for mistakes that could make the position of the company or product untenable.

CONCLUDING REMARKS

This paper is a brief review of just some of the risks that may be faced in an agricultural biotech business. Any company or organization should have a risk management strategy in place. With an honest and thorough review of the risks that may be faced, a business will be able to move forward to achieve its goals. Too often we see in early stage companies an almost total focus on product development. Of course, this has to be the major focus but it is unwise to not look to the market that the product will ultimately serve.

The complexity of the intellectual property issues around agricultural biotechnology makes it essential that a clear review of the intellectual property position of the company is made. This is not trivial and resources must be allocated to the task. Getting an agricultural product to market is extremely costly, not just in terms of R&D, but also to meet regulatory requirements. Therefore, the hard-fought-for financial resources that may have come from angel investors, venture capital or private equity must be managed effectively [5].

Start-ups must also understand the market that they will serve and this must be looked at proactively. Consumer perceptions and likely acceptance of a product will need to be assessed and managed. If there are perceptions of risk in the target market then these must be addressed with proactive risk communication strategies.

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MANAGING INVESTMENT RISKS IN AGRICULTURAL TECHNOLOGIES

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INTRODUCTION

Over the course of the 21st century, the world has had to rely more and more on the agriculture sector to feed its burgeoning population. Furthermore, the Food and Agricultural Organization of the United Nations (FAO) expects the world's population to reach 9.1 billion by 2050. Along with increased demand for food, the need for more fiber, feed, and fuel expectedly follows. The food price crisis in 2007–08 plunged millions of people, who spend more than half of their income on food, into poverty. While no food shortage is currently being experienced, global food prices in 2011–12 again spiked to historic heights [1]. This brings into question the world's ability to cope with feeding its population, both now and in the coming decades.

The challenge of producing food in a sustainable manner is clearly huge, as estimates indicate that food production will have to rise 60% by 2050 to meet rising demand [2]. With high population growth, diminishing arable land, and growing water scarcity, farmers need to produce more food on less land [3]. Adding further to the concerns is climate change, of which agriculture is both cause and victim. Intensification of agricultural production must be accompanied by concerted action to reduce agricultural greenhouse gas emissions to avoid the further acceleration of climate change and avert threats to the long-term viability of global agriculture [4].

In developing countries, 80% of the necessary production increases will have to come from increased yields and cropping intensity, with only 20% from expansion of arable land. However, the global rate of growth in yields of the major cereal crops has been steadily declining, dropping from 3.2% per year in 1960 to 1.5% in 2000.

The challenge for technology is to reverse this decline, as a continuous linear increase in yields at a global level following the established pattern of the past five decades will not be possible or sufficient to meet food needs [2].

Reducing losses to crop production due to pests and environmental factors is crucial to maintaining and increasing productivity. CropLife International reported that between 26% and 40% of the world's potential crop production is lost annually due to the effects of weeds, pests, and diseases; however, crop losses could double without the use of crop protection products [3]. It is estimated that in Asia alone, the value of annual losses due to pest attack is about USD145.2 billion [3]. Continuous improvements in pest management and control, especially in those areas where agriculture is the most crucial economic activity, are essential if the world is to continue producing the necessary quantity and quality of agricultural output. Additionally, the world must maintain environmental diversity and limit the encroachment of agriculture onto important natural resources, such as land, soil, water, and biodiversity. More than 50 case studies have been documented and published on the benefits of crop protection products for various crops, demonstrating how these products are helping farmers contribute to a nutritious and abundant food supply, while improving their livelihoods, and looking after the environment [5].

In the case of biotech crops, Brookes and Barfoot reported that their global cultivation during 1996–2011 was responsible for the production of an additional 110 million metric tons (MMT) of soybeans, 195 MMT of maize, 15.8 MMT of cotton lint and 6.6 MMT of canola [6]. If biotech crops were not available to the 16.7 million farmers using the technology in 2011, maintaining the 2011 global production levels would have required an additional hectarage of 15.7 million for the said crops. The report also announced that biotech crop cultivation reduced the release of greenhouse gas emissions from agricultural practices thanks to both less fuel use and the additional sequestration of carbon from reduced tillage as compared to conventional varieties. This was equivalent to removing 23 billion kg of carbon dioxide from the atmosphere or to removing 10.2 million cars from the road for a year. Moreover, the cultivation of pest-resistant biotech crops reduced pesticide spraying by 474 million kg between 1996 and 2011. Indeed, biotechnology offers a viable complementary approach to conventional agriculture in addressing global food security challenges.

The plant science industry invests heavily in developing ever more innovative products in crop protection, plant biotechnology, and seed production to ensure that agricultural productivity is increased using fewer resources and in environmentally sustainable ways. Among the stakeholders in the plant science industry is CropLife Asia, a regional network of CropLife International, which promotes the benefits of crop protection products, seeds, plant biotechnology, their importance to sustainable agriculture and food production, and their responsible use through stewardship activities [7].

CropLife is a global federation representing the plant science industry consisting of innovation-driven companies such as BASF, Bayer CropScience, Dow Agrosciences, DuPont, FMC, Monsanto, Sumitomo, and Syngenta [8]. It supports a 15-member network of regional and national associations in 91 countries. CropLife Asia envisions a region where productive food and agricultural systems, enabled through innovative crop science and technologies, contribute to improving food security and the living standards of all in an economically, socially and environmentally sustainable manner.

CropLife Asia initially started as the Asia Pacific Crop Protection Association in 1996, before adopting its present name in 2002 [9]. At the time when the agriculture sector was experiencing an unprecedented adoption of transgenic crops, CropLife Asia widened its outreach efforts to include plant biotechnology from its original focus on crop protection technologies.

DRIVERS AND INVESTMENT IN AGRICULTURE

Overall the agriculture sector operates within a challenging myriad of factors that are interconnected and interdependent. These include macroeconomic factors, policy factors, market forces, global factors, technology, and climate factors.

Taking the food crisis of 2007–08 as an example, the price of rice spiked even though the major rice producers had good harvests in 2008. Stocks were not low and even had increased in 2007–08 [10]. Several factors contributed to this situation, such as the deceleration in rice yield growth rate; the reduction in the stock level; the growth in demand; reduced public investment in agricultural R&D and infrastructure; oil prices; exchange rate movements; export restrictions; and panic in the marketplace. Timmer underscored the importance of a supportive macroeconomic policy, one yielding low inflation, a reasonably stable exchange rate, positive real interest rates, and some monitoring of disruptive short-run capital flows to maintain price stability [11]. Another important component is extending good macroeconomic policy to the trade arena, where an open economy with low barriers to both internal and external trade should generate a level playing field for producers and consumers alike. Fan recommended that national governments should be encouraged to eliminate harmful trade restrictions, refrain from imposing new ones so as to reduce food price volatility, and enhance the efficiency of agricultural markets [12].

As one of the world's fastest growing regions, Asia is rebounding strongly from the recent global economic, financial, food price, and fuel price crises. The region's strong macroeconomic fundamentals, coupled with the emergency fiscal and monetary stimulus packages enacted by governments in the past, appear to be having their intended effect [13].

Timmer observed that no country has successfully transformed its agricultural sector without sharply improving the level of technology used in its farms [11]. Modern science has increasingly sourced these crop and livestock technologies. In PR China's case, Huang and Rozelle reported that since the completion of the household responsibility system in 1984, technological change has been the primary engine of agricultural growth [14].

Technological improvements have been by far, the largest contributor to crop production growth even during the early reform period. As an example, PR China's scientists developed hybrid rice in the late 1970s, and until the mid-1990s, PR China was the only country in the world to have commercialized this new technology.

For farmers to continue sustainable food production, they need to have broad access to appropriate innovations, particularly farm and crop technologies such as fertilizers, quality seed, crop protection products, machinery, and equipment combined with improved management strategies, including proven indigenous knowledge practices with emerging technologies, such as modern biotechnology. These in turn are affected by government policies influencing other key factors such as public and private investment in agriculture, practices in natural resource management, climate change resilience, credit, and financing access and farmer connectivity to the supply chain, among others.

PR China's experience demonstrates the importance of technological development, institutional change, market liberalization, public investment, and other policies conducive to improving agricultural productivity [14]. On the other hand, irrigation development has been one of the priority areas of agricultural development in India. In 2004–05, the gross irrigated area reached 79.5 million ha, and 41.6% of gross cropped area had irrigation facilities, made possible through huge investments from both government and farmers [15].

Fan noted a need to improve smallholders' productivity and market linkages [12]. To enhance the productivity of smallholder farmers, investments and institutional innovations should strengthen access to input and output markets, financial and extension services, and rural infrastructure, especially rural roads. Increasing smallholders' links with high-value supply chains and markets requires institutional arrangements such as group lending, producers' associations, and contract farming. Innovative insurance schemes can also help reduce the risks small farmers face from weather and price shocks.

Public and private institutions need to enhance and sustain their investments in R&D and extension of crop and farming technologies. The FAO reported that farmers have the biggest share in overall expenditures on agriculture, and as such, they must be central to any strategy aimed at increasing the quantity and effectiveness of agricultural investment [1].

On a positive note, Reardon et al. reported that positive transformations in the value chains of rice and potato in PR China, India, and Bangladesh were spurred by the governments' roles in enabling and providing incentives for the transformation [16]. The said governments invested in rural areas through (1) R&D, and distribution of seeds; (2) investments in irrigation canal, road, and railway systems; rural wholesale markets; power grids; and mobile phone communication grids; and (3) investment in extension.

Agricultural investment is essential for promoting agricultural growth, reducing poverty and hunger, and promoting environmental sustainability. Foreign direct investment (FDI) inflows to agriculture are those investments made in crop production, market gardening, and horticulture; livestock; mixed crops and livestock; agricultural and animal husbandry services (excluding veterinary activities); hunting, trapping, and game propagation; forestry and logging; and fishing, fish hatcheries, and fish farms [1].

For 2007 and 2008, comparable data on total FDI to all sectors are only available for 27 countries. For these countries, average annual inward FDI flows in those two years were estimated at USD922.4 billion, of which FDI into agriculture (including hunting, forestry, and fisheries) represented only 0.4%. A larger share, 5.6%, went to the food, beverages, and tobacco sectors, primarily in high-income countries [1]. But while FDI in agriculture may offer opportunities for developing countries in terms of employment and technology transfer, potentially negative social and environmental impacts of such investments (especially those that involve direct control of agricultural land) remain a reason for concern [1].

ASIAN FOOD SECURITY SITUATION

Food security is multi-dimensional, comprising food availability, economic and physical access, and stability [1]. Food production is vital to ensure that enough food is achieved through high yields, minimal losses from pests, diseases and environmental stress, and assured quality. A country that cannot produce enough food for its needs should be able to get them through imports, and have buffer stock as reserves to ensure a stable supply. These should be made available at affordable prices to its consumers (economic access), otherwise they could go hungry. The FAO, however, observed that the current world food and agricultural situation is characterized by continued high and volatile international food prices, as well as the persistence of hunger and malnutrition in many parts of the world [1]. A total of 868 million people in 2010–12, or 12.5% of all people in the world, were estimated to be chronically undernourished, and 563 million of them or 65% of the total were found in Asia [17]. Hence, improving the region's food security would clearly help improve global food security.

Southern and eastern Asia accounts for 29.1% of the world's undernourished [17]. A Gallup Poll confirmed the presence of the problem in selected countries in Southeast Asia by asking respondents whether there have been times when they had gone hungry in the past 12 months. Of the respondents, in Cambodia 34% responded "yes," compared with 33% in the Philippines and 15% for both Laos and Indonesia. Thailand, on the other hand, had 14%, while both Singapore and Malaysia had 3% who confirmed they had gone hungry.

Fan has warned that Asia's food security is under stress from a complex web of factors that include population growth, demographic changes, high and volatile food prices, natural resource constraints, and climate change [12]. And despite the strong economic growth observed in a number of Asian countries towards middle income status, these middle income countries are home to an overwhelming 86% of the region's undernourished [12].

Addressing the food-security challenge in Asia can continue to be boosted by biotechnology in the form of crop varieties derived from genetic engineering, and crop protection products that play vital roles in controlling pests and diseases that threaten food production and supply systems.

CROP BIOTECHNOLOGY FOR A SUSTAINABLE FUTURE

Global and Asian Adoption of Biotech Crops for Cultivation

Biotechnology crops are also known as biotech crops, genetically engineered crop varieties or genetically modified (GM) plants. Starting from the introduction of LL Canola in 1995, 36 other GM traits have been introduced into the market up to 2011. The area planted to biotech crops has had an impressive increase each year since they were first commercially grown on 1.7 million ha in 1996. In 2012, an estimated 170 million ha were planted to biotech crops worldwide, a 100-fold increase, and this is considered the most widespread and high-valued of all modern biotechnology applications in agriculture [18].

Grown in 28 countries, 20 of which are developing countries, an estimated 17.3 million farmers have adopted the planting of biotech crops. The value of biotech crop seeds has increased exponentially to USD14.84 billion in 2012 [18], although Phillips McDougall estimates that the 2012 global value has reached USD15.7 billion [19]. In Asia, five countries have commercial cultivation of biotech crops totalling 18.7 million ha [18]. India has the highest area (10.8 million ha), followed by PR China (4 million ha), Pakistan (2.8 million ha), the Philippines (0.8 million ha), and Myanmar (0.3 million ha). Obviously, significant opportunities exist to increase the adoption of biotech crops for food, feed, and fiber in Asia.

Investments in R&D of Agrochemicals, Seeds and Traits

Getting these innovative agrochemical products and biotech crops from the laboratory to farmers' fields requires tremendous R&D investment. The total R&D investment in 2011 of the top six plant science companies (BASF, Bayer CropScience, Dow AgroSciences, DuPont, Monsanto, and Syngenta) amounted to USD5.9 billion, equivalent to 10.4% of their aggregate sales. This amount consisted of USD3.4 billion for seeds and traits, and USD2.5 billion for agrochemicals R&D. Agrochemicals R&D reached USD2.943 billion in 2012 [19].

The R&D investment of the plant science industry is comparable to that of the top information technology companies. In 2011, Nokia invested USD7.3 billion (14.5% of total sales), Amazon used USD2.9 billion (6.1%), Hewlett-Packard USD3.3 billion (3%), Samsung USD9.1 billion (6%), and Google spent USD5.2 billion (13.6%). Apple and Microsoft allocated in 2012 USD3.4 billion (2%) and USD9.8 billion (13%), respectively [20].

Cost of Bringing a New Product to Market

A new agrochemical product requires an R&D investment of USD256 million before it can reach the market. Of this amount, USD85 million goes to research, USD146 million for development, and USD25 million for registration expenses, with the whole process taking an average of 9.8 years. From 2000–09, the average annual rate of introduction of agrochemical products is 10.3 per year, but has gone down to 6.5 per year in 2010–11 [21].

The 2011 research survey conducted by Phillips McDougall for CropLife International found that a new plant biotechnology trait requires an R&D investment of USD136 million and an average of 13.1 years from the discovery of the trait to first commercial sale [19]. The survey covered the six largest biotech crop developers: BASF, Bayer CropScience, Dow AgroSciences, DuPont/Pioneer Hi-Bred, Monsanto and Syngenta AG. For specific crops, it takes 11.7 years for canola, 12 years for maize, 12.7 years for cotton, and 16.3 years for soybean. The duration does not include the time to develop and obtain regulatory approval for stacked trait varieties which are the final products in most crops at present. In contrast, it took 10,000 years of artificial selection for man to develop the modern day maize from its wild-type predecessor, teosinte.

The time associated with the intense requirements for registration and regulatory affairs has increased from a mean of 44.5 months (3.7 years) for an event introduced before 2002, to the current (2011) estimated 65.5 months (5.5 years). Regulatory science, registration, and regulatory affairs account for the longest phase in product development, estimated at 36.7% of total time involved and costing about USD35.1 million.

In addition, the survey demonstrated that the trend in the number of units (candidate genes, constructs or genetic events) being subjected to screening in order to develop one trait is increasing from a mean of 1,638 for an event introduced before 2002, to 6,204 for an event introduced between 2008 and 2012.

Biotechnology R&D in Developing Countries

Developing countries are increasing their R&D efforts to develop their own biotech crops in partnership with companies from the plant science industry and researchers from the developed countries. This indicates the slight shift of such countries from just being end-markets to being developers, and these locally developed products may garner higher consumer acceptance as they are tailored to address local or regional concerns [22].

The International Food Policy Research Institute (IFPRI) summarized the progress so far of biotech crops in developing countries in Table 1. It should be noted that, except for the Philippines, the Southeast Asian countries in the matrix have not yet moved into commercially planting the biotech crops currently available in the market. Moreover, the list contains crop commodities considered as small-market crops. R&D on these crops were facilitated by public–private partnerships between public institutions in these countries and the plant science industry.

Table 1. Biotech crops being developed by countries in Asia

Country	Events	Transformation events grouped by country, crops andphenotypic category	Phenotypic category
PR China	30	Cabbage, chilli, cotton, maize, melon, papaya, potato, rice, soybean, tomato	AP, FR, IR, VR
India	21	Cabbage, cauliflower, chickpea, citrus, eggplant, mung bean, muskmelon, mustard/rapeseed, potato, rice, tomato	AP, FR, HT/AP, IR, IR/BR, OO, PQ, VR
Indonesia	14	Cacao, cassava, chilli pepper, coffee, groundnut, maize, mung bean, papaya, potato, rice, shallot, soybean, sugarcane, sweet potato	AF, FR, IR, PQ, VR
Malaysia	5	Oil palm, papaya, rice	HT, IR, VR
Pakistan	5	Cotton, maize	HT, IR, PQ, VR
Philippines	17	Maize, eggplant, rice, banana and plantain, mango, tomato	AP, OO, VR

(...continued)

Country	Events	Transformation events grouped by country, crops andphenotypic category	Phenotypic category
Thailand	7	Cotton, papaya, pepper, rice	AP, BR, IR, VR

Notes: An event is defined as the stable transformation – incorporation of foreign DNA into a living plant cell undertaken by a single institute among the participating countries, thereby providing a unique crop and trait combination. Phenotypes are defined as follows: AP, agronomic phenotype; BR, bacterial resistant; FR, fungal resistant; HT, herbicide tolerant; IR, insect resistant; OO, other quality traits; PQ, product quality; VR, virus resistant.

Technology Access Initiatives

CropLife Asia vigorously supports the continued global adoption of biotech crops. Its outreach and advocacy program includes knowledge sharing and dissemination, capacity building, continual dialogue, partnership and collaboration, and networking with its stakeholders such as governments, international trading partners, players in the value chain, and society as a whole.

As part of its initiatives, CropLife Asia developed the Pan-Asia Farmers Exchange Program in 2007 as a way to share expert and farmer knowledge on biotech crops with other farmers [9]. The program aims to enhance the knowledge of farmers and other biotechnology stakeholders about biotech crops, demonstrate how a regulatory framework for crop biotechnology works in practice, and promote regional knowledge-sharing and agriculture networks. Since its inception, the exchange program has expanded to include other stakeholder groups such as regulators, policy makers, researchers, and journalists, with around 40 people from across Asia participating annually. CropLife steadfastly commits to stewardship in plant biotechnology, the life-cycle approach for responsible management of a product. This cycle starts from gene discovery to plant development, seed production, seed marketing and distribution, crop production, and crop utilization up until product discontinuation. Guided by its product launch stewardship policy, the plant science industry brings products to market only after a thorough trade and market assessment, as well as compliance with extremely stringent regulations and safety assessments so that the released biotech products can be considered as safe as conventional products of plant breeding [3].

Stewardship is emphasised within the FAO's International Code of Conduct on the Distribution and Use of Pesticides, a voluntary code aimed at providing appropriate standards for the safe handling and responsible use of crop protection products, and is particularly aimed at those countries where appropriate regulation is either not in place or not enforced. Adherence to this Code is a requirement for membership with CropLife International.

The industry has also led the creation of globally recognized industry stewardship standards in the form of the Excellence Through Stewardship (ETS) [23]. Created in 2008 by 11 organizations involved in the research and/or production of biotechnology-derived plant products, ETS is a global industry-coordinated organization that promotes the universal adoption of stewardship programs and quality management systems for the full life cycle of biotechnology-derived plant products (Figure 1). ETS components include principles and management practices for responsible global management (handling, governance, oversight, etc.) of biotechnology-derived plant products, guides to understanding and implementing stewardship and quality management systems, and a global stewardship audit process [23].

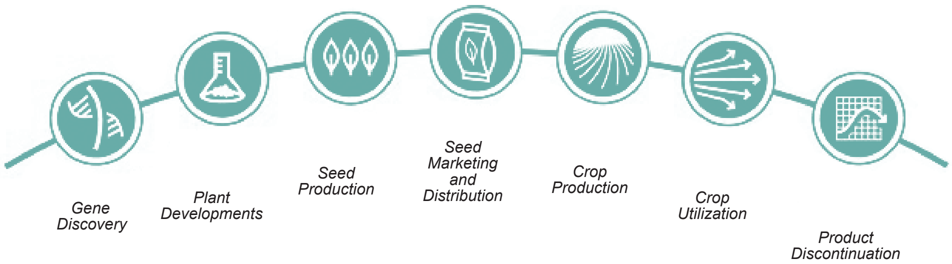

Figure 1. Full life-cycle of biotechnology-derived plant products.

CropLife International and its global network continue to support and collaborate with ETS. Nearly a dozen regional and national plant biotech associations in Africa, Asia, and Latin America are ETS associate members, locally promoting best stewardship practices and the ETS program to stakeholders, governments, and researchers and developers through workshops, training sessions, and other communications materials [3].

ENABLING ENVIRONMENTS FOR MANAGING INVESTMENT RISKS IN AGRICULTURAL TECHNOLOGIES

Developing agricultural technologies in the form of crop protection products, biotech crops, and traits requires considerable R&D investments. As such, it is imperative that enabling environments are present to effectively manage investment risks. This need is more pronounced in developing biotech crops. These favorable and enabling environments include science and evidence-based regulations, increased investment in research, intellectual property (IP) protection to attract investment, regulatory work-sharing, and harmonization wherever possible, and market creation and integration.

Science and Evidence-based Regulations

Sound regulatory environments that are predictable, transparent and guided by good science, gives the plant science industry the confidence to bring new products to market and ensure that farmers have access to a continued stream of innovative technologies. However, the biosafety regulations put in place to provide assurance on the safety of biotech crops and products have been observed to significantly increase the cost of biotech crop product development and commercialization [22]. As mentioned earlier, it has also increased the time associated with registration and regulatory affairs from a mean of 3.7 years in 2002 to 5.5 years in 2011. With the vast accumulated knowledge and experience with biotech crops since they were first cultivated in 1996, government regulations should now be able to reflect a robust and science-based approach.

The World Development Report 2008 [24] deemed it urgent to improve the capacity to evaluate the risks and regulate these technologies in ways that are cost-effective and inspire public confidence in them. The potential benefits of these technologies for the poor will be missed unless the international development community sharply increases its support to interested countries.

The political environment affects the type of policies that govern the activities of a country. Policy makers enunciate opinions and make decisions that have significant influence or impact on national policies, laws, and regulations as well as the overall direction of the country's agricultural development programs.

India's success with Bt cotton has seen millions of small farmers adopting the technology, but has not made it easier to remove a current roadblock with Bt eggplant (brinjal). Bt cotton was first commercialized in India in 2002 and has seen record high adoption rates since, wherein the area planted increased from 50,000 ha to 10.8 million ha in 2012 [18]. This enabled India to become the number one exporter of cotton globally and the second largest cotton producer in the world. In 2010, however, the environment minister, Mr. Jairam Ramesh, rejected the commercial planting of Bt eggplant in India, overturning a national regulatory panel's decision on its safety. According to Mr. Ramesh, "Although India's Genetic Engineering Approval Committee, under the Environment Ministry, cleared Bt eggplant for cultivation in October 2009, a call on Bt eggplant would have to be a 'political' decision." The decision was made after conducting a series of national consultations to help decide whether to allow the genetically modified version of the vegetable to be grown in India [25].

In contrast, Brazil increased its hectarage of biotech crops for the fourth consecutive year. More than any other country, it registered an impressive record increase of 6.3 million ha, up

21% from 2011, reaching 36.6 million ha, next only in hectarage to the USA [18]. Edilson Paiva, President of CTNBio, said "The creation and implementation of the biosafety legislation in Brazil has been successful regarding scientific participation, but it has been a real chaos when one considers the political and judicial participation in decisions." [26] These cases epitomize the political and cultural factors evident in expanding the applications of biotech crops and their benefits to various countries. Even with the existing complete regulatory frameworks, they can either be overturned or prove an excessively expensive and lengthy process to get a biotech crop approved for cultivation and use.

The complexities of the regulatory system make the path to commercialization tedious, costly, time-consuming, and burdensome, more so for crops produced and tested by public institutions, especially the small-market crops. As with the plant science industry, the biotech activities of public institutions need to hurdle the bars set by regulatory policies. Potrykus argued that the lessons learned from the Golden Rice project likely apply to all genetically modified organism (GMO) projects initiated by public institutions for the public good [27]. As such, there is a de facto monopoly in the use of the technology by a few financially powerful companies with industrial crops and projects that promise a return of not less than USD100 million. There is no room for humanitarian or small projects with orphan crops for public good.

Potrykus believes that the present situation on the registration and regulatory affairs governing biotech crops guarantees continued public hostility and plays into the hands of anti-GMO activists [27].

He aptly summed up the following important points:

- GMO regulation delays the use of GMO-based products for more than 10 years and carries a huge financial penalty

- Time and costs for the delivery of a GMO product to the market are so immense that no public institution or small or medium-sized private enterprise can afford the necessary investment

- Numerous public GMO projects, including many from developing country laboratories and with orphan crops, will not make it to the market place

- The damage to life and welfare is enormous. This affects the poor and not the rich Western societies responsible for the hostile anti-GMO attitude

- There is no scientific justification for the worldwide established GMO-specific regulatory system based on the concept of an extreme precautionary principle

- There is, to the contrary, a moral imperative to make GMO technology available for public good such as for nutrition security

Finally, Potrykus is convinced that a powerful technology for public good is wasted if the existing regulation is not revolutionized from ideology-based regulation of the technology to science-based regulation of the trait [27].

INCREASED INVESTMENT IN RESEARCH

Now more than ever, increased R&D investments are needed to meet the future demand for food. These investments should cover both conventional agriculture and biotech crop development. As discussed earlier, the plant science industry ranks among the top global sectors for the most investment in developing new products. This is despite the fact that registration and sale of a novel product are not certainties, making the investment of time and money a high-risk act. More government initiatives are needed in collaborative partnership with developed countries and large biotech companies. Almost all promising transgenics with traits important to poor people have been developed by the public sector, but the effort remains modest owing to significant underinvestment in agricultural R&D generally and in biotechnology in particular [24]. Huang and Rozelle reported that PR China ranks among the global leaders in agricultural biotechnology R&D [14]. In the late 1990s, it invested more in agricultural biotechnology research than all other developing countries combined, and its public spending on agricultural biotechnology was second only to the USA. Investment in government-sponsored R&D increased 5.5% annually between 1995 and 2000, and by more than 15% per year after 2000.

Need for IP Protection to Attract Investment

The protection of IP rights is at the heart of encouraging the plant science industry sector to continue investing in innovation and ensure technological advances. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is the most influential international IP rights agreement and all members of the World Trade Organisation are bound by the TRIPS provisions. Since entering into force, TRIPS has proven instrumental in enhancing the IP laws of a considerable number of countries by setting minimum standards for protecting various forms of IP.

Modern agricultural biotechnology is proprietary in nature, of which six types of IP rights are most important to the plant science industry: patents, trade secrets, protection of safety and efficacy data (protection from unauthorised commercial use of health and efficacy data submitted for regulatory purposes), plant variety rights, copyright, and trademarks [28]. Although patents, trade secrets, and the protection of safety and efficacy data are frequently applicable for the same product, it must be noted that they are provided for different aspects of that product. The rights are also applied at different time periods.

Protecting IP rights reduces the risks that technology providers experience when investing significant resources into the research, development, and authorization process required to develop new biotech-derived products [7]. More importantly for developing countries, IP protections support access to new technologies, enabling the plant science industry to partner with public sector institutions to donate new technologies to address local agricultural challenges. Such partnerships share resources and expertise to ensure that innovations reach and benefit farmers in developing regions, while helping to build agricultural knowledge at a local level. As a result, greater innovation can be put in the hands of the world's farmers, while companies maintain the protections needed to develop the next generation of technologies [29].

Regulatory Work-sharing and Harmonization Wherever Possible

Biotech crops are strictly regulated for food and environmental safety at the national level. As more and more biotech events and biotech crops are approved for use or cultivation in developed countries, regulatory approvals of new biotech crops across different countries have become less synchronized. Under such conditions, a large and increasing number of new biotech crops have received regulatory approval for use and cultivation in one or more countries, but is still unauthorized in others. Some countries have approved a large number of new biotech events but mostly for use as food or feed, or for further processing, and not for planting, while some countries have no biosafety regulatory framework at all [31].

Initiatives should be underway to harmonize the different regulatory processes for biotech crops in different countries. Whenever possible, joint safety reviews, mutual acceptance of safety assessment, and mutual acceptance of approval, at least those concerning the food/feed aspects, should be in place.

Creating and Integrating Markets

Low level presence (LLP) and asynchronous approval can potentially disrupt trade and cause economic problems, in particular for the feed and livestock sectors, especially in countries that have a "zero tolerance" policy or which reject imports that contain only traces of GMOs. LLP is the unintentional presence of a biotech crop that is approved in the country of cultivation, but not yet approved in the country of detection [7]. While LLP can be minimized, as a practical matter it cannot be eliminated entirely and is not unique to crops enhanced through biotechnology. A sustained advocacy should be in place promoting the adoption of predictable, transparent policies to address LLP and asynchronous approvals [7]. For actors in the global agricultural food chain, the main problem of LLP is the economic risk of rejections of shipments, part of which consists of destination risk, or the official testing for unauthorized material only in the port of destination [31]. When compliance with a zero-tolerance policy for LLP becomes impossible, exporters may only deal with "preferred buyers" who are known to create few problems. Otherwise, if the risk of rejection increases, so will the price of agricultural imports. Kalaitzandonakes et al. showed that smaller importing countries, whose trade can be more easily shifted across alternative suppliers, would likely experience 2%–8% price increases as a result of trade disruptions, whereas larger importers would experience price increases of 9%–20% [30].

CONCLUSION

This paper discussed how multinational companies see the application landscape of biotechnology in Asia and what hurdles need to be overcome. The plant science industry sector is steadfast in its commitment to develop innovative products to increase food production and advance sustainable agriculture.

The global demand for biotech crops, particularly in developing countries, is increasing with the available products and those in the pipelines becoming more complex. Subsequently, international biotech crop trade is increasing in tonnage, types of products, and number of markets.

The plant science industry believes that reducing the gap between approvals in both the country of origin and the importing country is critical to the entire value chain, and to importing countries. In addition, the process for approving these crops has become so costly and burdensome that it is stifling innovation. Industry can do its part by submitting dossiers simultaneously, but also needs importing countries to reduce delays. Without significant regulatory reform and adoption of science-based LLP policies, trade is likely to be disrupted with significant follow-on costs.

Civilization depends on agriculture's expanding ability to produce food efficiently, which has markedly accelerated, thanks to science and technology.

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RISK MANAGEMENT SYSTEMS IN BIOTECHNOLOGY SMES

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INTRODUCTION

The production of genetically modified (GM) crops is currently concentrated in just 28 countries worldwide, while more countries are experimenting with new traits. In this article, the regulation of genetically modified organisms (GMO) in the Republic of China (ROC), i.e., the safety assessment and labeling of GMOs, is discussed.

As the world population reached 6 billion at the end of the last century, several major advancements in crop improvement and breeding technologies, such as the Green Revolution, propelled a dramatic increase in food productivity. As of today, world food production has reached a level at which every person on this planet could have sufficient amounts of food [1, 2]. Even though a recent assessment indicates that there is a drastic deceleration in world demographic growth, the world population reached 6 billion at the turn of the new millennium, and the UN projects that it will reach 8.1 billion in 2030 [3].

Although there has been significant improvement in world food productivity, an alarming portion of the world's population is still on the verge of starvation. According to the latest FAO statistics [4], there are 815 million undernourished people in the world. Among them, a majority of 777 million live in developing countries. Rather than insufficient food production, today's food insecurity problem is actually closely related to issues of distribution; of unequal access and poverty [5].

Biotechnology is, by all counts, the most controversial agricultural technology innovation today, due in part to the prevailing uncertainty and concerns raised by many about its biosafety and environmental impacts. The rise of modern biotechnologies and life sciences is bringing many surprises with it, which may change the existing paradigms of society and revolutionize our daily lives. Against the many exciting and successful examples of biotechnology, it is important to realize that all technologies (bio and non-bio), are to serve the ultimate objective of improving the overall welfare of human beings and nature.

Agricultural biotechnology is no exception. It is the foundation of people's livelihood. The application of agricultural biotechnology should be prioritized based on providing stable food supplies and improving food quality.

By genetically improving drought-resistant crops, people will have better access to food through increased supply. Another example is the development of the GM rice "Golden Rice," to improve the nutrition of the poor in Africa and Asia.

However, many people believe that biotechnology will cause irreversible damage to the world. This opposition comes largely from environmental, consumer, and certain religious groups. To these groups, the risks posed by biotechnology outweigh the benefits. Insufficient information and lack of confidence in the public sector's ability to properly regulate biotechnology further complicates the situation [6].

APPLICATION OF BIOTECHNOLOGY TO AGRICULTURE

Many applications of biotechnology have been developed and extensively used around the world. Some biotechnologies have been practiced for millennia, including manipulating microorganisms in fermentation to make bread, beer, wine, beverage, soy sauce, cheese, and many other food products.

Accumulated knowledge about DNA stimulated the rapid development of genetic engineering technology. With genetic engineering, scientists are now able to manipulate various traits in different species. New technologies such as tissue culture, cell culture, embryo transfer, as well as various techniques of molecular manipulation in agriculture, have emerged. Transgenic technologies have been widely used in crop breeding and propagation of plants. Furthermore, modern biotechnology can now be applied to cure diseases, prolong lives, and even clone living organisms.

The controversy surrounding agricultural biotechnology differs from application to application. With the wide application of genetic engineering technologies in manipulating genetic traits, novel species known as GMOs and living modified organisms (LMO) began to emerge. The potential agricultural application of biotechnology also attracts the attention of various stakeholders. Nevertheless GM crops, in particular, are increasing in production at a very fast speed.

Current Status of Genetically Modified Organisms

There were virtually no GM crops in farmers' fields before the 1990s. The first GM crop, tomato, was sold in the market in 1994. Nowadays, the estimated global area of transgenic or GM crops for 2012 is already 170.3 million ha in 28 countries [7]. The global area of biotech crops for 1996–2012, by crop and by countries is shown in Figures 1 and 2.

The increase between 2013 and 2014 was 8.4 million ha and represents a 4% increase. Between 1996 and 2004, the total area of GM crops grew about 30 times. Production of GM crops is currently concentrated in some 28 countries while more countries are experimenting with new traits. In 2014, more than 90% of GM crops were produced in six countries: USA 40.8%, Brazil 21.5%, Argentina 14.0%, Canada 6.8%, India 6.3%, and PR China 2.3%. In terms of crops, GM soybean made up 47.4% of the global area of GM crops, with GM maize accounting for 32.3%, followed by GM cotton (14.2%), and GM canola (5.4%). GM soybean and cotton each accounted for 81% of the global total planted area of soybean and cotton [7].

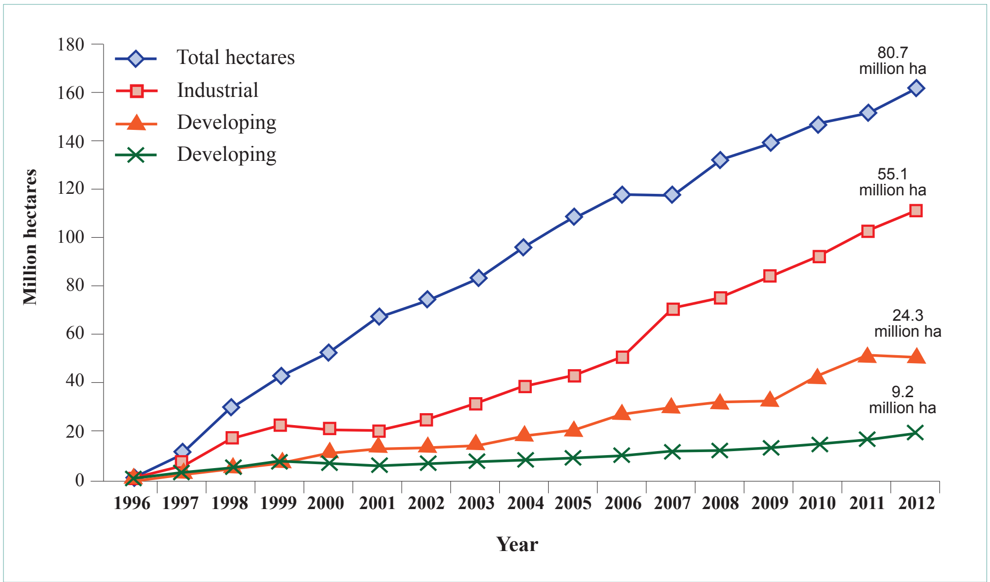

Figure 1. Global area of biotech crops (million hectares), 1996–2012.

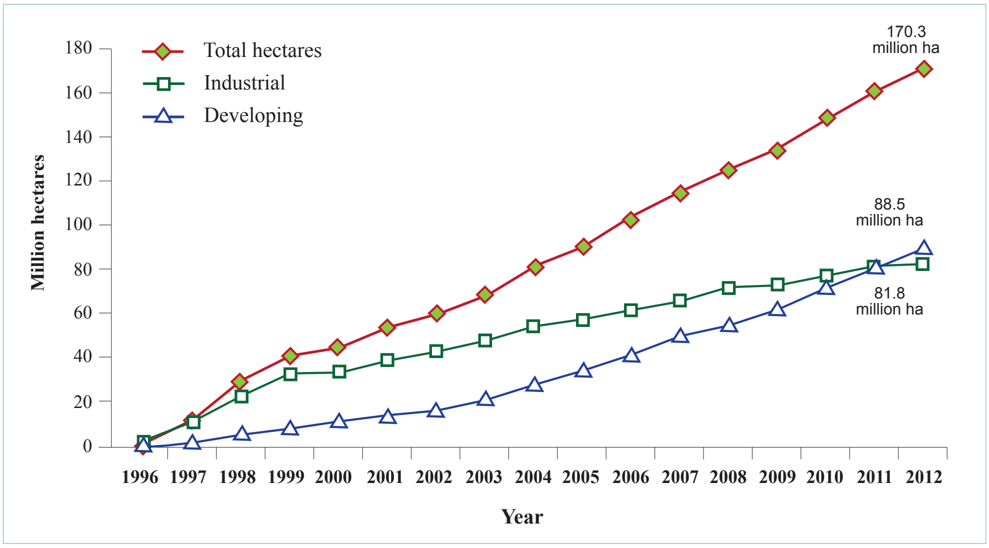

Figure 2. Global area of biotech crops in industrial and developing countries (million hectares), 1996–2012.

The Benefits of Biotechnology in Agriculture

Biotechnology's benefits have long been recognized by many, including Norman Borlaugh, who was the leader of the Green Revolution and 1970 Nobel Peace Prize laureate. Perhaps one of the most frequently cited benefits of biotechnology in agriculture is to increase crop productivity and hence reduce hunger. Others include improving nutritional intake, reducing pesticide and herbicide use in order to conserve the environment, and improving food quality [8–11]. Two major events further mark the beginning of the global biotechnology era: the conclusion of the Cartagena Protocol on Biosafety in 2000 and the World Food Summit held in Rome in June 2002 [12]. The Cartagena Protocol on Biosafety represents the first major consensus that turned all biotechnology issues from philosophical or ideological ones into those of a more technical nature. This transformation of conflicting arguments into workable topics was a great accomplishment.

According to Brookes & Barfoot, more than 50 million metric tons of additional soybeans, maize, cotton lint, and canola were produced in 2011 because of biotechnology, and from 1996 to 2011, USD98.2 billion in global farm income benefit was achieved by planting GMOs [13]. At the same time, the use of 473.7 million kg of pesticide was reduced in the same period, representing a decrease of 8.9%. Owing to the use of GMO technology, the reduction of carbon dioxide (CO2) emissions was equal to removing about 9.38 million cars from the road for a year in 2011 [13]. Endorsement by the 2002 World Food Summit further confirmed the international community's willingness to accept biotechnology application in agricultural development, particularly in pursuing food security. It was especially important that developing countries were accepting, as they will likely be the major users and beneficiaries of biotechnology in the future. In order to present a balanced view of the role of biotechnology in agriculture, biosafety and risks also need to be examined.

Biosafety and Risks of GM Products

Against this background, there are several issues surrounding the biosafety of biotechnology. The core is risk and uncertainty. The major difference between the “science-based approach” of exporting countries, and the “precautionary principle” of importing countries, comes down to differing views on risk and a resulting disagreement on how GM products should be managed. Environmental and ethical concerns arise from the perceived risk of GM products for future generations. Consumers demand that GM products be labeled on the food they buy in order to minimize the perceived risk of consuming these products. Therefore, it may be fair to say that the key to solving these current concerns and debates over biotechnology, is regulation.

As many GM products are used for food, the general public needs to be assured that proper regulation and risk assessments are being conducted. Therefore, biosafety issues related to GM products must be properly addressed to make sure that there is no potential hazard to human beings and the environment as a whole, before they are introduced to the market. The approaches to manage GM and biotechnology regulation have been debated on various occasions around the world. There seems to be an emerging consensus over a potential set of policy tools such as labeling, standards, and assessment procedures. In 2001, a conference in Bangkok co-hosted by the OECD, Food and Agriculture Organization of the United Nations (FAO), World Health Organization (WHO), United Nations Environment Programme (UNEP), Convention on Biological Diversity (CBD) Secretariat, and the British and Thai governments brought forth broad views for discussing several related issues including anticipating unintended effects, risk and benefit assessment methodologies, information validation, public sector support for research, and a coordinated multilateral process [14]. With continuous dialogue and concerted efforts like this, the public sector will play an increasingly important role in the development of biotechnology.

The environmental concerns arising from GM products are perhaps the most difficult to address, since their effects on the ecosystem are not easily observable in the short-term. Those who oppose agricultural biotechnology argue that GMO species may crossbreed with non-GMO species and become the dominant species, thus changing the ecosystem. There are also concerns over the possibility of detrimental effects on other species, soil flora and fauna, biodiversity loss, development of resistance mechanisms, and interruption of the ecosystem. In this regard, Serageldin and Persley proposed that the following areas must receive continuous emphasis: efficient regulations, clear guidelines for field tests and commercialization of LMOs, systematic capacity building, international support of an early warning system, and more scientific research on the impact to the environment and risks to biodiversity [15]. The impacts of GM products on the environment have been discussed on many occasions. It is clear that all stakeholders seem to agree that the development and promotion of agro-biotechnology and GM products must take environmental factors into full consideration during any risk assessment to avoid unpredictable environmental hazards.

Regulation of GMOs in ROC

In 2012, the Genetically Modified Food Advisory Committee (GMFAC) was commissioned by the Ministry of Health and Welfare (MHW) to evaluate GM food safety according to the guidelines set by the "Guidance of Safety Assessment for Genetically Modified Food" by conducting science-based risk assessments on a case-by-case basis [16]. GMFAC membership comprises experts from universities and research institutes in a variety of disciplines such as molecular biology, botany, agronomics, nutrition, toxicology, immunology, and food science. These experts are recruited through an open process that relies on public recommendations from professional sources. The GMO evaluation process of the Taiwan Food and Drug Administration (TFDA), MHW is shown in Figure 3. Biotech companies deliver the documents to the Division of Food Safety (DFS), and at the same time submit a sample of the GM food to the Division of Research and Analysis (DRA).

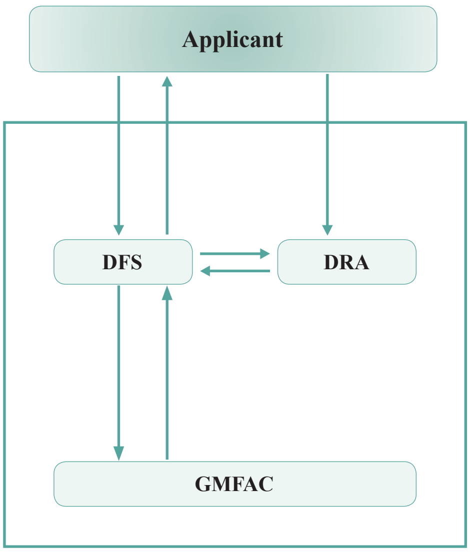

Figure 3. Taiwan Food and Drug Administration (TFDA) GMO evaluation process, DFS, Division of Food Safety; DRA, Division of Research and Analysis; GMFAC: GM Food Advisory Committee (in charge of the scientific evaluation of food safety); GMO, genetically modified organism; TFDA (in charge of the administration and development of the detection method).

Once receiving the necessary documentation and GMO sample, the DFS and DRA will conduct Phase 1 of the risk assessment. The data requirements for the safety assessments are as follows:

- Description of the r-DNA plant
- Description of the host plant and its use as food
- Description of the donor organism(s)
- Description of the genetic modification(s)
- Characterization of the genetic modification(s)
- Safety assessment: compositional analyses, initial assessment of possible toxicity/ allergenicity of newly expressed substances, evaluation of metabolites, and nutritional modification
- Antibiotic resistance marker genes
- Literature and references

If the Phase 1 assessment results indicate the presence of possible toxins and/or allergens in the GM foods derived from recombinant-DNA plants, it is necessary to carry out Phase 2 assessments. Phase 2 assessments include safety assessments of possible toxicity and allergenicity. If both Phase 1 and Phase 2 assessments indicate that the available data are inconclusive, properly designed animal studies are requested for these foods.

After the initial screening, the documents are transferred to the GMFAC. The committee meets every two months to evaluate the documents. The decision of the committee, as well as the analysis results of the DRA, is returned to the DFS. If everything is in order, then licenses are issued to the concerned biotech companies.

As of 30 June 2013, eight applications, including one for GM soybean and seven for GM maize, have been submitted to the TFDA. As of the same date, the GMFAC had approved 28 single-trait GM foods and 34 stacked-trait GM foods (Tables 1 and 2) [16].

Table 1. Current approvals of genetically modified foods in ROC – single trait

	Unique Identifier	Product	Name	Event	Applicant	Date of Approval	Date of Expiration
1	MON-Ø4Ø32-6	Soybean	Glyphosate-tolerant Roundup Ready soybean	40-3-2 (RRS)	Monsanto Far East Ltd., ROC Branch	22 July 2002	22 July 2017
2	MON-ØØ81Ø-6	Maize	Insect-resistant YieldGard corn (maize)	MON810	Monsanto Far East Ltd., ROC Branch	15 October 2002	15 October 2017

(...continued)

	Unique Identifier	Product	Name	Event	Applicant	Date of Approval	Date of Expiration
3	MON-ØØ6Ø3-6	Maize	Glyphosate-tolerant Roundup Ready corn	NK603	Monsanto Far East Ltd., ROC Branch	11 April 2003	11 April 2018
4	SYN-BTØ11-1	Maize	Insect-resistant & Glufosinate-tolerant corn	Bt11	Syngenta Taiwan Ltd.	2 June 2004	2 June 2013
5	SYN-EV176-9	Maize	Insect-resistant & Glufosinate-tolerant corn	Event176	Syngenta Taiwan Ltd.	2 June 2004	2 June 2013
6	ACS-ZMØØ3-2	Maize	Glufosinate-tolerant corn	T25	Bayer Taiwan Ltd.	16 August 2002	16 August 2017
7	DAS-Ø15Ø7-1	Maize	Insect-resistant & Glufosinate-tolerant corn	TC1507	DuPont Taiwan Ltd.	17 November 2003	17 November 2013
8	MON-ØØ863-5	Maize	Insect-resistant, YieldGard Rootworm corn	MON863	Monsanto Far East Ltd., ROC Branch	16 October 2003	16 October 2013
9	DAS-59122-7	Maize	Insect-resistant & Glufosinate-tolerant corn	59122	DuPont Taiwan Ltd.	21 December 2005	21 December 2015
10	MON-88Ø17-3	Maize	YieldGard Rootworm/ Roundup Ready corn	MON88017	Monsanto Far East Ltd., ROC Branch	20 March 2006	20 March 2016
11	ACS-GMØØ5-3	Soybean	Glufosinate-tolerant soybean	A2704-12	Bayer Taiwan Ltd.	1 May 2007	1 May 2017
12	SYN-IR6Ø4-5	Maize	Insect-resistant corn	MIR604	Syngenta Taiwan Ltd.	22 October 2007	22 October 2017
13	MON-89788-1	Soybean	Roundup Ready 2-Yield soybean	MON89788	Monsanto Far East Ltd., ROC Branch	28 December 2007	28 December 2017
14	MON-ØØØ21-9	Maize	Glyphosate-tolerant corn	GA21	Syngenta Taiwan Ltd.	23 July 2008	23 July 2013
15	MON-89Ø34-3	Maize	Insect-resistant corn	MON89034	Monsanto Far East Ltd., ROC Branch	25 July 2008	25 July 2013
16	SYN-IR162-4	Maize	Insect-resistant corn	MIR162	Syngenta Taiwan Ltd.	20 April 2009	20 April 2014
17	DP-356Ø43-5	Soybean	Glyphosate and Acetolactate Synthase (ALS)-Inhibiting herbicides- tolerant soybean	DP-356043-5	DuPont Taiwan Ltd.	11 May 2009	11 May 2014
18	DP-3Ø5423-1	Soybean	High-oleic soybean	DP-305423-1	DuPont Taiwan Ltd.	23 July 2010	23 July 2015
19	SYN-E3272-5	Maize	α-Amylase corn	Event 3272	Syngenta Taiwan Ltd.	26 July 2010	26 July 2015

(...continued)

	Unique Identifier	Product	Name	Event	Applicant	Date of Approval	Date of Expiration
20	ACS-GMØØ6-4	Soybean	Glufosinate-tolerant soybean	A5547-127	Bayer Taiwan Ltd.	31 August 2010	31 August 2015
21	MON-877Ø1-2	Soybean	Insect-protected soybean	MON87701	Monsanto Far East Ltd., ROC Branch	6 July 2011	6 July 2016
22	MON-8746Ø-4	Maize	Drought-tolerant corn	MON87460	Monsanto Far East Ltd., ROC Branch	3 November 2011	3 November 2016
23	DAS-4Ø278-9	Maize	DAS-40278-9 corn	DAS-40278-9	Dow AgroSciences Taiwan Ltd.	7 November 2011	7 November 2016
24	MON-87427-7	Maize	Maize with tissue-selective glyphosate tolerance facilitating the production of hybrid maize seed	MON87427	Monsanto Far East Ltd., ROC Branch	24 October 2012	24 October 2017
25	SYN-Ø53Ø7-1	Maize	Insect-resistant corn	Event 5307	Syngenta Taiwan Ltd.	17 December 2012	17 December 2017
26	MON-877Ø5-6	Soybean	Low-saturated fat and high-oleic-acid soybean	MON87705	Monsanto Far East Ltd., ROC Branch	8 February 2013	8 February 2018
27	MON-877Ø8-9	Soybean	Dicamba-tolerant soybean	MON87708	Monsanto Far East Ltd., ROC Branch	2 April 2013	2 April 2018
28	BPS-CV-127-9	Soybean	Imidazolinone herbicides-tolerant soybean	BPS-CV-127-9	BASF Taiwan Ltd.	16 April 2013	16 April 2018

Table 2. Current approvals of genetically modified foods in ROC – stacked trait

	Unique Identifier	Product	Name	Event	Applicant	Date of Approval	Date of Expiration
1	MON-89Ø34-3 x MON-88Ø17-3	Maize	YieldGard VT Triple PRO corn (maize)	MON89034 x MON88017	Monsanto Far East Ltd., ROC Branch	17 February 2009	17 February 2014
2	MON-89Ø34-3 x MON-ØØ6Ø3-6	Maize	YieldGard VT PRO x Roundup Ready corn 2	MON89034 x NK603	Monsanto Far East Ltd., ROC Branch	17 February 2009	17 February 2014
3	MON-88Ø17-3 x MON-ØØ81Ø-6	Maize	YieldGard VT Triple corn	MON88017 x MON810	Monsanto Far East Ltd., ROC Branch	17 February 2009	17 February 2014
4	MON-ØØ81Ø-6 x MON-ØØ6Ø3-6	Maize	YieldGard x Roundup Ready corn 2	MON810 x NK603	Monsanto Far East Ltd., ROC Branch	17 February 2009	17 February 2014
5	MON-ØØ863-5 x MON-ØØ81Ø-6 x MONØØ6Ø3-6	Maize	YieldGard Plus x Roundup Ready corn 2	MON863 x MON810 x NK603	Monsanto Far East Ltd., ROC Branch	4 March 2009	4 March 2014
6	MON-ØØ863-5 x MONØØ6Ø3-6	Maize	YieldGard RootwormRoundup Ready corn 2	MON863 x NK603	Monsanto Far East Ltd., ROC Branch	25 May 2009	25 May 2014

(...continued)

	Unique Identifier	Product	Name	Event	Applicant	Date of Approval	Date of Expiration
7	MON-ØØ863-5 x MON-ØØ81Ø-6	Maize	YieldGard Plus Corn	MON863 x MON810	Monsanto Far East Ltd., ROC Branch	10 July 2009	10 July 2014
8	SYN-BT011-1 x SYN-IR604-5	Maize	Bt11 x MIR604 maize	Bt11 x MIR604	Syngenta Taiwan Ltd.	3 August 2009	3 August 2014
9	SYN-BT011-1 x MON-ØØØ21-9	Maize	Bt11 x GA21 maize	Bt11 x GA21	Syngenta Taiwan Ltd.	3 August 2009	3 August 2014
10	SYN-IR604-5 x MON-ØØØ21-9	Maize	MIR604 x GA21 maize	MIR604 x GA21	Syngenta Taiwan Ltd.	3 August 2009	3 August 2014
11	SYN-BT011-1 x SYN-IR604-5 x MON-ØØØ21-9	Maize	Bt11 x MIR604 x GA21 maize	Bt11 x MIR604 x GA21	Syngenta Taiwan Ltd.	3 August 2009	3 August 2014
12	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7	Maize	MON89034 x TC1507 x MON88017 x DAS-59122-7 corn	MON89034 x TC1507 x MON88017 x DAS-59122-7	Monsanto Far East Ltd., ROC Branch	12 October 2009	12 October 2014
13	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7	Maize	MON89034 x TC1507 x MON88017 x DAS-59122-7 corn	MON89034 x TC1507 x MON88017 x DAS-59122-7	Dow AgroSciences Taiwan Ltd.	12 October 2009	12 October 2014
14	DAS-Ø15Ø7-1 x MON-ØØ603-6	Maize	TC1507 X AS-59122-7 maize	TC1507 x DAS-59122-7	DuPont Taiwan Ltd.	12 December 2009	12 December 2014
15	DAS-Ø15Ø7-1 x DAS-59122-7	Maize	TC1507 xNK603 maize	TC1507 x NK603	DuPont Taiwan Ltd.	15 December 2009	15 December 2014
16	DAS-59122-7 x DAS-Ø15Ø7-1 x MON-ØØ603-6	Maize	DAS-59122xTC1507 x NK603 maize	DAS-59122 x TC1507 x NK603	DuPont Taiwan Ltd.	15 December 2009	15 December 2014
17	DAS-59122-7 x MON-ØØ603-6	Maize	DAS-59122 x NK603 maize	DAS-59122 x NK603	DuPont Taiwan Ltd.	3 January 2011	3 January 2016
18	MON ØØ6Ø3-6 x ACS-ZMØØ3-2	Maize	NK603 x T25	NK603 x T25	Monsanto Far East Ltd., ROC Branch	30 May 2011	30 May 2016
19	DAS-Ø15Ø7-1 x DAS-59122-7 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6	Maize	TC1507 x DAS-59122-7 x MON810xNK603	TC1507 x DAS-59122-7 x MON810 x NK603	DuPont Taiwan Ltd.	30 May 2011	30 May 2016
20	DAS-Ø15Ø7-1 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6	Maize	TC1507 x MON810 x NK603	TC1507 x MON810 x NK603	DuPont Taiwan Ltd.	30 May 2011	30 May 2016
21	SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x MON- ØØØ21-9	Maize	Bt11xMIR162 x MIR604 X GA21	Bt11 x MIR162 x MIR604 x GA21	Syngenta Taiwan Ltd.	30 May 2011	30 May 2016
22	SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØØ21-9	Maize	Bt11 x MIR162xGA21	Bt11 x MIR162 x GA21	Syngenta Taiwan Ltd.	30 May 2011	30 May 2016

(...continued)

	Unique Identifier	Product	Name	Event	Applicant	Date of Approval	Date of Expiration
23	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6	Maize	MON89034 x TC1507xNK603	MON89034 x TC1507 x NK603	Dow AgroSciences Taiwan Ltd.; Monsanto Far East Ltd., ROC Branch	22 August 2011	22 August 2016
24	SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR6Ø4-5 x MON-ØØØ21-9	Maize	3272 x Bt11xMIR604 x GA21	3272 x Bt11 x MIR604 x GA21	Syngenta Taiwan Ltd.	5 September 2011	5 September 2016
25	SYN-BTØ11-1 x SYN-IR162-4 x DAS-Ø15Ø7-1 x MON-ØØØ21-9	Maize	Bt11 X MIR162 x TC1507xGA21	Bt11 x MIR162 x TC1507 x GA21	Syngenta Taiwan Ltd.	14 October 2011	14 October 2016
26	DAS-Ø15Ø7-1 x SYN-IR6Ø4-5 x MON-ØØ6Ø3-6	Maize	TC1507 x MIR604 x NK603 maize	TC1507 x MIR604 x NK603	DuPont Taiwan Ltd.	1 December 2011	1 December 2016
27	DP-3Ø5423-1 x MON-Ø4Ø32-6	Maize	DP-305423-1 x 40-3-2 soybean	DP-305423-1 x 40-3-2	DuPont Taiwan Ltd.	11 June 2012	11 June 2017
28	MON-8746Ø-4 x MON ØØ6Ø3-6	Maize	MON87460 x NK603 corn	MON87460 x NK603	Monsanto Far East Ltd., ROC Branch	27 July 2012	27 July 2017
29	MON-8746Ø-4 x MON-89Ø34-3 x MON-88Ø17-3	Maize	MON87460 x MON89034 XMON88017 corn	MON87460 x MON89034 x MON88017	Monsanto Far East Ltd., ROC Branch	27 July 2012	27 July 2017
30	MON-8746Ø-4 x MON-89Ø34-3 x MON ØØ6Ø3-6	Maize	MON87460 x MON89034 x NK603 corn	MON87460 x MON89034 x NK603	Monsanto Far East Ltd., ROC Branch	27 July 2012	27 July 2017
31	SYN-BTØ11-1 x DAS-59122-7 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9	Maize	Bt11 x DAS-59122-7 x MIR604 x TC1507 x GA21	Bt11 x DAS-59122-7 x MIR604 x TC1507 x GA21	Syngenta Taiwan Ltd.	27 July 2012	27 July 2017
32	DAS-Ø15Ø7-1 x DAS-59122-7 x MON-ØØ81Ø-6 xSYN-IR6Ø4-5 x MON-ØØ6Ø3-6	Maize	TC1507 x DAS-59122-7 x MON810 x MIR604 x NK603	TC1507 x DAS-59122-7 x MON810 x MIR604 x NK603	DuPont Taiwan Ltd.	27 July 2012	27 July 2017
33	MON-877Ø1-2 x MON-89788-1	Maize	MON87701 x MON89788 soybean	MON87701 x MON89788	Monsanto Far East Ltd., ROC Branch	24 September 2012	24 September 2017
34	DAS-Ø15Ø7-1 x MON-ØØ81Ø-6 x SYN-IR162-4 x MON-ØØ6Ø3-6	Maize	TC1507 x MON810 x MIR162 x NK603 corn	TC1507 x MON810 x MIR162 x NK603	DuPont Taiwan Ltd.	2 May 2013	2 May 2018

Source: Stein and Cerezo, 2009 [5].

GM Food Labeling in ROC

GM food labeling in ROC includes both voluntary and mandatory labeling. Voluntary labeling for non-GM foods started on 1 January 2001. Mandatory labeling of GM foods was implemented on 1 January 2003, and included GM soy and maize. The threshold for labeling is 5%.

Exemptions include:

- Highly refined products i.e. oil, soy sauce, starch etc
- Foods prepared at point of sale
- Packaged foods

The ROC has thus far smoothly carried out both risk assessment and management of GM foods.

CONCLUDING REMARKS

Modern biotechnology now can be applied to cure diseases, prolong lives, and even clone living organisms. The controversy surrounding agricultural biotechnology differs from application to application. Thanks to the wide application of genetic engineering technologies in manipulating genetic traits, novel species known as GMOs and living modified organisms (LMO) emerged. Biotechnology's agricultural applications have also attracted the attention of various stakeholders. GM crops in particular are increasing in production at very fast speeds. The ROC has thus far smoothly carried out both risk assessment and management of GM foods.

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5

BIOTECHNOLOGY AND GREEN PRODUCTIVITY IN AGRICULTURE

BIOTECHNOLOGY AND GREEN FOOD PRODUCTION

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INTRODUCTION

The increasing world population has put tremendous pressure on agricultural systems to produce sufficient food, feed, and fiber. As the world's population expands towards the projected 9 billion people by 2050, food production has to meet the increasing needs of the growing population on limited agricultural land area, dwindling water resources, and nutrient-deficient agricultural soils. Patterns of population growth and food consumption indicate that current agricultural production will have to at least double to meet food requirements in developing countries by 2050.

Improved productivity and food security are dependent on investment in agriculture. Regrettably, public investment levels in agricultural research have been very minimal, particularly in developing countries. Worldwide, investment in agricultural R&D makes up only 5% of total R&D spending on science, and although increasing in recent decades, it is still at a slower rate than in the 1970s during the Green Revolution [1]. An analysis of global crop yields covering the period 1990–2007 indicates slowdown in productivity and yield growth rates for major commodity crops such as maize, soybeans, wheat, and rice [2]. This slowdown is attributed to decreasing support for agricultural research, rather than to the inadequacy of ingredients for varietal improvement.

Current data indicates that many parts of the world already suffer from limited availability of and access to food, as well as significant numbers of hungry and undernourished people. While progress in reducing hunger had been achieved in the preceding decades, almost 870 million people, or 12.5% of the global population, were still chronically undernourished in 2010–12. The vast majority of hungry people live in developing countries, particularly in sub-Saharan Africa and Asia [3].

Climate change poses additional risks to food security and the agriculture sector. Severe droughts, floods, and extreme temperatures associated with climate change are already being experienced worldwide. Continued emissions of greenhouse gases will cause further changes in all components of the climate system. The negative effects of climate change are likely to seriously affect populations in developing countries, which are already vulnerable and food-insecure.

The importance and promise of genetic modification as a component of modern biotechnology applications should be given attention as a potential solution to these challenges. This paper aims to stimulate discussion on the importance of biotech crops to achieving sustainable agricultural productivity and food security objectives.

AGRICULTURAL PRODUCTION AND PRODUCTIVITY

Doubling agricultural production to meet the food demands of the growing population by 2050 would require at least 2.4% crop production growth rate per year. However, recent studies indicate that yields of major agricultural crops may no longer be increasing in many parts of the world. Yields are no longer improving on 24%–39% of the most important cropland areas [4].

A more recent assessment in patterns of yield growth for the four key global crops (maize, rice, wheat, and soybean) indicates significant production shortfall to meet projected demands in 2050 [5]. Yields in these major crops are increasing at non-compounding rates of 1.6% for maize, 1.0% for rice, 0.9% for wheat and 1.3% for soybean per year (Table 1), which are less than the 2.4% per year required to double global production by 2050. At these rates, global production would increase by 67% for maize, 42% for rice, 38% for wheat, and 55% for soybean, which are far below what is needed to meet projected demands in 2050. Together, these four crops produce about two-thirds of current global crop calories [3, 6].

Table 1. Global yield trends in major crops

	Maize	Rice	Wheat	Soybean
Mean yield change per year (%/year)	1.6%	1.0%	0.9%	1.3%
Mean yield change per year (kilograms/hectare/year)	84	40	27	31
Projected average yield in 2025 (metric tons/hectare)	6.5	4.9	3.4	3.0
Projected average yield in 2050 (metric tons/hectare)	8.6	5.9	4.1	3.8

(...continued)

	Maize	Rice	Wheat	Soybean
Projected production in 2025 (MMT/year at fixed cropland harvested area of 2008)	1,016	760	741	275
Projected production in 2050 (MMT/year at fixed cropland harvested area of 2008)	1,343	915	891	347
Projected production shortfall in 2025 (MMT/year)	100	160	157	43
Projected production shortfall in 2050 (MMT/year)	247	394	388	107
Yield in the year 2008 (metric tons/hectare)	5.2	4.4	3.1	2.4

Source: Ray et al., 2013 [4].
Note: MMT, million metric tons.

Projections show that feeding a world population of 9 billion in 2050 would require raising overall food production by 70% between now and 2050. Significant increases in the production of key commodities are needed, with developing countries having to almost double their production. For instance, annual cereal production would need to grow by almost one billion metric tons [7]. Demand for cereals, for both food and animal feed uses, is projected to reach about 3 billion metric tons by 2050, up from the present demand of nearly 2.1 billion metric tons [8]. However, PR China, India, and the USA (the top three wheat producers), were posting yield increases of only 1.7%, 1.1%, and 0.8% per year, respectively [5]. Crop yields are clearly not improving fast enough to keep up with the projected demands for 2050. Investments in agriculture should therefore be targeted towards sustainable increase in crop yields.

CLIMATE CHANGE AND AGRICULTURE

Even without climate change, agricultural systems in many developing countries are already under stress with the increasing demand for food, feed, and fiber. Agricultural land in many parts of the globe has already reached its production potential, while in others it is already exhibiting declines in production due to decreasing water supply, soil nutrient depletion, and the growing resiliency of pests and diseases to conventional control methods. Indeed, climate change can further exacerbate problems in agricultural production systems with changes in temperature and the hydrological cycle. Droughts, floods, and temperature changes are predicted to become more prevalent and more severe with climate change, threatening global food security.

Studies suggest that varying temperature levels can affect crop yields [9]. Crops are often more sensitive to temperature extremes than to averages, performing better at optimum temperatures, at which yields per hectare are greater than at either higher or lower temperatures [10]. Although a wide range of variability in yield changes across available studies was observed, declining yield patterns were evident in some crops with temperatures above the threshold. For instance, global analysis of crop yields from 1981 to 2002 showed a negative response for wheat, maize, and barley yields to rising temperatures [11]. A similar pattern was observed on maize and soybean productivity in the northern Corn Belt region of the United States from 1976 to 2006 during episodes of rising temperatures in the growing season [12]. Yield-depressing effects were found in tropical and subtropical regions for all crops, indicating a lower growing temperature threshold capacity in these areas [13].

Under drought conditions, yields declined more rapidly due to temperature increases and limited water availability. The immediate consequence of drought is a fall in crop production. Drought stress affects plant physiology and the ability to produce grains or fruits. For instance, maize yield is most sensitive to water stress during flowering and pollination, followed by kernel development (grain-filling), and then vegetative growth stages [14]. Severe drought episodes during the grain-filling stage in maize can reduce yield by 20%–30%. Water stress during grain filling reduces yield by 2.5%–5.8% with each day of stress [14]. Severe stress at flowering may lead to the complete abortion of ears and the plant becomes barren. Drought-affected ears typically have fewer kernels, which will be poorly filled if drought extends throughout the grain-filling stage [15]. A recent study shows that world drought is increasing as a consequence of climate change and global warming [16]. Dry periods lasting for years have occurred many times during the last millennium over North America, West Africa, and East Asia. The global area of arid lands has substantially expanded since the 1970s due to recent drying over Africa, southern Europe, East and South Asia, and eastern Australia [16].

Recent episodes of severe droughts have caused devastating effects. Between July 2011 and mid-2012, severe drought affected the entire East Africa region. The worst to hit in 60 years, the drought caused a severe food crisis across Somalia, Djibouti, Ethiopia, and Kenya. The drought that hit the USA in 2012 was the worst ever experienced in 50 years, affecting 26 of the 52 states, and covered at least 55% of the entire land area [17]. Maize and soybean losses due to drought were estimated at a high of 30% [18]. Climate change and global warming are predicted to increase the frequency and severity of drought due to increased evaporation.

Studies on the impact of climate change on agricultural production, consumption, prices, and trade, including the cost of investments to offset negative impacts on the health and well-being of children, provide some insights into potential effects of this weather anomaly on agriculture. The analysis utilized a global agricultural supply-and-demand projection model (IMPACT 2009) linked to a biophysical crop model (DSSAT) to quantify impacts on five important crops: Rice, wheat, maize, soybeans, and groundnuts [19]. Results of the analysis indicate that agriculture and human well-being will be negatively affected by climate change. Specifically, the predicted effects of climate change include the following:

- Yield declines for the most important crops in developing countries; South Asia will be seriously affected.

- Varying effects on irrigated yields across regions, but irrigated yields for all crops in South Asia will experience large declines.

- Additional price increases for most agricultural crops; Rice, wheat, maize and soybeans. Higher feed prices will result in higher meat prices. Consequently, there will be a slight reduction in meat consumption and a more substantial decline in cereals consumption.

- The world's calorie availability in 2050 will be lower, relative to 2000 levels throughout the developing world.

- By 2050, the decline in calorie availability will increase child malnutrition by 20%.

Climate change will no doubt impact the availability of agricultural resources and the sustainability of food security. Current and future increases in temperature are perhaps the most significant challenge that would require adaptive measures and long-term solutions. Farmers will need to adjust production systems and technologies in order to continue meeting global agricultural demands. To adapt to the inevitable effects of climate change, it is essential to apply the rapidly developing resources of plant genetics and biotechnology to the creation of heat-resistant and drought-resistant crops and cultivars [10].

ADOPTION OF BIOTECH CROPS

Global plantings of biotech crops have continued to expand dramatically over the years since its first commercial adoption in 1996 [17]. In 2012, a record 170.3 million ha of biotech crops were grown in 28 countries worldwide. Table 2 shows the list of countries, total area, and biotech crops planted. Almost three-fourths of the countries that commercially grow biotech crops were developing countries (20) and the rest were industrial countries (8). Developing countries also had a greater area planted, with 52% of the global biotech crop area compared with industrial countries at 48%.

In 2012, more than half of the global biotech crop area, equivalent to 88.5 million ha,was located in developing countries where growth continued to be strong. Higher adoption rates are expected to continue in the future with more countries expected to adopt biotech crops.

Table 2. Global area (million hectares) of biotech crops by country in 2012

Rank	Country	Area (million hectares)	Biotech crops
1	USA	69.5	Maize, soybean, cotton, canola, sugar beet, alfalfa, papaya, squash
2	Brazil	36.6	Soybean, maize, cotton
3	Argentina	23.9	Soybean, maize, cotton
4	Canada	11.6	Canola, maize, soybean, sugar beet
5	India	10.8	Cotton
6	PR China	4.0	Cotton, papaya, poplar, tomato, sweet pepper
7	Paraguay	3.4	Soybean, maize, cotton
8	South Africa	2.9	Maize, soybean, cotton
9	Pakistan	2.8	Cotton
10	Uruguay	1.4	Soybean, maize
11	Bolivia	1.0	Soybean
12	Philippines	0.8	Maize
13	Australia	0.7	Cotton, canola
14	Burkina Faso	0.3	Cotton
15	Myanmar	0.3	Cotton
16	Mexico	0.2	Cotton, soybean
17	Spain	0.1	Maize
18	Chile	<0.1	Maize, soybean, canola
19	Colombia	<0.1	Cotton
20	Honduras	<0.1	Maize
21	Sudan	<0.1	Cotton
22	Portugal	<0.1	Maize
23	Czech Republic	<0.1	Maize
24	Cuba	<0.1	Maize
25	Egypt	<0.1	Maize
26	Costa Rica	<0.1	Cotton, soybean
27	Romania	<0.1	Maize
28	Slovakia	<0.1	Maize
	Total	**170.3**	

Source: James, 2012 [17].

Notes: 18 biotech mega-countries growing 50,000 ha or more; hectarage rounded off to nearest hundred thousand.

In addition to the countries that planted biotech crops commercially in 2012, 31 countries have granted regulatory approvals for biotech crop import, food and feed use, and release into the environment. While not planting biotech crops commercially, countries such as Japan, Republic of Korea (ROK), New Zealand, the European Union, and Republic of China (ROC) have extensively approved the import of biotech crop products for food and feed use. Competent authorities have issued a total of 2,497 regulatory approvals involving 25 biotech crops and 319 biotech crop events. Of these approvals, 1,129 are for direct food use or processing, 813 are for direct feed use or processing, and 555 are for planting or release into the environment. A comprehensive inventory of biotech crop products that have received regulatory approvals for food import, feed use, and release into the environment (including planting in specific countries), can be found at the International Service for the Acquisition of Agri-biotech Applications website (http://www.isaaa.org/gmapprovaldatabase/default.asp).

In terms of biotech crops' share of production in the biotech mega-countries (i.e., those growing 50,000 ha or more) in 2012, four biotech crops (soybean, maize, cotton and canola) accounted for important shares of production, specifically in the following countries:

- *USA*: The leader of the six "founder biotech crop countries," having spear-headed the commercialization of biotech crops in 1996. It continues to be the lead biotech country with close to 68.3 million ha devoted to biotech maize, soybean, cotton, and canola. The rest were devoted to biotech sugar beet, alfalfa, papaya and squash.

- *Brazil, Argentina, and Paraguay*: Biotech soybean, maize and cotton dominate commercial production in these countries. Brazil posted the largest increase in biotech area in 2012 and placed second in the world while Argentina maintained its ranking as the world's third largest producer of biotech crops. Paraguay has been growing biotech soybean since 2004 and approved the commercial plantings of Bt cotton in 2011 and biotech maize in 2012. An estimated 3.4 million ha were planted to these biotech crops.

- *Canada*: Ranked fourth in the rankings of biotech mega-countries in 2012, posted 12% year-over-year growth for the four biotech crops of canola, maize, soybean, and sugar beet. Most of the growth was due to higher plantings of biotech canola at a 97.5% adoption rate.

- *India, PR China, and Pakistan*: Bt cotton, which confers resistance to important insect pests of cotton, is the dominant biotech crop grown in different parts of these countries. The majority of the Bt cotton hybrid adopters in India are small-scale, resource-poor farmers in major growing states with total area of about 10.8 million ha (or 93% of total area devoted to cotton). The adoption rate of Bt cotton in PR China was estimated at 80% with an estimated 4 million ha planted to Bt cotton. Pakistan approved commercial production of Bt cotton in 2010 covering 2.4 million ha, which expanded to 2.8 million ha, or 82% of total area devoted to cotton in 2012.

- *South Africa*: Hectarage occupied by biotech crops continued to increase in 2012, driven mainly by increased areas under maize and soybean.

Biotech soybeans continued to dominate biotech crop global adoption in 2012, followed by maize, cotton, and canola (Table 3). Biotech soybeans occupied the largest area globally with 80.7 million ha, accounting for almost 81% of the total global area for soybean production Biotech maize has the second highest area at 55.1 million ha, or 35% of the global hectarage of maize. Biotech cotton was planted in 24.3 million ha, or 81% of the global area of cotton. Biotech canola was grown in 9.2 million ha. Sizeable areas are also planted to biotech sugar beet at 500,000 ha and biotech alfalfa at 400,000 ha. Small areas of biotech papaya resistant to papaya ringspot virus were planted in Hawaii and PR China.

Table 3. Global area of biotech crops in 2012

Crop	Area (million hectares)	% of Global Biotech Crop Area	% of Global Crop Area
Soybean	80.7	47	81
Maize	55.1	32	35
Cotton	24.3	14	81
Canola	9.2	5	30
Sugar beet	0.5	>1	
Alfalfa	0.4	>1	
Papaya	>0.1	>1	
Others	>0.1	>1	
Total	**170.3**	**100**	

Source: James, 2012 [17].

Herbicide tolerance has consistently been the dominant trait deployed in soybean, maize, canola, cotton, sugar beet, and alfalfa (Table 4). More than 100 million ha were planted to herbicide-tolerant biotech crops, or 59% of the global biotech crop area in 2012. Commercial plantings of stacked traits with insect resistance and herbicide tolerance continue to expand as more stacked traits are deployed and become more prevalent in other countries. Stacked traits accounted for 26% of the global biotech crop area in 2012.

Table 4. Global area (million hectares) of biotech crops by trait and crop in 2012

Trait	Area (million hectares)	% of Global area	Biotech crop	Area (million hectares)	% of Global area
Herbicide tolerance	100.5	59	Herbicide-tolerant soybean	80.7	47
Stacked traits	43.7	26	Stacked-traits maize	39.9	23
Insect resistance (Bt)	26.1	15	Bt cotton	18.8	11
Virus resistance/ other	<1.0	<1	Herbicide-tolerant canola	9.2	5
			Herbicide-tolerant maize	7.8	5
			Bt maize	7.5	4
			Stacked-traits cotton	3.7	2
			Herbicide-tolerant cotton	1.8	1
			Herbicide-tolerant sugar beet	0.5	<1
			Herbicide-tolerant alfalfa	0.4	<1
			Others	<0.1	<1
Total	**170.3**			**170.3**	

Source: James, 2012 [17].

Recent estimates indicate that by 2015, there could be new additional biotech crops in the market. It is likely that there will be more than 120 different biotech crop events worldwide, which is about a four-fold increase in the number of events found in current commercially cultivated biotech crops [20]. New biotech events and traits for specific crops are anticipated to be commercialized in the near term (Figure 1). Focal areas of R&D for next generation biotech crops are presented in Table 5.

Table 5. Examples of focal areas of crop biotech R&D toward the next generation of improved crops

Focus	Detail	References
Nutritional enhancement and functional foods	Development and crop varieties (such as tomato, potato, cassava and banana) with enhanced levels of beta-carotene, protein or essential amino acids and minerals	[22–29]
Abiotic stress tolerance	Biotech approaches to address salt, drought, and extreme-temperature tolerance with emphasis on characterizing and testing genes involved in the biosynthesis of osmoprotectants, osmolytes, and temperature-sensitive transcription factors	[30–32]
Increased digestibility	Development of cereal and oilseed crop varieties with low phytic acid that can help improve human and animal nutrition	[33–37]
Increased volume of biomass for biofuel	Applications of biotech on crops not usually utilized or grown as source of food such as poplar, switchgrass, *Miscanthus*, and big bluestern grass	[38–40]
Better fiber quality	Development of naturally colored cottons or those with improved fiber characteristics	[41–44]
Flower color and scent modification	Development of flower color variants or ornamental varieties with novel traits such as more fragrant flowers	[45–47]
Production of industrial and pharmaceutical compounds	Research on use of biotech plants as a production platform for novel proteins used in industry and medicine	[39] [48–51]
Less allergenicity	Silenced expression of genes in carrot, tomato, and peanut to reduce allergenicity in sensitive individuals	[52–54]
Enhanced food flavor and aroma	Identification and genetic engineering of genes involved in aroma biosynthesis in apple and tomato	[55–56]
Phytoremediation	Looking into biotech crops for potential in cleaning up contaminated soils and water systems; development of biotech plants which can detoxify xenobiotic compounds in soils	[57–59]
Healthier oils	Development of biotech crops that can produce oils with higher amounts of omega-3 and omega-6 polyunsaturated fatty acids	[60–63]

Source: Compiled by Cruz and Hautea, 2011 [20].

The Asian region is predicted to contribute to a substantial increase in biotech crop hectarage with biotech rice [21]. PR China has already issued biosafety certificates for biotech rice resistant to insect borers. Based on a study conducted by the Center for Chinese Agricultural Policy (CCAP), this insect-resistant (Bt) biotech rice can increase yields up to 8% and reduce insecticide application by nearly 80% [17]. Golden Rice, a biotech rice that contains enhanced levels of beta-carotene, is undergoing multiple location field trials in the Philippines and is expected for commercial release in 2015.

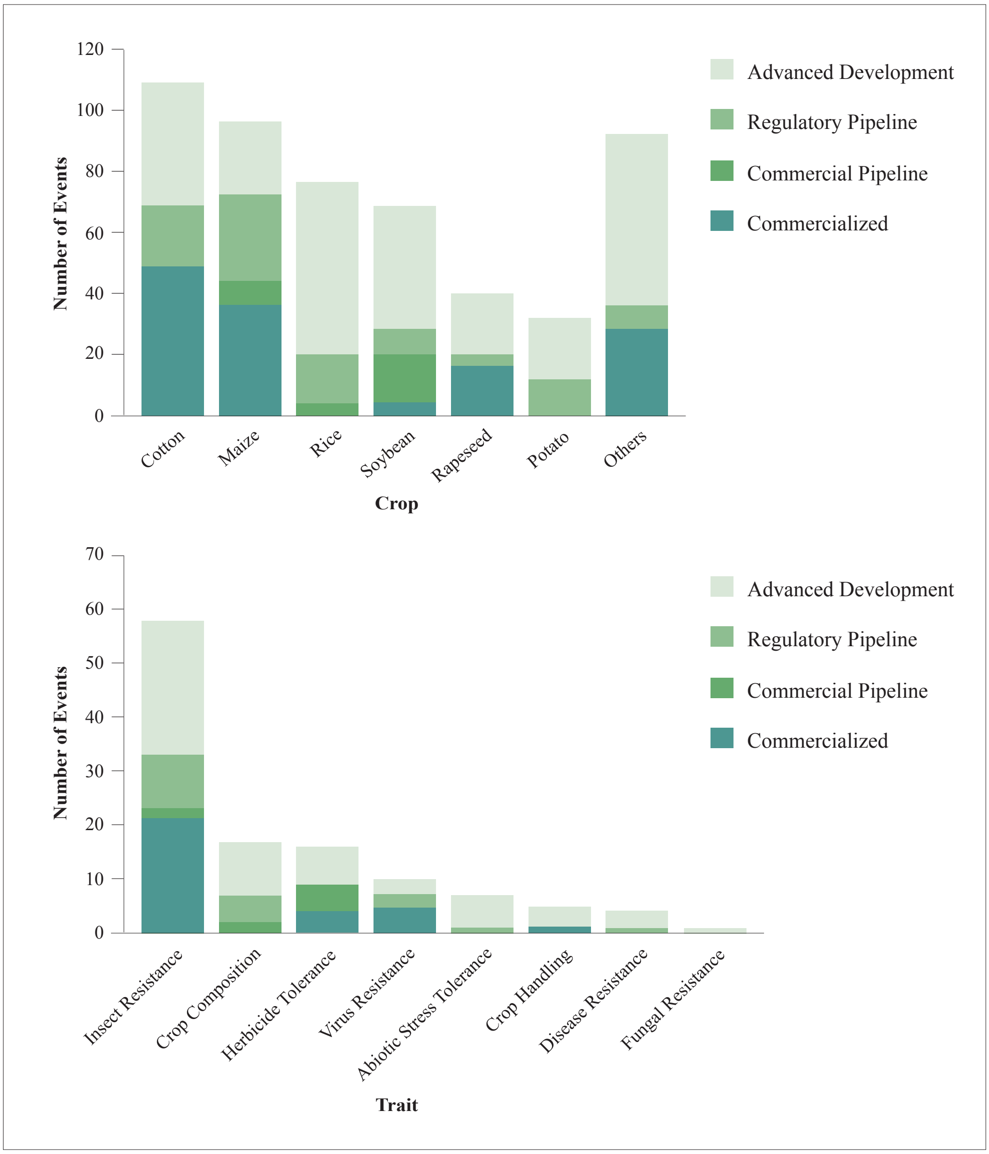

Figure 1. Overview of commercial pipeline of biotech crops in 2015, by crop and trait.

Source: Cruz and Hautea, 2011 [20].

DOCUMENTED BENEFITS OF BIOTECH CROPS

There is a large and growing literature on the adoption and impacts of biotech crops. Many of the studies conducted measure the socio-economic and environmental benefits of the adoption of first-generation biotech crops. The magnitude of documented benefits varies by country, crop, and time. Documented benefits associated with the adoption of biotech crops include reduced crop losses from pests and diseases, reduced expenditures on farm inputs such as pesticides and herbicides, increased farm income, and improvement in environmental quality.

A recent study compiled and summarized the research findings from studies into the global socio-economic and environmental impacts of biotech crops in the 16 years (1996–2011) since they were commercially planted [64]. The study focused on economic impacts on yield, key costs of production, direct farm income, and effects and impacts on the production base of the four main crops of soybean, maize, cotton, and canola. Environmental impacts were quantified in terms of insecticide and herbicide use, as measured by carbon sequestration and the Environmental Impact Quotient (EIQ). EIQ measures the impact on farm workers, consumers, and ecology by providing an aggregate measure of environmental impacts associated with pesticide use. It measures key toxicity and environmental exposure data as related to different pesticides. The EIQ value is multiplied by the amount of pesticide active ingredient (a.i.) used per hectare to produce a field EIQ value, The analysis covered not only the impacts for the latest available year (2011) but also the cumulative impact over the 16-year period. A summary of the quantified impacts is presented in Table 6.

Biotech crops have added significant volumes to the global production of maize, cotton, canola, and soybeans over 16 years of commercialization. Over this period, the added production amounts due to biotechnology have been substantial. Biotechnology has added 195 million metric tons (MMT) to global maize production, 110.2 MMT of biotech soybeans, 15.85 MMT of biotech cotton, and 6.55 MMT of biotech canola. Without these biotech crops, agriculture would have needed to either use more land to cultivate these crops or increase production by other means.

Farmers worldwide have gained more than USD98 billion in farm income during the 16-year period, of which 48% was due to yield gains from lower pest pressure, with the balance from reductions in the cost of production. A little over 50% of these gains went to farmers in developing countries. Net economic benefits at the farm level in 2011 amounted to USD19.8 billion, of which 51.2% were earned by farmers in developing countries. Substantial farm income gains have been from the use of herbicide-tolerant soybeans and insect-resistant cotton and maize. The experiences of small farmers in developing countries planting biotech crops clearly show that they can also benefit from the technology. The most consistent observation of farmers in growing biotech crops is its profitability owing to yield gains and reduced production costs. Estimates of the global average yield gains show yield advantages of 65% for biotech cotton, 45% for maize, 25% for canola and 12% for soybeans [65].

Biotech crop adoption has contributed to reductions in the volume of herbicides and insecticides used by about 474 million kg of active ingredient, a reduction of 18.3% in environmental impact as measured by the indicator EIQ. The largest reduction in volume of a.i. used has been with the adoption of insect-resistant maize and cotton. Important environmental gains have also been realized with herbicide-resistant soybeans and canola. Herbicide use decreased by 12.5 million kg with biotech soybean and 14.8 million kg with biotech canola.

Table 6. Quantified economic and environmental impacts of biotech crops

Crop Trait	1996–2011	2011
Additional crop production (MMT)		
Maize	195.00	34.54
Soybeans	110.20	12.74
Cotton	15.85	2.48
Canola	6.55	0.44
Sugar beet	0.45	0.13
Farm income benefits (million USD)		
HT soybeans	32,211.9	3,879.2
HT maize	4,212.2	1,540.2
HT cotton	1,224.1	166.9
HT canola	3,131.4	433.2
IR maize	25,762.0	7,104.9
IR cotton	31,263.2	6,559.6
Others	412.0	83.3
Total	**98,216.8**	**19,767.3**

(...continued)

Environmental impact from changes in insecticide and herbicide use (1996–2011)				
Trait	**Change in volume of active ingredient used (million kilograms)**	**Change in field EIQ impact (in terms of million field EIQ/hectares)**	**Change in active ingredient use on biotech crops (%)**	**Change in environmental impact (%)**
HT soybeans	–12.5	–6,444.2	–0.6	–15.5
HT maize	–193.1	–5,168.0	–10.1	–12.5
HT canola	–14.8	–501.5	–17.3	–27.1
HT cotton	–15.5	–420.9	–6.1	–8.9
IR maize	–50.0	–1,884.2	–45.2	–41.7
IR cotton	–188.7	–8,498.0	–24.8	–27.3
HT sugar beet	+0.87	–3.3	+23.9	–4.1
Total	**–473.73**	**–22,920.1**	**–8.9**	**–18.3**

Source: Brookes and Barfoot, 2013 [64].
Notes: EIQ, Environmental Impact Quotient; HT, herbicide tolerant; IR, insect resistant; MMT, million metric tons; USD, United States dollars.

The contribution of biotech crops to reducing greenhouse gases and mitigating climate change impacts occurs in two ways: first, permanent savings in carbon dioxide (CO_2) emissions through reduced use of fossil fuels due to fewer applications of pesticides and herbicides and soil cultivation; and second, soil carbon sequestration associated with conservation tillage in herbicide-tolerant biotech crop fields. Over the period 1996–2011, the cumulative reduction in fuel use was estimated at 5,472 million L, equivalent to permanent reduction of 14,610 million kg of CO_2. Additional soil carbon sequestration due to reduced/no tillage farming system resulted in carbon saving of 170,961 million kg.

CONCLUDING REMARKS

Among the many agricultural technologies that had been deployed to address the numerous challenges related to food, feed, and fiber production, biotech crops have become the fastest-adopted crop technology in recent history. From an estimated area of 1.7 million ha planted to biotech crops in 1996, they now cover an estimated record 170.3 million ha grown in 28 countries worldwide in 2012. Increased and rapid adoption is becoming more evident in developing countries, which accounted for 58% of global biotech crops hectarage in 2012. Small-scale farmers in developing countries are the prime movers of biotech crops with an estimated 17.3 million adopting the technology. The majority of these farmers are from PR China, India, and the Philippines.

During the last 16 years (1996–2011) of adoption, biotech crops have delivered economic and environmental gains through cost-effective and environmentally friendly farming practices. Economic gains were evident in terms of yield improvements, resulting in the increased world production levels of major crops, reduction in production costs, and profitability to farmers. Changes in farming systems with the use of the technology allowed reductions in agriculture's environmental footprint, notably lower levels of greenhouse gas emissions and soil carbon sequestration. Clearly, biotech crops have the potential to contribute to sustainability objectives in the following areas:

- *Food, feed, and fiber security and self-sufficiency by increasing productivity and economic benefits at the farm level*: Economic gains at the farm level were generated globally by biotech crops through yield increases and reduced production costs.

- *Biodiversity conservation*: Biotech crops are a land-saving technology, as a result of their higher productivity. They can help preclude conversion of forest lands for agricultural purposes, protect biodiversity in forests, and in other in situ biodiversity sanctuaries.

- *Alleviation of poverty and hunger*: Biotech crops have already made significant contributions to improving farmers' incomes, particularly in developing countries.

- *Improvement in environmental quality*: Biotech crops can reduce the environmental footprint of agriculture with significant reductions in pesticide use, saving fossil fuels, reducing CO_2 emissions through no/less ploughing, and conserving soil and moisture with no tillage regime.

- *Mitigation of climate change impacts*: Biotech crops contribute to reduced greenhouse gases and mitigate climate change impacts in two ways: first, permanent savings in CO_2 emissions through reduced use of fossil fuels associated with less use of pesticides and herbicides; and second, soil carbon sequestration associated with no-till and reduced till farming system. Next-generation biotech crops well-adapted to changing climatic conditions are also being developed and may be deployed in the near term.

Continuous communication of biotech crop benefits to consumers in terms of economic and environmental impacts will influence adoption and further acceptance of the technology as a complement to existing agricultural production systems.

Next-generation biotech crops in the pipeline indicate a sustained interest and investment in R&D of biotech crops with superior traits, improved properties and quality traits that can further enhance agricultural productivity and address food security objectives. R&D efforts escalating in developing countries indicate a shift of such countries from being mere end-markets to being developers. Clearly, locally developed products may garner higher consumer acceptance as they are tailored to specifically address local or regional concerns.

The issue of food security, particularly in developing countries, remains a formidable challenge, more so with the looming negative effects of climate change to agricultural production systems and pressure from the growing population. As a result, farmers will need to adjust production systems and technologies in order to continue meeting global food requirements. The rapidly developing resources of plant genetics and biotechnology can be further harnessed to address this issue. Clearly, farmer experiences with first-generation biotech crops already present a body of evidence of the greater potential of the technology in attaining sustainable agricultural production.

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THE USE OF BIOTECHNOLOGY IN WASTE MANAGEMENT: BIOGAS

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INTRODUCTION

The Thirteenth Conference of the Parties to the United Nations Framework Convention on Climate Change and the Third Meeting of the Parties to the Kyoto Protocol (COP13/MOP3) recently confirmed the Bali Roadmap, which requests that developing countries adopt measurable, reportable and verifiable greenhouse gas (GHG) reduction measures. Although the Republic of China (ROC) is neither a member of the UN, or a party to the Kyoto Protocol, it is a primary supplier of global electronics components and a major exporter of industrial goods. Failure to set relevant reduction strategies will inevitably intensify the impact of regulations of other countries on ROC and may lead to trade controls in the future. The tentative plan to use food waste and pig farm sludge for anaerobic digestion into biomethane has tremendous implications for ROC's endeavor to actively promote a green energy policy. The Environmental Protection Administration, ROC (TEPA), ultimately intends to use this energy source to power ROC's environmental industries. The Pingtung County government stresses that the county has ample sunlight, accounting for its diverse array of agricultural products and leftover organic materials from butchering, fruit and vegetable processing, as well as other food processing operations. The nearly 40,000 metric tons of organic waste produced annually include livestock effluent and food waste, all of which can provide a renewable energy source.

CURRENT GREEN POLICIES IN ROC

Green Living Information Platform

To raise public awareness of green consumerism and green lifestyles, TEPA has streamlined four websites related to Green Mark eco-labeling information into one. This website provides a single window through which citizens, enterprises, and governmental agencies can acquire information on green consumption, the Green Mark, and related products [1].

By fully exploiting the internet to raise public awareness of green consumption and green lifestyles, TEPA has reintegrated Green Mark websites and added new functions to create the Green Living information website (http://greenliving.epa.gov.tw/). This new website was officially launched on 1 January 2008.

Waste to Wealth: Renewable Energy from Pig Farm Effluents

With TEPA support, the Pingtung County government actively promotes the Organic Waste Bioenergy Demonstration Plan. In ROC, pig farm effluent is channeled into wastewater treatment plants to reduce its polluting effects and derive methane to generate electricity. Pingtung County has over 1.7 million pigs. The Pingtung County government tentatively plans to use sludge digestion tanks of the Liukuaicuo (Lakdeitsu) Wastewater Treatment Plant, which have a daily additional capacity of 235 m^3, to treat pig farm effluents. Methane is retrieved from the sludge for use in generating electricity, thus reducing the threat of pollution and improving river water quality [2].

Low-Carbon Communities to be Established

ROC will establish 50 low-carbon communities by the end of 2011 with six low-carbon cities to be established by 2014 as part of an overall strategy to reduce carbon emissions and gradually transform ROC into a low-carbon island economy. By 2020, the government plans to divide the island into four low-carbon living spheres: northern, central, southern, and eastern. Major emitters of CO_2, including industrial and energy suppliers, are largely responsible for reducing greenhouse gas emissions. However, nearly one-third of the nation's CO_2 emissions originate from daily life activities of the average inhabitant, including transportation, housing construction, commercial activity, agriculture, and livestock husbandry. As reducing emissions is everyone's responsibility, the most effective way to do so involves creating a low-carbon living environment to which individuals can easily adapt [3].

Sustainable Development Policy Guidelines

In August 2009, ROC completed the "Sustainable Development Policy Guidelines" to reinforce its visions of sustainability: present and future generations can enjoy a "tranquil and diverse environmental ecology," "vital, open and prosperous economy," and "safe and harmonious welfare society." To pursue national sustainable development, the ROC legislative body Executive Yuan established the National Council for Sustainable Development (NCSD) in 1997 to facilitate national sustainable development and implement the Sustainable Development Action Plan, National Sustainable Development Indicators and other important documents [4].

The policy guidelines reflect ROC's current sustainable development situation, with UN sustainable development concepts and principles used as a valuable reference. Effective response measures to global trends and formulation of governmental policies will spur civic participation in sustainable development and implement national sustainable development strategies.

Greenhouse Gas Reduction Management Office

The combined effects of greenhouse emissions and climate change have raised global concerns. Although accounting for only 0.3% of the global population, ROC produces nearly 1% of all global GHG emissions. Given global mandates for reductions in GHG, the inauguration of the GHG Reduction Management Office on 10 January 2008 marked an important milestone for TEPA. This office focuses mainly on promoting a national GHG registration platform and providing a comprehensive inventory of domestic emissions from each sector. In addition to serving as a valuable reference for future reductions, this information will facilitate an early response to global trends. Establishment of this office complements ROC's initiatives to legislate the Greenhouse Gas Reduction Act (draft), by creating a specialized governmental organization to showcase ROC's determination to reduce GHG [5].

The GHG Reduction Management Office will coordinate with each department to construct a GHG inspection system and voluntary reduction management mechanisms. The GHG Reduction Management Office has three divisions: strategic planning and evaluation; inventory registration and trade management; and global cooperation. The preliminary stage largely focuses on promoting the establishment of a nationwide GHG registration platform. In addition to continuously promoting the Greenhouse Gas Reduction Act (draft) and legislation of related bylaws, the office will strengthen collaboration between relevant government departments and organizations, as well as remain abreast of global developments.

CURRENT STATUS OF BIOGAS UTILIZATION EFFORTS IN ROC

In 2012, ROC had 9,273 pig farms with a total of 6,004,717 pigs [6]. Of these farms, 3,868 had 982,165 black pigs, i.e., about 15.83% of all pigs in ROC. Although ROC had only 1,703 pig farms (16.85% of total number of farms) with more than 1,000 pigs each, these farms had a total of 4,069,461 pigs, constituting 66.42% of total number of pigs. The pig farms are divided into two feeding types, kitchen leftovers, and pig feed. Pigs in the first group are mainly fed kitchen leftovers supplemented with soy meal. ROC had 6,053 pig farms with more than 100 pigs in 2011. Of these farms, 1,560 (25.37%) were kitchen leftover-feeding pig farms and 4,509 (74.63%) were pig feed-feeding farms [7]. However, ROC had 4,124 pig farms each with less than 100 pigs in 2010. Of these farms 2,891 (70.10%) were kitchen leftover-feeding farms and 1,233 (29.90%) were pig feed-feeding farms.

Pork is the largest economic meat source for the ROC population, with a per capita pork consumption of about 38 kg/year, according to statistical data from the National Animal Industry Foundation (NAIF) [8]. Pig farming is the dominant livestock industry in ROC in terms of production value totaling around USD2,225,098,033, i.e., about 14.0% of all agricultural production value (USD15,930,430,600) in 2012. Moreover, pig farming production value is approximately 45% of all livestock production value (USD4,948,476,500) in 2012 [8]. As such, pig farms were a natural choice to begin biogas production.

In addition to pig farms, in 2012 ROC had 325,095 heads of ruminant animals in its farms, comprising 2,496 cattle farms with 146,083 heads and 2,589 goat farms with 179,012 heads. The cattle farms had beef cattle (35,048 heads; 10.8%), dairy cattle (108,454 heads; 33.4%), and draft (working) cattle (2,581 heads; 0.8%), while goat farms had 122,204 heads (37.6%) of goats for meat consumption, and 56,808 heads (17.5%) of dairy goats [6]. Additionally, ROC livestock farms had deer (751 deer farms, 23,294 heads), horses (116 horse farms, 1,158 heads), and rabbits (30 rabbit farms, 13,104 heads). Poultry farms had chickens (36,752,000 heads of layers and 52,908,000 heads of broilers), ducks (2,436,000 heads of laying ducks and 6,979,000 heads of meat ducks), geese (1,622,000 heads), turkeys (112,000 heads), ostriches (2,077 heads), and quails (2,576,000 heads) [6]. These farms are potential additional sources for biogas production in ROC.

Biogas produced by covered anaerobic wastewater treatment basins of pig farms in ROC contains 60.06%–76.95% of methane and 18.21%–26.71% of CO_2 [9]. In 2012, pigs produced 26,841,085 kg of manure daily based on the average manure amount of 4.47 kg/head (average weight = 60 kg/head). The annual average biogas production was about 219,172,171 m^3 per year (0.1 m^3 biogas/head/day) for 6,004,717 farm pigs in the same year. This biogas can generate approximately 1,127,171,165 MJ per year of electricity (1 kWh = 0.7m^3 biogas; 1 kWh = 3.6MJ) by using biogas electricity generators [10] in ROC.

Collectively, pig farms can save electricity expenses totaling about USD25,048,248 per year based on USD0.08/3.6MJ. This arrangement can significantly lower production costs for pig farmers. Untreated biogas instead of desulfurized biogas is commonly used in heating lamps during winter in ROC. Using untreated biogas in heating lamps produces black smoke containing sulfur dioxide and decreases lamp life. During summer, biogas is emitted directly into the ambient atmosphere from anaerobic digesters at most livestock farms.

A governmental administration department of agriculture established “The Adjustment Proposal of Pig Farming Policy” to control piggery wastewater pollution and rescue the pig farming sector at the beginning of 1991. This policy regulates the effluents of treated piggery wastewater to comply with the effluent requirements of TEPA such as biochemical oxygen demand (BOD) (80 mg/L), chemical oxygen demand (COD) (600 mg/L), and suspended solids (SS) (150 mg/L). This policy affects almost 100% of all pig farms raising over 200 pigs each and with piggery wastewater treatment facilities in ROC. The double solid/liquid separation process can remove much of the manure (as much as is possible), thereby allowing the effluents of pig farms to easily comply with the TEPA’s requirements on effluent. Although higher manure content can produce more biogas with higher methane content, the effluent may not satisfy TEPA’s effluent requirements. TEPA authorities must thus carefully consider how to achieve a balance in developing livestock renewable energy in ROC.

PIGGERY WASTEWATER TREATMENT SYSTEM AND COMPOSTING

Piggery Wastewater Treatment System

A three-step piggery wastewater treatment (TPWT) system is the most common livestock wastewater treatment system in ROC and consists of solid/liquid separation, anaerobic digestion, and activated sludge treatment (Figure 1).

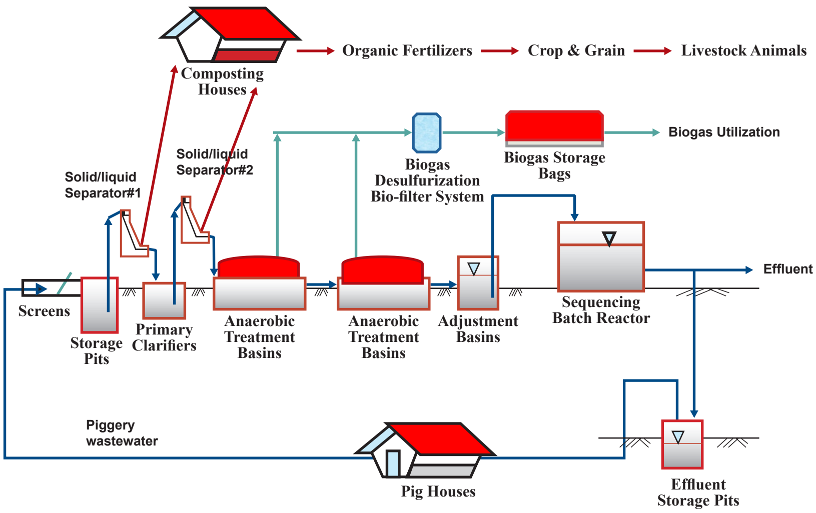

Figure 1. Flowchart of the three-step piggery wastewater treatment (TPWT) system.
Source: Su J.J.

Solid/liquid Separation

The solid part of pig slurry (used as manure), contains a significant amount of BOD, i.e., about 107,647 mg/L. Therefore, the solid part has to be separated from the rest of the slurry before treating the wastewater. On a daily basis, this also reduces the overall loading of piggery wastewater. Solid/liquid separation is thus the first stage of piggery wastewater treatment. The solid part is then processed for composting.

Anaerobic Treatment

Anaerobic treatment is the second step of treatment and undertaken inside the anaerobic basins covered with "Red-Mud Plastic Cover" (a polyvinyl chloride (PVC) material), after solid/liquid separation. The material is corrosion-resistant, and gas and water impermeable. While generally slower, this treatment saves on the energy deemed necessary for forced aeration. This three-step treatment process can also salvage a portion of the chemical energy content of wastewater by generating methane. The optimal hydraulic retention time is about 7–10 days, and the anticipated BOD removal is about 80%. Biogas produced from covered anaerobic basins by anaerobic bacteria includes methane (60% to 80%), carbon dioxide ($CO2$; 16% to 38%), dinitrogen gas (1% to 2%), hydrogen gas (1%), and hydrogen sulfide (0.2% to 0.5%). Methane can be used as fuel for applications such as electricity generators, boilers, heating facilities of piglets, and pig carcass incinerators.

Aerobic Treatment

Following the anaerobic basin treatment, the aerobic treatment process uses some aerobic microorganisms (activated sludge). The aerobic treatment efficiency depends on the level of dissolved oxygen (1–4 mg/L) and sludge volume of the activated sludge basins.

Sequencing Batch Reactor System with Automation

A full-scale sequencing batch reactor (SBR) with simple equipment occupies less space than the TPWT facility [11]. This SBR system, developed by the Animal Technology Institute Taiwan (ATIT), can be applied for aerobic treatment after the anaerobic basin treatment.

Composting

The organic portion of the solid parts from the solid/liquid separation process can be biodegraded by composting. Through this process, solid heterogeneous organics are degraded by aerobic, mesophilic, and thermophilic micro-organisms. The particle size of composting components should be homogeneous. The entire process depends on microbial activity, explaining why supplying an optimal carbon/nitrogen (C/N) ratio is critical for microbial growth. The optimal C/N is normally 20. The C/N of solid pig feces, chicken feces, and cattle feces is about 10–14, 8–10, and 20–30, respectively. Thus, rice husks (C/N=70–80) and sawdust (C/N>500) are always added as additional carbon sources. Additionally, moisture must be at adequate levels (50%–60%); 65% water content is optimal, but excess moisture (≥70%) interferes with aeration and lowers self-heating owing to the large heat capacity of water. The optimal pile height is 1.5 meters when the pile moisture is 65%. Notably, microbial growth is inhibited when pile moisture is below 30%. However, excessively high humidity implies low permeability of oxygen going into the composting piles. Microbial growth is thus restricted, making it impossible for microorganisms to decompose organics. Therefore, mechanical turning is normally applied in composting to mix a sufficient amount of oxygen into compost piles. Oxygen supply is essential for successful composting.

Microorganisms responsible for the composting process are mostly aerobic bacteria. Under favorable conditions, self-heating typically raises the temperature inside a static compost pile to 60–70 ºC in two to three days. However, after a few days at this optimal level, the temperature gradually declines unless the pile is turned to re-supply oxygen, thus ensuring that the thermophilic process occurs throughout the pile, rather than only at the core. During this process, pathogens are killed at high temperatures. Roughly two months are required to decompose sludge and pig manure in order to compost completely.

MAJOR APPROACHES FOR LIVESTOCK BIOGAS UTILIZATION IN ROC: A CASE STUDY

As a by-product of anaerobic digestion of organic matter (e.g., animal manure, sewage sludge, and food-processing waste), fermentation of animal manure and other wastes produces hydrogen sulfide concentrations in biogas of 2,800–8,400 mg/m^3 [12]. Combustion of biogas containing hydrogen sulfide yields sulfur oxides, thus limiting the use of biogas for heat and power generation. Importantly, sulfide and sulfur dioxide corrode metal generator parts and contaminate engine oil in biogas motors. Additionally, most industrial factories operate a conventional water scrubber system to remove hydrogen sulfide from biogas. This system requires considerable amounts of water and electricity to dissolve hydrogen sulfide in water, thus increasing operating costs but making the reduction of hydrogen sulfide concentrations in biogas feasible. However, a novel and cost-effective biogas biofilter system (BBS) for bio-desulfurization (H2S®S0®SO42-) was successfully developed by our research team and is being used in more than four pig farms (Figure 2) [13]. Both pilot and full-scale BBS were tested and evaluated on selected farms from 2006 to 2010, during which time the average hydrogen sulfide removal efficiency exceeded 95% (Figure 3) [14–15]. This farm-scale BBS with three patents was conferred an award at the 7th National Innovation Award in ROC in 2010. In addition, another farm-scale BBS was established and put in operation in 2013 at a 25,000-head pig farm (Figure 4).

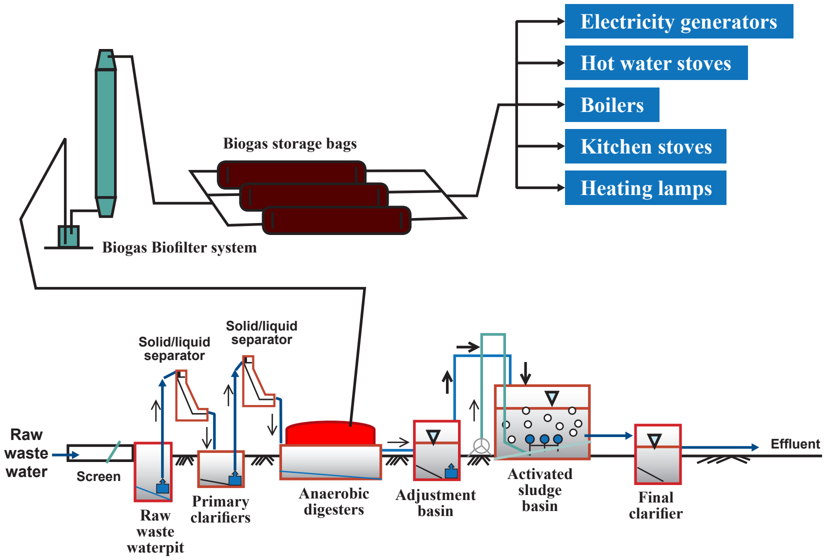

Figure 2. Flowchart of the Three-step Piggery Wastewater Treatment (TPWT) system with a biogas desulfurization biofilter.

Source: Su J.J.

Figure 3. Farm-scale biogas biofilter system established in 2009 (for 9,000-head pig farm).

Source: Su J.J.

Figure 4. Contract signing press conference for biogas power generation with a farm-scale biogas biofilter in 2013 (for 25,000-head pig farm).

Source: Pingtung Government, Republic of China.

Economic evaluations for electricity generation using pig farm biogas showed that investment payback periods for the 1,000, 2,000, 3,000, 5,000, and 10,000-head pig farms might be 6.2, 3.7, 3.0, 2.2, and 1.8 years, respectively (Table 1). With carbon reduction benefit factored in, the investment payback periods for these farms might be 2.3, 1.4, 1.1, 0.82, and 0.67 years, respectively (Table 2).

However, biogas electricity generation can produce waste heat, with lower efficiency than direct biogas combustion. Electricity efficiency using micro-turbines is about 28% [16]. Hot water recovery integrated with electricity generation, can provide biogas an overall conversion efficiency of 65%–85% [17]. Thus, pig farms using kitchen leftovers as feed may use biogas boilers to boil the leftovers, i.e., direct biogas combustion. The investment payback periods for the 1,000, 2,000, and 3,000-head pig farms might become 1.0, 0.63, and 0.40 years, respectively (Table 3). Hopefully, the proposed BBS facility can help mitigate GHG emissions through livestock manure management.

Table 1. Economic evaluation of electricity generation using pig farm biogas in ROC

Pigs on farms (heads)	COST					REVENUE			Investment payback period (years)
	BBS facility (USD10,000 per set)	Electricity generator (kW per USD10,000)	Machinery maintenance (USD10,000 per year)	Biogas storage and related cost (USD)	Total (USD 10,000 per year)	Biogas production (m^3 per year)	Electricity generation (kWh/yr)/ Benefit (USD10,000 per year)	Total (USD10,000 per year)	
1,000	1.27	12/1.13	0.22	By case	2.62	36,500	52,143/ 0.42	0.42	6.2
2,000	1.27	20/1.57	0.23	By case	3.07	73,000	104,286/ 0.83	0.83	3.7
3,000	1.53	30/1.87	0.30	By case	3.70	109,500	156,429/ 1.25	1.25	3.0
5,000	1.93	50/2.23	0.40	By case	4.56	182,500	260,714/ 2.09	2.09	2.2
10,000	3.27	100/3.60	0.57	By case	7.44	365,000	521,429/ 4.14	4.14	1.8

Notes: BBS, biogas biofilter system; USD, United States dollar.

Table 2. Economic evaluation of electricity generation using pig farm biogas with GHG reduction benefits in ROC

Pigs on farms (heads)	COST					REVENUE					Investment payback period (years)
	BBS facility (USD 10,000 per set)	Electricity generator (kW per USD 10,000)	Machinery maintenance (USD10,000 per year)	Biogas storage and related cost (USD)	Total (USD 10,000 per year)	Biogas production (m^3 per year)	Electricity generation (kWh/yr)/ Benefit (USD10,000 per year)	Greenhouse gas (GHG) reduction (tCO_2e peryear)	Economic benefit (USD 10,000 per year)	Total (USD 10,000 per year)	
1,000	1.27	12/1.13	0.22	By case	2.62	36,500	52,143/ 0.42	1,000	0.7	1.12	2.3
2,000	1.27	20/1.57	0.23	By case	3.07	73,000	104,286/ 0.83	2,000	1.4	2.23	1.4
3,000	1.53	30/1.87	0.30	By case	3.70	109,500	156,429/ 1.25	3,000	2.1	3.35	1.1
5,000	1.93	50/2.23	0.40	By case	4.56	182,500	260,714/ 2.09	5,000	3.5	5.59	0.82
10,000	3.27	100/3.60	0.57	By case	7.44	365,000	521,429/ 4.14	10,000	7.0	11.14	0.67

Notes: BBS, biogas biofilter system; tCO_2e, tonnes of carbon dioxide emission; USD, United States dollar.

Table 3. Economic evaluation of boilers using pig farm biogas for kitchen leftover-heating in ROC

Pigs on farms (heads)	COST				REVENUE			Economic benefit (USD10,000 per year)	Investment payback period (years)
	BBS facility (USD10,000 per set)	Machinery maintenance (USD10,000 per year	Biogas storage and related cost (USD)	Total (USD 10,000/ yr)	Biogas production (m^3 per year)	Offset against cost of heavy oil (USD 10,000 per year)	Total (USD 10,000 per year)		
1,000	1.27	0.22	By case	1.5	36,500	1.5	1.5	0	1.00
2,000	1.27	0.23	By case	1.5	73,000	2.4	2.4	0.9	0.63
3,000	1.53	0.30	By case	1.8	109,500	4.5	4.5	2.7	0.40

Source: Su J.J.

Notes: BBS, biogas biofilter system; CDM, clean development mechanism; tCO_2e, tonnes of carbon dioxide emissions; USD, United States dollar; VCS, verified carbon standard.

[A] Biogas production= $0.1m^3$/head/day (measured data in pig farms).

[B] Electricity generation = 1 kWh/$0.7m^3$ (data from Taiwan Livestock Research Institute).

[C] Electricity generation benefit = USD0.08/kWh.

[D] Greenhouse gas reduction =1 tCO_2e/head/year (based on CDM methodologies).

[E] Benefit of greenhouse gas reduction= USD7/tCO_2e (based on tentative VCS reference price).

[F] Biogas boilers have not estimated greenhouse reduction by using CDM methods.

FEASIBILITY OF CARBON OFFSET FOR LIVESTOCK FARMS IN ROC: A CASE STUDY

The livestock industry can obtain voluntary carbon units (VCUs) from biogas utilization after complying with voluntary carbon standard (VCS) criteria. The manufacturing industry can create joint ventures by combining carbon-offset programs with the livestock industry for biogas utilizations on farms. The first document of VCS's project design document (PDD) was completed for a 9,000-pig farm (Ping-Shun pig farm) in 2009. Two methodologies (AMS-III.H. and AMS-I.D.) of the Clean Development Mechanism (CDM) were used for PDD preparation. The validated PDD indicates that approximately 3,163 tCO_2e per year can be reduced by biogas electricity production in a 9,000-pig farm with only one set of 30kW electricity generators. However, the biogas volume for a 9,000-pig farm can provide three sets of 30kW electricity generators. About 9,489 tCO_2e per year can be reduced by biogas electricity production for a 9,000-pig farm with three 30 kW electricity generators. This finding implies that combustion from one pig's manure can be counted as 1 tCO_2e equivalent per year (i.e. 1 tCO_2e/pig/year). Moreover, about 6,195,221 tCO_2e per year can be reduced when biogas is used for electricity generation or other direct combustion. The first copy of the validation report (ISO 14064-2) and statement of carbon reduction for a pig farm was validated by SGS Taiwan, Ltd. with the BBS system developed by ATIT (Figure 5).

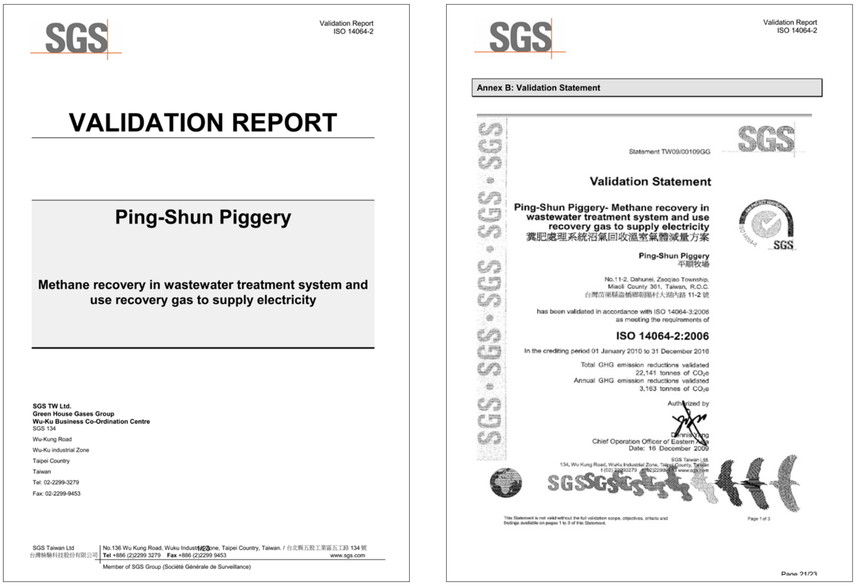

Figure 5. First copy of validation report and statement of carbon reduction for livestock farms in ROC.

Source: Su J.J.

SUMMARY AND CONCLUDING REMARKS

As estimated, total GHG inventory in the livestock sector is 893,925.24 tCO_2e per year in ROC, including enteric fermentation and manure management using the Intergovernmental Panel on Climate Change (IPCC) protocols. The ratios of GHG inventory in agricultural and livestock sectors for the entire ROC GHG inventory estimated by COA (2010) are 4.21% and 0.43%, respectively.

The carbon footprint of pork production is about 5 $kgCO_2e$/kg pork calculated using SimaPro software, and approximately 50% of carbon footprints accounted are from biogas production (Unpublished data). Thus, biogas combustion is the most effective strategy for mitigating GHG levels in Taiwanese livestock sector.

The following actions are proposed:

1. Promotion of biogas collection and utilization in livestock farms by subsidizing part of the expenses for biogas collection and combustion facilities.

2. Enhancement of the legal framework for GHG registration for domestic carbon offset between the livestock industry and high carbon emitters such as steelmakers and chemical plants. Despite the establishment of the National Taiwan GHG Emission Registry [18], strong law enforcement is still needed to further the practice of carbon offset.

3. Transformation of traditional livestock farms into eco-farms by encouraging livestock farmers to collaborate with surrounding farmers to recycle livestock and agricultural wastes in cooperative farms.

4. Establishment of centralized biogas plants or bionatural gas plants by accumulating animal manure from small-scale pig farms (less than 5,000 pigs per farm) and subsidizing biogas production, desulfurization, purification, and electricity generation facilities for centralized composting houses. A feasible business model is one in which pig farmers, together with joint venture partners, also own and operates biogas plants (modified from centralized composting houses) and markets the biogas, electricity and heat generated.

Some economics researchers have become much better at measuring what actually makes life worthwhile, rather than relying on GDP as the sole indicator [19]. The environmental and social effects of GDP growth can be estimated, as can the effects of income difference. These are expressed in monetary units, making them more readily comparable to GDP. Such indices consider annual income, net savings and wealth. However, environmental costs and benefits can also be factored in. Thus, sustainable progress of environment-friendly industries should be considered superior to GDP growth for making life valuable.

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THE REPUBLIC OF KOREA'S AGRIFOOD TRACEABILITY SYSTEM

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INTRODUCTION

This paper is an excerpt from the report made by the National Institute of Animal Science, Rural Development Administration (RDA) in the Republic of Korea (ROK). The paper attempts to describe the status of traceability (standards, control systems and mechanisms) in ROK to match the themes of the First Asian Food and Agribusiness Conference: Biotechnology and Global Competitiveness, hosted by the APO in 2013. This document elaborates the principles and procedures used to assist competent authorities in utilizing traceability as a tool for meat inspection and certification systems.

Traceability/product tracing is a tool that may be applied, as and when appropriate, in order to contribute to consumer protection against food-borne hazards, deceptive marketing practices, and facilitate accurate trade-based product descriptions.

Background Information

The purpose of the Act on the Traceability of Cattle and Beef in ROK is to contribute to the development of the livestock industry, protect consumers by efficiently preventing epidemics, and ensure meat safety through the establishment of an effective management system for cattle and beef nationwide. The information management system allows each handling step for meat products in the livestock industry to be identified and traced from the date of birth to the sale of any livestock.

Definitions

There are several terms used in this paper that relate to ROK's traceability systems. They are as follows:

Inspection: The examination of meat as food or systems for controlling food, raw materials, processing, and distribution. This includes in-process and finished products in order to verify that all the steps comply with the minimum requirements.

Certification: The procedures by which official certification bodies and officially recognized bodies provide written or equivalent assurances that food or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities, which may include continuous online inspection, auditing of quality assurance systems, and examination of finished products.

Equivalence: The capability of different inspection and certification systems to meet the same objectives.

Traceability: The ability to follow the movement of a food product through the specified stages of production, processing and distribution.

TRACEABILITY IN ROK

Due to increased global concern about bovine spongiform encephalopathy (BSE), meat product quality assurance has been given a high priority to prevent any possible epidemic outbreak. Consumers are worried about meat safety, especially with regard to the origin and integrity of meat products from slaughter to consumption. In ROK, Hanwoo (Korean cattle) is the preferred cattle breed, which comprises about 69% of beef production and has been the major source of revenue for farmers. The Hanwoo meat production system goes through several independent steps such as cattle production, registration, slaughter, processing, marketing, and distribution. The production system should ensure consumers that the meat products they buy are safe. Information at each stage of the process must be integrated so that the public can trace the whole, or part, of a production chain.

In order to ensure that meat quality and sanitation meet customers' demands, a traceability system for systematic animal identification was developed to increase the efficiency of animal production, postproduction, and processing. In addition, the system was also designed for easy management, data collection, and storage using bar codes, registration and farm numbers. Specifically, the system aimed to provide standard ear tags and radio frequency identification (RFID) technology for livestock management to guarantee meat product safety, give farmers incentives to produce quality meat products, and provide a unified system for national livestock management. Approaches using DNA markers are incorporated into this traceability system [1].

Expectations

The beef traceability system means to assure consumers of meat safety by closely monitoring the routine production process, promptly detecting any safety related issues, and enhancing the clarity of the distribution system by guaranteeing fair trade. This system enables the recording and management of all information at every step from production to consumption. The beef traceability system is expected to greatly improve both the livestock distribution system and genetic animal improvement at nationwide levels. Furthermore, the traceability system has merged with national genotyping systems that focus on identifying and analyzing associations with economically important traits. This helps to improve animal quality and locate particular quantitative trait loci (QTL) in the animal genome.

System

The traceability tool may be applied to all or specified stages of the food chain (from production to distribution), as appropriate to the objectives of the food inspection and certification system, identifying the status of meat products, starting with where the food came from (one step back), to where the food went (one step forward). The objectives, scope, and related procedures of the traceability-based food inspection and certification system was envisioned with the objectives of transparency and providing information upon request to the competent authorities from the importing countries.

The system, which has been running since 2003, was developed using a highly recognizable technique for read/writable RFID ear tags operating in a passive mode. The RFID memory is partitioned to five sections as follows:

1. A security section that sets unique serial numbers in the tags to prevent illegal duplication;
2. An identification (ID) section, including animal ID, parents' ID, and birth date;
3. A medical treatment section holding data on latest treatments;
4. A vaccination history section that stores the latest vaccination history; and
5. A reserved section for future uses.

The device is designed to handle the information with a portable terminal-type device that automatically reads animal ID. The purpose of RFID, which has minimum errors from human intervention, is to track and monitor each animal. This basic information, including the animal's sex, birth date, pedigree, farmer's name, slaughter date, and packer ID are labeled on the chip and can be displayed via cellular phone. If a customer who bought packaged beef registers the serial number and customer information on the website, the system can trace all the information regarding the animal and take proper action if necessary. Figure 1 illustrates the system tree for the traceability system in ROK.

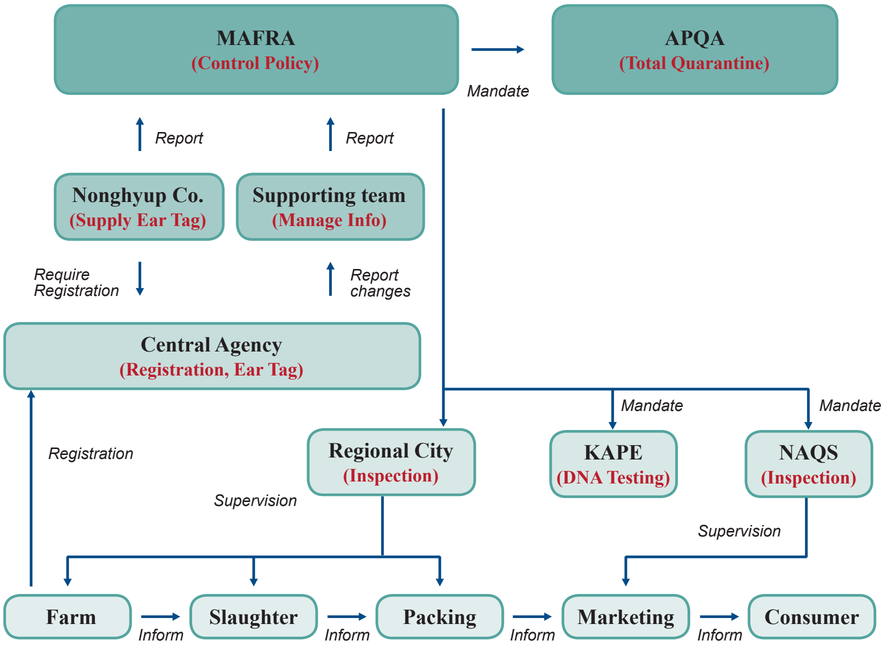

Figure 1. The system tree for traceability in the Republic of Korea. APQA, Animal Plant Quarantine Agency; KAPE, Korea Institute for Animal Products Quality Evaluation; MAFRA, Ministry of Agriculture, Food and Rural Affairs; NAQS, National Agricultural Products Quality Management Service.

Source: Korea Institute for Animal Products Quality Evaluation (KAPE) [2].

Importance of Traceability

Meat and food safety and sanitation are considered key issues to ensure overall food security in ROK. Food is the major source of human exposure to both chemical and biological (viruses, parasites, bacteria) pathogenic agents, from which no individual is spared. The importance of food safety stems from two realities: that food is the primary means of infectious disease transmission and agricultural development elevates food as a major export potential, thus earning foreign exchange, and promoting individual and community health, as well as national productivity. Furthermore, food has emerged as a prominent source of conflict in international agricultural trade.

Potential Risks in Food

A wide range of endemic, hyperendemic and pandemic diseases can be encountered. BSE, or mad cow disease, is suspected to have caused a new variant in humans, Creutzfeldt-Jakob disease. The recent occurrence of the “bird flu” disease in poultry caused by avian viruses is also a major issue.

Coordinating Mechanisms

Regulation and management for the food traceability system is managed at three overall levels: policy, controls and enforcement.

Policy

A central agency, advised by various government units, organizes national policies for meat safety that is regulated by special committee members. These policies are further championed by regional agencies, setting controls within their areas and coordination with other regions.

Controls

Several organizations exist in ROK to coordinate food control activities, and information sharing among organizations. A partnership between the Korea National Institute of Health (KNIH) and the Ministry of Agriculture, Food and Rural Affairs (MAFRA) is fully operative.

Enforcement

A Food Safety Advisory Committee or Minimum Standard Fixing Committee has been set up focusing on particular meat products. MAFRA has full responsibility for all legal actions. Every single food-safety-related law and rule in ROK empowers the relevant authorities to enforce provisions regarding inspection, sampling, testing, and prosecution, if applicable, against producers and/or marketing agents.

Traceability in the Slaughter Process

The use of traceability in the slaughter process is illustrated in Figure 2.

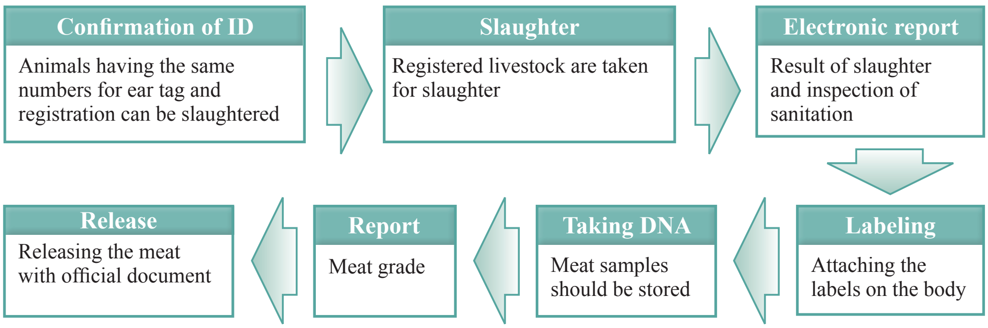

Figure 2. Traceability in the slaughter process.

Source: Korea Institute for Animal Products Quality Evaluation (KAPE) [2].

Legislation

Domestic policy on traceability is dictated and enforced by MAFRA. Table 1 illustrates the established legislation and legal actions against labeling non-compliance.

Table 1. Penalties for non-compliance of traceability requirements

Actions	Act no.	Fine (KRW10,000)			
		1st	2nd	3rd	4th
Against article no. 11, sections 1 and 2 *Not providing or destroying the identification numbers*	Section 1 Number 5	30	60	120	240
Against article no. 11, section 3 *Not supplying legislation numbers in official document*	Section 1 Number 6	30	60	120	240
Against article no. 12 *Not following civic betterment*	Section 1 Number 14	30	60	120	240
Against the article no. 13 *Not reporting animal information, false (fraudulent) claims, not keeping documents within official retention periods*	Section 1 Number 16	20	40	80	320

Note: KRW, Korean Won.

The traceability process in the livestock food chain is explained in Tables 2, 3, 4, 5, and 6.

Table 2. Registration of birth of livestock

Birth certification	• Farms provide birth certificates for both imported and exported animals with the ear-tag* numbers, as provided by the regional registration agency.
Farm reporting	• Farms report the sale, purchase, and death of animals to the regional agency. • In case of slaughter, farms provide the slaughter station with all animal information before submission for slaughter. If the information of any animal is changed, the farms must report these changes to the regional agency.

Discrepancies	• If there are discrepancies within the database, the agency will notify the farms immediately. The farms must submit a valid written explanation to the regional agency. • If the changes are made intentionally, the agency reports the case to the central agency for appropriate legal action.

Note:
* Farms are fully responsible for the information stored in the registered ear tags.

Table 3. Slaughter

Slaughterhouse inspection	• The slaughterhouse takes all farm applications and accepts/denies after evaluating whether the application information and individual identification numbers from the national database match. It also checks the registration status.
Sampling	• After inspection, the slaughterhouse informs the regional registration agency on the status of the animals' information, and takes meat samples to check DNA similarity.

Table 4. Packing

Packaging	• Applications for inspection plans are submitted to the packing facility. • After confirming the ID, meat is packed according to the meat parts with labeling for individual ID numbers.
Labeling	• The packer labels each inspected box based on ID, and delivers the products to regional distributors.

Table 5. Distribution

Distribution	• The boxes are routinely verified so that the ID matches the barcodes printed from the central agency. • After confirming the information, meat products are packed into small sizes for sale in commercial markets labeled with the same ID numbers.
Customer tracking	• The law requires that the markets label the ID numbers on the products so that consumers can exercise their right to screen and trace the animal's history. • The central database provides consumers all animal information through mobile phones and personal computers.

Table 6. DNA typing (agencies)

DNA sample collection	• Meat samples are collected from the slaughter station, and the isolated DNA samples are stored in the central evaluation agency.*
Sample testing	• The agency will test the three samples (collected from the three previous stages) for identity according to molecular techniques such as PCR, electrophoresis. • If the results are for the three samples do not match, the agency shall report the results to the central agency to take the necessary legal actions.

Note:
* For the inspection, all the samples are collected from the packing facility and commercial markets to compare DNA similarities.

Genotyping Kits

Genotyping analysis from 13 microsatellite loci are shown in Table 7. Standardized procedures for genotyping are set for every testing facility. Each testing station is authorized by a central governmental agency and has a valid number of experts with fully inspected typing instruments. The central agency also decides to type any microsatellite loci containing 11 markers, and if necessary, add more microsatellite markers. The central agency should also have written permission from the typing committee that consists of five professionals from four institutions, one governmental agency, two academics, and two industry experts.

Table 7. Analyses of genotyping from microsatellite loci

Loci	Chromosome	Fluorescent	Annealing Temperature (^{o}C)
TGLA227	18	FAM	56
BM2113	2	FAM	58
TGLA53	16	FAM	60
ETH10	5	FAM	58
SPS115	15	FAM	58
TGLA126	20	VIC	58
TGLA122	21	VIC	58
INRA23	3	VIC	61

(...continued)

Loci	Chromosome	Fluorescent	Annealing Temperature (°C)
ETH3	19	NED	60
ETH225	9	NED	60
BM1824	1	NED	58
BOV_X	X	PET	56
BOV_Y	Y	PET	56

ISSUES AND CHALLENGES FOR ROK

At the time of this paper, ROK faced two main challenges. While the first was more immediately resolvable, the second involves long-term research and planning:

1. After frequent reports of fraudulently labelled Hanwoo dairy cattle meat products were reported, ROK used the traceability system to investigate the matter based on annual reports from KAPE for illegal actions. Currently there are no further cases in Korea.

2. For developing preferred animal traits nationwide, a research trend using records from traceability issues will be projected with data from molecular analyses for targeted genetic variants. In addition, a high-throughput analysis of single nucleotide polymorphisms (SNP), covering the entire genomic area will be enforced to discover the causative combinations of genetic variants related to genetic diseases of current concern, as well as economically important traits in commercial markets.

Future Challenges

Future challenges facing ROK agribusiness have been identified and will be addressed by both the Animal Genomics and Bioinformatics Division and the Animal Genetic Improvement Division. These are summarized below.

Animal Genomics and Bioinformatics Division

Challenge: Obtaining SNP chip genotyping data and ensuring statistical accuracy for analysis in entire genomic areas over a large population.

- All SNP information will be collected using SNP chip analysis, and particular traits will be identified according to the significant levels of SNP.

- Records from traceability will be used to test associations between SNP and quantitative traits that are related to animal performance.

- Based on the analyzed data, information will be re-organized to find genetic networks for the identified traits.

Animal Genetic Improvement Division

Challenge: Implementing the National Institute of Animal Science's goal of resetting the national livestock breeding goals to 10 year terms.

- The action is according to the guidelines from MAFRA (Ministry of Agriculture, Food and Rural Affairs), which align to international guidelines [3]. The committee members consist of 31 officials from 12 organizations. The committee holds two official meetings each year to select sires and to discuss national breeding goals.

- Committee members will discuss pedigree information, management, performance data collection, candidate animal examination in test stations, evaluation of carcass grades, and production of semen to promote a variety of tasks in the national livestock breeding programs. The central agency will have full responsibility for setting up breeding goals.

CONCLUSION

Recommendations for Improving the Safety System

In addition, there are several suggestions that this paper will make to improve the existing food safety system. These are summarized below.

Construction of a Risk Database

- Adequate data should be generated for use in risk assessment work and stored in a database. This data would be used for consumer protection and harmonizing the existing standards with safety standards under central agency guidelines.

- The food safety information database should be expanded according to the guidelines from Korea National Institute of Health (KNIH) to provide more complete information on the incidence of food-borne disease by pathogen and meat products.

- Improved surveillance programs to collect more precise information about the incidence of food-borne illnesses, especially those caused by chemical and microbiological poisoning, as well as illegal activities involving modification of identification numbers.

- Expand nationwide networking systems on traceability, diseases, and risk assessments.

- Share information for mutual usage and utilization (particularly to reduce risks).

Law Enforcement

- The laws in place should be implemented with full force. Hurdles in implementing the existing laws against adulteration must be eliminated.

Arsenic Contamination

- Scientists, researchers, consumers, and donors should come forward with integrated efforts to formulate a strategic plan to solve this problem.

- Awareness should be increased among consumers to select and purchase safe food from the open market.

Awareness Building

- Provide priority education, awareness, training through manuals, material on, and practical demonstrations of, the system and its regulatory measures to farmers, food processors, government regulators, policy makers, vendors, and other persons involved in the system for compliance.

- Adequate knowledge and guidance should be available to farmers for strict application of good agricultural and marketing practices for their food crops.

- Launch programs to educate consumers about food safety.

Research

- A study of the collective impact of unsafe meat intake should be carried out when traceability systems malfunction.

- Launch research into the fields of production, processing, marketing, and consumption for meat products.

- Launch research into finding causative genetic variants with recent molecular genetic technologies to position the exact variations on the animal genome.

Recommendations for the Regional Action Plan for Meat Safety

- Review laws, infrastructure, and coordinating mechanisms. Provide technical assistance to keep these up to date.

- Review standards and certification systems that meet international requirements for measurements of products.

- Review research and study programs that conduct research projects.

- Provide support for publishing a regional meat safety bulletin containing news and views on safety data, events, information, and development.

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6

DEVELOPING COMPETITIVE AGRICULTURAL BIOTECHNOLOGY BUSINESS ENVIRONMENTS

BIOTECHNOLOGY: FOOD SECURITY AND FARMING COMPETITIVENESS

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INTRODUCTION

Agriculture has been a mainstay of many developing economies in Asia. Historically, farming in the countryside has been the main food source for city dwellers. However, when viewed holistically, Asia, with over 60% of the world's population (half of whom live in cities), only has 34% of the world's arable land and 36% of the world's fresh water [1]. This makes the region very vulnerable to factors that may directly or indirectly reduce this land and water.

Apart from agriculture being a source of food, it has also been a source of industrial crops and employment, creating wealth for many smallholders in Southeast Asia. Agriculture is therefore a source of both economic growth and food security in large parts of Asia. Many governments depend on export revenues from agriculture to fuel economic growth. In this regard, competitiveness in each country's agricultural sector is important to maintain market shares in a host of commodities such as rubber, palm oil, cacao, coffee, and rice. At the same time, Asia is also a major producer of important crops that sustain food security, from staples like rice and wheat, to vegetables, fruits, beverages, and spices.

To maintain a competitive agriculture sector that is able to contribute to food security requires the judicious use of technology to increase both productivity and total production. Experience has shown that engineering technology and biotechnology are two types of technologies that have played important roles in modernizing Asian agriculture [1].

In this paper, only the role of biotechnology will be discussed in relation to agricultural competitiveness and food security. This will be preceded by setting the context which agriculture plays in the Asian landscape and by explicating the scope of modern biotechnology in agriculture.

CHANGES IN THE ASIAN AGRICULTURE LANDSCAPE

In the context of competitiveness and food security, three issues within the agricultural landscape in Asia may be highlighted: trade, production, and the natural resource base for production [2, 3].

Agricultural Trade (Agricultural Food Imports And Exports)

Asia currently is a major importer of the world's surplus production of key food commodities (Table 1), accounting in the trade year 2011–12 for 78% of global soybean exports, 38% of global maize exports, 27% of global milled rice exports, and 26% of global wheat exports. Given population projections and Asia's demand for key commodities such as wheat, rice, maize, and soybean in recent years, the import of these key commodities is likely to increase further in the next two decades.

Table 1. Global production and Asia imports of key food commodities for 2011–12 – livestock effluent and food waste (potential sources of renewable energy)

Crop	Category	Million Metric Tons	Percentage of global exports
Wheat	Global production	696	
	Asia imports	40	26%
Rice (milled)	Global production	466	
	Asia imports	11	27%
Maize	Global production	883	
	Asia imports	40	38%
Soybean	Global production	240	
	Asia imports	71	78%

Source: United States Department of Agriculture (USDA) [4].

When the imports are disaggregated by subregion, Southeast Asia accounted for 44.5% of the Asian import of wheat, and 56.2% of the Asian import of rice in 2011–12 (Table 2). Most of the world's soybean and maize are imported by East Asia, mainly PR China, Japan, and Republic of Korea (ROK), reflecting the growing demand for animal feed to meet an increasing appetite for animal protein, which has risen commensurate with the rise of a middle class population. Within the Southeast Asian region, the top importers were Indonesia for wheat and rice, Malaysia for maize and Thailand for soybean. These trade figures show how dependent Asia is on inflows of the key agricultural food commodities from the Americas and the relative inefficiencies of Asian agriculture to produce the same four commodities. For example, while Southeast Asia is the region with the most rice production and exports, it is also the region which imports the most.

Table 2. Asia subregional imports of key food commodities

Sub-Region	Wheat		Rice		Maize		Soybean	
	MMT	%*	MMT	%*	MMT	%*	MMT	%*
East Asia	16,865	42.0	4,125	43.0	32,339	82.1	65,449	92.0
South Asia	5,402	13.4	790	8.2	0	0	0	0
Southeast Asia	17,863	44.5	5,510	56.2	7,064	17.9	5,681	8.0

Source: United States Department of Agriculture (USDA) [4].
Notes: MMT, million metric tons.
* Percent of Asian total.

Intra-Asian trade in recent years has become an important source of food supply to many countries to either make up for their own shortages in production, or to add to the diversity of food demanded by the growing middle classes [5]. This is also a reflection of the growing importance of food supply chains, which through various trade mechanisms, ensure the movement of food from agriculture surplus production areas to agriculture deficit production areas of the world. The rural landscape in most Asian countries is therefore no longer the sole source of food for their urban population. Rather, many cities now import food from a distance.

Agricultural Production and Productivity

Another factor that is adding to change in the agriculture landscape is the declining contribution of the sector to national economic growth. For example, agriculture's share of GDP has fallen from 43% to 18% between 1961 and 2009 in South Asia, [2,6]. There are also less and less of the rural population working in agriculture, with the number declining from 66% in 1980 to 50% in 2010; this number is projected to further fall to 45% by 2020 [7]. In terms of farm size, farms are getting even smaller as a result of population growth and inheritance-based fragmentation [8].

A more worrying trend is the declining performance of agriculture. According to Trostle, the annual growth in productivity, measured in terms of average aggregate yield has slowed down over the years [9]. Global aggregate yield growth of grains and oilseeds averaged

2% per year between 1970 and 1990, but declined to 1.1% between 1990 and 2007 [10]. It is projected to continue to decline over the next 10 years, to less than 1% per year. Asia's farmers are also growing older. For example, according to the Japanese Agriculture Ministry, 70% of Japan's 3 million farmers are 60 years or older [11].

A Degraded Natural Resource Base for Food Production

Agricultural production capacity in Asia, which in the past was sustained by practices that safeguarded the natural resource bases of land and water, is under severe stress due mainly to anthropogenic activities. Out of a total land area of approximately 4.3 billion ha, Asia contains some 1.7 billion ha of arid, semi-arid, and dry subhumid land [12]. This region has the most number of people affected by desertification and drought. According to the International Soil Reference and Information Centre, water erosion is a dominant feature in degraded soils in South and Southeast Asia, followed by chemical deterioration, and wind erosion [13]. Water erosion covers 21% of the total land area in the region (or 46% of the total degraded area). It is predominant in large parts of PR China, India, and in the sloping parts of Indochina, the Philippines, and Indonesia. Water scarcity is particularly serious in southern Asia and northern areas of PR China, and when compounded with the increasing demand for animal protein food from a growing middle class in Asia (estimated to reach 3.2 billion by 2030), the issue of water demand becomes a critical one. For example, studies have shown that on average, it requires 16.7 L of water to produce 1 kg of beef and 5.5 L of water to produce 1 kg of pork.

This section has highlighted three issues in agriculture that are related to competitiveness and food security, both of which will be discussed in more detail in a later section. Next, to understand the role that biotechnology can play in addressing competitiveness and food security, it will be necessary to explicate the scope of biotechnology.

SCOPE OF BIOTECHNOLOGY

Applications of Biotechnology in Agriculture

Modern biotechnology encompasses a range of technologies that may be grouped according to their application domains: crops, aquaculture, livestock, environment, and natural products [1]. Biotechnology applications in crops have included plant tissue culture, biopesticides, biofertilisers, diagnostics, marker-aided selected crop varieties, and biotechnology (genetically modified) crops [14]. In aquaculture, biotechnology has been used in the development of vaccines and diagnostics for crustaceans and finfish, mainly to expand the gene pool through marker-aided selection, and to guide the development of more nutritious feed. For livestock, biotechnology has led to improved feed and feed additives, vaccines and diagnostic kits, drugs for various diseases, and also for breed improvement through marker-aided selection. Biotechnology applications for the environment have focused on bioremediation and the breeding of drought- and flood-tolerant crop varieties. In the domain of natural products, biotechnology has been used in the extraction of metabolites, development of nutraceuticals, phytomedicine and functional foods, and drug discovery.

Agriculture, however, remains an important area of impact for biotechnology due to the importance of assuring food security. Modern biotechnology applications in agriculture may be divided into several broad categories [14], such as:

1. Diagnostic and early detection tools
2. Inputs such as biofertilizers and biopesticides
3. Crop varieties derived from marker-aided selection
4. Crop varieties derived from tissue culture
5. Crop varieties derived from genetic engineering

Diagnostic kits produced from biotechnology include those for confirming specific animal and plant diseases; many are based on immunology, e.g., the kit for detecting the fungus causing rice blast disease, Magnaporthe grisea, allows the detection of the fungus and also confirm its identity. With increasing trade in biotechnology products, the detection of the low-level presence of genetically modified ingredients in traded products has also spawned an industry to help countries meet international reporting requirements.

The biopesticide and biofertilizer industries have grown in recent years due to two factors: The demand by the organic foods sector for substitutes to synthetic chemical fertilizers and pesticides, and the demand for reduced dependency on petroleum-based fertilizers and pesticides. This has also been supported by scientific breakthroughs in isolating microbes and engineering them for increased efficiency as fertilizers and pesticides.

Marker-aided selection makes use of information from genetic markers, which indicates the presence of specific major genes in a crop parent used in plant breeding; this makes breeding less of a process based on phenotypes and more based on genotypes. Crop varieties derived from tissue culture are also grown widely, especially through the planting of clones from the same genetic background, such as the large areas of rubber and oil palm in Southeast Asia. The adoption and use of diagnostics, biofertilizers, biopesticides, marker-aided selection, and tissue culture techniques are widespread across the Asia-Pacific region.

Status of Biotechnology Crops

Biotechnology crops, also known as genetically engineered crop varieties or genetically modified (GM) plants, are the most widespread and high-valued of all modern biotechnology applications in agriculture. These biotech crops have shown some impressive double-digit growth rates in areas planted each year since they were first commercialized in 1996, making them the fastest adopted crop technology in the recent history of agriculture [15].

The latest data show that worldwide, an estimated 17.3 million farmers in 28 countries grow 170 million ha of GM crops. James [15] estimated the following value for biotech seeds: 1996, USD93 million; 2000, USD2,429 million; 2005, USD5,714 million; 2006, USD6,670 million; 2007, USD7,773 million; 2008, USD9,045 million; 2009, USD10,607 million; 2010, USD11,780 million; 2011, USD13,251 million; and 2012, USD14,840 million, showing how in less than two decades, the value multiplication has been over 15,000%!

However the use of GM plants has not been as far-reaching as need demands. So far, only six countries in the Asian region have GM crops under commercial cultivation: India, PR China, the Philippines, Australia, and most recently Pakistan and Myanmar. Some details follow.

India has seen record high adoption rates since 2002 when Bt cotton was first commercialized. The area under Bt cotton increased from 50,000 ha in 2002 to 10.8 million ha in 2012 (equivalent to an adoption rate of more than 90%) [15]. The deployment of Bt cotton over the last eight years has resulted in India becoming the number one exporter of cotton globally, as well as the second-largest cotton producer in the world. These are important testaments to the increased competitiveness which biotechnology has provided to the Indian cotton industry.

PR China has successfully planted Bt cotton since 1997 and is currently the largest producer of cotton in the world, with 65% of its 5.4 million ha planted with Bt cotton in 2010. In Guangdong province, the principal province for papaya, approximately 90% of the papaya was planted with biotech papaya resistant to papaya ring spot virus. In addition to cotton and papayas, plantations of Bt poplar continued to be grown on approximately 450 ha [15].

The adoption of biotech maize in the Philippines has increased consistently every year since it was first introduced in 2003. In 2010, the Philippines planted close to half a million hectares of biotech maize. An estimated 250,000 farmers planted an average 2 ha of biotech maize. Notably, the area occupied in 2010 by maize with stacked Bt and herbicide tolerance traits was 411,000 ha compared to only 200,000 ha in 2008, reflecting the preference of farmers for stacked traits and the benefits they offer over single traits.

There still exists significant opportunities to increase the use of biotechnology in agriculture for food, feed and fiber in Asia. This is supported by analysts' reports of the extensive pipeline of biotechnology crops that exists globally [16].

Issues in Agricultural Competitiveness Addressed by Biotechnology

Competitiveness has been addressed from a number of different perspectives in various literature [17]. Researchers focusing on the national level have defined competitiveness as the ability to sustain an acceptable growth rate and a real standard of living for the citizenry, while efficiently providing employment and maintaining the growth potential, as well as the standard of living for future generations. This definition is linked to a nation's employment and consequently, the standard of living of its citizens. However, the level of national employment, growth of employment, and the standard of living in an economy depends on the competitiveness of firms within the country. Hence, a nation's competitiveness depends on the underlying factors that influence the competitiveness of individual firms and industries.

Other definitions contrast competitiveness with comparative advantage. The law of comparative advantage suggests that trade flows occur as the result of relative opportunity-cost differentials between countries. This may not apply to a more realistic world with market-distorting government policies and competitiveness. So it may be possible to view competitiveness from a national perspective, suggesting that government policy affects competitiveness. An example is biotechnology to explain the competitiveness between North America and the European Union, in which biotech crops have given the North Americans an advantage due to strong supportive policies that foster innovation. Later, this section will detail how biotechnology improves competitiveness. Thus, a description of the linkages between the sources and indicators of competitiveness must account for the effects of government policies and consumer demand.

Porter M. suggests that firms, rather than nations, compete with one another in international markets [18]. When competitiveness is considered, the emphasis must be placed not on the economy as a whole, but on specific industries and industry segments. Competitive advantage results from the difference between the value a firm is able to create for its buyers and the cost of creating that value. Superior value results when a firm offers lower prices than its competitors for equivalent benefits or provides unique benefits that more than offset a higher price.

These results raise the question: if a firm is profitable, is it necessarily competitive? Various economists have put firm-level definitions of competitiveness forward. For example, competitiveness is defined as the ability to deliver goods and services at the time, at the place, and in the form sought by buyers at prices as good as or better than those of other suppliers, while earning at least opportunity costs on the resources employed [19]. This definition, though it views competitiveness from the perspective of the firm, fails to address the sources that give firms the ability to deliver goods or services at "competitive" prices. Another view of competitiveness is that it is the sustained ability to profitably gain and maintain market share in domestic or foreign markets. This firm perspective explains competitiveness in terms of performance indicators (e.g., net worth, profitability. and market share). These definitions contrast the differing approaches used to analyze competitiveness [17].

Competitiveness in agriculture can occur between any number of entities such as between farmers for markets, between companies specializing in similar products, between companies producing different products with the same application, between different sectors, and between countries.

For developing countries, a pragmatic view of national agriculture competitiveness is that given by the Southeast Asia Center for Graduate Study and Research in Agriculture (SEARCA):

- Agricultural competitiveness is defined as the sustained ability of a country's agriculture sector to participate and compete in a given domestic or foreign market.

- Agricultural competitiveness needs to be mindful of food security and rural poverty alleviation as overriding goals. Agricultural competitiveness is not just about revenue generation by big businesses.

- Along this line, the concept of agricultural competitiveness is intrinsically linked to natural resource endowment and management, and hence to rural people, their livelihoods, and rural growth [20].

The competitiveness of a nation's specific sector in international markets is clearly related to the relative quality of its products and the quantity of resources available to that sector in the country. SEARCA has explicitly addressed the issue of loss of livelihood as a result of displacement by competitors, putting a social aspect to managing competitiveness. Two questions are particularly germane to competitiveness:

- Can a food product be produced at the same or lower cost, i.e., is there a *comparative advantage*?

- Are resources that can be put to other more economically beneficial activities being used to produce food products, i.e., is there an *opportunity cost*?

The answer to the first question would suggest that entities that produce higher quantities at higher quality, as well as cheaper products would, over the mid- to long term, outpace their competitors, thereby forcing some to fail. The second question is a more macro one as it would suggest that if insufficient investment is made in food production, a country's exports might not remain competitive in a completely free market system, especially in developing countries.

The literature shows that agricultural competitiveness is affected by endogenous and exogenous factors such as:

- Production technology
- Infrastructure development
- Domestic and international markets and marketing environment
- R&D and policy environment
- Desired social and development goals

For small firms and farmers in Asia, firm-level factors are a) those that affect the firm's relative cost of production, such as input costs (chemicals, labor, etc.), and profitability; and b) those that affect the quality, or perceived quality, of its product or business enterprise [21]. In practice, improved competitiveness in agriculture through individual farmers and firms may be obtained by:

- Reducing input costs
- Increasing yield
- Improving product quality

All three have been achieved through biotechnology crop varieties. A case study is given below on Bt crops in India, in which 12 years of data were analyzed by James, 2012 [15]. Table 3 shows the competitiveness factors directly attributable to biotechnology, and the range of advantages conferred by biotechnology.

Table 3. Competitiveness factors improved by biotechnology crops

Competitive factor	Biotech Crop Trait	Effect
Input cost: pesticides	Bt (All crops)	Reduced cost to farmer
Input cost: labor for pest control	Bt (All crops)	Reduced cost to farmer
Product quality	Bt (Maize)	Reduced molds and mycotoxins

(...continued)

Competitive factor	Biotech Crop Trait	Effect
Product quality	Delayed senescence	Extended shelf life and freshness of fruits and vegetables
Farmer health	Bt (All crops)	Reduced exposure to pesticides and reduced medical expenses
Environmental health	Bt Herbicide tolerance (All crops)	Resurgent populations of beneficial organisms in agro-ecosystems
Net Profit	All traits	Increased profit per hectare to farmers; Cheaper product

Note: Bt, Bacillus thuringiensis.

A detailed study of biotechnology traits in India by James is shown in Table 4, and affirms the significant benefits conferred [15].

Table 4. Summary of 12 Indian studies on benefits of Bt cotton, 1998–2010

Production factor	Metric range
Yield increase	31% to 60%–90%
Reduction in number of insecticide applications	21% to 75%
Increased profit	50% to 110%
Average increase in profit per hectare	USD76 to USD250

Source: James, 2012, Table 18 [15].
Note: Maximum increase in trials ranged between 60%–90%.

The data shows that biotechnology crop competitiveness is conferred directly through input cost reduction, improved product quality, and profitability. In addition, other positive outcomes such as improved farmers' health and environmental quality contribute to competitiveness and sustainability. All competitiveness factors were increased by over 10%, each attributable to biotechnology. Apart from the above, biotechnology crops confer stability of production every season to assure product buyers continued access to the food, and food or fiber products.

In PR China, biotechnology crops have proven to be farm-size neutral and led to decreased input costs as early as 2000 [22]. After more years of Bt cotton in PR China, the benefits continue [17]. When input costs (seed, insecticide and labor) were taken together, the Bt cotton had 22% lower costs than the non-Bt susceptible varieties. In addition, comparable farms of Bt cotton out-yielded non-Bt by double digit percentages. Also, the Bt varieties had 82% less insecticide applied to them than the non-Bt. It would also appear that the income change in growing Bt cotton benefited the smaller farms.

James has further pointed out that in the years indicated, there has been a 49% productivity gain of 328 million metric tons (MMT) (1996–2011) and 78% or 50.2 MMT (2011) from biotech soybean, maize, cotton, and canola at the macro global level [15]. Also in the same periods, biotech crops have reduced cost of ploughing by 51% (1996–2011) and 22% (2011). Total economic benefits accrued amounted to USD98.2 billion (1996–2011) and USD19.75 billion (2011), globally. Every country that grows biotechnology crops has seen its competitiveness increase against those that do not grow biotech crops.

ISSUES IN FOOD SECURITY ADDRESSED BY BIOTECHNOLOGY

In order to explicate the link between biotechnology and food security, this section will firstly discuss food security in today's context, followed by an elaboration of the factors which affect food security, and finally explain how biotechnology may offer solutions to ameliorate the effect of these factors on food security.

Scope of Food Security

Needless to say, Asia faces formidable challenges in producing enough food, feed and fiber for an increasing population. It is still under constraints of land, water, and labor. Food security, on which political stability and economic development are so dependent, is under tremendous challenge in Asia. Food security is the raison d'être for agriculture and makes agriculture a renewed priority for many Asian governments today. While it has had remarkable success in reducing poverty and hunger over the years, Asia still suffers from high levels of food insecurity and malnutrition [23].

In 1996, the Food and Agricultural Organization of the United Nations (FAO) moved away from the initial focus on food supply, and redefined food security as a condition "when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life." [24]

This definition may be interpreted to suggest that food security can only be achieved if the following four basic dimensions are simultaneously met: availability, physical access, economic access, and utilization, which has been conceptualized into a four dimensional food security model [23]. The FAO often adds a fifth dimension, stability, to emphasize the importance of the stability of the four dimensions over time. While each dimension is necessary for overall food security, they may weigh differently in a rural setting as compared with an urban setting, and even across countries with different incomes and net food trade balances [23].

The first dimension of food security, food availability, addresses the food supply aspect, whether through primary production of crops and animals, reserve stock levels, or food imports. Raising agricultural productivity is the main need of countries that are dependent on their own agriculture to supply most of the country's food requirement. On the other hand, imports and reserves play a larger role in net-food importing countries such as Singapore and Hong Kong. Within a region, stable agricultural systems are essential to ensure surpluses which allow food trade by importing countries. While food availability is necessary, it is not sufficient on its own to ensure food security at the household level.

The second dimension of food security is physical access to food. Consumers and, in particular, vulnerable households must be able to physically reach food supplies, whether through their own production or through the marketplace. Physical access to food is affected by civil disturbances, war and conflict, poor infrastructure, inadequate logistics for food distribution and market imperfections. A rising middle-class in Asia demanding exotic food products has also seen market supply chains become longer and originating from other geographic regions. The level of science and technology in a country can heavily influence the availability and physical access dimensions of food security. Countries that have invested more in agricultural research and development, whether through better seeds and inputs, or better postharvest and processing technologies or better infrastructure, generally have higher agricultural productivity levels and incur lower losses in food production and distribution.

Economic access to food (the ability of a household to buy the food it requires) is the third dimension critical for food security. This weighs in more heavily in an urban setting where poorer consumers can spend a significant proportion of their household budget on food. Factors that influence this dimension include employment and income security, macro-economic policies and, of course, market prices. Managing this dimension is key to ensure access to affordable food since any small increase in price can result in fewer meals a day for the more vulnerable sectors of society, becoming a catalyst for civil disobedience.

The fourth dimension in food security is food utilization, which is typically reflected in the nutritional status of an individual and generally reflects food quality, nutrition (diet), and food safety. Factors that can influence this dimension include the quantity and quality of food, general childcare and feeding practices, food preparation, food storage, and an individual's health status [25]. It is not sufficient to have enough food if it cannot be consumed properly due to poor health, or if food safety is wanting. As the distance between consumers and the source of food increases in urban areas, there is a greater need to ensure the freshness and safety of foods as they are transported over longer distances.

The interplay of a range of interconnected factors operating at various levels strongly suggests that different sets of policies, services, and interventions will be required to help countries develop comprehensive solutions to food security. The need to maintain an acceptable level of food security supports the FAO designation of food stability as the fifth dimension in its definition.

Factors Influencing Food Security in Asia

Currently, the food security ecosystem in Asia is under significant pressure from a number of factors, some of which may be ameliorated using biotechnology [3]. The factors influencing food security may be grouped into factors causing chronic food security and factors causing acute food security.

Chronic factors are demographic changes, HIV, poverty, underinvestment in infrastructure and technology, climate change, degraded natural resource bases, unfriendly policies towards farmers, declining number of and ageing farmers, and globalisation. Acute food security factors are severe weather disruptions, natural calamities, pest and disease outbreaks, rising energy prices, competition from the energy sector, sudden policy changes (e.g., trade policies), lower holdings of cereal stocks (hoarding), diversion from staple to cash crops, conflict/terrorist activities, economic factors, price hikes, food safety/contamination, alternative uses of biomass, and human health crises (e.g., SARS).

Climate change will further aggravate the natural resource situation through higher and more variable temperatures, changes in precipitation patterns, and increased occurrences of extreme weather events [26]. According to recent projections by the International Food Policy Research Institute, Asia's production of irrigated wheat and rice will be 14% and 11% lower, respectively, in 2050 than in 2000 due to climate change [2].

Role of Biotechnology in Food Security

In the preceding sections, the scope of food security and the forces influencing food security, were discussed. In the context of biotechnology's role, the main biotechnology application in food security has been through biotech crops and their impact on making more food and feed available, as noted previously.

More specifically, biotechnology can address the following issues in food security:

- Provide surplus food production: more with less; price stability
- Provide labor-saving production technology
- Reduce negative externalities, e.g., pesticide pollution
- Reduce effects of environmental stress (drought, floods)
- Reduce effects of biotic stress (pests, diseases)
- Improve nutritional and safety value of food
- Increase trade in food

Some of these were discussed in the earlier section on competitiveness, but not in the context of food security. The role that biotechnology plays to address each dimension of food security (availability, physical access, economic access, and utilization) varies. Key parameters influencing food availability through production, with their corresponding biotechnology crop trait, are as follows:

- *Crop yield*: Bt/herbicide tolerance, improved photosynthesis, disease resistance
- *Access to technology*: Herbicide tolerance, conservation tillage
- *Competing uses for biofuel*: Bt/herbicide tolerance
- *Competing uses for animal feed*: Phytase
- *Environmental factors such as frequency of severe weather*: drought tolerance, submergence tolerance, heat-stress tolerance
- *Degraded land*: Tolerance to salinity
- *Nutritional quality*: Enhanced nutritive value of biotechnology crop such as high iron; and
- *Freshness*: Delayed senescence [16]

Stresses such as those arising from environmental and biotic stresses cause reductions in crop yield; the traits in biotechnology crops that reduce the effects of stresses on agricultural production are among the most beneficial to food security. By reducing crop losses due to stresses, any surplus production would enable the countryside to feed those living in cities.

Assuring physical access to food requires that food be transported from farm to consumer via a supply chain involving logistics and infrastructure. In developing countries where modern cold-chain management to preserve freshness of perishable foodstuffs is lacking, biotechnology crops can provide traits through delayed senescence genes, which prolong the shelf life of fruits and vegetables. Traits such as Bt have also been shown to reduce the level of mycotoxins in maize during transport. In times of conflict, or when there is delay in the transport of food, such traits can mean the difference between having edible food and unsafe food. Another aspect of physical access to food is through trade. Increasingly, biotechnology tools like detection kits or polymerase chain reaction (PCR) allow traders to comply with international agreements, such as the Cartagena Protocol on Biosafety, since most of the maize and soybeans grown in the world are varieties of biotechnology crops. Asia especially imports most of the world's surplus maize and soybean to feed animals in response to the increasing demand for protein. Biotechnology-based detection kits facilitate trade and movement of biotech crops, without which Asia will not be able to meet its protein demand.

Economic access to food is strongly influenced by the price for key food commodities such as soybeans, maize, and some vegetables. Biotechnology crops, by assuring stability and surplus in production, have generally kept prices down except during extreme weather events that cause significant crop loss. The situation could have been worse since the 2007–08 food supply disruption crisis, which only led to occasional price hikes. Traits like drought-tolerance in maize and submergence-tolerance in rice have ensured some level of agriculture in spite of extreme weather. In the case of vegetables, biotechnology traits such as virus-resistance have prevented losses, which disrupt supply resulting in lowered economic access to food. Studies have shown that any rise in food prices increases the proportion of the populace who go hungry.

Food utilization is strongly dependent on the nutritive value of the food and its safety for consumption. Biotechnology traits, such as increased levels of omega-3 fatty acid and vitamin A, have both been designed to improve foodstuffs such as soybean and rice. Delayed ripening and Bt traits assure safety through freshness, while detection kits allow rapid tests for certain bacteria.

SUMMARY AND CONCLUDING REMARKS

The analysis in this paper affirms an underpinning feature of food security today, which is that national food security is strongly linked to regional and global food security due to the many aspects of the globalizing economy and international food supply chains. These are especially true for the major food commodities such as wheat, maize, and soybeans. Hence, any proactive approach to managing food security in Asia must be cognizant of general developments and situations in other world regions. A food insecurity situation in one country may well precipitate supply disruptions to another country due to increased competition for the same goods.

The challenge facing researchers and planners alike is how to use modern science and technology to develop measures that will ameliorate the anticipated disruptive effects on agriculture (and consequently food security).

Competitiveness and food security are two attributes in any country's economic development, which have to be maintained, if not improved. With the growing competition from alternate producers of the same food product, countries and companies have to continuously innovate to reduce cost, improve quality and generally improve profitability. Biotechnology offers many opportunities to enhance competitiveness, especially crops with biotechnology traits such as Bt and herbicide resistance, which improve productivity.

Food security is essential to allow economic development. Food security is multi-dimensional and comprises food availability, physical access, economic access, and utilization. All four of these aspects are underpinned by stability. Food availability consists of food production, imports, and reserves. Food production is key to ensure surplus food through high crop yields, minimal losses due to pests, diseases and environmental stress, and assuring quality, all of which require biotechnology traits. Without surplus production, it would not be possible to have food security. Biotechnology tools such as detection kits facilitate physical access through trade and logistical support of safety.

Economic access to food means affordability stemming from surpluses and a stable supply of food. Any disruptions in the supply chain will likely raise prices and result in more hungry people. The food utilization dimension of food security is premised on nutritive value and food safety. Biotechnology can confer traits in crop varieties that preserve freshness, ensure mycotoxin-free commodities, and longer shelf life of fruits and vegetables. Overall, biotechnology has only just begun to confer benefits to agriculture and food trade.

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PROMOTING SAFE BIOTECHNOLOGY PRACTICES IN ASIA AND THE PACIFIC

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INTRODUCTION

The Asia-Pacific region comprises three developed and 38 developing countries of Southeast Asia, South and Southwest Asia, Central Asia, East Asia, and the Pacific islands [1]. It accounts for 38.6% of the global land area and 59.2% of the population, with nearly 2 billion of its 4 billion people engaged in agriculture in one form or the other (Figure 1). The Asia-Pacific region contributes significantly to world agricultural production. More than 70% of the world's vegetables are produced in the region, as well as between 46% and 51% of other commodities like cereals, roots and tubers, pulses, and fruits. However, agricultural productivity varies greatly among and within the countries and has been highly unstable over the years. The resulting volatility in food prices, combined with growing demand due to burgeoning populations, as well as increasing purchasing power of rising social classes pose challenges to the goal of achieving food and nutrition security, particularly in developing countries. South Asia continues to show below world average calorie consumption and the world's largest number of undernourished people (552 million), live in Asia [2, 3]. PR China and Japan figure among the world's top five importers of agricultural commodities [4]. Between 2010 and 2012, agricultural imports by PR China increased from EUR50 billion to EUR82 billion, while those by Japan increased from EUR40 billion to EUR50 billion.

There is an obvious need for increasing agricultural output while reducing the cost and environmental impact of production. One of the means of achieving this objective is to adopt modern technologies, including biotechnology, that improve productivity, reduce use of inputs, and enable remunerative production even under adverse cultivation environments. This article briefly reviews the status and potential of biotechnology to meet food and other agricultural commodity needs with particular reference to the Asia-Pacific region.

BIOTECHNOLOGY POLICY AND INVESTMENT

Most countries in the region recognize agriculture as an important driver of economic growth, and essential for overall self-sufficiency, food security, and social welfare. A number of countries have established large national agricultural R&D systems with proven track records of contribution to both the food security and economy of the country. The remarkable improvement in agricultural productivity and farmers' incomes in Asia brought about during the Green Revolution was largely driven by R&D efforts of public agricultural research systems [5]. Even at present, much of the research and variety development of major staple crops in the region's developing countries is generated by public-sector institutions.

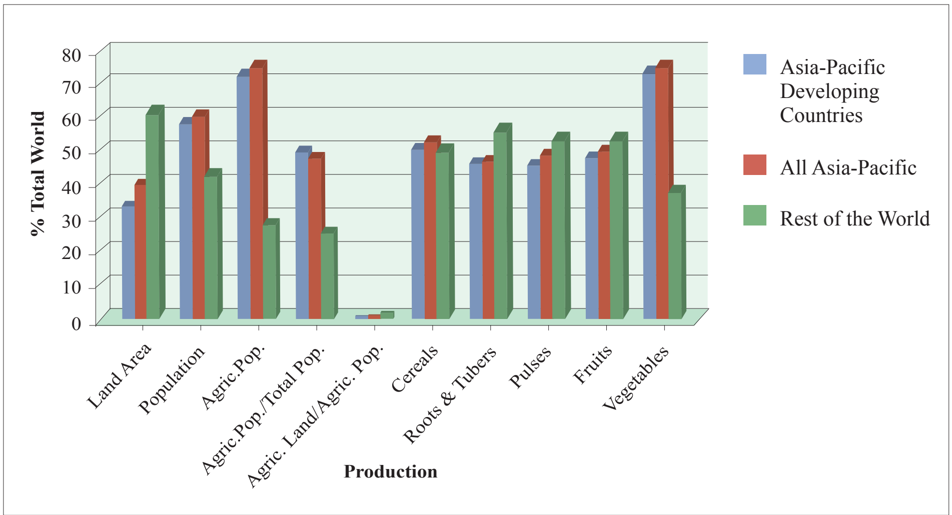

Figure 1. Land, population and agricultural production in the Asia-Pacific in relation to world statistics. Agric., Agricultural; Pop., Population.

Source: Food and Agricultural Organization of the United Nations–Regional Office for Asia and the Pacific in relation to world statistics [1].

For the region's developing countries, the public sector is the most prominent investor in agricultural research, development and commercialization. PR China, India, and Thailand are the three largest public investors in agriculture with a total spending of USD88.68 billion, USD23.46 billion, and USD6.31 billion in purchase power parity (PPP) terms (constant 2005 USD) in 2007, respectively [6]. India and PR China made the largest increases in agricultural R&D investment from 2000 onwards, whereas investment by the rest of Asia-Pacific countries taken together increased marginally.

In India, public-sector investment in agricultural R&D grew from USD271.8 million in 1994–95 to USD563.2–USD688.3 million in 2008–09 (PPP constant 2005 USD) [7]. During the same period, private-sector investment grew from USD54 million to USD251.3 million raising its share of total investment from 16.6% to between 26.7% and 30.9%. Overall investment in the biotechnology sector in India has grown from USD521 million in 2002–03 to USD4 billion in 2010–11 [8]. The top private seed companies, Nuziveed Seeds, Rassi Seeds, Mahyco, Ankur Seeds, Krishidhan Seeds, and Monsanto also have substantial presence in the Bt cotton seed market, cotton being the only genetically modified (GM) crop released in India so far.

AGRICULTURAL BIOTECHNOLOGY RESEARCH AND COMMERCIALIZATION

Several Asia-Pacific countries have been pursuing R&D in a number of biotechnology areas including tissue culture, GM crops, fermentation technology, induced mutations, genomics, biopesticides and biofertilizers, marker-assisted breeding, assisted reproductive technologies in farm animals, and diagnostics [9,10]. Gupta et al. [11] summarized the progress in research and development of GM crops in the region. In 2013, the Food and Agriculture Organization of the United Nations (FAO) conducted an email survey on GM crops and products in the pipeline, which provides information on the ongoing GM crops R&D activities in several developing countries' laboratories [12]. Perusal of these reports indicates that both developed and developing countries in Asia-Pacific are vigorously pursuing the option of genetic modification to improve their major crops. Almost all the important staple and industrial crops in different countries are being genetically modified for traits like biotic and abiotic stress resistance, nutritional quality, growth behaviour, yield, and other useful traits. Most experiments are in the laboratory phase whereas in India, PR China, the Philippines, Indonesia, and Pakistan, a number of crops and events are at field-trial phase.

Table 1 lists the GM crops and traits approved for food, feed, or commercial cultivation in the Asia-Pacific region. The majority of these represent events and/or products developed in other countries and imported for food, feed, or processing. In crops meant for commercial cultivation, most often the events have been transferred to local germplasm in the respective countries.

Table 1. GM crops, traits, and events approved for various purposes and under cultivation in the Asia-Pacific countries

Country	Approved for food or livestock feed or cultivation		Under cultivation	
	Crop, (traits)	**Events**	**Crop**	**Area (million hectares)**
Australia	Alfalfa (HT), Argentine canola (HT, PC), carnation (HT, MC), cotton (HT, IR), maize (HT, IR, OQ), potato (IR, VR), rice (HT), soybean (HT, MO), sugarbeet (HT)	100	Argentine canola, cotton	0.6
Bangladesh	Eggplant (IR)	1	–	–
PR China	Argentine canola (HT, PC), cotton (HT, IR), papaya (VR), petunia (MC), maize (HT, IR, OQ), poplar (IR), soybean (HT), sweet pepper (VR), tomato (AFR, VR)	55	Cotton, papaya, tomato, sweet pepper	4.2
Japan	Alfalfa (HT), Argentine canola (HT, PC), carnation (HT, MC), cotton (HT, IR), maize (HT, IR), potato (IR, VR), soybean (HT, MO), sugarbeet (HT), tomato (AFR)	201	–	–
India	Cotton (IR)	6	Cotton	11.0
Indonesia	Maize (IR), soybean (HT, IR), sugarcane (AR)	12	–	–
Myanmar	Cotton (IR)	1	Cotton	0.3
Republic of Korea	Alfalfa (HT), Argentine canola (HT, PC), cotton (HT, IR), maize (HT IR), potato (IR, VR), soybean (HT), sugarbeet (HT)	113	–	–
Malaysia	Maize (IR), soybean (HT)	18	–	–
Pakistan	Cotton (IR)	2	Cotton	2.8
Philippines	Alfalfa (HT), Argentine canola (HT), cotton (IR, HT), maize (IR, HT), potato (IR, VR), soybean (HT), sugarbeet (HT)	74	Maize	0.8
Republic of China	Maize (HT, IR), soybean (HT, MO)	75	–	–

Sources: Center for Environmental Risk Assessment (CERA) [62]; The International Service for the Acquisition of Agri-biotech; Applcations (ISAAA) [63].

Notes: AFR, altered fruit ripening; AR, abiotic resistant; GM, genetically modified; HT, herbicide tolerant; IR, insect resistant; MC, modified color; MO, modified oil composition; OQ, other quality traits; PC, pollination control; VR, virus resistant.

GM crops are under commercial cultivation in PR China, India, Myanmar, Pakistan, and the Philippines. Detailed case studies on adoption, field performance, economic, and social impacts of GM crops being grown in some Asia-Pacific countries have been published [13–19]. With regard to Bt cotton in India, the studies reveal that Bt cotton adoption has increased from 29,000 ha in 2002–03 to 11.14 million ha in 2011–12, and production increased from 1.6 million bales to 3.53 million bales. Pesticide spraying has been reduced by about 30% resulting in savings of USD20–USD24/ha. The increased yield and savings on inputs have led to an increase in profitability of farmers by USD82–USD365/ha. Raw cotton exports by India increased from USD16.5 million in 2002–03 to USD2.6 billion in 2010 taking the country from fifth to second position among cotton-exporting countries [20]. Substantial benefits have also been reported from Bt maize cultivation in the Philippines, where smallholder farmers adopting the technology increased their net farm as well as off-farm and household income [21].

Due to perceived environmental and health risks associated with GM technology, regulation has become an integral component of GM research and product development. Accordingly, international and national instruments have been framed to regulate development, cultivation, and commercialization of GM crops. In the Asia-Pacific region, Australia, Bangladesh, PR China, India, Indonesia, IR Iran, Japan, Malaysia, Myanmar, Pakistan, Philippines, Republic of Korea (ROK), Thailand, Vietnam, and the Republic of China (ROC) have developed and enforced national biosafety regulations. Regulations are at various stages of development in Bhutan, Democratic People's Republic of Korea (DPRK), Laos, Nepal, Pacific countries, and Sri Lanka [11, 22].

Extensive scientific data have been generated for nearly two decades on the various safety aspects of GM crops [23]. Most of the studies indicate that GM crops are safe for human health and the environment. Moreover, consumption of GM crops and products ever since their commercialization in the USA and other countries has not brought to light any adverse health effects. It is also worth noting that several countries opposed to human consumption and cultivation of GM crops import large quantities of GM crop products for animal feed. For example, during 2012, more that 90% of the soybean meal imported by the European Union (EU) was from Argentina and Brazil in which 92% to nearly 100% of soybean under cultivation is GM [4, 19].

Other biotechnological interventions have also contributed significantly to agricultural development and farm income [9, 10]. Tissue culture for mass multiplication of ornamentals and plantation crops is a global industry of long standing [24]. Smallholder farmers in a number of the Asia-Pacific countries have successfully adopted tissue culture-developed seedlings of potato, sugarcane, sweet potato, banana, and date palm [25–29]. Studies carried out in PR China, Vietnam, India, and some African countries have shown that farmers adopting the technology have gained through higher yields, better quality of produce, and higher incomes [27–28]. At the same time, micro-enterprises for producing disease-free propagating material have developed in rural areas, enabling additional local employment.

Marker-assisted breeding, genomics, and related technologies are becoming integral components of both public and private sector breeding programs [30–32]. The application of molecular breeding approaches such as marker-assisted selection, marker-assisted backcross breeding, and genome-wide selection, render greater precision to breeding programs and help the faster development of germplasm and varieties with desired traits.

Marker-assisted selection was used by the International Crop Research Institute for Semi-Arid Tropics (ICRISAT) to develop the powdery-mildew-resistant pearl millet hybrid "HHB 67-improved" [33]. Bacterial blight resistant varieties of rice have been developed in PR China and India through marker-assisted selection. At the International Rice Research Institute (IRRI), submergence tolerance gene (SUB1A) was introgressed into popular rice variety "IR 64" using molecular breeding to develop "IR 64 sub-1." The gene has also been used as a donor for developing submergence tolerant rice varieties in India, Bangladesh, and Nepal [34]. In India, "Improved Pusa Basmati 1" and "Pusa Sugandh 6" rice varieties having resistance to bacterial blight and blast, respectively, were developed through marker-assisted backcross breeding and pyramiding [35–38].

Induced mutations have long been used to develop improved crop varieties [39]. To date, 3,218 mutant crop varieties have been developed the world over including in PR China, India, Pakistan, and Vietnam [40]. In Vietnam, the large-scale adoption of mutant rice varieties with high food quality and tolerance to salinity has led to increases in farmers' incomes by USD350/year [41].

FUTURE CHALLENGES AND THE WAY AHEAD

The United Nations estimates that the world population will reach 9.5 billion by 2050, 5.2 billion of whom will be living in Asia [42]. Some countries in the region with high levels of poverty and malnutrition are likely to experience higher population growth than others. Climate change, predicted to reduce production by up to 50% in tropical countries, poses an added challenge to agriculture in most of the Asia-Pacific countries [43]. Even those countries that presently possess the economic capacity to import food, face the prospect of escalating import bills due to increasing world population, growing prosperity, and changing food habits from predominantly cereal-based diets to meat-, fruit-, and vegetable-based diets. Hence, increasing agricultural productivity and improving the nutritional quality of food should remain essential elements of national policies for growth, development, and welfare. With the already low per capita availability of agricultural land and scarcity of water, R&D efforts need to focus on producing more from less land, water, and other inputs.

As detailed earlier, except for India and PR China, public-sector investment in agricultural R&D in developing countries of the Asia-Pacific region has not increased in real terms during the past few decades. Several studies have shown that public investment in agriculture R&D yields substantial returns on investment and is a very potent strategy for reducing poverty and hunger [6]. Figure 2, showing agricultural R&D investment and crop production growth in India, provides clear evidence of a strong positive correlation between the two. Hence, increasing investment in R&D is imperative to achieve rapid agricultural growth and poverty alleviation.

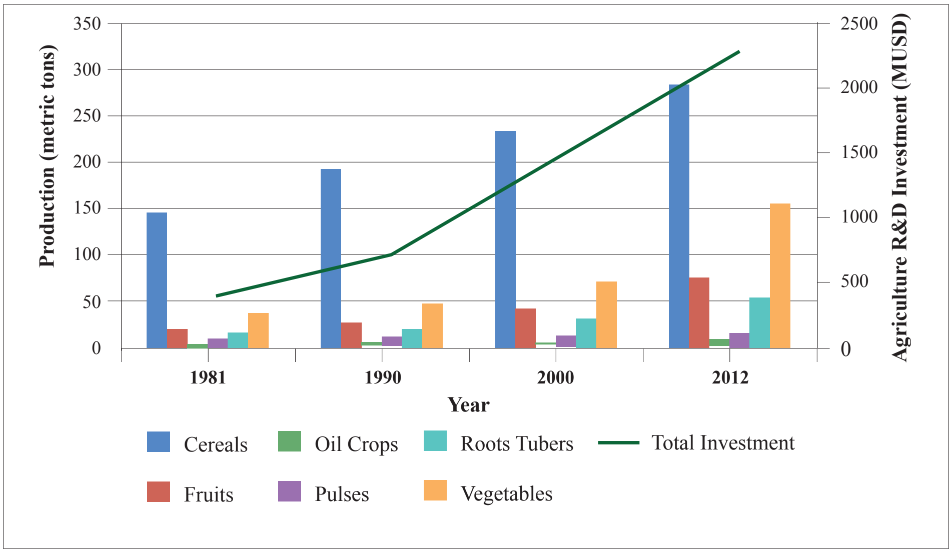

Figure 2. Investment in Agricultural Research and Development, and Production of Major Agricultural Commodities in India during 1981–2012, MUSD, million US dollars.

Source: Food and Agricultural Organization of the United Nations (FAO) [6]; FAO Statistics Division (FAOSTAT) [20]; National Horticulture Board [61].

Along with public investment, private sector investment and participation in agricultural R&D needs to be encouraged through appropriate and stable policies with well-defined terms of participation. Considerable advances in the practical applications of GM technology, molecular breeding, micropropagation, and other biotechnologies have been made in the private sector. Public–private participation can accelerate the transfer of new technologies to public laboratories, technology adaptation to local needs, and adoption by farmers. On the other hand, the private sector needs to invest more in basic and discovery research in developing countries, in addition to variety development and seed production.

Effective adaptation and positioning of technologies to suit local agroecologies, farming systems, and socioeconomic conditions are essential to ensure their uptake and adoption by smallholder farmers. For example, large-scale adoption of tissue-culture-developed potato, banana, and other planting material has become possible through developing low-cost infrastructure and laboratory protocols, as well as integrating laboratory micropropagation with conventional propagation. These have reduced production costs and thus increased affordability for farmers [25, 27, 44]. Along with low-cost, efficient and reliable mass production, delivery systems need to be in place to ensure quality and timely availability for farmers. Furthermore, well-equipped extension services possessing strong linkages with technology experts are essential to ensure that farmers harvest the promised benefits of improved seed and production technologies.

Public acceptance of GM crops is still a matter of considerable debate [45–50]. As detailed in Table 1, only 11 countries in the region have approved GM crops for food/livestock feed and only five actually grow them in farmers' fields. Sharply polarised views in favor of or against GM technology have re-emerged during the past few years, leading to inordinate delays in decision-making and, consequently, uncertainty in GM R&D. The release of Bt eggplant in India and the Philippines has faced several hurdles meaning that years of research, development, and regulatory costs have yet to bear any practical result [51–52].

Other than safety concerns, fears that multinationals will dominate the national seed sector and that farmers will have less control have been the key arguments for those opposing GM technology. A number of steps need to be taken to overcome negative perceptions about GM technology to ensure that its benefits become available to farmers and other stakeholders while ensuring safety of health and environment. The countries with biosafety systems in the pipeline need to implement these with the required laws, rules, and regulations, as well as appropriate infrastructure and human resources. Furthermore, regulatory decisions need to be based on transparent and rigorous scientific evaluations.

The regulatory system needs to be dynamic and responsive to evolving scientific and technological developments in biotechnology and biosafety. The system should proactively engage in the review and public communication of public interest reports pertaining to the subject appearing around the world. For example, the European Food Safety Authority (EFSA) reviewed and made public its opinion on a widely reported article on the adverse effect of GM maize on rats soon after it appeared in the press [53–54].

The intervention helped to create a balanced public opinion on the topic, which otherwise would have remained one-sided. There is a need for public-sector organizations involved in R&D in biotechnology to enhance and improve public communication of scientifically accurate and unbiased information on different aspects of biotechnology and biosafety.

The following list of suggestions for promoting the safe application of biotechnology for the benefit of society is based on outputs of several high-level regional policy and technical discussions organized by the Asia-Pacific Association of Agricultural Research Institutions (APAARI), and Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB), in collaboration with national agricultural research systems of the Asia-Pacific region [55–60]:

1. Strengthening agricultural biotechnology R&D and commercialization

- Extend policy support by recognizing biotechnology as an integral component of the strategy to achieve food security and overcome the adverse impacts of climate change on food production.

- Provide appropriate funding support to R&D commensurate with the needs to build required infrastructure and human capacity.

- Adopt need-based biotechnology options along with a complete package of practices for successful adoption by farmers and other stakeholders. Develop technology packages that are especially suited to smallholders.

- Encourage public–private partnerships through providing the required policy support.

- Develop intellectual property and benefit-sharing policies that facilitate the transfer of technologies to users, while providing a fair share of benefit to technology developers.

2. Improving biosafety regulatory management

- Adopt regulations with robust, science-based, and transparent approval processes.

- Simplify regulatory norms for GM crops and traits of known environment and human safety.

- Build confidence in technology by generating and communicating impartial and reliable science-based information on biotechnology and biosafety.

3. Regional and sub-regional collaboration

- Cooperate and collaborate across countries on biotechnology applications of common interest, biosafety management, and capacity development.

- Align and synergize existing policies, which currently exist under different national competent authorities, within each country and across sub-regional or regional economic/political associations.

- Resolve co-existence and related issues among conventional agriculture, organic farming and GM crop cultivation.

SUMMARY AND CONCLUSION

Growing food and other agricultural commodity needs of Asia-Pacific countries necessitate the adoption of the vast repertoire of tools and techniques offered by biotechnology to improve productivity, efficiency, profitability, and global competitiveness of agriculture. Several examples of the successful applications of tissue culture, molecular breeding, induced mutations, and GM technology exist in the Asia-Pacific region that have benefited smallholder farmers through higher crop production, better incomes, and other social benefits. With the growing demand for food and feed in the face of limited and deteriorating land, water and climate, along with the increasing evidence of its safety, it is anticipated that biotechnology and its products will find increasing acceptance and adoption around the globe. Developing countries of the Asia-Pacific need to accelerate their efforts towards harnessing the benefits of biotechnology through a series of policy and administrative measures. These include increasing investments, promoting R&D, commercialization of appropriate technologies and package of practices, establishing transparent and science-based regulatory systems, effective public communication, and enhancing regional and sub-regional collaboration to facilitate transfer of technologies and products.

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BIOTECHNOLOGY SMES: TOWARDS GLOBAL COMPETITIVENESS

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INTRODUCTION

Similar to many countries, the Republic of China (ROC), has traditionally built its research capacity in the public sector. In the past, the public sector's results in agricultural R&D were regarded as free public property, to be given away gratuitously to agribusinesses and farmers. However, the late 1990s brought the challenges of a global knowledge-based economy. As a result, in 1999 the ROC government introduced a system based on the USA's Bayh–Dole Act, entitled the Fundamental Science and Technology Act. From then on, the ROC Department of Science and Technology's Council of Agriculture (COA) paid more attention to developing advanced measures to improve and strengthen the management, protection, and application of intellectual property rights in ROC agriculture. It also began to transfer or license public R&D results non-gratuitously.

Small and medium-sized enterprises (SMEs) are common in ROC, especially in agriculture. According to recent government statistics, 99% of the 11,800 agricultural companies in ROC are agribusiness SMEs [1]. In ROC, SMEs are defined as business establishments with less than USD3.3 million in gross revenues, or have less than 100 regular employees. These agribusiness SMEs face similar challenges, such as:

- Small scale, with relatively low R&D budgets and manpower input
- Lack of financial support and familiarity with capital markets
- More focus on production, but less effort on management and marketing
- Less integration or interaction between different disciplines

POLICY AND STRATEGY FOR CAPACITY-BUILDING OF AGRIBUSINESS SMES

After understanding the major challenges facing ROC agribusiness SMEs, the government implemented more policies and strategies to help these SMEs elevate their R&D capabilities and business management skills in order to improve their capacity in every aspect. The measures may be classified into six functional types of support, each described in detail in the following sections.

Research and Development

In ROC, basic research is mostly undertaken by universities and the national research institute, the Academia Sinica. Applied research (and some basic research) falls to the 16 affiliated research institutes of the COA. These comprise nine research institutes and seven district agricultural research and extension stations. The R&D results from these research institutes could potentially be directly applicable to farming, or developing new products for farmers and agribusinesses. There exists, therefore, an established agricultural research and extension/transfer framework (Figure 1). In order to accelerate the industrialization of agricultural technologies, the COA encourages agribusiness SMEs to apply these research results and technologies to their business. Furthermore, agribusiness SMEs are encouraged to supplement those results with their own research or prototyping before commercialization.

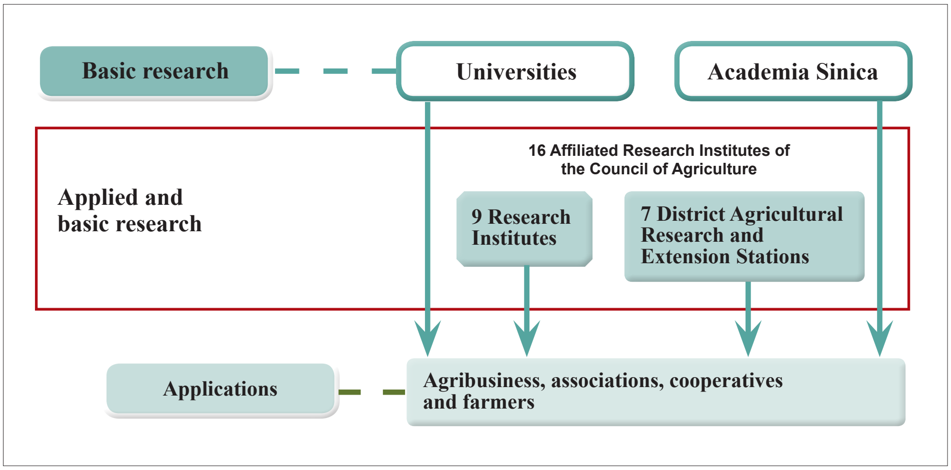

Figure 1. Agricultural Research and Technology Extension or Transfer Framework in ROC.

Since 2004, the COA has offered two kinds of programs to make agribusinesses more competent in commercializing technology. These are the Industry–Academia Cooperation Program and the Industry Technology Development Program. The former aims at promoting cooperation and integrating public and private sector resources. By accelerating commercialization, pre-production prototypes from public sector research are more likely to become manufactured commodities. Under the rules of this program, the related intellectual property rights (IPRs) belong to the public sector, but the cooperative agribusinesses would have first priority to obtain their licenses. Likewise, the Industry Technology Development Program aims to improve agribusiness' ownership of research, especially at the final stage of technology commercialization. In this program, the government's role is only to fund R&D. With their own R&D investment, related IPRs in the Industry Technology Development Program belong to the agribusiness entities, in contrast to the former program.

Financial Support

Financial support is a key element for agribusiness SMEs. To assist them, the COA developed three kinds of financial support programs, which are explained below.

Firstly, SMEs are eligible for a preferential loan if they move into an agricultural technology park. The funds go towards working capital, building, and/or purchasing facilities. The loans are at an interest rate 1.5% lower than the average commercial rate offered by banks and the credit limit is USD2.7 million.

Secondly, considering the agribusinesses specific features, the COA enacted a regulation entitled "Operation Directions for the Contracted Provision of Assessment Opinions Regarding Marketability under Applications by Technology Agribusiness" to hasten an agribusiness's ability to raise funds from the capital market. Once the COA adopts the stock exchange's (both the Taiwan Stock Exchange and the Taipei Exchange) product marketability assessments, an innovative agribusiness company would not be constrained by the prevailing requirements of profitability, or periods of establishment to raise the necessary funding as ruled by both stock exchanges.

Lastly, the COA also enacted a regulation entitled "Operation Directions for the Contracted Provision of Assessment Opinions Regarding Corporate Research under Application by Agribusiness" to treat expenditures for corporate research as investments. Once the COA reviews the proposed research project for risk and, and issues its opinion to the National Taxation Bureau, the agribusiness would have the opportunity to have its taxes reduced.

Human Resources

Human resources are another key factor for the agribusiness sector. To encourage more people to work in agriculture, the COA offers two talent-training programs for agribusiness: the Technology Management Program and the Agribusiness Management Program.

These programs share three features; first, they combine related resources from universities, governments, and industries; second, trainees from both programs can receive cross-disciplinary training; and third, trainees can receive course credits for a master's degree if they complete the program, as well as recognized professional certification, which is provided by the training provider.

The main difference between them is in the courses offered. The Technology Management Program courses include IPR management, technology transfer, finance, innovation, new business models in technology and entrepreneurship. Every year, 50 participants are trained. Since 2005, 400 trainees have completed this program. The trainees not only acquired the related knowledge, but also took the initiative to organize an association to integrate resources from the different disciplines to build their own network.

In contrast, the Agribusiness Management Program is oriented to improve the agribusiness's operational efficiency. The courses in this program comprise management skills training related to production, marketing, human resources, R&D management, finance and accounting, and information services. Every year, 40 participants are trained. Since 2010, 129 trainees have completed the course, and nine of them have applied for advanced studies at the National Taiwan University. The trainees also organized an association of their own.

Production

In 2002, the COA recognized the need to stimulate entrepreneurship in agribusiness SMEs to develop their own technologies and business models, and encouraged its research institutes to set up an SME innovation incubation environment [2]. In 2005, the Livestock Research Institute set up the first innovation incubation center under the COA. In 2009, the Agricultural Research Institute and Fisheries Research Institute established their own centers. These centers offer innovative agribusiness SMEs space and facilities to start up new companies. By July 2013, these three incubation centers had approved 49 resident companies.

Additionally, in 2003 the government approved the "Establishment and Development Program for Agricultural Biotechnology Parks" to promote R&D in agricultural biotechnology products, cultivate talent in agricultural biotechnology, expedite transformation of the agriculture industry, and to improve incubation and marketing functions in both quality and quantity.

There are currently two prominent biotechnology parks in ROC. One is the Pingtung County Agricultural Biotechnology Park (PABP), located in Pingtung County, and the other is Taiwan Orchid Plantation (TOP), located in Tainan City. The former belongs to the COA, and the latter belongs to the local city government. PABP, covering 233 ha, cost USD280 million to construct, and started operations in 2005. As of July 2013, there were 70 resident companies in PABP that had invested about USD192 million. Similarly, TOP was approved for the world-famous orchid industry, and operations began in 2006. Compared to PABP, TOP is smaller in size, construction budget, and resident numbers. However, the quantum of investment by companies in TOP is more than for PABP (Table 1).

Table 1. Comparison of basic data between PABP and TOP

	Pingtung Agricultural Biotechnology Park	Taiwan Orchid Plantation
Operated (year)	2005	2006
Area of park (hectares)	233	175
Budget of capital construction (million USD)	280	62
Park residents (companies)	70	51
Investment of enterprises (million USD)	192	209

Notes: PABP, Pingtung Agricultural Biotechnology Park; TOP, Taiwan Orchid Plantation; USD, United States dollar.

Marketing

Exhibitions are a vital channel for agribusiness SMEs to promote themselves to the market. Every year, three important technology exhibitions are held for agribusinesses; the Taipei International Invention and Technomart, the Bio Taiwan Conferences & Exhibition, and the BIO International Convention held in the USA. The Technomart specially serves as the platform for agribusiness SMEs to accept technologies from the public sector through licensing. The other two exhibitions serve as platforms for them to promote and market their products. Agribusinesses gain access to the exhibitions with the COA's permission. About 30 biotechnology companies may exhibit their products at the Bio Taiwan Conferences & Exhibition, but only about four companies are selected to participate in the BIO International Convention. Even though participation is low, the US BIO International Convention is considered an important channel to reach the global market. For example, Reber Genetics Company, one of the resident companies in PABP, developed a business cooperation relationship with an international vaccine company when they attended the BIO 2012 convention.

Information Dissemination

The COA provides two channels for agribusinesses to obtain information: the Office for Agricultural Technology Industry (AgriTI) and the Taiwan Agriculture TechnoMart (TATM).

Operated by the COA commission, AgriTI is tasked with the mission to facilitate the development, protection, and commercialization of R&D results, as well as the COA's IPRs. AgriTI also provides information and counseling for researchers from all the COA research institutes and agribusinesses to facilitate technology transfers between them on all aspects of intellectual property arising from their research activities. It also assists in the disclosure, development, and legal protection of the COA's inventions to encourage further technical innovation.

The COA also established a TATM website, which is operated by AgriTI. It is the first agricultural technology-licensing platform in ROC. With the collected research results in the COA database, the TATM platform aims to meet agribusiness technology needs, providing complete and timely firsthand technology transfer announcements to all industries. The platform further establishes two-way communication channels to facilitate information exchanges for the COA's research institutes and registered agribusinesses.

Other Support

Besides the six functional support entities mentioned above, the COA has implemented additional programs to help agribusinesses upgrade their managerial capabilities. These include awards for outstanding agribusiness SMEs, providing subsidies for upgrades, commissioning experts to carry out international market analyses for the industry, and offering advisory services for supply chain integration.

Two of these support programs will be further explained. Firstly, the COA developed a four-year Assistance Program for Management Improvement in 2009 to improve the management capacity of agribusinesses. Nine target agricultural science and technology industries were selected, such as flowers, ornamental fish, animal vaccines, and so on. In this program, experts were invited to offer counseling and assistance to help these agribusinesses improve their management. For one company, the program assisted the managers to build up its management capacity. For a center-satellite system operation, the program helped all members within the system to have more consensus and stronger relationships. In the four-year implementation period, the program has improved the business management capacity of 154 businesses and assisted in 11 center-satellite system cases.

Secondly, the COA annually holds an Innovation in Scientific and Technological Agribusiness Award ceremony for agribusinesses that have made outstanding achievements in both technology innovation and application. Five awards for each industry area are granted each year. The honor of receiving this award encourages many agribusiness SMEs to strive for further growth and improvement. Their successful experiences have been broadcast widely for other SMEs to learn from.

PERFORMANCE

The COA has achieved much after investing over 10 years of effort in enhancing the global competitiveness of ROC agribusiness SMEs. These achievements may be viewed from three aspects: technology commercialization, business operation, and industrialization.

Technology Commercialization

Increasing technology transfer from the COA

According to the COA's statistics, the numbers of COA released technologies have been dramatically increasing each year [2]. The number of technologies released in 2012 was 37 times that of 2002, from three to 111, and the corresponding licensing fees and royalties that the COA received increased 65 times from USD39,000 to USD2,549,000. The COA appears to have successfully strengthened the mechanisms of technology commercialization and industrialization (Figure 2).

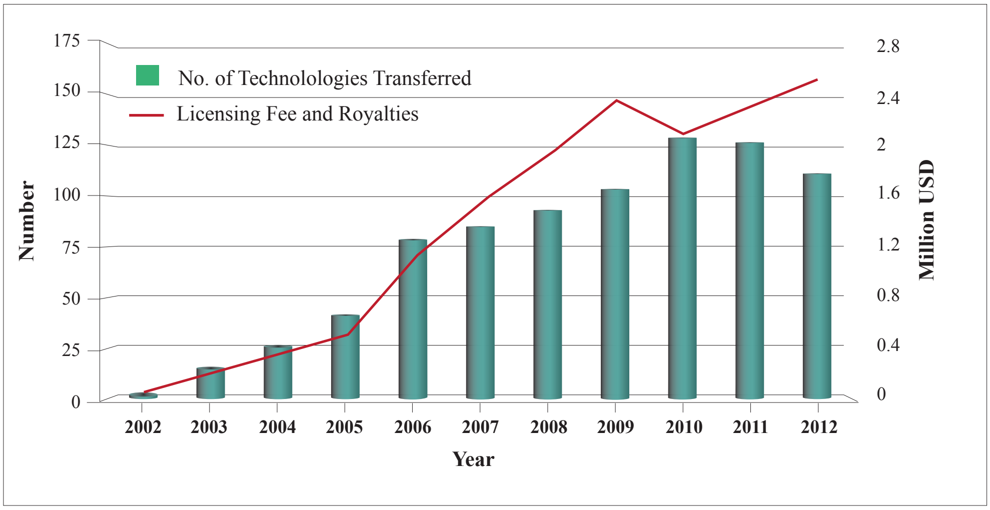

Figure 2. Trend of transferred technologies from 2002 to 2012. USD, United States dollar.

Accelerating R&D and Manufacturing Investment

Achievements in the Industry Technology Development Program illustrate how successfully the program has assisted agribusinesses towards investing in R&D and manufacturing. During 2007–12, there were 41 agribusiness SMEs receiving grants from the program. These agribusiness SMEs invested more than USD6.7 million in R&D, and created 30 innovative products. In total, the derived value reached USD12 million. On average, every dollar input by the COA brought about 5.88 dollars in output [2].

Promoting the Development of New Technologies and Products

Through the implementation of these R&D assistance programs, many new technologies and products were developed by agribusiness SMEs. For example, a green energy lighting technology was designed and fabricated for use in deep-sea fishing. The light-emitting diode fish light attractors significantly increased fish catches. According to a field report, after using this technology for two years, the experimental ship consumed 15% to 20% less fuel than its counterparts. With this equipment, fishing businesses could not only save costs of about USD69,000 per trip, but also contribute to the protection of the environment by using eco-friendly devices.

Another example is the application of high-pressure sterilizing technology to produce high-quality fresh juices. The Chia Meei Company, which is a major raw material supplier for juice production, applied this high-pressure processing technology to limit heat damage, and preserve the natural texture, taste, flavor, and nutrition of its freshly squeezed fruit juices.

Business Operations

Upgrading the Efficiency of the Center-satellite System

The Jy Lin Company is the biggest exporter of ornamental fish in ROC. Its famous green or pink fluorescent fish have been successfully developed as a result of cooperation between universities and the Academia Sinica. Jy Lin cooperates with more than 150 different breeding farms, which allows Jy Lin to offer 400 different kinds of ornamental fish. The cooperation relationship forms a center-satellite system, but not a stable and efficient one. Therefore, the COA assisted the company to implement the enterprise resource planning system in its production and marketing processes. These led to enhanced operating capacities between center and satellite fields, and built a set of systematic marketing strategies for overseas markets.

These initiatives elevated the system's operational efficiency and shortened the communication time between the centers and satellite fields. Jy Lin Company states that customer satisfaction increased and an investment of about USD700,000 has been made to scale up the operation [1].

Enhancing Agribusiness Relationship Networks

Two training programs, the Technology Management Program and Agribusiness Management Program, have given trainees more opportunities to collaborate and interact with other disciplines.

Some cooperation opportunities were even developed by chance discussions. For example, a trainee combined his bamboo charcoal product with his classmate's mouth rinse product to come up with an entirely new product. In addition, some alumni have shared marketing channels, leading to increased cooperation and outreach [1].

With closer relationships, trainees organized their own networks to serve as platforms for innovative marketing. For instance, one group used radio frequency identification (RFID) technology to track the production process of shrimps, while another group created an innovative communication system to connect a shrimp company with a famous restaurant chain. When consumers order the RFID shrimps in the restaurant chain, they can use electronic equipment to understand the production process [2].

Industrialization

Constructing a Value Chain from R&D to Export Market

Cooperation between a research institute and food-processing companies for vegetable soybean is an excellent example of how value chains have been constructed and developed from R&D to export market.

First of all, Kaohsiung's District Agricultural Research and Extension Station bred vegetable soybean varieties Kaohsiung No.6 to No.11 with good flavor, high yield, and suitable attributes for mechanical harvesting. The plant breeder's IPRs were subsequently approved locally in ROC and in Japan. These varieties were licensed to food processing companies and licensing fees and royalties of USD600,000 paid to the breeder over the past ten years. Lastly, the food-processing companies contracted farmers to carry out large-scale cultivation and mechanical harvesting based on a profit-sharing model. The value of these production contracts was USD253 million. In 2012, the value of exports to Japan was USD557 million and the market share was over 40%, which is the largest in the Japanese market [3].

Establishing Innovative Cooperation Models for the Global Market

Another case of successful technology commercialization is the swine atrophic rhinitis vaccine (AR vaccine), the result of academia–industry cooperation between National Chung Hsing University (NCHU) and Ta Foong Veterinary Company (TAVC). After NCHU transferred the AR vaccine production technology to TAVC, Bayer Taiwan Company joined in the venture by offering its international marketing channel. In 2008, this cooperation model enabled the AR vaccine to be sold in the Republic of Korea (ROK), where it captured 14% of the swine vaccine market in the first six months. The licensing fee was just USD20,000, but the running royalty NCHU received was over USD333,000 from 2008 to 2012.

Industrial Clusters within the PABP

PABP has six major industry clusters, namely, natural products for health and cosmetics, agricultural biotechnology products, biotechnical services, aquaculture, animal health and feeds, energy saving, and ecological agro-production systems. In a land area of 233 ha, 70 companies are either in operation or under construction. Some of them lead the way in technology industrialization [3].

Take Reber Genetics Company Limited for example. This company was the first in the world to transfer the porcine reproductive and respiratory syndrome (PRRS) subunit vaccine's production technology from a research institute. It continued to successfully develop the subunit vaccine against PRRS. The advantage that ROC had in animal vaccine R&D attracted a well-known foreign vaccine company to invest more than USD25 million in PABP for building new factories and an R&D center in late 2013.

Furthermore, aquaculture companies in the PABP possess many cutting-edge technologies to breed ornamental fish. These companies have won many championships in various international ornamental fish contests. Their products, such as crown fish, multi-colored crystal shrimp, and transgenic fluorescent fish, have not only been sold domestically, but also exported to foreign markets.

FUTURE PROSPECTS

After making great effort to build all aspects of the capacity of agribusiness SMEs, we expect that these SMEs will eventually reap value through commercialization, business operation, and industrialization. They will also be expected to invest more money towards innovative R&D and commercialization. The COA will continue to keep agribusinesses innovative, value-added, and competitive.

Meanwhile, in the face of increasing international competitiveness, the COA is ready to provide more support for the 10 target potential industries, such as animal vaccines and bio-pesticides, by strengthening internationalization in invention and technology transfers. Based on past R&D results and current technology advantages, it is believed that traditional agribusinesses will be transformed and upgraded, with the result that more innovative products will be created and manufactured in ROC to satisfy requirements around the world.

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7

COUNTRY PAPERS AND CASE STUDIES

AGRICULTURAL BIOTECHNOLOGY IN THE REPUBLIC OF CHINA

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INTRODUCTION

The land area of the Republic of China (ROC) is about 36,000 sq km. Two-thirds of this is mountainous and sloping, with cultivable land only making up 22% of the island. ROC is located in subtropical and tropical regions characterized by high temperatures and heavy rainfall. These conditions are suitable for agriculture, but also favorable for the propagation of insects and diseases. In 2011, ROC's agriculture reached a production value of TWD475.5 billion (USD16.1billion) (Figure 1).

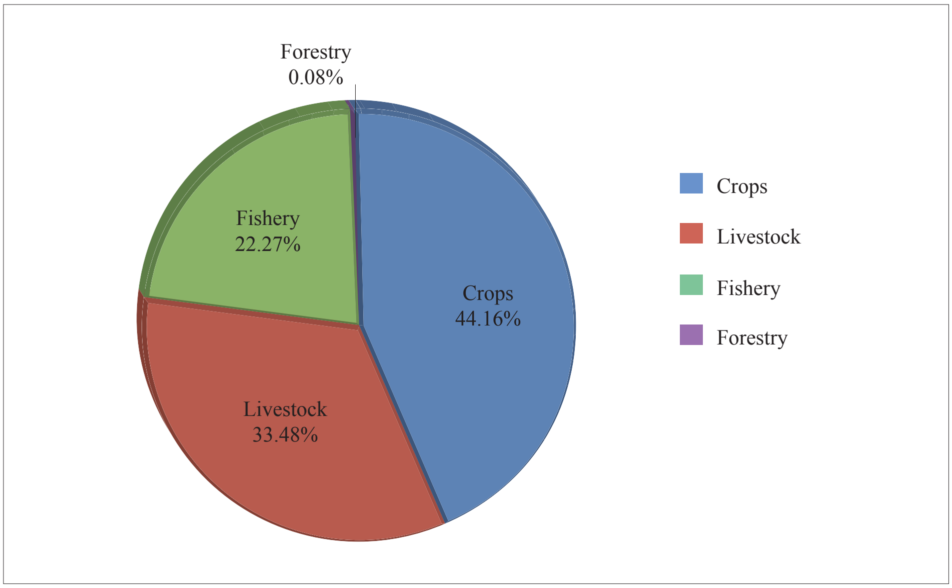

Figure 1. 2011 Republic of China (ROC) agricultural production profile.

Source: 2011 Agricultural Statistics Year Book. Council of Agriculture, Executive Yuan, ROC [1].

ROC's accession to the World Trade Organization in 2002 has created new opportunities for investment and trade. However, the opening of its own domestic market has also made ROC face strong foreign competition.

With the advantages of its geographical location, temperate climate in the mountain areas, and a well-established system that provides solid training to produce agricultural R&D talent, ROC has experienced success in agricultural development. This has given rise to niches for advancing agricultural biotech in ROC and promoting its industrialization.

CURRENT STATUS, MAIN CHALLENGES, AND PRINCIPAL TRENDS

International competition and the global trend towards free trade have placed great pressure on ROC's agriculture industry. This has led to an urgent need to transform the traditional agriculture sector. One of the focal points is agricultural biotech, which serves as an important facilitator for the transformation. In 2011, agricultural biotech in ROC created a value of TWD6.39 billion (USD213 million) [2].

ROC's agricultural biotech operates in a dual-track mode: i.e. to improve the quality of traditional agriculture by combining biotechnology with conventional technologies in breeding, cultivation, husbandry, health inspection, and quarantine, as well as applications of fertilizers, pesticides and feeds, etc. The other is to apply newly developed biotechnologies to advance multi-disciplinary cooperation, thus enhancing innovations in agriculture, medicine, food, and environmental protection terrains.

The advantage of agricultural biotech in ROC lies in the talent present within the interwoven R&D organizations, including agriculture-related research institutes, such as various organs under the Council of Agriculture (COA), universities and colleges, and non-profit organizations. Achievements from the research organizations have successfully initiated investments in the industry.

Besides competition in international agricultural trade, climate change is also an important factor in influencing the transformation of the agriculture sector. Therefore, to establish sustainable agriculture, protect the natural environment, and extend into the world market, the government has legislated various rules to encourage R&D and industry investments in agricultural biotech. These goals led to the establishment of an Agricultural Biotechnology Park.

The advantages ROC has over other countries in the Asia-Pacific region and the rest of the world are as follows:

1. ROC has nurtured and accumulated plentiful human resources for R&D in agricultural technology (crops, livestock, fisheries, and forestry). Research teams are composed of talented people with expertise in agricultural technology.

2. Its tropical and subtropical climate benefits agricultural production. Furthermore, geographically ROC is in a pivotal position within Asia, with prompt access to the markets of PR China, Japan, Southeast Asia, etc.

3. The lower investment threshold for agricultural biotech, as compared to the biomedical industry, enables the agriculture sector to confront international competition. ROC's agricultural biotech sector exhibits strength in vegetables, orchids, tropical crops (flowers and fruits), ornamental fish, and aquaculture (such as grouper farming).

APPLICATIONS OF BIOTECHNOLOGY TO THE AGRICULTURE SECTOR

Inspiring Initiatives

Development Program for Industrialization of Agricultural Biotechnology

Recognizing the critical role of biotech in ROC's agriculture sector, the government implemented the inter-agency National Science and Technology Program for Agricultural Biotechnology (NSTP/AB) from 1999 to 2008 [2]. After 2008, the NSTP/AB was succeeded by the present five-year Development Program for Industrialization of Agricultural Biotechnology (DPIAB). Starting from 2009, DPIAB has had two major aims:

1. To promote the industrialization of NSTP/AB's promising results, as accumulated during the 10-year period.

2. To consider those areas in the global agricultural biotech development arena that ROC has a competitive advantage, and organize top-down integrated projects as the focus for this program.

The program is supported by multiple agencies, including COA, Department of Health, Ministry of Education (MOE), National Science Council (NSC), Academia Sinica, and Industry Bureau of the Ministry of Economic Affairs (MOEA), with COA as the major agency in charge of administrative coordination. Their missions are shown in Figure 2.

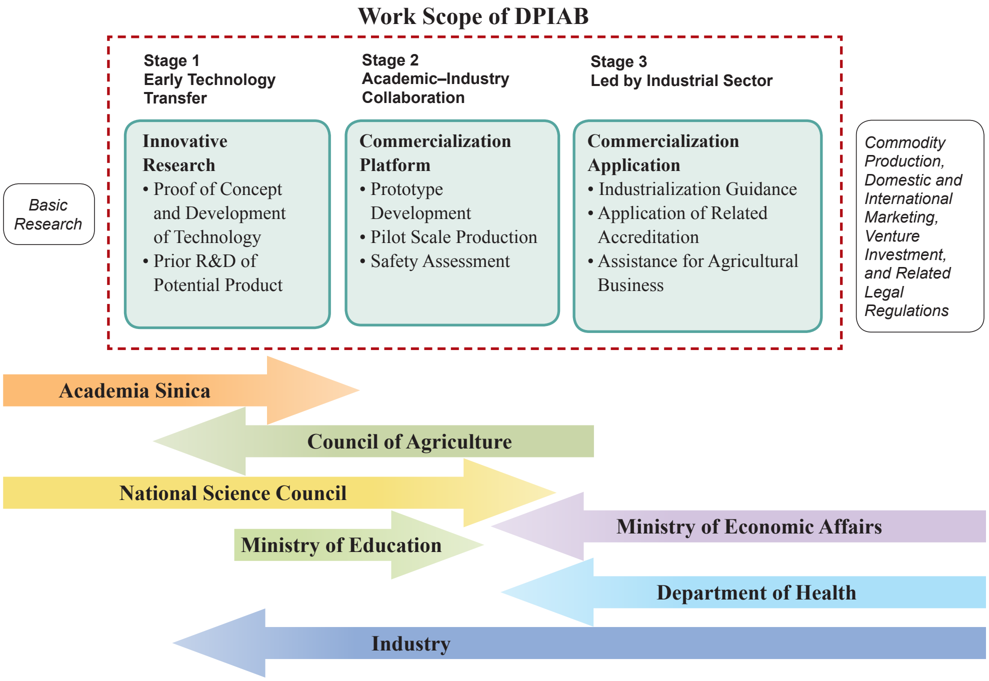

Figure 2. Development Program for Industrialization of Agricultural Biotechnology Planning (DPIAB) Scheme.

Pingtung Agricultural Biotechnology Park

ROC's agricultural biotech sector mainly consists of mini and small companies, with inadequate resources for R&D. On the other hand, academic and research institutes are very capable and have accumulated many R&D results. Bridging the gap between them is the key to exploit and transform the results into products/techniques, thus helping the industrialization process build a competitive agricultural sector. The science-based-industry park, Pingtung Agricultural Biotechnology Park (PABP), was thus founded for this purpose. It clusters companies with R&D capacity and manufacturing plants. So far it is the only national-scale scientific park focusing on agricultural biotechnology in ROC. Its goal is to promote application of R&D results, product innovation, and manufacturing to assure a thriving agriculture industry.

PABP was launched in December 2006. It combines the resources of neighboring farmland and is conferred tax incentives. These benefits create a superior investment environment for R&D, manufacturing, and sales in the domestic and overseas markets. There are now more than 70 companies registered, of which more than 50 are in active operation. The total investment is about TWD6 billion (USD203 million), and annual output is about TWD3 billion (USD102 million). Items produced include medicinal herbs, functional foods, biocosmetics, biopesticides, biofertilizers, animal vaccines, testing reagents for diseases and pests of animals and plants, biotechnology services, functional feed additives, ornamental fish, fish fry, etc. Their technologies are supported by COA's research institutes and more than 30 universities and colleges in ROC.

Many characteristic products have been developed, making it an outstanding industry cluster in ROC, with exports to more than 30 countries. To implement a policy to promote the development of ornamental fish and fish fry, the Yaitai Operational Center for Aquaculture (YTOCA) was established in April 2013 in the PABP (Figure 3). Its mission was to promote industry development through a platform of measures covering R&D, import/export quarantine, customs clearance, and marketing.

Figure 3. Yaitai Operational Center for Aquaculture in Pingtung Agricultural Biotechnology Park (PABP).

Achievements of Biotechnology in Agriculture

Plant Biotechnology

The orchid industry in ROC uses excellent technology and has established an integrated industrial value chain. It employs sophisticated tissue culture and cultivation skills, and a good control system for diseases and pests. The orchids produced (including young plantlets) are of high quality and sold globally. It is worth mentioning that the *Phalaenopsis* orchid, known as the moth orchid, from ROC is the only plant that can be exported to the USA and Australia with the supporting culture media. The export value of ROC's flowers and plantlets was USD194.56 million in 2012. The export of *Phalaenopsis* orchids exceeded USD100 million and, with a 16% growth rate, is the first agricultural product to set a new historical high in export value.

Furthermore, the "Taiwan International Orchid Show" (TIOS) held at the Taiwan Orchid Plantation in March each year has become one of the top three orchid exhibitions in the world. It provides the biggest international trade platform for the *Phalaenopsis* orchids. In the past two years, international business procurement conferences have been held there. The emphasis of the exhibition is to showcase commercial varieties of orchids and plant breeders' rights, which lay the foundation for ROC's leading role in the orchid industry. The products include orchid cut flowers, potted flowers, and have extended into landscaping. ROC orchids have won many prizes in the "Japan Grand Prix International Orchid Festival" and "Chelsea Flower Show" in England in recent years. These awards indicate that ROC's flower industry has gained international status.

In the area of medicinal herbs, ROC yew is used to produce taxol, a cancer therapy drug. Through selected plants, the taxol has been produced in three ways: from harvested branches and leaves, from tissue culture, and from genetically engineered cells to increase the yield. "TY1" is a variety bred from *Taxus sumatrana*, which can produce high amounts of taxol and the derivative 10-deacetylbaccatin (10-DAB). This achievement has led to the commercial planting of these trees. A company has invested TWD50 million to build a 45 ha yew farm. In 2012, the exported weight of yew branches and leaves was around 41 metric tons, with a value of TWD10 million (USD0.34 million). It is estimated that the annual production could be more than 73 metric tons in the future.

Transgenic Ornamental Fish

The ROC's transgenic ornamental fish technology uses excellent technology and has an integrated industrial value chain. In 2001, ROC bred small-sized transgenic rice fish with beautiful fluorescent green bodies. Later, in 2010, academic institutes collaborated with an aquaculture biotech company and again succeeded in developing transgenic angelfish and convict cichlid, which are the first medium-sized transgenic fish bred in the world. This was followed in 2012 by fluorescent pink angelfish with an adorable appearance (Figure 4).

In the future, work will continue on cloning new genes from ocean organisms which encode proteins with beautiful colors, such as novel purple chromoprotein and its mutant derivatives. It will help integrate new colors into ornamental fish varieties, and it is believed that the ornamental fish industry in ROC will become much more competitive than that of other countries.

Figure 4. (From left) Ornamental fluorescent fish; transgenic fluorescent fish; convict cichlid. (*Archocentrus nigrofasciatus var*.); and green and pink angelfish (*Pterophyllum scalare varierty)*

Source: Development Program for Industrialization of Agricultural Biotechnology (DPIAB), Republic of China Council of Agriculture [1].

Grouper Aquaculture

ROC's grouper aquaculture has a 30-year history [3]. The accumulated experiences and technology made ROC well known as the "groupers' kingdom," and a leader in the world. The industry's strength is its brood fish nursery technology and fish fry cultivation. Of the 10 grouper varieties that can be mass-produced, ROC can produce seven. However, viral nervous necrosis (VNN) and iridovirus diseases have threatened the industry and caused severe losses. A monovalent inactivated vaccine against iridovirus was developed and has been sold in the market since 2012. Another two vaccines, VNN inactivated-immersion type and VNN and iridovirus mixed vaccines, have passed laboratory safety and efficacy tests.

With regard to feed additives, the Institute of Biotechnology at National Cheng Kung University successfully developed an "aqua-fatten" immune technology that can accelerate groupers' growth by three months with a 25% feed saving. This technology reduces the feed cost and raises the output values by about 15%. Additionally, it can also be applied to livestock and other aquaculture species. To date, this technology has been transferred to four companies and used in the industry.

Livestock and Poultry Biotechnology

Molecular markers are used in brood selection for swine, cattle, chicken, etc., in order to improve breeding efficiency. For example, gene markers for appearance traits, as well as bioinformatics have been applied to remove undesired traits of ROC country chicken. For poultry, desired traits are fertility, quality meat, high spermatogenecity, large size, and powerful hind legs. The needed technology includes poultry germplasm, breeding improvement and elevating culture efficiency. In addition, transgenic technology is used to create livestock with biomedical applications, such as transgenic swine producing human coagulation factor IX and fluorescent swine as a model animal.

ROC academic and research institutes cooperatively developed a transgenic swine producing human coagulation factor IX, which has been licensed to TTY Biopharm Company Ltd. The Animal Technology Institute Taiwan continues the follow-up tests for validation of the production procedure and clinical trials. This product is expected to enter the market within 5−7 years. The recombinant human coagulation factor IX will provide hemophilia patients with a safer and more accessible medicine source by preventing the use of contaminated blood plasma. This technology is a combination of agricultural biotech and biomedicine industries, not only increasing the value of agriculture but also raising the biomedical industry competitiveness in the world.

The research team at National Taiwan University succeeded in developing a neuron cell line that secretes dopamine. The cell line was differentiated from swine embryonic stem cells (bearing a jellyfish fluorescent gene). Then the neuron cells were transferred into the brain of rats suffering from Parkinson's disease and verified that it could effectively alleviate the rotation symptom. This is the first report of a study with this animal model and was published in the journal *Cellular Reprogramming*, and it has shed light on the therapy of Parkinson's disease [4].

Animal Vaccines

A joint vaccine research team formed by Reber Genetic Co. Ltd. and Animal Technology Institute Taiwan developed a vaccine against porcine reproductive and respiratory syndrome (PRRS), the first targeting subunit vaccine in the world. PRRS is the so-called blue-ear disease, a widespread, worldwide viral disease found in swine. The infected female swine is prone to abortion, and mortality in adult swine can reach 20%. The disease incidence in piglets is almost 100% and it may cause a 70% mortality rate. For many years there has not been a good strategy to combat this disease, which leads to severe losses. Compared to the present PRRS live vaccine, the non-toxic subunit vaccine does not have the issue of toxicity recovery, which is the problem of live vaccines. This novel vaccine possesses advantages of high safety and high efficacy. It was marketed in 2012 and has become the best-selling vaccine replacing foreign products, such as vaccines made in Germany.

FUTURE DEVELOPMENT FOCUS WITH POSSIBLE CONTRIBUTIONS

To improve the development of ROC's agricultural biotech industry, innovative R&D will be continued. With appropriate legislation and implementation systems, R&D results can efficiently be converted into products for commercialization. Focusing on high potential R&D results, cooperation between academic and research institutes and industry will increase the output of biotechnology, such as animal vaccines, biopesticides, feed additives, etc. The focus will be on the development of key technologies, function validation, pilot manufacturing, as well as the protection of intellectual property rights. The lead-time to get a product to market can then be shortened, and the industry will grow and flourish continuously.

The government will also enhance supporting services for enterprises, farmer associations, and individual farmers [5]. These services include consultations for product evaluation and manufacturing, brand design and marketing, regulation of standards/rules, and suggestions for intellectual property right protection, etc. This initiative is expected to expedite commercialization and industrialization of new products and technologies. Through policy implementation, it is hoped that our agricultural biotech sector is innovative, has competitive advantage in the world, and that our enterprises and farmers are not survivors, but winners.

SUMMARY AND CONCLUDING REMARKS

The goal of ROC's agriculture is to provide safe and secure food within a sustainable ecosystem. Employing biotechnology to promote "Quality Agriculture" is our strategy, and the current goal is to reinforce the safety verification of farm produce that meets international standards for the global market. Furthermore, industrial operation systems (which are one of ROC's advantages) will be introduced into the agriculture system to enhance industrialization. The mission is to promote technology commercialization, investment industrialization, and marketing internationalization. The development priorities are animal vaccines, biopesticides and feed additives, and the connection between R&D results and industry application will be promoted. Through strengthened multidisciplinary integration and resource utilization, a new agricultural value chain will be constructed. In the future, it is highly anticipated that ROC's agriculture will not only be a thriving local business, but also a worldwide green gold industry.

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BIOTECHNOLOGY AND GLOBAL COMPETITIVENESS IN INDIA

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INTRODUCTION

Almost a decade ago, the ground-breaking publication of the human genome sequence drew public attention to genetics and biotechnology. In the wake of this, a group of entrepreneurs in India founded Metahelix Life Sciences Ltd.,venturing to unleash the potential of such new technology to change Indian agriculture.

In the 1970s and 1980s India had 3%–4% of annual growth in food-grain production. In subsequent decades, this growth hit a plateau at about 1.2%. Two decades ago, agriculture contributed about 30% of India's GDP, now it makes up about 15%. However, there are some notable successes. Today, India is the second largest producer of cotton in the world, compared to its relatively low total production a decade ago. Consequently, India is the largest exporter of cotton in the world today whereas it used to be a net importer. This has happened with just one technology (namely, biotechnology) and one crop (namely, cotton). If this result could be replicated with other food crops, then the outlook for Indian agriculture would appear bountiful.

More and more, the seed business is being driven by technology. Contrary to popular notions that they are poor and ignorant laggards, Indian farmers are actually very receptive to technology. The statistics on genetically modified (GM) crops are impressive. The global production of GM crops, from their introduction in 1996, has been growing at up to 13% a year. Production of the only GM crop in India, Bt cotton, has been growing at 150%–160% a year. This explains why 95% of all cotton grown in India today is Bt cotton.

CYCLE OF PROFIT

The notion that the costs involved in growing GM crops would dissuade farmers is a flawed one. Some farmers may be unable to pay because of the initial capital cost, but that is where the government can provide subsidies or other types of support. Once the cycle starts and the farmer begins cultivating, profits will flow. This is a better option than the subsistence farming that is so persistent in India today. We should shift our farmers' mindset away from subsistence farming. We have seen that Indian farmers are willing to invest and pay more for seeds if they see value. In the case of cotton, they were spending five times more on GM seeds, and still making profits. Other new GM seeds would perform better in water-stress conditions, making their adoption more likely.

The major concern is the long gestation period required to develop a GM product. It takes six to seven years to get the right kind of seed. Beyond commercial offerings, what really matters in this business is the kind of pipeline available to bring in new products. The market lifecycle of a seed is short: every three to five years, companies have to come out with a new version. Adding to the cost factor is the capital-intensive nature of the business. This is one reason why companies have started sharing the expenses involved in research with different players, each concentrating on different aspects of the development process. Besides the time factor, there are trials that need to be completed for regulatory purposes. Simply put, biotechnology demands a lot of money.

The advantage India has with developing GM technologies for farming is the country's significant biodiversity. However, collaborative research has to improve for the most to be made of this bounty. The country no longer talks so much about starvation as it does about rotting stock. Still, food stocks are rotting while millions are going hungry. India needs to improve its post-harvest infrastructure, and furthermore, has to double (at the very least) its food-grain production by 2020–25 to meet the needs of its growing population. The current 1.2% growth in production will not be sufficient.

Demonization of GM technology in the media has hampered the progress a great deal. This is an issue that gets confused with the debate concerning patents and monopolies in third world markets. That debate should not be confused with the question of introducing new GM crops. There are other challenges facing the biotechnology industry in India, below we will briefly summarize the business challenges, and go into more detail on some of the technological challenges being faced.

Business Challenges

Business challenges fall into two groups, those that emanate from the "demand side," and those that arise from the "supply side." Demand side challenges include global food security, food wastage, inflation and stock hoarding, while supply side challenges include the active role of government in R&D, postharvest infrastructure, urbanization and natural calamities.

Technological Challenges

The public and private sectors in India's agricultural biotechnology industry employ both conventional and modern molecular tools to develop and deliver products based on consumer needs. Two technological challenges are highlighted in this section.

Viability of Transgenic Crops

Traditionally, plant breeders and farmers have selected plants with improved growth rates, yields, and enhanced resistance to pests and diseases by cross-breeding plants with desirable traits. Today, in addition to conventional breeding, scientists take advantage of advanced molecular tools to genetically modify plants to impart these desirable traits. Since bollworm-resistant GM cotton was made commercially available in India in 2002, cotton farmers rapidly adopted it not only because it served as a better pest-management tool, but also due to its lower production costs and increased yields. For the future, the focus of agricultural biotechnology is gradually evolving from creating benefits for farmers from improved crop protection, to creating traits that directly benefit consumers in terms of nutritional and pharmaceutical uses [1]. Despite the broad acceptance of GM crops in several countries, concerns over the evolution of resistance in pests and indirect long-term ecological effects should not be overlooked. The successful replacement of the Bollgard-I (single gene Cry1Ac) version of cotton with Bollgard-II (two genes, Cry1Ac and Cry2Ab) is the best example for slowing down the gain of resistance of target pests to toxins. The insertion of only one or two genes in GM crops may be extremely effective against some pests, but less effective against others. The use of several versions of toxic proteins appears to provide a better solution. Other strategies include gene stacking and combining toxins with completely different modes of action. Furthermore, constant exploration of novel and effective toxins, and replacing existing versions of GM crops with new ones every few years could serve as a better alternative.

Conventional Breeding Challenges

Although genetically modified and nutritionally enhanced food crops are available (for example, Golden Rice), they are still far from consumer reach due to several regulatory and policy issues. The rice hybrids developed by the public and private sectors are seen as better alternatives to traditional varieties with their improved crop protection and yields. Yet, less than 5% of the total area under rice is occupied by hybrid rice.

Some of the reasons for the poor spread of hybrid rice technology are moderate levels of heterosis, low hybrid seed yield, and high seed cost. The extent of heterosis realized in the hybrids is a function of the genetic distance between the combining parents. Most of the hybrids developed during the initial phase of hybrid rice development in India used the common female parent IR58025A, a cytoplasmic male sterile (CMS) line. Hence, these hybrids can be genetically considered as half-sibs. A similar exploitation of the common cytoplasmic source in CMS-T (Texas cytoplasm of maize) -based hybrid maize resulted in the outbreak of Southern Corn Leaf Blight in the United States several decades ago. Therefore, with a view to enhancing the magnitude of heterosis and to prevent the outbreak of diseases and pests, it is very necessary to diversify the cytoplasmic, as well as the nuclear, background of the CMS lines. Alternatively, hybrids can be developed by making use of nuclear male sterile systems [2, 3].

CONCLUDING REMARKS

Technology has played the role of a growth catalyst and enabler in several businesses across numerous sectors. With the potential to serve global food security needs, agricultural biotechnology needs a collaborative co-innovation approach. Governments and forums should now streamline channels for collaborating on research to promote the wide adoption of agricultural biotechnology. Cross-company and cross-border collaboration in solving various agricultural challenges faced by farmers needs immediate focus and attention. The sector also needs information and communication technology (ICT) enablers to take the local initiatives to a global scale. Some of the enablers that can add value to the agricultural sector are:

- A virtual co-innovation platform for businesses to post their requirements, and explore alliances and solutions together.

- A platform for the sector to collaborate with the entire agricultural network involving all stakeholders in the value chain.

These ICT enablers, along with appropriate government support and regulations can help to grow the agricultural biotech ecosystem and meet the broader challenges of mitigating global food insecurity and promoting health.

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INDIA'S ANIMAL BIOTECHNOLOGIES TODAY AND FUTURE PROSPECTS

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INTRODUCTION

The Indian livestock production system operates on a low input and output basis. Hence, curative measures are less feasible and economical as compared to prevention and control through immunoprophylaxis. Vaccines and diagnostics are two sides of the same coin. Much progress has been made not only in expanding the range of available veterinary vaccines, but also in increasing their efficacy with reduced side effects. However, there is still ample scope to incorporate new knowledge and technologies into vaccine design, production, validation, and marketing. This gap is wider in the realm of veterinary diagnostics as there are only a few user-friendly and cheap diagnostic kit savailable for field use. These are mostly restricted to the poultry sector.

TRANSLATIONAL RESEARCH

Research is traditionally categorized as basic research (also called fundamental or pure research) and applied research. Basic research is more speculative and takes a long time to be applied in any practical context. Basic research often leads to breakthroughs or paradigm-shifts in practice. Applied research, on the other hand, is characterized as being capable of having an impact on practice within a relatively short time, but often represents incremental improvements to current processes, rather than delivering radical breakthroughs [1].

Translation refers to applying the basic biomedical research results to the practice of medicine. More specifically, it describes the process of converting laboratory discoveries into clinical interventions that provide a direct benefit to animal health. It often refers to research that facilitates rapid and effective transition of basic research results, which go toward large-scale evaluation and validation for ultimate use in improving animal health and productivity.

In India, several institutions are engaged in animal science research that invariably ends in the development of products and processes, leads or candidate proteins for vaccines, or diagnostic reagents. However, these leads/candidates may not ultimately be converted into products that are marketable or available in the market shelves for stakeholders and farmers. This means that science is not converted into technology, nor knowledge into wealth. Translatability of the advances made in research projects and findings into tangible benefits for farmers seems to be lacking the desired extent. This responsibility lies with academia, government, and the industry sector. The expressions “lab to land,” “field to fork,” “bench to bedside,” “mind to market,” etc., seem to suffer from a “translational disconnect.” [2]

The challenges of translational research are:

- Limited ability to study complex and dynamic biological systems in health or disease
- Need for multi-disciplinary and trans-disciplinary approach to problem solving
- Interventions should be relevant, feasible, effective, and sustainable
- Complex regulatory environment

VETERINARY DIAGNOSTICS—THE INDIAN SCENARIO

Animal disease diagnosis, as with all diagnostic methods, is contextual; the diagnostic results are fraught with limitations and each assay used has its own pros and cons [3].

There are three main contexts in which diagnostic methods are used:

1. *Clinical diagnosis*: Commercial potential only when it drives the line of treatment;
2. *Epidemiological diagnosis*: Useful in disease eradication programs; adds to cost; not much use to farmers; and
3. *Vaccine efficacy*: Checks the efficacy of vaccines; useful to the vaccine manufacturer but not to the farmer.

What Dictates the Success of a Kit?

Some guiding questions are as follows:

- Does it need to generate money through commercialization?
- Should it be useful in controlling the disease?
- Should it be used in national surveillance programs?
- Should there be a demand from users?

There appears to be a great divide between farmers' requirements and what is capable of generating revenue.

Why Do Some Kits End Up in Deep Freezers and Not on Market Shelves?

Reasons include the following:

- Technologies always change
- Lack of continuity in research and personnel
- Changing priorities as dictated by funding
- Lack of drive and zeal on the inventor's part
- Insufficient validation support

The Challenges for a Veterinary Diagnostician with Regard to Diagnostic Kits

The challenges include:

- Cost
- Determining whether treatment will change
- Ultimatum to sell or slaughter an animal; greater economic burden if diagnostic costs are involved
- Poor reproducibility of assays
- Need for technical expertise for performance and interpretation
- Mindset of the end-user in terms of confirmatory or laboratory-based diagnosis

One of the technical challenges for the veterinary diagnostician is to directly apply the imported kits with their cut-off values to the Indian population. This danger is exemplified well in the diagnosis of leptospirosis. We did a preliminary study involving five commercial kits for leptospira diagnosis and Table 1 shows their sensitivity and specificity in the suspected sera samples, as compared to their claimed sensitivity and specificity.

Table 1. Comparison of the sensitivity and specificity of claims on diagnostic kits

Commercial kits	Claimed sensitivity and specificity		Observed sensitivity and specificity *(TAGS analysis)*		Observed sensitivity and specificity *(In comparison with Gold standard)*	
	Specificity	**Sensitivity**	**Specificity**	**Sensitivity**	**Specificity**	**Sensitivity**
ELISA 1	96%	97%	64%	60%	63.2%	41.9%
ELISA 2	98.50%	96.50%	82%	60%	81.8%	46.2%
LFA 1	99.50%	99%	98%	60%	100%	43.5%
LFA 2	95.30%	96.30%	89%	80%	90%	47.5%
LFA 3	99%	90%	100%	100%	100%	44%

Notes: Observed with the microscopic agglutination test (MAT) as gold standard or observed in the absence of gold standard (TAGS). ELISA, enzyme-linked immunosorbent assay; LFA, lateral flow assay.

On comparing correlation of samples with all tests, only 3% of positive samples correlate with all five tests. In contrast, 60% of the negative samples correlate with all the five kits (Figure 1).

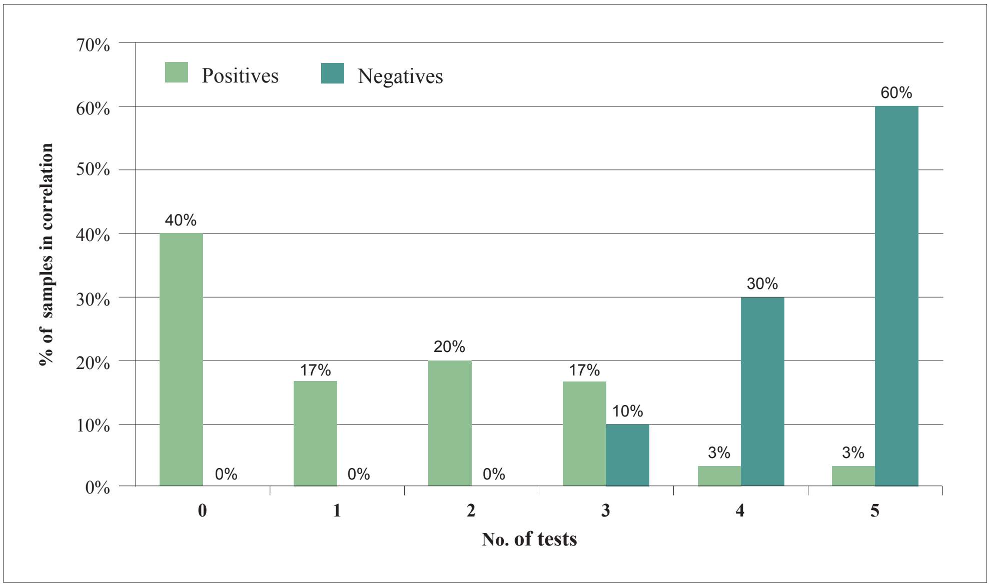

Figure 1. Percentage correlation of the results obtained among all five commercial kits (Authors' unpublished study, Department of Science and Technology (DST), New Delhi scheme).

VETERINARY VACCINES

In India, the last 10 years have seen only the "peste des petites ruminants" virus (PPRV) vaccine introduced into the market. Only a few recombinant veterinary vaccines have been licensed globally. Two veterinary DNA vaccines have so far been granted regulatory approval. The United States Food and Drug Administration has granted a license to Fort Dodge, a subsidiary of Wyeth, to market West Nile Innovator DNA, a vaccine to prevent West Nile virus infection in horses. Also, the Canadian Food Inspection Agency has granted a license to Aqua Health Limited, a subsidiary of Novartis, to market APEX-IHN, a DNA vaccine to protect farm-raised salmon fish against infectious hematopoietic necrosis virus. So far, no DNA vaccine has been licensed for use in humans.

Several recombinant veterinary vaccines are presently in the development and clinical trial stages. Some of them include the Porcine Corona virus in pigs; Pseudorabies virus in pigs; classical swine fever virus in pigs; bovine herpes virus-1 in cattle; equine influenza virus in horses; MDV (HVT) and infectious bursal disease virus in poultry; Newcastle disease virus in poultry; rabies virus for cats, canines and wild life; and canine parvovirus 1, canine corona virus and canine distemper virus in dogs [4].

The regulatory mechanism for introducing vaccines and biologicals varies depending on the type of vaccines, i.e., conventional or recombinant. For recombinant vaccines, extra clearance and approval from the Review Committee on Genetic Manipulation is required for pre-clinical toxicology trials and approval of clinical trial reports. The approval of the Genetic Engineering Advisory Committee is mandatory if the product is derived from live bacterial or viral vectors, or if the recombinant product contains the live organisms. The challenge of cost is exemplified by the following analysis of the cost of vaccines at the retail market (Table 2).

Table 2. Retail cost of vaccines

Species	Cost Per Dose in Indian Rupees		
	FY 2010	FY 2013	% Change
Poultry	0.50	0.26	–48.00%
Sheep	2.90	1.43	–50.69%
Bovine	5.00	9.35	87.00%
Canine	100.00	271.00	171.00%

During the period from 2010 to 2013, the cost of poultry and sheep/goat vaccines decreased, while increases were seen in dog and bovine vaccines (Figure 2).

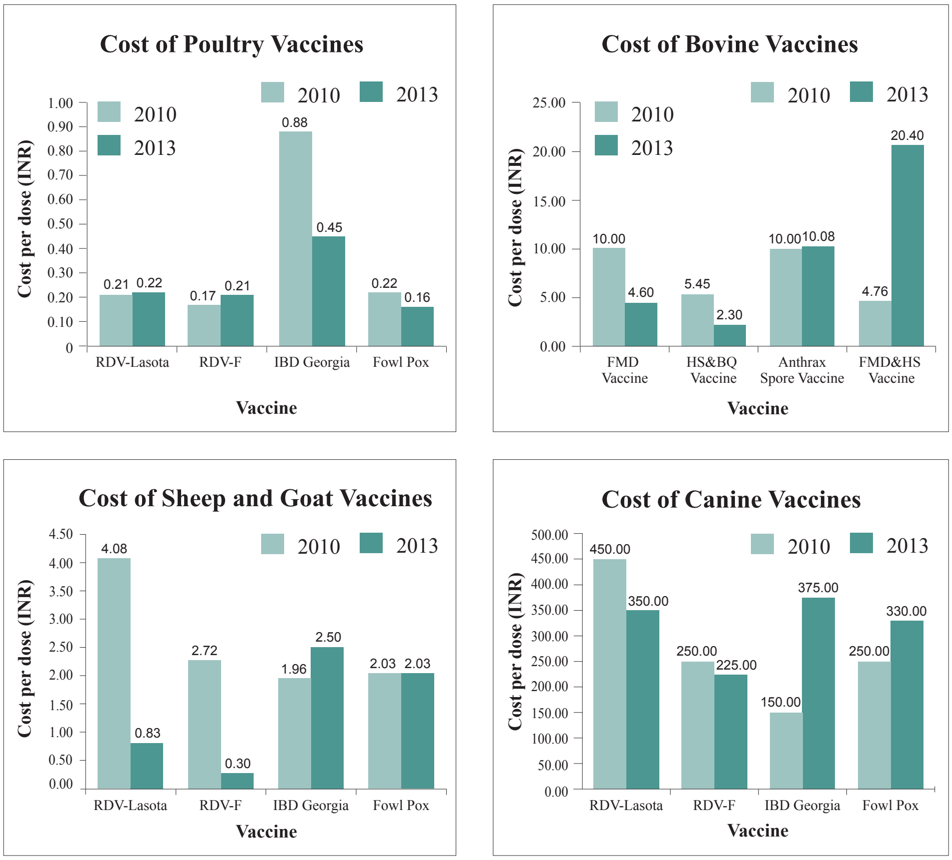

Figure 2. Retail cost of individual vaccines in 2010 and 2013. BQ, black quarter; FMD, foot-and-mouth disease vaccine; HS, haemorrhagic septicaemia; IBD, infectious bursal disease; INR, Indian Rupee; RDV, Ranikhet disease vaccine, F-strain.

TRANSLATIONAL RESEARCH PLATFORM FOR VETERINARY BIOLOGICALS (TRPVB)

There exists a “translational disconnect” between conception, gestation and growth, and maturity. To rectify this disconnect and bring an “end-to-end vaccine discovery to development-market approval process,” a three-pronged strategy is needed based on research innovations,industry perspective, and regulatory perspective. The critical issues in commercializing animal biotechnologies in India and the measures to overcome them are highlighted in Table 3.

Table 3. Critical issues in commercialization of animal biotechnologies in India and measures to overcome them

Critical issues in commercialization of animal biotechnologies in India	Likely measures needed to overcome these constraints
High cost forbids affordability by the end-user (farmer)	1. National immunization policy fostered and subsidized by the government 2. Free diagnostic support for vaccine purchases 3. Multi-component vaccine/diagnostics 4. Thermo-stable vaccines with better protection duration 5. Needle free vaccine delivery 6. Involvement of NGOs for veterinary healthcare 7. Slaughter of animals for food only if they are healthy, and discouraging the practice of disposal of unproductive animals for food
Paucity of information on market demand for veterinary vaccines and diagnostics	1. A methodical epidemiological survey with disease burden for veterinary diseases 2. Networking disease prevalence and reporting system 3. Encourage reporting of disease outbreaks by any veterinary professional, instead of restricting to state animal husbandry departments alone 4. Needs assessment based on disease burden estimates
Limited availability of technical experts opting for commercialization	1. Foster high quality interdisciplinary PhD scholars with inclusion of translational research in the curriculum 2. Nurturing entrepreneurship among students 3. Reward innovative academicians 4. Offer dual–degree programs and fellowships
Lack of regulatory guidelines for validating veterinary diagnostics and some vaccines	1. Prepare draft proposals for upcoming vaccine technologies with inputs from academy, industry, and regulatory body for inclusion in referral documents like Pharmacopoeia 2. Create awareness about the recommended standards to meet global requirements 3. A "single-window" system for approval
Few takers from industry to commercialize laboratory research outputs	1. Propose a national immunization policy and approved diagnostics for national surveillance programs, to create a relatively uniform demand for vaccines and diagnostics 2. Facilitate Industry–Academia dialogue through national research funding agencies such asthe government's DBT, DST, and ICAR to obtain support through to commercialization (even for "start up" companies) 3. Conducive policies and laws to encourage entrepreneurship among faculty to become investment partners 4. "Fee for service" concept as for material transfers
Delay in the turnaround time from concept to product	1. Development of products for which proof of concept already exists 2. Industry–Academia collaboration from initial stages of product development

(...continued)

Critical issues in commercialization of animal biotechnologies in India	Likely measures needed to overcome these constraints
	3. Encourage angel investors and venture capitalists, even at the R&D level 4. "Single window" regulatory approvals.
Huge quantum of work involved	1. Pumping-in motivated and creative manpower. 2. Interdisciplinary research involving experts from healthcare professionals, life sciences, technocrats, and industrialists. 3. Conduct frequent scientific forums for sharing expertise. 4. Introduce corporate models for design, governance and decision-making.

Notes: DBT, Department of Biotechnology; DST, Department of Science and Technology; ICAR, Indian Council of Agricultural Research; NGO, Non-governmental organization.

Research Innovations

To further improve deliverables from existing research programs, the following strategies may be "fodder for thought":

- Development of a formal mechanism to identify research gaps
- Priority accorded to innovations and "out of the box" ideas
- Consortium mode of operation
- Incentives to the researcher/inventor
- Facility for the inventor from public-funded institutions to his own start-up company
- Lack of biological resources in terms of inbred lines, transgenics, gene knock-outs, cell lines, etc.
- Fewer people entering animal sciences research after the information sector boom

Industry Perspective

The constraints in terms of the commercialization requirements from the perspective of the industry are:

- Lack of market potential for the product
- Mass production strategies are not accounted for in the development stages
- Market for veterinary vaccines is relatively small and fragmented with a multiplicity of target species and diseases

- Large multinational companies dominate the animal health industry due to the establishment of manufacturing facilities in different parts of the world
- The "incubation time" to bring a new product to market is between 5 and 10 years
- Lack of global markets due to differences in the type of pathogens
- Constant updating required to check whether the circulating pathogens are still "protected" or "detected" by the vaccines or kits respectively

Regulatory Aspects

Catering to the regulatory requirements of the particular country is important in establishing and maintaining consumer confidence in the safety, quality, and efficacy of products. However, the man-made challenges in this area are enormous:

- Lack of knowledge of procedures for obtaining regulatory approvals
- Considerable increase in investment and time to bring the final product to market
- Increase in cost due to time lag
- Lack of adequate animal-testing facilities
- More stringent regulatory requirements for recombinant vaccines and products

All of these underline the need for a coordinated, transparent, and multidisciplinary research effort from basic sciences through to the emerging technologies, and onto product development, production, authorisation, and distribution.

The recently initiated partnership program between the Department of Biotechnologyand Tamil Nadu Veterinary and Animal Sciences University (DBT-TANUVAS), called the "Translational Research Platform for Veterinary Biologicals (TRPVB)," aims to bring the above three vertices together in an attempt to foster "productization" of the leads, vaccine candidates, antigens, and prototype kits into marketable products (www.trpvb.org.in).

CONCLUSION

The "vicious circle" involving the challenges of teaching, researching, publishing and competing for competitive grants, coupled with pursuing career aims and ambitions, can seem daunting. However, it can also be deeply satisfying when the fruits of the experimental laboratory research are translated into improved healthcare delivery to our animal patients. To do this, the basic motive to do research has to change in terms of addressing a pressing problem and not to start with another publication.

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THE CURRENT STATUS OF BIOTECHNOLOGY IN INDONESIA

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INTRODUCTION

Indonesia is an archipelago consisting of around 17,000 islands with a total land area of about 1.919 million km^2 and a maritime area of about 7.9 million km^2. About 192 million ha are occupied and about 62 million ha are used for agriculture. The population of Indonesia is the fourth highest in the world with about 240 million people. About 120 million people live on Java Island, making it the world's most populated island. About 20% of the population work as farmers (40 million people) with average land occupation estimated at 0.5 ha per farmer. Population growth was about 1.5% whereas economic growth was about 6.2% in 2010 [1]. The agricultural total factor productivity (TFP) was increasing from 1970 to 1980, and remained stagnant after 1990 [2]. However the agriculture sector still has the fourth biggest impact on the national economy.

Food security is a major agenda item when considering current and future agricultural development. It is one of the major determining factors in a country's national stability as viewed from economic, security, political, and social perspectives. Indonesia's food security targets are directed at households and individuals, and on food availability, accessibility, and nutritional content for a healthy and productive life. In the Ministry of Agriculture's strategic plan, rice is the most important commodity among the five major food commodities that also include maize, soybean, sugarcane, and beef cattle. The national research priorities are shown in Table 1. The Ministry of Agriculture is targeting to achieve sustainable self-sufficiency in food crops, i.e., rice, maize, soybeans, peanuts, green beans, cassava, and yams, for the period 2010–14. As rice self-sufficiency has been the government's position since 2007, the attainment of targets for 2010–14 are ongoing, with the goal of increasing production to 75.7 million metric tons (MMT) of paddy (unhusked and dried).

NATIONAL AGRICULTURAL RESEARCH

The national organization responsible for agricultural research under the Indonesian Minister of Agriculture is the Indonesian Agency for Agiculture Research and Development (IAARD). IAARD manages 17 research institutions, three research stations, and 32 assessment institutes located throughout the provinces in the country. The main function of these institutes is to manage R&D of food crops, horticulture, estate crops, livestock, veterinary, soil and agroclimate, agricultural socioeconomics, machinery development, postharvest technology, biotechnology, and agriculture technology assessment. IAARD's research and assessment institutions undertake work that aims to improve research, assessment and development in agriculture. The research institutes and research centers then transfer any new technology developed to the Assessment Institutes for Agricultural Technology (AIATs).

Research Focus

IAARD has about 1,540 researchers (18% of its total staff) located throughout the country in different research areas. The Indonesian Centre for Agriculture Biotechnology and Genetic Resource Research and Development (ICABIOGRAD), one of the research centers under IAARD, is supported by 63 researchers. IAARD determines research priorities for each major commodity group: food crops, horticulture crops, estate crops, and livestock (Table 1).

Table 1. Research priorities of Indonesian Agency for Agriculture Research and Development (IAARD)

No.	Major commodity group	Commodity focus
1.	Food crops	Rice, maize, soybean, cassava, peanut, sweet potato, and mungbean
2.	Horticulture crops	Vegetables (chili, tomato, shallot, string bean, and potato), fruits (citrus, mango, banana, mangosteen, melon, and durian), ornamentals (orchids, roses, gladioli, chrysanthemums, carnations, and lilies)
3.	Estate crops	Palm oil, rubber, coffee, cacao, tea, chincona, sugarcane, coconut, black pepper, cashew, clove, tobacco, cotton, ginger, greater galingale, tumeric, patchauli, nutmeg, vanilla, kenaf, kapok, jute, and sago
4.	Livestock	Beef cattle, sheep, goat, native chicken, duck, and dairy cattle

Besides setting research priorities, IAARD also conducts several major thematic research projects to secure national food production, including agricultural land resources (land, water and agroclimate resources, biotechnology and genetic resources), commodity improvement, socioeconomic and agriculture added value, assessment and acceleration of agricultural innovation and dissemination, and institutional development and communication.

CURRENT STATUS, MAIN CHALLENGES, AND PRINCIPAL TRENDS

Food security is the first challenge to be addressed with a growing population. In Indonesia's second long-term development plan (1994–2019), food security emerged as one of the most important issues in the national agricultural development framework. With an expected population growth rate of 1.4% per year between 2000 and 2010, rice consumption was expected to grow from 48.5–50 million metric tons (MMT) in 2000 to 50–57.5 MMT in 2010 [2]. Indonesia is thus looking to new and improved agricultural technologies to increase farm productivity and recognizes the role biotechnology must play in research.

The Indonesian government has given high priority to plant biotechnology research in the hope of addressing the pressing challenges related to improving productivity and farmers' livelihoods, driving rural development, and meeting food security demands. Since the 1990s Indonesia has adopted technology in many areas such as agriculture, health, industry, and environment. ICABIOGRAD has been mandated to conduct agricultural research using biotechnology. Many universities, as well as public and private research institutions have also contributed to the development of several products using biotechnology techniques.

Since 1994, the government has provided competitive grants for biotechnology research, resulting in significant increases in high-quality research activities. At present, several public institutions are engaged in biotechnology research in food crops (e.g., rice, maize, sweet potato, soybean) as well as other important commodities such as cacao and oil palm. Plant tissue culture and micropropagation techniques are well established at several laboratories, and large-scale commercial production of oil palm planting material has been developed. Diagnostics, *in vitro* technologies, and molecular marker technologies continue to be used in improving horticultural crops, including garlic, pepper, potato, citrus, banana, mango, and others. Research using more advanced recombinant DNA technologies is also starting to make headway. Limited field-testing is being done for insect-resistant transgenic potato and rice.

The majority of biotechnology products in Indonesia are still at the laboratory stage, focusing on agricultural commodities and the utilization of indigenous biological resources.

Government institutions take the lead in biotechnology R&D. Aside from ICABIOGRAD, other institutions under IAARD are the Indonesian Research Institute for Estate Crops (IRIEC), Indonesian Tobacco and Fiber Crop Research Institute (ITOFCRI), and Indonesian Center for Rice Research (ICRR). Transgenic crop R&D is also done at public university research centers and a limited number of private laboratories [3–4]. Other government institutions conducting biotechnology research include the Indonesian Institute of Science (ISS) and the Agency for the Assessment and Application of Technology (AAAT) under the coordination of the State Ministry for Research and Technology. They have been assigned to undertake R&D in industrial, medical, and agricultural biotechnology [5]. Research institutes under the Ministry of Agriculture have a more specific task to conduct biotechnology R&D to improve food and crops as well as animal production, whereas institutions under the universities undertake more diverse research, such as in human resource development as well as basic research of biotechnology.

At present there are several university research centers conducting research in biotechnology such as Bogor Agricultural University (IPB), Bandung Institute of Technology (ITB), Gajah Mada University (UGM), University of Brawijaya (UNIBRAW), University of Jember (UNEJ), and Udayana University (UNUD). Table 2 shows research activities on biotechnology agriculture in the laboratory phase.

Table 2. Research activities on transgenic crops in laboratory stages

No.	Institution	Crops and traits	Gene
1.	ICABIOGRAD	Rice resistance to bacterial leaf blight	OsWRKY76
		Rice Nitrogen use efficiency	CsNitri1-L
		Sugarcane delayed yield loss	SAI
2.	IRIEC	Cacao resistance to pod borer	Cry1A(c)
		Cotton resistance to bollworm	CPTi
		Drought-tolerant cotton	DREB
		Oil palm resistance to Ganoderma sp	Chitinase
		High-oil-content Jatropha	DGAT1
		Early flowering mangosteen	Apekalfa-1 (AP-1)
3.	Agency for Assessment and Application of Technology	Palm oil with high level of oleic acid	Theoesterase and KASII
4.	Bogor Agricultural University	Potato resistance to Fusarium sp and cyst nematode	Chitinase
		Potato resistance to diseases	Hordotionin
		Viral-resistant chili	CP

(...continued)

No.	Institution	Crops and traits	Gene
		Aluminum-tolerant soybean	Mamt2
		Drought-tolerant rice	Trehalose
		High P absorption sugarcane	Phytase
	Bogor Agriculture University-IRIEC	Early flowering mangosteen	Apekalfa-1 (AP-1)
5.	Bandung Institute for Technology-IRIEC	Less-flowering teak	Leafy
		Low-calorie sugarcane	Pallatinosa (pall)
6.	Brawijaya University	Citrus, soybean, abaca, jatropha, resistance to fungi pathogen	Chitinase, glucanase
7.	Gajah Mada University	Orchid flower quality	Knox
8.	Research Institute for Oil Palm-IRIEC	Oil palm resistance to Ganoderma sp	Chitinase

Source: Modified from Bahagiawati A.H. Agricultural biotechnology R&D and its application in Indonesia [6].
Notes: ICABIOGRAD, Indonesian Centre for Agriculture Biotechnology and Genetic Resource Research and Development; IRIEC, Indonesian Research Institute for Estate Crops.

Indonesia will likely have the capacity to multiply transgenic seeds or commercialize transgenic crops in the coming year. Currently, the government has carried out confined field-testing on several transgenic crops, including rice (resistant to biotic stress), sugarcane (tolerant to abiotic stress and modification of high glucose content), cassava (modification of amylase), potato (resistant to biotic stress), and tomato (resistant to biotic stress). Transgenic rice has already been field-tested in 22 locations throughout Indonesia, but further testing is required in another 16 locations before receiving approval from the National Seed Agency for licensing. Additional government research projects on transgenic plants, such as virus resistance for tomatoes and potatoes, delayed ripening for papaya, sweet potato pest resistance, drought-tolerant rice, and pest-resistant soybeans, remain ongoing, albeit at a relatively modest pace. Table 3 shows biotechnology research at the containment facility stage and in limited field trials.

Table 3. Transgenic crops at containment facility stage and in limited field trials

No.	Institution	Crops and traits	Genes
At laboratory stage			
1.	ICABIOGRAD	Rice resistance to bacterial leaf blight	OsWRKY76
		Nitrogen-use efficiency	CsNitri1-L
		Delayed-ripening papaya	Antisense OCC oxidase
		Seedless tomato	defH9-IaaM and defH9-RI- IaaM
		Soybean resistance to podborer	Cry1Ab
		Drought-tolerant rice	OsDREB1A, OSERA, OsPPCK
	ICABIOGRAD-BAU	Tomato resistance TYLCV and CMV	CP
2.	Indonesian Institute of Science (IIS)	Rice resistance to stemborer	Cry1B-cry1Aa, cry1B
		Drought-tolerant rice	Hd-Zip (oshox)
		Rice resistance to leaf blight	entC, pmsB
		Fast-growth albisia	Xylosase, Xylo-glucanase, polygalactorunase, xylanase
		High-cellulose acacia	Xylosase, Xylo-glucanase, polygalactorunase, xylanase
		Low-amylase cassava	Bleaching enzyme be-1 and be-2
3.	Bogor Agriculture University	Potato resistance to Fusarium sp and cyst nematode	chitinase
		Peanut resistance to virus	CP
		High P-absorption sugarcane	phytase
4.	University of Brawijaya and Udayana University	Citrus resistance to CVPD	CVPD
5.	Udayana University	High-productivity soybean	SPS and albumin

(...continued)

No.	Institution	Crops and traits	Genes
At limited field trial stage			
1.	ICABIOGRAD-IVEGRI	Potato resistance to late blight (*Phytophthora infestans*)	Rb
2.	IIS-ICABIOGRAD	Cassava low amylase content and herbicide tolerance	IRC-GBSS
3.	IIS	Rice resistance to stemborer	Cry1AB
4.	PTPN XI- Jember University	High sugar content sugarcane	SosPS1

Source: Modified from Bahagiawati A.H. Agricultural biotechnology R&D and its application in Indonesia [7].
Notes: BAU, Bogor Agricultural University; CMV, curly mosaic virus; CP, coat protein; CVPD, citrus vein phloem degeneration virus (citrus greening disease); ICABIOGRAD, Indonesian Centre for Agriculture Biotechnology and Genetic Resource Research and Development; IIS, Indonesia Institute of Science; IVEGRI, Indonesian Vegetables Research Institute; PTPNXI, Perkebunan Nusantara X (Persero–largest sugar producer in Indonesia); SPS, sucrose phosphate synthase; TYLCV, tomato yellow leaf curl virus.

Multiple location field trials for both soybean and maize, developed by the private sector, have been completed and are next in the pipeline for approval (Table 4).

Table 4. Transgenic products developed by private companies and status of biosafety approvals

No	Transgenic Product	Biosafety committee recommendations	Government approval status
1.	Bt Cotton variety Bt DP 90 B & PM 1560 B Event MON 531/757/1076 (MON-OO531-6, MON-OO757-7)	Safe towards environment and biodiversity (1999)	Limited release based on the decree of Minister of Agriculture in 2001
2.	Roundup Ready Cotton Variety DP 5690 RR (identical to 1220 RRA 68022) & DR 90 RR (identical to 90 RE 60012) Event MON 1445/1698 (MON- O1445-2)	Safe towards environment and biodiversity (1999)	Approved by the National Biosafety Committee
3.	Roundup Ready Soybean Variety Cristalina RR & Jatoba RR Event GTS 40-3-2- (MON-04032-6)	Safe towards environment and biodiversity (1999)	Approved by the National Biosafety Committee

(...continued)

No	Transgenic Product	Biosafety committee recommendations	Government approval status
4.	Roundup Ready corn (maize) Variety RR-1 &RR-2 Event GA 21 (MON –OO21-9)	Safe towards environment and biodiversity (1999)	Approved by the Chairman of National Biosafety Committee
5.	Bt Corn Variety Bt MON 810-1 &Bt Mon 810-2 Event MON 810 (MON-OO810-6)	Safe towards environment and biodiversity (1999)	Approved by the National Biosafety Committee
6.	Ronozyme – P (probiotic feed)	Safe towards environment and biodiversity (2001)	-
7.	Finase P and Finase-L (probiotic feed)	Safe towards environment and biodiversity (2001)	Biosafety recommendation from the Director General of Agriculture Research and Development Agency, Ministry of Agriculture

Source: Indonesia Biosafety Clearing House [8].

Bt maize, Bt cotton, RR corn, and RR soybeans seeds have passed the biosafety assessment process and are approved for food, feed and processing, but not for planting. In addition, Ronozyme-P and Finase L and P (as protein enrichment for feed) are reported to be in the pipeline. Table 5 shows the crop types and events and their approval status.

Table 5. Transgenic crops approved for biosafety

Plant	Trait	Gene	Source	Gene transfer technology	Event
Cotton	Insect resistance	Cry1Ac	*Bacillus thuringiensis subs kurstaki*	*Agrobacterium tumefaciens*	MON531/757/1076
Cotton	Glyphosate herbicide tolerance	CP4 EPSPS	*B. thuringiensis strain CP4*	*A. tumefaciens*	MON1445/1698

(...continued)

Plant	Trait	Gene	Source	Gene transfer technology	Event
Soybean	Glyphosate herbicide tolerance	CP4 EPSPS	*B. thuringiensis strain CP4*	Particle gun method	GTS 40-3-2
Maize	Glyphosate herbicide tolerance	mEPSPS	*B. thuringiensis*	Particle gun method	GA 21
Maize	Insect resistance	Cry1AB	*Bacillus thuringiensis subs kurstaki*	Particle gun method	MON810
Sugarcane	Drought tolerant	betA	*Rhizobium melioti*	*A. tumefaciens* strain LBA 4404	PRG NXI-4T

Source: Modified from ICABIOGRAD [9].

Plant Biosafety Policy

Having ratified the Cartagena protocol, and in anticipation of biotechnology products, Indonesia has enormous scope for progress in the area of biosafety regulation, especially to ensure applicability. In addition, biotechnology regulation enhances credibility and acceptability of biotechnology.

The government has issued several regulations and guidelines to protect the public from any possible negative consequences of biotechnology utilization. Its policy is formulated conservatively with due regard to environmental safety, food safety, and/or feed safety based on scientific approaches, also taking into consideration the prevailing religious, ethical, sociocultural, and aesthetical norms. The Ministers of Environment, Agriculture, Forestry, Marine Affairs and Fisheries, and the Head of the National Agency of Drug and Food Control are the authorities responsible for approving and releasing transgenic products.

Main National Challenge

Asia will have the highest absolute increase in population, from an estimated 3 billion to 4.5 billion in the next 20–25 years. During the same period, the urban population is expected to nearly double from 1.2 billion to 2 billion, as rural people move to the cities in search of employment. The population of Indonesia is projected to continue to increase over the next 25 years from 205.1 million in 2000 to 273.2 million in 2025 [1].

Urbanization and income growth frequently lead to shifts from a diet based on root crops (cassava, yam, and sweet potato), sorghum, millets, and maize, to rice and wheat, which require less preparation time, and to more meat, milk, fruits, vegetables, and processed foods. Meeting the food needs of Asia's growing and increasingly urbanized population requires increases in agricultural productivity, and matching these increases to dietary changes and rising incomes. The global demand for cereal production is predicted to increase by about 40% from the present level of 650 MMT between the 2006/08 average and 2050. This increase will have to be achieved with less labor, water, and arable land, because there is no scope for increasing the cultivated area. Therefore R&D using biotechnology in agriculture is expected to increase the productivity of food crops to meet the needs of an increasing population.

However, certain constraints may halt the development of this technology, such as research funding in the areas of biosafety, risk assessment, and risk management, all of which needs to be increased. Relative to other member countries of the Association of Southeast Asian Nations (ASEAN), research funding in Indonesia is very low. In terms of GDP percentage, agricultural biotechnology research was only 0.21%, as compared to 2.67% in Japan, 0.93% in the Republic of Korea (ROK), and 0.41% in PR China. In order to ensure safe application of modern biotechnology with maximum impact on the Indonesian economy, a strong government commitment to provide facilities, funding, and continuous support for human resource development is a must.

To win public acceptance for transgenic plants and their derivative products for domestic use or exports, regulations that comply with international standards and that guarantee food, feed, and environmental safety are needed. Several regulations in this matter have been issued in Indonesia, from the ministerial level to Presidential decrees. The regulations have continually evolved since their inception in 1996, in the form of the Food Law and other kinds of regulations, to the publication of Government Regulation No. 28 in 2004 on the food safety of genetically modified products, and Government Regulation No. 21 in 2005 on the biosafety of genetically modified products.

In order to facilitate and accelerate the development of transgenic technologies in Indonesia, a regulatory apparatus that can be implemented easily, economically, and consistently is required so that public acceptance toward transgenic plants can be further improved. However, the regulations have to be based on international standards, have a solid scientific basis, and be accompanied by clear operational and technical guidelines

DEVELOPMENT SCOPE AND OPPORTUNITIES

Generally, life has improved for many Asians, including Indonesians. However, about 900 million still live in poverty, and approximately 536 million of them remain undernourished. Growth rates in crop yields, on the other hand, have slowed between 1987 and 2001 [10]. By 2050, it is estimated that food production must double to offset population growth. Several studies predict that Indonesia will continue to be the world's third-largest rice producer, where 49% of dietary energy is provided by rice, yet yield improvement rates are low, at 0.4% per year. Maize yields are generally increasing across Asia. Yield improvement rates are currently on track to double production in some parts of the Islamic Republic of Iran (IR Iran), Pakistan, India, PR China, Indonesia, Bangladesh, Lao PDR, Cambodia, Vietnam, and Turkey [11].

The intensification of agriculture and the reliance on irrigation and chemical inputs have resulted in problems of soil salinity, pesticide misuse, and degradation of natural resources in some parts of the world. Green Revolution technologies were useful in favorable and irrigated environments, but they have had little impact on the millions of smallholders living in rainfed and marginal areas.

Biotechnology had, in Indonesia, become a national priority for national science and technology development since 1988 for maintaining sustainable agriculture production. The State Ministry for Science and Technology established the National Committee on Biotechnology, which is responsible for preparing and formulating a national biotechnology policy and development program to assist national development. The committee also gives guidance and encouragement to the development of the biotechnology sector and its supporting R&D grants and human resources. The committee also gives directions for the establishment of national, regional, and international networks of cooperation on biotechnology, and monitors implementation of the national policy on biotechnology. Since 1994, the government has been providing competitive grants for biotechnology research, resulting in a significant increase in high-quality research activities. At present, several public institutions are engaged in biotechnology research in food crops (e.g., rice, maize, sweet potato, soybean), as well as other important commodities, such as cacao and oil palm.

Biotechnology research collaboration includes enhanced technology (research), and post-harvest investment with a focus on trade capacity building (regulatory reform based on science, production systems, value-added processing, supply-chain distribution, and farm-to-market infrastructure). Collaborating partners include bilateral government agencies, private sector agribusiness companies, and agricultural (land grant) universities. National collaboration includes capacity building for researchers throughout the country.

A variety of R&D collaborations involving elements of academia, business, and government (ABG) have been conducted. In addition, a variety of international cooperation modes has been developed with various organizations, among others: the Centre for Science and Technology of the Non-Aligned and Other Developing Countries (NAM S&T Centre), the Asia Pacific Economic Cooperation Industrial Science and Technology Working Group (APEC-ISTWG), and SEA-EU-NET (an international science cooperation network deepening science and technology cooperation between Southeast Asia and Europe), etc.

In addition, bilateral cooperation has been established with 21 countries: South Africa, USA, Australia, Austria, Netherlands, PR China, Cuba, Hungary, India, IR Iran, Italy, Germany, ROK, the Democratic Republic of North Korea, Malaysia, France, Romania, Russia, Slovenia, Sudan, and Tunisia. However, the contribution of science and technology to the overall economy, described in terms of Total Factor Productivity (TFP), is still low. As an example, Indonesian TFP for crops decreased from 3.95% (1961–1980) to –0.78% (1981–2001) and TFP for livestock decreased from 3.08% (1961–1980) to 2.41% (1981–2001). Negative values indicate that TFP increase in inputs does not lead to increased outputs; meaning that where there is insignificant contribution of technology in the production process, the production process takes place less efficiently.

Additional information on agricultural biotechnology in Indonesia may be found at the following websites:

- Indonesia Biosafety Clearing-House: http://indonesiabch.org
- Indonesian Agency for Agriculture Research and Development: http://www.litbang.deptan.go.id/
- ICABIOGRAD, Ministry of Agriculture: http://biogen.litbang.deptan.go.id/cms/
- Clearing House Mechanism of National Biodiversity: http://bk.menlh.go.id/?&lang=en.
- Indobic. http://www.indobic.or.id/indobic/biotech-crop-commercialization-increased-growth-since-2/
- State Ministry of Science and Technology National http://www.ristek.go.id/english.php.
- http://www.ristek.go.id/file/upload/File/profil/jakstra2010/193MKpIV2010%20JAKSTRANAS.pdf.

CONCLUSION

Biotechnology in Indonesia is a flagship technology that is expected to meet national food needs and support the national economy. Several national institutions and research centers have been conducting biotechnology R&D in agricultural crops to support national programs to meet national food requirements for an increasing population. Many research incentives have been provided for research collaboration both nationally and internationally. A biosafety program has also been established in anticipation of biotechnology product releases in the near future.

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AGRICULTURAL BIOTECHNOLOGY IN THE ISLAMIC REPUBLIC OF IRAN

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INTRODUCTION

Remarkable progress has been made over the past few decades to increase food production at the global level. However, this increase has not been distributed equally, leading to regional problems of food deficit and chronic hunger. Approximately half the population in the developing world lacks access to adequate food supplies. Biotechnology can help to improve agriculture and the food industry, and developing countries should develop their own capacities in order to gain greater benefit from it.

Agricultural biotechnology is experiencing rapid progress in the Islamic Republic of Iran (IR Iran). According to the National Biotechnology Strategy, IR Iran has to grow a minimum of 0.5% of the global area under transgenic crops. IR Iran has experienced remarkable advances in the R&D of agricultural biotechnology during the last few decades. In addition to more than 100 laboratories in universities and research organizations, six major research institutes/centers are now involved in agricultural biotechnology R&D. Both traditional and modern biotechnologies have been explored in order to meet the agricultural needs of about 77 million people living in IR Iran. The country has seen increases in animal vaccine production, insect-resistant rice commercialization, the production of transgenic goats expressing Factor VIII in their milk, improved insect-resistant crops, herbicide tolerance, better food quality, molecular farming, mass biofertilizer production, biological insecticides, and disease-free planting materials produced through tissue culture, with some products even being exported overseas. Biotechnology will certainly play a major role in the future of agriculture in IR Iran. With rapid developments in biotechnology and genetic engineering techniques, many scientists in IR Iran hope to solve the country's food problems more rapidly and efficiently.

AGRICULTURAL BIOTECHNOLOGY AND GENETIC ENGINEERING IN IR IRAN

Genetic engineering programs in IR Iran started as early as 1980. However, the agricultural biotechnology program was started almost two decades later (1999). The Agricultural Biotechnology Research Institute of Iran (ABRII) is the main research body for agricultural biotechnology in IR Iran. It is a part of the Agricultural Research, Education and Extension Organization (AREEO) under the Ministry of Agriculture. ABRII was established in 1999.

IR Iran was the first Islamic country to officially release any biotech crop plant (an insect-resistant transgenic rice variety). The plant performed well in the hands of farmers, and the scientific society was strongly supportive of the risk assessment and environmental studies conducted by the developer [1]. Overall, the risk assessment results indicated no significant threats from this Bt rice to the rice-growing environment in IR Iran, in particular, on non-target organisms beyond the effect of existing pest-control measures. The Ministry of Health has also declared that the genetically modified (GM) rice is safe. There are however, some concerns raised by some middle-class authorities who have slowed down the progress of GM crop commercialization in IR Iran.

In addition to Bt rice, the country will soon see the release of several domestically produced transgenic crop plants. These include, but are not restricted to, insect-resistant and fungal-disease-tolerant cotton plants (stacked genes), insect-resistant sugar beet, insect-resistant alfalfa, insect-resistant potato, herbicide-tolerant canola, and herbicide-tolerant rice. There are also attempts to improve crop tolerance against abiotic stresses, mainly drought and salinity. Some examples include the over-expression of proline-5-carboxylate synthase (P5CS) in order to enhance osmotic stress resistance in transgenic tobacco, isolation of salt-inducible genes from wheat, identification of salt-inducible genes from *Aeluropus lagopoides*, and identification and cloning of drought-inducible genes from *Aeluropus lagopoides*.

There are several ongoing projects in the field of molecular farming as well. The following are some examples:

- Cloning and expression of the tissue plasminogen activator gene (tPA) in tobacco for stroke treatment. tPA is a protein involved in the breakdown of blood clots, catalyzing the conversion of plasminogen to plasmin, which is the major enzyme responsible for clot breakdown. Because it works on the clotting system, tPA is used to treat embolic or thrombolytic stroke.

- Expression and characterization of a recombinant monoclonal antibody against MUC1 Mucin in tobacco. MUC1 is a protein expressed on most secretory epithelia, including the mammary gland. In breast cancer, MUC1 is overexpressed by more than 90%. The ultimate goal is to produce a plant antibody against MUC1 and prevent cancer development.

- Successful cloning and expression of a tobacco recombinant camelid single-domain antibody.

- The production of a novel camel single-domain antibody specific for the Type III Mutant epidermal growth factor receptor (EGFR).

- Expression of human interferon gamma (IFNG) in canola seed. IFNG was transferred to canola under the control of a seed specific promoter (napin). IFNG is a soluble cytokine that is the only member of the type II class of interferons. IFNG is critical for innate and adaptive immunity against viral and intracellular bacterial infections, as well as tumor control.

IR Iran has not only produced GM crop plants, but is also producing transgenic animals. In January 2010, Iranian researchers announced the birth of the first transgenic animals to be produced in any Islamic country [2]. This was accomplished at the Royan Research Institute (RRI) in Isfahan. RRI is closely supervised and supported by Ayatollah Khamenei, the Supreme Leader of the country. He has emphasized on many occasions “to pay good attention to biotechnology since it is a very important field.” This indicates the full support and official stand of the country’s leader towards the application of modern biotechnology. The two goats produced through genetic engineering for pharmaceuticals in their milk are called Shangool and Mangool, two of the three characters of the famous Iranian popular folk story, “Shangool, Mangool and Habbe-ye angoor.” Foreign proteins are expressed in these biotech animals’ milk for human therapy. Last year the third goat, Habbe-ye angoor, was also born.

NON-GM AGRICULTURAL BIOTECHNOLOGY PRODUCTS IN IR IRAN’S MARKET

Biofertilizers

Phosphate Biofertilizer Barvar 2

This product results from several years of studying phosphate-dissolving bacteria. These bacteria occupy the plant root region and cause phosphorous release from insoluble minerals and organic soil compounds, resulting in increased availability of phosphate for the plant. About 80% of chemical phosphate fertilizers convert into an insoluble form in the soil very quickly. This means that excessive amounts of phosphorous must be added to the soil, resulting in increased costs and environmental contamination due to fertilizer residues. Phosphate biofertilizer can decrease phosphate chemical fertilizer usage by 50%, while increasing the yield by 10%–50%, thus eventually doubling the benefit to farmers. The product is formulated and marketed by the private sector and is currently exported to several countries in the region.

Nitrogeneous Biofertilizer

Economic, health, and environmental problems have resulted from the use of chemical nitrogen fertilizers, demonstrating the importance of alternative plant feeding methods. After seven years of research, Iranian researchers have produced nitrogen fertilizers containing native rhizobacters as a nitrogen fixative. These bacteria can increase N-uptake in native rice cultivars by 69%.

Biopesticides

Pests reduce crop yield worldwide by 10%–20% annually. Due to both the harmful effects of chemical pesticides and economic costs, biopesticides are considered to be a viable alternative. Bt-derived pesticides are the most conventional and environmentally friendly. In IR Iran, Bt-derived Cry proteins are produced on a large scale as a biopesticide, and have been shown to effectively control one of the most important rice pests. the green rice caterpillar (*Naranga aenescens*).

Production of New Cultivars through Modern Biotechnology

IR Iran has also succeeded in the following:

- Mass production of healthy and virus-free potato mini and micro tubers, pistachio, date palm, apple, olive, roses, and several other species through tissue culture techniques

- Identification and isolation of candidate genes for Fusarium head-blight resistance and molecular breeding for improved Fusarium head-blight resistance in wheat

- Production and evaluation of high-yielding doubled-haploid wheat and barley lines with resistance to yellow rust

- Introduction of kallar grass (*Leptochloa fusca*) as an ideal crop for fodder production and bio-reclamation of salt affected soils
- Production of biofertilizer prepared from N-fixing microalgae in rice fields
- Identification of candidate genes involved in saline and drought tolerance in *Sueada aegyptiaca*, sugar beet, and wheat using proteomics techniques

BUSINESS POTENTIAL FOR AGRICULTURAL BIOTECHNOLOGY PRODUCTS

Production of Pistachio Seedlings Using Tissue Culture

A major project of the Ministry of Jihad-e Agriculture is to develop of areas cultivated with high-quality pistachio and an increase the yields of pistachio per hectare. This will require large numbers of high-quality pistachio seedlings.

Production of Date Palm Seedlings Using Tissue Culture

One of the successful agribusiness sectors in this field is the Rana Agro-industry Company; a producer and distributer of date palm seedlings in the southern part of IR Iran.

CONSTRAINTS ON COMMERCIALIZATION

Technophobia

Technophobia among some middle-class authorities is the major constraint. The views of the country's president H.E. Dr. Hassan Rouhani about biotechnology and other new technologies are promising, judging by the activities and publications of the new Technologies Division of the Center for Strategic Research (CSR) under his presidency. Dr. Rouhani responded to questions posed to him during the election campaign saying, "… biotechnology and genetic engineering play a key role in medicine, agriculture, environment, and industry." He promised that he "will appoint a presidential adviser in new technologies." We hope that this will be a turning point, and facilitate the commercialization of biotech products in IR Iran.

Privatization

Every idea needs investment to support commercialization. Generally, the private sector provides the best investors. Unfortunately, the private sector for agricultural biotechnology in IR Iran is in its infancy. This is in direct contrast to medical biotechnology. Additionally, most still prefer to invest into sectors such as petroleum, electronics, and construction. It will be necessary to educate investors about this new industry and demonstrate that its benefits are worthwhile. Success in other countries will be helpful in convincing Iranian investors.

Biosafety Challenges

This is a common problem with biotechnology worldwide. These concerns arise primarily from political, not scientific, considerations. However, building public awareness is likely to be very effective, especially in a society that includes many uneducated people. Fortunately, the situation is changing to some extent.

INSPIRING INITIATIVES AND KNOWN BEST PRACTICES IN BIOTECHNOLOGY APPLICATIONS, COMMERCIALIZATION, AND INVESTMENT IN THE AGRICULTURE, FOOD, AND AGRIBUSINESS SECTORS

A Case Study: Insect-Resistant GM Rice in Iran

Table 1 compares the import of rice during four decades (1961–2000) among PR China, India, and IR Iran. It indicates that while IR Iran was not a very important rice-importing country in 1961, it is now importing more than a million metric tons of polished rice every year.

Table 1. Polished rice imported by three Asian countries from 1961 to 2000 (thousand metric tons)

Year	PR China	India	IR Iran
1961	118.4	737.7	11.3
1966	53.5	995.0	28.5
1971	–	534.1	60.5
1976	126.3	414.6	260.0
1981	285.7	51.6	586.6

(...continued)

Year	PR China	India	IR Iran
1986	326.0	21.1	474.7
1991	145.9	12.1	630.3
1996	765.1	0.0	1150.0
2000	244.5	13.2	1129.5

Source: The International Rice Research Institute (IFPRI) [3].

This is partly due to land and water shortages for agriculture. IR Iran grows about 600,000 ha of rice per year. Of the chemical insecticides used in the country, 88% is for rice stem borers only [4], resulting in serious negative impact to environmental safety and human health. Residual levels of these harmful insecticides have always been a safety concern of consumers. The International Rice Research Institute (IRRI) had not discovered any source for stem borer resistance, even after testing 120,000 rice germplasms. Genetic engineering was therefore used as an approach to deal with this problem.

In 2004, coinciding with the International Year of Rice, the Iranian government officially released an insect-resistant rice line as the country's first transgenic crop plant [5]. This transgenic rice (line # 827; cultivar Tarom Molaii), containing a synthetic cry1Ab gene under the control of a green tissue specific PEP-carboxylase promoter, was developed in collaboration with the IRRI [6, 7]. Biosafety studies and risk assessments were conducted prior to the environmental release of this plant and included the comprehensive molecular characterization of the transgenic plant, establishment of substantial equivalence of the GM rice with its parental conventional cultivar, nutritional and biochemical compositional analysis, animal feeding trials, five years of field trials to study insect resistance and agronomic characteristics at field condition, insect bioassays on four lepidopteran insect pests (*Chilo suppressalis, Scirpophaga incertulas, Cnaphalocrocis medinalis and Naranga aenescens*), and environmental studies. Several studies were conducted to address the environmental concerns related to the release of this Bt rice. These studies included the assessment of the risk of gene flow and generation of "super weeds" in the IR Iran environment, the possibility of evolved insect resistance to the introduced protein, assessments of the effects on soil microorganisms, and the effect of GM rice on non-target organisms.

Results indicated the following:

1. Stability of the transgene and its expression over more than 16 generations

2. Efficiency as a "high-dose" plant in causing 100% mortality on the tested lepidopteran insects

3. Absence of Cry1Ab protein from root, pollen, and any tissue other than green tissue, and hence no negative effects on soil microorganisms and pollinators

4. Low possibility of gene flow due to the absence of the wild rice *Oryza* genus from the IR Iran environment

5. No adverse effects on non-target organisms, in particular *Andrallus spinidens*, a predator of *Naranga enescense*, and on *Trichogramma brassicae*, a parasitoid of *Chilo suppressalis* eggs since no live larvae was found to lay eggs after the first and second instar larvae fed on transgenic rice

IR Iran's farmers embraced this biotech crop plant as the seeds were distributed at no extra cost (as compared to traditional seeds), and further saved them expense in chemical insecticides and their application. It is estimated that full commercialization of Bt rice in IR Iran will result in a significant increase in the yield and production of rice, a significant reduction in the cost of rice production due to savings in application of chemical insecticides and labor, reduced importation of rice, and increased environmental safety thanks to reduced application of synthetic chemical insecticides. In 2008, more than 30 million ha of transgenic crops globally were insect resistant. Limited amount of disease-resistant crops (virus-resistant papaya and virus-resistant squash) were also commercialized [8].

There are several more transgenic plants with different improved traits in the pipeline waiting for approval. These include, but are not limited to, transgenic insect-resistant cotton, potato and sugar beet, and drought- and cold-tolerant lentil and chickpea.

GENERAL FEATURES OF AN EFFECTIVE BIOTECHNOLOGY POLICY FRAMEWORK

An effective biotechnology policy framework allows GM products to be produced, imported into developing countries and transitional markets, and in turn, for developing countries to export their products to external markets. General economic and commercial policies present in a country or region plays a major role in determining the business and investment climate for agricultural biotechnology, and also whether or not an investor will engage in specific biotechnology initiatives.

In general, the characteristics of an effective biotechnology policy framework are:

- Biosafety regulations ensuring that human, animal, agricultural, and environmental safety is protected

- Novel food standards and regulations are in place and implemented

- An effective intellectual property rights (IPR) or patent regime for plant breeders' is put in place and respected

- Incentives for local investment and innovation are provided and science-based regulations are developed and implemented

- Foreign and host-country institutions are treated equally

Developing countries need to increase their own capacity to access this technology as soon as possible, or else those who have access may prevent others from enjoying its benefits. Radically new technologies are creating a completely new dynamic for agricultural systems, not only in developed countries, but also in the developing world.

The Need for "Biosafety"

Rapid growth in transgenic crop production and the release of large amounts of genetically modified organisms (GMOs) into the environment has raised concerns and different public opinions about controls and regulation. The magnitude of these deliberate field releases has intensified the need for biosafety. Environmentalists, consumers, agronomists, and many others have their own concerns about this new and powerful, but at the same time controversial, technology. Biosafety takes this into account and responds to these concerns.

Though there is no internationally agreed definition for the term "biosafety," it is generally used to describe frameworks encompassing policy, regulation, and management to control the potential risks associated with the use of "modern biotechnology." This includes the use, release, and trans-boundary movement of GMOs resulting from modern biotechnology. In other words, the term "biosafety" is used for the regulatory systems designed to ensure that applications of modern biotechnology are safe for human health, agriculture, and the environment. Such biosafety frameworks may occur at the international, regional, or national levels. Biosafety frameworks may also address risk communication issues, or even more generic impacts such as those that are potentially positive, negative economic, or social. The term "biosafety" is used in the Cartagena Protocol, but is otherwise rarely used in other international instruments. For example, both the World Health Organization (WHO) and the Food and Agricultural Organization of the United Nations (FAO) use the term "safety" only, even when they are referring to the safety of the products of modern biotechnology.

Biosafety is not a "no" to the application of modern biotechnology; rather, it is an emphatic "yes" to the access and safe use of the technology. In other words, we need biosafety because we want "modern biotechnology."

Biosafety is now considered an essential component for the development and marketing of modern biotechnology products. Therefore, in addition to investment (which is required for the R&D of biotechnology products), preparation, ratification, and implementation of a sound regulatory framework is also needed to prevent the risk of recombinant DNA technology causing damage to either humans or the environment. Before any genetic transformation technology or materials may be transferred, the recipient country must have a regulatory approval mechanism in place to ensure the safe transfer, handling, use, and environmental release of transgenic materials.

National polices, laws, and effective institutional capacities should be developed and implemented. Issues relating to appropriate agricultural technologies, technology access, and management should also be emphasized. The benefits of IPR in both international and local arenas should be examined and determined. In accordance with the General Agreement on Tariffs and Trade (GATT), these regulations must be applied equally to internal and external sectors.

Finally, a compromise between the "germplasm owners" and the "technology owners" should be made before an irreversible resistance is generated against biotechnology in developing countries. As Dale noted in 1995, "Fair, responsible and workable technology transfer and remuneration agreements must be arranged with developing countries – sources of germplasm diversity for many key crops." [9]

Biotechnology can help to improve agriculture and the food industry. Therefore, biotechnology should be given priority in the food and agriculture sectors in general, especially in developing countries.

Biotechnology can also help to improve post-harvest quality and prevent the post-harvest loss of fresh produce and crops, which is one of the causes for the region's lower production efficiency.

It is very unfortunate (and in the personal view of the authors, suspicious), that before developing countries are assisted to build capacity in developing and accessing these technologies, they are faced with colorful and attractive offers for capacity-building and "regulation" of the technology. This will result in developing countries having no capacity to develop their own technology and reliant on the technology of others.

International organizations will intensify their involvement in both biosafety and biotechnology. Rules and regulations, standards and guidelines will become so sophisticated and complex that no developing country will have the capacity to implement them properly. Developing countries should not fight for more stringent regimes! They will be the first victims themselves. Developing countries should fight for easing up, not with respect to the importation of the goods, but to the development of in-house technologies and their release.

FUTURE DEVELOPMENT FOCUS WITH POSSIBLE CONTRIBUTION

Strategies for the Development of Biotechnology

The strategic objective of agricultural biotechnology is to construct and provide platforms for the commercialization of its R&D results. Establishing a modern and internationally competitive biotechnology R&D system requires substantial investment in human resources and financial capacities. The role of the government should be to prepare a comprehensive plan for biotechnology training, and provide policies to encourage growth in the biotech sector through direction-setting and providing basic infrastructure. The private sector should be concerned with applied R&D and commercialization. The development-oriented NGOs should concentrate on farmer retooling and organizing so that the latter can be globally competitive producers and traders. Legislation of intellectual property laws relevant to biotechnology, preparation of national standards for biotechnological products, and promotion of public awareness and public acceptance should be main goals. Allocation of funds, provision of facilities according to priorities, and facilitation of joint investment in domestic and foreign biotechnology agencies to achieve advanced biotechnology, are all important strategies for developing biotechnology in IR Iran.

Strategies for Industrialization and Production, Support of the Private Sector, Trade, and Markets

As a country endowed with vast biodiversity, IR Iran has all the ingredients for a successful biotechnology industry. Therefore, biotechnology has received governmental support and commitments, particularly in terms of R&D. In 2004, the Biotechnology Development

Council (BDC) was established to coordinate countrywide biotechnology activities. It has undertaken the tasks of leading biotechnology activities in the public sector, promoting private/public sector participation, and raising public awareness about biotechnology.

Different Strategies for Industrialization

Supporting and promoting innovation in small and medium-sized enterprises, and establishing biotechnological parks/centers in biotechnological development zones to increase the production and export of biotechnological products, are considered important strategies in IR Iran. It is essential to transfer biotechnology from research centers to beneficiaries. To achieve this, partnerships between public-funded organizations and the private industry are crucial in the science-to-product value chain. It is proposed that at least 30% of government funded programs must have a commercial partner, and these partners will be responsible for directing R&D towards commercialization. The process of industrializing GM crops will include actions such as monitoring the trade, collecting market intelligence of GM crops and products, following the trend of organic markets, watching international developments to identify niche markets, monitoring countries that are rejecting GM foods, and feeding this intelligence to concerned agencies. In order to develop a market for biotechnological products, it is important to prepare the groundwork for exploiting existing capacities in the country and in neighboring countries. Establishing an effective presence in local and international exhibitions, as well as conferences to develop a market for biotechnological products would be one effective strategy. Other helpful strategies include introducing effective procedures to attract foreign investment, and the establishment of special customs regulations for biotechnology products.

SUMMARY AND CONCLUDING REMARKS

Iranian policymakers consider agricultural biotechnology to be a strategically significant tool for improving national food security, raising agricultural productivity, and creating a competitive position in international agricultural markets. Investment in IR Iran's biotechnology R&D is essential for the nation to promote its biotechnology industry. Investment in biosafety management capacity and policy implementation are also critical factors for the health and sustainable development of this industry. Private sector participation has great potential in the commercialization of agricultural biotechnology products. However, there is a need to put in place appropriate government policies to encourage both scientists and private investors. Success in recruiting private investors from other countries will likewise be helpful.

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BIOTECHNOLOGY: ANSWER TO FOOD SECURITY IN PAKISTAN

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INTRODUCTION

Pakistan is located in southern Asia, bordering the Arabian Sea between India to the east, the Islamic Republic of Iran (IR Iran) and Afghanistan to the west, and PR China to the north. It has an area of 796,095 sq km, of which 770,875 sq km is land and 25,220 sq km is water. Pakistan's principal natural resources are arable land and water. About 25% of Pakistan's total land area is under cultivation and is watered by one of the largest irrigation systems in the world. Pakistan irrigates three times more hectares than Russia. Agriculture accounts for about 21.0% of GDP and employs about 43.7% of the labor force [1]. The most important crops are wheat, sugarcane, cotton, rice, and maize, which together account for more than 75% of the value of total crop output (Table 1). There are also citrus, mango, guava, apple, peach, apricot, and date palm orchards. Only about 4% of land in Pakistan is covered with forest. According to the Economic Survey of Pakistan, the livestock sector contributes about half of the value added (55.91%) in the agriculture sector of Pakistan [1]. Fisheries and forestry make up about 3.55% of the GDP. Pakistan is a net food exporter, except in occasional years when its harvest is adversely affected by drought. Pakistan exports rice, cotton, fish, fruits (especially Kinnow mandarins and mangoes), and vegetables. The country imports vegetable oil, wheat, pulses, and consumer foods and has the largest camel market in Asia.

Pakistan, with an annual population growth rate of 1.8%, adds 3 million people each year. According to the United Nations Integrated Regional Information Network (IRIN), the food security situation in Pakistan seems extremely chaotic as, despite the fact that farmers are producing more and more (especially wheat) and the country is enjoying surplus crops, the masses are still suffering shortages and unabated price hikes [2].

The food security issue is becoming serious because of nefarious elements such as middlemen and smuggling mafia. Food experts are critically examining this situation, warning that the country's food security is under threat due to the shallow approach of economic managers whose policies inflict serious difficulties not only on farmers, but also on consumers.

Table 1. Production of important crops in Pakistan ('000 metric tons*)

Year	Cotton*	Sugarcane	Rice	Maize	Wheat
2007-08	11,665	63,920	5,563	3,605	20,959
	–	–	–	–	–
2008-09	11,819	50,045	6,952	3,593	24,033
	1.4%	–21.7%	25.0%	–0.3%	14.7%
2009-10	12,914	49,373	6,883	3,216	23,311
	9.3%	–1.3%	–1.0%	–9.2%	–3.0%
2010-11	11,460	55,309	4,823	3,707	25,214
	–11.3%	12.0%	–29.9%	13.7%	8.2%
2011-12	13,595	58,397	6,160	4,338	23,473
	18.6%	5.6%	27.7%	17.0%	–6.9%
2012-13	13,030.7	63,449.9	5,535.9	4,220.1	24,224.4
	–4.1%	8.3%	–10.1%	–2.7%	3.0%
2013–14	12,768.9	67,460.1	6,798.1	4,944.2	28,979.4P
	–2.0%	5.5%	18.4%	14.6%	6.8%

Source: Pakistan Bureau of Statistics [3].
Notes: Figures in the second row of each time period are growth/decline rates relative to the previous period. P, provisional (July–March).
* Cotton production is in thousand bales of 375 lbs each.

CURRENT STATUS OF BIOTECHNOLOGY

In all key national science and technology policies, the role of biotechnology as a potential tool for growth and socioeconomic development is well acknowledged. Modern biotechnology use in Pakistan started in 1985. Today, there are more than 29 biotech centers/institutes in the country. However, few centers have appropriate physical facilities and trained manpower to develop genetically modified (GM) crops. Most of the activities have focused on rice and cotton, which are among the top five crops of Pakistan. Biotic (virus/bacterial/insect) and abiotic (salt) resistance and quality (male sterility) genes have already been incorporated in some crop plants (Table 2). Despite acquiring the capacity to produce transgenic plants, no GM crops (either produced locally or imported), have been released in the country.

Table 2. Crops undergoing transformation in Pakistan

Crop	Institutes
Cotton	• Centre of Excellence in Molecular Biology, Lahore • National Institute of Biotechnonology and Genetic Engineering, Faislabad • Institute of Agricultural Sciences, Punjab University, Lahore • National Agriculture Research Centre, Islamabad
Brassica	• Institute of Biotechnonology and Genetic Engineering, Peshawar • Dr. A.Q. Khan Institute of Biotechnonology and Genetic Engineering, Karachi • Agricultural Biotechnology Research Institute, Faislabad • Ayub Agricultural Research Institute, Faislabad
Rice	• Centre of Excellence in Molecular Biology, Lahore • National Institute of Biotechnonology and Genetic Engineering, Faislabad • National Agriculture Research Centre, Islamabad • School of Biological Sciences, Punjab University, Lahore
Wheat	• National Institute of Biotechnonology and Genetic Engineering, Faislabad • Forman Christian College, Lahore • Centre of Agricultural Biochemistry and Biotechnology, University of Agriculture, Faisalabad • Dr. A.Q. Khan Institute of Biotechnonology and Genetic Engineering, Karachi. • National Agriculture Research Centre, Islamabad
Potato	• National Institute of Biotechnonology and Genetic Engineering, Faislabad • Quad-i-Azam University, Islamabad
Groundnut	• National Agriculture Research Centre, Islamabad • University of Arid Agriculture, Rawalpindi
Chickpea	• Centre of Excellence in Molecular Biology, Lahore • National Agriculture Research Centre, Islamabad • Comsats Institute of Information Technology, Islamabad (Pea)
Sugarcane	• National Institute of Biotechnonology and Genetic Engineering, Faislabad • School of Biological Sciences, Punjab University, Lahore
Tomato	• National Institute of Biotechnonology and Genetic Engineering, Faislabad • National Agriculture Research Centre, Islamabad • Quaid-i-Azam University, Islamabad
Chilli	• National Institute of Biotechnonology and Genetic Engineering, Faislabad • Quaid-i-Azam University, Islamabad
Soybean	• Quaid-i-Azam University, Islamabad

Source: Roberts et al. [4].

The agriculture sector has so far not benefited from the full potential of plant tissue culture technology, except for potato and to some extent banana, as research efforts at public and private levels are low [5].

The size of these efforts in terms of researchers and financial resources is still very small and not supportive of commercial scaling up in other plant species.

Despite the initial recognition and quick response, biotechnology did not take root as an emerging source of socioeconomic development in the country. For example, Pakistan started research on insect-resistant transgenic cotton varieties in 1995 and developed some transgenic lines, but it took almost 15 years to finally launch legal commercial cultivation of these varieties in 2010. Other leading cotton-producing countries, namely, USA, PR China, and India adopted and commercialized transgenic cotton varieties in 1996, 1997, and 2002, respectively, and farmers in these countries earned huge economic gains (Table 3).

In addition, Pakistan is also lagging behind other countries in the development of second-generation transgenic crops with improved tolerance to environmental stresses and crops for bioenergy production. Dependency on fossil fuels as energy sources could decline because of the enormous potential of biofeed stocks (crops, trees, and grasses) to produce bioenergy products such as ethanol, biodiesel, butanol, and petroleum on an industrial scale.

Table 3. Global area of biotechnology crops in 2011–12: by country in million hectares*

Country	2011	2012	Country	2011	2012
USA[†]	69.0	69.5	Myanmar[†]	0.2	0.3
Brazil[†]	30.3	36.6	Mexico	0.2	0.2
Argentina[†]	23.7	23.9	Spain	0.1	0.1
Canada[†]	10.4	11.6	Chile	<0.1	<0.1
India[†]	10.6	10.8	Columbia	<0.1	<0.1
PR China[†]	3.9	4.0	Honduras	<0.1	<0.1
Paraguay[†]	2.8	3.4	Sudan	<0.1	<0.1
South Africa[†]	2.3	2.9	Portugal	<0.1	<0.1
Pakistan[†]	2.6	2.8	Czech Republic	<0.1	<0.1
Uruguay[†]	1.3	1.4	Cuba	<0.1	<0.1
Bolivia[†]	0.9	1.0	Egypt	<0.1	<0.1
Philippines[†]	0.6	0.8	Costa Rica	<0.1	<0.1
Australia[†]	0.7	0.7	Romania	<0.1	<0.1
Burkina Faso[†]	0.3	0.3	Slovakia	<0.1	<0.1

Source: James [6].
Notes:
[*] Biotech mega-countries which grow more than 50,000 ha or more.
[†] Rounded off to the nearest hundred thousand.

Research Infrastructure

Pakistan has a pro-biotech government with a generally supportive public that emphasizes research, the introduction of transgenic crops. Biotechnology is recognized as a priority area of research. There are a number of new transgenic technologies relevant to major crops being worked on, in addition to insect- and herbicide-tolerant technologies. Most are output traits but there are also some new input traits for disease control and RNA mutations [6].

Several ministries and departments are responsible for biotechnology research, policy and regulation. These include the Ministry of Food, Agriculture and Livestock (MINFAL); the Ministry of Science and Technology Research; Higher Education Commission; National Commission on Biotechnology; Pakistan Council of Science and Technology; and the Pakistan Atomic Energy Agency. Biosafety aspects are the responsibility of the Ministry of Environment, Local Bodies, and Rural Affairs.

The Pakistan Council for Science and Technology is the country's central body responsible for formulating policies and projects in support of national development. It works in close consultation with the federal ministries and provincial departments, major R&D organizations, universities and the private sector. Its plans are reviewed by the Executive Committee of the National Commission on Science and Technology (ECNCST) before approval from the National Commission on Science and Technology (NCST). Pakistan Agricultural Research Council (PARC), under the Ministry of National Food Security and Research, supports, coordinates, and promotes agricultural research. Under its management, the National Agriculture Research Centre (NARC), Islamabad, tests and disseminates germplasm for various food grains, vegetables, and fruit crops. The Center of Agricultural Biochemistry and Biotechnology (CABB) in the University of Agriculture, Faisalabad, also has good research infrastructure and an experienced faculty. MINFAL deals with the production and release of GM crops. It has developed several standard operating procedures for handling cases of improvement, approval, and release of GM products. The secretary of the Ministry of Environment heads the National Biosafety Committee (NBC) and is responsible for oversight of all laboratory work and field trials, as well as authorizing the commercial release of GM products. NBC, Technical Advisory Committee (TAC) and Institutional Biosafety Committee (IBC) administer the enforcement of national biosafety guidelines, awarding exemptions for laboratory and fieldwork related with bioengineered products.

Pakistan has several capable institutions currently working on various aspects of biotechnology. There are a number of universities that offer various degrees in this discipline. However, there is a serious lack of appreciation of biotechnology at the public and industrial levels. Coordination and exchange of information among institutions and practitioners of biotechnology is less than adequate. Therefore, there is a need for a resource center in Pakistan that can initiate multidisciplinary research and enhance the awareness and appreciation of biotechnology locally and internationally. Hence, the Pakistan Biotechnology Information Center (PABIC) was established at Latif Ebrahim Jamal National Science Information Center, University of Karachi, under the patronage of the International Service for Acquisition of Agri-Biotech Applications (ISAAA) and the National Commission on Biotechnology.

Biosafety Rules and Regulations

Pakistan is signatory to the World Trade Organization (WTO), the Convention on Biological Diversity, and the Cartagena Protocol on Biosafety. Several pieces of legislation based on the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) have been promulgated in the country. National Biosafety Guidelines were promulgated in April 2005. The Plant Breeders Rights Act, amendments to the Seed Act 1976, and proposed geographical indication for goods are still undergoing discussion, evaluation, and analysis.

Part of the challenge stems from the need for a regulatory framework for introducing biotech products and technology for humans, plants, and animals. To make progress on this front, Pakistan has ratified the Cartagena Protocol on Biosafety with a framework for handling genetically modified organisms (GMOs). The proposed regulatory guidelines are built upon a three-tier system composed of the NBC, TAC and IBC, according to the US Department of Agriculture Global Agricultural Information Network (USDA-GAIN) report on Pakistan.

Achievements

The following are some salient achievements in the overall field of biotechnology:

- Control of cotton leaf-curl virus
- Reclamation of saline and sodic soils by biological methods
- Use of biotechnology to extract minerals and fossil fuels (extraction of copper and uranium using bacteria)
- Use of microbes in the cleanup of textile industry effluents
- Identification of the gene responsible for Retinitis pigmentosa, a hereditary degenerative disease, which leads to a complete loss of sight
- NBC has allowed stacked genes (Cry 1A and Cry 2Ab) in cotton
- Initiation of research on nano-biotechnology
- Complete human gene-mapping collaboration with Beijing Genomics Institute
- Production of biotechnology-based pharmaceuticals to produce interferon for treatment of hepatitis

Private-Sector Contribution

In Pakistan, the fertilizer and agrochemical sectors have been separated from government control, and are run by the private sector through national and multinational companies (MNCs). Major MNCs such as Monsanto, Bayer Crop Science, Dupont Pioneer, Syngenta, FMC, ICI-Astra Zeneca, Nichimen (now Arysta Life Science) and several Chinese companies have a prominent presence in both the agrochemical and seed sectors. There are also more than 600 national seed companies operating in the country. Most of them are just distributors while very few (4–6) have some reasonable R&D capacity. MNCs also import advanced lines and multiply or evaluate them in the country. Out of 155 cases submitted to the NBC, there were four cases by Monsanto for GM cotton and GM corn, two cases by Bayer Crop Science for GM cotton, two cases by Dupont Pioneer for GM corn and two cases by Syngenta, also for GM corn. All are being field tested in adherence with all the criteria for biosafety and contained field-testing.

Among national seed companies, Ali Akbar Company, in collaboration with Center of Excellence in Molecular Biology, Lahore, submitted cases of GM cotton with 2–3 genes of insect-resistance and herbicide-tolerance (*cry1Ac, cry2Aa and EPSPS*). Another national seed company, Guard Seed Company, collaborated with an Indian seed company (Nath Seeds) and obtained approval of hybrid Bt cotton (*cry1Ac* + Cowpea trypsin, inhibitor-CPTI), which was originally developed by Biocentury Transgene of PR China. A public-sector seed company, Punjab Seed Corporation (PSC, Lahore), signed a memorandum of understanding with Silver Land Company of PR China to develop GM cotton, especially insect-resistant cotton. Several national seed companies are launching projects under public-private partnerships; these include Allahdin Group of Companies, Multan with PARC, 4B Group of companies with CEMB, and Jhallander Seed Company with the Nuclear Institute of Agriculture and Biology, Faisalabad, to acquire research-based advanced materials for evaluation, selection and commercialization. Another company, Augira Chemical Company, developed collaboration with Hubei Seed Company, PR China to bring hybrid rice and GM cotton into the country.

CHALLENGES AND LIMITATIONS

Several ministries (Agriculture, Education, Environment, Health, Textile, and Science and Technology) and research organizations (Pakistan Atomic Energy Commission [PAEC], PARC, Higher Education Commission [HEC], National Institute of Health [NIH], Pakistan Medical Research Council [PMRC], etc.) have launched biotech programs with little or no coordination. This has resulted in the dilution of meager resources and duplication of research activities. This, in turn, has reduced the ability of research to achieve any visible or significant socioeconomic impact resulting from biotechnology, except in a few specific areas such as molecular diagnostics and GM cotton release in the country.

The seed dealers, as well as an informal sector of seed developers (so-called progressive farmers), are making substantial profits with little or no investment in R&D. The weak Seed Act of 1976, poor implementation of patent rules and absence of plant varietal protection regulations are major hurdles in the development of a viable and responsive private seed sector in the country. Though financial risks are high, some multinational companies and a few major national seed companies are proceeding with R&D because the Pakistan seed sector is large and offers huge potential for business. Proposed amendments to the Seed Act of 1976 and promulgation of the Plant Breeder Rights Act are intended to strengthen the private seed sector and attract foreign direct investment for the benefit of the farmers. At present, the private seed sector is flourishing exclusively in the hybrid seed sector (sunflowers, canola, corn, and fodder).

Pakistan is a founding member of WTO and, therefore, of the TRIPS agreement. The patent rules were modified to encompass microbes, genes, vectors, etc. by Intellectual Property Organization of Pakistan (IPO-PAK) and first promulgated in 2002. Multinational companies have re-acquired patents for these genes in Pakistan to avoid piracy and infringement. However, the weak capacity of IPO-PAK is another reason for ineffective implementation, although due administrative and legislative rules and regulations have been incorporated in the intellectual property rights ordinance. So far private seed companies have obtained licenses from Chinese companies (Biocentury Transgene, Hubei Provincial Seed Group Company, Ltd., Silver Land and Xinxiang Keda Seed Company, Ltd.) and only one with Indian seed company (Nath Seed) for utilization of insect-resistant genes for cotton [3]. No agreement yet has been made by any multinational company (Monsanto, Bayer Crop Sciences, Syngenta and Dupont-Pioneer) with any public or private organization in Pakistan.

Biological innovations, or bio-innovations, can only be realized when policy and governance mechanisms are in place so that the benefits of the new technologies outweigh the risks. Illegal import and multiplication of Bt cotton seeds have created havoc in farmers' fields. Absence of biosafety guidelines and lack of awareness among farmers further complicate the issue. Extra caution is absolutely warranted before introducing GMOs in the environment. An irrational fear of the unknown would be unacceptable in a country like Pakistan with its dwindling water resources and a growing young population that needs to be fed, clothed, educated and nurtured. Clearly, technology can help cure diseases and lead to development of new drought-resistant crop varieties producing high yields.

Some policy interventions have been made to translate laboratory work into commercial enterprise. The Higher Education Commission has directed all public sector universities to have an Office of Research, Innovation and Commercialization (ORIC) in every campus to provide a one-window operation for entrepreneurs. Three universities are in the process of developing industrial or biotech parks to launch high value, small volume industrial units by utilizing the R&D resources of the university.

FUTURE FOCUS

The Government is emphasizing the use of biotechnology and promoting the culture of GM crops and agricultural biotechnology in Pakistan. Efforts are being made to create awareness among farmers and other stakeholders, and to remove legal hindrances. The following points are under focus to strengthen the direction of biotechnology towards a product-oriented discipline that will contribute to the socioeconomic development of the country:

- Setting priority research areas to avoid research duplication and loss of resources
- Tight monitoring and evaluation to ensure quality of research
- Meeting international regulatory obligations
- Setting up proper infrastructure for biosafety of transgenic plants
- Linking the local industry with biotech research
- Seeking international donors and multinational companies to invest in the biotech sector
- Protection of intellectual property rights and patents
- Education and awareness of the general public towards biotech adoption
- Inclusion of biotech courses in schools and colleges
- Creation of jobs for biotech graduates

CONCLUSION

Genomics applications have great potential to fight diseases, help improve human lives, and increase productivity. So far, the benefits of these advances have accrued mostly to the rich countries. The time has now come for Pakistan to take advantage of such technological advances. The application of biotechnology by Pakistani farmers would not only result in enhancing productivity but would also help in addressing food-security challenges faced by the country. At a time when nations all around the world are increasing their agriculture productivity, preventing disease prevalence and solving the problem of environmental pollution, Pakistan needs a strong national strategy and plan of action to use this revolutionary technology for solving and preventing problems, and for rapid development. Biotech crops can increase productivity and income significantly, hence serving as an engine of rural economic growth that can contribute to the alleviation of poverty for small and resource-poor farmers.

Overall, Pakistan needs to strengthen its legal, institutional, scientific and technical capacities. These can be achieved through training, study or exchange visits, workshops, public awareness and education programs, and public-private partnerships. Biosafety regulation in Pakistan faces many daunting challenges, including broad social and political disruption, and difficulty in enforcement of existing and related regulations. However, there is a pressing need for a functional biosafety system in order to allow the development of beneficial agricultural technologies to meet the country's long-term agricultural development needs.

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AGRICULTURAL BIOTECHNOLOGY FRAMEWORKS IN THE PHILIPPINES

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INTRODUCTION

The Philippines has an open and enlightened outlook on biotechnology, and its role in addressing national issues such as food security, global competitiveness, and adaptation to climate change. Having an estimated population of more than 91 million in 2009, which is expected to reach 122 million by 2020, the country needs to deal with food-related issues to ensure food availability and security in the future. Despite the country's relatively small total agricultural land (including livestock and fishery production areas) of only about 11.5 million ha compared to its neighboring countries, there are still opportunities to improve agricultural production efficiency, as well as expand global exchange and trade with due consideration to the effects of climate change on the agriculture sector [1–3].

Since the 1980s, the Philippines has been exploring the huge potential of applying biotechnology to improve agricultural, livestock, and fisheries productivity; in enhancing the nutritional value of commodities, and in developing commercial processes and products. As the policy climate in the country had been favorable to biotechnology advancement, the Philippine government was able to establish the necessary policy framework that placed paramount consideration on the anticipated benefits of agricultural biotechnology, while ensuring its safe and responsible use.

PHILIPPINE BIOTECHNOLOGY EXPERIENCE

Commercialization of Agricultural Biotechnology: Current Status

According to the 2013 US Department of Agriculture Global Agricultural Information Network (USDA GAIN) Report, the Philippines is considered the regional leader in biotechnology, and a model of biotechnology policy for other developing countries [4]. To date, various biotech products and services have successfully undergone the thorough pre-commercialization research and testing process in accordance with the country's policy, and are available on the market.

In 2002, Bt maize (event MON 810) became the first biotech crop approved for propagation in the Philippines. Developed by Monsanto to be resistant to Asiatic corn borer, Bt corn went through environmental, and food and feed safety studies in partnership with Philippine institutions to ensure its safety in both these areas. Bt maize's approval for local production is considered a major strategic development in agricultural biotechnology, as it is the first major transgenic food/feed crop commercialized in Asia. As of June 2012, 32 transformation events and 28 stacked-traits products have been approved by the Department of Agriculture-Bureau of Plant Industry (DA-BPI) for direct use as food and feed, and for propagation.

There are also research agencies in the Philippines that harness the potential of traditional biotechnology. Mykovam® inoculants and Gut Aide® animal probiotics were just some of the products developed by the National Institute of Molecular Biology and Biotechnology (BIOTECH) under the University of the Philippines Los Baños (UPLB). Other locally developed biotechnology-derived products are listed in Table 1. These products were successfully commercialized through a synergistic partnership of UPLB with both the public and private sectors.

Table 1. Commercially available biotech-derived products and services in the Philippines

Product/Services	Description/Industry application
Diagnostic kits and specialty products	
Diagnostic kits for monitoring red tide toxins and mycotoxins	• Detects red tide toxins from mussel and other shellfish and mycotoxins (aflatoxin B1, zearalenone, ochratoxin A, and fumonisin B1) in food, feed, and feed ingredients
Essential oils	• Oils extracted through enzymatic extraction from patchouli, lemon grass, citronella leaves, and ylang-ylang flowers

(...continued)

Product/Services	Description/Industry application
Gut Aide (Probiotics)	• For animal health and nutrition
PCR-based detection kits for food and feed pathogen	• Detects bacterial pathogens such as *Salmonella, E. coli* and *S. aureus* in food, water, and animal feed
Specialty fats and oils	• Oils from local seeds and nuts extracted and tailored for enhanced medical and nutritional properties
Biofertilizers	
Bio Groe	• Plant growth promoter for vegetables and ornamentals
Bio N	• Microbial-based fertilizer that supplies nitrogen and enhances growth of rice, maize, and vegetables
Brown Magic	• Effective growth enhancer and biocontrol of root diseases of various orchid species
Bio-Green	• Bio-organic fertilizer (BOF) derived from farm and industrial wastes composted by selected strains of *Trichoderma* (Bio-Quick) and enriched with nitrogen fixing bacteria (Bio-Fix)
Bio-Quick	• Composting inoculant containing the fungus *Trichoderma* sp.
Bio-Fix	• Enrichment inoculant enhancing the nutritive value and effectivity of BOF
Cocogro	• Growth hormone from coconut water, which enhances and promotes growth of orchids, vegetables, and ornamentals
Mycogroe	• Tree vitamin to enhance growth and development in forest trees and commercial plantations
Mykovam	• Soil-based biofertilizer for fruit trees, agricultural crops, reforestation species, and ornamentals
Nitro Plus	• Nitrogen supplement for legumes such as peanut, string bean, soybean, and mungbean
VAM Root Inoculant	• Promotes growth of agricultural and horticultural crops, trees, and ornamentals
Vaccines, antibiotics, and pesticides	
BioVac-FC	• Protects chickens and ducks against fowl cholera
BioVac-HS	• Increases resistance of young cows and water buffaloes to pasteurellosis or HS
Pelmichtrol	• *Bacillus thuringiensis* pesticide against mosquito larvae
Tylosin	• Acts as therapeutic agent, growth promoter, and animal antibiotic
NPV	• Pesticide containing nucleopolyhedrosis virus used to control the common cutworm or *Harabas*, a major onion pest

(...continued)

Product/Services	Description/Industry application
Bactrolep	• Microbial pesticide containing *Bacillus thuringiensis*, which kills Asiatic corn borer and Diamondback moth
Bt for OFF	• Used to kill Oriental fruit flies (OFF insecticide)
Services	
Central Analytical Service Laboratory	• Performs routine chemical analyses, and tests • Modifies and standardizes analytical methods for applications to specific samples • Develops new analytical techniques
Electron Microscopy Service Laboratory	• Supports research on ultrastructure analysis (especially for biological specimens), which is vital in the pursuit of basic knowledge and understanding of the different biological, physical and chemical processes
Philippine National Collection of Microorganisms	• Serves as the national repository of microbial strains in the country • Offers microbiological analyses, identification of isolates, and preservation of cultures • PNCM is an accredited laboratory of the Food and Drug Administration-Department of Health and identified as a National Reference Laboratory for microbiology by the Bureau of Products Standard of the Department of Trade and Industry. It is also a member of the World Federation for Culture Collection
Fermentation Engineering and Services Laboratory	• Converts the biotechnologies developed in laboratories into commercial and viable scale by providing engineering and technical support to BIOTECH research groups and other interested clients
National Immunological Testing Laboratory	• Converts the biotechnologies developed in laboratories into commercial and viable scale by providing engineering and technical support to BIOTECH research groups and other interested clients • Serves as a center for regular monitoring of mussels & other shellfish for red tide infestation

Source: University of the Philippines Los Baños, National Institute of Biology and Biotechnology (Biotech) [5].
Notes: BIOTECH, National Institute of Molecular Biology and Biotechnology - University of the Philippines Los Baños; BOF, bio-organic fertilizer; FC, fowl cholera; HS, hemorrhagic septicemia; NPV, nucleopolyhedrosis virus; PNCM, Philippine National Collection of Microorganisms.

Consistent Policies

As early as the 1970s, the Philippines recognized the need for an integrated mechanism to mobilize the various departments and disciplines in engineering, chemistry, and applied microbiology for research, training, and extension. Through the Letter of Instruction No. 1005, then-President Ferdinand E. Marcos instructed the National Treasury to fund the establishment of the National Institute of Biotechnology and Applied Microbiology (now BIOTECH) [6]. The establishment of BIOTECH at UPLB in 1979 started biotechnology research and development (R&D) in the Philippines. As the premier national R&D institution, BIOTECH pursues traditional and modern biotechnological tools to develop innovative products and processes for agriculture, health, energy, industry, and the environment.

In 1990, recognizing the possible concomitant risks of new technologies, Executive Order 430 was signed by then-President Corazon Aquino. The Order constituted the National Committee on Biosafety of the Philippines (NCBP) to regulate genetic engineering R&D. This makes the Philippines the first Association of Southeast Asian Nations (ASEAN) country to regulate modern biotechnology. NCBP is an inter-agency body chaired by the under secretary for R&D of the Department of Science and Technology (DOST). Other members of the NCBP are representatives from three regulatory agencies: The Bureau of Plant Industry (BPI) of the Department of Agriculture (DA), Bureau of Food and Drugs (now the Food and Drug Administration) of the Department of Health, and Ecosystems Research and Development Bureau (ERDB) of the Department of Environment and Natural Resources, four scientists representing the fields of physical, social, environmental, and biological sciences, and two community representatives.

From 1986 to 1998, DOST identified biotechnology as a flagship of cutting-edge technologies. In 1998, the agency issued the “Guidelines on Planned Release of Genetically Modified Organisms and Potentially Harmful Exotic Species.”

In 1997, the Agriculture and Fisheries Modernization Act (AFMA) was approved by then-President Fidel V. Ramos. The law prescribes measures to modernize the country’s agriculture and fisheries sectors, boost profitability, and prepare for globalization challenges through adequate, focused, and rational delivery of necessary support services [7]. AFMA recognizes the potential of biotechnology to help transform agriculture and fisheries from resource-based into technology-based sectors. As such, the R&D budget allocation prioritized the biotechnology program.

In 2000, then-President Joseph E. Estrada pursued the institutionalization of biotechnology in government programs. Consistent with this, the DA, with support from the US Public Law 480 Food for Peace Program, created the Philippine Agriculture and Fisheries Biotechnology

Program to help orchestrate policy and infrastructure support to ensure judicious utilizations of biotechnology for agricultural productivity enhancement. In 2001, then-President Gloria Macapagal-Arroyo issued a national policy statement that promoted the safe and responsible use of modern biotechnology towards achieving food security, equal access to health services, a sustainable and safe environment, and industry development.

The policy framework was further developed as the DA issued Administrative Order (AO) No. 8 in 2002, stipulating the rules and regulations for the importation and release into the environment of plants, and plant products derived from the use of modern biotechnology.

The NCBP was further strengthened in 2006 with the formulation of Executive Order 514, titled "Establishing the National Biosafety Framework (NBF), Prescribing Guidelines for its Implementation, Strengthening the National Committee on Biosafety of the Philippines and for Other Purposes." This issuance reiterated the policy, regulatory, and capacity-building functions of the NCBP, delineated the regulatory functions of its member-agencies and established a system to resolve regulatory overlaps and conflicts among the agencies. In the same year, the Cartagena Protocol on Biosafety to the United Nations Convention on Biological Diversity was ratified by the Philippines.

Institutional and Regulatory Frameworks

These policies and regulatory frameworks, established and improved over the years, have guided the effective and efficient utilization of biotechnology. In this system, biotechnology development always goes hand-in-hand with biosafety. The NCBP regulates R&D activities of modern biotechnology by assessing and managing any potential risks associated with its application in laboratory and confined field tests. To complement this, DA AO 8 regulates importation and release into the environment, including open and multi-location field trials of plants and plant products derived from the use of modern biotechnology. BPI, as the lead regulatory agency for modern biotechnology, is implementing DA AO 8. To ensure human, food, feed, and environmental safety, BPI regulates four activities involving modern biotech crops through a permit system. These activities are:

1. Importation for contained use;
2. Importation for direct use for food/feed/processing;
3. Conduct of field experiments; and
4. Release of seeds for propagation.

Risk assessment is the cornerstone of decision-making for permit issuance and is mainly conducted by BPI, with technical assistance from an independent body called the Scientific and Technical Review Panel (STRP). The STRP is composed of a pool of scientists, experts, and representatives from the Fertilizer and Pesticide Authority, Bureau of Animal Industry, and Bureau of Agriculture and Fisheries Product Standards. Risk assessments are conducted in accordance with internationally accepted principles and practices such as those of the Cartagena Protocol on Biosafety, Codex Alimentarius Commission, OECD, Food and Agriculture Organization of the United Nations (FAO), and other relevant international bodies.

In adherence to the internationally recognized principles on transparency and participatory administration, the public and other agencies are provided with opportunities to participate in biotechnology regulation starting from policy formulation and review to policy implementation. DA organizes public consultations regarding administrative issuances, which various stakeholders such as farmer groups, non-governmental organizations, civil society, commodity importers, feed millers, and food manufacturers are invited to attend (Figure 1). Local communities of target sites for modern biotech crop field trials are also informed accordingly of any existing field trial proposals in their locality. They are encouraged to actively participate in public consultations as well as in the monitoring of field trial regulatory compliance by being members of the institutional biosafety committees.

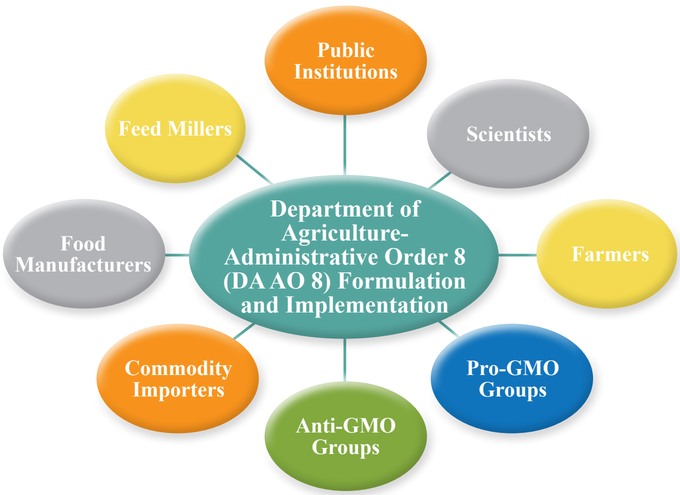

Figure 1. DA AO 8: Participatory regulatory approach.

SUCCESS STORIES AND CHALLENGES

Success Stories

Ten years after approving the first (and so far the only) modern biotech crop in the Philippines for commercialization, genetically modified (GM) maize has provided significant benefits to the agriculture sector, especially in the areas of farm yield and income, maize feedstock production, and impact on the livestock and poultry sector. In the span of 10 years, GM maize areas in the country expanded to reach over 700,000 ha in 2012. This turnabout had its humble beginning with only 10,000 ha in 2003. In 2011, GM maize areas comprised 27% of the total maize area in the Philippines [8–9].

After successfully completing several safety tests under the regulatory oversight of NCBP and BA-BPI, GM maize was approved for commercial propagation in 2002. GM maize is presently still regulated and governed by DA AO 8, as its propagation permit stipulated specific conditions for product stewardship, such as the conduct of insect resistance management for Bt corn (maize), weed resistance management for herbicide-tolerant maize, post-approval monitoring activities, seed-sales reporting, and required studies.

Several studies have been completed on the economic impact of GM maize technology in increasing productivity and income (Table 2). The reported benefits range from 13% to as much as 55% yield advantage over non-GM counterparts, with a farm income advantage of as much as 75%, and production cost savings of about 21%. In 2011, a global study estimated that farm net income from GM technology in the Philippines was USD108 million from 2003 to 2009 [10].

Table 2. Impact of genetically modified maize in the Philippines: studies and farmer testimonials

Reference	Yield advantage over non-biotech*	
Gonzales (2005) [10]	20%–23%	
Yorobe & Quicoy (2006) [11]	33%–35%	
Ramon (2005) [12]	13%–15%	
Farmer testimonials: Edwin Paraluman (S. Cotabato) [13] Rosalie Ellasus (Pangasinan)[14]	 44%–48% 44%	 3.7–4.5 metric tons per hectare 5 metric tons per hectare

(...continued)

Reference	Yield advantage over non-biotech*
	Reduction in production cost
Gonzales (2005) [10]	21% cost savings advantage
Yorobe & Quicoy (2005) [11]	Cost lowered by PHP0.23 per kilogram
	Farm income benefits
Gonzales (2005) [10]	38% income advantage PHP7,080–PHP7,482
Gonzales (2007) as cited by Umengan, 2013 [15]	20%–48% income advantage: Dry season 5%–14% income advantage: Wet season
Gonzales (2009) as cited by Umengan, 2013 [15]	1%–75% income advantage: Dry season (per hectare) 3%–75% income advantage: Wet season (per hectare)
Yorobe & Quicoy (2005) as cited by Umengan, 2013 [15]	PHP10,132 additional profit per hectare†
G. Brookes and P. Barfoot (2011) [9]	USD108 million (overall cumulative farm net income benefits from 2003 to 2009)†
Farmer testimonials: Delson Sonza (Iloilo) [16]	PHP15,760 additional income per hectare

Notes:
* Yield advantage as defined by percentage, metric tons or percentage per hectare.
† PHP, Philippine peso.
†† USD, United States dollar.

GM maize technology has likewise helped achieve substantial improvements in overall maize productivity. 60% of the total volume of yellow maize harvested in the first half of 2012 was GM maize [18]. This input in productivity has boosted the overall production of maize as the Bureau of Agricultural Statistics recorded an approximate 71% share of yellow maize, or a contribution of about 5.2 million metric tons in total maize productivity, averaging at 4.09 metric tons yield per hectare in 2012. Consumed in the Philippines as feed ingredient, GM maize lessened feedstock supply insecurity, and silage maize has eased dairy and cattle pressure on sparse pasture [16]. It also helped in efforts to attain self-sufficiency in food by supporting the production and supply of meat and meat products (proteins).

The benefits of this technology would not have been realized without a sound policy environment and a science-based regulatory system that prioritized biosafety along with technological advancement.

Challenges

The expected population increase over the coming years brings the challenge of increasing the country's rice production by 40%. However, continuing deforestation, overgrazing, and massive land conversion hinders the possibility of increasing agricultural productivity. Utilizing the country's critical pool of biotechnology experts and the equipped R&D infrastructure for biotechnological use, the country needs to strengthen the ties between its research institutions and industry communities for a synergistic result.

Though biotech crops are on their way to general acceptability, there are still hurdles that delay the full-blown maximization of biotechnology application in agriculture. Just recently, the multi-location field trials of Bt eggplant (brinjal) were stopped through a ruling by the Court of Appeals. Local and international anti-GMO groups have been extensively campaigning against modern biotech crops in the country. Also, the Philippine livestock sector is challenged to strengthen the livestock sector and develop a regulatory policy that will address the bounds of a safe and responsible biotech livestock, a sustainable risk communication and biotech advocacy, and an effective biosafety regulatory system that will govern livestock biotech R&D and eventual commercialization of transgenic animals and animal products.

PROSPECTS FOR AGRICULTURAL BIOTECHNOLOGY

As agricultural biotechnology in the Philippines sails towards more advances to deliver actual benefits to farmers, fisherfolk, and the consuming public, the country must continuously equip itself with the appropriate technical and regulatory propellers to steer steadfast efforts in ensuring the safe and responsible use of modern biotechnology. In this sense, proposals for future cooperation all point towards a partnership that will help the Philippines train its manpower resources and modernize facilities for GMO detection and risk management. Concomitant to this will be a cadre of highly skilled technical personnel and advanced facilities to strengthen the integrity of the regulatory system, and exemplify the confidence of farmers, technology developers, agricultural industries, and the consuming public.

The DA Biotech Program has been aggressive in its current R&D projects, which include several GM crops in the pipeline:

1. Philippine Rice Research Institute's (PhilRice) 3-in-1 Rice to address the country's Vitamin A deficiency, 50% yield loss from tungro, and 20% yield loss from bacterial blight problems;

2. Cotton Development Authority's Bt cotton field trial; and

3. UPLB's Bt eggplant to address problems of fruit and shoot borers that lead to 54%–70% yield loss and over-usage of insecticides.

Dealing with the country's livestock sector, the Philippine Council for Agriculture, Aquatic and Natural Resources Research and Development of DOST (PCAARRD-DOST), together with its partner government agencies, state colleges, and universities, have projects on the way to adoption by target beneficiaries. For buffalo and swine breeding, the use of molecular markers is being studied to characterize and map out genome linkages in order to verify the parentage for animals of interest, identify the specific traits for enhancing productivity, and identify the genes that control disease susceptibility. In addition, a positional cloning protocol has been developed for cloning desired genes under optimal conditions.

Areas in production management, particularly animal health, the utilization of rapid and timely test kits like Enzyme-linked Immunosorbent Assay (ELISA), Loop Mediated Isothermal Amplification (LAMP), and Polymerase Chain Reaction (PCR) in the diagnosis of animal diseases are avenues being explored to minimize mortalities and prevent the further spread of highly infectious diseases.

In 2010, the Philippine swine industry ranked eighth in the world, boasting a total sow population of 12.3 million head, hence providing 60% of the country's total meat requirement. The industry contributed 12.4% (PHP73 billion) to the total value of agricultural production. However, diseases led to huge economic losses, accounting for about 20% of the value in swine production, which roughly translated to PHP14.6 billion in losses [19].

Hence, R&D initiatives to diagnose swine enteric and respiratory diseases are currently being undertaken by PCAARRD-DOST, in partnership with the Australian Centre for International Agricultural Research (ACIAR), Central Luzon State University (CLSU), and the Bureau of Animal Industry under the Department of Agriculture using the LAMP assay. Institutionalization and technology transfers of LAMP-based assays in government-owned diagnostic laboratories are seen to enhance their capability in disease diagnosis. These assays will provide timely, highly reliable, and cheap diagnostic tools in the early diagnosis of major swine infections. Positive results in this project may help reduce the total swine mortality in the country by 50%, or, an additional 5.32% increase in the total pig population.

With the advent of accurate science and technology interventions and its status as a foot-and-mouth disease-free country, the Philippines can depend on the increased productivity of these commodities to tap international and export markets.

SUMMARY AND CONCLUSION

The Philippines recognizes the potential of biotechnology to meet the challenges of securing food, increasing incomes in agriculture, and adapting to climate change. Since the 1970s, the national government has been consistent in providing support to R&D and in establishing the necessary policy environment for technological advancement while ensuring biosafety. The country's considerable success in setting up and implementing its regulatory system for modern biotechnology is reflected in the benefits that are currently being experienced by maize farmers, the maize sector, and the livestock and poultry industry. Amidst the government's efforts to improve the lives of Filipinos with biotechnology, controversies and false marketing strategies (especially those related to biotech crops), dampen the clear farmer and consumer benefits that these products bring. Moreover, the country's livestock sector needs to be strengthened with regulatory policies, risk assessment, and biotech advocacy.

The Philippines, as of the biotechnology mega-countries, will continue to adhere to its national policy to promote safe and responsible usage of modern biotechnology and its products, as one of several means to achieve and sustain food security, equitable access to health services, a sustainable and safe environment, and industry development [20].

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AGRICULTURAL BIOTECHNOLOGY IN SRI LANKA

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INTRODUCTION

Sri Lanka is an island in the Indian Ocean that had a population of around 20.6 million people in 2012. Diverse climate conditions with plenty of sunshine and rain bestow rich biodiversity and natural resources on the island. Although Sri Lanka is traditionally an agriculture-based economy, the current contribution of the sector to country's GDP, of around 11%, is low compared with 31.5% from industries and 57.5% from services [1].

Biotechnology, meaning in a broad sense the manipulation of biological systems, is considered the most recent technological advancement of the 20th century in agriculture. Biotechnology as a base technology has many applications in all sectors, such as agriculture, industry, and services, and serves to improve public health, enhance the quality of life, and contribute to the economic growth of the country. Hence, biotechnology can be used widely to improve agriculture, healthcare, and the environment in a country [2]. Biotechnology also presents exceptional opportunities for driving economic growth and enhancing industrial productivity as an integral part of the knowledge-based economy of a country. For a developing and traditionally agriculture-based country like Sri Lanka, it is prudent to keep abreast of the rapid developments in the agricultural sector, such as with biotechnology.

In agriculture, plant biotechnology is being used to produce plants with herbicide tolerance, insect and disease resistance, nitrogen fixation properties, and drought and salinity tolerance. It is also used in the production of pesticides, herbicides, and fertilizers based on biological material, all of which are safe for human and animal health and the environment. Also, micro-propagation and tissue culture are being used to produce elite, healthy, virus-free, and economically more productive horticultural plants on a large scale. Biotechnology is also used in cleaner industrial processes and leads to a cleaner environment through waste management. Thus, agricultural biotechnology ultimately increases farmers' productivity, reduces use of fertilizers, and boosts the nutritional value of crops.

The potential of biotechnology, especially its industrial applications, is still not exploited for maximum benefit in many developing countries, including Sri Lanka. Many biotechnological products, such as agricultural products, therapeutics, diagnostics and vaccines in the biopharmaceutical industry, are imported and highly consumed in Sri Lanka. Unfortunately, it has not been possible to directly apply global developments in the biotechnology industry to obtain maximum benefit for Sri Lanka [3].

CURRENT STATUS

The government of Sri Lanka has a strong agriculture-focused development plan within its 10-year comprehensive national development program (2006–16). Called Mahinda Chinthanaya, it aims to ensure food security, improve the income of farmers (since agriculture immensely contributes to economic development), and enhance the rural livelihood of the country (which involves almost 70% of the population). Therefore, the country has recognized the application of novel techniques, such as biotechnology, as a driving force in enhancing public health, ensuring food security and sustainable economic growth, and improving the environment [4].

Biotechnology R&D in Sri Lanka is happening very slowly in dispersed ways, based on the interests of individual researchers. Sri Lanka initiated the potential use of biotechnology in the early 1970s through commercial production of orchids using tissue culture. At the same time, universities, research institutes, and the Department of Agriculture (DOA) started research on in vitro culture techniques for ornamental flowering and foliage plants, fruit crops, timber crops, spice crops, and root and tuber crops. Following this, foliage export companies such as Haleys Agro Biotech, Mike Flora, Serendib Horticulture Technologies Private Limited, etc., engaged in mass production through tissue culture of ornamental flowering and foliage plants; however, this has had very little impact on the country's economy.

Plant tissue culture is highly applied in the mass production of: ornamental flowering plants (orchid, chrysanthemum, African violet, anthurium, gerbera, agapanthus); ornamental foliage plants (aglaonema, bamboo, Bird's Nest fern, caladium, cordyline, calathea); fruit plants (banana, dragon fruit, pineapples, oranges, grapes); spice crops (vanilla, cardamom, turmeric, ginger); root and tuber crops (potato, colocasia); timber crops (teak, mahogany); and medicinal plants.

Research is being conducted on the production of biofertilizers, bioherbicides, and biopesticides to reduce chemical use in agriculture, although commercial application is still limited.

Biotechnology to improve farm animal productivity, disease diagnostics, and vaccine production, is mostly in the research stage. Artificial insemination to breed high-potential livestock is extensively applied in the livestock industry with the help of the Ministry of Livestock Production and Animal Health.

In the food industry, biotechnology is being used to improve baking processes, produce fermentation-derived preservatives, improve analysis techniques for food safety, and for assessment of food quality.

Growth of aquatic organisms in a controlled environment, especially for shrimp farming and ornamental fish culture, and the mass production of ornamental aquatic plants are the major applications in aquaculture in Sri Lanka.

For a safer environment, biotechnology applications are employed in water- and wastewater-treatment systems, and solid-waste management. Waste recycling and bioremediation are carried out by local government bodies in the urban areas of the country. Biogas production is limited in Sri Lanka.

Fermentation using microorganisms in the dairy industry to produce yoghurt, curd, butter, and cheese is done on a large scale by some private companies like Kotmale Private Limited, Ambewela, Rich Life Private Limited, and on a small scale by cottage industries. Production of alcohol, such as beer, toddy, ethyl alcohol, arrack, spirits, and vinegar, are run mainly by the private sector. The Pelwatte Sugar Company supplies larger quantities of alcohol based on sugar molasses to the market, and the Distilleries Corporation imports alcohol for blending to prepare arrack. Beer companies, such as Lion Brewery, produce beer based on rice in Sri Lanka.

Utilization of genetically modified (GM) crops and their products is still subject to public debate, particularly in relation to their impact on human health and the environment. Scientists have been urged to study the toxicity of GM food and feed, and address safety issues related to GM foods. Since new methods of testing for safety are still at a primary level in Sri Lanka, the application of GM crops is not yet possible.

MAIN CHALLENGES

There is a large technology gap between developing countries and developed countries. A measurement of commitment towards agricultural biotechnology is the amount of resources and funds allocated for R&D. The funds allocated for agricultural biotechnology by the Sri Lanka Council for Agriculture Research and Policy (SLCARP) is around 3% of the SLCARP budget [5]. Hence, relatively little emphasis has been put into capacity-building of human resources and infrastructure development for agricultural biotechnology.

Although there is much imported food in Sri Lankan markets, at present there is no proper mechanism to test for GM ingredients either in local food or food items produced overseas. Ethical and religious concerns toward use of genetic engineering techniques and their products are very high in a developing country like Sri Lanka.

There is no real assessment of threats to biodiversity protection in the country from the wide use of biotechnology in crop plants and farm animals. Sri Lanka signed and ratified the Cartegena Protocol on Biosafety in 2004. The Ministry of Environment and Natural Resources is the national focal point for biosafety and the controlling authority for all issues related to biosafety, such as the establishment of relevant legislation, protocols, and guidelines.

In developing countries there are concerns of access to new technologies, unfair exploitation of genetic resources, and fair and equitable sharing of benefits. There is no proper mechanism or adequate and convenient access to acquire intellectual property rights for biotech innovations. To deal with biosecurity issues, Sri Lanka has various types of ordinances and acts, such as the Plant Variety Protection Act, Plant Quarantine Act, Wild Life Ordinance, Fauna and Flora Protection Ordinance, Fisheries and Aquatic Resources Act, and Intellectual Property Act.

For the development of biotechnology industries, commercialization of research outcomes is critical. Commercialization of biotechnology research should be done through establishing effective linkages between academia and industry. However the linkage is poor at present. Although the biotechnology research done in universities and government research institutes is mainly focused on solving local problems, there are funding constraints and a lack of trained and skilled manpower.

The private sector has shown little interest to enter the biotechnology space due to the high initial capital investment required. Therefore there is a great need to develop and promote biotechnology and entrepreneurship in this field.

Also, there is poor access to information from international networks and databases. No central facility in the country has relevant international data nor is there one that provides access to the necessary software for potential research. The country needs to formulate a National Research Policy to integrate all the stakeholders and to coordinate all research and industry work,

Principal Trends

The Ministry of Economic Reform, Science and Technology recognizes biotechnology as an important area for development in Sri Lanka. The National Science Foundation (NSF) under this Ministry plays an important role in this respect.

The Plant Genetic Resources Center was established in 1988 with assistance from the Japan International Cooperation Agency. It has capabilities to undertake plant genetic conservation and conduct biotechnological research. Programs are conducted for conserving genetic resources in the form of seed, both in vitro, and in the field. Strategic research on callus culture, embryo culture, anther culture, and protoplast culture is conducted on a number of species, and suitable protocols have been established. Biochemical techniques such as isozyme analysis are conducted to assess genetic variability and identify economically important traits for use in crop improvement activities. In 1992, the NSF established a biotechnology steering committee with the mandate to provide advice to the NSF and, thereby, to the Sri Lankan government on the promotion and support of biotechnology research in universities and research institutes, and the development of biotechnology in the country.

The ADB has identified biotechnology as a thrust area in Sri Lanka to be improved, and a loan was granted to develop the human resources and infrastructure of the research laboratories. The ADB-funded industry–institute partnership program under the Ministry of Science and Technology aims to strengthen the linkages between universities and industries through facilitating students' industrial training and staff exchanges.

The NSF, National Research Council, and SLCARP grant funds for biotechnology-based research in Sri Lanka. For health and environmental safety, the NSF has prepared biosafety guidelines for laboratory and greenhouse-based experiments.

The Ministry of Environment and Natural Resources (MENR) is preparing guidelines for large-scale field trials, release, and commercialization of GM plants and organisms. The MENR initiated the National Biosafety Framework Development Project with the aim of preparing a National Biosafety Framework for Sri Lanka, in order to regulate the importation of genetically modified organisms, GM foods, feed, and processed products.

An agricultural biotechnology workshop, aimed at creating awareness of biosafety for genetically engineered crops and promoting best practices from biotechnology laboratories to the farmers' fields, was organized by the US Embassy in Sri Lanka, GENETECH Sri Lanka, and Science Foundation of Sri Lanka, and it was funded by the International Centre for Genetic Engineering and Biotechnology.

Poor motivation from the private sector to participate in biotechnology industries is driven by the large investment requirement for infrastructure, skilled manpower and the unavailability of trained and skilled personnel.

The Code of Intellectual Property Act No. 52 was implemented in 1979. All activities related to intellectual property rights are handled by the National Intellectual Property Office of Sri Lanka.

The National Committee on Agricultural Biotechnology established in 2009 under SLCARP, is mandated to identify and formulate policies and strategies related to agricultural biotechnology, and entrusted to set national research priorities in line with the agricultural development policies of the government. National priorities in agricultural biotechnology for 2011–16 facilitated the application of appropriate biotechnologies in Sri Lanka to improve agricultural production and, consequently, contribute to the enhancement of food security and socioeconomic standards in the country [6]. National priorities for major crops grown in Sri Lanka are: productivity improvement through biotechnology; production of quality planting material; development of improved varieties that are resistant to abiotic and biotic stresses; improvement of quality agricultural products; improvement of production of biofuels; development of disease diagnostics tools; and conservation of endangered crop wild relatives [6].

For livestock, poultry, and fisheries, the national priorities are: improvement of production of milk and milk products of cattle, buffaloes and goats; improvement and development of vaccines for bacterial, viral and parasitic infections using molecular techniques; improvement of nutrient availability of animal feeds through manipulation of rumen and gut micro flora; enhancement of nutrient availability of locally available animal feed resources by using molecular techniques; improvement of production and processing of inland and marine fish; development of resistant brood stock of prawns; and marker-assisted selection for high growth rate of fresh water fish and prawn brood stock.

The National Agricultural Biotechnology Research and Development Program presented by Dr. Girihagama, the national coordinator of biotechnology of SLCARP, at the Sixth Asian Biotechnology Development Conference in India in 2012, was as follows: create an enabling policy environment and functional regulatory framework in support of biotechnology R&D; strengthen institutions and support services to increase relevance and efficiency of biotechnology R&D for agricultural development; enhance technology and information access through regional and international collaboration and networking; biotechnology research and development applications for food security and rural livelihoods; biotechnology transfer, commercialization and delivery systems; build communication and information systems for public awareness and stakeholder participation; and human resources development and incentive programs [5].

The DOA pioneered tissue culture techniques in 1976 to support the demand for rapid clonal multiplication of orchids and anthuriums for the cut-flower industry. In 1984, tissue culture activities were expanded to fulfill the need for pathogen-free micropropagation of fruit crops such as bananas, citrus, passion fruit, and pineapples. Subsequently, the program was enlarged to include micropropagation of rambutans, strawberries, ginger, etc. Research was undertaken on the mini tuber production of potato varieties, and the technology is expected to be forthcoming in the near future. Cuttings produced using potato micropropagation, through apical meristem culture to obtain disease-free planting material, have been distributed to farmers. The DOA supplies about 25% of farmers’ requirements of planting materials and the rest is supplied by the private sector.

INSPIRING INITIATIVES AND BEST PRACTICES IN BIOTECHNOLOGY APPLICATIONS AND COMMERCIALIZATION

In the agricultural biotechnology sector, technology is being used in multiple pursuits as outlined in Table 1.

Table 1. Summary of projects by technology type

Technology type	Projects
Plant biotechnology	• Shoot tip culture for micropropogation - plant multiplication for ornamental plants, fruit, timber, spices, roots and tuber crops • Callus and cell cultures of medicinal plants and research in cell culture • Mass propagation, extraction of medicinal compounds and purification, and quality control of medicinal plants • Embryo culture and anther culture of crops • DNA fingerprinting to characterize crop germplasm • Molecular marker techniques to test true hybridity • Disease diagnostic through molecular techniques

(...continued)

Technology type	Projects
	• Crop improvement using traditional and molecular breeding techniques • Plant cell culture techniques using bioreactors • Production of plant vaccines against diseases • GM testing through polymerase chain reaction based technology
Animal biotechnology	• Genotyping of animals • Artificial insemination • Embryo transfer • Vaccine production • Identification of meat types • Starter cultures and probiotics • Use of exogenous enzymes in animal feed
Marine biotechnology	• Detection of viral pathogens in the shrimp culture industry

A recent biotechnology product developed and ready for transfer is a Sri Lankan strain of Bt developed by Industrial Technology Institute. Table 2 shows the list of names and major activities of the key research and development organizations and academic institutions involved in agricultural biotechnology activities [7].

Table 2. Major activities of key research and development organizations and academic institutions in agricultural biotechnology

Name	Type of Organization	Major Biotech Activities
National Science Foundation	Funding, science & technology academic and research	Research funding, overseas training, pre/post doctoral fellowships, short-term training, convenes and support National Biotechnology Committee, and implement its decision, focal point for ICGEB, Federation of Asian Biotechnology Associations, SAARC Biotechnology working group activities
Institute of Biochemistry, Molecular Biology and Biotechnology, University of Colombo	Academic and research	Research activities in biomedical sciences, molecular entomology, plant molecular sciences, conduct degree programs
Faculty of Science, University of Colombo	Academic	Research, conduct undergraduate and postgraduate degree programs,

(...continued)

Name	Type of Organization	Major Biotech Activities
Agricultural Biotechnology Center, University of Peradeniya	Academic and research	Research and development, undergraduate and postgraduate teaching and training
Faculty of Science, University of Kelaniya	Academic	Research, postgraduate degree programs, microbial culture collection center
Faculty of Science, University of Sri Jayawardane Pura	Academic	Research, postgraduate degree programs
Faculty of Science and Faculty of Agriculture, University of Peradeniya	Academic	Research, degree programs
Faculty of Science and Faculty of Agriculture, University of Ruhuna	Academic	Research, postgraduate degree in Molecular Biology and Biotechnology
Faculty of Science, University of Jaffna	Academic	Research, postgraduate degree
Department of Biotechnology, Wayamba University	Academic	Research, undergraduate degree
Faculty of Agriculture, Rajarata University	Academic	Research, postgraduate degree
Uva Wellassa University	Academic	Research, undergraduate teaching
Faculty of Applied Science, South Eastern University	Academic	Undergraduate, postgraduate programs
Rice Research and Development Institute	Research and development	Research and training
Coconut Research Institute of Sri Lanka	Research and development	Research and training
Tea Research Institute	Research and development	Research and training
Rubber Research Institute	Research and development	Research and training
Sugarcane Research Institute	Research and development	Research and training
Institute of Fundamental Studies	Research and development	Research
Institute of Postharvest Technology	Research and development	Research
Industrial Technology Institute	Research and development	Research
National Aquatic Resources Development and Research Agency	Research and development	Research and training

(...continued)

Name	Type of Organization	Major Biotech Activities
Plant Genetic Resources Centre	Research and development	Research and training
Horticultural Crop Research and Development Institute	Research and development	Research and training
Plant Virus Indexing Centre	Research and development	Research and training
Veterinary Research Institute	Research and development	Research
Bandaranayake Memorial Ayurveda Research Institute	Research and development	Research
Institute of Indigenous Medicine	Research and development	Research, degree programs
Sri Lanka Council for Agricultural Research Policy	Science and technology	Funding research in agriculture and allied fields, training
National Research Council	Science and technology	Funding research
Genetech	Private	Research, molecular diagnostics, paternity testing, forensics
CIC Agri Business	Private	Mass propagation of horticultural plants, marketing and production of high quality seeds, production of weedicides, insecticides, fungicides
Ceylinco Foliage Export Pvt. Ltd.	Private	Mass propagation of cut foliage
Hayleys Agro Biotech	Private	Micropropagation of ornamental flowering and foliage plants, timber crops, fruit crops,
Mikeflora Pvt. Ltd.	Private	Tissue culture ornamental plants
Serendib Horticulture Technologies Pvt. Ltd.	Private	Tissue culture ornamental plants
Bio Power Lanka Pvt. Ltd.	Private	Biofertilizer
Sri-Biotech Lanka	Private	Biofertilizer, biopesticides
Sri Lanka Institute of Information Technology	Private	Bioinformatics

Source: International Centre for Genetic Engineering and Biotechnology (ICGEB); South Asian Association for Regional Cooperation (SAARC) [7].

Future Development Focus

The transfer of technology from research to industry and the promotion of a biotechnology industry are both highly needed in the country today. Therefore, a proper mechanism should be established for technology transfer. At the same time, there should be a proper mechanism to ensure biosafety and product quality, and to address ethical issues through a process of regulation and monitoring.

The agricultural biotechnologies proposed by the Biotechnology Committee of the NSF of Sri Lanka are: micropropagation to improve the agriculture and horticulture industry; development of biofertilizer and compost; development of biopesticides and bioherbicides; production of biogas; production of fermented milk products; production of fuel alcohol and alcoholic beverages; production of microbial enzymes and other useful products; waste treatment; pollution control; bioremediation; development and use of diagnostics and vaccines in farm animals; production of proteins, enzymes and probiotics using farm animals; production of high value compounds from marine organisms and feedstuff and agar from seaweed; quality control including GM testing for GM foods; production of nutraceuticals and value addition to food [8].

The Biotechnology Committee of the NSF of Sri Lanka suggested a framework for the establishment, promotion, regulation, and monitoring of the biotechnology sector [8]. However, the commitment of Sri Lanka's government is essential to establish and promote the sector. It should show strong support by establishing proper linkages among institutes and industries for industrial and commercial applications of biotechnology.

The government has considered the need to rapidly develop biotechnology-based sectors, the very high potential they can contribute to the national economy, and the regulatory and safety concerns of these industries. To this end, the government formed a separate apex body for biotechnology under the Ministry of Science and Technology. This apex body aims to directly support the establishment, promotion, regulation, and monitoring of biotechnology industries in Sri Lanka. This apex body can advise the government on building up a sound base of higher education and research in biotechnology; identify the need for specialized technologies; develop manpower skills for these specialized technologies; accelerate the transfer of biotechnology discoveries to commercial applications by developing links between researchers and industries; promote the transfer of technology from R&D to industry through maintaining a database and network of the R&D sector and industry; establish bio-incubators, biotechnology parks, and regional and international assistance and collaboration; and develop entrepreneurship, assist in finding funding sources and create awareness among all stakeholders.

To address biosafety issues in Sri Lanka, the local consultant for this apex body, the National Biotechnology Council, suggested two components for a proposed Biosafety Project of the Ministry of Environment.

The suggested components are:

1. *Two centers supported for transgenic crop production*: The proposal is to set up state-of-the-art greenhouses at each center.

2. *Three laboratories supported for GM testing, training, etc.*: The proposal is to set up high tech facilities with capabilities such as DNA sequencing and real-time PCR in the proposed centralized laboratories.

CONCLUDING REMARKS

Biotechnology is a promising tool for the rapid development of agriculture through improving productivity, quality, safety, and affordability. The rising use of modern molecular biology tools such as genetic mapping and marker-assisted selection, aids the improvement of crops, livestock, fish, and tree species. Therefore, there is a vast potential for biotechnology applications in the agriculture sector. At present, academic and research collaboration is highly needed to support industrial development and economic growth in Sri Lanka's agriculture-based industries to establish a sustainable bioindustry.

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AGRICULTURAL BIOTECHNOLOGY IN THAILAND

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INTRODUCTION

Many developing countries in Asia have proposed biotechnology as a key investment area to stimulate agricultural productivity. The application of biotechnology in agriculture has resulted in benefits to farmers, producers, and consumers in many countries. Agricultural biotechnologies use technological tools to improve crops, better enabling the world to both feed and fuel a growing population that has surpassed 7 billion, and the UN expects it to reach 9 billion by 2050 [1].

Thailand recognizes the importance of agricultural biotechnology to enhance the quality of people's lives, increase food security in a sustainable manner, and as an alternative option to increase yields for food and feed crops [2].

In this paper, six aspects of agricultural biotechnology will be discussed:

1. Plant micro-propagation;
2. Agribusiness promotion;
3. Rice biotechnology;
4. R&D and technology transfer in agricultural biotechnology using a case study of a research institute in Thailand;
5. Genetically modified (GM) plants; and
6. Challenges facing Thailand.

PLANT MICRO-PROPAGATION

Agricultural biotechnology, including mass propagation, is a powerful tool for agribusiness. Tissue culture technology has become widely used in agriculture. In Thailand, attempts have been made by various organizations (such as the Department of Agriculture (DOA), National Center for Genetic Engineering and Biotechnology (BIOTEC), and universities) and the private sector to use tissue cultures to enhance the quality of propagated plant materials.

Successful large-scale production of both economic and ornamental crops was made possible thanks to quality outputs of *in vitro* culture (micro-propagation). In addition, higher yields (45%–88%) have been obtained from pathogen-free planting materials. In grapevines, a high total yield increment of up to 300% can be obtained by using virus-free plants [3]. The application of this technique for the production of pathogen-free planting materials is described below.

Research and Development in Sugarcane

Sugarcane (*Saccharum spp.*) is an industrial crop that is used as raw material for sugar and ethanol production. It is cultivated in almost 60 countries, and Thailand is the second largest exporter of raw sugar to the world market.

While tissue culture technology has been successfully used as a tool for rapid sugarcane propogation, a serious sugarcane white leaf disease caused by stem-attacking phytoplasma, is widely found in Thailand. This disease causes high losses in yield. Currently, Thai farmers use hot water treatment on sugarcane stem cuttings to destroy the pathogen. However, this technique does not eradicate the microorganisms residing in the plant cells.

The use of plant tissue culture in combination with other specific techniques could be an alternative for the production of phytoplasma-free planting materials in sugarcane, such as:

- *Cryotherapy*: Using liquid nitrogen to induce ultra-low temperatures (at –196 ºC) to eradicate pathogens infecting plant tissues, specifically in plant tissue culture [3].

- *Antibiotic application*: The antibiotic oxytetracycline HCl could delay phytoplasma multiplication of phytoplasma. Additionally, it could be possible to obtain pathogen-free microshoots by harvesting new shoots from tissue cultures with frequent subcultures.

- *Apical meristem culture*: Using this method, a National Agricultural Experiment Station in Japan has successfully made 50 varieties of 12 plant species virus free. To date, appproximately 20 kinds of viruses have been eliminated by meristem culture.

Currently, successful examples of phytoplasma elimination in commercial sugarcane have included the use of oxytetracycline and apical meristem culture. These techniques resulted in more than 85% of *in vitro* microshoots becoming phytoplasma-free, as confirmed by the nested polymerase chain reaction (PCR) method.

Powerful Tool for Micro-propagation

After obtaining the phytoplasma-free materials, these can be used as starters for rapid clonal propagation. Micro-propagation is extremely labor-intensive, with nearly half (46%) of the total costs being due to labor alone [5]. However, temporary immersion bioreactors (TIBs) can be a powerful system to enhance the production of good quality propagated materials. The use of TIBs reduces cost and improves the quality of plants produced in vitro. This technique displays a substantial increase in multiplication rate, as well as in plant quality. Various commercial varieties of sugarcane have been successfully propagated using the TIB technique.

Future Development

It is possible to reduce the number of infected sugarcane plants through the large-scale planting of pathrogen-free stocks. This would reduce the inoculum scources of phytoplasma. However, this action would require intensive farm management. These sugarcane solutions show that it is possible to reduce the numbers of infected plans by using technology accompanied with good agricultural practices. Besides sugarcane, other economic or industrial crops such as cassava, grape, and potato, require further research for the production of pathogen-free plant propagation materials. It is only then that production costs can be reduced.

AGRIBUSINESS PROMOTION

The Bank for Agriculture and Agricultural Cooperatives (BAAC) is a financial institution (a state-owned enterprise to support the government) that provides financial assistance to farmers, helping to improve their socioeconomic status and standard of living by increasing their farm income. BAAC's service includes extending credit-in-kind, marketing, and storage services. BAAC's vision is "to be a secure rural development bank with modern managerial technology focusing on uplifting small-scale farmers' quality of life" and its missions are:

- To render integrated credit services to enhance farmers' opportunities for effective and improved productivity

- To improve resource management learning to upgrade farmers' quality of life

- To administer and manage funds so that they are adequate and operating capital is appropriate

- To train and recruit highly qualified staff in order to develop new areas of services that effectively increases productivity and effectively and productively meets farmers' needs

To these ends, BAAC has championed a "Five-Year Operational Strategies" plan to proactively extend credit lines and support work plans in order to improve product value through the entire value chain from upstream, through midstream, and finally, downstream. The plan covers food crops as well as commercial farm animal industries, which rely on community business networks and cooperatives for success. The policy includes credit services whereby opportunities to access funding sources are created for farmers, while small-scale farming clients are encouraged to effectively increase their output and learning. Encouraging clients to strengthen their learning potential is essential, in order to ensure sustainable improvements in the quality of their lives. Emphasis is also put on creating opportunities for new groups of clients to access loans, while credit support and knowledge development is provided to increase the market share of business-oriented farms. In the area of development, the emphasis is on enhancement by means of production grouping, adding value to farm products, and boosting business and marketing skills through group selling to boost price bargaining power.

Given the current economic situation, BAAC needs to define suitable technologies that can work alongside credit facilities to finance the entire agriculture value chain. So far, BAAC has concentrated on assisting individual farmers; as they figuratively represent the first link of the production chain process. Subsequent links have not received adequate support, even though they function as key mediators in the production process (processing, transportation, and distribution). These would include operators, organizations, farmers' institutions, manufacturing plants, processing plants, and distributors, whose active participation is needed to generate a value chain that will eventually benefit the farmers upstream. Despite the small resources dedicated to biotechnology, BAAC still expects to provide these services in aiding biotechnology implemention and providing value for agricultural commodities, to generate extra income for farmers.

Biotechnology and global competitiveness exemplify the challenges that BAAC faces. With its operations, it is seen to play a key role in creating opportunities to generate extra income for farmers and participating parties within the supply chain.

RICE BIOTECHNOLOGY

Cultivated *indica* rice (Oryza sativa L.) is the most important source of carbohydrates for Thais as well as many other Asian countries. In addition, rice has evolved to become a major cultural symbol in Thailand. A major challenge confronting all plant breeders is increasing rice production from already limited paddy areas to feed an increasingly growing world population. Improving the yield potential of rice genotypes can increase rice production, and improving biotic and abiotic stress genotypes can maintain the stability of rice yield.

Recent rice genome sequences have accelerated gene discovery and rice improvement. Significant progress in rice functional genomics offers great opportunities to breeders towards improving rice through molecular breeding. Several DNA markers have been developed, applying for marker-assisted selection (MAS) in rice-breeding programs worldwide, including those in Thailand. The current status of rice biotechnology in Thailand is described below.

Rice Variety Improvement

MAS has been used as a tool to develop important traits in rice, such as tolerance to unfavorable environmental conditions, resistance to pests and diseases, cooking quality, and nutrition. Desirable traits were introduced to the rice cultivar KDML105, which is characterized by its good fragrance and eating quality with fragrance. It has been accepted in markets as premium jasmine rice. KDML105 has been extensively used as a parental line to develop new rice lines with favorable traits such as resistance to brown planthoppers, blast, and bacterial blight, and tolerance to drought, salinity, and submergence [6–10]. Through collaborations with several government organizations and universities in Thailand, new improved rice varieties are bred and distributed to farmers.

Genetic Diversity of Rice and Pests

DNA markers have been used to study genetic diversity in rice cultivars and rice pests. Assessing genetic diversity and molecular characterizations in Thai cultivated rice varieties, is an important step for germplasm management, varietal identification, and DNA fingerprinting. Microsatellite markers have been used to characterize and discriminate between varieties. However, with next-generation sequencing (NGS), vast germplasm resources will reduce sequencing costs and studying genome-wide associations will become feasible, thus enabling the allelic variation in rice's underlying agronomic traits to be studied.

Genetic diversity and biotypes of rice gall midge populations in Thailand were studied using amplified fragment length polymorphism and biotype-specific markers. Two biotypes of the gall midge were identified [11]. Recently, Thai and Japanese scientists developed genomic microsatellite markers for the brown planthopper. The developed markers were used to characterize genetic diversity, construct the first genetic linkage map, and discover a virulence-associated gene in the brown planthopper [12–13]. The information from the studies will facilitate strategies to control major rice insect pests.

Future of Rice Improvement

Advances associated with NGS technologies, coupled with the completion of high-quality reference genome sequences, open the opportunity to redesign genotyping strategies for more effective genetic mapping and genome analyses in rice. The technologies illustrate the promise of a new era of rice genomics. These technologies will be applied for developing new Thai rice varieties that have good cooking quality, resistance against multiple insects and diseases, high nutrition, and tolerance of drought, salinity, and submergence in the near future.

AGRICULTURAL BIOTECHNOLOGY R&D AND TECHNOLOGY TRANSFER: A CASE STUDY

The Thailand Institute of Scientific and Technological Research (TISTR) is an organization of integrated technologies with special emphasis on food, health products, renewable energy, and the environment. For agricultural technology, TISTR conducts R&D, technology transfer and incubation projects for the production of new economic plants, herbal plants, vegetables, fruits, organic fertilizer, biofertilizer, and environment-friendly protective agents and pesticides.

Below are selected examples of TISTR's research work and achievements in technology transfer:

- *Rice starch*: TISTR was successful in developing rice starch from broken jasmine rice (KDML105) by physical modification of starch using heat moisture treatment. The modified rice starch can be used as a thickening agent and fat replacer in non-fat dressing products mixed with inulin, another type of thickening agent. The formula for the appropriate ratio was also developed in order to produce non-fat salad dressings with the same texture as full-fat salad dressing, which consumers find acceptable.

- *Ready-to-drink duku juice*: adding fructose to the juice improved the drink's taste and popularity. The pasteurized products were of two types: pasteurized bottles which could be kept for more than one month at 40ºC and pasteurized Tetra packs which could be kept for more than one year at 25ºC.

- *Development and production of Nostoc commune*: *TISTR 8878:* This product provides essential amino acids, vitamins, minerals, chlorophyll, and phytocyanin (an anti-oxidant) making it popular among health-conscious consumers.

- *Health products from Thai vegetables and fruits*: TISTR conducted an integrated research with a process that carried through chemical extraction from anti-oxidant substances in strict quality-control environments. Anti-oxidant activities were determined through various pharmacological test methods both in vivo and in vitro. The test results revealed that two vegetables, Pak Chiang Da (*Gymnema inodorum*) and Pak Wan Ban (*Sauropus androgynus*), had high potential for antioxidant activity relevant to diabetes-causing conditions.

- *Cosmeceuticals from a Thai medicinal plant (Stephania suberosa Forman)*: TISTR successfully developed an acne treatment line, including a mask, gel wash, and spot corrector.

- *Plygersic from the extracts of Phlai (Zingiber cassumunar) and ginger (Zingiber officinale)*: The product is used for treating joint inflammation caused by osteoarthritis and its quality was scientifically proven by essential tests such as pharmaceutical, product safety, and clinical tests.

- *"Musacid"*: from banana and ginger (350 mg/tablet) as a supplement tablet for ulcer prevention. Clinical studies showed that Musacid (1,050 mg per tablet) was effective in volunteers who had good health but suffered from ulcers. The Musacid tablet also had no hazardous effects on the volunteers' liver, kidney, or circulatory systems.

- *TISTRAMIN, an anti-oxidant dietary supplement*: TISTR transferred the technology for the production of TISTRAMIN, the curcumin extract with high anti-oxidant activity, to the Union of Thai Traditional Medicine Society. At present, the product is awaiting Food and Drug Administration (FDA) approval.

- *Golden oyster mushrooms*: TISTR, in collaboration with the Royal Project Foundation, is growing golden oyster mushrooms at the Temperate Mushroom Research and Development Centre, Doi Pui, Chiang Mai. Training for mushroom cultivation on a commercial scale will be carried out to promote community businesses and SMEs.

CURRENT STATUS OF GM PLANTS IN THAILAND

Research and Development

The development of transgenic plants is in its early stages (laboratory and greenhouse) at government organizations and universities such as the DOA, Kasetsart University, and BIOTEC. A number of plants are ready for biosafety testing such as ringspot-virus PRSV-resistant papaya, delayed-ripening papaya, tomato yellow leaf curl virus (TYLCV)-resistant tomato, vein-banding-mottle-virus-resistant chili, and color-changed orchids [14].

Policy on GM Plants

Thailand is not currently trading in GM plants except for: processed food; and imports or sales of soybeans and corn for feed use, human consumption, and industrial use. However, Thailand acceded to the Cartagena Protocol on Biosafety on 10 November 2005, and it came into force on 8 February 2006.

The Office of Natural Resources and Environmental Policy and Planning has been nominated as the national focal point for the Protocol and Biosafety Clearing House. The ratification will ensure Thailand can participate fully in this new multilateral approach in managing the potential risks of living modified organisms.

To strengthen R&D capability, on 25 December 2007, the Cabinet approved the conduct of field trials within government research stations with a number of conditions: researchers have to define the planting area and type of crop; propose risk-management measures; provide information on possible effects on the environment and human health; and gather public opinion [15].

Regulation of GM Plants

Importation

Under the Plant Quarantine Act, the DOA, under the Ministry of Agriculture and Cooperatives, regulates GM seed importation. The Act prohibits the import of 33 species, 51 genera and one family into Thailand, except for R&D purposes in compliance with DOA biosafety guidelines on importation of prohibited materials [16]. However, soybean and corn grains are exempted for a wide-range of domestic uses in both the feed-milling and food-processing industries [17].

GM food labelling

The FDA has drafted a labeling regulation for food containing ingredients derived from GM organisms. It became Ministerial Regulation No. 251 B.E.E 2545 (2002) and has been enforced since 11 May 2003. Only GM soybean, corn, and their products (22 items) have to be labeled. The threshold level has been determined to be 5% of DNA or protein from each of the product's top three ingredients, and each ingredient should be more than 5% by weight of the product [18].

Draft Biosafety Act (2006)

The Thai government's decision to become a party to the Cartagena Protocol on Biosafety highlighted the need to establish a legislative framework for the entire country. Obligations to the Cartagena Protocol on Biosafety were synthesized in order to identify which existing components of Thailand's biosafety laws should be included so that the protocol could be effectively implemented for the benefit of the country. A drafting committee approved the draft Biosafety Act (issued in April 2007), which consisted of 108 Articles in 10 sections. Such a framework would define how Thailand could regulate and promote modern biotechnology at a pace faster than in the past. The National Biosafety Act was approved by the Cabinet in January 2008, but is still pending enactment [19].

CHALLENGES FOR THAILAND

Challenges in Compliance Regulation

Field trials are an important component of the approval process before a GM plant is allowed for commercial cultivation. The high requirements for GM plant biosafety testing, which emerged in the second half of the 1990s, led to the cancellation of R&D projects related to agricultural GM organisms, and decreased scientific output [20].

Between 1992 and 2001, many GM plants were developed in Thailand and 40 transgenic plants were approved for study [21]. On 3 April 2001, the Cabinet decided to place a moratorium on all open field trials. However, on 25 December 2007, the Cabinet approved an extension of GM plant trials conducted within government experimental stations. The plan required: clear definitions of the planting area, the crop, and control methods; studies of environmental effects and human health in nearby locales; and gathering public opinion and that of other interested parties in accordance with Article 67 of the Constitution of Thailand [15]. Although field trials in government fields were reinstated, these requirements are, in reality, obstacles that make field trials practically impossible [22].

Challenges in Public Perception

Public awareness may be a key factor influencing consumer acceptance of GM plants. Despite efforts to publicly disseminate such information, most consumers are not knowledgeable about this area. It is reasonable to infer that this has contributed to the growing public sentiment against genetic engineering [23].

Realizing the importance of public awareness about the technology, government institutes and some private partners have started educational campaigns that use mass media and publications to communicate scientific information about GM organisms. This is in order to advance the development of knowledge-based public participation through which the public can evaluate concerns with scientific facts. Public education on complicated science has been facilitated by translating biotechnology and biosafety information into various forms of "nice-and-easy" articles and educational material for broadcasting and publication, including cartoon books for children (Figure 1). Educational tools for learning about DNA, gene transformation, and biosafety were also specially designed and produced to enhance the learning atmosphere in a learn-and-play manner.

Figure 1. Thai easy-to-read publications on biosafety of genetically modified plants.

Source: Technical Biosafety Committee. Thailand Updated Status and Perspective on Research and Development of Modern Biotechnology and Biosafety Regulation [15].

Challenges in Human Resource Development

Capacity building is the main challenge to developing countries as they aim to safely apply modern biotechnologies, and implement related biosafety frameworks [24]. Capacity-building initiatives play an important role in supporting individuals, institutions, and governmental authorities by providing training and/or physical structures and technical assistance. There are many types of capacity building activities.

Food and environmental risk assessments require competent, technical-specific, and experienced experts. Thailand is consequently building capacity for food and environment risk assessors.

A training course and curriculum for regional experts in the country is being developed to screen for qualified personnel to be listed in a roster of biosafety country experts. Those selected will serve the risk assessment process in the near future [25].

SUMMARY AND CONCLUDING REMARKS

Modern biotechnology, or genetic engineering, is an indispensable tool to increase the efficiency of Thailand's agriculture and food industry. If Thailand wants to successfully transform from an agrarian to a knowledge-based economy, R&D in biotechnology is essential.

However, precautionary measures must be enforced to ensure that public confidence in the use of gene technology is without risk. Capacity building and public awareness are the main challenges to the safe application of GM plants in Thailand, as well as in the implementation of the related biosafety regulations. A good regulatory framework and control are keys to success in gaining the public's acceptance for this technology. Finally, it is hoped that by the time the public realizes the positive benefits of biotechnology and tries to reap it, Thailand will have established a proper management and risk management process for the technology, but not have already lost its preeminent position in the agricultural world.

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APPENDIX 2: PROGRAM OF ACTIVITIES

Day 1: Monday, 15 July 2013	
Time	**Activity**
8:30–9:00	Registration
9:00–10:00	Opening session • Welcome remarks by Mr. Joselito C. Bernardo, Director, Agriculture Department, APO • Opening remarks by Dr. Eugene Y. Lin, Director of Planning and Training Division, CPC • Inaugural remarks by Mr. Wen-Deh Chen, Deputy Minister of COA • Photo session
10:00–10:30	Coffee break & networking
10:30–11:00	*Overview of the conference program* by Dr. Muhammad Saeed, Senior Program Officer, Asian Productivity Organization, Tokyo, Japan
Session 1: Global trends in biotechnology applications *Chairperson: Dr. Siang Hee Tan*	
11:00–11:30	***Speaker 1.*** *Trends in the global biotechnology industry* by Dr. Yali E. Friedman, Chief Editor and Publisher, Journal of Commercial Biotechnology, Washington, D.C., USA
11:30–12:00	***Speaker 2.*** *An analysis of global developments in biotechnology crops and animals* by Dr. Randy A. Hautea, Southeast Asia Center Director of the International Service for the Acquisition of Agri-biotech Applications (ISAAA) and ISAAA Global Coordinator, Philippines
12:00–12:30	***Speaker 3.*** *Meeting the global demand for more food, feed, fiber and fuel using biotechnology* by Dr. Ying Yeh, Director General, Department of Science and Technology, Council of Agriculture, Executive Yuan, ROC
12:30–13:00	Open forum: Q & A, Comments, and suggestions
13:00–14:00	Lunch break & networking
Session 2: Commercialization of agricultural biotechnology: Policy, institutional, and regulatory frameworks *Chairperson: Professor Dr. Paul Teng*	
14:00–14:40	***Speaker 1.*** *What does it take to successfully commercialize biotechnology products?* by Dr. Yali E. Friedman, Chief Editor and Publisher, Journal of Commercial Biotechnology, Washington, D.C., USA

(...continued)

Day 1: Monday, 15 July 2013	
Time	**Activity**
14:40–15:20	***Speaker 2.*** *Overcoming policy, institutional and regulatory hurdles in biotechnology commercialization and preparing the consumer for acceptance modern biotechnology products* by Dr. Andrew Powell, Chief Executive Officer, Asia BioBusiness Pte. Ltd., Singapore
15:20–15:50	Coffee break & networking
15:50–16:30	***Speaker 3.*** *Agri-bio business creates infinitive commercial opportunity: Experience of Taiwan* by Dr. Jen-Pin Chen, Deputy-Director of Agriculture and Food Agency, Council of Agriculture, ROC
16:30–17:00	Open forum: Q & A, Comments, and suggestions
18:30–20:30	Welcome dinner hosted by the APO (Venue: The Mellow Field Hotel, B1)
Day 2: Tuesday, 16 July 2013	
Session 3: Risk management by agricultural/ biotechnology-based SMEs for sustainable business *Chairperson: Dr. J.L. Karihaloo*	
8:30–9:00	***Speaker 1.*** *Assessing and managing risks associated with starting and sustaining agricultural biotechnology businesses* by Dr. Andrew Powell, Chief Executive Officer Asia BioBusiness Pte. Ltd., Singapore
9:00–9:30	***Speaker 2.*** *Managing investment risks in agricultural technologies aimed at increasing food production* by Dr. Siang Hee Tan, Executive Director, CropLife Asia, Singapore
9:30–10:00	***Speaker 3.*** *Risk assessment and management for/by biotechnology-based industry SMEs* by Dr. Tzu-Ming Pan, Distinguished professor, Department of Biochemical Science and Technology, National Taiwan University
10:00–10:30	Coffee break & networking
10:30–11:00	***Speaker 4.*** *Role of Communication in Risk Management: Experience of the SEARCA BIC* by Ms. Jenny A. Panopio, Special Project Coordinator and Network Administrator, Biotechnology Information Center, Southeast Asian Regional Center for Graduate Study and Research in Agriculture (SEARCA) College, Banos, Laguna, the Philippines
11:00–11:30	Open forum: Q & A, comments, and suggestions
Session 4: Biotechnology and Green Productivity (GP) in agriculture *Chairperson: Dr. Yali E. Friedman*	
11:30–12:00	***Speaker 1.*** *How does biotechnology contribute to green food production by reducing inputs and increasing profits?* by Dr. Randy A. Hautea, Southeast Asia Center Director of the International Service for the Acquisition of Agri-biotech Applications (ISAAA) and ISAAA Global Coordinator, Philippines.

(...continued)

Day 2: Tuesday, 16 July 2013	
Time	**Activity**
12:00–12:30	***Speaker 2.*** *Use of biotechnology in waste management: case of livestock biogas production and utilization for reducing environmental impact* by Dr. Jung-Jeng Su, Assistant Professor, Dept. of Animal Science and Technology, National Taiwan University
12:30–13:30	Lunch break & networking
13:30–14:00	***Speaker 3.*** *Development of bio-material industry for increasing green agricultural productivity in Taiwan* b Dr. Gwo-Chen Li, Member of DOH GMF Committee, previous Director of Agricultural Chemicals and Toxic Substances Research Institute, Council of Agriculture, ROC
14:00–14:30	Open forum: Q & A, Comments, and suggestions
14:30–15:00	Coffee break & networking
Session 5: Investment in agricultural biotechnology *Chairperson: Dr. Andrew Powell*	
15:00–15:40	***Speaker 1.*** *Multinational company investments in agricultural biotechnology* by Dr. Siang Hee Tan, Executive Director, CropLife Asia, Singapore
15:40–16:20	***Speaker 2.*** *Investment instruments to drive biotechnology applications and facilitating country-level, public investments in biotechnology* by Mr. Vincent Yong, Manager, Malaysian Biotechnology Corporation Sdn. Bhd., Malaysia (On behalf of Dato' Dr. Mohd Nazlee Kamal, CEO, Malaysian Biotech. Corp. Sdn. Bhd.,)
16:20–17:00	***Speaker 3.*** *Financing biotechnology research and development* by Dr. Howard S. Lee, Partner of the CID Group Ltd., ROC
17:00–17:30	Open forum: Q & A, Comments, and suggestions
Day 3: Wednesday, 17 July 2013	
Session 6: Agricultural biotechnology and global competitiveness *Chairperson: Dr. Randy A. Hautea*	
8:30–9:00	***Speaker 1.*** *Importance of biotechnology to increasing agricultural competitiveness and ensuring food security* by Dr. Paul Teng, Professor and Dean, Graduate Studies & Professional Learning, National Institute of Education, Nanyang Technological University, Singapore
9:00–9:30	***Speaker 2.*** *Promoting safe application of agricultural biotechnology in Asia and the Pacific region for greater global competitiveness* by Dr. J.L. Karihaloo, Coordinator, Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB), New Delhi, India

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Day 3: Wednesday, 17 July 2013	
Time	**Activity**
9:30–10:00	***Speaker 3.*** *Enhancing trade in biotechnology products: Case of US Biotech Soybeans* by Mr. Anthony Thang, Republic of China Country Director, US Soybean Export Council, ROC
10:00–10:30	***Speaker 4.*** *Capacity building of biotechnology-based agribusiness SMEs for enhancing global competitiveness* by Ms. Hung-Hsi Lee, Deputy Director General, Department of Science and Technology, Council of Agriculture, Executive Yuan, ROC
10:30–11:00	Open forum: Q & A, comments, and suggestions
11:00–11:30	Coffee break & networking
11:30–13:00	**Session 7. Panel discussion: Biotechnology applications in agriculture and food industry –The way forward** ***Moderator:*** *Professor Dr. Paul Teng* ***Panelists:*** *Dr. Yali E. Friedman* *Dr. Randy A. Hautea* *Dr. Siang Hee Tan* *Dr. J.L. Karihaloo* *Dr. Ying Yeh*
13:00–14:00	Lunch break & networking
14:00–15:00	**Session 8. Review and finalizing the conference recommendations Each Rapporteur in consultation with the respective session chairperson finalizes the recommendations** ***Moderator:*** *Dr. Andrew Powell*
15:00–15:30	Coffee break & networking
15:30–16:30	**Session 9. Concluding session** Each session chairperson reports on the summary session recommendations
16:30–17:00	Closing
18:30–20:30	Farewell Dinner hosted at the MARKET CAFÉ by the COA and FFTC

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