APAARI
Asia-Pacific Association of Agricultural Research Institutions

Asia-Pacific Consortium on
APCoAB
Agricultural Biotechnology and Bioresources

Australian Government
Australian Centre for International Agricultural Research

CGIAR
RESEARCH PROGRAM ON
Grain Legumes and Dryland Cereals

BCIL

DEPARTMENT OF AGRICULTURE

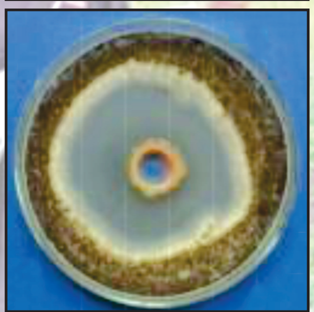
Regional Expert Consultation on

Agricultural Biotechnology – Scoping Partnerships to Improve Livelihoods of Farmers in Asia and The Pacific

Bangkok, Thailand
May 29-31, 2018

Strategic Papers and Country Status Reports

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Front Cover row top to bottom, left to right : 1. GM cotton (ACIAR, Australia); 2. Tissue culture lab at NAFRI (NAFRI, Lao, PDR); 3. Production of disease-free seed stocks of sugarcane at Sugarcane Research Institute, Sri Lanka (SLCARP, Sri Lanka); 4. Biocontrol development and application (VAAS, Vietnam); 5. Probiotics development and application for poultry (VAAS, Vietnam); 6. Capacity development through training programs for PNG (NARI, PNG); 7. 'Rajat', a highly-ranked progeny-tested Murrah bull (MU-4393) recreated several years after its death (ICAR, India)

Front Cover Background picture : Subsistence farming by small holder farmers (NARI, PNG)

Back Cover : Climate ready rice : SUB1 gene confers tolerance of transient submergence variety (right) compared to control (left) in fields of Uttar Pradesh, India (IRRI, Philippines)

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Contents

Foreword

Biotechnology impacted millions of lives in the world. The technology has not been harnessed to its potential in the Asia Pacific Region (APR) except for *Bt* cotton dominant spread in countries such as India and Pakistan and GM maize in Philippines. Among the other crops, *Bt* brinjal and golden rice are in the initial stages of penetration and may take several years to reach status of Bt cotton for various reasons. Some of the countries in the region effectively used the technology in fisheries and animal sciences also. Few countries in the region have remained largely away from advancements in biotechnology due to policy constraints (Nepal and Bhutan) and lack of investments (Pacific). There is huge gap within the APR on utilisation of biotechnology to improve livelihoods of farmers. In this context APAARI took the lead in conducting a "Regional Expert Consultation on Agricultural Biotechnology - Scoping Partnership to Improve Livelihoods of Farmers in Asia-Pacific" in Bangkok, Thailand from 29-31 May 2018.

Seventeen global experts delivered the talks on biotechnology strategies covering the areas of crops, aquaculture and livestock to promote partnerships within and across the globe, review the status of long term investments in biotechnology, highlight efforts of relevant CGIAR institutes, success story of public private partnership park in the region, individual success stories of technology in select countries, funding opportunities and private industry perspective in globalisation of advanced technologies. The consultation provided an opportunity to country representatives/members of APAARI to interact with the global experts on scoping partnerships in biotechnology. Biotechnology status was also reviewed for 15 countries in the region. A unique process of World Café Discussion was organized on priority research areas, capacity and infrastructure development, public awareness and policy advocacy, and possible partnerships. A Panel Discussion was also organized on 'Partnership and innovative funding mechanism for priority areas in agricultural biotechnology to achieve SDGs'. The discussions and recommendations were presented and reviewed in a brief 'Plenary Session'.

I am happy to see this publication on "Strategic Papers and Country Status Reports" edited and compiled for use by all the concerned stakeholders within the region and across the globe. I wish that the country status reports are reviewed and presented to the respective country policy makers to facilitate partnerships and enhance the use of advanced biotechnology to improve livelihoods of farmers in agriculture including aqua and livestock sectors. Another publication on "Proceedings and Recommendations" that has comprehensively covered the discussions, recommendations and proposed actions to be taken at all levels, has already been printed.

I appreciate and acknowledge all the participants of this regional consultation for their valuable contributions and time. I am extremely happy to acknowledge the leadership of Dr Rishi K. Tyagi in organizing this regional consultation on biotechnology. I wish to place on record the technical and financial contributions of the organizers of this regional expert consultation, without which it would not have happened the grand way. I am also happy to thank the capable editorial team and APAARI staff efforts in making the consultation successful and in bringing out the expected publications.

APAARI is committed to promote biotechnology not only for prosperity but also for sustainability in the APR working in harmony with the member countries, respecting their priorities and needs. All cooperation will be extended to establish partnerships in biotechnology to promote livelihoods of farmers in the region.

Ravi K. Khetarpal
Executive Secretary, APAARI

Acknowledgements

On behalf of Asia-Pacific Association of Agricultural Research Institutions (APAARI), Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB) and my own behalf, it is my great pleasure to acknowledge and profusely thank all the Co-Organizers - Council of Agriculture (COA), Taiwan, Department of Agriculture (DOA), Thailand and Australian Centre for International Agricultural Research (ACIAR), Australia; Co-Sponsors - CGIAR Research Program - Grain Legumes and Dryland Cereals (CRP-GLDC), International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) and Technical Support Partner, Biotech Consortium India Limited (BCIL) and participants for their respective roles in the Expert Consultation on 'Agricultural Biotechnology - Scoping Partnerships to Improve Livelihood of Farmers in Asia and the Pacific'. Besides organizational support, strategic and technical input of individuals is equally important. Profound thanks are accorded to Mr Chung-Hsiu Hung, Director General, Department of International Affairs, COA, Taiwan, for delivering the inaugural address of the meeting and setting the tone of the deliberations. We are immensely grateful to Dr Yusuf Zafar, Chairman, APAARI, for his guidance, suggestions and encouragement during preparation and organization of the meeting. Thanks are due to Dr Andrew Alford, Research Program Manager, ACIAR, Australia, for his participation and representing Ms Mellissa Wood, General Manager Global Programs, ACIAR. Dr Rajeev K. Varshney, Research Program Director for Genetic Gains, ICRISAT, Hyderabad, India, is thanked for his support and networking not only for this meeting, but also for many other programs involving collaboration with APAARI and ICRISAT. Dr Siriporn Boonchoo, Deputy Director General, DOA, Thailand, is thanked for her presence and input in the meeting as well as the collaboration and support extended to APAARI in other major programmes. Dr Ravi Khetarpal, Executive Secretary, APAARI, was the key person responsible for smooth execution of this Expert Consultation. He provided valuable input in developing the concept note, technical program, financial guidance and networking, which are important for the success of the meeting. Sincere thanks are accorded for his overall leadership.

We place on record our gratitude to all Heads and their nominees from National Agricultural Research Systems (NARS) for their presence, sacrificing precious time for providing inputs in the consultation. Grateful thanks are extended to all the Co-Chairs for conducting the respective sessions efficiently and steering the discussions, which resulted in important and useful recommendations. All the speakers and panellists of various technical sessions and panel discussion are thanked immensely for their excellent contributions, and participants/discussants for their insightful interventions. All the rapporteurs and facilitators of technical and plenary sessions, World Cafe and panel discussions are acknowledged for meticulously capturing the salient points that emerged from the presentations/discussion and also for drafting the recommendations.

Most sincere appreciation is extended to all staff members of APAARI Secretariat, namely, Dr Norah Omot, Mr Fai Collins, Ms Martina Spisiakova, Ms Geralidine Nemrod, Ms Thansita Tanaphatrujira, Mr Vishwanath K Sah, Ms Celilu Bitong and Ms Tarathip Sanboonkrong, for their concerted, untiring efforts and valuable contributions in the preparatory phase as well as during the event. They have worked constantly behind the scene to manage with all financial, logistic and administrative aspects in organization of the Expert Consultation.

This publication contains all the Country Status Reports and available Strategy Papers presented during the meeting except "Success Story on Bt Brinjal in Bangladesh" which has been printed as a separate document. A few Strategy Papers were not available, therefore, could not be included.

Sincere thanks are due to the Co-editors, especially Drs K.S. Varaprasad, Anitha Kodaru and Anuradha Agrawal, for their intensive involvement in collation and critical editing in giving shape to the publication in present form.

Rishi Tyagi
Coordinator, APCoAB
Co-Chair, Organizing Committee

The Organizers

Asia-Pacific Association of Agricultural Research Institutions

The Asia-Pacific Association of Agricultural Research Institutions (APAARI), with its headquarters in Bangkok, is a unique voluntary, membership-based, self-mandated, apolitical and multi-stakeholder regional organization in the Asia-Pacific region. It promotes and strengthens agriculture and agri-food research and innovation systems through partnerships and collaboration, capacity development and advocacy for sustainable agricultural development in the region. Since its establishment in 1990, APAARI has significantly contributed towards addressing agricultural research needs and enhancing food and nutritional security in the region. The close links, networks, partnerships and collaboration with stakeholders that APAARI has developed over the years, as well as its goodwill, authority and focus on results, make the Association an important actor in the region. The ultimate aim of APAARI is to help realising sustainable development goals in Asia and the Pacific. For more details, please visit the website: *http://www.apaari.org*

Asia-Pacific Consortium on Agricultural Biotechnology and Bioresources

The The Asia-Pacific Consortium on Agricultural Biotechnology and Bioresources (APCoAB) was established in 2003 under the umbrella of APAARI. Later in 2017, it was renamed as Asia-Pacific Consortium on Agricultural Biotechnology and Bioresources (APCoAB). APCoAB has the mission to harness the benefits of agricultural biotechnology bioresources for human and animal welfare through the application of latest scientific technologies while safeguarding the environment for the advancement of society in the Asia-Pacific region. For more details please visit the website: *http://www.apcoab.org; http://www.apaari.org/web/our-projects/apcoab/*

Council of Agriculture Research

The Council of Agricultural Research (COA), Taiwan is the competent authority on the agricultural, forestry, fishery, animal husbandry and food affairs in Taiwan. Its responsibilities include guiding and supervising provincial and municipal offices in these areas. Under the council, there are Department of Planning, Department of Animal Industry, Department of Farmers' Services, Department of International Affairs, Department of Science and Technology, Department of Irrigation and Engineering, Secretariat, Personnel Office, Accounting Office, Civil Service Ethics Office, Legal Affairs Committee, Petitions and Appeals Committee and Information Management Center respectively in-charge of related affairs. For more details, please visit the website: *http://eng.coa.gov.tw*

Australian Centre for International Agricultural Research

The Australian Centre for International Agricultural Research (ACIAR) is a statutory authority within the Foreign Affairs and Trade portfolio operating under the ACIAR Act. ACIAR contributes to the objectives of advancing Australia's national interests, promoting economic growth and increasing sustainability through assisting and encouraging

Australian scientists and institutions to use their skills to develop solutions to agricultural problems in developing countries. Its mandate is to plan, fund and manage projects across a broad range of agricultural and development areas. Approximately three quarters of the Centre's research budget is allocated to bilateral collaborative development-related research between Australia and developing countries. The remaining quarter of the research budget is allocated to multilateral development related research through contributions to international agricultural research centres. Besides, ACIAR provides training and development activities, including fellowships and support for training courses, as well as training provided within research projects, to help build capacity in research application and implementation in partner countries. For more details, please visit the website: *http://aciar.gov.au*

RESEARCH PROGRAM ON Grain Legumes and Dryland Cereals

CGIAR

CGIAR Research Program - Grain Legumes and Dryland Cereals

The CGIAR Research Program on Grain Legumes and Dryland Cereals (GLDC) builds on the work done by three CGIAR Research Programs from 2012 to 2016: Grain Legumes, Dryland Cereals and Dryland Systems. GLDC aims is to increase the productivity, profitability, resilience and marketability of critical and nutritious grain legumes and cereals within the semi-arid and sub-humid dryland agroecologies of sub-Saharan Africa and South Asia. These agroecologies are where poverty, malnutrition, climate change and soil degradation are among the most acute globally. For more details, please visit the website: *http:// http://gldc.cgiar.org/*

BCIL

Biotech Consortium India Limited

Biotech Consortium India Limited (BCIL) is a public limited company, promoted by the Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India and All India Financial Institutions for providing the necessary linkages among stakeholders and business support for facilitating accelerated commercialization of biotechnology. BCIL has been actively involved in technology transfer, project consultancy, fund syndication, information dissemination, and manpower training & placement related to biotechnology over the last decade and half. It has assisted hundreds of clients including scientists, technologies, research institutions, universities, first entrepreneurs, the corporate sector, national and international organizations, central government, various state governments, banks and financial institutions. For more details, please visit the website: *http://www.bcil.nic.in/*

DEPARTMENT OF AGRICULTURE

Department of Agriculture

The Department of Agriculture (DOA) was established since October 1, 1972 under the Revolutionary Decree No. 216 dated September 29, 1972 by merging the former Department of Agriculture and the Rice Department. The union was aimed to facilitate coordination among the Departments and officers as well as to streamline its function to enable a more efficient implementation of is mandates. The 15 pioneering units of the Department of Agriculture were the Office of the Secretary, Finance Division, Personnel Division, Planning Division, Rice Division, Field Crops Division, Horticulture Division, Sericulture Division, Rubber Division, Agricultural Engineering Division, Plant Pathology Division, Entomology and Zoology Division, and Agricultural Chemistry Division, a total of 95 research centres, stations and plant quarantine stations were then established throughout the country. For more details, please visit the website: *www.doa.go.th/en/*

Acronyms and Abbreviations

AAT	Asia Agri-Tech
AARINENA	Association of Agricultural Research Institutions in the Near East and North Africa
AB	Agricultural Biotechnology
ABI	Agro-Biotechnology Institute
ABRC	Agricultural Biotechnology Research Centre
ABSP	Agricultural Biotechnological Support Project
ACIAR	Australian Centre for International Agricultural Research
ADS	Agriculture Development Strategy
AFLP	Amplified Fragment Length Polymorphism
AFMA	Agriculture and Fisheries Modernization Act
AFRS	Agriculture and Forestry Research Strategy
AI	Artificial Insemination
AIT	Asian Institute of Technology
AMAF	ASEAN Ministerial Meeting on Agriculture and Forestry
AP	Asia-Pacific
APAARI	Asia-Pacific Association of Agricultural Research Institutions
APCC	Asia and Pacific Coconut Community
APCoAB	Asia-Pacific Consortium on Agricultural Biotechnology and Bioresources
APCoM	Asia-Pacific Consortium on Micropropagation
APEC	Asia-Pacific Economic Cooperation
APGRs	Agricultural Plant Genetic Resources
APHIS	Animal and Plant Health Inspection Service
APNAN	Asia Pacific Natural Agriculture Network
APR	Asia-Pacific Region
ARC	Agricultural Research Centre
ARDC	Agriculture Research and Development Centre
AREEO	Agricultural Research, Education and Extension Organization
ARS	Agricultural Research Services
ASEAN	Association of Southeast Asian Nations
ASP	Agricultural Sector Plan
AusAID	Australian Agency for International Development
BAFRA	Bhutan Agriculture and Food Regulatory Authority
BARC	Bangladesh Agricultural Research Council
BARI	Bangladesh Agricultural Research Institute
BASIC	Brazil, South Africa, India, China

BAU	Bangladesh Agricultural University
BBCH	Bhutan Biosafety Clearing House
BCH	Biosafety Clearing-House
BCIL	Biotech Consortium India Limited
BCP	Biotech Coalition of the Philippines
BFRI	Bangladesh Fisheries Research Institute
BIMSTEC	Bay of Bengal Initiative for Multi-Sectoral Technical and Economic Cooperation
BINA	Bangladesh Institute of Nuclear Agriculture
BIOTEC	National Center for Genetic Engineering and Biotechnology
BIOTECH-UPLB	National Institute of Molecular Biology and Biotechnology
BIRAC	Biotechnology Industry Research Assistance Council
BJRI	Bangladesh Jute Research Institute
BLRI	Bangladesh Livestock Research Institute
BNP	BioNexus Partners
BOI	Board of Investment of Thailand
BPI	Bureau of Plant Industry
BPIPO	Biotechnology & Pharmaceutical Industries Program Office
BRAI	Biotechnology Regulatory Authority of India
BRICS	Brazil, Russia, India, China and South Africa
BRRI	Bangladesh Rice Research Institute
BSO	Biological Safety Officer
BSRI	Bangladesh Sugar Crop Research Institute
Bt	*Bacillus thuringiensis*
BTP	Bioeconomy Transformation Programme
CABI	Centre for Agriculture and Bioscience International
CARP	Council for Agricultural Research Policy
CBBP	Community-Based Breeding Programs
CBD	Convention on Biological Diversity
CEGSB	Center of Excellence in Genomics and Systems Biology
CEMB	Center of Excellence in Molecular Biology
CEPA	Conservation and Environment Protection Authority
CePaCT	Centre for Pacific Crops and Trees
CESAIN	Centre of Excellence on Sustainable Agricultural Intensification and Nutrition
CGIAR	Consultative Group on International Agricultural Research
CIAT	International Center for Tropical Agriculture
CIMMYT	International Maize and Wheat Improvement Centre
CLA	Crop Life Asia
CLCV	*Cotton Leaf Curl Virus*
CNAs	Competent National Authorities
COA	Council of Agriculture
CoE	Centre of Excellence
COGENT	International Coconut Genetic Resources Network
CPB	Cartagena Protocol of Biosafety
CRI	Coconut Research Institute
CRISPR	Clustered, Regularly Interspaced, Short Palindromic Repeats
CROP	Council of Regional Organizations of the Pacific

CRP-GLDC	CGIAR Research Program – Grain Legumes and Dryland Cereals
CSA	Climate Smart Agriculture
CSD	Cotton Seed Distributors
CSIR	Council of Scientific and Industrial Research
CSO	Civil Society Organization
CTA	Technical Center for Agricultural and Rural Cooperation
CWR	Crop Wild Relatives
DA	Department of Agriculture
DA-AO8	Department of Agriculture Administrative Order No, 8
DAPH	Department of Animal Production and Health
DARE	Department of Agricultural Research and Education
DArT	Diversity Arrays Technology
DBT	Department of Biotechnology
DEA	Department of Export Agriculture
DENR	Department of Environment and Natural Resources
DFAT	Department of Foreign Affairs and Trade
DFID	Department for International Development
DILG	Department of Interior and Local Government
DNA	Deoxyribo Nucleic Acid
DOA	Department of Agriculture
DOH	Department of Health
DPIAB	Development Program of Industrialization for Agricultural Biotechnology
DST	Department of Science and Technology
EBN	Edible Bird Nest
ELISA	Enzyme Linked Immunosorbent Assay
EM	Effective Microorganisms
EPA	Environmental Protection Agency
EPO	Environmental Protection Organization
ERS	Economic Research Services
ET	Embryo Transfer
FAO	Food and Agriculture Organization
FAO RAP	Food and Agriculture Organization Regional Office for Asia and the Pacific
FAS	Foreign Agricultural Service
FCRDI	Field Crops Research and Development Institute
FDA	Food and Drug Administration
FFP	Food Feed for Processing
FMD	Foot and Mouth Disease
FNBC	Federal National Biosafety Committee
FNPP	FAO Netherlands Partnership Programme
FO	Farmers Organisation
FP	Framework Programme
FRDI	Fruit Research and Development Institute
FSW	Food Security Week
FTAI	Fixed-Time Artificial Insemination
FtF	Feed the Future
FTI	Fundraising, Technology Transfer and Innovation

GAP	Good Agricultural Practices
GDP	Gross Domestic Product
GE	Genetically Engineered
GEAC	Genetic Engineering Appraisal Committee
GLCs	Government-Linked Companies
GM	Genetically Modified
GMO	Genetically Modified Organism
GMO	Genetically Modified Organism
GNI	Gross National Income
GOI	Government of India
GOP	Government of Pakistan
HEC	Higher Education Commission
HLPDAB	High Level Policies Dialogue on Agricultural Biotechnology
HNRDA	Harmonized National R&D Agenda
HORDI	Horticultural Crops Research and Development Institute
HT	Herbicide Tolerant
IAEA	International Atomic Energy Agency
IBC	Institutional Biosafety Committee
IBSA	India, Brazil, South Africa
IBSC	Institutional Biosafety Committees
IBT	Institute of Biotechnology
ICAR	Indian Council of Agricultural Research
ICARDA	International Centre for Agricultural Research in the Dryland Areas
ICDF	International Cooperation for Development Fund
ICGEB	International Centre for Genetic Engineering and Biotechnology
ICGSC	International Chickpea Genome Sequencing Consortium
ICRAF	International Council for Research in Agro-Forestry
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
ICT	Information and Communication Technology
IDE	Innovation Driven Entrepreneurship
IEC	Information, Education, and Communication
IFAD	International Fund for Agricultural Development
IFNG	Interferon Gamma
IIPG	International Initiative on Pigeonpea Genomics
IISBR	Institute for Interdisciplinary Salivary Bioscience Research
IITA	International Institute of Tropical Agriculture
ILRI	International Livestock Research Institute
IMISAP	Implementation Strategy and Action Plan
IP	Integrated Programs
IPMGSC	International Pearl Millet Genome Sequence Consortium
IPR	Intellectual Property Rights
IR	Insect Resistant
IRIC	International Rice Informatics Consortium
IRRI	International Rice Research Institute
ISAAA	International Service for the Acquisition of Agri-biotech Applications
ISHS	International Society for Horticultural Science

ISTA	International Seed Testing Association
ITC	International Transit Centre
ITPGRFA	International Treaty for Plant Genetic Resources for Food and Agriculture
IUFRO	International Union of Forest Research Organizations
IVF	In Vitro Fertilization
IWMI	International Water Management Institute
JAF	Jute and Allied Fibres
JDC	Joint Department Circular
JICA	Japan International Cooperation Agency
JIRCAS	Japan International Research Center for Agricultural Sciences
KUL	Katholieke Universiteit Leuven
LAMP	Loop Mediated Isothermal Amplification
LB	Livestock Biotechnology
LMOs	Living Modified Organisms
LRD	Land Resources Division
MABC	Marker Assisted Back Crossing
MARD	Ministry of Agriculture and Rural Development
MARDI	Malaysian Agricultural Research and Development Institute
MAS	Marker Assisted Selection
MBC	Malaysian Biotechnology Corporation
MDGs	Millennium Development Goals
MDV	Malaysian Debt Ventures
MIDA	Malaysian Industrial Development Authority
MNRE	Minister of Natural Resources and Environment
MoA	Ministry of Agriculture
MoAC	Ministry of Agriculture and Cooperatives
MoAF	Ministry of Agriculture and Forests
MOAF	Ministry of Agriculture and Fisheries
MoALC	Ministry of Agriculture, Land Management and Cooperative
MOALI	Ministry of Agriculture, Livestock and Irrigation
MoEF&CC	Ministry of Environment, Forests and Climate Change
MoF	Ministry of Finance
MoFE	Ministry of Forests and Environment
MoH	Ministry of Health
MoHE	Ministry of Higher Education
MoHW	Ministry of Health and Welfare
MoNRE	Ministry of Natural Resources and Environment
MoPH	Ministry of Public Health
MoST	Ministry of Science and Technology
MoSTI	Ministry of Science, Technology and Innovation
MSCA	Marie Skłodowska-Curie Actions
MTDC	Malaysian Technology Development Corporation
MTEC	Thailand National Metal and Materials Technology Center
NACA	Network of Aquaculture Centres in Asia-Pacific
NANOTEC	National Nanotechnology Center
NARC	Nepal Agricultural Research Council (Nepal)

NARC	National Agricultural Research Council (Pakistan)
NARI	National Agricultural Research Institute
NARS	National Agricultural Research System
NAST	Nepal Academy of Science and Technology
NBC	Nuclear Breeding Centre
NBC	National Biosafety Commission
NBDS	National Biotechnology Development Strategy
NBF	National Biosafety Framework
NBIN	National Broodstock Improvement Network
NBP	National Biotechnology Policy
NBPS	National Biosafety Policy for Samoa
NBSAP	National Biodiversity Strategy and Action Plan
NBSC	National Biosafety Committee
NBW	National Biotechnology Week
NCA	National Competent Authority
NCB	National Committee on Biosafety
NCBP	National Committee on Biosafety of the Philippines
NCD	Non-Communicable Diseases
NCSTPC	National Certification System for Plant Tissue Culture Plants
NEC	National Environment Commission
NECTEC	National Electronics and Computer Technology Center
NFO	New Funding Opportunities
NGOs	Non-Government Organizations
NGS	Next-Generation Sequencing
NIB	National Institute of Biotechnology
NIBGE	National Institute for Biotechnology and Genetic Engineering
NIBM	National Institutes of Biotechnology Malaysia
NIFA	National Institute of Food and Agriculture
NIGAB	National Institute for Genomics and Advanced Biotech
NIGEB	National Institute of Genetic Engineering and Biotechnology
NIMBB	National Institute of Molecular Biology and Biotechnology
NPBTs	New Plant Breeding Techniques
NPPOs	National Plant Protection Organizations
NRC	National Research Council
NRCT	National Research Council of Thailand
NSC (Bhutan)	National Seed Centre
NSC (Taiwan)	National Science Council
NSF	National Science Foundation
NSP	Non-Structural Protein
NSSC	National Soil Science Centre
NSTC	National Science and Technology Commission
NSTDA	National Science and Technology Development Agency
NUST	National University of Sciences and Technology
OECD	Organization for Economic Cooperation and Development
OGTR	Office of the Gene Technology Regulator

OPEC	Organization of Petroleum Exporting Countries
OPU	Ovum Pick Up
PABIC	Pakistan Biotechnology Information Center
PABP	Pingtung Agricultural Biotechnology Park
PARC	Pakistan Agricultural Research Council
PBS	Program for Biosafety Systems
PCAARRD	Philippine Council for Agriculture, Aquatic and Natural Resources Research and Development
PCR	Polymerase Chain Reaction
PFOs	Potential Funding Opportunities
PGI	Pigeonpea Genomics Initiative
PGR	Plant Genetic Resources
PICTs	Pacific Island Countries and Territories
PNG	Papua New Guinea
PPP	Public Private Partnership
PSDP	Public Sector Development Program
QMS	Quality Management System
QTL	Quantitative Trait Loci
R&D	Research and Development
R4D	Research for Development
RAPD	Random Amplification of Polymorphic DNA
RCA	Research Collaboration Agreements
RCGM	Review Committee on Genetic Manipulation
RGOB	Royal Government of Bhutan
RIS	Research and Information System
RRC	Regional Research Centres
RRDI	Rice Research and Development Institute
RRI	Rubber Research Institute
S&T	Science and Technology
SAP	School Agriculture Program
SAP	Structural Adjustment Programme
SDC	Swiss Agency for Development and Cooperation
SDGs	Sustainable Development Goals
SDS	Strategy for the Development of Samoa
SE	South East
SEARCA-BIC	Southeast Asian Regional Center for Graduate Study and Research in Agriculture - Biotechnology Information Center
SLCARP	Sri Lanka Council for Agricultural Research Policy
SME	Small and Medium Enterprise
SMTA	Standard Material Transfer Agreement
SNP	Single Nucleotide Polymorphism
SOPs	Standard Operating Procedures
SPC	Secretariat of the Pacific Community
SPF	Specific Pathogen Free
SPS	Sanitary and Phytosanitary
SQCC	Seed Quality Control Centre

SRI	Sugarcane Research Institute
SSA	Sub-Saharan African
SSC	South-South Cooperation
SSL	Self Sufficiency Level
SSR	Simple Sequence Repeat
STEA	Science Technology and Environment Agency
STI	Science, Technology and Innovation Policy
SUCs	State Universities and Colleges
SW	South West
TAC	Technical Advisory Committee
TALEN	Transcription Activator-like Effector Nuclease
TARI	Taiwan Agricultural Research Institute
TCELS	Thailand Center of Excellence for Life Sciences
TIADC	Taiwan International Agricultural Development Company
TMC	Technology Management Center
TPM	Technology Park Malaysia
TRI	Tea Research Institute
TRL	Technology Readiness Level
TSP	Thailand Science Park
TTO	Technology Transfer Organizations
UNEP-GEF	United Nations Environment Programme-Global Environment Facility
UNESCO	United Nations Educational, Scientific and Cultural Organization
UoT	University of Technology
UP	University of the Philippines
USA	United States of America
USAID	United States Agency for International Development
UUC	Under-Utilized Crop
VAAS	Vietnam Academy of Agricultural Sciences
VAST	Vietnam Academy of Science and Technology
VNN	Viral Nervous Necrosis
VPD	Vapour Pressure Deficit
ZFN	Zinc Finger Nucleases

Strategic Papers

ACIAR: Partnerships and Investment in Agri-biotechnology in Asia-Pacific

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ABSTRACT: Australian Centre for International Agricultural Research (ACIAR) is the Australian Government's specialist agricultural research for development (R4D) agency, which was established in 1982 and now works in over 30 countries. The agency's research covers cropping, livestock, soils and water, fisheries, forestry and social science, economic and policy technical themes, linking Australian research capacity with partner country priorities and researchers. ACIAR's projects are designed to produce research outputs that can contribute to development outcomes such as improved food security, better nutrition, improved health, and increased prosperity. In 2016-17, ACIAR managed A$78 million worth of projects in addition to investments in multilateral research programmes of A$19.6 million and A$7.5 million targeting research capacity within partner countries (ACIAR, 2017). Core to ACIAR's approach to research for development is the building of partnerships. These partnerships are designed to generate new knowledge and innovations that underpin agricultural productivity, sustainability and food system resilience. Partnerships are established between Australian and partner country scientists and international researchers, government agencies, the private sector, Non-Government Organisations (NGOs) and importantly, communities in partner countries.

1. Introduction

Biotechnologies have significant potential to help transform agricultural production and food systems in developing countries. In applying agricultural biotechnologies in R4D investments, partnerships are essential. It is important that biotechnologies are employed to address problems that will ultimately contribute to realising positive impacts on rural populations and smallholders in developing countries. While the specialized skill sets and intellectual property (IP), typical of biotechnology research, may reside with a few research institutions or private businesses, when applied in a R4D context, the impact pathway to smallholders and communities must be considered. This requires linkages between scientists, government agencies (including extension providers and policy makers), private sector actors, NGOs and farming communities.

The ACIAR has considerable experience in implementing research projects with country partners, which have involved technologies such as molecular markers, molecular diagnostics, biotechnology derived vaccines, tissue culture and genetic modification, to address farming, forestry or fisheries issues. Some examples include the use of genetic markers to accelerate wheat breeding in India and Australia, improve mungbean in South and South-East Asia, and cocoa germplasm in Indonesia. Genetic markers and tissue culture tools have been applied to establish sustainable giant grouper aquaculture industries in Vietnam, Philippines and Australia.

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Alongside any biotechnology derived solution, ACIAR supports research of the production systems and value chain with a focus on smallholders. These research partnerships also consider science capacity and policy and institutional arrangements in partner countries, including monitoring or managing some biotechnology derived outputs. Also, the farming community and broader community needs to be informed, and their expectations in relation to agri-food biotechnologies respected.

2. ACIAR and Partnerships

ACIAR is effectively a partnership broker. Through commissioning international partnerships, productive and typically long-term research collaborations take place that are responsive to partner country priorities. Successful partnerships must be built on key principles including strong people to people linkages, trust, transparency and mutual benefit. ACIAR's model is to commission international research partnerships to effectively address high-priority needs in partner countries. It recognises that long-term benefits come from research collaboration, not just through the delivery of research results. Novel partnerships are developed in ACIAR projects that bring together people and agencies that have not typically worked together. These novel partnerships also involve the private sector as co-investors who bring benefits including:

- access to and understanding of market dynamics and opportunities
- innovation capability, such as machinery development and adaptation
- exposure of the private sector to research innovations
- scale-out capability of the private sector through its own supply and buying networks, and
- a better understanding of commercial constraints relating to an industry that may not be well understood by government agencies

Further, partnerships in R4D are particularly effective where they can be supported over longer time periods that are often needed to deliver impacts from research (Horne, 2016).

3. ACIAR and Agri-biotechnologies

The challenges of producing not only substantially more food for an expanding global population, but more nutritious food to address malnutrition will require new frontiers in research and new partnerships especially given the context of variable climate change impacts across agro-climatic regions. Transformational changes are needed in food production systems, agricultural value chains and to address post-harvest loss and wastage. Research will need to embrace a wide range of 'blue sky' and on-farm adaptation options and value chains. Biotechnology will continue to make a substantial contribution to addressing these challenges.

ACIAR recognises the appropriate use of biotechnologies (including genetic engineering) as valid tools in the quest for improved global food security and for reducing the environmental footprint of food production. In the case of plant industries for example, biotechnologies can potentially make a significant contribution to characteristics needed in crops produced in developing countries, such as increased crop yields and tolerance to stresses, improved processing and post-harvest quality and storage life, and improved nutritional quality. Engineered herbicide-resistance in crops can also reduce labour costs while introduction of insect tolerance can bring farmer health and environmental benefits through reduced insecticide requirements (ACIAR, 2014).

In response to the research opportunity provided by biotechnologies, ACIAR has established a biotechnology policy that covers various elements of when and how agri-biotechnologies, in particular genetic modification, will be used in its research projects (ACIAR, 2014). This policy addresses issues such as the specific request of particular ACIAR partner country for the research, formal consultations or agreed priorities of the partner country and agreements to collaborate, approval of relevant government policymakers, regulatory authorities and the research partners. Also, the policy covers various biosafety, regulatory and enforcement systems for the use of genetically modified organisms

(GMOs) in keeping with laws and regulations in Australia and the partner countries, as well as relevant international conventions.

Importantly ACIAR understands that biotechnology and the resulting technologies intended for adoption by farmers or application in agri-food value chains are not a 'silver bullet', but rather one of a set of approaches in the development of improved production systems.

4. ACIAR Supported Biotechnology Research and Partnerships

ACIAR collaborates with partners to ensure appropriate application of technologies to address agricultural problems or opportunities with the end goal of contributing to development impacts including benefits for smallholders and rural communities. With biotechnology expertise and associated IP typically residing in research institutions and private businesses, it is clear that to achieve development impacts, research projects and their impact pathways must incorporate strong partnerships between researchers, government and the private sector.

From ACIARs perspective, research projects are based on partnerships that are in part identified by the project's impact pathway. This impact pathway is customised for the farming system, and accounts for the social, political and environmental contexts. Alongside the biotechnology derived solution, projects consider inclusive value chains, so that farming inputs and subsequent markets for produce are equitable and accessible for smallholder farmers. For example, improved plant varieties arising from the application of biotechnologies still require effective seed distribution channels for smallholders, access to complementary inputs such as fertilizer to optimise yields, and knowledge and extension support.

Similarly, the partner country's science capacity, government policy and institutional arrangements should be sufficient to monitor and manage the implementation and adoption of some agri-biotechnologies by producers and industry. Further, informed community expectations and those of farmers in relation to agri-food biotechnologies need to be respected. Consequently, ACIAR projects incorporating biotechnology applications typically partner with government, NGO and private sector actors, community and extension practitioners including farming systems and agricultural value chains specialists, and policy makers. Alternatively, projects are designed to sit within a cluster of projects or a programme of research, that when taken as a whole, apply a systems approach to agricultural R4D.

The benefits of strong long-term partnerships that utilize biotechnologies for the benefit of farmers and communities is illustrated in the Australian cotton industry and the application of GMOs. Adoption of the research outcomes has led to significantly improved agricultural productivity and sustainability for the Australian cotton industry. Core to Australia's GM cotton crop's development and adoption, has been the long-term productive partnerships between private industry (farmers and agri-businesses), research institutes (delivering research and education), and the government (providing policies, monitoring and evaluation, and regulatory frameworks to mitigate potential risks). The partnerships between scientists, industry and government have been characterized by strong people to people linkages developed over decades, trust, transparency and established mutual benefit for each of the partners. Partners include public research institutes such as the Commonwealth Science and Industry Research Organisation (CSIRO) and the Cotton R&D Corporation, an industry company Cotton Seed Distributors (CSD, made up of farmer and industry members), who provides cotton seed to the Australian industry, government and industry extension agencies, and private companies such as Bayer and Monsanto. A number of these partnerships have evolved since the late 1960s and resulted in CSD commercialising many higher yielding strains developed by the joint research programme.

This platform of technology and know-how was established and continually invested in over the longer term to deliver value to industry customers, farmers, Australian small and medium enterprises and multinationals. These relationships have required careful balancing and investment over time as needs change, and the consistent relationships, personnel, continuity and equity of investment and management structures have been fundamental. At the same time the Australian Government's oversight by the Office of Gene Technology Regulator (OGTR), Food Standards Australia New Zealand (FSANZ) and the Australian Pesticides and Veterinary Medicines Authority (APVMA) has been critical (CSIRO, 2015).

The results are 30 years of cotton breeding and 100 varieties underpinning a more profitable and environmentally friendly A$2.5 billion industry. Over 99 per cent of Australian cotton planted today incorporates transgenic traits with insecticidal (*Bt*) and herbicide tolerant traits (Cotton Australia, 2016). Cotton is now Australia's third largest agricultural export and has the most productive cotton yields in the world which has reduced pesticide use by up to 92 per cent and herbicide use by about 52 per cent (Cotton Australia, 2017).

This Australian example of a partnership utilizing agri-biotechnology highlights the need for robust and valued linkages between research partners which can lead to sustained innovation. In this regard it is similar to the well-recognised Netherlands agri-food industry partnership approach, termed the "golden triangle", acknowledged for its relationships between private industry (farmers and businesses), the government (responsible for policies, monitoring and evaluation, and support where market failure is identified, such as environmental sustainability) and knowledge institutes (delivering research and education) that stimulate innovation. This cooperation between the government, education, and the business sector is seen as the engine behind the success of Dutch agriculture (OECD, 2015).

5. Examples of ACIAR Projects Utilizing Agri-Biotechnologies

ACIAR has invested in many research projects with our partner countries, which have been involved in the development and application of technologies such as molecular markers, molecular diagnostics, biotechnology-derived vaccines, tissue culture and genetic modification, to address farming, forestry or fisheries issues. Several examples of such ACIAR follow and include brief descriptions of key partnerships between researchers, private sector actors and extensions agencies formally and while most of these projects are also supported with partnerships involving local farm communities. The descriptions of the application of the biotechnology within the broader R4D context are also highlighted.

5.1 International Mungbean Improvement Network

Mungbean is an important food and cash crop in the rice-based farming systems of South and South-East Asia. It is well suited to smallholder production having a short crop duration, low input requirements and high global demand, thus providing additional income, additional nutrient-rich food, and increased soil fertility. As the crop has a narrow genetic base from limited improvement programmes, the species is especially susceptible to emerging pests, diseases and seasonal variability, in South and South-East Asian countries, as well as in Australia. The network initiated and supported by the ACIAR project is undertaking variety improvement and training for researchers and extension services in partner countries. The network is designed to provide ownership of the research by national scientists and capture synergies between the research institutions in the participating countries. Biotechnologies are being utilized in the project including genome sequencing and the development of genetic markers. In addition, genotyping for the identification of *Mungbean yellow mosaic virus* is being undertaken amongst the scientists (World Vegetable Centre, 2016). Importantly, this project is being conducted in concert with an ACIAR project aimed at improving mungbean harvesting and seed production systems for Bangladesh, Myanmar and Pakistan and the World Vegetable Center partnering with government extension departments, NGOs and private seed production and machinery companies across the partner countries. A better understanding of the seed supply chain and access at a reasonable price by smallholder farmers is an important outcome.

5.1.1 Research partners: Department of Agricultural Research, Burma; Bangladesh Agricultural Research Institute, Bangladesh; Indian Institute of Pulses Research, India; Queensland Department of Agriculture and Fisheries, Australia.

5.2 Cocoa germplasm, Indonesia

Evaluation of molecular marker technology for the identification of elite cocoa germplasm in Indonesia and the South Pacific was applied in ACIAR linked research. The improved cocoa lines, supported through the application of advanced genetic markers, including those identified by the food company Mars Incorporated, in their cocoa breeding programmes and shared with the project partners has taken place within a series of linked farming system research projects. To complement the improved clones, better soil fertilization practices, dissemination of cocoa cloning and improved farm management techniques including integrated pest and disease management programmes, have been developed and disseminated to extension staff and smallholder farmers in Indonesia.

5.2.1 Research partners: University of Sydney, Australia; Mars Asia Pacific, Australia; University of Hassanudin, Indonesia; Biotechnology Research Institute for Estate Crops, Indonesia; Assessment Institute for Agricultural Technology, South Sulawesi, Indonesia; Indonesian Coffee and Cocoa Research Institute, Indonesia; University of Papua, Indonesia; Provincial Agricultural Services (Estates), Indonesia; Assessment Institute for Agricultural Technology, Papua, Indonesia; PT Mars Symbioscience Indonesia, Indonesia

5.3 Molecular marker technologies for faster wheat breeding in India

Development of new genetic materials, selected using molecular markers, are valuable to both countries to undertake marker assisted selection. New genomic selection techniques use historical yield trial data and high density genotyping (35,000 Single Nucleotide Polymorphism assay - 35K SNP) outsourced to a local Indian company, Imperial Life Sciences in Haryana.

5.3.1 Research partners: From India- Indian Institute for Wheat and Barley Research, Karnal; Punjab Agricultural University, Ludhiana; Bihar Agricultural University, Sabour; Birsa Agricultural University, Ranchi. From Australia - The Plant Breeding Institute, University of Sydney; Global Crop Innovations Pvt Ltd; Department of Agriculture and Food, Western Australia University of Adelaide.

5.4 Genetic markers, tissue culture in fisheries in Vietnam, Philippines and Australia

Groupers form the basis of the live reef food-fish trade in the South-East Asian region. Due to considerable pressure on wild populations, it is already difficult to source wild-caught giant grouper (*Epinephelus lanceolatus*)in some countries. The giant grouper is a high-value, fast-growing grouper species with significant aquaculture potential. A research project with Vietnamese, Philippines and Australian partners aims to build the foundation skills and knowledge for establishing sustainable hatchery production of giant grouper, closing the life cycle of the giant grouper in captivity and managing the broodstock and larval rearing in a sustainable and profitable manner. The project includes the application of biotechnology to control reproduction in the species including giant grouper surrogacy. Seed production by smaller surrogate broodstock will enable many more fish farmers to hold and manage the smaller broodstock while still producing seed from giant or hybrid groupers.

The research has produced a recombinant giant grouper follicle stimulating hormone and a recombinant luteinizing hormone, to enable full control over giant grouper breeding in captivity as well as in other grouper species. The project is also using large male giant grouper broodstock sperm for hybridisation with other grouper species. Such hybrids are in high demand in Vietnam as they are fast growing and anecdotal evidence suggests that they are more disease-resistant. Additionally, the project is sequencing the genome of various strains of Viral Nervous Necrosis (VNN), a significant disease in grouper aquaculture and identifying genetic markers for resistance to the VNN virus.

5.4.1 Partners: Research Institute for Aquaculture No. 1, Vietnam, Southeast Asian Fisheries Development Centre, Aquaculture Centre, Philippines; Research Institute for Aquaculture No. 3, Vietnam; University of the Sunshine Coast, Australia; Department of Agriculture, Fisheries and Forestry, Northern Fisheries Centre, Australia; FinFish Enterprise Pvt Ltd, Australia.

6. Conclusions

For ACIAR and our country partners, biotechnologies where appropriate, provide substantial benefits for agriculture, forestry and fisheries in developing countries. In applying these agri-biotechnologies in R4D investments, partnerships are essential, given that biotechnology capacity and IP often reside in specialized research institutes or private companies. Therefore, for ACIAR, the research project applying biotechnologies must be considered in the broader development context to understand the impact pathway to smallholders and community benefits. ACIAR experience has also highlighted that research partnerships must be based upon strong people to people linkages, trust and transparency and acknowledge the mutual benefit for partner involvement, for them to be sustainable and productive.

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Current Status and Long-Term Investments in Agricultural Biotechnology for Sustainable Development in Asia-Pacific

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ABSTRACT: The global area of biotech crops in 2016 increased from 179.7 to 185.1 million ha, a 3 per cent increase equivalent to 5.4 million ha. Some 26 countries planted biotech crops, 19 of which were developing countries and seven were industrial. Sixteen countries (eight cultivated and eight imported) adopted biotech crops in the Asia-Pacific region (APR), which provided benefits for some 16 million smallholder farmers and their families in the region. The region planted the primary raw materials for food, feed, and fiber with biotech canola, eggplant, maize and cotton, respectively. The enabling biosafety regulations of biotech-commercializing countries in the region, namely, India, Pakistan, China, Australia, Philippines, Myanmar, Vietnam and Bangladesh allowed science-based assessment of new biotech crops and traits efficiently and with transparency. The increasing population in the region would need an enhancement of productivity to lessen imports for food and feed purposes, especially biotech soybeans, alfalfa, sugar beets, potato and apple. There are investments to develop home grown biotech crops and traits to sustain the benefits contributed by biotech crops on productivity, food and environmental safety and socio-economic improvements in the region.

1. Introduction

The rapid adoption of biotech crops over the last 21 years of commercialization (1996 to 2016) reflects the substantial multiple benefits realized by both large and small farmers in industrial and developing countries that have commercially grown biotech crops. During this period, biotech crops have been planted to an accumulated area of 2.1 billion ha, which contribute significantly to more than 7.6 billion people globally. In 2016, a 3 per cent increase, equivalent to 5.4 million ha was achieved to reach a global biotech crop area of 185.1 million ha, planted by 18 million farmers in 26 countries (Table 1) (ISAAA Brief 52, 2016).

It is estimated that the world would require some 50 to 70 per cent increase in food production in the midst of dwindling resources of land and water, along with environmental and agricultural challenges brought by climate change (FAO, 2009).The benefits gained in the last 21 years through biotech crops prove that conventional crop technology alone is not sufficient to feed the immense population that will increase to 9.8 billion in 2050 and 11.2 billion in 210 (United Nations, 2017). But neither is biotechnology a panacea. The global scientific community adheres to the option of a balanced, safe and sustainable approach using

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the best of conventional crop technology, such as well-adapted and agronomically desirable and high-yielding germplasm, and the best of biotechnology (GM and non-GM traits) to achieve sustainable intensification of crop productivity on the 1.5 billion ha of cropland.

This paper provides information on the global and regional adoption of biotech crops, its contribution to food security and sustainability, socio-economic and environmental impact, and in the alleviation of poverty and hunger, based on ISAAA Brief 52 for 2016. Country data and situations were obtained from large number of sources from both the public and private sectors, in many countries throughout the world. Databases vary by country and include where available, government statistics, independent surveys, and estimates from commodity groups, seed associations and a range of proprietary databases. A discussion on investments for agricultural biotechnology research and development of some countries in the APR provides information on how countries intend to harness the potentials of the technology for domestic and international market.

Table 1. Global area of biotech crops in 2015 and 2016, by country (million ha*)

Country**	2015	%	2016	%	+/-	%
USA	70.9	39	72.9	39	2.0	3
Brazil	44.2	25	49.1	27	4.9	11
Argentina	24.5	14	23.8	13	-0.7	-3
Canada	11.0	6	11.6	6	0.6	5
India	11.6	6	10.8	6	-0.8	-7
Paraguay	3.6	2	3.6	2	0	0
Pakistan	2.9	2	2.9	2	0	0
China	3.7	2	2.8	2	-0.9	-24
South Africa	2.3	1	2.7	1	0.4	17
Uruguay	1.4	1	1.3	1	-0.1	-7
Bolivia	1.1	1	1.2	1	0.1	9
Australia	0.7	<1	0.9	<1	0.2	29
Philippines	0.7	<1	0.8	<1	0.1	14
Myanmar	0.3	<1	0.3	<1	0	0
Spain	0.1	<1	0.1	<1	0.1	0
Sudan	0.1	<1	0.1	<1	0.1	0
Mexico	0.1	<1	0.1	<1	0.1	0
Colombia	0.1	<1	0.1	<1	<0.1	<0.1
Vietnam	<0.1	<1	<0.1	<1	<0.1	<0.1
Honduras	<0.1	<1	<0.1	<1	<0.1	<0.1
Chile	<0.1	<1	<0.1	<1	<0.1	<0.1
Portugal	<0.1	<1	<0.1	<1	<0.1	<0.1
Bangladesh	<0.1	<1	<0.1	<1	<0.1	<0.1
Costa Rica	<0.1	<1	<0.1	<1	<0.1	<0.1
Slovakia	<0.1	<1	<0.1		<0.1	<0.1
Czech Republic	<0.1	<1	<0.1	<1	<0.1	<0.1
Burkina Faso	0.5	<1	--	--	--	--
Romania	<0.1	<1	--	--	--	--
Total	**179.7**	**100**				

**Rounded-off to the nearest hundred thousand or more*
***Biotech mega-countries growing 50,000 ha or more [Source: ISAAA Brief 52 (2016)]*

2. Global Biotech Crop Adoption in 2016

In 2016, there were 26 countries that grew biotech crops, of which 19 were developing and 7 were industrial (Table 1). Eight of the top 10 countries, each growing 1.0 million ha or more of biotech crops, are developing countries, namely, Brazil, Argentina, India, Paraguay, Pakistan, China, South Africa and Uruguay. Only two countries are industrial, *i.e.* USA and Canada. Burkina Faso did not plant biotech crops in 2016 due to farmers' preference for a much better cotton germplasm that harbour the insect resistant trait. Romanian farmers opted not to plant due to the onerous reporting requirements of biotech crops area.

Eighteen biotech "mega countries" grew 50,000 ha, or more of biotech crops. Notably, 14 of the 18 mega-countries are developing countries from Latin America, Asia and Africa. The high proportion of biotech mega countries in 2016, 18 out of 26 (69%), reflects the significant broadening, deepening and stabilizing in biotech crop adoption that has occurred within the group of more progressive mega-countries adopting more than 50,000 ha of biotech crops on all six continents. Of the 26 countries that planted biotech crops, 12 (46%) were in the Americas, 8 (31%) in Asia, 4 (15%) in Europe, and 2 (8%) in Africa. On a hectare basis, of the 26 countries that planted biotech crops in 2016, 88 per cent were in the Americas, 10 per cent in Asia, 2 per cent in Africa, and <1 per cent in Europe.

Developing countries planted more biotech crops compared to industrial countries since 2012 (five years). Prior to 2011, industrial countries planted more than the developing countries, but by 2011, the global area of biotech crops was evenly distributed between industrial and developing countries. Starting 2012, developing countries consistently increased in area, and by 2016, a difference of 14.1 million ha between developing and industrial countries was achieved. Developing countries grew 54 per cent of the global biotech area compared to 46 per cent for industrial countries. Moreover, industrial countries increased by 3.5 per cent in 2016, compared to 2015, while developing countries increased by 2.6 per cent.

The 3.5 per cent increase in industrial countries between 2015 and 2016 is mainly due to increases in the USA at 2 per cent, Canada at 0.6 per cent and Australia at 0.2 per cent. Increases in developing countries, led by Brazil at 4.9 per cent and South Africa at 0.4 per cent contributed mainly to the 2.5 per cent difference in 2015 and 2016. The trend for a higher share of global biotech crops in developing countries is likely to continue in the near, mid, and long-term, firstly, due to more countries from the southern hemisphere adopting biotech crops and traits, and secondly, expansion of area planted to biotech crops.

The country having the largest year-over-year growth, in 2016, was Brazil with 4.9 million ha, followed by the USA with 2 million ha, Canada with 0.6 million ha, South Africa with 0.4 million ha and Australia with 0.2 million ha. Other countries with increased planting include Bolivia, Philippines, Spain, Vietnam, Costa Rica and Bangladesh. Those with minimal increases in biotech area include Colombia, Honduras, Chile, Sudan, Slovakia and Costa Rica.

A few countries had decreased biotech crop plantings. The decreases were due to global low cotton prices such as in India, Argentina, Uruguay and Mexico, and high cotton reserve stocks particularly in China; low profitability in soybean and competition with maize in Paraguay and Uruguay; environmental stress (drought/submergence) in soybean planting in South Africa and Argentina, marginal decreases in the area of crop production for maize in Portugal, negative biotech perceptions in China and onerous reporting for biotech maize planting in the Czech Republic.

3. Contribution of Biotech Crops to Food Security, Sustainability and Climate Change

Biotech crops contributed to food security and sustainability by yielding as much as 574 million tons of food, feed and fiber from major species (soybean, maize, cotton and canola) valued at US$167.8 billion in 1996-2015; and correspondingly, 75 million tons in 2015 valued at US$15.4 billion (Brookes and Barfoot, 2017). This productivity is the result of substantial yield gains per hectare and reduced production cost from minimal farm inputs. The high productivity from biotech crops helped in conserving biodiversity and saved land by as much as 174 million ha in 1996 to 2015 and 19.4 million ha in 2015 alone (Brookes and Barfoot, 2017). Thus, biotech crops can preclude deforestation and protect biodiversity in forests and in other *in situ* biodiversity sanctuaries.

Conventional agriculture has impacted significantly on the environment, and biotechnology can be used to reduce the environmental footprint of agriculture. In 1996-2015, biotech crops contributed in saving 620 million kg pesticide active ingredient and by as much as 37.4 million kg in 2015. Moreover, pesticide application was reduced by 8.1 per cent in 1996-2015, and 67.1 per cent in 2015 alone. When expressed as Environmental Impact Quotient (EIQ), the composite measure based on various factors contributing to the net environmental impact of an individual active ingredient - there was a corresponding reduction of 19 per cent in 1996-2015 and by 18.4 per cent in 2015 alone (Brookes and Barfoot, 2017).

Biotech crops help mitigate climate change and decrease greenhouse gases through permanent savings in CO_2 from the reduction of fossil-based fuels associated with fewer insecticide and herbicide sprays and from conservation tillage (need for less or no ploughing, facilitated by herbicide tolerant biotech crops). In 2015 alone, CO_2 emission was reduced by 26.7 billion kg, equivalent to taking 11.9 million cars off the road for one year (Brookes and Barfoot, 2017).

Through the contribution of biotech crops to food security, sustainability and mitigation of climate change, some 65 million farmers and their families globally, are being benefited. Fifty percent of the world's poorest people are small and resource-poor farmers, and another 20 per cent are the rural landless completely dependent on agriculture for their livelihoods. Cumulatively, from 1996 to 2015, the global economic benefits from biotech crops were US$167,610 million and for 2015 alone was US$15,391 million. In the APR, a total of 26 per cent or US$43.7 billion economic benefits were enjoyed by farmers from the start of the cultivation till 2015, and US$3.8 billion for 2015 alone (Table 2, Brookes and Barfoot, 2017). Increasing the income of more than 16 million small and resource-poor farmers in up to 30 countries, could improve economic, health and social benefits through biotech crops and directly contribute to poverty alleviation of a large majority (70%) of the world's poorest people.

Table 2. Economic benefits from biotech crops in the APR during 2016

Country	Economic benefits (US$ million)	
	Accumulated	For 2015
India (2002-2015)	19,559	1,330
China (1997-2015)	18,654	1,005
Pakistan (2010-2015)	4,312	398
Australia (1996-2015)	1,023	73
Philippines (2003-2015)	82	642
Myanmar (2016-2015)	47	308
Total for APR	**43,677 (26%*)**	**3,756 (24%*)**
Global Total	**167,610**	**15,391**

**Percentage of global biotech economic benefits (Source: Brookes and Barfoot, 2017).*

4. Biotech Crop Adoption in the APR during 2016

A total of 16 countries adopted biotech crops in the APR in 2016; eight cultivated and eight imported biotech crops. The eight countries that planted biotech crops include India, Pakistan, and China which planted more than 1 million ha of biotech cotton and belong to the top ten countries, followed by Australia (biotech cotton and canola), Philippines (biotech maize), Myanmar (biotech cotton), Vietnam (biotech maize) and Bangladesh (biotech eggplant) in decreasing area of biotech crops (Table 1). Adoption of these biotech crops varied; India and China's biotech cotton fields were extremely affected by low global cotton price, while Pakistan and Myanmar maintained their biotech cotton area. Biotech maize area in the Philippines and Vietnam increased due to increasing needs for livestock and poultry feeds, as well as the favorable weather conditions to grow maize. Similarly, the favorable weather conditions in Australia encouraged farmers to grow more biotech cotton and canola after two years of drought spells. Moreover, farmers were provided BollgardIII/RR®Flexcotton variety for extreme insect pest protection with herbicide tolerance. Bangladesh increased its *Bt* eggplant planting to 700 ha and more brinjal varieties with *Bt* gene were under field testing for future commercialization.

The additional eight countries that import biotech crops for food, feed and processing include, Indonesia, Japan, New Zealand, Malaysia, Singapore, South Korea, Taiwan, and Thailand. Thus, a total of 16 countries adopted biotech crops for food, feed, processing and cultivation in the APR.

5. Investments in Agricultural Biotechnology

With the enormous benefits that biotech crops contribute to small farmers and their families, countries planting biotech crops in the APR are continuously providing an enabling environment to harness its potentials.

5.1 India

In the last several years, India has become the top cotton producing country in the world with cotton production surpassing 35 million bales despite the slowed down global cotton market. Moreover, in the last 15 years (2002-2016), cotton seed has become an important source of oilseeds in India. The production of *Bt* cotton-based oil increased by three-fold from 0.46 million tons in 2002-2003 to 1.5 million tons in 2016-17, contributing 15 per cent of the total 8 million tons of edible oil from all domestic sources. Thus, the adoption rate of *Bt* cotton in India at 96 per cent in 2016 elevated the country's economy and improved the socio-economic status of some 7.2 million small farmers and their families. To sustain the economic boost from biotech crops, the biosafety regulations in the country have been streamlined with revised guidelines on the monitoring of confined field trials of biotech crops. Moreover, the Indian Government through its Ministry of Environment, Forests and Climate Change (MoEF&CC) prepared a series of crop-specific biology documents as reference for developers, evaluators and regulators of biotech crops under regulatory review, as well as those new biotech crops and traits under development in the country. These included Indian mustard, pigeonpea, papaya, chickpea, rubber, tomato, potato and sorghum. In addition, the Genetic Engineering Appraisal Committee (GEAC), in its 2016 meeting, approved a large number of events in different crops including stacked insect resistant (IR)/herbicide tolerant (HT) cotton; IR, HT and stacked IR/HT maize; IR pigeonpea; IR chickpea; IR, drought, and salinity tolerant rice; drought tolerant sugarcane. The GEAC issued permits for the conduct of event selection trials and biosafety research trials in 2016. Biotech mustard, which is a home-grown biotech crop is awaiting final approval as it is expected to revive mustard production and enhance yield which has remained stagnant for the past 20 years (The Hindu Business Line, 2016). The country continues to invest in biotech R&D with it's strong science-based regulation, farmer support and available biotech experts.

5.2 Pakistan

An area of 2.9 million ha of IR (*Bt*) cotton, equivalent to 97 per cent of the total 3 million ha of total cotton area was planted. This high adoption rate indicates farmer satisfaction with *Bt* technology that may be replicated with the adoption of biotech maize in the country. In the past few years, biosafety regulations have been streamlined in the country to cater to the increasing needs of farmers and food producers to adopt and import biotech crops. Thus, in 2016, a total of 34 cotton varieties was approved by the Federal National Biosafety Committee (FNBC) providing more options for farmers in planting insect resistant biotech cotton. The official approval of old and new IR (*Bt*) cotton varieties by the FNBC ensured supply of genuine and good quality IR cotton seeds that meet minimum specifications including resistance to *Cotton leaf curl virus* (CLCV), well-adapted to the different ecologies, posses required fibre quality standards, and other desirable features. In 2016, the National Biosafety Committee officially approved the commercial cultivation of single and stacked IR/HT maize events, subject to varietal registration by the Federal Seed Certification and Registration Committee, Ministry of National Food Security and Research. Various biotech crops and traits are in different stages of development including several IR, HT and stacked IR/HT cotton; rust resistance, drought and salt tolerance, and iron and zinc biofortified wheat; IR and bacterial blight resistant rice; IR/IR maize; IR and drought tolerant sugarcane;

IR chickpea, IR and salt tolerant tobacco; disease resistant potato: and HT and disease resistant potato (USDA FAS GAIN - Pakistan, 2017).

5.3 China

China has been one of the leaders in planting IR (*Bt*) cotton since 1997, and in 2016, IR cotton was planted on 2.8 million ha at 96 per cent adoption rate, virus resistant papaya on 8,500 ha and some 543 ha IR (*Bt*) poplar trees. Similar to India, biotech IR cotton has propelled the country into cotton self-sufficiency, and the bountiful harvest obtained since 2015 has made China the no. 3 cotton producing country in the world, after India and the USA. The prospects for further expansion of biotech cotton area in the country depend on the stabilization of the cotton commodity prices. The government led by President Xi Jing is committed to make the country a strong biotech country, granting US$3 billion to support biotech research and capacity building. Since 2015, President Xi Jing has been actively supporting "strong research and innovation" on biotech crops such as drought resistant wheat, disease resistant rice, drought resistant maize, and peanuts and soybeans to produce more and healthier oil. This government's support of biotechnology is also reflected in the acquisition of Switzerland's Syngenta by the government-owned corporation ChemChina to strengthen the country's portfolio of biotech crops (Business Insider, 2016). China has been increasingly dependent on imports of biotech soybean and maize for livestock and poultry feeds. In 2016-17, some 85 million tons of soybean and 3.17 million tons of maize were imported from the USA, 90 per cent of which was biotech. Phytase maize and IR (*Bt*) rice have been in the pipeline awaiting government approval for planting in the last five years. Adoption of these biotech crops in the very near future will benefit livestock and poultry farmers and consequentially improve the country's economy.

5.4 Australia

Australia ranks 11th among the countries planting biotech crops in 2016, with 852,000 ha biotech cotton (405,000) and canola (447,000) grown in 2016. Since 1996, when Australia started growing biotech crops, biosafety regulation and approvals for biotech research, field trials and commercialization by dedicated agencies, have shown a remarkable efficiency, such as the OGTR and the Food Standards Australia and New Zealand. Various researches on the development of other biotech crops such as bananas, barley, canola, cotton, grapevines, Indian mustard, maize, papaya, perennial ryegrass, pineapple, safflower, sugarcane, tall fescue, torenia, wheat and white clover are being conducted, with field trials under the supervision of OGTR. These crops possess different insect and disease resistance traits, tolerance to abiotic stress and with enhanced nutritional quality. Moreover, farmers who have been planting cotton and canola were benefited with the lifting of the biotech crop planting moratorium in Western Australia in 2015. Hence, farmers who were planting some 1.5 million conventional canola have shifted to biotech in subsequent years (Western Australia, 2015). This opened door for the development and adoption of other biotech crops and traits.

5.5 Philippines

The country had 812,000 ha of biotech maize planted in 2016, comprising 133,000 ha of herbicide tolerant maize and 679,000 ha of IR/HT maize. The IR (*Bt*) maize has not been planted since 2013. The adoption rate of biotech maize increased from 63 per cent in 2015 to 65 per cent in 2016. Biotech maize has been planted since 2003 and the country is gearing up for the possible commercialization of products of public-private sector collaborations such as golden rice, *Bt* eggplant, virus resistant papaya and *Bt* cotton (Aldemita *et al*., 2015). Acceptance of biotech crops in the country has been demonstrated by farmers, consumers, academia, and the general public such that a Joint Departmental Circular (JDC) was quickly put together in record time of three months. Guidelines for approval and renewal of permits by each government department are still not completed, which may affect entry of new biotech maize traits for commercialization. Future commercialization of *Bt* eggplant, golden rice, PRSV-papaya and *Bt* cotton will be regulated under the new JDC. The government is putting lot of efforts to capacitate the regulatory offices involved in the new JDC. The country imports various other biotech crops for food, feed and processing including alfalfa, canola, cotton, potato, rice, soybean and sugarbeet, which are mostly biotech. Thus, investing on cultivation of these biotech crops could lessen the millions of dollars spent on crop imports.

5.6 Myanmar

Mynamar grew two insect resistant *Bt* cotton varieties on approximately 325,000 ha, equivalent to an adoption rate of 93 per cent of the 350,000 ha of cotton grown in 2016. The two cotton varieties *Ngwe chi-6* and *Ngwe chi-9* were locally-developed and planted since 2006 by increasing the number of smallholder farmers. Efforts were made by the Department of Agriculture (DOA) to promote public-private partnership in seed multiplication of open-pollinated varieties and hybrids of rice, maize, cotton and vegetable crops. In particular, the emphasis has been on enhancing collaboration with private seed companies to increase the availability of quality seeds. In 2015, DuPont Pioneer has opened an office in Myanmar to use new technologies to modify seeds and set up a marketing network to provide high value and high yielding hybrid seeds of maize and rice to farmers in Myanmar (Myanmar Times, 2015). The private sector engagement in breeding of improved crop varieties such as rice, maize, sugarcane, cotton and vegetables will attract investments not only in establishing processing plants and distribution value chain but also in setting up of R&D and breeding station in different parts of the country. Myanmar has the potential to become the hybrid seed production center in the near future not only to cater to Asian Economic Community, but also to neighbouring countries of the South Asian Association for Regional Cooperation (SAARC).

5.7 Vietnam

Vietnam started biotech maize commercialization in 2015 at a minimal area of 3,500 ha. In 2016, farmers adopted the technology quickly with a 10-fold increase to 35,000 ha of stacked IR/HT varieties. Biotech maize was reported to increase productivity by as much as 25 per cent compared to non-GM crops (VN Express, 2016) that could provide incentive for biotech maize farmers and future adopters. In addition, the need for an immediate source of livestock feeds, and the government's shift towards conversion of rice areas to maize, paved the way for the commercialization of maize. Various field trials of biotech maize are being conducted in prime maize areas of the country. Moreover, with the enabling policies of the government, other biotech crops and traits may gain approval for planting in the country, including biotech cotton and soybean. The country has been dependent on imported biotech feed ingredients as domestic supplies are unable to fuel the growing livestock and poultry sectors. For example, Vietnam's 2016 imports of maize increased to 2.9 MMT from 2.59 MMT in 2015 (USDA FAS GAIN- Vietnam, 2016). Thus, the cultivation of biotech soybean, alfalfa, cotton, and canola for human and animal consumption is therefore an excellent option to lessen the country's imports.

5.8 Bangladesh

Introduced *Bt* brinjal as the country's first GM crop, to protect brinjal from the deadly fruit and shoot borer. Commercial planting of *Bt* brinjal/eggplant increased from 25 ha in 2015 to 675-700 ha in 2016, planted by 2,500 farmers. The insect pest causes losses up to 70 per cent in commercial plantings. The large scale planting of IR (*Bt*) brinjal has resulted in a substantial reduction in insecticide applications and lowered the cost of producing a more bountiful harvest of blemish-free brinjal fruits. Experiments to-date showed that *Bt* brinjal increases yield by at least 30 per cent and reduces the number of insecticide applications by 70-90 per cent, resulting in a net economic benefit of US$1,868 per ha over non-*Bt* brinjal (James, 2014). Biotech late blight resistant potato, golden rice and IR cotton are in the various stages of field testing for future introduction in the country to address economic and nutrient-deficiency problem. The government is implementing the recently approved Seventh Five Year Plan (2016-2020) to set the roadmap for policy makers and researchers to develop biotic and abiotic stress tolerant crops in order to mitigate negative effects of climate change on agriculture and food production. In this direction, the Bangladesh Agricultural Research Institute (BARI) has devised a robust research plan and activities to expand the area under approved *Bt* brinjal varieties and develop new varieties of GM potato, cotton, rice and tomato.

6. Regulation of Biotech Crops

Onerous regulation for transgenic biotech crops remains the principal constraint to adoption, which is particularly important for many developing countries, denied the opportunity of using them to address food, feed and fiber security. The encouraging outlook is that technology in conjunction with conducive policies, can double food production. However, the doubling of food production cannot be realized by society unless it ensures that regulation of biotech crops is science-evidence-based, fit-for purpose, and to the extent possible harmonized globally, as exemplified by the eight countries described above. Regulatory hurdles on biotech crop commercialization are still being felt by other countries of Indonesia, Cambodia, Laos, and other smaller Asian countries. Failure by global society to ensure timely and appropriate regulation on food production will have dire consequences. On one hand, the world will suffer because of inadequate food supplies, while on the other hand, the power of science and technology to produce a safe, adequate and assured supply of food for all of mankind will be rejected because of the dominant ideological voices of the opponents of the new biotech technologies.

7. Conclusions

The global commercialization of biotech crops in 2016 was marked by a renewed increase in the global area of 5.4 million ha from 179.7 million ha in 2015 to 185.1 million ha in 2016. This increased area is a manifestation of trust by farmers, consumers and the government in the technology that has delivered benefits and contributed to food accessibility, sustainability, food and environmental safety and uplifted the socio-economic conditions of the poor and the hungry. Acceptance of biotech crops in the APR was exceptionally high especially in the biotech cotton countries of India, Pakistan, and China, with Myanmar slowly increasing its area with the establishment of the country's biosafety guidelines. The Philippines has been successfully growing biotech maize, followed by Vietnam. Biotech cotton and canola in Australia have gained farmer and government support since 1996. Continued investments in the use of the technology have been mounting in order to develop new biotech crops and traits that would cater to the increasing domestic and international food demand. Biotech soybean, alfalfa, sugarbeet, potato and apple that are commercialized in other regions may find new markets for cultivation in the APR, which have been importing such biotech products in large amounts. Lastly, a science-based and efficient biosafety regulation should accompany the development of these technologies for the benefit of the global community who rely on affordable and nutritious food for survival. This will assure that future generations can benefit more from wide choices of biotech crops with improved traits for high yield and nutrition that are ideally safe for consumption and the environment.

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Agricultural Biotechnology for the South-South Cooperation

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ABSTRACT: The South-South Cooperation (SSC) with its unique set of principles and modalities provides an effective platform to encourage cooperation among the Southern countries in the field of agricultural biotechnology. There are many avenues in which there is a need for strengthening of partnerships and joint efforts in the domain of agriculture; it can be in promoting Research and Development (R&D) in new and emerging technologies or in framing a suitable regulatory architecture. This short paper intends to reflect on these issues, and it describes how SSC can be leveraged to excel in the domain of agricultural biotechnology.

1. Introduction

Continued high growth in some developing countries and persistent patterns of low growth in the industrialized North pose a challenge in coining conventional terminology used for classifying countries against economic growth criteria. For example, the term 'South', emerged after the Second World War, represents the countries in which levels of economic development were far lower than the countries in the North. At this time also, 'West' and 'East' signified, respectively, capitalist countries, and socialist and communist bloc. And the most countries, which belonged to neither East nor West, ended up in a group, called the South.

2. Evolution of South-South Cooperation

A central issue was definition of a theoretical basis for the SSC. There were a few attempts at this; but it was clear, nevertheless, that the emergence of the Organization of Petroleum Exporting Countries (OPEC) Fund, a multilateral development finance institution fund, established by the OPEC, could shatter many ideological positions in the theoretical debates on the development. According to Bhagwati (1986), the Fund signified that (i) foreign-aid from the North was not automatically the best instrument for redistribution of income; (ii) efficient aid delivery need not mean falling into the trap of 'conditionalities' and (iii) the route to success was through the control of primary natural resources.

These imperatives in the OPEC model posed a major challenge to the ideological hegemony that dominated developmental thinking in 1990s; and it was best exemplified in the Washington Consensus.

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3. South-South Cooperation - Principles and Modalities

There are certain values or features around which the SSC has emerged over years. As argued by Chaturvedi (2014), the essential principles and modalities of the SSC are given in Table 1.

Table 1. Essential principles and modalities of SSC

Essential Principles	Modalities
• Respect for national sovereignty	• Capacity-building
• National ownership	• In-house training
• Independence	• Technology transfer
• Equality	• Financial assistance (Grant)
• Non-conditionality	• Lines of credit
• Non-interference	• Humanitarian assistance
• Mutual benefit	

4. Development Compact

The modalities followed by India in pursuing her mission of the SSC are referred to in the relevant literature as "Development Compact". The idea was derived from the original proposal of Stoltenberg (1989), and later articulated by Sengupta (1993), when he argued in the context of the hardships faced by the developing countries in fulfilling their contractual agreements linked to Structural Adjustment Programme (SAP), which had emerged as the cornerstone of what was labeled as "Washington Consensus". He proposed that "compacts (or agreements) be established between industrialized and developing countries to ensure that the latter received sufficient resources for development as they tried to reform their economies though programmes such as SAP, and in that way minimize social costs of reform".

According to Chaturvedi (2016), Sengupta's concept of development compact can be explained based on the principles of 'mutuality of obligation' and 'reciprocity of conditionality'. Under the compact, developed countries and international organizations will provide assistance necessary for the successful implementation of development plans in poor countries, while in return developing countries will cooperate in the process through bold reform programmes. In the absence of appropriate capacity within a developing country, the developed countries will be obligated to provide whatever assistance is necessary for developing countries to achieve their targets. The development compact envisages a reciprocal obligation between developing countries and bilateral donors, international organizations and the UN system; hence it will be a country-specific arrangement, instead of a traditional 'one-size-fits all' solution applied across the board to all problems of developing countries.

Such a framework of cooperation among the developing countries created an effective roadmap to development that was intended not to inflict any pain of conditional ties linked to internal structural reforms, and was aimed at garnering "mutual benefits" for the partners engaged in such cooperation. A perusal of the modalities of the development cooperation pursued by India has revealed how following five components of the development compact have been effectively utilized to contribute meaningfully not only to the development of partner countries without infringing on their sovereignty, but also how the engaged countries could derive mutual benefits by being in such a partnership (Table 2).

5. South-South Cooperation in Agriculture

South is no more a mute spectator. China and Korea are spending more on R&D than most of the developed countries in terms of per cent of GDP. In agricultural R&D, at least 10 countries in the South are working on Clustered, Regularly Interspaced, Short Palindromic Repeats (CRISPR)/Genome Editing. The public sector R&D in agriculture is still strong in many countries, including Brazil, South Africa, China and India, and some of these countries are in co-operation with countries in Africa. The issue is more

Table 2. Components of modalities of development cooperation pursued by India

Capacity building	• Training programme in the host country • Sending experts to partner countries • Scholarships • Third country training programmes • Deploying volunteers • Conducting feasibility studies • Prototype production and training centre
Development finance	• Concessional loans on interest with or without capacity- building component • Commercial rate of interest for different time periods
Trade and investment	• Duty-free trade preference • Trade permits • Infrastructure improvement for trade facilitation • Trade promotion and trade support services • Providing business facilitation services • Assistance for improving regulatory capacity • Providing investment funds • Developing intra-regional supply chains • Regional and sub-regional trade agreements • Providing freely convertible currency for trade • Tax preference for FDI
Technology transfer	• Technical cooperation • Joint scientific and academic research • Turnkey projects • Technology transfer with or without component of capacity- building. • Subsidizing licensing or exemption from Intellectual Property Rights (IPR) arrangements
Grants	• Debt forgiveness • Grant in kind

of building synergies that would propel SSC in agri-biotech than capacity *per se*. There is a need of a strategy to evaluate technological strength of South in agri-biotech and also to identify how SSC can be developed in agri-biotech. Ideas like Technology Bank, Patent Pooling and Clearing Houses for the SSC in agri-biotech can be explored.

The SSC is an important mechanism in technology development, transfer and diffusion. For this, credit goes to the support lend by respective governments with massive investments in R&D; many developing nations developed home-grown technologies in agricultural biotechnology, ranging from tissue culture to development of genetically modified organisms and gene-stacking.

A study on biotechnology capacity by Research and Information System (RIS) in 2014 in the APR showed that while many countries remained at the low-end of agricultural biotechnologies, some could move rapidly to high-end technologies. The scenario in Africa and Latin America was no different. In Africa, agricultural biotechnology has taken roots in a few countries such as South Africa and in many others, it is in the nascent stage. Similarly, in Latin America, while countries like Argentina, Brazil and Mexico have applied rapidly this technology despite controversies, and in others, it is in the initial stage.

Another important concern in agricultural biotechnologies is of biosafety, many developing nations have ratified the Cartagena Protocol on Biosafety. In fact, countries with very limited activities in agricultural biotechnologies have ratified the Protocol, and hence are bound by it.

For effective utilization of agricultural biotechnologies, it is essential that countries should have a functional innovation system in the agriculture sector. This is crucial for technology adoption and further development of agricultural biotechnology. There are many case studies to show that the SSC has helped countries move upward on the trajectory. Cooperation for capacity building in biosafety management, joint R&D and primary biotechnology are some of the avenues, which need to be explored further.

Partnerships have helped in adoption of new technologies. The establishment of the regional bioscience facilities and technology platforms with the partnership of the International Livestock Research Institute (ILRI) and the New Partnership for Africa's Development, leading to Biosciences eastern and central Africa (BecA), is a clear evidence of this in the African region.

In the long-run, SSC in agricultural biotechnology should be based on an integrated approach including product development along with capacity-building. The groupings like India, Brazil, South Africa (IBSA) and Brazil, Russia, India, China and South Africa (BRICS) can play an important role as they can engage in SSC as a group, complementing each other's strengths. As the countries in these groups have the capacity to develop genetically modified (GM) and non-GM boutiques of agricultural biotechnology, they can jointly promote SSC projects in this field.

6. Open Innovation

This means combining strengths and capabilities of different parties to find a solution or to address a complex problem. Open Innovation is used by industries in different sectors with schemes to incentivize innovative solutions by rewards and prizes. Open Innovation can be used to promote SSC in agri-biotechnology; there are examples such as UN Food and Agriculture Organization (FAO)'s "Agrisource", a free online platform. It is Europe's first open innovation platform for climate-smart agriculture. This platform empowers international actors to implement climate-smart agricultural practices across the supply chain. Similarly, MIT Media Lab Open Agriculture Initiative (OpenAg) brings together partners from industry, government and academia in a research collective by creating collaborative tools and open technology platforms for exploration of future food systems.

7. Open Source and Open Data

Open Source and Open Data with Open Hardware can be used in the SSC. Last year, the Department of Biotechnology (India) took an initiative on Open Data for farming so that farmers can have access to relevant data as Open Data. South's capacity in information technology (IT) and bioinformatics can be channelized to promote platforms, which provide open data and value-added services, and SSC can be facilitator in this, for example, a regional level sharing of open data and value-added services.

Open Source Seeds is a concept that is being tested in Africa and India. Governments should pay attention to open source seeds in agri-biotech. Open Sourcing and Open Data can open up new possibilities in creating new platforms, embodying principles of the SSC.

8. Regulatory Architecture

Governance of the technology calls for cooperation in responding to rapidly advancing technologies in biosciences. Governing CRISPR is becoming a challenge. Instead of looking at North, Southern nations can develop a framework that can be more suitable to them and would provide them flexibility. The North took the lead in GM regulation through Organization for Economic Cooperation and Development (OECD) and despite differences, they had built-up the scientific basis for regulation. South should do it for post-GM and genomics based agri-biotech through the SSC by forming working groups and inter-agency collaboration. This would give an opportunity to develop regulation more suited to South and with the principle of governance more relevant for South. To begin with, at least in regional grouping or in groupings like IBSA or Brazil, South Africa, India and China (BASIC), the scope for SSC needs to be discussed.

9. Agri-Biotech and Bio-Pharma

Research has shown that in bio-pharma, SSC worked well, as countries had a good understanding of their capacities and roles. This means that joint R&D is one of the options. But localizing, technology transfer and adoption are important for SSC to succeed. Moreover, synergy in SSC has to be developed. In agri-biotech, a similar approach can be adopted by identifying immediate or relevant needs in applications and services-for example, joint development of genome edited crops for enhancing food security.

10. Future Strategies

There is a need to identify the scope for SSC in agri-biotech, and thus arises a need for the SWOT analysis of the current SSC in agriculture. Select two or three key issues/themes to work on with a time-frame, deliverables and budget. There is a need to develop synergies and in combining available technological prowess in different disciplines to identify areas for upstream and downstream research; to build a network of groups and institutions, which would work on the identified themes/issues; and to think in terms of leap-frogging and going beyond GM technology in SSC.

New technological choices with open-source tools combined with gene-editing methods, like CRISPR, Zinc Finger Nucleases (ZFNs) *etc.*, would provide new opportunities. This can be a good news for smallholder farmers. It may help in opening new doors at a significantly reduced cost. However, issues related to the precision of these technological choices are yet to be fully addressed.

Mega-mergers in the agricultural biotechnology sector are a growing trend. With the entry of China's public sector, this trend is energized further. The time is ripe for a new generation of innovative public-private partnerships and new agricultural biotechnology paradigms, specifically, aimed at the needs of the small and marginal farmers, meeting food security and nutrition needs of the poor and vulnerable groups.

The SSC is an important opportunity for wider adoption of agricultural biotechnologies with concerns and modalities to be discussed among the leading economies from the South.

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FAO's Role in Agricultural Biotechnologies

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ABSTRACT: Biotechnology can be of significant assistance in meeting the needs of an increasingly urbanized population when appropriately integrated with other technologies for the production of food, agricultural products and services. Biotechnology provides powerful tools for the sustainable development of agriculture, fisheries and forestry, as well as the food industry. Food and Agricultural Organization (FAO) of the United Nations' assists its member countries by providing a common forum for discussing the policies and technical issues related to agricultural biotechnology. It also provides them with legal and technical advice, assists them in developing their capacities in the specified area and provides them with access to high quality, science-based information. The present paper enlightens the role of FAO in promoting the use of modern biotechnology along with the future strategies, namely, creation of knowledge platform on agricultural biotechnologies, promote public-private partnership and improve technology transfer in the use of agricultural biotechnologies.

1. Introduction

The Food and Agriculture Organization (FAO) of the United Nations uses a broad definition for biotechnology, based on Article 2 of the Convention on Biological Diversity (CBD), which states that it is "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use". The term 'agricultural biotechnologies', therefore, covers a broad range of technologies used in food and agriculture. These biotechnologies range from low-tech approaches involving artificial insemination, fermentation techniques, biofertilizers *etc.*, to high-tech approaches involving advanced DNA-based methodologies. They are used for many different purposes, such as the genetic improvement of plants and animals to increase their yields or efficiency; the characterization and conservation of genetic resources for food and agriculture; plant and animal disease diagnosis; vaccine development; and the production of fermented foods. Some of these technologies may be applied to all the food and agricultural sectors, such as the use of molecular markers or genetic modification, while others are more sector-specific, such as tissue culture (in crops and forest trees), embryo transfer (livestock) or sex-reversal (fish). The term agriculture includes crops, livestock, fisheries and forestry, so the term 'agricultural biotechnologies' encompasses their use in any of these sectors.

2. Biotechnology and FAO

FAO considers that the application of science and technology, including but not limited to agricultural

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biotechnologies, is one option that can play a substantial role in providing solutions to the unprecedented challenges of feeding an expanding world population in the face of climate change. Therefore, regarding agricultural biotechnology, FAO assists its member countries and their institutions by approaches listed hereunder.

2.1 Offering a neutral forum to discuss policy and technical issues related to biotechnology

- The FAO organized an international symposium on 'The Role of Agricultural Biotechnologies in Sustainable Food Systems and Nutrition' in February 2016 at FAO headquarters, Rome. The aim of the symposium was to explore the application of biotechnologies for the benefit of smallholders in developing sustainable food systems and improving nutrition in the context of climate change (FAO, 2017).
- As a follow-up to the international symposium, FAO organized two regional meetings in the Asia-Pacific and Sub-Saharan Africa, during September 11-13, 2017 in Malaysia and November 22-24, 2017 in Ethiopia, respectively. At these regional meetings, FAO offered an open and neutral forum for the exchange of ideas and practices between representatives of member countries, inter-governmental organizations, research institutions, farmer organizations, cooperatives, academia, civil society and the private sector.

2.2 Providing legal and technical advice

- The FAO assists member countries in establishing priorities for biotechnology within the broad context of their agricultural research needs and policies or in identifying appropriate biotechnologies, taking into account all possible negative impacts, and provide guidance on their use. It assisted a number of countries to develop their national biotechnology policies and strategies including Bangladesh, Nicaragua, Paraguay and Swaziland, at their request.
- At the request of governments, FAO also advises on project development. In the fishery sector, it has developed a number of projects that use agricultural biotechnologies on topics such as disease prevention and diagnosis in South-East Asia.

2.3 Assisting to develop capacities in agricultural biotechnologies and related issues

- Upon request, FAO provides technical assistance directly to its member countries in areas such as building or strengthening national biotechnology and biosafety capacities, including development and implementation of regulations, training of scientists and personnel of regulatory bodies, communication and public participation in biosafety-related decision making, upgrading of laboratory capacities, and establishing effective linkages among all relevant stakeholders.

2.4 Providing access to high quality, balanced and science-based information

- This is done using the internet, e-mail conferences and newsletters as well as providing member countries with access to articles, books, glossaries, proceedings and studies published by FAO concerning biotechnologies in food and agriculture.
- The FAO produced four short videos with real examples of biotechnologies being applied to meet the needs of smallholders in Asia-Pacific in 2017. They covered the topics such as use of artificial insemination and semen sexing in dairy cows for milk production in Nepal; DNA-based diagnostics and probiotics for disease management in shrimp populations in Thailand; DNA marker-assisted selection to develop Swarna-Sub1, a rice variety tolerant to floods in India; and tissue culture for propagating tree planting stock for agroforestry in Thailand. Videos were uploaded on FAO website (FAO, 2018).
- The FAO carried out a study on "The State of Application, Capacities and the Enabling Environment for Agricultural Biotechnologies in the Asia-Pacific Region" in 2017. The study covered 43 countries

in Asia and the Pacific. The study indicates that there is significant divergence among the countries and within the sub-regions of Asia-Pacific in the levels of application of agricultural biotechnologies as well as in their capacities to develop them and in their existing enabling environments. This divergence is growing and the results are that some countries are moving forward quickly while others are not benefiting as much as they would like from science and technology, including agricultural biotechnologies. The low and medium technologies are widely used in the region, but only few countries have adopted high technology applications such as genome editing and genome mapping. Many countries in the region have specific policies to promote agricultural biotechnologies, and many countries have integrated agricultural biotechnologies in their agricultural development plans. The enabling environment is mostly positive and there is new dynamism in some countries in supporting agricultural biotechnologies.

- Same study on the 'State of Application, Capacities and the Enabling Environment for Agricultural Biotechnologies' was carried out in Sub-Saharan African (SSA) Region in 2017. The study covered all 39 SSA countries.

3. Future Strategies

3.1 Creation of a knowledge platform on agricultural biotechnologies

Despite the extensive use of a wide range of agricultural biotechnologies, the application of which can vary widely across differing farming systems (from subsistence farms to large enterprises), most of the potential users do not have even cursory knowledge on those technologies. Building on the call from regional meeting participants for improved communication and networking, increased knowledge exchange and strengthened partnerships regarding agricultural biotechnologies, it is suggested to create a platform, involving stakeholders, especially those who are in the forefront of technology application, where they can gain access to knowledge on the diversity of agricultural biotechnologies, their applications, returns, limiting factors/constraints, opportunities, *etc.*, that may provide answers to their many questions related to food security and safety, productivity increase, *etc.*

3.2 Promote public-private partnership and South-South cooperation for agricultural biotechnologies

One of the key constraints in development and application of agricultural biotechnologies is inadequate investment. It has dual effects - limited public investments in agriculture, and private sector's money tied up in few staple biotechnology products only, do not provide much incentive to, and may even constrain, the use of agricultural biotechnologies on farms. Biotechnology development initiatives in developing countries are often hampered by lack of investment and funding sources. This is an underlying cause to many other constraints in agricultural biotechnology development such as poor regulatory frameworks, lack of scientific materials and sufficient human capacities, and unsupportive environment for intellectual property right protection. The hypothesis is that fostering and strengthening public-private partnerships and South-South Cooperation to be more synergistic, and to fill investment gaps where necessary, is an innovative approach that would help developing countries to move a step closer to exploiting the benefits of agricultural biotechnologies for their needs.

3.3. Improve technology transfer in the Pacific countries

Pacific countries are highly vulnerable to the effects of climate change and natural disasters, which can be potentially reduced by adoption of relevant agricultural biotechnologies. Although, they can benefit farmers and environment as well, in various ways, and play and will continue to play important role in agriculture development in the Pacific small island countries, such benefits are not appreciably enough in practice, due to geographical isolation and limited market size of those countries. Agricultural biotechnology development initiatives are often hampered by lack of investment and funding sources. However, it is not necessary for the Pacific countries to develop their own or new limited market size of those countries. Since many Asian countries have enough technologies already available, it is important for island countries to take a good advantage of those technologies through technology transfer and improvement of their absorptive capacities.

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Advances in Genomics Research and Molecular Breeding in Dryland Crops through Partnership for Achieving Food and Nutritional Security

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ABSTRACT: Biotechnology e.g. genomics contributes to future food and nutritional security benefiting sustainable small-farm agriculture of the world. Research-based agricultural productivity that has fed millions, served as the basis of economic transformation in many poor countries, especially in developing countries. The crop productivity for majority of crops in dryland areas, however, has been very low. Genomics-assisted breeding can help enhancing crop productivity as well as nutrition in these crops. However, until recently, majority of these crops have remained untouched with genomics revolution. Two key reasons for this situation include engagement of only few institutes and availability of limited resources at international level for research and development in these crops. With an objective to address these issues, Center of Excellence in Genomics and Systems Biology (CEGSB) at International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) floated several multi-institutional consortia by collaborating with >180 partners from >35 countries to advance genomics research and deploy molecular breeding. As a result of collaborative efforts from such strong partnership, a large number of genomic resources including genome sequences for 11 crops and several improved lines have been developed through molecular breeding in addition to developing a collaborative network and empowering the National Agricultural Research System (NARS) partners. In summary, the partnership of CEGSB together with technological advances has transformed the so-called 'orphan crops' to 'genomic resources-rich crops'.

1. Introduction

Food security has become a major challenge in the wake of the burgeoning world population which is expected to increase beyond 13 billion by 2100 (Raftery *et al.,* 2017). This also includes 5.5 billion people from the developing countries, many of them falling under the Asia-Pacific region of the world which is also one of the most vulnerable to the effects of climate change and severe water insecurity. Until recently, efforts were made to face the issue of food security through improving the cultivated crop varieties through conventional breeding practices. However, conventional plant breeding is random and imprecise, which requires many years to produce the desired variety. On the other hand, agricultural biotechnology has played a major role in agriculture development and socio-economic

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change especially in the developing countries. Agricultural production system can be divided into two major systems called 'cropping system' and the 'livestock production system'. The major focus of the ICRISAT has been in the cropping system of cereals and legumes grown in semi-arid tropics of Asia and Sub-Saharan Africa.

Towards this, the CEGSB at ICRISAT (cegsb.icrisat.org) has contributed towards genomics and molecular breeding for improvement of crops especially important for the semi-arid regions of the world. The genesis of CEGSB goes back to one grant entitled "Centre of Excellence(CoE) for High-throughput Allele Determination for Molecular Breeding" under CoE scheme of the Department of Biotechnology (DBT), Government of India to ICRISAT, mainly to provide genotyping services for Simple Sequence Repeat (SSR) and Diversity Arrays Technology (DArT) markers and training courses to National Agricultural Research System (NARS) researchers in 2007. The CoE subsequently was institutionalized by ICRISAT as research, service and training centre with three major modules: (i) Applied Genomics and Molecular Breeding, (ii) Sequencing and Genotyping Services and (iii) Capacity Building. CEGSB serves as a cost-effective genomics platform for scientists and research staff from different Themes/Research Programmes of ICRISAT as well as NARS partners. At present, the CEGSB with a mission to strive towards efficient breeding and research for better crop performance and human health has 184 collaborators from 35 countries of six continents (Figure 1).

We believe in strategic international partnerships and collectively with national/international organizations moved towards generation of genomic resources in ICRISAT mandate crops. In 2007, availability of genomic resources was very limited in ICRISAT mandate crops, such as chickpea, pigeonpea, groundnut, pearl millet, sorghum and finger millet. Although, these crops are very important to provide protein and nutrition, progress in the area of genomics and molecular breeding has been at a slow pace until recently. Some of the reasons for this slow pace include engagement of limited number of organizations

Figure 1. *Partnership of CEGSB for advancing genomics research and molecular breeding in dryland crops*

and non-availability of financial resources at international level when genomics research especially 10 years back was more expensive and needed technical expertise. Therefore, the CEGSB scientists initiated collaborations and floated several multi-institutional partnerships for advancing genomics research in these dryland crops.

As a result of collaborative efforts with several institutes coupled with technological advances significant progress has been made towards developing large scale molecular markers, generating transcript sequence data, developing genetic, transcript and physical maps, developing cost-effective and high throughput marker genotyping platforms as well as decoding genome sequences of several crops. While analyzing the sequence, a number of computational genomic tools and databases were developed. Furthermore, in partnership with a number of organizations from Asia and Africa, genomics research was translated successfully in developing several superior lines in many crops. In terms of empowering NARS partners, CEGSB offered services for SSR, DArT, Single Nucleotide Polymorphism (SNP) genotyping and sequencing services at cost-to-cost basis. Furthermore, CEGSB organized several training courses, many national and international workshops/symposia/conferences and hosted a number of research scholars/post-docs/ visiting scientists. This article highlights role of partnership to make significant achievements in the area of genomics and molecular breeding in so called orphan crops.

2. Genome Sequencing and Re-Sequencing Efforts

The unprecedented evolution in the Next-Generation Sequencing (NGS) technologies has made it possible to develop high quality genome assemblies in crop plants including complex and large sized genomes. CEGSB together with its partners have deployed NGS technologies in developing high quality reference genomes for the so-called orphan crops. Pigeonpea was among the first orphan legume crop and probably the first non-industrial crop in which NGS was adopted for developing its draft genome sequences (Varshney *et al.,* 2012). This became possible because of hard work and partnership of International Initiative on Pigeonpea Genomics (IIPG, 2011; Saxena and Varshney 2017). The IIPG included ICRISAT and 11 partner institutes from six different countries (Table 1). In fact, the genesis of IIPG goes back to the Pigeonpea Genomics Initiative (PGI) that started in 2006 with financial support from Indian Council of Agricultural Research (ICAR), US National Science Foundation's Plant Genome Research Programme and the Generation Challenge Programme under the umbrella of Indo-US agricultural knowledge initiative (Varshney *et al.,* 2010). Similarly, ICRISAT led several other genome sequencing consortia/initiatives such as International Chickpea Genome Sequencing Consortium (ICGSC, 2018; Thudi and Varshney, 2017) and International Pearl Millet Genome Sequence Consortium (IPMGSC, 2018). In the case of ICGSC, ICRISAT partnered with 22 partner institutes from 10 different countries to sequence the chickpea genome (Varshney *et al.,* 2013). For the pearl millet genome, the IPMGSC included ICRISAT and 33 partner institutes from 11 countries (Varshney *et al.,* 2017a) (Figure 2).

CEGSB also co-led the Diploid Progenitor Peanut A-Genome Sequencing Consortium (DPPAGSC, 2018) for progenitor species of cultivated groundnut *i.e.*, *Arachis duranensis* (A-genome) (Chen *et al.,* 2016) and also played a key role in the International Peanut Genome Initiative (Peanut Base, 2017) to sequence the genome of *A. duranensis* (A-genome) and *A. ipaensis* (B-genome) species (Bertioli *et al.,* 2016; Wang *et al.,* 2017). Genome sequence for sorghum was made available by the US-led team in collaboration with ICRISAT (Paterson *et al.,* 2009). In brief, draft genome assemblies as mentioned above could have been possible because of strong partnership of CEGSB with several partners across the world (Figure 2). In addition to sequencing the genomes of ICRISAT mandate crops, the CEGSB scientists also collaborated with several partners to sequence genomes of other plant species such as adzuki bean (*Vigna angularis*) (Yang *et al.,* 2015; Kang *et al.,* 2015), mungbean (*Vigna radiata*) (Kang *et al.,* 2014), sesame *(Sesamum indicum)* (Wang *et al.,* 2014) and longan (*Dimocarpus longan*) (Lin *et al.,* 2017). In summary CEGSB scientists have led/contributed in sequencing of 11 crop genomes, which is unprecedented in the Consultative Group on International Agricultural Research (CGIAR) system, to which ICRISAT belongs.

Table 1. Advances in the genomics, trait mapping and molecular breeding during last decade in the ICRISAT mandate crops

Features	Chickpea		Pigeonpea		Groundnut		Sorghum		Pearl Millet	
	2007	2007	2007	2007	2007	2007	2007	2007	2007	2007
Molecular markers										
SSR markers	**	***	*	***	*	***	***	****	*	***
SNP markers	No	***	No	***	No	**	**	****	No	****
DArT markers	No	***	No	***	No	***	No	***	No	*
Diagnostic markers	No	***	No	***	NO	***	NO	***	NO	***
Maps										
Genetic maps	*	***	No	***	*	***	**	***	*	***
Physical maps	No	*	No	No	No	*				
Assembly										
Genome	No	***	No	***	No	**	No	***	No	***
Transcriptome	No	***	No	***	No	***	No	**	No	**
Marker genotyping platforms										
KASP assays	No	***	No	***	No	**	No	**	No	**
Golden Gate	No	**	No	**	No	**	No	**		**
SNP arrays	No	***	No	***	No	***	No	No	No	No
Trait mapping										
Biotic stress	*	***	No	***	*	**	**	***	*	**
Abiotic stress	*	***	No	**	No	*	*	***	*	**
Other traits	*	***	No	**	*	***	*	**	*	***
Molecular breeding products										
Superior lines	No	***	No	No	No	***	*	**	*	**

**limited, **optimum, ***abundant, ****highly abundant, No - non availability*

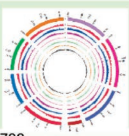
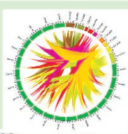
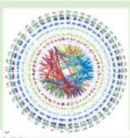
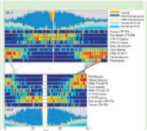
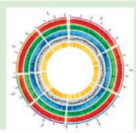
Features	Chickpea	Pigeonpea	Groundnut	Groundnut	Groundnut	Sorghum	Pearl Millet
Scientific name	*Cicer arietinum*	*Cajanus cajan*	*Arachis duranensis*	*Arachis duranensis*	*Arachis ipaensis*	*Sorghum bicolor*	*Pennisetum glaucum*
Chromosome no.	2n=2x=16	2n = 2x = 22	2n = 2x = 20	2n = 2x = 20	2n = 2x = 20	2n = 2x = 20	2n = 2x = 14
Genotype sequenced	CDC Frontier	ICPL 87119 (Asha)	PI475845	V14167	K30076	BTx623	Tift 23D$_2$B$_1$-P1-P5
Reference	Varshney et al. (2013)	Varshney et al. (2012)	Chen et al 2016	Bertioli et al. 2016	Bertioli et al. 2016	Paterson et al. (2009)	Varshney et al. (2017a)
Circular representation of Genome assembly							
Genome size (Mb)	738	833	1250	1250	1560	730	1790
Assembly size (Mb)	532	606	1051	1211	1512	679	1760
No of gene models	28,269	48,680	50,324	36,734	41,840	34,496	38,579
No of genes annotated	28,255	46,750	-	-	-	27,640	38,542
No of scaffolds	7,163	137,542	8,173	635,392	759,499	679	25,241
N50	40 Mb	516 Kb	650 Kb	948 Kb	5343 Kb	35 Kb	18.18 Kb
Longest scaffold	59.46 Mb	48.97 Mb	5.3 Mb	8.5 Mb	21.2 Mb	-	4.8 Mb
GC content	30.78 %	32.80 %	31.79 %	-	-	-	47.90 %
No. partners (other than ICRISAT)	42	24	39	38	38	44	53
No. of institutes	23	12	10	26	26	21	34
India (NARS) partners (Institutes)	4 (4)	-	-	-	-	-	6 (6)
No. of countries	10	6	4	6	6	6	11

Figure 2. *Features and engagement of partners in genome sequencing of ICRISAT mandate crops*

In order to harness genetic diversity from germplasm collection in these important crops, various re-sequencing efforts were carried out. For instance, in the case of chickpea, ICRISAT-led team has undertaken the sequencing of thousands of chickpea genomes as part of 'The 3,000 Chickpea Genome Sequencing Initiative'- an international effort to sequence and phenotype the chickpea global composite collection. The collection includes ICRISAT's 1,956 accessions, with an additional 709 accessions contributed by the International Centre for Agriculture Research in the Dry Areas (ICARDA). The initiative has also sequenced several advanced breeding lines and cultivars, as well as morphological variants, wild species, and more than 200 accessions that are known to carry specific traits such as resistance to different biotic/abiotic stresses (Thudi *et al.,* 2015; 2016). Similar efforts were carried out in pigeonpea (Varshney *et al.,* 2017b), groundnut (Clevenger *et al.,* 2017; Pandey *et al.,* 2017), sorghum and pearl millet (Varshney *et al.,* 2017a).

Of all the genomic resources, reference genome and genetic markers are the most important for accelerating trait mapping and molecular breeding. The availability of marker resources facilitated development and deployment through different suitable platforms over the last decades. The journey for these crops started genotyping with limited SSRs through Polymerase Chain Reaction and agarose gels in 2007 to today's sequencing- and array- based high throughput SNP genotyping in almost all the ICRISAT mandate crops (Table 1). Continuous efforts were made by CEGSB for developing low cost and high throughput genotyping platforms to deploy markers in trait mapping and breeding.

Genomic data, combined with the new phenotyping information, should provide superior alleles for use in breeding programmes. Such international projects on genomic-rich resources would enable researchers to recognize and understand the crop, in terms of resistance to climate change and pests, thereby increasing yields of key crops across the developing world. In addition, the genome architecture as well as millions of variations will be catalogued in these crops.

3. Trait Mapping

By using genomic resources, genotyping platforms and working in collaboration with breeders, physiologists, pathologists, entomologists, microbiologists, genetic resource and pre-breeding specialists from ICRISAT and other collaborating institutes, CEGSB has been successful to map 20 to 50 traits in the ICRISAT mandate crops. List of mapped traits have been provided in Table 2. It is important to mention here that mapped traits do not essentially mean that diagnostic markers are available for all these traits. In fact, in terms of availability of diagnostic markers, they are available for limited number of traits, so far. Efforts need to be accelerated to map desired traits in cost-effective and faster manner.

4. Translating Genomics Research into Product Development

Molecular markers associated with different breeding traits were deployed in several breeding programmes both in ICRISAT as well as collaborating national programmes in India and Africa. As a result of extensive collaboration with breeding colleagues, several superior lines have been developed for a number of traits in different crops (Table 3). CEGSB has now initiated some efforts in the area of deployment of genomic selection in crop improvement programmes.

5. Sequencing and Genotyping Services and Capacity Building

Other important activities of CEGSB are sequencing and genotyping services and capacity building. Over the past 10 years, genotyping and sequencing services have been provided for 34 crops and 40 organizations from 12 different countries across the globe. More than 3.5 million data points (during last 8 years) and more than 50 Tb sequencing data (during last 5 years) has been generated. About 300 scientists from national/international institutes/universities have been trained at ICRISAT through formal training courses. CEGSB has organized around 10 international conferences/ symposia/ workshops during the last 10 years.

Table 2. Key traits mapped in ICRISAT mandate crops by CEGSB and its partners

Chickpea	Pigeonpea	Groundnut	Sorghum	Pearl millet
		Abiotic stresses		
Drought tolerance (Root traits such as root length density, root length, root surface area, yield, harvest index, 100-seed weight, number pods per plant, biomass, specific leaf area, delta carbon ratio, days to flowering, days to maturity); **Heat tolerance** (Pods per plant, heat tolerance index, yield, biomass, harvest index, days to flowering, days to maturity); **Salinity tolerance** (Pod number, seed number, seed yield, shoot dry weight, harvest index, 100 seed weight)	**Drought tolerance**	**Drought tolerance** (Transpiration efficiency, Spad Chlorophyll Meter Readings (SCMR), leaf area, leaf dry weight, shoot dry weight, harvest index)	**Drought tolerance** (Transpiration efficiency, response to Vapour Pressure Deficit (VPD), leaf canopy, leaf size, leaf angle through Leasy scan, harvest index)	**Terminal drought tolerance** (tiller number, panicle diameter, total biomass dry weight, leaf dry weight, root dry weight, shoot dry weight, stem dry weight, leaf area, specific leaf weight, transpiration efficiency, absolute transpiration, leaf rolling, delayed leaf senescence, low VPD transpiration rate, high VPD transpiration rate); **Salinity tolerance**
		Biotic stresses		
Ascochyta blight; **Helicoverpa** (Leaf damage rating, unit larval weight, Helicoverpa larvae/10 plants, days to first flowering); **Fusarium wilt**; **Botrytis grey mould**	**Fusarium wilt; Sterility mosaic disease**	**Resistance to viral and bacterial diseases** (Tomato spotted wilt virus, peanut bud necrosis, bacterial wilt); **Resistance to fungal diseases** (Rust, early leaf spot and late leaf spot)	**Stem borer; Leaf diseases** (Anthracnose, leaf blight)	**DM resistance; Blast resistance; Rust resistance**
		Nutritional traits		
Protein content	**Protein content**	**Quality and nutritional traits** (Oil content, fatty acid content (oleic, linoleic, palmitic, arachidic *etc.*), Fe and Zn content, fresh seed dormancy, aflatoxin contamination)	**Iron and zinc content**	**Grain and forage quality** (Grain Fe and Zn content, *in-vitro* organic matter digestibility, metabolizable energy, neutral detergent fiber (cellulose, hemicellulose, lignin), nitrogen on dry matter basis, gas volume, sugar content on dry matter basis, fresh and dry stover yield)
		Other traits		
	Seed purity (CMS seed purity, Hybrid seed purity); **Hybrid related traits** (Obcordate leaf shape, fertility restoration); **Yield related traits** (Flowering time, days to maturity, pods per plant, 100 seed weight, plant height, seeds per pod, seed yield per plant, primary branches, secondary branches)	**Yield related traits** (Seed weight, seed size, pod yield, shoot dry weight, number of fruit branches, shelling percentage, haulm weight); **Physiological traits** (Leaf length, specific leaf area, total leaf weight, shoot weight, iron deficiency in soil)	**Yield related traits** (Seed weight, seed size, panicle; harvest index, harvest index); **Fodder traits** (fodder yield, fodder quality); **Special traits related to adaptation** (Biological nitrification inhibition)	**Yield related traits** (Flowering time, plant height, panicle length, seed weight, panicle harvest index, grain harvest index, grain number per panicle, harvest index, biomass, grain yield under moisture stress and irrigated conditions); **Heterotic gene pools for hybrid parental lines; General and specific combining** (ability for grain yield under drought stress an irrigated conditions)

Table 3. Success stories of translational genomics through molecular breeding in ICRISAT mandate crops

Crop / Improved genotypes targeted	Trait (s) improved	Current status of improved lines	ICRISAT's partner institutes	Reference
Chickpea				
JG 11 and ICCV 10	Drought tolerance	Superior lines are in multi-location trials for evaluation and release	• Indian Agricultural Research Institute, New Delhi, **India** • CGIAR Generation Challenge Programme, **Mexico** • Hokkaido University, Sapporo, **Japan**	Varshney *et al.* (2013)
C 214	Fusarium wilt and Ascochyta blight resistance	Superior lines are in multi-location trials for evaluation and release	• Punjab Agricultural University, Ludhiana, **India** • CGIAR Generation Challenge Programme, **Mexico**	Varshney *et al.* (2014a)
		Groundnut		
ICGV 91114, JL 24 and TAG 24	Leaf rust resistance	Superior lines are in multi-location trials for evaluation and release	• CGIAR Generation Challenge Programme, **Mexico** • University of Agricultural Sciences, Dharwad, **India** • Directorate of Groundnut Research, Junagadh, **India**	Varshney *et al.* (2014b)
ICGV 06110, ICGV 06142 and ICGV 06420	Oil quality (high oleic acid)	Superior lines are in multi-location trials for evaluation and release	• Directorate of Groundnut Research, Junagadh, **India** • Tamil Nadu Agricultural University, Coimbatore, **India** • Junagadh Agricultural University, Junagadh, **India** • Acharya NG Ranga Agricultural University, Tirupati, **India**	Janila *et al.* (2016)
DH 86, ICGV 87846, ICGV 00350, ICGV 03128, ICGV 05155 and ICGV 00351	Resistance to leaf rust and late leaf spot; oil quality (high oleic acid)	Introgression lines (BC_3F_2 generation) during rainy 2017 season	Directorate of Groundnut Research, Junagadh, **India**	Unpublished
GJG 9, GG20 and GJGHPS1	Resistance to leaf rust and late leaf spot; oil quality (high oleic acid)	Pyramided lines (F_3 generation) during rainy 2017 season	Directorate of Groundnut Research, Junagadh, **India**	Unpublished
		Pigeonpea		
ICPH 2671 and ICPH 3438	Hybrid purity	SSR based hybrid seed testing purity kits developed	• Department of Genetics, Osmania University, Hyderabad, **India** • Barkatullah University, Bhopal, **India** • University of California, Davis, **USA** • University of Agricultural Sciences, Bangalore, **India** • CCS Haryana Agricultural University, Hisar, **India** • National Center for Genome Resources, Santa Fe, **USA** • National Research Center on Plant Biotechnology, New Delhi, **India** • J. Craig Venter Institute, Rockville, **USA** • Generation Challenge Programme, **Mexico**	Saxena *et al.* (2010); Bohra *et al.*(2011)

Crop / Improved genotypes targeted	Trait (s) improved	Current status of improved lines	ICRISAT's partner institutes	Reference
		Sorghum		
M 35-1, Phule Vasudha, CRS1, Parbhani Moti, SPV 2217, BJV44, SVD806, GS23, GS16, GRS1 (DSV5)	Post-flowering drought tolerance (stay-green trait) and shoot fly resistance	Introgression lines at (BC_3F_2:F_3 generation) for field evaluation during post-rainy 2017	NARS partners	Unpublished
IS 8813, IS 13256, IS 23120, IS 18542	Low lignin	Introgression lines at (BC_3F_2:F_3 generation) for field evaluation during post-rainy 2017	NARS partners	Unpublished
		Pearl Millet		
H 77/833-2, J 2340 and ICMB 93333	Resistance to downy mildew and drought tolerance	The test cross hybrids (HHB 67 Improved and GHB 538 Improved) in multi-location trials for evaluation and release while introgression lines (BC_3F_3) for ICMB 93333 developed and the test cross hybrids tested.	ICAR	AICRP-PM Annual Report (2016-2017)
ICMB 95222 and pollen parent of popular hybrid 9444	Blast resistance	QTL introgression lines (BC_3F_3 and BC_4F_3) and the test cross hybrids (HHB 146 Improved and Bayer-9444) are being tested	NARS partners	Unpublished

6. Conclusions

As evident from above, because of strong partnership coupled with technological advances, the CEGSB/ ICRISAT has made significant efforts in the area of development of genomic resources and generation of molecular breeding products. In summary, CEGSB has enjoyed the partnership of 184 institutes from 35 countries to generate high-quality science, develop molecular breeding products and empower NARS partners through genotyping and sequencing services and training courses. It is evident from above that the partnership plays an important role in developing and using biotechnology tools for small-holder agriculture. Such efforts can be replicated in the other areas of biotechnology in Asia-Pacific Association of Agricultural Research Institution(APAARI) targeted institutes in the Asia-Pacific region.

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National Broodstock Improvement Network: A Project of The Network of Aquaculture Centres in Asia-Pacific

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ABSTRACT: The National Broodstock Improvement Network (NBIN) is the strategy proposed by Network of Aquaculture Centres in Asia-Pacific (NACA) for genetic improvement. The NBIN aquaculture genetic exchange network is for exchanging genetic material (including broodstock, eggs, sperm and perhaps nuclei) as well as information about gene pools. This network concept allows concurrent, rapid adaptation to local climate change threats and opportunities in a range of environments avoiding inbreeding and genetic erosion. The long-term outcome of the programme will be a network of participating farmers and hatcheries that exchange genetic information, broodstock and seed for their own individual benefit. The NBIN researches on reduction of farm-level inbreeding and its consequences for disease prevalence and risk of epidemics, and adaptation to climate change and other stressors. The details on NBIN structure and organization, organizational challenges in an aquaculture germplasm exchange network are briefly discussed in the present paper.

1. Introduction

The Network of Aquaculture Centres in Asia-Pacific (NACA) proposes a strategy for genetic improvement called a 'National Broodstock Improvement Network' (NBIN), consisting of partially interconnected but independently evolving broodstocks (Doyle *et al*., 2015, 2018). There are two principal motivations, which are closely related, for establishing such a community-based breeding programme for aquaculture: (i) reduction of farm-level inbreeding and its consequences for disease prevalence and risk of epidemics and (ii) adaptation to climate change and other stresses.

The NBIN aquaculture genetic exchange network concept is a special case of smallholder genetic exchange networks for terrestrial plants and animals, variously called 'community-based breeding programs' (CBBP) (Mueller *et al.,* 2015), 'participatory plant breeding'(Ceccarelli *et al.,* 2010) or 'on-farm dynamic management' (Thomas *et al.,* 2015), that allow concurrent, rapid adaptation to local climate change threats and opportunities in a range of environments. The CBBP enables dynamic change that characterizes terrestrial crop 'landrace' systems, open, decentralized genetic systems that are constantly evolving

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(Sthapit *et al.,* 2010; Loeuille *et al.,* 2013; Hellin *et al.,* 2014; Bellon *et al*., 2015; Poudel *et al.,* 2015; Thomas *et al.,* 2015), while avoiding inbreeding and genetic erosion (Doyle, 2016; Doyle *et al*., 2018).

The NBIN aquaculture genetic exchange network strategy is complementary to, but very different from, a traditional 'Nuclear Breeding Centre' (NBC) strategy that has a single, centralized breeding programme and one or very few separate gene pools. We emphasize that the NBIN aquaculture genetic exchange network is a network of aquaculture gene pools, and not a network of institutions. To be more precise, it is a network for exchanging genetic material (germplasm including broodstock, eggs, sperm and perhaps nuclei) as well as information about gene pools.

Physical exchange of breeders, fry, PLs *etc.* already takes place just about everywhere aquaculture is practiced, usually with inadequate control of pathogen transmission. In the real world of tropical aquaculture, informal, non-secure genetic exchange is taking place all the time (Doyle, 2014, 2016). An NBIN aquaculture genetic exchange network should make these ongoing exchanges more beneficial to individual hatcheries and at the same time block the runaway positive feedback loop that we suggest (Doyle, 2014; Doyle *et al.,* 2018), is amplifying disease problems at the national and regional levels.

The NBIN concept focuses on economically beneficial uses of genetic diversity. The long-term outcome of the programme will be a network of participating farmers and hatcheries that exchange genetic information, broodstock and seed for their own individual benefit. Similar programmes can be economically self-sustaining in relevant cultural milieus and levels of technological maturity are demonstrated by the success of crop and livestock farmer associations in India, Thailand, Denmark and France. The wider, common benefit, *i.e.* sustainable genetic diversity on regional and global scales is recognized and appreciated, but is not the financial motivator of network participants. We will be guided by the experience of crop and livestock associations, including aquaculture programmes in developed countries (e.g. AQUATRACE) that share some of the objectives of our proposal. New technical procedures must be developed and development will be expensive. In farm and hatchery use, however, the new procedures can be made to be cost-effective and possibly even cheap.

2. Reduction of Farm-level Inbreeding and its Consequences for Disease Prevalence and Risk of Epidemics

Disease crisis in tropical shrimp aquaculture, like diseases in all other animals and plants that have been studied, are amplified by inbreeding (Doyle, 2016). In aquaculture, the biological effect may be exacerbated by a process whereby increased mortality from disease raises the level of biosecurity regulation, and tightened regulation increases inbreeding that further increases mortality. And we go round and round in a self-amplifying feedback loop while disease crises grow worse (Doyle, 2014).

A key component of this feedback hypothesis is that current strategies for countering disease cause, as a side effect, a progressive reduction of the number, size and genetic diversity of aquaculture gene pools. This is a direct result of biosecurity and stock-transfer restrictions, and indirectly of higher prices and reduced availability of high-quality stocks as biosecurity tightens. Generally speaking, the smaller a population the faster it accumulates inbreeding. Smallhold farmers in particular rely on seed from small and poorly managed hatcheries. Many such hatcheries are presumed to produce seed that is both inbred and without biosecurity protection. Hatcheries participating in an NBIN aquaculture genetic exchange network would, in aggregate, constitute a national 'meta-population' with enhanced environmental resilience, genetic diversity, rapid local adaptation, very large effective population size and minimal, local inbreeding depression. Such a meta-population would not sustain a runaway feedback loop that connects inbreeding with disease and environmental stress.

The need for an aquaculture system redesign that both uses and conserves genetic diversity is especially acute in India, Asia-Pacific and other regions where subsistence and small-hold farmers occupy a wide range of environments and are largely depend on seed from small and medium-sized hatcheries. Diluted, inappropriate, misrepresented and inbred seed reduces productivity and local adaptation, and is a major threat to the livelihoods of subsistence and small-hold farmers.

3. Adaptation to Climate Change and Other Stressors

Since domestication of animals began more than 15,000 years ago, people have adapted to new environments by genetically modifying the animals they depend upon. At present, with increasing environmental variability, having a diversity of combinations of genes and traits that are constantly selected in response to changing situations and growing knowledge should allow aquaculture to adapt better to climate change (Doyle, 2014; Doyle *et al*., 2018).

Smallholder aquaculture is sustainable indefinitely in the face of climate change only, we propose, if smallholders can develop genetic strains adapted to their increasingly unpredictable local environments. We further suggest that this is more likely to happen if aquaculture smallholders participate in genetic exchange networks, variously called 'CBBP' or 'on-farm dynamic management', that allow concurrent, rapid adaptation to local climate change threats and opportunities in a range of environments. CBBP enables the dynamic change that characterizes terrestrial crop 'landrace' systems (open, decentralized genetic systems) that are constantly evolving (Sthapit *et al.,* 2010; Loeuille *et al.,* 2013; Hellin *et al.,* 2014; Bellon *et al*., 2015; Poudel *et al.,* 2015; Thomas *et al.,* 2015) while avoiding inbreeding and genetic erosion (Doyle, 2014; Doyle *et al*., 2018).

Networked breeders and farmers exert on-farm selection pressures that change from location to location and over time in the face of climate change stressors and emerging pathogens (Loeuille *et al.,* 2013; Hellin *et al.,* 2014). The key aspect of an NBIN aquaculture genetic exchange network, like other CPPB, is that, while local strains are continuously developed for cultivation, the networked, global 'meta-population' will continue to evolve indefinitely as a sustainable source of continuously better-adapted genetic material for industrial aquaculture as well as smallholders(Ceccarelli *et al.,* 2010). A networking approach allows efforts to be directed at enhancing diverse local adaptive capacities as a complement to a small number of world-wide (generally industrial) adaptations (Hellin *et al.,* 2014).

The high level of uncertainty in the details of climate-change predictions is reflected in growing interest in adaptive capacity as an alternative focus of policy efforts, rather than specific adaptations, e.g. controlled industrial environments that are isolated from environmental and pathogenic stressors associated with climate change (Sthapit *et al.,* 2010; Hellin *et al.,* 2014). The fact that CBBP systems can be economically self-sustaining, while remaining dependent on technical and other support from advanced technical institutions and organizations, in relevant cultural milieus and levels of technological maturity is demonstrated by the success of terrestrial crop and livestock farmer associations in India, Thailand, Denmark, France, the Americas and elsewhere.

4. NBIN Structure and Organization

4.1 Essential genetic conservation and improvement roles of smallholder hatcheries and farms

An NBIN aquaculture genetic exchange network can facilitate the co-existence of any number of public and private broodstocks of different sizes, locations and origins. Traditional NBCs could and should be important components of an NBIN but their objectives, increased yield, would be folded into a wider national strategy for long-term preservation of genetic biodiversity. The NBIN aquaculture genetic exchange network would both assist and make best use of NBCs and the myriad small-hold farmer/breeder operations that spring up wherever easily propagated aquatic species such as shrimp, tilapia, carp and catfish are cultured.

The high fecundity of shrimp can lead to rapid inbreeding and enhanced susceptibility to disease (Bellon *et al*., 2015; Doyle, 2016) as well as the reduced capacity to evolve, which results from loss of genetic diversity in small broodstocks. Unfortunately, while genetic exchange is widespread among smallhold aquaculture farmers, it is largely undocumented and not informed by genetics (Szuster, 2006). As noted above, "Strengthening the collective actions of (CBBP) communities in variety access, selection and seed production activities will ensure the flow of quality seeds in the community. This process will strengthen farmers' capacity to cope up with climate change in traditional production systems" (Poudel *et al.,* 2015).

Local exchanges of aquaculture broodstock and seed are already existing and are popular and somewhat organized in some places. But existing networks are defective in one crucial respect that their participants lack the genetic information that is required to manage inbreeding. The strategic target of the NBIN aquaculture genetic exchange network is to conserve genetic biodiversity at the national level and minimize inbreeding at farm level, thus reducing susceptibility to disease as well as providing other production benefits.

NBIN aquaculture genetic exchange networks will facilitate gene flow among broodstock populations of various sizes located in different parts of the country and managed in different ways with different selection objectives and types of ownership both public and private. Satisfying the individual needs of local participants would, if calculations on the DNA data are properly done, automatically increase the effective population size and reduce the loss of diversity at the national level. A wide variety of selection objectives and selection environments is inherent in the NBIN aquaculture genetic exchange network concept because it can extend over a range of environments (climate, salinity, disease *etc.*), farming systems (cage, pond, intensive and super-intensive culture) and selection objectives.

NBIN participants would, in aggregate, constitute a national meta-population (to use an ecological genetic term) with all the evolutionary advantages that implies in terms of environmental resilience, genetic diversity, rapid local adaptation, very large effective population size and minimal inbreeding depression in the component broodstocks. Inbreeding associated with strong selection would be virtually eliminated by the large effective population size of the interconnected meta-population. Local additive genetic diversity, scope for evolution, would be maintained by gene flow between the component gene pools.

4.2 Organizational challenges in an NBIN aquaculture germplasm exchange network

A key objective of the NACA NBIN project is to bring developing country aquaculture genetics into the modern era of high and sustainable production, while preserving the livelihoods of independent, small-hold hatcheries and the diversity of grow-out environments and farming systems. How to achieve "shared-value" is a crucial concern in this project, because we recognize that to be sustainable, every link in the aquaculture production chain must be profitable to those engaged in it.

Adding germplasm exchange functions to existing or new aquaculture networks, and to their supporting organizations and institutions, will present both technical and social challenges, as described in many of the cited references. The most obvious technical/social/policy challenge is procedures for exchanging germplasm that do not also cause the spread of disease. Existing national and international disease-control policies (essentially, broodstock isolation) inhibit the formation of CBBP germplasm exchange networks that would constitute an evolutionary basis for sustainable, diverse, long term, adaptive resistance to pathogens (Doyle, 2014; Doyle *et al*., 2018). The heart of the technical/policy dilemma is a feedback system within which, while pathogens are evolving in response to climate change, broodstock isolation reduces the genetic and evolutionary capacity to resist new and increasing disease threats. The feedback loop is completed when a decrease in aquaculture production caused by disease results, in accordance with isolation policies, increased genetic erosion and inbreeding (Doyle, 2014).

The agro-economic system of tropical aquaculture is based on a trade in genetic material, in the form of adult spawners and offspring "seed", through a network of interconnected transactions between breeders, large and small hatcheries and farmers. Documentation of international transfers currently includes animal health certificates but not genetic composition. Internal trade rarely includes documentation of any sort. Small-hold farmers in particular often rely on seed from small and poorly managed hatcheries, many of which sell seed that is both inbred and without biosecurity protection. Biosecurity regulations, such as requirements that internationally transferred material be certified Specific Pathogen-Free (SPF), are a necessary component of disease management. However, the volume of trade in aquaculture broodstock and seed is severely constrained by SPF protocols and there is consequently a flourishing, illegal trade that has negative genetic consequences for animal health (susceptibility to pathogens and other stressors) due to inbreeding depression and genotype monoculture.

Developing an NBIN aquaculture genetic exchange network on the model of terrestrial CBBP networks will not be easy, although the basic social frameworks for CBBP already exist in many places (Szuster, 2006; Pautasso *et al.,* 2013; Bellon *et al*., 2015; Frison, 2016). Technical help from local and regional governmental organizations and institutions, as well as NGOs, will be required (Sthapit *et al.,* 2010; Mueller *et al.,* 2015). A recent review and analysis of CBBP in Latin America, Africa and Asia highlights this high dependence of CBBP on external organizational, technical and financial support (Hellin *et al.,* 2014; Mueller *et al.,* 2015).

Coping with an increasing rate of climate change in smallholder aquaculture may, as in terrestrial plant and animal production, requires the development of new social networks of a modern type (Pautasso *et al.,* 2013; Bellon *et al*., 2015; Frison, 2016). It is most unlikely that this can be solely a 'bottom-up' process, as evidenced for example in Thailand (Szuster, 2006). Farmers ability to cope up with impact of climate change will be strengthened if the research and development institutions can [strengthen] social seed networks and policy supports that promote farmer-to-farmer [germplasm] exchange systems" (Sthapit *et al.,* 2010). At least 59 different types of interventions for supporting on-farm conservation have been identified (Bellon and van Etten, 2014). Research and development agencies will play a crucial role in technical and organizational aspects of guiding germplasm exchanges within aquaculture networks that are adapting to climate change (Sthapit *et al.,* 2010; Pautasso *et al.,* 2013; Bellon and van Etten, 2014, Carroll *et al*., 2014, Hellin *et al.,* 2014; Mueller *et al.,* 2015). Furthermore, modern, 'high-tech' crop varieties are often grown together with local landraces in agricultural communities experiencing a range of climates (Pautasso *et al.,* 2013; Bellon *et al*., 2015).

4.3 Role of a central genetics laboratory in a NBIN

A central laboratory would be needed to characterize DNA received from participating broodstock owners and also to give advice on what broodstock exchange or purchase would be most useful for each breeder participating in the network. Technical developments that facilitate such networking will also enable national and supra-national agencies to monitor and manage aquaculture networks as large 'meta-populations' which, collectively, preserve the genetic diversity of domesticated stocks indefinitely as a global, common genetic resource. The need for an aquaculture genetic management system that both creatively uses and conserves or increases genetic diversity is especially acute in Asia-Pacific and other regions where smallholders are currently responsible for an estimated 70 per cent of total shrimp production (Doyle, 2016). Although we emphasize that to become a successful aquaculture genetic exchange network, NBIN will need the involvement of other institutions and extension staff (Mueller *et al.,* 2015). Nevertheless, the power of decision-making will remain with farmers as their local climates change. Smallhold farmers and hatcheries will have social ownership of the CPPB evolutionary and germplasm exchange programmes (Mueller *et al.,* 2015).

5. Conclusions

The present paper dealt with NBIN, which is a network for exchanging genetic material that includes broodstock, eggs, sperm and nuclei as well as information about gene pools. The major aim of this strategy is to establish a community-based breeding programme for aquaculture to reduce farm-level inbreeding and its consequences for disease prevalence and risk of epidemics and, adaptation to climate change and other stressors. Hatcheries participating in an NBIN aquaculture genetic exchange network would constitute a national 'meta-population' with enhanced environmental resilience, genetic diversity, rapid local adaptation, very large effective population size and minimal, local inbreeding depression. CBBP enables the dynamic change that characterizes terrestrial crop 'landrace' systems (open, decentralized genetic systems) that are constantly evolving, while avoiding inbreeding and genetic erosion. Inbreeding associated with strong selection would be virtually eliminated by the large effective population size of the interconnected meta-population. Local additive genetic diversity, scope for evolution, would be maintained by gene flow between the component gene pools.

Existing national and international disease-control policies (essentially, broodstock isolation) inhibit the formation of CBBP germplasm exchange networks that would constitute an evolutionary basis for sustainable, diverse, long term, adaptive resistance to pathogens. The volume of trade in aquaculture broodstock and seed is severely constrained by SPF protocols and there is consequently a flourishing, illegal trade that has negative genetic consequences for animal health due to inbreeding depression and genotype monoculture. The need for an aquaculture genetic management system that both creatively uses and conserves or increases genetic diversity is emphasized.

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Agricultural Biotechnology Park in Public-Private Partnership

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ABSTRACT: Technology is the driving force for progress and advancement of agriculture. The key to alleviate the possible impact of market liberalization in the future is to coordinate public and private sectors and drive agriculture from primary production by farmers to technology-intensive production by agri-enterprises. The strategy of Taiwan agricultural development is to turn the original measure of assisting farmers with the application of traditional agricultural skills to new business model of innovation-oriented including harnessing cutting-edge technologies such as biotechnology, Information and Communication Technology (ICT) *etc*. Pingtung Agricultural Biotechnology Park (PABP), established by the Council of Agriculture (COA) and opened in December 2006, is the core base for Taiwan government to upgrade and industrialize the agriculture sector through the application of technology and partnering of public and private sectors as well as industry and academia. The park with its developed infrastructure, provides efficient administrative services and Research & Development and marketing supports to its park tenant enterprises. PABP has now successfully established the industrial cluster with over 100 park tenants, and will expand the base area to near 400 ha, which is capable of housing 180 park tenants with 6,000 job opportunities and an annual output value of USD 600 million. This article is to share Taiwan's experiences in integrating public, private and academia sectors to jointly advance traditional agriculture to technology-intensive, innovative, value-added and environmental friendly industry.

1. Introduction

Taiwan, located in subtropical area, is an island with mountains, warm climate, and abundant rainfalls. It is suitable for agricultural production, but vulnerable for diseases and pests. With natural disasters like typhoons, heavy rainfalls and earthquakes, it is inevitable to cause adverse impact on agricultural development. Due to the limited arable land, the average farm size per farming household is only 1.02 ha, which is the type of smallholder farming and the majority of farmers are part-time farmers (National Statistics, 2016). The agricultural production cost in Taiwan is high, and is less competitive with other countries. Recently, in order to cope up with the challenges of climate change, trade internationalization and liberalization, as well as the growing consumers' concerns on environmental protection and food safety, agricultural policies of Taiwan have to focus not only on the increase of productivity, but also on other aspects like raising agricultural value, ensuring farmers' welfare and profits, and enriching diverse agricultural cultures and rural life. It should also give consideration to the safety of consumers, recycling of resources, and ecological sustainability to shape the new agriculture which benefits all people.

Dr Su-San Chang is the Director General of Pingtung Agricultural Biotechnology Park (PABP) under the Council of Agriculture (COA) of Taiwan. She obtained her Ph.D. in Soil Science from University of California at Davis, USA. Dr Susan served in various government agencies of Taiwan. PABP is the only one science park dedicated for agricultural industry in Taiwan. Given its complete infrastructure, efficient administrative services and incentives for investment and R&D, the park has attracted more than 100 agricultural enterprises to base in the park with their total investment amounted to 350 million USD and have formed 6 industrial clusters of technology-intensive, high added-value and environmental friendly agricultural industries.

As most agricultural products are limited by short shelf-life, high transportation cost and high perishing rate, Taiwan agricultural exportation often confronts trade barriers such as the Sanitary and Phytosanitary (SPS) requirements set up by other countries. However, benefited by the fast development of value-added agriculture and biotechnology, it provides one important propellant to Taiwan's agricultural transformation. Related researches have shown that the development of value-added agriculture and biotechnology brings positive impacts on sustainable agricultural development. When agricultural skills and technologies are advanced, it can help agricultural development and increase the cost-effectiveness of the sector. Thus, in the industrial structure of new agriculture, the most vital role as well as the last part of industrial chain is the agri-enterprises, which focus on agricultural product processing and marketing. The sustainable and prosperous development of agriculture in Taiwan can be effectively created only through the competitive agri-enterprises and their innovative business model to process agricultural materials into value-added products, which are widely accepted by global consumers.

The strong capability of subtropical agriculture accumulated in Taiwan over the past 60 years, plus the establishment of PABP, the value-added industrial clusters set up in southern Taiwan by the COA of the central government is the core base to integrate public, private and academia sectors to jointly advance traditional agriculture to technology-intensive, innovative, value-added and environmental friendly industry.

2. PABP Incubates Agri-Enterprises and Facilitates Agricultural Development in Taiwan

The PABP, set up by the COA in accordance with the industrial trend and national policy, is to foster the development of technology-intensive, high value-added, and environment friendly agricultural biotechnology industry. The mandate of PABP is to develop agri-biotechnology talents, establish an industrial cluster, and promote the R&D, innovation incubation, and marketing of agricultural biotechnology products for sustainable agricultural development. The first phase construction area of the park is 233 ha. The base development planning and environmental impact assessment of the park were completed in 2003. After the accomplishment of infrastructure construction including site preparation, drainage, detention basin, underground pipelines, and landscape, PABP officially started its operations on December 21, 2006 (PABP, 2018).

Currently, all roads, underground pipelines including electricity, water, gas, sewage, and telecom are completed. The public facilities like import/export warehouse, Fortune Mall (containing Bank of Taiwan, restaurant, shops *etc.*), Sunny Chateau Residence (residential area for park tenants), community park, bike path, and water detention basins are all set up. Since more than 90 per cent of land for rental in the park has been booked, the Executive Yuan approved the "Expansion Project of Agricultural Biotechnology Park" on August 5, 2014 to increase 165 ha base area with one Multi-Functional Storage Area and one Industrial Talent Training Center, which will be accomplished by the end of 2019 to enlarge industrial cluster scale in the park.

The purpose of establishment of PABP is to offer the excellent investment environment to foster agricultural development and form an industrial cluster. Since one-stop services offers rapid administration efficiency, PABP administration is authorized by other relevant agencies to issue company registration, factory registration, construction/building use permit, import/export license, certificate of origin, and certificate of power for agricultural use *etc.* (PABP, 2018). The enterprises stationed in the park can enjoy the benefits of single-window administrative services, tax exemption in the bonded zone, one-stop convenient import/export customs clearance (including services of Customs, SPS competent authority, as well as Fish Disease Laboratory of Animal Health Research Institute), low-interest loans, R&D assistance, industry-academia collaboration and consultancy (PABP, 2018). Regarding industry-academia collaboration, there are Kaohsiung District Agricultural Research and Extension Station, Fengshan Tropical Horticultural Experiment Branch of Agricultural Research Institute, Tungkang Biotechnology Research Center of Fisheries Research Institute, which are the research institutes under the COA, adjacent PABP to support the R&D for park tenants. Besides, PABP has set up the Academia-Industry Consortium for Agricultural Biotechnology Park, and invited over 30 universities into it as the members in order to promote the cooperation between industry and academia. Some of them include National Taiwan University, National Cheng Kung University, National Pingtung University of Science and Technology, Tajen University, and Meiho University *etc.* This will help to fill in the abundant R&D resources and match up with park tenants, and increase companies' competitiveness by integrating various resources from public, private, and academia sectors.

The whole area of PABP has been set up as the bonded park to enhance the exportation of high value-added products, and accelerate the formation of the value-added agricultural industrial clusters for enhancing the functions of R&D, production, trade, and transshipment. PABP also coordinates the cooperation between farmers groups and park tenants and establishes the satellite farms supply system to offer the raw agricultural materials for making functional food, cosmetics, and Chinese herbal medicines as well as the cultivation places for ornamental fish exportation. The satellite farms are also used for testing and promotion of agro-bio materials like biofertilizers, biopesticides, feed additives, and animal vaccines *etc.* This aids in bringing the mutual benefits for the development of agriculture and PABP industries.

The key industries developed in PABP contain natural products for health and beauty, aqua breeding (including ornamental fish), husbandry material and animal health, agro-bio material, biotechnical services, and energy-saving and ecological agro-production system (PABP, 2018). Up to the end of April 2018, there are 104 enterprises approved to base in PABP and the total investment reached around USD 348 million. About 1,550 employments have been created and the output value is over USD 216 million in 2017. PABP keeps leading Taiwan agriculture towards technology-intensive, high value-added, and environment friendly agricultural biotechnology industries, and combining nearby academia and research institutes to build up the competitive industrial cluster. The current status and illustration of each cluster are listed in Table 1.

Table 1. Current status of industrial clusters in PABP (PABP, 2018)

Cluster	Products	Park tenants
Natural products for health and beauty	Functional food, herbal medicine, cosmetics, editable mushrooms and fungi etc.	TCI Co., Ltd., Kitoku Shinryo Co., Ltd., Taiwan Ariake Foods Co., Ltd.
Aqua breeding	Ornamental fish, aqua breeding, aqua-related peripherals etc.	Taikong Group, Skyfish Aqua Co., Ltd.
Agro-biomaterials	Biofertilizers, biopesticides, soil conditioners, control-release fertilizers etc.	Advanced Green Biotech Corp., Dayi Agritech Corp., Wellness Top Biotech Co., Ltd.
Husbandry material and animal health	Animal vaccines, feed additives, nutritional supplements (probiotics) etc.	Verbac Group, Chainwin Agrotech, T-Ham Co., Ltd.
Biotechnical services	Diagnostic kits for animals and plants, molecular analysis, food safety examination etc.	Favorgen Biotech Corp., JBM Co., Ltd.
Energy-saving and ecological agro-production system	Renewable energy, plant factory, aquaponics, automatic-controlled production facility	Hanns Top Biotech Co., Ltd., Hokto Corp.

3. Gaps between Public and Private Sectors during Development of Agri-Enterprises

Among the enterprises related to agriculture, forestry, fishery, and husbandry in Taiwan, since over 90 per cent of them belong to Small and Medium Enterprises (SMEs, the turnover is less than USD 3.33 million or employees are less than 100 people). They possess the advantages of innovation, flexible operation, long industry chain, and pooling-of-interest. However, such individual SME agri-enterprise is normally insufficient in operation, R&D, and ability to expand international market (SMEA, 2016). In this regard, in the process of propelling New Agriculture and New Southbound Policy (COA, 2018), those SMEs would confront many challenges and impacts. It is necessary to integrate the resources of public and private sectors and upstream/downstream industry chain to cope with this difficulty.

The gaps between public and private sectors during development of agri-enterprises are the following:

(i) For industry: SMEs possess the advantages of innovation, flexible operation, long industry chain, and pooling-of-interest. However, individual agri-enterprise is normally insufficient in operation, R&D, and the ability to expand international market;

(ii) For academia/research institutes: There are cutting-edge agricultural technology research and development achievements, particularly in the research institutes under the COA. Although the R&D staff own abundant practical experience and expertise, their research outcomes belong to different institutes. When we are developing smart agriculture and circular economy, it may be lack of the window to integrate those research results so that it cannot timely fill up the gaps of key technologies needed by enterprises; and

(iii) For authority: Taiwan government invests huge resources to foster the development of agri-enterprises. However, because agricultural biotechnology industry is still emerging, relevant regulations should respond accordingly to industrial developments. Enterprises also need to adjust their operation measures such as quarantine and inspection, biosecurity control of the entire production process *etc.* There is a need for a specific agency that is able to follow the industrial trend and manage relevant matters to effectively facilitate the industrial innovation and make a breakthrough.

4. Experience of Public-Private Partnering in PABP

Effective integration of the public-private resources like government, industry, and academia to create the favorable environment for enterprises' operations is the key to boom the industry. This is also the important purpose of the establishment of industrial parks like PABP. Thus, in order to fill up the gap of resource and demand between public and private sectors, PABP has taken the following steps:

4.1 Promoting agricultural technology and value-added industrial cluster, promoting industry- research institutes/academia cooperation to reinforce the competitiveness

Flagship enterprises such as animal vaccines, feed additives, aqua-breeding, biofertilizers, biopesticides, processing of agricultural products, diagnostic kits and testing, and protected agriculture are chosen as the core industries in PABP. This is done to attract academia/research institutes and upstream/downstream companies, which flock together to build up strong industrial group and strengthen their competitiveness in the global market.

4.2 Setting up satellite farms to establish the stable and safe tracing mechanism of raw material sources

Agriculture is different from other industries as the supply of raw materials could be affected by inevitable external factors such as growing season, climate, diseases, transportation and post-harvest handling losses. The stability of raw material quality and supplying quantity is the key factor for agri-enterprises to be ahead of the curve.

PABP integrates the competent authorities and academia/research institutes to introduce the technology such as organic agro-materials, general taxes on polluting activities, production management *etc.*, and to help farmers to sign the cooperation contract with agri-enterprises or farmers associations. This would promote farmers to join the supply chain as satellite farms and provide excellent raw materials to agri-enterprises. Agri-enterprises then turns the agricultural products into innovative agri-bioproducts through processing to expand the market and create a higher industrial chain value. Under this mode, agri-enterprises acquire the long-term and stable quality raw materials, while farmers also gain the profits and prevent from the price decreasing. This makes agri-enterprises support the transformation of traditional agriculture, and traditional agriculture is the backup for the development of agri-enterprises.

4.3 Strengthening technology transfer from academia/research institutes to industry to expand the market

In accordance with the New Agriculture Policy launched by Taiwan government, PABP integrates over 30 academia/research institutes with over 300 specialists and experts to set up the collaboration network for industry and academia/research institutes. It matches up the cooperation between agri-enterprises and academia/research institutes, and promotes the industrialization of research findings as well as encourages company to get involved in R&D. Meanwhile, PABP conducts the R&D subsidy programme with proper scale according to park tenants' demand to increase their core technology and facilitate the industrial upgrading. By doing so, the competitiveness of park tenants can be reinforced.

4.4 Simplifying the customs clearance procedure to stimulate the exportation

By integrating the services of various organizations/departments, namely, Customs Administration, Ministry of Finance-MOF (Kaohsiung Branch), Bureau of Animal and Plant Health Inspection and Quarantine, Animal Health Research Institute, and the import/export warehouse and logistics center, PABP keeps refining the functions of Service E Netcom and offers various rapid services like customs clearance, bonding system, quality control for control articles, biosecurity system for aquatic animals, E-account book *etc.*, which can assist park tenants to proceed customs clearance 24/7 through the logistics center with sound system and shorten the procedure for import/export.

4.5 Implementing the sound inspection and quarantine system in PABP

PABP integrates the Customs, Bureau of Animal and Plant Health Inspection and Quarantine and National Animal Health Research Institute to provide the services of 24/7 licensing operation system, rapid quarantine and customs clearance for easy exportation according to the request of park tenants. As for importation, PABP is continuously implementing the biosecurity system for aquatic animals and establishing the fish disease monitoring and control system for the companies and their suppliers to prevent from diseases at the beginning. This builds up the sound inspection and quarantine system in PABP to increase the agri-enterprises' competitiveness.

4.6 Taking care of both agricultural development and ecology conservation to build up the brand image of PABP

PABP frequently conducts various construction works and improvements in accordance with agri-enterprises' suggestions, and undertakes environmental impact assessment monitoring, and road and landscape maintenance to assure the whole environmental quality of the park. The park contains several tourism factories, which possess the functions of production, marketing and tourism, like Timing Pharmaceutical Co., Ltd. and JBM Co., Ltd. *etc.*, and functional utility facilities like Aquaculture Exhibition Center and a multifunctional living service area (including Industrial Talent Training Center), which would be completed by the end of 2018. This helps to promote the industry image, marketing, dining and accommodation, and, furthermore, integrates the local resources to build up the high quality image in international market.

4.7 Creating the environment for industrial innovation and sustainable development and pooling international and domestic investments

PABP devotes to building up favorable environment for talent flow, money flow, logistic flow, and information flow *etc.* As for talent flow, PABP actively organizes systematic training programmes, which combine theory and practices in the light of agri-enterprises' attributions and demands. As for money flow, PABP urges banking institutions to provide various financial services like import/export bills negotiations, currency exchanges, and financial loans *etc.* As for logistic and information flows, PABP has established the import/export warehouse, completed the autonomous management system, set up the international transshipment center for rapid customs clearance, and installed the cloud platform

(Service E Netcom) for park tenants' e-business. Through integrating talent cultivation, finance, venture capital and logistics, PABP builds up the sound development environment for industry and increases the cluster competitiveness.

4.8 Coordinating the administration resources to set up one-stop services

PABP is authorized by other agencies to set up one-stop services. All the administrative requirements, such as company registration, factory registration, construction permit, import/export license, and certificate of origin, can be done and approved by PABP. This would help park tenants shorten enterprises' investment timeline.

4.9 Integrating the resources of public and private sectors to expand international market and innovative business model

PABP invites the experts with the expertise in marketing channels and conducts the market expansion policies of preferential loans and New Southbound Policy to actively assist agri-enterprises to participate in the important business exhibitions, such as BIO Taiwan, Food Ingredient Asia *etc.*, and increase the industrial communication with Southeast Asian countries like Vietnam, Thailand *etc.*, and expand the international markets.

5. Conclusions

Trade liberalization is the world trend. Advancement in information technology gradually changes consumption patterns. Consumers focus not only on the product itself but also on the value the product brings. Taiwan agriculture is constrained by limited land with dense population, and it is difficult to take the advantage of economies of scale. However, with the support of public sectors on infrastructure and R&D, and those new varieties/breeds and innovative production technologies developed by farmers and research institutes, Taiwan agricultural products are competitive to similar products from other countries by means of providing premium quality products to consumers in international markets.

Technology is the driving force for progress and advancement of agriculture. Investments on the so-called "Green Gold" is lifting a burst of whirlwind worldwide. Advanced countries and multinational corporations are enthusiastically dedicating to agricultural technology R&D and industrialization. It turns the original measure of assisting farmers with the application of traditional agricultural skills to new business model of innovation-oriented. The strategy of Taiwan agricultural development cannot merely focus on production and sales of primary agricultural products, and ignore the value of harnessing cutting-edge technologies such as biotechnology, ICT, *etc.* The key to alleviate the possible impact of market liberalization in the future is to coordinate public and private sectors and drive agriculture from primary production by farmers to technology-intensive production by agri-enterprises. Promoting the commercialization and industrialization of research findings is the way to facilitate the new agricultural business development and to reach the goal of upgrading agriculture.

PABP is the core base for Taiwan government to upgrade and industrialize the agriculture sector through the application of technology and partnering of public and private sectors as well as industry and academia. PABP now has successfully established the industrial cluster with over 100 park tenants, and will expand the base area to near 400 ha, which is capable of housing 180 park tenants with 6,000 job opportunities and an annual output value of USD 600 million. In addition to expansion of the base, PABP is also undertaking the takeover of 'Taiwan Orchid Plantation' and the development of 'Taoyuan Agricultural Logistics Center' and 'Central Taiwan Agricultural High-Technology Park' to build up as the industrialization platform for the cooperation of public and private sectors in developing the New Agriculture of Taiwan.

PABP will keep integrating the resources from public and private sectors. Following the government's governance blueprint of innovation, employment, distribution and sustainability. PABP will carry out the policies including application of biomedical technology to agricultural industry, development of circular agriculture and smart agriculture, increasing the agricultural added value, and creation of international marketing channels *etc.* It will lead the transformation and upgrading of Taiwan agriculture by public and private cooperation.

PABP is more than happy to share the experience in public-private collaboration for agricultural industrial development, and look forward to cooperate with all countries in the world to create prosperity of agriculture in the region.

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Success of GM Maize in the Philippines

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ABSTRACT: The Philippines has history of policies supporting biotechnology research and development as early as 1979 and biosafety regulations since 1990. These two factors were the major reasons for the commercialization of a Genetically Modified (GM) crop approved for food and feed by the Philippines ahead of its neighboring countries. The regulatory system was ready for contained efficacy testing of GM maize, specifically MON 810 in 1997 leading to approval for large scale propagation in 2002. GM maize has been shown to positively contribute to national maize production and the welfare of farmers. Improvements in productivity and resource use efficiency in national maize production can be partially attributed to GM technology. GM maize farmers have been shown to benefit significantly, and area planted has increased from 10,769 ha in 2002 to 656,084 ha in 2016. Several transformation events have been approved for contained experiments, field trials, commercial propagation and direct use over the years. However, the Philippines currently faces regulatory changes brought about by legal challenges on Bt eggplant. Adjustments are needed to ensure that the benefits of modern biotechnology, and not just GM maize, are continued for national development.

1. Introduction

1.1 Biotechnology policies

The Philippines has a history of policies supporting biotechnology. The government has established biotechnology institutions starting with the National Institutes of Biotechnology and Applied Microbiology in the University of the Philippines (UP), Los Banos in 1979 and renamed it as National Institute of Molecular Biology and Biotechnology (BIOTECH-UPLB) in 1995 and became part of a network of molecular biology and biotechnology institutes of the UP System. On the other hand, the Department of Agriculture institutionalized their agri-biotech centers in 1995. The Philippine Genome Center under the UP Systems was launched in 2011, which is heavily involved in genomics and bioinformatics research.

The Philippines government recognized the potential of modern biotechnology for crop production, agriculture modernization, and a sustainable environment in various policy statements. Further, the Philippines celebrates the National Biotechnology Week yearly since 2004 to build public understanding of the technology and appreciation of its potential applications in the field of agriculture, medicine, industry and the environment.

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2. Enabling Regulations: Scientific Risk Assessment of GM Maize

The need for enabling biosafety regulations are needed side-by-side with biotechnology policies. Science based risk assessment is needed to ensure the safe and responsible use of modern biotechnology.

Executive Order 430 "Constituting the National Committee on Biosafety of the Philippines (NCBP) and for Other Purposes" was signed on October 15, 1990. It is said to be the first biosafety system in a developing country (BIC, 1990). This regulation allowed for contained testing up to multi-location trials of GM maize, specifically MON 810.

The Department of Agriculture Administrative Order No. 8 (DA-AO8) on "Rules and Regulations for the Importation and Release into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology" was signed on April 3, 2002 (BIC, 2002). With AO8, field trials, commercial propagation and deregulation came under the purview of the DA- Bureau of Plant Industry (DA-BPI). The commercial propagation of MON 810 was made possible under DA-AO8.

The Philippines signed the Cartagena Protocol on Biosafety on May 24, 2000 and it entered into force on January 3, 2007. Prior to signing the Protocol, the Philippines biosafety system has been based on voluntary disclosure. Declaration of genetically modified organism (GMO) presence in a product became mandatory after the Philippines ratified the Protocol.

Executive Order No. 514 on "Establishing the National Biosafety Framework, Prescribing Guidelines for its Implementation, Strengthening the NCBP, and for Other Purposes" was issued on March 17, 2006 (BIC, 2006). The Philippines was a beneficiary of the United Nations Environment Programme/Global Environment Facility (UNEP/GEF) Global Project on Development of National Biosafety Frameworks (NBF). The NBF was developed as a major output of this project (DENR-PAWB, 2004). Increase in area planted with GM maize as well as the use of GM products for direct use for food, feed and processing continued under EO 514.

3. GM Maize Approval and Utilization in the Philippines

MON 810 was the first corn line introduced for eventual large-scale cultivation in the Philippines (Ebora *et al.*, 2005). It went through the various stages of testing as shown in Table 1 (Carino, 2009; NCBP, 2018). The MON 810 Variety is preferred in the Philippines for feed but was evaluated as safe for food and feed. It is the first approval in Asia of a GM crop for food and feed.

Table 1. Stages of testing for MON 810 GM corn in Philippines

Stage	Approved by	Date
Contained efficacy testing	NCBP	September 10, 1997
Limited confined field testing	NCBP	August 25, 1999
Multi-location, two-season field testing	NCBP	June 6, 2001
Large scale propagation, Use as Food or Feed	BPI DA	December 4, 2002

The area planted to *Bt* corn in 2003 was 10,769 ha. From 2003 to 2005, only *Bt* corn was approved for commercialization. By 2006, herbicide tolerant GM corn as well as stacked insect resistant × herbicide tolerant varieties were available in the market. By 2008, farmers preferred the stacks more than the single trait GM corn. Area planted under GM corn in March 2016 was 656,084 ha, comprising almost entirely with stacked traits. All GM maize planted in the Philippines are preferred for feed but are approved as safe for food and feed.

4. Impact of GM Maize on National Maize Production

In Philippines, the area planted with commercial GM maize in 2015 was 0.68 million ha (Table 2 and Figure 1), compared with the total area planted with yellow maize in 2015, which was 1.3 M ha. (PSA, 2016). The average area planted and harvested in yellow maize was 1.05 ha with a range of 0.62 ha to 2 hectare in 2013 (PSA, 2014). Planting seasons can range from one to three depending on the area in the country (Gerpacio *et al.,* 2004).

Gonzales (2011) attributes improvements in productivity and resource use efficiency in national maize production partially to GM technology. The paper reviewed the introduction of new technologies in the corn subsector and used trend analysis and the production function approach. The analysis was conducted from 1991 to 2009. Marked improvements were seen after the introduction of GM maize. The impact of GM maize in production was determined through analysis of the following variables:

(i) In both human labor (Figure 2) and animal-machine labor (Figure 3), the amount of labor utilization is minimized for every metric ton of corn grain produced.

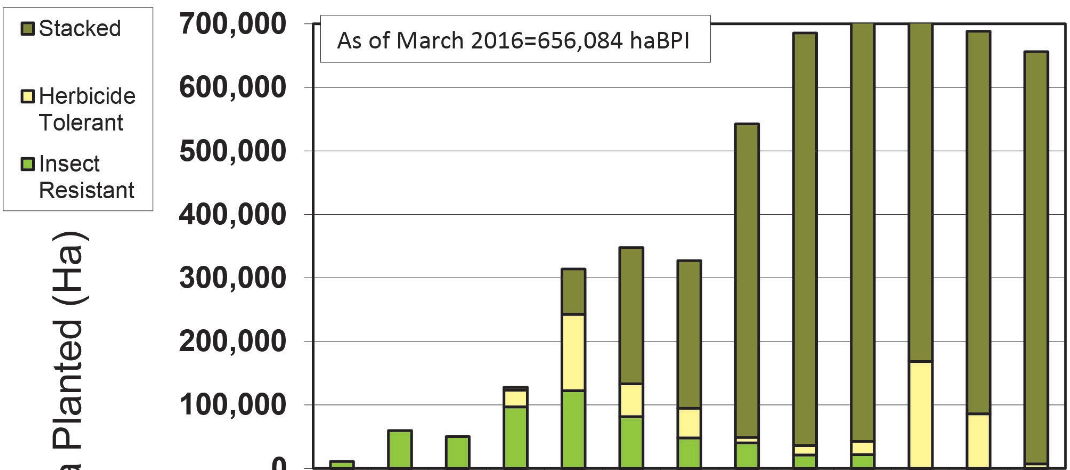
(ii) Chemical use efficiency data (Figure 4) shows a general increase in yield while there is a consistent decrease in application rate of farm chemicals (insecticides and weedicides).

(iii) Fertilizer use efficiency data (Figure 5) show a higher growth of yield compared to growth of NPK fertilizer use.

Table 2. Aggregate data of GM maize adoption by Region as of March, 2016 (DA BPI, 2016 and Figure 6)

Region	Area planted under GM maize (ha)	Rank
CAR	37,048	5
I	57,368	2
II	342,885	1
III	31,317	6
IV-A	5,866	11
IV-B	19,664	8
V	10,437	12
VI	27,708	7
IX	4,431	13
X	49,249	3
XI	1,172	14
XII	38,809	4
XIII	18,712	9
ARMM	11,418	10
Grand Total	**656,084**	

On the farm level, Yorobe and Smale (2012) determined that the use of GM maize has a statistically significant net-income increasing effect of 4,300.05 Philippine Pesos (US$82.70) per hectare. Data were gathered from August 2007 to February 2008 from 466 corn farmers randomly selected in major corn producing villages of major corn producing provinces.



	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014-15	2016
Stacked	0	0	0	4,580	71,279	214,438	232,394	493,599	649,130	676,806	559,628	602,026	649,037
Herbicide Tolerant	0	0	0	26,493	120,023	51,485	46,809	8,690	15,038	20,948	168,450	86,192.	7,047
Insect Resistant	10,769	59,756	50,009	96,800	122,593	81,651	48,022	40,235	21,205	21,693	0	0	0

Figure 1: *Area planted to GM Maize in the Philippines as of March 2016 (DA BPI, 2016)*

5. Capacity Building for Regulators

Capacity building for regulators must be combined with enabling regulations. In the early years, capacity building was focused on DA BPI as they were the single entry point for GM crop applications. However, while focus was on BPI, other government agencies were represented. Capacity building on environmental risk assessment and food safety assessment were conducted. The need for capacity building on insect resistance management was also addressed.

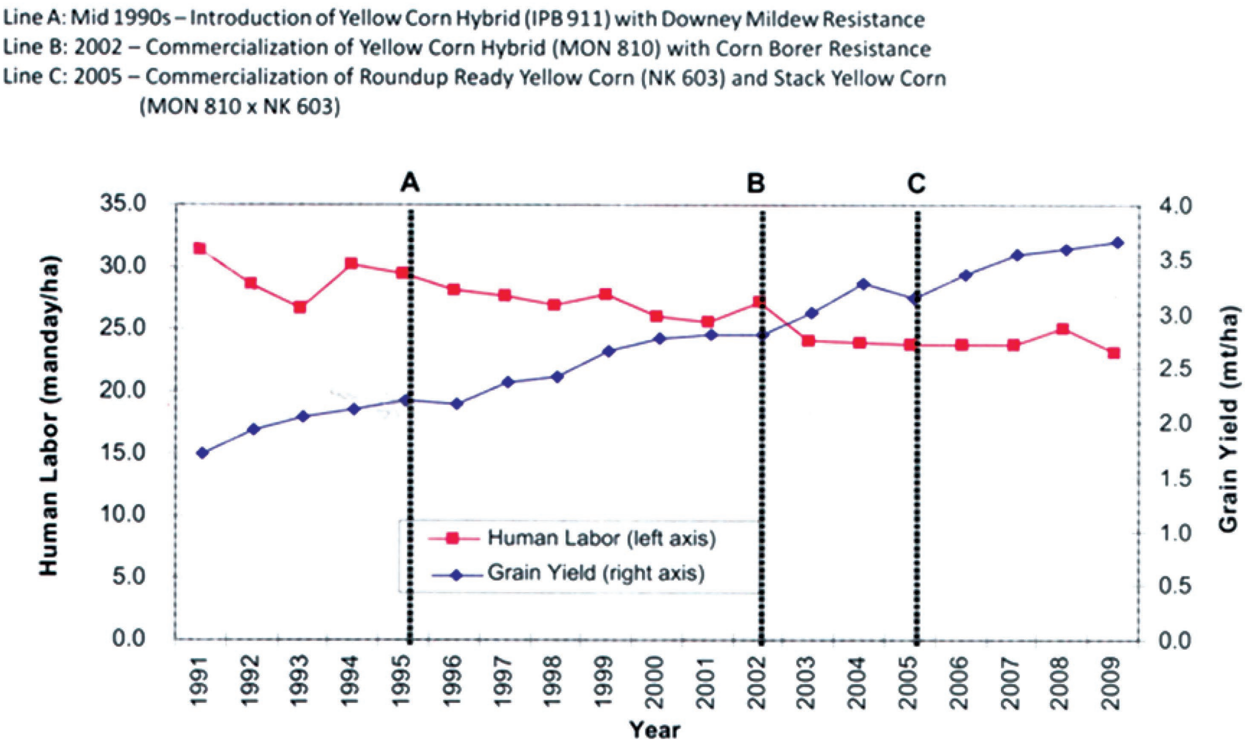


Figure 2: *Trends in Human Labor Use Efficiency of Yellow Corn, Philippines, 1991-2009 (Gonzales, 2011)*

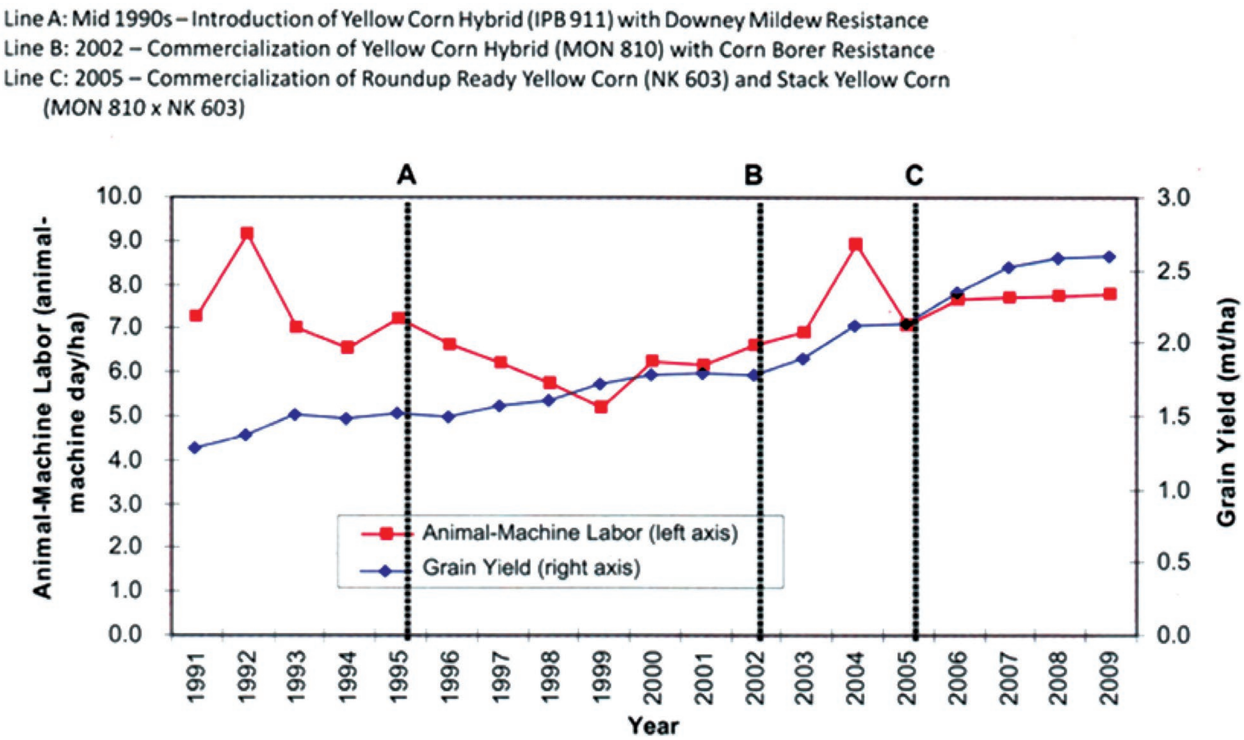


Figure 3: *Trends in Animal-Machine Labor Use Efficiency of Yellow Corn, Philippines, 1991-2009 (Gonzales, 2011)*

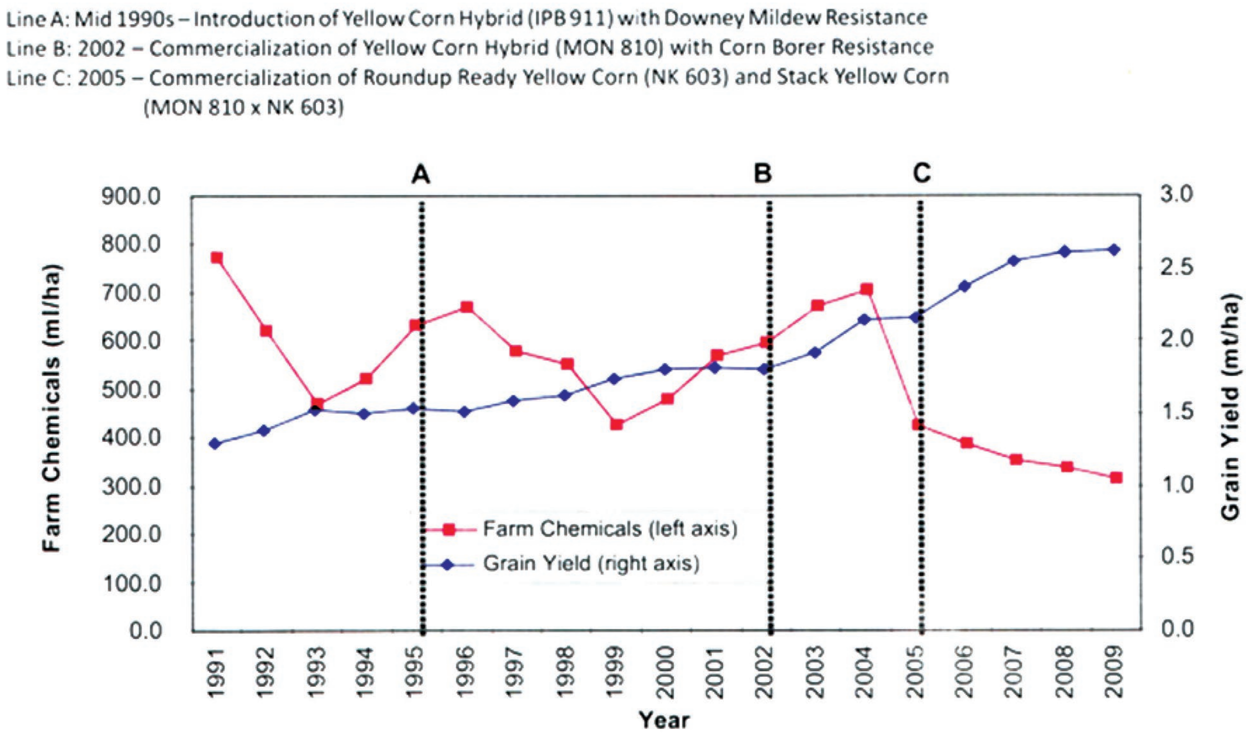


Figure 4: *Trends in Farm Chemical Use Efficiency of Yellow Corn, Philippines, 1991-2009 (Gonzales, 2011)*

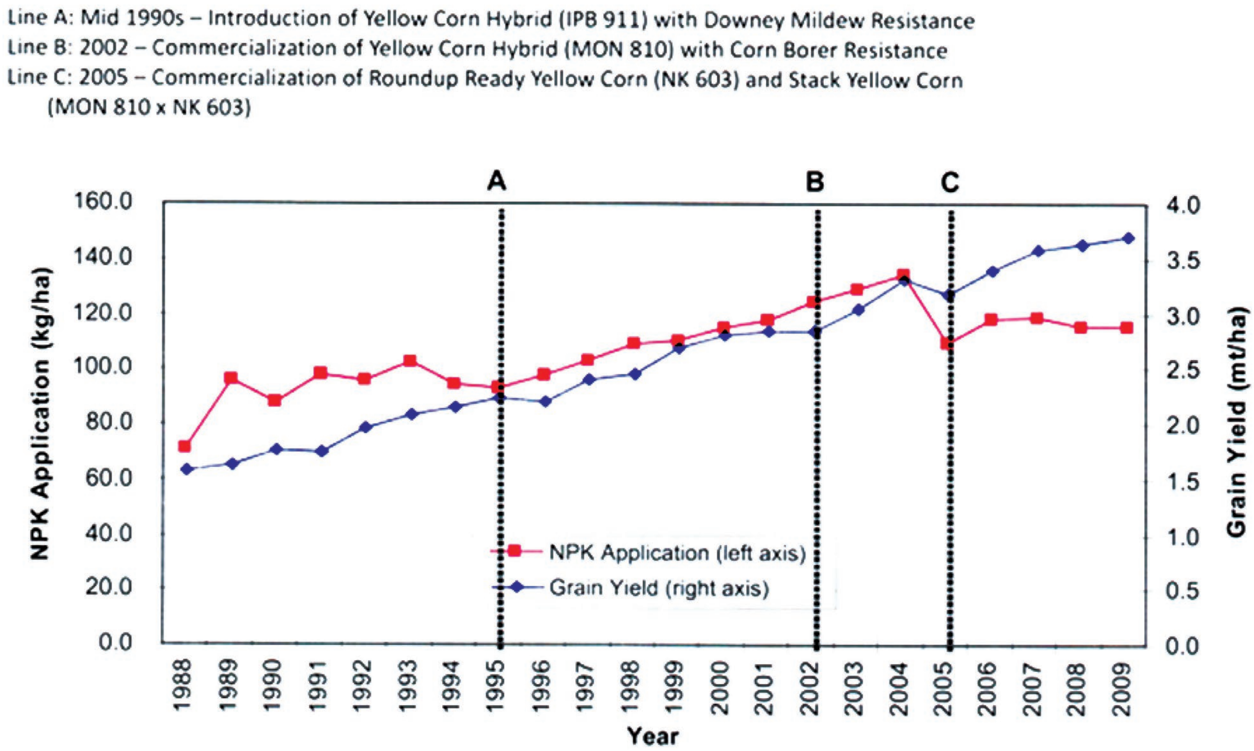


Figure 5: *Trends in Fertilizer Use Efficiency of Yellow Corn, Philippines, 1991-2009 (Gonzales, 2011)*

When EO 514 was promulgated, introductory capacity building for Competent National Authorities (CNAs) were conducted in anticipation of their greater roles. The capacity building was matched to the mandate of the agency such as conducting environmental risk assessment for the Department of Environment and Natural Resources (DENR), and food safety risk assessment for the Department of Health (DOH).

The Program for Biosafety Systems (PBS) is an international programme, which assists partner governments in the development of evidence-based regulatory systems through technical assistance and capacity building. It is managed by the International Food Policy Research Institute. PBS conducts these capacity building activities in partnership with relevant government agencies. PBS started capacity building activities in the Philippines in 2004 as regulatory agencies were still gaining proficiency in risk assessment and management of GM crops and products and has sustained its efforts through the years in response to capacity building needs.

6. Sustained Communication Activities

Information, Education, and Communication (IEC) activities are needed to keep stakeholders updated on scientific facts.

Proclamation No. 1414-2007, which declared every last week of November as the National Biotechnology Week (NBW), seeks to increase public awareness, education, and understanding of biotechnology for its responsible application and regulation. The Proclamation identifies DA, Department of Science and Technology (DOST), DOH, DENR, Department of Trade and Industry (DTI), Department of Interior and Local Government (DILG), and Department of Education (DepEd) to organize the NBW celebration yearly.

Various IEC activities were conducted. While GM maize has been adopted by farmers in major maize growing areas, communication training for collaborators of public sector GM crops was conducted to enable them respond to needs on-site. IEC campaigns to strategic sectors such as the legislative branch of the government and traders seek to ensure support for modern biotechnology. Engagement with the media, especially those covering the science and agriculture, make certain that accurate information reaches the public.

Institutions such as the International Service for the Acquisition of Agri-biotech Applications (ISAAA), Southeast Asian Regional Center for Graduate Study and Research in Agriculture-Biotechnology Information Center (SEARCA-BIC), and the Biotechnology Coalition of the Philippines (BCP) are at the forefront of IEC activities.

7. Joint Department Circular (JDC) No. 1, Series of 2016

JDC 1-2016 on "Rules and Regulations for the Research and Development, Handling and Use, Transboundary Movement, Release into the Environment, and Management of Genetically-Modified Plant and Plant Products Derived from the Use of Modern Biotechnology" was formulated as a response to the Supreme Court ruling of December 2015 on the *Bt* eggplant court case (JDC, 2016). A case was filed against the *Bt* eggplant in 2012. The court decision in December 2015 nullified AO8, as a result JDC 1-2016 was crafted (Genetic Literacy Project, 2015).

The defining characteristics of JDC 1-2016 are a response to the December 2015 ruling of the Supreme Court. Government Departments will have a greater role in biosafety assessments than in AO8. Public hearings for field trial applications were required. Information on socio-economic, cultural and ethical consideration became part of approval requirements. Requirements for community representatives in Institutional Biosafety Committees were specified as i) One of the community representatives shall be an elected official in the local government unit; and ii) the other community representative shall be selected from residents who are members of the Civil Society Organizations represented in the Local Poverty Reduction Action Team.

As of May 8, 2018, applications under JDC 1-2016 are as follows:

- Field trials
  - ♦ 1 on process (Golden Rice)
- Commercial Propagation
  - ♦ 1 approved (corn)
  - ♦ 2 on process (corn)
- Direct Use
  - ♦ 5 approved (soybean, corn)
  - ♦ 40 on process/pending (corn, cotton, alfalfa, soybean, canola, Golden Rice)

Figure 6: Top GM Maize Producing Regions in the Philippines

8. Conclusions

Benefits from GM maize have resulted in high adoption rates as farmers realize the advantage. This has also resulted in improvement in maize production on a macro level. Information campaigns regarding GM maize in particular and modern biotechnology in general, must be sustained so that the public can make an informed choice.

There is a need for capacity building for agencies now involved in the evaluation of GM crop applications to enable them to make science-based biosafety assessments. There is also a need for policy formulation fora to cover new requirements under JDC 1. Awareness building for stakeholders about JDC 1-2016 to enable an informed public discourse. Conversely, farmers' and traders' voices need to be heard in national dialogues. A sustained scientific outreach to legislative and judicial branches of the government is vital for legislations that are based on science.

It would also be advantageous for the Philippines to increase policy dialogues and information campaigns on gene editing technologies. The Philippines has shown through the GM maize experience that early preparations in research policies and regulations results in benefits.

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Investing in Agricultural Biotechnologies in the Pacific: Striving for an Effective Broad Stakeholder Alliance

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ABSTRACT: Secretariat of the Pacific Community (SPC) is an international organization that provides scientific and technical support to the development in the Pacific Region. The Land Resources Division (LRD) of SPC, provides expert scientific advice and services on agriculture and forestry, promoting the latest innovative and relevant applications for sustainable food and nutritional security and building the resilience of the Pacific Communities. The SPC LRD established the Regional Germplasm Centre (RGC) in 1998, changed its name in 2007 as The Centre for Pacific Crops and Trees (CePaCT), which is a unique resource that has access to and shares genetic resources with international gene banks around the world. The partnerships of LRD with international organizations in identifying climate ready crop diversity and pest and disease management, and the role of CePaCT in assisting Pacific Island countries and territories (PICTs) to conserve the region's genetic resources are highlighted in the present paper.

1. Introduction

The Secretariat of the Pacific Community (SPC) is an International Organization established by a treaty in 1947, owned, and governed by 26 members including 22 Pacific Island Countries and Territories (PICTs). It is one of the nine member agencies of the Council of Regional Organizations of the Pacific (CROP). It provides scientific and technical support to the development in the Pacific Region, which has three main goals, namely sustainable economic development; empowered and resilient communities; and communities that live long and healthy life. The Land Resources Division (LRD) is one of SPC's 10 Divisions and/or programmes. LRD's mission is to provide expert scientific advice and services on agriculture and forestry, promoting the latest innovative and relevant applications for sustainable food and nutritional security and building the resilience of the Pacific Communities.

To enhance food and nutrition security and build resilience, LRD promotes both programmatic effectiveness and operational efficiency. Programmatic effectiveness is realized through improved coordination and the establishment of synergies as well as by forging strong impact pathways. LRD postulates a few Integrated Programs (IPs) that will be the drivers for change contributing to the Sustainable Development Goals (SDGs). Operational efficiency is realized through principles of robust programme planning, budgetary management and improved project management.

***Mr Jan Helsen** is the Director of the Land Resources Division in the Pacific. His responsibilities include four thematic pillars (genetic resources, sustainable forestry and land use, sustainable agriculture and markets and value chains) and four integrated programmes (climate smart agriculture, pest and disease management, animal health and production and coconuts for livelihoods). Mr Helsen holds MSc of Science in Agricultural Economics from University of London. Mr. Helsen served in different capacities that include Leader, Resilience Initiatives in FAO for Horn of Africa and Great lakes Region; Project Manager for a food security Initiative at the International Institute of Tropical Agriculture (IITA) and for a pan-African Seeds Systems Project at the World Vegetable Centre and as Principal Agronomist at the African Development Bank.

LRD upholds a matrix structure that embraces four pillars in genetic resources, sustainable forest and land management, sustainable agriculture and markets for livelihoods and four IPs: (i) Pacific Seeds for Life (PS4L); (ii) Coconut Based Livelihoods; (iii) Climate Smart Agriculture (CSA) and (iv) Sustainable Forestry and Land Degradation Neutrality. The Division's core competencies concern CSA and pest and disease management and, from an operational perspective expertise in Planning, Monitoring, Evaluation and Learning (P-MEL), Information Communication and Knowledge Management (ICKM) and Research and Development effectiveness.

2. Biotechnology in Genetic Resources Management

LRD's business pillar lies in its genetic resources capacity; *i.e.* its capacity to conserve and use plant and tree crop genetic resources for food and nutrition security. The Centre for Pacific Crops and Trees (CePaCT) is a unique resource that provides support to the PICTs in climate readiness as well as to assist in combatting non-communicable diseases (NCDs). Through its partnerships with the Consultative Group for International Agricultural Research (CGIAR), CePaCT has access to, and shares genetic resources with international gene banks around the world (CePaCT, 2018). It also provides the Science for Purpose incubator for diversified partnerships such as Australian Centre for International Agricultural Research (ACIAR), Asia-Pacific Association of Agricultural Research Institution (APAARI), CGIAR, Food and Agricultural Organization (FAO), International Atomic Energy Agency (IAEA) and is the provider of integrated solutions for integrated deliverables.

CePaCT conserves the region's major food crops with over 2,100 accessions. It has the largest collection of taro diversity globally and maintains a unique global collection of over 1,100 accessions. Conservation is the centre's core activity, with priority given to the region's staple crops: taro, yam, sweet potato, banana, cassava and breadfruit. Distribution of climate ready crop diversity assists farmers to build their resilience to climate change and disasters. The Centre strengthens food, nutrition and trade security through sourcing and sharing crop varieties with farmers and partners. The Centre also aims to develop and improve protocols for screening, breeding, tissue culture, virus elimination, storage methods and rapid multiplication (Figure 1). CePaCT helps in building capacity for scientists and students on biotechnologies, including training for countries without tissue culture laboratories on handling and growing tissue culture materials. Conservation methods have improved over the decades from field collection, which proved vulnerable to pest and natural disasters. Cryopreservation is a long-term conservation method that is proposed to improve CePaCT's operations. The facility may be expensive to establish but it is cost effective for long-term conservation and does not carry the risk of somaclonal variation, which is inherent to long-term *in vitro* conservation.

In June 2017, the Global Crop Diversity Trust, a partner of LRD, carried out a review of its operations. This review highlighted several gaps and areas that would require support and postulated a number of high-level priorities for the short, medium and long run. In the short run, the intent is to making CePaCT an effective and cost-effective conservation centre; in the medium run LRD aims to reach

Figure 1. *Breeding and evaluation research performed on CePaCT crop varieties at Fiji's Koronivia Research Station field genebank.*

out and build the capacities in conservation through a community of practice – the Pacific Agriculture Plant Genetic Resources Network (PAPGREN) and, in the medium to long-run to establish a Centre of Excellence (CoE).

The realization of a CoE urges the introduction of a Quality a Management System (QMS) and Standard Operations Procedures (SOPs) to be developed. These protocols will benefit the Centre in attaining its core needs, collective core needs and in enhancing improvement in collection and outreach. The integration of CePaCT with the Pacific Islands Tree Seed Centre (PITSC) is another ongoing upgrade that is being implemented. Other factors that require attention are the administration: programme development, human resources and capacity building. LRD requires support for its core gene-bank operations, core collective needs and for the collection, outreach and partnerships.

Virus indexing is one of its major activities, using molecular diagnostic techniques such as Polymerase Chain Reaction and Enzyme-linked immunosorbent assay to detect viruses present in the plants and animal specimen. Once detected protocols such as meristem extraction and thermotherapy assist in the elimination of these viruses in plants. Other technologies include a bioreactor system based on temporary immersion. Sourced in 2011, its major objective is to improve access to quality planting material. Mass propagation protocols improved subsequently which resulted in increased demand for bioreactors (Figure 2).

Figure 2. *Bioreactor Temporary Immersion system used to mass propagated crops requested by countries and supports urgent requests during natural disasters.*

3. Biotic Stress Management

Many pests, diseases, natural disasters and nutritional deficiencies affect the Pacific region. This has prompted LRD to increase research on crop tolerance and import improved crop varieties from other CGIAR centres with tolerant traits. As part of an IP on CSA, LRD is at the fore in the evaluation of CSA while it has a number of participatory breeding initiatives for adaptation to climate change. These and other varieties are incorporated in multi-location trials at farmers' level to assess their climate readiness in integrated crop-livestock home garden models. The LRD is also modelling a number of soil fertility protocols for the Atoll Countries.

One of the bigger threats in recent years concerns the increased incursion of pests and diseases, notably the rapid spread of the coconut Rhinoceros beetle (Guam Strain) and Bogia disease which, especially in Melanesia is having a fast impact on coconut based livelihoods and that threatens the existence of the only regional coconut genepool in PNG. With other Research for Development partners (R4D) partners, LRD established a concerted coordination mechanism for awareness creation, early warning, green waste management and improved phyto-sanitation, increased border and post border surveillance and research on biological control.

4. Fostering Partnership

From a partnership perspective, LRD will be adding value to the design and implementation of future programmes in joint programme development. Existing partnerships will be deepened to support the quest for essential R&D services in the Pacific. New partnerships will be forged with national, regional and global organizations to address the issues of innovation, scale and scope. An important factor in the partnership arrangements is its relative contribution to both operational and programmatic effectiveness and efficiency. LRD anticipates that partnerships will aim at complementarity and thus contributing to the development puzzle rather than to duplication.

LRD sees itself as the glue in the Pacific region. It is strengthening its relationships with R4D partners notably ACIAR, Crop Trust and FAO's International Treaty on Plant Genetic Resources. It also pursues a One-Health approach in addressing the nexus of animal, public and environmental welfare. Specialized partnerships that foster innovation, learning and impact will be nurtured while partnerships that deepen our Research for Purpose capacity will be enhanced (Landcare; agriculture research). Global development programmes within the context of NCD and improved adaptation to Climate Change are with partners such as the Green Climate Fund (GCF), Global Environment Facility (GEF) and accredited partners including German Agency for International Cooperation (GIZ), FAO among others. Partnerships with the French Overseas Territories (New Caledonia, French Polynesia, Wallis and Futuna) will be strengthened with support of the European Union.

The APAARI would be a great addition to this partnership for improving the services at SPC's CePaCT. APAARI has an extensive network of members from research institutes, genebanks, research and development centres, universities, extension services and civil society. This network would not only improve CePaCT's performance but LRD activities too. APAARI's linkage and collaboration with its wide network has bridged national, regional and global stakeholders for a collective change in agri-food systems in Asia and the Pacific. This experience would assist LRD and CePaCT to bridge the gap that has affected our efforts to serve the region effectively and efficiently.

5. Conclusions

The LRD is an integral part of the SPC and it's mission is to provide expert scientific advice and services on agriculture and forestry, promoting the latest innovative and relevant applications for sustainable food and nutritional security and building the resilience of the Pacific Communities. CePaCT acts as a pillar for LRD in conserving genetic resources and has access to and shares genetic resources with international gene banks around the world. LRD is strengthening its relationships with R4D partners, namely ACIAR, Crop Trust and FAO's ITPGRFA. LRD's linkages with APAARI network would be highly beneficial in improving the services at CePaCT. New partnerships will be built with national, regional and global organizations to address the issues of innovation, scale and scope.

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Leveraging Funds for Basic Research in Agricultural Biotechnology: The ICGEB Experience

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ABSTRACT: In times of shrinking public budgets, obtaining financial resources to support scientific research is becoming ever more challenging. Basic research in agricultural biotechnology also follows the same path, and research institutes and universities need to be prepared for the challenge. There are strategies that can be pursued at the policy level to foster partnerships, particularly public-private partnerships, such as the agricultural European Innovation Partnership (EIP)-Agri initiative, promoted by the European Commission, and there are actions that can be implemented at the local level, in universities and research centres to increase the level of funding. Building upon the experience of the International Centre for Genetic Engineering and Biotechnology (ICGEB), an inter-governmental organization and a unique international research centre composed of 64 Member States and having research laboratories in Italy, India and South Africa, this contribution aims to describe current and emerging challenges in fundraising and attracting investments and it also proposes strategies to tackle these challenges. We have found that one set of elements appears to make a difference when evaluating a proposal for partnership or funding: networking with key actors in the arena, developing quality collaborations and project proposals, in addition to the accountability and reputation. Proper policies for the management of the Intellectual Property Rights (IPRs) are also an enabling factor for attracting investments. The necessary legal obligations in the context of the Nagoya Protocol on access and benefit sharing of genetic resources are also explored.

1. Introduction

Research organizations and universities have more than an educational role to play in helping countries achieve the Sustainable Development Goals (SDGs). They have the responsibility to anticipate the human capital needs of future societies. In this context, the challenges that basic research is facing in all fields, and in the field of agricultural biotechnology in particular, is shortage of public funds, an increase in top-down and highly competitive funding mechanisms, and weak dialogue between academy and industry. According to the 'UNESCO Science Report, Towards 2030' (UNESCO, 2015), a tension between competing objectives of scientific excellence and scientific practice characterizes much of the South-East Asian Region.

At a policy level, this implies that governments are confronted with a dilemma whether to make science respond to short-term economic objectives, which could be detrimental to many areas of research that underpin socio-economic development in the fields of health, environment and education or to find strategies to foster these areas and address global sustainability challenges through appropriate Science

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and Technology (S&T) policies. The International Centre for Genetic Engineering and Biotechnology (ICGEB) conducts its activities within this context as a unique international constituency guided by eminent scientists.

The Asia-Pacific region (APR) has established itself as a major source of global economic development, and the development of biotechnology is well-established, although it is not evenly implemented. The creation of Association of Southeast Asian Nations (ASEAN) in late 2015 was a key undertaking to boost economic growth in the region and to spur both the cross-border movement of researchers and greater specialisation. Countries are increasingly collaborating with one another (UNESCO, 2015). For example, India has the third biggest biotech industry in the APR, which is recognized for developing the second highest number of USFDA-approved plants, and is especially noted for being the leading producer of Hepatitis B recombinant vaccine.

2. Background Information on the ICGEB

The ICGEB is an inter-governmental organization with the unique mandate of fostering research, capacity building and technology transfer in Life Sciences, with the ultimate purpose of promoting sustainable global development. The ICGEB forms an interactive network of internationally recognized scientists and state-of-the-art laboratories with 64 Member States and more than 20 signatory countries (Figure 1).

The Organization offers a unique technological and educational platform to promote scientific learning and innovation, supporting its Member States in progressing towards the achievement of the 2030 Agenda on Sustainable Development. The ICGEB's activities aim to reap the benefits that modern biotechnology can provide in solving major problems affecting health, nutrition, agriculture, food security and industrial development. It does this through an interacting, multi-faceted approach incorporating combinations of: cutting-edge scientific research in life sciences, both basic and applied, in its component laboratories in Italy, India and South Africa, as well as in its affiliated centres, and forthcoming Regional Research Centres; research is undertaken by staff, and pre- and post-doctoral researchers funded by long-and

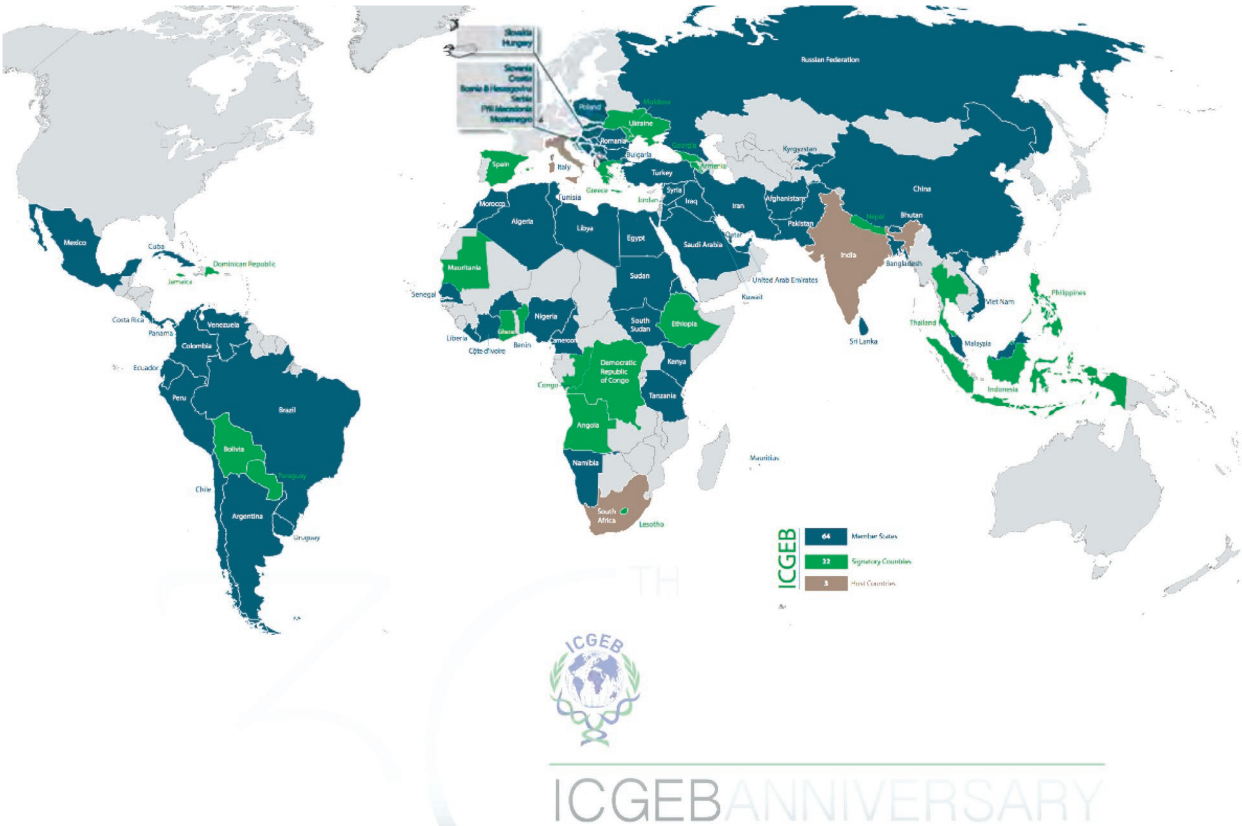

Figure 1. *The ICGEB Constituency*

short-term fellowships (ICGEB, 2018) and collaborative research grants and Early Career Return Grants (ICGEB, 2018a).

The above programmes interweave into capacity enhancement and scientific knowledge dissemination efforts at the individual level through the organization of conference and meetings (ICGEB, 2018b) and at the institutional level, via the provision of technical assistance and advisory services, especially focussing on technology transfer to industry (ICGEB, 2018c) for the production of biotherapeutics, diagnostics and vaccines, and agricultural products; and on their regulation by national governments, particularly in the field of biosafety (ICGEB, 2018d).

The demand for more efficient and sustainable agriculture, able to cope with the exponential increase in the human population and the constraints imposed by current climate changes, is growing in the ICGEB community. Genetic engineering of plants, development of eco-friendly biofertilizers, and other agricultural biotechnologies, together with molecular studies on the resistance of plants to biotic and abiotic stress, are among the main research topics (Box 1).

Box 1. ICGEB Research Groups in the Areas of Agricultural Biotechnology

ICGEB Research Groups in the field of improvement in food production and nutritional yield

In New Delhi, the Crop Improvement Group modifies rice plants to protect them against adverse environmental conditions by reducing oxidative stress, using the most recent targeted genome editing technologies based on CRISPR/Cas9.

The Nutritional Improvement of Crops Group aims to improve the nutritional value of food by generating cereals, legumes and tomatoes free of phytic acid, which sequesters micronutrients from being absorbed by the gut. It also seeks to obtain non-selective herbicide-resistant rice plants for weed control, in addition to identifying genetic solutions to avoid premature ripening of fruits post-harvest.

The Plant Transformation Group aims to improve the cotton plant by introducing genes that confer insect and virus resistance and improve the fiber quality. This Group also expresses enzymes important for biofuel production, such as xylanase in tobacco plants, through chloroplast transformation.

The Bacteriology Group in Trieste focuses on interkingdom signaling between plants and plant-associated bacteria, with special attention to beneficial bacteria and emerging bacterial plant pathogens of rice and other food plants. In addition, the Group has a programme to isolate and identify bacterial endophytes, to be developed as plant probiotics. The Bacteriology Group has a large and unique collection of endophytes and is collaborating with industry to develop microbial products as biofertilizers.

ICGEB Research Groups in the field of edible plant biotic and abiotic stress

In New Delhi, the Plant Insect Interaction Group studies the interaction of the rice plant with the Asian rice gall midge, an insect responsible for considerable yield loss for farmers in Asia and Africa.

The Plant RNAi Biology Group is interested in elucidating the RNA interference mechanisms operative in rice plants in response to increasing soil salinity, high temperature and virus infection, all conditions of particular importance due to current climate change.

The Plant Stress Biology Group develops genetic solutions to solve the problems posed in agriculture by the abiotic stress caused by salinity and drought. In particular, the Group modifies rice plants with several genes that reduce cellular toxicity, permitting plants to grow in soils with high levels of salt and metal ions and low levels of water.

The Industrial Biotechnology Group, located at the ICGEB Outstation in Argentina focuses on the development of biotechnological products and processes to be used in agriculture and industry, specifically on the study of endophytic bacteria having beneficial effects for crops.

The main opportunities available for ICGEB members to expand research and training in these areas, are represented by its core programmes that are briefly outlined in the sections below.

3. Fellowships

Each year, through the launch of two calls, the ICGEB assigns a number of Fellowships to young scientists to undertake research in its laboratories to pursue a Ph.D. degree (Pre-doc), to perform research at the post-doctoral level (Post-doc), or to perform short periods of research (Short-term Fellowships) to acquire specific knowledge and research techniques. The programme also supports research collaborations between laboratories located in ICGEB Member States through the SMART Fellowship Programme, thus, promoting South-South Cooperation. In 2017, 28 Fellows from Asian countries (plus others covered by extra-budgetary projects) were on board at the ICGEB Components. In the context of an agreement signed between the ICGEB and the Chinese Ministry of Science and Technology, a new call for fellowships will be published for scientists from ICGEB Member States in the region to perform research projects in top scientific laboratories in China.

4. Meetings and Courses Programme

Through an annual call dedicated to its Member States, the ICGEB organizes over 30 practical and theoretical courses per year, on subjects at the forefront of biomedical research and biotechnology applications, with the aim of facilitating interactions between internationally renowned scientists and young researchers from Member States. On an average, over 1,200 researchers participate in ICGEB events from all over the world each year. In the years 2010-2017, approximately 1,600 participants were from Asian countries. Meetings, courses and seminars were recorded and distributed freely through podcasts and on iTunes U, Apple's digital platform. Each month, over 11,000 users from over 80 different countries preview and download ICGEB's scientific videos. Scientists of ICGEB laboratories are also actively involved in dissemination events laid for the public and for ICGEB supported scientific events in Asia in 2018 (Table 1).

Table 1. Scientific events organized in the region in the context of the meetings and courses programme 2018

Event type	Title	Location	Dates in 2018
Workshop	Smart metabolic engineering of plants for drug biosynthesis	New Delhi, India	16-17 March
Conference	ICGEB-NASSL South Asian Biotechnology Conference 2018	Colombo, Sri Lanka	28-30 March
Course	Theoretical and practical genomics of parasitic zoonoses: diagnosis, epidemiology, phylogeny and evolution	Hanoi, Vietnam	10-12 June
Workshop	Viruses and RNAi	New Delhi, India	4-6 October
Workshop	Plant responses to light and stress: emerging issues in climate change	New Delhi, India	10-12 October
Workshop	VI ICGEB Workshop on Human RNA Viruses	Shanghai, China	26-28 October
Course	New frontiers in algal omics	New Delhi, India	19-30 November

5. Collaborative Research Programme (CRP)

A research grant mechanism for laboratories located in ICGEB Member States is available through the CRP, a dedicated source of funding aimed at financing projects addressing original scientific problems of particular relevance for the host country, but which are also of regional importance.

Established in 1988, the programme aims to stimulate collaborative research in Member States with the ICGEB Component laboratories, to promote the training of young scientists and to facilitate the creation of appropriate research facilities. To date, over 500 projects have been funded, for a global financial commitment of almost 21 million. In the period 2010-2017, approximately 20 per cent of the resources were dedicated to CRPs in the fields of Plant Science & Agriculture, Industry & Environment. Since 2015, 25 projects have been funded in Asia and at present, 7 CRP projects are active in the region. For CRPs awarded in this area in the period 2015-2017 (Table 2 and Figure 2).

Table 2. CRPs awarded in the Asian region in the period 2015-2017

Country	Project Title	Year
Vietnam	Co-expression of the Arabidopsis AVP1 and NHX1 to enhance salt tolerance in transgenic soybean (*Glycine max* (L.) Merrill)	2015
China	The role of RABL4 small GTPase IFT27 in IFT-BBSome coupling of cilia	2015
India	Structural basis of Dock3-NEDD9 interactions and their role in tumour cell plasticity	2015
China	Identification of novel hypoxia induced radioresistance signaling for endemic nasopharyngeal carcinoma	2016
Vietnam	Development a simple, low-cost, high sensitivity fluorescent biosensor for hydrogen peroxide (H2O2), glucose and cholesterol sensing based on ZnO nanorods decorated metal nanoparticles	2017
Bangladesh	Elucidation of taxol biosynthetic pathway in entophytic fungi Grammothele lineata - SDL-CO-2015-S1	2017
Malaysia	Mode of action of a new antibiotic Phomopsidione on Pseudomonas aeruginosa	2017
Pakistan	Development of recombinant vaccine to combat inclusion-body hepatitis-hydropericardium syndrome in poultry	2017
Sri Lanka	Development of an antigen-based immunodiagnostic test for Leptospirosis	2017
Malaysia	D-amino acids as potential modulators of age-related functional decline in natural and accelerated aging	2017

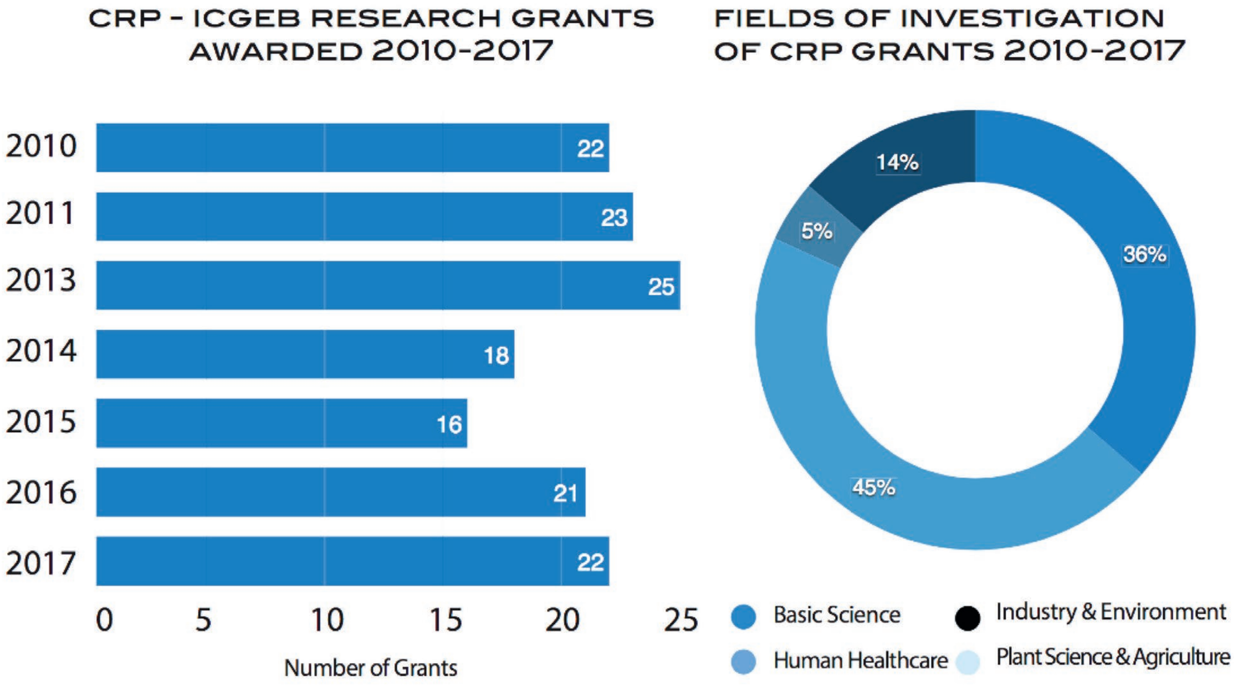

Figure 2. *Number of CRP - Research Grants awarded 2010-2017 and fields of investigation*

Similar programmes could be easily replicated at a regional level, focusing on basic research for agriculture biotechnology, thus favoring collaboration among scientists facing similar challenges.

6. Technical Assistance in the Area of Biosafety

The ICGEB also represents a scientific reference point for Parties that have ratified the Convention on Biological Diversity. Through its Biosafety Group, the Centre assists its Member States in enhancing their capacity to identify, regulate, manage and monitor biotechnological products, with particular reference to the establishment of national GMOs regulatory frameworks and offices. The Group is working mainly with countries in sub-Saharan Africa and in Latin America and the Caribbean, in partnership with the Bill & Melinda Gates Foundation, and the United Nations Environment Programme-Global Environment Facility (UNEP-GEF), respectively. Major achievements in 2017 include the adoption of the CARICOM's Regional Policy on Biosafety, and the adoption of the National Biosafety Bill in Uganda. Recently, discussions have been held with a number of countries to co-develop projects for the provision of technical assistance in the field of access and benefit sharing and traceability of genetic resources.

7. Partnerships

To promote institutional activities that are instrumental in fulfilling its mission, and at the same time to pool resources and efforts in relevant research and capacity enhancement areas, the ICGEB is actively working in partnership with other regional and international institutions such as the EC Joint Research Centre (JRC), United Nations University (UNU), International Centre for Theoretical Physics (ICTP), The World Academy of Sciences (TWAS), United Nations Inter-Agency Committee on Bioethics (UNIACB), Organization for Economic Cooperation and Development (OECD), United Nations Industrial Development Organization (UNIDO), World Health Organization (WHO), Association of Brazil, Russia, India, China, South Africa (BRICS) and COMSATS, among others. These collaborations are usually in the form of Memoranda of Understanding, defining joint activities or implying exchange visits and joint participation in regional fora and working groups. The purpose is to combine complementary skills, competencies and networks.

8. ICGEB Regional Research Centres

In 2016, the ICGEB launched a new initiative aimed at establishing new international seats for the activities of the Centre, the ICGEB Regional Research Centres (RRC). The RRCs will be national-based institutions benefitting of the scientific technical assistance of the ICGEB and will aim (i) to conduct scientific research to the highest international standards, according to the needs of the Hosting Country and other countries in the same geographical area; (ii) to provide an international centre for short- and long-term research training activities, and (iii) to enhance the biotechnological capacity of the scientific community in the geographical region.

At the Board of Governors convened in Trieste, Italy on 10-11 May 2018, Sri Lanka will submit its proposal to establish an ICGEB RRC with the objectives of supporting biotechnology research and innovation in alignment with national and regional priorities, of facilitating and supporting the adoption of cutting-edge biotechnological innovations, and of developing strategic partnerships with universities, public research institutes, private sector, and global biotech centres-of-excellence. Among many others, crop improvement and bioproducts are research fields to be strongly supported in the future Centre. The RRC that will soon be established in Taizhou Medical Hi-Tech Zone in China, is in advanced stage of development and will focus on vaccines, biological products, and diagnostics.

9. Fundraising, Technology Transfer and Innovation

In the past few years, the ICGEB began to expand its capacity to raise additional funds for research activities and collaborations with industrial partners. An office dedicated to Fundraising, Technology Transfer and Innovation (FTI) was established in 2017 with the mission to implement a fundraising strategy, develop technology transfer activities, and identify new business models to support the implementation of the ICGEB General Programme. It provides research support services, assisting scientists in obtaining new funds, dealing with intellectual property-related issues and technology transfer.

9.1 Fundraising

Additional funds are raised mainly by responding to national, European and international calls for proposals. The FTI office assistance ranges from the dissemination of relevant funding opportunities, to proposal formulation and revision. These calls have proved to be good channels for funding collaborative scientific projects and promoting further scientific networking and exchange of best practices. The high-caliber of ICGEB research activities is reflected in the ability to attract research funding from prestigious international funding bodies, including the Bill and Melinda Gates Foundation, the Wellcome Trust, the European Commission and the European Research Council, Telethon, AFM Téléthon France, among others.

In the context of Bilateral Scientific and Technological Collaboration Programmes promoted by the Italian Ministry of Foreign Affairs and International Cooperation (MAECI), Italy has signed agreements with many countries, including several in South-East Asia. For example, the ICGEB has been awarded the project "The role of microbiome in rice plant health" in the framework of the S&T collaboration programme with Vietnam (2017-2019). Partners in the project are the Bacteriology Group of the ICGEB Trieste and the Microbial Ecology Laboratory, Institute of Microbiology and Biotechnology (IMBT) of the Vietnam National University Hanoi (VNUH). Rice is the primary staple food and its cultivation has to face biotic and abiotic stresses related to drought, climate changes and pests. Results obtained within this project could provide avenues for the design of microbial solutions for a more sustainable rice agriculture with a decreased use of pesticide and an increased attention to human and environmental health.

In Europe, a large amount of scientific research is funded through Horizon2020, which is the 8th Framework Programme (FP) for research and innovation funded by the European Commission, running from 2014 to 2020, with an overall budget of 77 billion. One of the core characteristics of H2020 is to be "open to the world", allowing European researchers to collaborate with their counterparts worldwide on any topic, and it is envisaged that the next FP (2020-2027), currently under development, will be similar. In addition, a number of topics, also related to agricultural biotechnology, have been flagged as being particularly suitable for international cooperation, and consortia are encouraged to include non-EU partners (EC-RIPP, 2018). This may provide an opportunity for scientists in South Asia to reach out to collaborators and colleagues in Europe, who may be actively looking for partners with whom to prepare a call. Furthermore, the H2020 Work Programme on "Food security, sustainable agriculture and forestry, marine, maritime and inland water research and the bioeconomy" includes calls specifically dedicated to agricultural research (H2020, 2018). Considering that among the G20 Countries Europe is still a key player for world shares of Gastroesophageal reflux disease (GERD), researchers, publications *etc.*, the opportunities offered under H2020 could also contribute to boost the quality of research and innovation activities in the South Asia region.

The H2020 Programmes offers also fellowship schemes open to researchers worldwide in any field of science: the 'Marie Skłodowska-Curie Actions (MSCA)' has been the European Union's main programme for researchers' career development since 1996. The MSCA foster innovation, research-business cooperation and include a strong international component. The scheme is open to researchers at all career stages and for flexible funding periods; and mobility between countries is a condition (or must have happened recently) and a strong accent is given to participation of non-academic organizations (H2020, 2018a).

In addition to competitive research grants, the FTI office also contacts big donors, charities and international foundations, such as the OPEC Fund for International Development (OFID), the Swedish International Development Cooperation Agency (SIDA), the German Agency for International Cooperation (GIZ), to propose specific projects to be funded or co-developed.

9.2 Major Challenges

Based on our experience, one of the major shortcomings in this context is that the curricula of university programmes in the Life Sciences do not include subjects such as grant writing, project management and IPRs management. These skills are often crucial when scientists commence their career in either academia or industry, as they increase the ability to attract public or private funding in the very competitive research and innovation context. As the scientific excellence of the research proposal is taken for granted, the ability to highlight the potential scientific and social impacts of the project and to describe ways to maximise exploitation opportunities for basic research results, come into play. Generally speaking, many donors will evaluate proposals by their answers to the following questions: what is the expected impact of the project on the research area? Have adequate measures been planned to ensure communication and dissemination of results? Does the project reflect a robust logical framework?

On the other hand, in the particular case of basic research, a long-term risk should also be considered: the shift of human capital from basic questions animated by scientific curiosity, to industry-driven priorities. In this scenario, the establishment of a fundraising and technology transfer office dedicated to supporting research and research collaborations by increasing the level of funding deriving from international projects, foundations, funding bodies, *etc.*, represents one way for universities to retain their best scientists while pursuing public-driven objectives.

The FTI office is also trying to establish durable partnerships with private foundations and companies to support innovative funding schemes, sponsorships and new Research Collaboration Agreements (RCA). As an example, the “Bridge-the-Gap” scheme, supported by a private foundation, and the “Made in Trieste” project, supported by the Region Friuli Venezia Giulia in Italy, are helping to fund small and specific research activities in ICGEB laboratories for the advancement of early stage and/or patented technologies towards industrial development and commercialization. In our experience, the support of foundations, accelerators and brokers is quite important to advance basic research and the Technology Readiness Level (TRL)[1] of new biotechnology products and processes to be able to attract bigger investments from industry.

The ability of Principal Investigators to network with colleagues participating in conferences, brokerage events, calls for experts and evaluators, and to become a member of major international associations dedicated to the research field of interest, certainly increases the opportunity to leverage resources for their activities. The accountability and reputation of the research institute is finally essential when it comes to fundraising.

9.3 Technology Transfer

It is now widely recognized that progress towards knowledge-based societies depends crucially on each country acquiring, developing, managing and properly applying appropriate knowledge. This can play a key role in addressing health, food security, environmental and other priorities, and will contribute substantially to the achievement of SDGs. For knowledge-based societies to effectively address these priorities, innovation is required, meaning that new products or processes are developed and adopted. IP protection is an integral part of any technology transfer process. As outlined in a EU Commission recommendation (CEC, 2008), developing and having in place an IP policy should be included in the long-term strategy and mission of public research organizations. The IP policy should be publicised internally and externally, and there should be a reference person in every institute for matters related to IP. An effective policy should provide clear rules for staff and students, in particular regarding the disclosure of new ideas with potential commercial interest, the ownership of research results, the management of conflicts of interest and conflicts in commitment, and engagement with third parties. Research institutes should promote the identification, exploitation and, where appropriate, protection of intellectual property, in line with their strategy and mission and with a view to maximising socio-economic benefits. To this end, research institutes may conduct regular IP audits, to identify what they have in-hand and to define a strategy for IP protection, considering also the limits imposed by internal budgets.

While having adequate IP policies is essential, it is also crucial to build strong/healthy relationships with collaborators, particularly those from industry. For example, is a good practice to have in place template Material Transfer Agreements and Confidentiality Agreements and to utilize these tools when

[1]According to the EU definition, technology readiness level is defined as follows: TRL 1 – basic principles observed; TRL 2 - technology concept formulated; TRL 3 – experimental proof of concept; TRL 4 – technology validated in lab; TRL 5 – technology validated in relevant environment; TRL 6 – technology demonstrated in relevant environment; TRL 7 – system prototype demonstration in operational environment; TRL 8 – system complete and qualified; TRL 9 – actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space)

sharing information, material or expertise for the purpose of evaluating a new collaboration or for any other purpose. Furthermore, it is important to enter into RCA clearly defining the relationship and the expectations of the parties. RCAs generally include terms and provisions covering grants and payments (if any), dispute resolution, intellectual property emerging from the research collaboration, IP ownership and confidentiality, and the expected duration of the agreement, as well as other related legal terms and definitions. The relationship and goals of the parties will define how the agreement is structured. The actual document will also vary, depending on whether the counterpart is a public or private sector entity, on whether the agreement is a collaborative-research agreement or a sponsorship agreement, and on the institutional and legal culture of the parties.

Such activities, maintenance of an IP policy, regulation of relationships with third parties, and IP support services are normally performed by Technology Transfer Offices (TTO). TTO provide scientists and PIs with assistance and support on all IP matters. They liaise with patent attorneys for the deposit and maintenance of patent applications, and disseminate information on IP protection (face to face meetings, seminars, organize lectures for young scientists). TTOs should ensure that IPRs are secured in the performance of RCAs and other forms of contracts, and advise on IPR issues. Having technology transfer procedures in place, does not guarantee attraction of investments, but certainly if nothing is in place it is very difficult to raise funds from technology transfer to support research and other activities of the research centre.

A good example of public private partnership to finance research that has potential for industrial application can be found in India, where the government promoted a successful initiative to stimulate, foster and enhance the strategic research and innovation capabilities of the Indian biotech industry. The Biotechnology Industry Research Assistance Council (BIRAC) is an agency that funds the emerging biotech enterprises to undertake strategic research and innovation in collaboration with research institutes and universities, addressing nationally relevant product development needs. Established as an industry-academia interface, it implements its mandate through a wide range of initiatives, by providing access to risk capital through targeted funding, technology transfer, and IP management schemes that help bring innovation excellence to the biotech firms and make them globally competitive. One of its missions is to bridge the existing gaps in the industry-academia innovation research, and to facilitate novel, high quality affordable product development through cutting edge technologies.

10. Conclusions

A knowledge-driven economy depends on collaboration between universities, the business sector and public actors. In this perspective, the role and impact of regional research collaborations is becoming more crucial to provide access to facilities for knowledge production and to highly educated workforces, both of which are elementary preconditions for economic growth.

The ICGEB is open to expand collaborations, both at bilateral and multilateral levels, aiming to promote basic research in the agricultural biotechnology areas. Collaboration with the ICGEB is an asset for its Members States, as it provides access to most advanced research techniques in the fields of molecular biology and biotechnology, it enhances human capital, provides funding for research projects aligned to the specific needs of the country and connects scientists from its Members in a truly international network of researchers. At a systemic level, to face the current and emerging challenges in obtaining investment for basic research in agricultural biotechnology, the ICGEB is increasingly strengthening its partnerships with research peers worldwide, with specialized organizations, donors and multilateral actors, as well as with the industrial sector. Dedicated working groups and regional platforms, such as the Regional Expert Consultation on Agricultural Biotechnology, facilitate the dialogue between academy and industry as well as focussing expertise and resources on public priorities. At the national level, the experience drawn from the ICGEB suggests that the quality of a proposal is essential to succeed in the fundraising challenge, and therefore training early career scientists in grant-writing, and having properly established fundraising offices in research institutes and universities, can help achieve better outcomes. Also, it is crucial to have measures in place to protect and to transfer expertise and IP, to maximise the exploitation of research results and to secure returns to further finance the basic research.

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Investments in Livestock Biotechnology and Scoping Partnership

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ABSTRACT: Biotechnological products and processes are widely used in livestock production as well as product development. As such, a more efficient and environmental friendly production system is propagated and safer foods are available for consumers. However, utilization of biotechnology in livestock industry varies from developed and developing countries, as well as within the country itself. Factors such as smallholding, high cost, insufficient policy and support as well as unavailability of local biotechnological institutions and companies hinders the usage of biotechnology in developing countries. This paper briefly discusses livestock industries in Malaysia and identifying investment opportunities in livestock biotechnology according to livestock sector. At the same time, institutions and companies that are readily to form partnership with international technical agencies and companies are listed. The partnership will further enhance development and utilization of biotechnology to improve farm management efficiency and farmers' income.

1. Introduction

Advances in livestock biotechnology development and utilization in developed countries facilitate the enhancement of livestock production efficiency. As a result, livestock products from developed countries are often of high quality. Consequently, some of the products are retailed at cheaper price when imported and marketed in developing countries, in spite of higher labour cost in developed countries. While in most developing countries, utilization of the available biotechnology is limited because they are too costly. Instead, improving other aspects of production inputs is more implementable. Efforts to develop own biotechnology and utilizing it to enhance livestock production are also inhibited because of limited capacity and capability to undertake such initiatives. Other constraints include the insufficient funding, inability to recognise and prioritize area of biotechnology intervention, poorly recognised relevant bodies and capable institutions. In addition, the roles of private and international partners are not clearly identified. Based on the livestock industry scenario in Malaysia, areas for biotechnology investments are identified, proposals are made for existing local partners and expectantly will be of interest to the international technical agencies and private entities to participate, collaborate and bridging the gap of livestock biotechnology utilization in developing countries.

2. Livestock Industry and Biotechnology Investment Opportunity

2.1 Poultry sector

Poultry meat and eggs are considered the cheapest and readily available source of protein produced by

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Malaysian farmers. Poultry farms are divided into two broad groups; highly integrated commercial farms and small producers (with less than 30,000 broilers per cycle) (Elsedig *et al*., 2015). The industry is producing more than enough meat [115 % self sufficient level (SSL)] and eggs (120% SSL). The farms are highly regulated and licensed under state's Poultry Production Enactment. Main feed ingredients used are corn and soyabean meal, which are imported mainly from Brazil and Argentina. Because of that, cost of producing chicken is also influenced by global price of these two ingredients. However, because of an efficient production system in place, as reflected by feed conversion of 1.6 kg feed/kg body weight, slight fluctuation in global price is well absorbed by the industry and not transferred to consumers. However, research to reduce import of corn is reintroduced recently using biotechnologically enhanced corn variety that thrives in humid tropical climate and resistant to fungus and insect infestation.

Commercial farms are shifting to a closed-house production system with controlled microclimate. The system resulted in higher feed conversion. As such a broiler is capable of reaching marketable weight of 2 kg in 5 weeks of age. Usage of probiotics and Effective Microorganisms (EM) to reduce incidence of antibiotic resistance and chicken dung odour is widely encouraged. Most probiotics and EM products are imported. However, interests in developing local products are growing.

Poultry health is reasonably well taken care. A closed-house with a good biosecurity system reduces risk of diseases transmission between farms. Vaccines against common diseases such as Newcastle Disease and Infectious Bronchitis are available and mostly imported from reputable companies that are registered after being evaluated by the Government Vaccines Registration Committee. However, development of vaccines using local strains, which give better protection is also occurring both at research and commercial level. In addition to disease prevention through vaccination, poultry sector is also enjoying a strong disease control and eradication measures implemented by the government. This is reflected in the success of Avian Influenza outbreaks eradication in 2004, 2006 and 2007. One of the significant enablers for the success is the capacity and capability of veterinary laboratories to utilize Polymerase Chain Reaction (PCR) biotechnology efficiently. Outbreaks are confirmed quickly and prompt eradication strategy was executed.

To address concerns and demands of certain consumer group, an organic poultry production is promoted in recent years. As expected, this production system is costly as compared to the normal production system. The willingness of selected consumers to pay for higher price will contribute to the growth of the organic production system in accordance with the consumer needs.

2.1.1 New Investment Opportunities in Poultry Sector

Based on current challenges and the need of consumers, it is suggested that the following initiatives are the new opportunities that need to be further explored:

- Production of suitable biotechnologically developed grain corn at a price comparable with imported grain
- Introduction of probiotics and additives in feed to reduce incidence of antibiotic resistance bacteria
- Usage of EM for chicken dung odour and fly control
- Development and utilization of common poultry disease vaccines using local isolates
- Development of organic poultry production system

2.2 Ruminant sector

Domestic ruminant production (beef, goat/sheep dairy) is dwindling. The SSLs for beef, goat/sheep meat and milk are only 29.8 per cent, 10.8 per cent and 5 per cent, respectively (DVS Malaysia, 2016). Consequently, imported products are controlling the domestic market. Numerous reasons that include small population base, limited resources especially land for farming, cheap imported products, and marginal enterprise profitability are acknowledged. Various initiatives and research recommendations are proposed and implemented, however the situation remains static. These include integration under oil palm plantation (addressing land shortage), feedlot farming utilizing Palm Kennel Cake, developing a number of ruminant parks and prohibiting slaughter of productive female cattle. The efforts, however managed to slow down the negative growth of ruminant population and keep the low SSL level almost constant throughout a number of years.

Although performances of ruminant sectors are pathetic, some biotechnology initiatives are also utilized. These include production of vaccines using local isolates for disease such as Haemorrhagic Septicaemia and Pasteurellosis in small ruminant. In addition, reproductive biotechnology such as artificial insemination is widely used.

Double Muscle cattle farming is recently propagated and seems to attract interest of many cattle farmers. Usage of Belgium Blue semen on crossbred cows producing calves that grow faster with double muscle and reach body weight of more than 700 kg (more than twice of local cattle) in two years and saleable at RM 12,000 that gives a net income of more than RM 5,000 per head. Prospect of double muscle cattle production is bright because the animal is easily managed utilizing local grass and supplemented with cattle/goat pellet.

Although SSL of dairy production is very low, a number of large dairy farms with cow population of more than 100 heads are active and they are focusing on liquid milk market. Various brands of pasteurized fresh milk products utilizing fresh milk from local farmers are available in groceries and supermarkets. Large dairy farms consume large amount of water, thus require a proper effluent management.

2.2.1 New Biotechnology Investment in Ruminant Sector

Although to further expand the ruminant sector is very challenging, a number of biotechnology initiatives are suggested to be pursued:

- Improve vaccine production using local strains
- Usage of EM to control negative effect of farm effluent and organic fertilizer production
- Bio-prospecting regional source of goat and cattle
- Further exploring and refining double muscle cattle production including producing semen locally with double muscle trait
- Biogas production to provide sufficient electricity requirement of the dairy farm

2.3 New Sector – Edible Bird Nest (EBN) Production

The EBN is by-product of a successful swiftlet (*Aerodramus fusiphagous*) breeding. After the young swiftlet fledged, the nest is left behind and collected and became edible bird nest after properly cleaned. Traditionally, the nests are collected from caves. However, the swiftlets migrated into premises close to human population perhaps for safety reason about a decade ago. Since then, swiftlet houses were built by farmers within house micro-environment and ambient similar to the cave situation. The "ranching" EBN production system expands phenomenally in Indonesia, Malaysia and Southern Thailand. The high price of EBN (about RM 4,000 per kg ex-farm), and minimal operating expenses are the main reasons for such expansion.

2.3.1 New Biotechnology Investment for EBN Production Sector

Although the EBN is a new livestock product and produced by a few ASEAN Member states, biotechnology initiatives could further develop this livestock sector. Such biotechnology includes:

- Development of a suitable EM for modulation of in-house microbe population
- Identification of factors that convert NO_2 to NO_3 that affected marketability of the EBN and develop products that will stop the conversion
- Explore insect production that can be used as supplemental feeding especially during draught season whereby natural habitat for wild insects population is reduced

3. Partners and Partnership in Livestock Biotechnology

The biotechnology initiatives identified can be implemented in collaboration with suitable partners. International technical agencies and other interested parties are encouraged to form partnership with national agencies or private companies to explore further the identified areas, to conduct research, produce products or implement projects with suitable farmers. Some of the potential national partners are listed as follows:

- Animal Institute of Biotechnology, Jerantut, Pahang. Department of Veterinary Services for ruminant semen production, cryopreservation, embryo transfer and biodiversity.
- Veterinary Research Institute, Ipoh, Department of Veterinary Services for research in area of vaccine production using local isolates, molecular diagnostic including PCR, DNA/RNA sequencing and genomic technology
- Malaysian Agricultural Research and Development Institute (MARDI) Serdang Selangor, research in area of organic farming, bioprospecting and biogas production
- Faculty of Veterinary Medicine, UPM, Serdang, Selangor, in research areas of reproductive biotechnology, poultry and goat disease vaccines development
- Malaysian Biotechnology Corporation Sdn Bhd, Kuala Lumpur, in research areas of embryo transfer and fertility management
- Green World Genetics Sdn Bhd, in biotechnology for seed production including corn for animal feed
- Swiftlet Gardern, Biodesaru, Johore in area of microenvironment management of swiftlet houses

4. Conclusions

The livestock biotechnology initiatives are identified in three sectors of livestock, namely, poultry, ruminant and EBN production. The possible initiatives are in research, product development and utilization as well as specific project utilizing existing biotechnology product. Participation of international agencies and partners in collaboration with local agencies or companies are expected to increase the number of biotechnological products and enhance efficiency of livestock production in Malaysia and subsequently improving farmer's income in a sustainable friendly livestock environment.

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Building-up the Partnership for Using Biotechnological Tools for Sustainable Conservation and Utilization of Bioresources – Role of Bioversity International

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ABSTRACT: Bioresources are critical for sustainable development. They provide the basis of nutrition and food for human being. Great efforts have been made in conservation and sustainable use of bioresources at national, regional and global levels. Over 7.4 million accessions of plant genetic resources for food and agriculture have been conserved in over 1,750 genebanks worldwide. It is important to ensure the safe and sustainable conservation and use of those valuable resources with available technologies, particularly biotechnology. Biotechnology is a powerful tool and can play an important role in conservation and sustainable use of bioresources though application of micropropagation for regeneration, in vitro storage for conservation, markers for genetic analysis, and trait or gene identification. Bioversity International is a specialized organization on conservation and use of agricultural bioresources, particularly crop genetic resources. It has worked closely with national partners and other relevant stakeholders and played an effective role in use of biotechnology for genetic resources management, particularly in developing technologies and tools for in vitro conservation, molecular characterization, and establishment of global platform for banana germplasm. More research efforts should be made in the partnerships with national, regional and international stakeholders with focus on developing enhanced methodologies for characterizing, managing, and using germplasm resources for sustainable development.

1. Introduction

Bioresources are resources from biological origin or the total biological variation presented in plants, animals and microorganisms. It is important resources for the development of improved crops and animals for higher yields and tolerance to biotic and abiotic stresses (Eneobong, 1997). Bioresources make the earth different, colorful and vibrant. However, sustainable management of bioresources faces many challenges. Climate change, infrastructure construction, urbanization and modern agriculture have caused the loss of bioresources, including those in the wild and domestication. In 1992, the Convention on Biological Diversity (CBD) was adopted by the United Nations to address the challenges in loss of biodiversity in the world. The CBD aims to improve the conservation of biological diversity, the sustainable use of the components of biological diversity and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. In 2004, the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA) adopted by Food and Agricultural Organization of United Nation became into force in harmony with the CBD of the world's plant genetic resources for food and agriculture, as , with aims at guaranteeing food security through the conservation, exchange and sustainable usewell

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as the fair and equitable benefit sharing arising from its use. The Treaty has established the Multilateral System of Access and Benefit-sharing to facilitate plant germplasm exchanges and benefit sharing through Standard Material Transfer Agreement (SMTA). Many kinds of knowledge and technologies are available for conservation and utilization of bioresources. Biotechnology is a powerful tool in managing bioresources, such as micropropagation, *in vitro* conservation, cryopreservation, tissue culture, molecular markers, somatic hybridization and genetic engineering, which has greatly advanced the progress of conservation and use of bioresources for sustainable agriculture. Bioversity International has played a critical role in the research and application of biotechnologies to the management of agricultural bioresources in partnerships with national, regional and international organizations.

2. Plant Genetic Resources Management

Plant genetic resources for food and agriculture are the basis of global nutrition and food supply. They comprise diversity of traditional varieties, modern cultivars and their wild relatives. Many countries have established the conservation system to prevent from the loss of plant genetic resources for food and agriculture. These conservation systems consist of diverse type of collections such as base and active collections as well as various ways including *ex situ*, *in situ* and on-farm conservation. Advances in biotechnology, especially in the area of *in vitro* culture techniques and molecular biology provide many useful tools for improved conservation and management of plant genetic resources.

3. Safe Conservation

For *ex situ* conservation, the total number of accessions has reached 7.4 million conserved in more than 1,750 individual genebanks worldwide (FAO, 2010). There are also substantial *ex situ* collections in botanical gardens around the world. The number of accessions of minor crops and crop wild relatives (CWR) has become a major part of the collection. Interest in collecting and conserving CWR, landraces and neglected and underutilized species, is growing as more diversity and biotic and abiotic resistant traits exist in these bioresources. The creation of the Global Crop Diversity Trust (GCDT) and the Svalbard Global Seed Vault (SGSV) is a major achievement of global efforts. The seed collections are larger and more secure overall, the situation of vegetatively propagated species and species whose seeds cannot be dried and stored at low temperatures need to be improved with particularly biotechnologies.

For *in situ* conservation, the number of protected areas in the world has reached approximately about 70,000 and the total area covered has expanded to 17.5 million km^2. A large number of surveys and inventories have been conducted in natural and agricultural ecosystems. Awareness of the importance and value of CWR and actions to conserve them *in situ* has increased in many countries (FAO, 2010). A global strategy for CWR conservation and use has been developed, and protocols for the *in situ* conservation of CWR are now available at national and regional levels (Maxted *et al*., 2017). The extended number and coverage of protected areas has indirectly led to a greater protection of CWR. Significant progress has been made in the development of tools and techniques to assess and monitor bioresources within agricultural production systems. Seed systems in countries have been recognized as important sources of the diversity and effective ways to maintain and distribute diversity to local farmers. The on-farm management with the participation of local stakeholders has created new mechanism to enable farmers to market genetically diverse varieties for income generation. In light of climate changes, pest and disease threats, more attention has been given to increasing genetic diversity within production systems by application of some best practices including agronomic practices, seed production and distribution systems, and the management of the interface between wild and cultivated species.

4. Sustainable Utilization

Sustainable and effective use of ITPGRFA is key to food security. Although a wide range of genetic resources is available nationally and internationally, breeders often select the majority of their parental materials from their own working collections due to lack of precise data on ITPGRFA as well as the difficulty of transferring genes from non-adapted backgrounds to the new breeding lines. Therefore, it needs comprehensive characterization and evaluation work to promote the effective use of the genetic resources stored in genebanks.

Characterization of PGRFA is the process by which accessions are described with regard to a particular set of morphological traits. PGRFA accessions can also be evaluated using modern biotechnological tools such as different kinds of molecular markers. The characterization and evaluation of PGRFA should aim to provide data about traits having actual or potential agronomic utility. These traits usually vary with the environment, and require evaluation in different environments. Recognizing the importance of PGRFA in genetic improvement, efforts are being made by national and international partners to identify important and potential traits with different approaches including phenotypic and genotypic approaches.

5. Biotechnology for Bioresources Management

The CBD defines biotechnology as: "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products for specific use". The FAO Glossary of biotechnology defines biotechnology broadly as "a range of different molecular technologies such as gene manipulation and gene transfer, DNA typing and cloning of plants and animals". Numerous new fields of biotechnology have been developed in recent decades that have potential applications in plant genetic resources management, including micropropagation, *in vitro* genebank, germplasm exchange, genetic diversity assessment, identification of useful traits or genes from germplasm collection by understanding their function and expression as well as the structure.

5.1 Micropropagation for regeneration

Regeneration of germplasm conserved in the field genebank and *in vitro* genebank depended on the micropropagation technique that multiply genetic materials *in vitro*. The simplest type of *in vitro* plant propagation is the stimulation of axillary bud development. One of the most exciting and important aspects of *in vitro* cell and tissue culture is the capability to regenerate and propagate plants from cultured cells and tissues. Usually plants derived from meristem (or vegetative buds) without a callus stage, tend to reduce or eliminate somaclonal variation, resulting in true clones. Axillary bud proliferation and culture of individual nodes are the techniques most widely used in commercial micropropagation and which show the least variation among the propagated plants. In recent years, *in vitro* approaches have been used as an efficient tool for micropropagation of trees and it proved that tissue culture technology is suitable for large-scale propagation of trees in short time (Pena and Seguin, 2001).

5.2 Tissue culture for conservation

Some root and tuber crops such as potato, cassava, yam, taro and sweet potato, and fruit trees such as apple, pear, citrus and banana are clonally propagated. These crops usually possess either no-seed production or recalcitrant seed. Tissue culture *in vitro* approaches are recognized as useful tools for medium-term conservation of these groups of species. Biotechnologies including shoot apical or axillary-meristem-based micropropagation, somatic embryogenesis, cell culture technologies and embryo rescue techniques could be used in conservation. Plantlets of the germplasm can be maintained under a slow growth condition, which provide an option for safe conservation of about 1,000 species, and for difficult-to-store seeds, constituting about 88,250 species throughout the world (Rajasekharan and Sahijram, 2015).

5.3 Cryopreservation

Cryopreservation is defined as the viable freezing of biological material and their subsequent storage at ultra-low temperatures, preferably at that of liquid nitrogen (-196°C) (Kartha and Engelmann, 1994). At this temperature, the vegetative cells enter in a state of absolute quiescence, as all the physical and biochemical reactions are practically halted; therefore, life of the materials conserved under this temperature condition can last very long. With the help of cryogenics for the maintenance of cell cultures, differentiated organs and tissues can be stored in the very low temperature, and their functionality can be fully recovered when bringing back to standard culture conditions. Effective procedures have been developed for the cryopreservation of shoot tips for many species such as poplar, plum, olive, chestnut and fruit rootstocks, dormant buds of persimmon and olive, seeds of *Citrus* spp., and embryogenic lines of olive, horse chestnut and ash (Lambardi *et al*., 2005). Many countries have established the facilities for cryopreservation and two cryopreservation protocols are available for a range of banana cultivar groups and Bioversity International is implementing a programme for cryopreserving its entire collection as a more cost-effective alternative for backup (FAO, 2010).

5.4 Genetic diversity assessment

Molecular markers have played an important role in many aspects of genetic resources management such as characterizing plant genetic diversity for purposes of improved acquisition, maintenance and use. There are two general types of DNA markers: (1) Those based on DNA-DNA hybridization such as Restriction Fragment Length Polymorphism (RFLP); and (2) Those based on amplification of DNA sequences using the Polymerase Chain Reaction (PCR) such as Random Amplified Polymorphic DNA (RAPD), Amplified Fragment Length Polymorphism (AFLP), Simple Sequence Repeat (SSR), Expressed Sequence Tagged Polymorphisms (ESTPs), Single Nucleotide Polymorphism (SNP), *etc.* These types of markers may identify dominance and co-dominance within the genome. Therefore, they are highly polymorphic nature, and remain stable under different environmental conditions and management practices (Joshi *et al*., 2004). They have been used extensively for characterization and evaluation of germplasm of food crops and horticultural plants. These applications include study of genetic variation of different characters such as salinity resistance and drought tolerance, cultivar identification, phylogenetic analysis *etc.*

5.5 Trait or gene identification

CWR contains abundant genes for crop improvement. However, it has been virtually impossible to utilize wild germplasm for the improvement of quantitatively inherited traits, such as yield, because the superior trait of interest cannot be identified phenotypically in the wild accessions. The linkage maps and markers represent a powerful tool for identifying positive QTL alleles for important agronomic traits. With molecular markers, agriculturally desirable alleles in CWR could be mapped out and transferred into cultivars. Based on molecular markers, the QTL mapping approach is effective to detect genes controlling useful traits in germplasm collections. The advent of molecular markers and maps makes it possible to identify individual quantitative trait loci associated with yield and its components, environmental stress tolerance, disease and insect resistance, and quality traits in a variety of crop plants such as nematode in *Gossypium barbadense* L. (Gutiérrez *et al*., 2011) and seed protein content in soybean (Jun *et al*., 2008), and kernel-width maize (Raihan *et al*., 2016).

6. Role of Bioversity International in Promoting Use of Biotechnology in Managing Bioresources

6.1 Research on *in vitro* conservation technologies and establishment of *in vitro* genebanks

Bioversity International collaborated with relevant national partners and carried out effective researches on *in vitro* conservation of vegetatively propagated species, particularly root and tube crops, and fruit trees through slow growth and cryopreservation (Zhao *et al*., 1999). Bioversity produced a Technical Guidelines for the management of *in vitro* germplasm collections. These guidelines first present general considerations for the establishment and management of *in vitro* germplasm collections. Secondly the guidelines focus on the procedures for the establishment and maintenance of *in vitro* collections. The laboratory and storage facilities required for the establishment and maintenance of *in vitro* collections are presented and the need for the establishment of detailed standard operational procedures is also highlighted. *In vitro* culture and conservation procedures are then presented and analyzed, including the establishment of a tissue culture system, the introduction of plant material *in vitro*, slow-growth storage, cryopreservation and distribution of plant material. Finally, research needs are identified aiming at improving *in vitro* conservation of plant germplasm collections (Reed *et al*., 2004).

Recently, Bioversity organized an Independent Expert Group on *in vitro* conservation and reviewed the state of crop cryopreservation in 26 institutes and collated information on field and *in vitro* collections around the world. The study highlights the advantages of cryopreservation for conservation of clonal/recalcitrant seed crop collections and recommends that a major global effort would be made to facilitate its wide-scale implementation and to overcome major practical constraints (Acker *et al*., 2017).

6.2 Partnerships on molecular characterization and evaluation of crop genetic resources

Molecular markers have an important role to play in many aspects of genetic resources such as characterising plant genetic diversity for purposes of improved acquisition, maintenance and use. Bioversity in collaboration with Institute of Crop Science of Chinese Academy of Agricultural Sciences, China and carried out the research on molecular characterization of underutilized crop species such as buckwheat and oat. We developed SSR markers as a tool for genotyping identification in oat. With SSR markers developed, we carried out genetic diversity analysis on oat (Wu *et al*., 2012), genetic linkage map construction and mapping QTLs for grain size of oat (Song *et al*., 2015). We analyzed the genetic diversity of 166 accessions of tartary buckwheat from 14 geographic regions with SSR markers. Principal components analysis (PCA) and unweighted pair group method with arithmetic mean (UPGMA) clustering both demonstrated close connections among accessions from Yunnan, Sichuan and Tibet (Han *et al*., 2012). This further confirmed that tartary buckwheat originated in southwest China. Efforts were also made to develop a genetic linkage map and locate QTLs for important agronomic traits of Tartary buckwheat with SSR and AFLP markers, and 11 QTLs were identified for agronomic traits, including plant height, branch number, leaf length, leaf width and grain weight (Du *et al*., 2013).

Bioversity worked with partners from Ethiopia and Italy and carried out molecular and phenotypic characterization of hundreds of Ethiopian durum wheat landraces and several Ethiopian improved lines. A total of 30,155 SNPs were used to survey the diversity, structure, and genome-specific variation. The uniqueness of Ethiopian germplasm using a collection of Mediterranean durum wheat accessions was revealed. At the same time, phenotypic variation of ten agronomic traits of Ethiopian durum wheat was characterized in two highly diversified Ethiopian environments for two consecutive years. With phenotypic and molecular data, a genome-wide association study was conducted and several loci underpinning agronomic traits of interest, both confirming loci already reported and describing new promising genomic regions were identified. These loci may be efficiently targeted with molecular markers already available to conduct marker-assisted selection in Ethiopian and international wheat (Mengistu *et al*., 2016).

6.3 Capacity building on using molecular tools in plant genetic resources management

Working in partnership with national programmes, research institutions and other organizations, Bioversity undertakes research and training and seeks to provide technical advice and information on use of biotechnology for germplasm management.

Bioversity in collaboration with key national partners such as Cornell University, United States, Huazhong Agricultural University, China organized a series of training courses for the national partners on using molecular tools in plant genetic resources management for the national partners in developing countries. The training materials covered two modules: (1) Using molecular marker technology in studies on plant genetic diversity. This training module is intended for scientists with a minimal background in genetics and plant molecular biology, but with a working knowledge of plant genetic resources and issues concerning their conservation and management. It is designed to understand the basic scientific concepts underlying molecular marker and DNA sequence technologies; (2) Genetic diversity analysis with molecular marker data: Learning module. This learning module is intended to help those who want to analyse genetic diversity with the aid of molecular data. It aimed to understand the scientific concepts of genetic diversity through the fundamentals of population genetics, become familiar with the mathematical expressions used to describe genetic diversity and be able to perform the indispensable calculations based on molecular marker data, and acquire the basic knowledge to apply molecular technologies for assessing genetic diversity and to interpret molecular data accordingly.

6.4 Providing guidelines

Bioversity developed a guide to the use of molecular tools in plant genetic resources management. The guide attempts to provide a brief overview of currently available techniques and to outline some of their strengths and limitations. It also provides a framework to assist users in identifying the most appropriate technique(s) required for their own needs. Molecular markers, therefore, may be used in measurements needed for effective *ex situ* conservation, that are useful in resolving the numerous operational, logistical, and biological questions that face genebank managers (Kresovich *et al*., 1992).

6.5 Global platform on banana germplasm conservation and genomic research

6.5.1. Maintaining in vitro genebank: Bioversity International maintains international banana collation by using tissue culture techniques and growth retardant conditions (temperature, light, chemicals) - Slow growth storage. The Genebank, hosted by the Katholieke Universiteit Leuven (KUL) in Belgium, has more than 1,600 accessions. Most of them are cultivars. The others are breeding material, including improved hybrids, and wild relatives. Most accessions in the genebank are held in trust for the benefit of future generations. They are conserved under the conditions of an agreement signed between Bioversity and the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), thereby placing these materials in the Multilateral System of Access and Benefit Sharing. Each accession is represented by 20 shoot cultures (tissue-culture plantlets) kept on nutrient medium in continuous light conditions at 16 °C. Even though the temperature and lighting are kept at a minimum to slow down the growth process, the plantlets eventually outgrow their test tube. As a consequence, each accession is re-cultured once a year on an average. After a number of years, new plantlets are cultured using material grown out in the field to control for the risks of somaclonal variation.

6.5.2. Establishing cryopreservation: In order to ensure the safe long-term conservation of *Musa* genetic resources, Bioversity International is supporting research on cryopreservation, *i.e.*, storage at ultra-low temperatures, usually that of liquid nitrogen (-196°C). This is the method of choice for ensuring cost-effective and safe, long-term storage of *Musa*. The research is being carried out at the KUL, Belgium and the techniques developed are now being used for routine cryopreservation of accessions held by Bioversity at its International Transit Centre (ITC). Two types of highly meristematic and regenerative *in vitro* tissues can be obtained from the banana: (i) individual meristems isolated from shoot-tip cultures and (ii) highly proliferating meristem cultures containing 'cauliflower-like' meristem groups. Cryopreservation methods have been developed for both tissue types. In addition, embryogenic cell suspensions of different cultivars belonging to distinct genomic groups can also be stored in liquid nitrogen. Bioversity has also released technical Guidelines for Cryopreservation of *Musa* germplasm. The aim of the Guidelines is to provide information and guidance on cryopreservation methodologies suitable for use on *Musa* germplasm. It is hoped that the detailed descriptions of the methodologies presented will facilitate their adoption and use in different laboratories worldwide (Panis and Thinh, 2001).

6.5.3. Facilitating germplasm exchange: The distribution of germplasm from Bioversity's ITC is regulated within the framework of the ITPGRFA. Germplasm is distributed only for the purposes of research, breeding and training for food and agriculture as set out in the terms and conditions of the SMTA. In principle anyone can order germplasm as long as it is used for the purposes mentioned in the SMTA. ITC distributes germplasm free of charge. Between 1985 and 2014 the ITC distributed over

17,000 samples of accessions to users in 109 countries. On an average, 75 per cent of the samples go to users in the main banana growing regions – Africa (27%) the Americas (25%) and Asia and Pacific (23%) with the remainder going to universities and research centres in Europe.

6.5.4. Characterizing banana diversity: The largest *ex situ Musa* germplasm collection is kept at the Bioversity's ITC in Leuven (Belgium) and currently comprises of over 1,500 accessions. Systematic cytological and molecular characterization of the *Musa* collection has been carried out. By December 2015, 630 accessions have been genotyped. The SSR markers confirmed the previous morphological based classification for 84 per cent of ITC accessions analyzed. The remaining 16 per cent of the genotyped entries may need field verification by taxonomist to decide if the unexpected classification by SSR genotyping was correct. The large-scale molecular characterization efforts are essential for the management and conservation of the global *Musa* germplasm collection and will facilitate its efficient use by the banana research and breeding community (Christelova *et al*., 2017). The genotyping system has identified potentially problematic accessions for which field or other verification were deemed necessary and it has also helped in proposing subgroup classification for corrections. Coupled to the flow cytometric estimation of ploidy level, this genotyping system presents the new standard for molecular characterization of *Musa* genebank accessions.

6.5.5. Conducting genomic analysis by sequence: Bioversity coordinated the Global *Musa* Genomics Consortium, an international network of scientists who contributed to the sequencing of the reference sequence genome. The sequencing was done by the French sequencing centre Genoscope, in collaboration with the French Agricultural Research Institute for Development (CIRAD), under the umbrella of the Consortium. The accession selected for sequencing was DH Pahang. It obtained the draft sequence of the 523-megabase genome of a *Musa acuminata* doubled-haploid genotype, providing a crucial stepping-stone for genetic improvement of banana. It was found that the banana genome contained more than 36,000 genes. The results of the sequencing were published in Nature. This first monocotyledon high-continuity whole-genome sequence reported outside Poales represents an essential bridge for comparative genome analysis in plants. As such, it clarifies commelinid monocotyledon phylogenetic relationships, reveals Poaceae specific features and has led to the discovery of conserved noncoding sequences predating monocotyledon-eudicotyledon divergence (D'Hont *et al*., 2012).

7. Conclusions

Bioresources are crucial for human survival and sustainable development. Over 7.4 million accessions of plant genetic resources for food and agriculture have been conserved in over 1,750 genebanks worldwide. It is important to safeguard and sustainable use of those valuable resources. Biotechnology is a powerful tool and can play an important role in conservation and sustainable use of bioresources though application of micropropagation for regeneration, *in vitro* storage for conservation, molecular markers for genetic analysis, and trait or gene identification. Bioversity International is a specialized organization on conservation and use of agricultural biodiversity, particularly crop genetic resources. It closely worked with national partners and other relevant stakeholders worldwide and has played effective role in the use of biotechnology in genetic resources management, particularly in developing technologies and tools for *in vitro* conservation, genotypic characterization, and establishment of global platform for banana genetic resources. It is suggested that more research efforts should be carried out on developing enhanced methodologies for characterizing, managing, and using germplasm resources to ensure safe conservation and sustainable use of agricultural bioresources in the world.

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Country Status Reports

Country Status Report - Bangladesh

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1. Introduction

The programme on plant biotechnology in Bangladesh was initiated in late 1970s in the Department of Botany, Dhaka University with tissue culture of jute. Within a span of 10-12 years, tissue culture research laboratories have been developed throughout the country. Bangladesh Livestock Research Institute (BLRI) and Bangladesh Agricultural University (BAU) have already initiated modern biotechnology programmes. The techniques of genetic engineering are yet to start in the country for the improvement of plant, animal, and industrial microorganisms and also to combat environmental pollution problems *etc.* Brief compilation of the status on agricultural biotechnology (AB) is given in Table 1; the national policies, their implementation challenges and significant achievements under different sectors is presented as country status report.

Table 1. Basic Information

Indicator	Details
Value of GDP (Trillion BDT) BDT=Bangladeshi Taka	19.76[*]
Value of GDP (Billion USD+)	249.75
Value of agriculture GDP (Billion BDT)	~2113.61
Value of agriculture GDP (Million USD+)	26714
Agriculture GDP as per cent of GDP	~14.74
Total investment in agricultural research (Million BDT)	6997[**]
Total investment in agricultural research (Million USD+)	88.44
Total investment in AB research (Million BDT)	55.54[***]
Total investment in AB research (Million USD+)	0.70

*Source: *World Bank (2017); **Estimated by BARC, 2018; ***Estimated data provided by NARS institutes; + 1 USD = 79.12 BDT*

2. National Policies

2.1 Current National Policies on Agricultural Biotechnology and Polices for Enhancing the Livelihood of Farmers through Agricultural Biotechnology

Dr Md Harunur Rashid is Principal Scientific Officer, Crops Division, Bangladesh Agricultural Research Council (BARC). He is an Agronomist by training. He obtained his PhD in Agronomy from BAU. He is a dedicated rice-based cropping systems scientist and a training specialist with more than 20 years experience in farming system technology development, refinement and dissemination. Dr Harunur's current responsibilities include research area prioritization, project development and coordination of national agricultural research systems (NARS) institutes' research in the context of achieving national plan of Vision 2021, SDG-2030 and Vision 2041.

2.1.1 National Biotechnology Policy, 2005 (CLCBD, 2005)

The main goal of the policy is to ensure sustainable development of agriculture food and other crops, nutrition, health, environment and livelihood of people, to enhance agricultural competitiveness in relation to global standards. The other important goals include strengthening of the national capabilities in modern biotechnology, biosafety and bioethics in order to ensure judicious use of this modern tool for socio-economic development of the country. The main objectives of the policy are to:

(i) Harness the opportunities of biotechnological applications for enhanced productivity, increased quality and value of products leading to sustained food security, poverty alleviation and health and livelihood improvement.

(ii) Take up a detailed inventory of bioresources in the country to promote biodiversity conservation and sustainable exploitation.

(iii) Create environment for R&D in biotechnology and allied fields through development of infrastructure and through appropriate incentives and regulatory framework for research in modern biotechnology.

(iv) Develop high quality infrastructure for setting up of Biotech Parks in different places.

(v) Focus on human resource development in different areas of biotechnology.

(vi) Develop bioinformatics and related ICT facilities for rapid development of biotechnology.

(vii) Create enabling environment for the growth of biotech industries.

(viii) Address issues such as Intellectual Property Rights, biosafety, biodiversity, and bioethics with due emphasis on knowledge, innovation and practices of indigenous and local community.

(ix) Create public awareness on biotechnology by involving all stakeholders to ensure adequate level of protection in the safe handling of this technology.

2.1.2 National Biosafety Framework (NBF), 2007

The NBF is a combination of policy, legal, administrative and technical instruments that are developed to ensure an adequate level of protection in the field of the safe transfer, handling and use of GMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (GoB, 2007). The Department of Environment, Government of the People's Republic of Bangladesh, has developed the National Biosafety Framework (NBF) taking into account the obligations and mandates under the Cartagena Protocol on Biosafety. The NBF provides the basis for developing a regulatory regime on biosafety for effective management of GMOs in Bangladesh.

2.1.3 Work Plan for the National Biotechnology Policy, 2012

On May 15, 2014, the Ministry of Science and Technology issued the Gazette notification on the Work Plan (WP) for the National Biotechnology Policy 2012. The Work Plan provides a list of national research and development priorities for biotechnology and a timeline for achieving these objectives. It focuses on agricultural, medical, and industrial biotechnology. The WP, 2014 provides a list of national research and development priorities for biotechnology and a timeline for achieving these objectives. The overarching goal is to advance the research and development of biotechnology in order to improve food security, increase the standard of living, and eliminate poverty. It focuses on agricultural, medical, and industrial biotechnology (USDA-FAS, 2016).

2.1.4 Bangladesh Biosafety Rules, 2012

The Government of Bangladesh published Bangladesh Biosafety Rules (BR), 2012, which provides regulations on the approval process for genetically engineered (GE) products developed domestically or by a third country. According to BR, 2012, all GE products need to be approved before they can be imported or sold domestically within Bangladesh (USDA-FAS, 2014).

2.1.5 Revised Biosafety Guidelines of Bangladesh, 2018

These guidelines are formulated to ensure an adequate level of protection for the environment and human health during the conduct of contained research, field trials, safe transfer, handling, use and transboundary movement of Genetically Modified Organisms (GMO). The Biosafety Guidelines of Bangladesh are intended to provide a framework, legally binding under the Biosafety Rules of Bangladesh, to permit the development of biotechnology in accordance with a biosafety review to assess any risks to the environment as well as human and animal health (MoEF, 2018).

2.1.6 Monitoring and Enforcement Manual for GMO, 2018

Monitoring is an essential part of the implementation of biosafety system in Bangladesh in order to manage the introduction of the products derived from modern biotechnology. Monitoring is also useful to reassure public concern over potential adverse impacts on environment and human and animal health. Because of the potential risk of GMOs on the environment and human health, continuous monitoring and enforcement on various uses of GMOs would ensure sustainable development in the modern biotechnology. The Monitoring and Enforcement Manual for GMOs has been prepared to provide a framework for monitoring and enforcement activities in the country (MoEF, 2018a).

2.2 Implementation of Policies

2.2.1 Government Bodies Responsible for Implementing Each Policy

The Department of Environment, Ministry of Environment and Forests is responsible for implementing the Bangladesh Biosafety Rules (BR), 2012. The National Committee on Biosafety (NCB), established by the Ministry of Environment and Forest (MoEF), ensures environmentally safe management of modern biotechnological development including research and development, introduction, use and transboundary movement of GMOs/LMOs. A Biosafety Core Committee shall be working to assist and accelerate the functions of NCB. Institutional Biosafety Committee (IBC), Field Level Biosafety Committee work under NCB and ensure safe management of biosafety activities in the laboratories and in the field, respectively.

2.2.2 Effectiveness of the Policy (ILSIRF, 2016)

The Bangladesh Agricultural Research Institute (BARI) released four *Bt* brinjal varieties following the existing policies. Confined field trials of late blight resistant potato at research stations at BARI and of golden rice by Bangladesh Rice Research Institute (BRRI) have been undertaken. Contained trial of *Bt* cotton in the greenhouse, edible vaccine producing transgenic rice in the net house of Biochemistry and Molecular Biology Department, Dhaka University and transgenic rice for salinity and drought tolerance have been tested.

2.3 Capacity Development

2.3.1 Existing Capacity Level

Altogether, there are about 60 scientists and 20 other staff working on biotechnological research in the eight national research institutes. The details, along with the existing lab facilities, of different institutes are given in Table 2.

Table 2. Existing capacity of different institutes of NARS

Institute	Manpower	Lab facilities
Bangladesh Rice Research Institute (BRRI)	Scientists (9) Lab attendants (2)	(i) Labs for rice tissue culture (seed culture, anther culture and embryo rescue), DNA fingerprinting, molecular marker-assisted selection, *Agrobacterium*-mediated genetic transformation and gene cloning (ii) Contained transgenic green-house (iii) Transgenic confined field trail site

Institute	Manpower	Lab facilities
Bangladesh Agricultural Research Institute (BARI)	Scientists (12)	Greenhouse (level:2), well equipped molecular and tissue culture laboratory
Bangladesh Institute of Nuclear Agriculture (BINA)	Scientists (5) Support staff (3)	Well-equipped laboratory
Bangladesh Jute Research Institute (BJRI)	Scientists (3) Support staff (2)	Two laboratories for tissue culture and DNA fingerprinting
Bangladesh Sugar Crop Research Institute (BSRI)	Scientists (5) Support staff (2)	Tissue culture, genetic transformation and DNA fingerprinting
National Institute of Biotechnology (NIB)	*Crops* Scientists (7) Scientific assistant (1) Lab attendants (2) *Animals* Scientists (6) Scientific assistant (1) Lab attendants (2) *Fisheries* Scientists (4) Scientific assistant (1) Lab attendants (1)	PCR machines, centrifuges, shaking incubator, gel electrophoresis, different freezers, compound microscope, biosafety cabinet, ELISA reader, hybridization unit, UV cross-linker *etc.* Infrastructure: Growth house, green house, animal house, several experimental ponds and field
Bangladesh Fisheries Research Institute (BFRI)	Scientists (10) and support staff (5) of Breeding Division are working on related activities	There is no biotechnology lab. However, some facilities are available in few laboratories for doing biotechnological research.
Bangladesh Livestock Research Institute (BLRI)	Scientists (9) Technician (1)	Capillary based DNA sequencer, real time PCR, automatic nucleic acid extraction machine, PCR machine, electrophoresis systems, tabletop centrifuge temperature controlled, gel documentation system, DNA/RNA quantification system, magnetic particle separator for extraction of mRNA, laminar air flow, DNA concentrator, CO_2 incubator, micromanipulator, florescence microscope, computer assisted automated semen analyzer, semen straw freezing machine, -196°C centrifuge, -80°C centrifuge, milk analyzer, ultrasonography, ovum aspirator, gas analyzer

2.3.2 Required Capacity for Future

The institute-wise details of required manpower to be engaged in biotechnology along with necessary required infrastructure are given in Table 3.

Table 3. Future capacity required for different institutes of National Agricultural Systems

Institute	Manpower	Lab facilities
BRRI	Scientific manpower should be doubled from existing level, and needs three laboratory technicians	Full-fledged facilities required for gene expression study, proteomics, bioinformatics, modern gene editing technology including CRISPR technology, gene sequencing and genotyping through single nucleotide polymorphism (SNP) markers; Modern equipment required for advanced molecular biology research
BARI	Hands-on training (short-term long-term training) to be provided to the existing staff	Lab facilities are adequate

Institute	Manpower	Lab facilities
BINA	Scientists (8) and support staff (4)	Facilities for proteomics lab, conference room, *etc.*
BJRI	Scientists (7) and support staff (6)	Well-equipped wet and dry laboratories and other facilities
BSRI	Scientists (8), scientific assistants and support staff (4)	Improved laboratory facilities such as gene mapping, gene editing, bioinformatics and genomic expression
NIB	Scientists (15)	PCR machines, centrifuges, shaking incubator, gel electrophoresis, deep freezer, compound microscope, biosafety cabinet; infrastructure such as growth house, green house, animal house
BFRI	Scientists (20) and support staff (10)	Separate biotechnology lab with modern equipment
BLRI	Scientists (6) and technicians (4)	Next generation DNA sequencing platform, DNA synthesizer, flourometer for library quantification, server and work station, microarray analysis system with all accessories, door air sterilizer, protein purification system with accessories, HPLC machine, atomic absorption spectrometer, environmental control house for animal trial, glassware washing and drying machine

2.4 Partnership

2.4.1 Existing Major Partnerships

The existing major partnerships for biotechnological research in Bangladesh are listed in Table 4.

Table 4. Existing major partnerships for biotechnology in Bangladesh

Institute	Existing major partnership
BRRI	United States Agency for International Development-USAID, USA, International Rice Research Institute (IRRI), Philippines
BARI	USAID (USA), World Vegetable Center (Taiwan), Commonwealth Scientific and Industrial Research Organization, Australia
BINA	Univeristi Kebaansang Malaysia and University of California, USA
BJRI	Sher-e-Bangla Agricultural University, NIB, Bangladesh
BSRI	BAU, Shahjalal Science and Technology University, International Center for Genetic Engineering and Biotechnology, India
NIB	Plant Breeding Division (International Centre for Genetic Engineering and Biotechnology-ICGEB, India), Animal Breeding Division (Bangladesh Academy of Sciences-USDA, BARC, (Krishi Gobeshona Foundation-KGF, The World Academy of Sciences-TWAS), FBD (BARC) BAS
BFRI	No effective partnership exists
BLRI	Gyeongsang National University, Republic of Korea: Technical cooperation in the field of reproductive biotechnology Asian food and agriculture cooperation initiative of Rural Development Administration, Republic of Korea: Research support and manpower development KGF: Research grant for biotechnology work Centres for disease control and prevention- CDC-USA: research grant for Antimicrobial resistant microbes Royal Veterinary College, University of London and Department for International Development-DFID: Grant for characterization of *Avian influenza virus* in Bangladesh

2.4.2 Scoping of New Partnerships

Government of Bangladesh is scoping for some new partnerships globally as detailed in Table 5 for the development of biotechnological research.

Table 5. New partnerships for biotechnology in Bangladesh

Institute	Scoping of new partners
BRRI	FAO; DFID; Japan International Cooperation Agency; Korea International Cooperation Agency; Gates Foundation; Indian Institute of Rice Research (IIRR), India; Africa Rice Center
BARI	International research organizations
BINA	Tottori University, Japan and Heidelberg University, Germany
BJRI	BINA; BAU; Dhaka University; Central Research Institute for Jute & Allied Fibers, India; Nankai University, China; University of Putra (Malaysia)
BSRI	University of Dhaka; Sugarcane Breeding Institute, India; Philippine Sugar Research Institute, Philippines; Australian Sugarcane Research Institute, Australia; Sugarcane Research Center (Centro de Tecnologia Canavieira), Piracicaba, Brazil
NIB	Open area (national, international, regional)
BFRI	NIB and different public universities
BLRI	International Livestock Research Institute (ILRI); Reputed universities in the world; Related research institutes/departments

2.5 Funding Mechanism (Public, Private, Other Source)

Different institutes in Bangladesh have funding mechanisms as detailed in Table 6.

Table 6. Existing funding mechanisms followed by different institutes in Bangladesh

Institute	Funding mechanism
BRRI	GOB and some foreign donor's fund for the capacity building and research activities of BRRI
BARI	Public and foreign collaboration
BINA	Public
BJRI	Public
BSRI	Public
NIB	Public and other source
BFRI	Public and donor assisted projects
BLRI	Public and very limited grant

3. National and Institutional Strategies

3.1 National Strategies for Research & Development

The WP, 2014 provides a list of national research and development priorities for biotechnology and a timeline for achieving these objectives. The overarching goal is to advance the R&D of biotechnology in order to improve food security, increase the standard of living, and eliminate poverty. It prioritizes various research activities besides improving regulations/laws for biotechnology. Some specific focus areas include plant biotechnology, animal biotechnology, medical biotechnology, and industrial biotechnology, as well as other topics such as nanotechnology and bioinformatics. Risk communication is also listed as a priority. Moreover, the WP, 2014 incorporates workforce development ranging from improving school programming to research capacity building. Activities have timelines for completion between two to 10 years.

3.2 Capacity Development

- Training to have strong understanding on bioinformatics, proteomics and gene-editing techniques
- Professional training for the scientists on biotechnology both home and aboard

- Post-graduate training on biotechnology
- Organizing and participating in seminars, workshops related to biotechnology
- The proposed and existing laboratory and infrastructure will be used for the capacity development also
- Creation of new posts and recruitment of new scientists for biotechnology research and development

3.3 Infrastructure Development

The requirement of organization-wise infrastructure development as per demand of the research organizations is listed in Table 7.

Table 7. Organization-wise infrastructure requirement

Institute	Infrastructure development
BRRI	Development of modern lab facilities for proteomics, bioinformatics and gene expression study
BARI	Greenhouse, net-house, lab development
BINA	Proteomics lab, conference room, *etc.*
BJRI	Independent biotechnology division with trained manpower, well-equipped biotechnology lab including sophisticated instrument, chemical reagents, hardening shade and green house
BSRI	Isolated biotechnology laboratory including all sophisticated instrument and chemical reagent, hardening shade and green house
NIB	Establishment of Genebank, biotechnology incubator, medical biotechnology division, *etc.*
BFRI	Establishment of Genebank, biotechnology incubator, medical biotechnology division, *etc.*
BLRI	Biotechnology cell establishment; Effective coordination among the prevailing research institutes and university for maximum utilization of existing research facilities; Strengthening capacity of existing biotechnology laboratories Government will support NIB, Government and Non-government institute/organizations to execute biotechnology activities in Bangladesh. Moreover, institute can execute biotechnology related activities jointly with national/international related institute/organization. Established biotechnology division at BLRI should be upgraded as a Biotechnology Research Center.

3.4 Communication Strategy

The following are some of the strategies required to be implemented for improving the communication related to biotechnology.

- Arranging seminars/workshop/trainings on different issues of AB and biosafety
- Publication of both scientific and popular articles on different activities of AB
- Visits of agricultural research institutes and agricultural universities by the senior level management staff
- Frequent communication with national and international research institutes under some Memorandum of Understanding and Material Transfer Agreement
- Establishment of national and international linkages with the universities and research organizations for collaborative research on modern biotechnology
- National biotechnology awareness fund development to facilitate education and teaching material development for consumers
- Development of specialized website for biotechnological and bioresources' activities
- Use of print and electronic media for publishing information on biotechnological products
- Development of awareness among undergraduate and post graduate students of universities/colleges on biosafety related issues
- Development of awareness among consumers and businessmen on biotechnology industry and developed products

- Communication with national and international community regarding prospect of biotechnology related business and investment in Bangladesh
- Training for the print and electronic media personnel

3.5 General Awareness

Following are some of the strategies for creating awareness about the importance of AB.

- Conducting field days, developing documentaries to create awareness about the benefit of AB for reducing hunger and securing food and nutritional security of the country
- Organization of seminar, dialogue and conference, including civil society to ensure transparency in biotechnology activities
- Campaign through poster, print and electronic media and national newspapers on specific biotechnology research area and its application
- Informal education for creation of awareness among mass people about biotechnology and genetic engineering
- Organization of public debate on challenges and opportunities associated with application of biotechnology tool
- Organization of National Biotechnology Day every year in the country to create awareness and motivate general public, environment worker, news personnel and policy makers on impact of application of biotechnology

3.6 Policy Advocacy

Policy advocacy is possible as per country specific needs by bringing harmony across different sectors and sections of society. In Bangladesh, with a coordinated effort, biosafety rules and regulations are formulated and published in the gazette. As of now the following policy documents are available.

- National Biotechnology Policy, 2012
- Guidelines for Fish and Animal Biotechnology
- Action Plan for National Biotechnology Policy, 2012
- Biosafety Guidelines of Bangladesh, 2012

4. Specific Focus on Research

- Biotechnology divisions of some research institutes have basic research on QTL/allele/gene identification and gene cloning
- Gene isolation and cloning, genetic transformation for crop improvement and functional studies of stress tolerant novel genes
- The information gathered from basic research will be applied for developing stress tolerant rice variety
- Applied research on double haploid production, wide hybridization followed by embryo rescue, creation of somaclonal, marker-assisted breeding, genetic engineering *etc.*
- Varietal improvement of jute, kenaf and mesta for stress tolerance
- Varietal development of major crops for climate resilience, stress tolerance *etc.*
- Strategy of BRRI and some other organization is to develop climate resilient rice variety using different modern biotechnology tools like CRISPR gene editing technique, genome wide sequencing, genotyping through SNP *etc.*
- Conservation of biodiversity and environmental resources in the country, by using appropriate biotechnology.
- Formulating effective programmes in order to create mass awareness about recent achievements in the field of biotechnology.

5. Priority Areas of Agricultural Biotechnology (GOB, 2014)

5.1 Different Sectors/Areas of Agriculture where Biotechnological Innovations/ Tools can be Applied

5.1.1 Crop Sector

- Developing standard of tissue culture/micropropagation method, for prompt preparation of high quality and disease-free seed/sapling of important plants producing crop, bamboo and timber
- Selection/reproduction of very important crops (paddy, wheat, pulse, oil seed, *etc.*) by marker, for specific use
- Developing nutritional value of crops; producing transgenic plants which are resistant to insects and diseases, abiotic stress tolerant and harmonious to climate change
- Identification, differentiation and determination of characteristics of necessary gene, in order to develop variety of plants by transfer of gene
  - Determination and conservation of molecular characteristics of plant (including medicinal plants) genetic resources and necessary microorganisms in agriculture sector
  - Revealing genome of important crops and forest grown plants for specific use
  - Introduction, evaluation and testing of transgenic crops
  - Identifying plant diseases at molecular level

5.1.2 Livestock Sector

- Identifying molecular characteristics of important pathogens of livestock and poultry through selection of suitable species for development of vaccine and micro-organs
- Manufacturing vaccine for identifying important diseases and use as antidotes for livestock and poultry
- Developing micro-organs of genetic engineering for proper and prompt identification of important diseases at livestock and poultry farms
- Production, differentiation of gene and identification of characteristics of monoclonal and polyclonal antibody, for development of suitable and identification method
- Selection and safe evaluation of GM food, in order to identify health hazards of livestock at farms
- Identifying salinity and disaster tolerant gene for development and conservation of salinity and disaster tolerant fodder (grass species)
- Differentiation, identification and use of lactic acid producing bacteria in order to enhance ensured fodder.
- Enhancing nutritional value of residual crop by enzyme manipulation
- Production of meat and milk by manipulation of microorganisms inside stomach
- Use of suitable microorganisms for increasing nutritional value of food and fodder of cattle
- Development and legalization of phytobiotics, prebiotics, probiotics, *etc.* for use by farm animals and poultry
- Development of starter culture for preparation of dairy products
- Determination, conservation and development of genetic characteristics of potential domestic cattle and poultry, in order to enhance their reproductive capacity
- Development of technology for identification of semen/embryo
- Implementation of method of development of multiple egg germination and *in vitro* fertilization and transfer of embryo

- Developing method of semen and embryo conservation in order to increase population with desired characteristics
- Identifying gene marker to determine meat, milk and disease preventive characteristics for livestock development and selection
- Developing method of identification of pregnancy of farm animals with utmost promptitude
- Developing investigation method of *in vivo* and *in vitro* fertilization
- Selection of livestock species of high economic value through marker system
- Conservation of domesticated and wild stocks

5.1.3 Fisheries Sector

- Innovating improved variety through selected breeding
- Gender transformation and layout of chromosome, creating unisex fish category applying both method
- Producing infertile transgenic fish
- Innovating molecular index on the basis of quantitative trait loci (QTLs) and selection of all important cultured fish through the index
- Gene cloning of economically significant characteristics of fish and producing fast growing and disease preventive transgenic fish
- Determining characteristics and karyotyping of all important species of fish and prawn, through appropriate molecular index
- Gene mapping of economically significant fish species through microsatellite index
- Establishing cryogenic gene bank in order to conserve improved variety and near extinct species
- Innovating molecular technology based on polymerase chain reaction (PCR) in order to diagnose infectious diseases promptly and effectively
- Inventing vaccine against harmful diseases and bacteria, through genetic engineering
- Producing probiotics and metabolites for consumption as supplementary fish-food
- Innovating single cell protein (SCP) for consumption as supplementary fish-food
- Innovating molecular technology to determine post-production standard of prawn and fish
- Innovating ingredients of biotechnology to produce standard prawn/fish products
- Innovating device of conservation of prawn/fish and products derived from them

5.2 Institute-wise Priority Areas in Plant, Animal, Aquatic Biotechnology for Low- and High-Tech Biotechnology

Institute wise priority areas in plant, animal, aquatic biotechnology for low and high-tech biotechnology are given in Table 8.

Table 8. Institute-wise priority areas in low- and high-tech biotechnology

Institute	Priority areas in biotechnology
BRRI	• Development of salt, drought, cold, heat tolerant, and blast and bacterial blight resistant rice varieties
BARI	• Development and utilization of markers in crop improvement • Plant genetic transformation
BINA	• Gene isolation and cloning of stress tolerant novel genes from different wild type and land races • Genetic transformation and development of transgenic plants

Institute	Priority areas in biotechnology
BJRI	• Development of plant regeneration protocol from different genotypes of jute, kenaf and mesta • Introduction of foreign genes in jute, kenaf and mesta through genetic transformation for crop improvement • DNA fingerprinting of jute, kenaf and mesta germplasm
BSRI	• Protocol for plant regeneration using leaf segments *via* callus culture for sugarcane somaclones development has been developed and optimized. Callus derived somaclones are being tested under field conditions • Protocol of micropropagation using shoot tip, leaf segments, tip and meristem for high quality setts production and rapid multiplication of sugarcane has been optimized. Yield performances of micropropagated plants are being evaluated in the field conditions • Tissue culture techniques for development of salt and drought tolerant sugarcane have been optimized. Somaclones developed from salt and drought tolerant callus are being tested in the field conditions • Protocols for development and rapid multiplication of stevia, an elite sweetening herb, *via* callus culture and shoot tip culture have been developed. Developed stevia plants were cultivated in the field and stevia tea was developed from harvested leaves • Protocols for mushroom tissue culture without Laminar-flow-hood with and without Aseptic Box and production using sugarcane bagasse have been optimized • DNA fingerprinting of all released sugarcane varieties and five chewing varieties have been completed. Fingerprinting of all germplasm has to be completed to generate data for genetic linkage mapping, QTLs determination and marker assisted selection (MAS) of sugarcane • Genetic position of sugarcane breeding programme of Bangladesh with Philippines, Indonesia, Thailand and Malaysia has been determined • Transformed sugarcane using *Agrobacterium*-mediated method is being maintained under *in vitro* contained conditions in the laboratory
NIB	• Plant tissue culture, plant genetic transformation, genome editing, gene cloning • Plant and animal disease detection with molecular marker • Animal health biotechnology, productive and reproductive biotechnology, genome research • Conservation of threatened fish through development of cryogenic gene bank • Transgenic fish production
BFRI	• Development of improved strains through selective breeding • Development of monosex population (all male or all female) using both sex inversion and chromosome set manipulation techniques • Production of genetically manipulated sterile fish • Development of QTLs molecular marker and marker-assisted selection for all major cultivated species • Cloning of genes of economic traits from fish and production of transgenic fish for enhanced growth and disease resistance • Characterization of all the important fish and shrimp species using suitable molecular markers and karyotyping • Gene mapping of commercially important fish species using microsatellite markers • Development of cryogenic gene banking for conservation of improved strains and threatened species • Development of PCR based molecular technique for rapid and effective diagnosis of infectious diseases • Development of genetically engineered vaccines against devastating pathogens • Production of probiotics and metabolites for fish feed supplementation • Development of techniques for the production of single cell protein • Development of molecular techniques for post harvest quality assessment of shrimp and fish • Development of biotechnological tools for quality shrimp/fish product development • Improved techniques for shrimp/fish and their products preservation and processing

Institute	Priority areas in biotechnology
BLRI	• Application of advanced biotechnology tools and artificial insemination, multiple ovulation and embryo transfer, sexed ova and sperm, embryo transfer technology for characterization, selective breeding, conservation and genetic improvement of livestock and poultry species • Disease diagnosis and molecular characterization of pathogens • Development of disease diagnostic kit, antibiotics, monoclonal antibody, genetically modified antibody, vaccines, stem cell for improved treatment of livestock and poultry species • Improvement of nutrient availability and utilization through application of nutritional biotechnology tools on crop by products, processed animal feed, straw and oil cake • Effective waste management through recycling of animal feed • Application of advanced biotechnology approaches for quality improvement and conservation of livestock products and their value added products • Transgenic animal production • Development of antibiotic alternative in animal feed from mines, medicinal plants and probiotics

6. Major Challenges and Opportunities

6.1 Challenges

- Ensuring food and nutrition security for the ever-increasing population
- Shortage of specialized, skilled manpower
- Lack of follow-up professional training
- Lack of modern equipment
- Lack of adequate infrastructure
- Lack of adequate fund for R&D
- Lack of availability of biotechnological grade chemicals and reagents in the local market
- Lack of international linkages
- Stress tolerant, climate smart, high yielding, short duration and nutritious quality variety/technology development
- QTL determination for sugarcane improvement

8.2 Opportunities

- Biotechnology Division has been established at BRRI with some lab facilities for doing research work on rice tissue culture, DNA-fingerprinting, molecular marker-assisted selection and *Agrobacterium*-mediated genetic transformation. BRRI also has a contained transgenic greenhouse and screen house. Biotechnological facilities at BRRI are likely to help for developing high yielding rice varieties with biotic and abiotic stress tolerance
- Diverse genetic resources
- QTL determination for sugarcane improvement
- Huge demand of animal produces (egg, meat and milk)
- Existing laboratory facilities (building, equipment and others)
- Government policies for enhancement of biotechnology research
- Very limited agricultural land availability triggering improvement of individual productivity of existing animal/poultry population

Future Outlook

Institute-wise future outlook in terms of short-(2018-19 to 2019-20), medium-(2018-19 to 2022-23), and long-term (2018-19 to 2027-28), strategies for promoting modern biotechnology in crop (Table 9), animal (Table 10) is summarized below:

Table 9. Future outlook in crop biotechnology

Institute	Future outlook
BRRI	**Short-term** • Developing double haploids and creation of somaclonal rice lines for low glycaemic index (GI), antioxidant enriched black rice, premium quality rice lines, DNA fingerprinting of rice germplasm, identification and cloning of drought, cold and salinity tolerant genes. Isolation of nitrogen and phosphorus fixing bacteria • Developing bacterial blight resistance and submergence tolerant rice lines **Medium-term** • Developing aromatic rice varieties through molecular marker-assisted selection • Gene pyramiding for bacterial blight, blast resistant rice lines • Developing drought and salinity tolerant homozygous rice lines through genetic engineering • Field evaluation of golden rice **Long-term** • Release of high yielding rice variety through anther culture, somaclonal variation, wide hybridization • Development of drought, salinity and heat tolerant transgenic rice variety • Development of biofertilizer using nitrogen and phosphorus fixing bacteria. Inclusion of proteomics in research activity to better understand molecular mechanisms for a certain trait
BARI	**Short-term:** Tissue culture of valuable crops **Medium-term:** Development of markers and marker assisted breeding **Long-term:** Genome sequencing
BINA	**Short-term** • Development of salinity, drought, cold and submergence tolerant with early maturing and high yielding rice through genetic engineering mutation and marker assisted breeding approaches • Development of pest and disease resistant crop varieties by inducing resistant genes from different sources (plant and microorganism) • Development of nutrient enriched (Zn and Fe) crop varieties through biofortification • Molecular characterization of endemic bacteria and fungus from different crops **Medium-term** • Genome analysis of novel genes from wild rice and landraces for their functional studies • Preparation of gene constructs (clones) of different stress tolerant novel genes for over expression and genetic transformation • Construction of cDNA library of novel stress-induced genes from different land races and wild relatives • Transformation and insertion of novel genes into popular crop varieties for the development of transgenics • Dissection of physiological traits for adaptation in different environments • Gene pyramiding for the development of diseases and pest tolerant crop varieties • Isolation and characterization of stress, disease and pest tolerant genes from desert and halo tolerant plants, microorganisms (bacteria and fungi) for the development of stress tolerant crop varieties • Crops with economic importance that are rare or available germplasm will be used for crop improvement through anther culture, embryo culture or tissue culture • QTL mapping, gene pyramiding and molecular characterization, mutation and Marker Assisted Back Cross (MABC) breeding will be done to address the stress environment, bio-fortification, early maturing and grain quality for consumer preference

Institute	Future outlook
	Long-term ● Isolation and analysis of novel genes from wild rice and landraces for their functional studies ● Constructs (clones) of different stress tolerant novel genes will be prepared for over expression and genetic transformation ● cDNA library of novel stress-induced genes from different land races and wild relatives of rice will be constructed ● Transformation and insertion of novel genes into popular crop varieties will be done for the development of transgenics ● Dissection of physiological traits for adaptation in different environments will be done ● Gene pyramiding for the development of diseases and pest tolerant crop varieties ● Isolation and characterization of stress, disease and pest tolerant genes from desert and halo tolerant plants, microorganisms (bacteria and fungi) for the development of stress tolerant crop varieties ● Crops with economic importance that are rare or available germplasm will be used for crop improvement through another culture, embryo culture or tissue culture ● QTL mapping, gene pyramiding and molecular characterization, MABC breeding will be done to address the stress environment, bio-fortification, early maturing and grain quality for consumer preference
BJRI	**Short-term** ● Molecular characterization of Jute, Kenaf and Mesta varieties and Jute and allied Fibres (JAF) germplasm through DNA fingerprinting ● Development of tissue culture protocol for JAF crops **Medium-term** ● Molecular characterization of Jute, Kenaf and Mesta varieties and JAF germplasm through DNA fingerprinting ● Development of tissue culture protocol for JAF crops
BSRI	**Short-term** ● Development of salt tolerant and drought tolerant sugarcane varieties for cultivation in southern regions of Bangladesh using tissue culture tools ● Development of flood tolerant sugarcane varieties for cultivation under flood prone areas of Bangladesh using tissue culture tools ● Molecular characterization and documentation of sugar crops using SSR markers **Medium- and long-term** ● Development of short duration sugarcane varieties in Bangladesh using tissue culture tools ● Development of seed producing sugar beet in Bangladesh using tissue culture techniques ● Development of tissue culture derived date palm in Bangladesh ● Development of salt tolerant sugarcane varieties for cultivation in southern regions of Bangladesh using tissue culture tools ● Development of flood resistant and drought tolerant sugarcane varieties through tissue culture tools ● Development of transgenic sugarcane varieties against biotic and abiotic stresses ● Development of somaclones of sugarcane, stevia, sugarbeet and date palm for releasing as varieties through callus culture
NIB	***Conventional plant biotechnology*** **Short-term** ● Protocol development for commercial-scale micropropagation of economically important plants ● Multiplication and introduction of potential exotic plants ● Establishment of detailed protocol for genetic transformation in model and crop plants **Medium term** ● Protocol development for commercial-scale micropropagation of economically important plants including forest and tree species ● Multiplication and introduction of potential exotic plants ● Transgenic plants in field evaluation

Institute	Future outlook
	Long term ● Protocol development for commercial-scale micro propagation of economically important plants including forest and tree species ● Transgenic plants in field evaluation ***Modern plant biotechnology*** **Short-term** ● Establishment of detailed protocol for using functional genomics tools (*i.e.* proteomics, transcriptomics and emerging techniques) ● Establishment of detailed protocol for CRISPR-Cas9 system **Medium-term** ● Understanding crop functional genomics for trait improvement ● Whole genome sequencing initiative of important crops ● Genome editing of crop plants for trait improvement ● Understanding molecular mechanism of plant disease and herbivore ● Establishment of plant cell culture for the production of functional compound **Long-term** ● Whole genome sequencing initiative of important crops ● Field trial of genome edited crops ● Study of plant metagenomics ● Recombinant protein production in cell culture (plant biofactory) ***Next generation plant biotechnology*** **Medium-term** ● Assembly and delivery of large DNA fragments to plant cells ● Understanding genetic variation and DNA fingerprinting of important plants **Long-term** ● Introduction of all new physiological pathway to produce industrially important compounds ● Development of synthetic/semi-synthetic plant cells ***Services*** **Short-term** ● Disease testing services for major crops ● Protocol development to detect GMO ● Analytical protocol development for toxicity and food ingredient determination in food crops **Medium-term** ● Genetic purity, hybridity test for seed enterprises ● GMO detection services ● Analytical service for toxicity and food ingredient determination in food crops **Long-term** ● Genetic transformation services (model plants) ● GMO detection services

Table 10. Future outlook in animal biotechnology

Institute	Future outlook
BLRI	**Short-term** ● Development of molecular tools for identification of livestock and poultry diseases ● Development of vaccine against Anthrax and Foot and Mouth disease (FMD) of ruminants and infectious laryngotracheitis and infectious bronchitis of poultry ● Development and use of phytobiotics, prebiotics and probiotics as animal feed ● Conservation of important farm animal species ● Development of starter culture for *dahi* (yogurt) preparation ● Buffalo semen cryopreservation technology ● Adoption of *in vitro* embryo production technology

Institute	Future outlook
	Medium-term ● Genetic improvement of productivity of farm animal and poultry species ● Genetic characterization of different farm animal and poultry species ● Application of ovum pick up (OPU) technology for multiplication of high yielding cattle and buffalo ● MAS of breeding animal/poultry to increase milk/meat/egg production ● Development of salt tolerant fodder variety ● Development of molecular tools for identification of livestock and poultry diseases ● Development and use of phytobiotics, prebiotics and probiotics as animal feed **Long-term** ● Sexed semen production ● Development of technology for early pregnancy diagnosis in farm animal ● Genetically modified animal feed production ● Development of draught/water tolerant fodder variety ● Development of silage inoculant ● Improvement of nutritional quality of crop residue using enzymes ● Reduction of enteric methane production through manipulation of rumen microbial population ● Development of multi strain probiotics ● Development of technology for detection of infertility in farm animals ● Development of molecular tools for identification of livestock and poultry diseases ● Development and use of phytobiotics, prebiotics and probiotics as animal feed

Future outlook in terms of short (2018-19 to 2019-20), medium (2018-19 to 2022-23), and long term (2018-19 to 2027-28), strategies in different areas of animal biotechnology (Table 11) and fisheries biotechnology (Table 12) is detailed hereunder:

Table 11. Future outlook in different areas of animal biotechnology division

Field	Future outlook
Animal health biotechnology	**Short term** ● Basic study for facilities creation and protocol adaptation for research on vaccine and probiotics development and disease diagnosis ● Study on livestock and poultry diseases ● Conventional vaccine development ● Molecular disease diagnosis lab establishment for livestock and poultry **Medium term** ● Study on livestock and poultry diseases ● Conventional vaccine production and technology transfer ● Probiotic production and technology transfer ● Ag and Ab production and technology transfer ● Recombinant vaccine production and technology transfer **Long term** ● Study on livestock and poultry diseases ● Probiotic production and technology transfer ● Ag and Ab production and technology transfer ● Recombinant/ DNA/ Subunit vaccine production and technology transfer
Productive and reproductive biotechnology	**Short term** ● Basic study for facilities creation and protocol adaptation-artificial insemination (AI), OPU, *in vitro* fertilization (IVF), gene cloning and gene transfer ● Marker gene/s study for different traits **Medium term** ● Marker gene/s study for different traits ● Transgenic animal production **Long term** ● Marker gene/s study for different traits ● Transgenic animal production

Field	Future outlook
Genome research	**Short term** ● Basic study for facilities creation and protocol adaptation-genetic diversity study, DNA barcoding, sequence analysis, SNP detection, genotyping, association mapping. **Medium term** ● Establishment of Genome Research Center **Long term** ● Whole genome sequencing of other livestock species and further analysis- DNA and RNA Seq, Assembling, SNP analysis, functional gene identification, gene/ MAS and breeding.
Services	**Short term** ● Livestock and poultry disease diagnosis ● Quality analysis of animal feed ingredients, composite feed, water, other relevant environmental samples, *etc.* **Medium term** ● Livestock and poultry disease diagnosis ● Quality analysis of animal feed ingredients, composite feed, water, other relevant environmental samples, *etc.* ● Semen and embryo sexing ● Vaccine quality test ● Genome sequencing and analysis **Long term** ● Livestock and poultry disease diagnosis. ● Quality analysis of animal feed ingredients, composite feed, water, other relevant environmental samples, *etc.* ● Semen and embryo sexing ● Vaccine quality test ● Genome sequencing and analysis

Table 12. Future outlook in different areas of fisheries biotechnology

Field	Future outlook
Fish health management	**Short term** ● Facilities and protocol establishment for research on fish disease diagnosis ● Disease diagnosis lab establishment for fish and shrimp **Medium term** ● Study on fish and aquatic species diseases ● Climate change adaptation study for fish ● Conventional vaccine production and technology transfer ● Probiotics production and technology transfer ● Phytoplankton, zooplankton production and technology transfer **Long term** ● Vaccine production; Disease resistant fish; Symbiotics production
Fish breeding, propagation and conservation	**Short term** ● Establishment of brood stock artificial propagation **Medium term** ● Fish cryopreservation ● Management and MAS **Long term** ● Transgenic fish production
Fish genomics	**Short term:** Fish barcoding; Fish genotyping **Medium term:** SNP analysis; Candidate gene association study; Gene mapping **Long term:** Whole genome sequencing of fish and other aquatic animals; DNA & RNA Sequencing; SNP analysis; Candidate gene association study; Gene mapping; Establishment of fish genome research Lab

Field	Future outlook
Services	**Short term** ● Molecular diagnosis of Fish disease **Medium term** ● Quality fish seed dissemination ● Molecular diagnosis of Fish disease ● Quality parameter analysis of aquatic environment **Long term** ● Quality fish seed dissemination ● Fish feed quality analysis, feed ingredients quality analysis ● Molecular diagnosis of Fish disease ● Quality parameter analysis of aquatic environment ● Phytoplankton, Zooplankton dissemination ● Genome sequencing and analysis

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Country Status Report - Bhutan

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Introduction

Agriculture in Bhutan has a dominant role in the Bhutan's economy. Some conventional biotechnological applications are modestly used in certain areas of traditional methods of plant and animal breeding, tissue culture applications and studies on conservation of nature, soil, forests, genetic resources and wild life by various research organizations. Bhutan has opted for a genetically modified organism (GMO) free strategy. The country would allow the introduction or import of processed or semi-processed genetically engineered (GE) products, incapable of reproduction and whose safety assessment has been conducted. The country would restrict the introduction, release and research involving genetically engineered organisms (GEOs). Research involving genetic modifications and development of GEOs is banned in Bhutan by a ministerial notification from the Ministry of Agriculture and Forests (MoAF) in April 2011. A brief outline on the updated status of agricultural biotechnology (AB) and biosafety is presented in this paper.

Table 1. Basic Information

Indicator	Details
Value of GDP (Billion BTN) BTN= Bhutanese Ngultrum	170.81[*]
Value of GDP (Billion USD)	2.51[**]
Value of agriculture GDP (Billion BTN)	7.79[@]
Value of agriculture GDP (Million USD[+])	107.97
Agriculture GDP in per cent of GDP	15.18[***]
Total investment in agricultural research (Billion BTN)	5.44[#]
Total investment in agricultural research (Million USD[+])	75.44
Total investment in AB research (Million BTN)	No data
Total investment in AB research in USD	No data

*Source: World Bank (*2017; **2017a; ***2017b); @Trading Economics (2017); #MoF (2017); [+]1USD=72.11 BTN*

Mr Wangda Dukpa is Chief Agriculture Officer, Department of Agriculture, Ministry of Agriculture and Forests, Bhutan. He worked in various capacities such as Programme Officer, Officer In-charge and Programme Director in the management positions for the last 10 years. Conducted rice research in cool temperate zone and introduced rice cultivation up to 2700 msl. Currently, Mr Dukpa is responsible for planning, coordinating and overseeing agriculture research programme.

2. National Policies

2.1 Current National Policies on Agricultural Biotechnology and Policies for Enhancing the Livelihood of Farmers through Agricultural Biotechnology

2.1.1 The Convention on Biological Diversity (CBD), 1992

Bhutan signed the Convention on Biological Diversity (CBD) at Rio Earth Summit in 1992. Bhutan was committed to the CBD from the advent of the convention. The Royal Government of Bhutan (RGOB) became Party to the Convention from August 25, 1995. Currently, there are 194 countries, who are Parties to the Convention. The objectives of the Convention are to promote the conservation of biodiversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the use of genetic resources (CHMB, 2018).

2.1.2 Plant Quarantine Act, 1993

This Act has come into existence to safeguard agricultural and wild flora from introduced pests, defined as "any form of plant or animal life, or any pathogenic agent, injurious or potentially injurious to plants or plant product." In particular it ensures that all imported plants are quarantined and screened prior to entry into the country (MoAF, 1993).

2.1.3 The Cartagena Protocol on Biosafety, 2000

The RGOB acceded to the Cartagena Protocol on Biosafety on September 11, 2003. The Protocol addresses the safe transfer, handling and use of Living Modified Organisms (LMOs) that may have adverse effects on biodiversity, taking into account of human health, with a specific focus on transboundary movements of LMOs (CHMB, 2018).

2.1.4 Seeds Act, 2000

The Seeds Act is to regulate import and export of planting material, prevent introduction of pests and diseases and promote seed industry in the country, with the aim to enhance rural income and livelihood. This Act facilitates timely availability of high quality seeds and planting materials of superior varieties of crops with a view to increase the production of crops, farmers' productivity, per capita farm income and export earnings (WIPO, 2000).

2.1.5 Environmental Assessment Act, 2000

This Act applies to strategic plans, policies, programmes and projects which may have an impact on the environment (eRegulations Bhutan, 2000).

2.1.6 Livestock Act, 2000

This Act ensures that only quality and appropriate breeds of livestock, poultry and fish are introduced and the units used for semen and embryo production and storage are free from diseases (WIPO, 2000a).

2.1.7 Biodiversity Act, 2003

This Act is mainly to ensure national sovereignty of the RGOB over genetic resources in accordance with relevant national and international laws(NCB, 2003).

2.1.8 Food Act, 2005

Addresses the issue of food safety resulting from GM food (WIPO, 2005).

2.1.9 Seed Rules and Regulations of Bhutan, 2006

The Seeds Act of Bhutan, 2000, under Section 21.2 empowers the MoAF to adopt Seed Rules and Regulations to administer the Act and implement the provisions contained therein; Recognizing that within the purview of the Act, MoAF shall facilitate timely availability of high quality seeds and planting materials of superior varieties of crops with a view to increase the production of crops, farmers' productivity, per capita farm incomes and export earnings (MoAF, 2006).

2.1.10 Draft National Biosafety Framework of the Kingdom of Bhutan, 2006

The Draft regulation is formulated mainly for the assessment, management and control of potential risks associated with the GMOs and products thereof, and activities associated with them, in order to enable the country to benefit from modern biotechnology and at the same time protect the biodiversity and people of Bhutan from their potential negative or adverse effects. The guidelines contained in this document provide appropriate regulatory measures to assist all stakeholders in the establishment and maintenance of national and institutional capacities to provide for safety in biotechnology, development of expert human resources and efficient exchange of information (UNEP, 2006).

2.1.11 Nagoya Protocol on Access and Benefit-Sharing, 2010

The RGOB also ratified the Nagoya Protocol on Access and Benefit-Sharing on September 30, 2013. The objective of the Protocol is the fair and equitable sharing of benefits arising from the utilization of genetic resources (CHMB, 2018).

2.1.12 Biosafety Bill of Bhutan, 2014

The National Assembly deliberated on the Biosafety Bill of Bhutan 2014 on May 21 and 22,2014 and adopted the Bill on May 23, 2014. The scope of the bill is extended to all GEOs; products derived from GEOs; all stages of import, export, and direct use of products that have GE content within the Kingdom. Exemptions are traditional and domestic methods of animal and plant breeding; traditional and domestic exchange and sale of local seeds, plants, and livestock;gene sequencing, tissue culture, and other similar methods, which do not involve the use of modern biotechnology; and products derived from GEOs for pharmaceuticals for human and veterinary use.

The bill established (i) National Biosafety Commission (NBC) - The statutory body to administer and make decisions on all biosafety related issues. (ii) Bhutan Agriculture and Food Regulatory Authority (BAFRA) - The National Competent Authority for implementation of all biosafety related activities. (iii) Technical Working Group on Biosafety - The key technical advisory committee (iv) Biotechnology (GM) Laboratory, A detection and quantification facility at the National Food Testing Laboratory, Yusipang, Thimphu (NCB, 2014).

2.1.13 In-country Livestock Biosecurity Guidelines, 2015

BAFRA has developed the In-country Livestock Biosecurity Guidelines, which shall be used in conjunction with the Livestock Act of Bhutan, 2001 and its rules as a reference resource to strengthen implementation of livestock biosecurity within the country. This document also details the standard biosecurity practices, which can be promoted to all farm operations, especially commercial poultry and dairy farms. Besides, it also outlines steps for conducting a livestock movement assessment process, which incorporates a routine evaluation of farm biosecurity practices and makes good biosecurity a condition of permitted livestock movement (BAFRA, 2015).

2.1.14 Biosafety Act of Bhutan, 2015

The Act came into force on the July 20, 2015 and extends to the whole of Bhutan. It shall apply to all GMOs, products derived from GMOs, all stages of import, export, and direct use of products that have genetically modified content, within the Kingdom. This Act shall not apply to traditional and domestic methods of animal and plant breeding; traditional and domestic exchange and sale of local seeds, plants, and livestock; gene sequencing, tissue culture, and other similar methods, which do not involve the use of modern biotechnology; and products derived from GMOs for pharmaceuticals for human and veterinary use (BAFRA, 2015a).

2.1.15 Biosafety Rules and Regulations of Bhutan, 2018

The GM food in Bhutan is regulated as per the Biosafety Act of Bhutan 2015 and its Rules and Regulations 2018. The Act was enacted in July 2015 considering the Kingdom's current interest and keeping in view the country's food security needs. For importation of GMOs for direct use as food, feed or for processing (FFP), GM food safety assessment/review is required. The National Biosafety Board reviews and makes decisions on events based on the scientific/technical risk review provided by the Biosafety Technical Working Group and also taking into consideration of the policy issues as well as public inputs (FAO, 2018).

2.2 Implementation of Policies (UNEP, 2006)

Following ministries/agencies are responsible for implementation of acts:

Act/Regulation	Ministry/Agency
Food Act	BAFRA under the Ministry of Agriculture (MoA)
Livestock Act	MoAF
Plant Quarantine Act	BAFRA under the MoA
Draft Regulation on Biosafety	BAFRA under the MoA Seeds Act: MoA
Biodiversity Act	NBC under MoA
Environmental Assessment Act	National Environment Commission (NEC)
Seed Rules and Regulations of Bhutan	BAFRA
Biosafety Act, 2015	BAFRA

The BAFRA is the national competent authority for the implementation and enforcement of the Biosafety Act and all other biosafety related activities in the Kingdom. BAFRA, consisting of the Minister, MoAF, the head of relevant departments and agencies under the MoAF; the Department of Public Health, Ministry of Health; the Department of Trade, Ministry of Economic Affairs; the Department of Revenue and Customs, Ministry of Finance; the Bureau of Law and Order, Ministry of Home and Cultural Affairs; One high-level representative from the NEC; and one high-level representative from the Bhutan Chamber of Commerce and Industry are responsible for the enforcement and implementation of the bill (BAFRA, 2015).The Biosafety Act of Bhutan, 2015 establishes the National Biosafety Board as the highest decision-making body for issues related to biosafety to apprise the esteemed members on the biosafety activities being carried out by BAFRA and review the Biosafety Rules and Regulations.

2.3 Capacity Development

- Prioritize human resources development to improve availability, retention and maintenance of a critical mass of researchers, and efficiently deploy and use researchers, technicians and other staff.
- Strengthen the critical mass of researchers in all fields by upgrading universities/research institutes and other first-degree graduates to Masters and Ph.D. levels, based on ability to carry out high quality and meaningful research.
- Give special priority to the training, recruitment and retention of socio-economic researchers for the Research and Development Centres (RDCs), given the high rate of attrition of this category of scientists in the past years.
- Implement an incentive scheme to increase the attraction and retention of researchers, including remuneration, teaching and consultancy opportunities, and recognition of work through professional, public service and civic citations and awards.
- Promote and designate researchers, including specialists, based on demonstrated contribution to research. The promotion criteria should include; number of peer-reviewed publications in national and international journals, adoption rate of a researcher's recommendations, and assessment of the researcher's impact on the sector's development.

2.4 Partnership

Partnership in strengthening the biotechnological research underlines the importance of linkage, collaboration, cooperation and coordination among the central agencies, RDCs and departments within the Ministry, national institutions and with regional and international research institutions and CG centres. The Agriculture Research and Extension Division, Department of Agriculture (DOA) is responsible for establishing and strengthening linkages and collaborations with international research institutions including development and signing of memorandum of understanding, letter of intent, agreements, *etc.* by proper planning and coordination. This division helps to explore increased funding for research activities as well as capacity building through sharing of knowledge, facilities and materials. In addition, the division uses international collaboration to develop Bhutan's research manpower capabilities through education and scholarship programmes, and secondment of Bhutanese scientists for teaching, research and other assignments with relevant international research institutions. Prioritization is given towards building more collaborative linkages in thematic and contemporary areas of research, such as climate change, conservation science, and food and nutrition security. Agriculture Research and Development Centres (ARDCs) and central programmes collaborate and cooperate with Agriculture Extension Officers in the districts in implementing research outreach programme, on-farm research trials, to package and share research results with extension institutions and/or, as necessary, directly with farmers.

Table 2. Surveys conducted in Bhutan revealed the existing users of biotechnology and arrangements of safe use of biotechnology

Activity	Partnership

Existing safe use of biotechnology, review and assessment of existing legislation that may impact on the use of modern biotechnology	• Ministry of Agriculture and Forests
	• Druk Seed Corporation-Seed production, tissue culture
	• RNR-RC-Introduce new improved crops and livestock
	• Vaccine Production Centre-Serbithang-Vaccine production
	• Food Corporation of Bhutan-Import of FFP
	• BAFRA-Regulates food safety and plant and animal quarantine
	• Ministry of Trade and Industry-Department of Trade- Trade policy and Business licence
	• Ministry of Finance
	  – Department of Revenue and Customs-regulate import of FFPs
	• Ministry of Health (MoH)
	  – Drugs, Vaccine and Equipment Division
	  – National Institute of Traditional Medicine-production of pharmaceuticals
	• Dzongkha Development Authority
	  – Leiden University- Bhutanese Genome Project (with DDA)

Survey on existing national, bilateral and multilateral co-operative programmes in capacity building, R&D and application of biotechnology	• Royal Civil Service Commission- HRD Masterplan • Ministry of Agriculture and Forests – Capacity building programmes and plans
Survey on existing national biosafety frameworks in the countries of the sub-region	• Government of India (NBF existing): Ministry of Environment and Forests • Royal Thai Govt (NBF Existing): National Biosafety Committee • Govt. of Malaysia (NBF Existing): National Biosafety Committee • His Majesty's Government (HMG), Nepal (NBF under process): Ministry of Forest and Soil Conservation • Govt. of Bangladesh (NBF under process): Ministry of Environment and Forests
Survey on existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data and data validation	• The United Nations Environment Programme (UNEP) and the Global Environment Facility Biosafety Unit
Survey on the extent and impact of release of GMOs and commercial products	Ministry of Agriculture; Ministry of Trade and Industry; Ministry of Health; Bhutan Chamber of Commerce and Industry; Food Importers and Business

Source: UNEP (2006)

2.5 Funding Mechanism

The Ministry of Finance, RGOB, allocates budget based on five-year plan and annual plan. National/ international projects also help in funding for biotechnological research.

Sponsored Research

- Encourage international or national agencies or individuals, including the private sector to fund research endeavours by Bhutanese researchers or research institutions.
- Set up the coordinating and clearing mechanisms in the Departments for any such sponsored research to be undertaken by researchers.
- Encourage donors to meet research needs identified under respective projects to supplement the regular public sector budget allocated.

3. National and Institutional Strategies

3.1 National Strategies for Research and Development

Agricultural biotechnology in Bhutan especially for agriculture (crop) sector includes tissue culture, biofertilizers, biopesticides and effective microorganisms (EM) technology. Tissue culture activity started in 1984 and experimented on various crops such as fruits (apple, peach, pear, plum, strawberry, grapes, kiwi, citrus, banana, *etc.*), ornamentals (orchids, rhododendron, lily, tulip, *etc.*), and potato. Currently, potato, banana, kiwi, apple and avocado are being propagated at the National Seed Centre (NSC) using tissue culture technology for rapid multiplication and production of clean planting materials. Pineapple propagation through tissue culture technology is under process. Upscaling tissue culture technology is essential for production and supply of adequate quantity of quality planting materials to the farmers.

The EM technology was introduced in Bhutan in 1995 in collaboration with Asia-Pacific Natural Agriculture Network (APNAN) for promotion of natural farming. APNAN continues to assist Bhutan in production of mother solution in the production units of Bhutan. EM programme is housed at National Soil Surveys Centre (NSSC) and School Agriculture Program (SAP). The Department in collaboration with NSSC promotes EM technologies. EM is used in compost making, sewerage treatment, agro-industry for recycling agro-industrial wastes, school toilets for suppressing foul smell, SAP for organic/natural farming, direct spray on vegetable beds and crops.

3.2 Capacity Development

The RGOB is promoting national/international training programmes for scientists and technical staff working in the field of biosecurity. Ten government officials from Bhutan participated in a workshop on LMOs biosafety and safety management from 21 to 24 April 2015 in Korea, as part of the Korea biosafety capacity building initiative announced at the 7th meeting of the Parties to the Cartegena Protocol. Two officials from Bhutan participated in a customized training programme on LMO detection and policy-making, conducted by The Republic of Korea from October 5-30, 2015 (CBD, 2016).

Training of laboratory officers and technicians working in the tissue culture laboratory at relevant institute could enhance the skills and knowledge on the latest tissue culture technology. Technical capacity to develop the Bhutan Biosafety Clearing House (BBCH) is crucial. Existing testing facilities include, surveillance on GM elements (35S promoter, Nosterminator, pFMV, cp4-epsps, Cry1A(b), Cry1Ac, Cry3Bb1, Cry1F, rActin1, Pat, BAR, nptII, Barnase, Barstar, CaMV); EU-method (RIKILT)surveillance-test kit and Real time PCR (Biorad). However, infrastructure such as powerful computers and servers, to support the BBCH is needed. Also, relevant people need to be trained on biosafety issues and effective dissemination techniques, including GM event detection techniques.

3.3 Infrastructure Development

Currently, there is only one tissue culture laboratory at NSC under the DoAF. The tissue culture facility at NSC was established in 1988 and the laboratory facilities need to be upgraded. In order to meet the quality seeds and planting materials requirement of the country in adequate quantity, it is crucial to expand the existing laboratory. Tissue culture laboratory with modest facility is also essential in all ARDCs to conduct research.

3.4 Communication Strategy

Regional cooperation mechanisms that would be beneficial in enhancing communication for the effective implementation of Bhutan's biosafety programme are as follows: (i) Sharing of experiences through regional workshops and visits; (ii) Identification of national biosafety experts in respective countries to exchange and share relevant information; (iii) Meet regularly as well as function as an informal multinational technical backstopping team; (iv) Development of "best practices" in Asia and sharing; (v) Establishment of on the job training/exchange programmes among the countries in the region; (vi) Development of a website at both regional and national levels to facilitate information sharing; (vii) Development and publication of a regular regional biosafety journal that documents experiences as well as the status of the implementation of biosafety procedures in the member countries (Biodiversity Asia, 2018).

3.5 General Awareness

Currently, public awareness, education, and participation on biosafety-related issues is non-existent. Therefore, raising awareness of the public in the field of biosafety, and establishing BBCH with all relevant biosafety information in Bhutan are two key objectives to fill the gaps. The Information and Communication Services (ICS), MoAF, which consists of publication section, audio/video section, information technology section and one stop information shop section, is often employed by BAFRA for publicity campaigns (UNEP, 2006). BAFRA shall coordinate with the NEC to ensure that announcements of applications for prior approval, opportunities for public comment, joint guidelines for monitoring and emergency response, and any other information relevant to the regulation and use of GMOs and GMO products in the Kingdom are made available to the BBCH in a timely manner.

The National Biodiversity Board and all relevant stakeholders may ensure public, school, institute and college to participate in awareness programmes on issues related to GMOs and products derived from GMOs and the regulation and use of products derived from GMOs in the Kingdom. BAFRA and other agencies, therefore, need to develop and implement programmes for public awareness, education and participation, including public access to information, concerning the safe transfer, handling and use of GMOs. In particular, BAFRA can make effective use of the media for this purpose. BAFRA should also submit to the BBCH information regarding their capacity needs, gaps, programmes and priorities with respect to public awareness, education and participation.

Special awareness workshops and training for the retail food importers are essential. Funds and capacity at the ICS and the Information and Communication Bureau are needed to produce TV commercials, brochures, and newspaper advertisements to reach this group. Capacity and funds to have all imported foods labeled are needed. Another important group is illiterate farmers. Audio-visuals and radio programmes can reach this group more effectively. Raising awareness among agricultural experts working in the Ministry of Agriculture is important, who can be harnessed to collect information on GMOs and inform colleagues, farmers, and consumers on biosafety (UNEP, 2006).

3.6 Policy Advocacy

Policies, standards, guidelines, rules and regulations and frameworks are required for smooth implementation of the programme. Biosafety Act (2015), Biosafety Rules and Regulations of Bhutan (2018) help in policy advocacy.

4. Priority Areas of Agricultural Biotechnology

4.1 Bioprospecting, Conservation and Sustainable Use of Bioresources

Bioprospecting laboratory was established in 2012 at the National Biodiversity Centre (NBC) and since then bioprospecting activities have been carried out. Information on traditional knowledge on treating different diseases using local plant materials has been recorded for all 20 districts and is due for publication. NBC has developed a product called '*Zhinor*', a massage balm for treating joint pains from *Zingiber cassumunar* and research is being conducted to develop other products. Similarly, bioprospecting research is being carried out by MoH and private agencies. NBC, MoAF, Menjong Sorig Pharmaceutical Corporation Ltd., MoH and Bio-Bhutan (Pvt. Company) have jointly launched nine nature-based products in line with Access and Benefit Sharing framework on April 5, 2018. The products were anti-wrinkle cream, massage balm, liniment, massage oil, perfume, soaps, and hand sanitizer to support sustainable rural livelihoods. Meanwhile, conservation of plant genetic resources, both *in situ* and *ex situ*, is being carried out by NBC for effective management and sustainable use of plant genetic resources.

4.2 Priority Areas in Plant, Animal, Aquatic Biotechnology for Low- and High-Tech Biotechnology

Priority in the future shall be given on the low-tech biotechnology initiatives focusing on adaptive and applied research. The DoA will give priority on strengthening tissue culture facilities for research and propagation of planting materials.

5. Major Challenges and Opportunities

5.1 Challenges

NSC is the only government seed agency under DoA with a mandate to produce and supply seeds and planting materials to the farmers. The centre is not able to produce adequate quantity of seeds and planting materials due to limited production capacity. Therefore, expansion of tissue culture laboratory will enable NSC in producing adequate quantity of seeds and planting materials.

5.2 Opportunities

There is a huge potential of enhancing seed potato production capacity of NSC through tissue culture technology, which will eventually enhance seed replacement rate of potato in the country. Similarly, there is a potential for enhancing the production capacity of planting materials of fruit crops through tissue culture technology.

6. Future Outlook

6.1 Short-term

- Strengthen technical capacity on tissue culture research
- Explore use of biotechnological tools to convert traditional knowledge into traditional medicines from plant materials

6.2 Medium- and Long-term

- Enhancement of bioinputs using biotech tools, developing testing laboratory facilities in place equipped with required laboratory officers
- Strengthen the laboratory and human resources capacity for bioprospecting programme
- Initiate collaborative activity on bioprospecting between ARDCs under Department of Agriculture and NBC.

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Country Status Report: India

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1. Introduction

Agricultural biotechnology (AB) is seen as a key driver for agricultural productivity, profitability and livelihood betterment. India is the second largest population in the world, after China. It is an agriculture-based country with more than 18 per cent of the total GDP to agriculture. India is the world's largest country to cultivate GM cotton, in about 11.0 million ha in 2013 (Dang *et al.*, 2015). Farmers in India had a net gain of US$82/ha and US$356/ha during 2002 and 2007, respectively. The understanding and implementation of agri-biotech policies and regulations are the keys to success to achieve food and nutritional security.

Table 1. Basic Information

Indicator	Details
Value of GDP (Trillion INR) INR= Indian Rupee	167.52*
Value of GDP (Trillion USD)	2.59**
Value of agriculture GDP (Trillion INR)	5.66@
Value of agriculture GDP (Billion USD+)	8.78
Agriculture GDP as percent of GDP	15.45***
Total investment in agricultural research (Billion crores INR)	~70
Total investment in agricultural research (Billion USD+)	~1.09
Total investment in AB research (Billion INR)	~1.00
Total investment in AB research (Million USD+)	~15.5

*Source: World Bank (*2017; **2017a; ***2017b); Trading Economics (2017); 1 USD=64.4977 INR*

2. National Policies

Many developed and developing countries like United States, India, Brazil, Argentina, Canada and China have

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become significant producer/exporter of agri-biotech products. Many countries like Australia, Bangladesh, Brazil, India, Kenya, Malaysia, Nepal, Netherlands, Nigeria, Paraguay, Peru, South Africa, Sri Lanka, Tanzania, Thailand and Zambia have enacted laws or have guidelines related to AB policies. Since late 1980s, India established its policy and regulatory system for agri-biotech development. The first set of regulations related to agri-biotech was enacted under the Environment Protection Act of 1986 to ensure safety from the use of GMOs and products thereof in research and application to the users as well as to the environment. The agri-biotech development in India varies in terms of different states.

2.1 Current National Policies on Agricultural Biotechnology and Policies for Enhancing the Livelihood of Farmers through Agricultural Biotechnology

2.1.1 National Biotechnology Development Strategy, 2015-2020

The Government of India (GoI), announced the first National Biotechnology Development Strategy (NBDS) in September 2007. The implementation of NBDS, 2007 has provided an insight into the enormous opportunities. Boundaries between disciplines once considered distant have started to blur and as a consequence of their convergence, given birth to newer opportunities and challenges. Thus, it was felt opportune to take a critical look at the Indian biotech sector.

In the year 2015, Department of Biotechnology (DBT) announced 'The National Biotechnology Development Strategy-2015-2020' (hereinafter referred to as 'Strategy-II'), which was framed after a wide consultation with stakeholders. Strategy-II was formulated and developed on the earlier strategy to accelerate the pace of growth of biotechnology sector at par with global requirements.

Key Elements of Strategy-II

Realizing that biotechnology has the potential to be a globally transformative intellectual enterprise of humankind, the renewed mission is to:

- Provide impetus to fulfilment of the potential for a new understanding of life processes and utilizing the knowledge and tools to the advantage of humanity
- Launch a major, well-directed effort backed by significant investment for generation of biotech products, processes and technologies to enhance efficiency, productivity, safety and cost-effectiveness of agriculture; food and nutritional security; affordable health and wellness; environmental safety; clean energy and biofuel; and biomanufacturing
- Empower India's incomparable human resource scientifically and technologically
- Create a strong infrastructure for research, development and commercialization for a robust bioeconomy
- Establish India as a world class biomanufacturing hub for the developing and developed markets

Guiding Principles of the Strategy-II

Consultations with stakeholders identified the following 10 guiding principles that shall drive the renewed mission through Strategy-II.

- Building a skilled workforce and leadership
- Revitalizing the knowledge environment at par with the growing bioeconomy
- Enhance research opportunities in basic, disciplinary and inter-disciplinary sciences
- Encourage use-inspired discovery research
- Focus on biotechnology tools for inclusive development
- Commercialization of technology-Nurturing innovation, translational capacity and entrepreneurship
- Biotechnology and society-Ensuring a transparent, efficient and globally best regulatory system and communication strategy
- Biotechnology cooperation-Fostering global and national alliances

- Strengthen institutional capacity with redesigned governance models
- Create a matrix of measurement of processes as well as outcome

Sectoral Priorities

The Department has identified the following sectors to accelerate the pace of growth of biotechnology sector at par with global requirements.

- Human resource
- Building knowledge environment
- Research opportunities: human genome research, vaccines, infectious and chronic disease biology, stem cells and regenerative medicine, basic research, translational research, human developmental and disease biology-maternal and child health, bioengineering and biodesign
- Agriculture, animal health and productivity
- Medicinal and aromatic plants
- Food fortification and biofortification
- Bioprospecting, value-added biomass and products
- Marine biotechnology and biodiversity
- Environmental management, clean bioenergy
- Nurturing entrepreneurship- IP landscaping, technology transfer, incubators, entrepreneurship, Small and Medium Enterprises (SMEs) support systems
- Biotechnology and society
- Biotechnology cooperation

Major Initiatives of the NBDS, 2015-2020

- Launch of four major missionsin healthcare, food and nutrition, clean energy and education
- Create a technology development and translation network across India with global partnership, including five new clusters, 40 biotech incubators, 150 Technology Transfer Organizations (TTOs) and 20 bioconnect centres
- Ensure strategic and focused investment in building the human capital by setting up a Life Sciences and Biotechnology Education Council

2.2 Implementation of Policies

2.2.1 Government Bodies Responsible for Implementing Each Policy

- Department of Biotechnology (DBT)
- Indian Council of Agricultural Research (ICAR)
- Department of Science and Technology (DST)
- Council of Scientific and Industrial Research (CSIR)
- Indian Council of Medical Research (ICMR)
- The Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)
- Ministry of Environment, Forest and Climate Change (MoEF&CC)
- Department of Agricultural Cooperation and Farmers' Welfare (DAC-FW)

A three tier mechanism comprising Institutional Biosafety Committees (IBSC) at the Institute/company; the Review Committee on Genetic Manipulation (RCGM) in the DBT; and the Genetic Engineering Appraisal Committee (GEAC) in the MoEF&CC for granting approval for research and development activities on recombinant DNA products, environmental release of GE crops and monitoring and evaluation of research activities involving recombinant DNA technology has been established. Applications in pharma/agriculture sectors for import/export/transfer/exchange of GE materials, including GE seeds, conduct of pre-clinical toxicity studies, evaluation of pre-clinical study reports and recommendations to Drug Controller General of India for appropriate phase of clinical trials of new drug(s) or similar biologics, confined field trials on GE crops,*etc.*, are examined by the RCGM and appropriate decisions taken. RCGM has taken several policy decisions on biosafety research on agricultural/ biopharmaceuticals/industrial products.

The Statutory bodies under Environmental Protection Agency, 1986 include: 1. The Recombinant DNA Advisory Committee (RDAC), 2. Institutional Biosafety Committee (IBSC), 3. Review Committee on Genetic Manipulation (RCGM), 4. Genetic Engineering Approval Committee (GEAC), 5. State Biotechnology Coordination Committee and 6. District Level Committee.

2.2.2 Effectiveness of Policy

The policies have been quite effective to develop products related to AB, their evaluation and release for commercial use. This only led to the development and release of *Bt*-cotton. However, there is always a scope for improvement in modifying the regulations based on the development in science and technology.

2.2.3 Initiatives and Successful Achievements by ICAR in Agri-Biotechnology

Different institutes of ICAR work on AB in field crops, horticultural crops, animal sciences and fisheries. The priority areas include transgenics, genomics and applied genomics for the development of varieties/breeds and related fundamental research. Besides, ICAR has initiated many projects in agri-biotechnology in network and consortium mode under National Agricultural Science Fund, Network projects in transgenics and Consortium Research Platforms (ICAR, 2018).

Crop Sciences

The successful achievements of ICAR/Indian national system (NRCPB, 2018) include the genome sequencing of rice (IRGSP, 2005), tomato (TTGC, 2012), wheat (IWGSC, 2014), pigeonpea, chickpea and ocimum (Singh *et al.,* 2012; Varshney *et al.,* 2013). The genome of pearl millet was sequenced by International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) (Singh *et al.,* 2015; Varshney *et al.,* 2017). Transgenics in rice, sugarcane, soybean, chickpea, pigeonpea, tomato, brinjal and potato have been developed and evaluated for different biotic and abiotic stresses. They are at different stages of evaluation. Many of them are either under 'Event selection trial' or under 'Confined field trial'. Varieties/advanced lines through molecular breeding in rice, wheat, maize, chickpea, tomato and onion have been developed and released for commercial cultivation. The varieties developed and released in rice include Improved Pusa Basmati 1, Swarna Sub 1 and Improved Samba Mahsuri. Similarly, the MAS derived hybrids in maize include Vivek QPM 9, Vivek QPM 21, Pusa HM4 Improved and Pusa HM8 Improved. The tissue culture based large-scale multiplication and use in banana and sugarcane at commercial level is a success story.

Animal Sciences

National Dairy Research Institute, Karnal, has established pregnancy using OPU-*In Vitro* Fertilization (IVF) in Sahiwal cattle and Green Fluorescent Protein expressing buffalo cloned blastocysts (NDRI, 2018). More than a dozen cloned calves have been produced in dairy animals. Indian Veterinary Research Institute, Izatnagar developed many vaccines like, live attenuated homologous Peste des Petits Ruminants (PPR) vaccine, goat pox vaccine, Brucella abortus cotton strain-19 vaccine, vero cell-based sheep pox vaccine, classical swine fever v cell culture vaccine, sheep pox vaccine Srinagar strain, and FMD vaccine (IVRI, 2018). Similarly, the diagnostic kits developed include, rapid test for detection of Non-Structural Protein (NSP) 3ABC antibodies from FMD virus infected animals, NSP 3ABC based diagnostic assay (Enzyme Linked Immunosorbent Assay-ELISA) for FMD to Differentiating Infected from Vaccinated Animals and Recombinant antigen (UP7 Protein) based indirect ELISA blue tongue antibody detection kit. All those technologies are already commercialized.

The technologies that are already developed and available for commercialization include, synthetic multiple antigenic peptides based effective diagnostic for bovine rotavirus infection, vero cell culture attenuated live camel pox vaccine for protection of camels against camel pox, and recombinant NS1 antigen based indirect IgG ELISA for sero-diagnosis of Japanese Encephalitis in swine. Buffalo draft genome assembly constructed using the cattle genome (Btau 4.0 assembly) as a reference. The assembly has read depth of 17-19X. The buffalo assembly represents ~ 91-95 per cent coverage in comparison to the cattle assembly Btau 4.0. Successful achievements of other ICAR institutes include establishment of transcriptome signature of buffalo mammary gland during heifer, peak lactation, and involution physiological stages and identification of stage specific genes and pathways, Expressed Sequence Tag libraries from buffalo mammary gland.

Fisheries Sciences

The notable achievements include development of database on fish barcode information system, fish karyome, fish and shellfish microsatellite database, and fish mitogenome resource, genomic resources including ESTs and gene associated markers in Indian catfish, *Clarias magur* and *Tenualosa ilisha*, initiation of whole genome sequencing of two commercially important fish species, *Labeo rohita* and *C. magur* and complete mitochondrial DNA sequenced in eight fish species (NBFGR, 2018).

2.3 Capacity Development

2.3.1 Existing Capacity Level

India has very strong capacity in terms of tissue culture, transformation, marker assisted breeding/selection, genetics, breeding and related work. There are many research institutes and academic organizations specializing in AB.

2.3.2 Required Capacity for Future

With the advancement of sciences in the field of genome editing, genomic selection, stem cell research, cloning, semen sexing, developmental biology, there is need to update and impart training in the critical areas of AB to the Indian scientists. This should be followed by collaboration and capacity building in true sense so that the Indian scientists will be able to handle programme in those critical areas independently.

2.4 Partnership

2.4.1 Existing Major Partnership

At present partnerships for AB exist among the researchers within the institutes and organizations like ICAR, DBT, DST, CSIR, central laboratories, state government organizations and universities. Besides, all the major organizations of GoI have funding to support the research in AB through competitive and sponsored mode.

2.4.2 Scoping of New Partnership

There is a great scope to increase and improve the quality of partnerships among the Indian researchers. Besides partnering among the Indian workers, there is a great need to bring partnership with advanced foreign laboratories in critical areas of research. This will not only impart training and capacity building, but also help in improving the scientific environment in India.

2.5 Funding Mechanism

At present, there is meagre amount of funding from private sector for research organizations on competitive mode. Most of the funding comes from public funding through various agencies including ICAR, DBT, DST and CSIR.

3. National and Institutional Strategies

3.1 National Strategies for Research & Development

3.1.1 Sustainable Agriculture for Food Requirement under 'NBDS, 2015-20'

Agriculture, with its allied sectors, is the largest livelihood activity in India. Sustainable agriculture, in terms of food security, rural employment, and environmentally sustainable technologies is the priority. The strategy strives to adopt modern tools in improving the productivity of the food sector through innovative research. The policy document under 'NBDS, 2015-20' has listed specific areas under different fields of agriculture, which would be the focus of research and development in various areas of AB.

Crop sciences

The aim is to achieve higher productivity and better-quality food while reducing resource inputs through research support to biotechnology programmes. The document has listed the following specific areas under crop science.

- Improved photosynthetic, nitrogen fixation and nutrient utilization potential
- Improved reproductive efficiency with regard to yield convertibility
- Protection of yield loss due to stress/climate change
- Mitigation of post-harvest loss
- Enhancement of nutritional value
- Pre-breeding research utilizing genomics information and interfaces with wide hybridization, molecular mapping
- Transgenic crops for resistance against biotic and abiotic stresses
- Heterosis breeding
- Introgression and pyramiding of useful genetic loci in diverse germplasm
- Studies addressing gaps between Quantitative Trait Loci (QTL) and MAS for drought/abiotic stress, drought (water relations, cellular tolerance, floral biology, stay green) and radiation use efficiency (photosynthesis efficiency, source to sink)

Animal sciences

Livestock sector plays an important role in the Indian economy. The contribution of this sector in national economy was approximately 4.11 per cent in 2015-16 (DAHD Annual Report, 2016-17). India ranks first in the world in milk production, with an estimated production of 165.4 million tonnes in 2016-17 (NDDB, 2018). India is also the third largest egg-producer in the world; over 82.9 billion eggs were produced in 2015-16 (Statista, 2018).

While the majority of India's animal products are consumed domestically, exports are also growing. India is the top global exporter of buffalo meat, and is also the fourth largest exporter of soybean meal, an important ingredient in commercial feed for farmed animals. In addition, India is the leading poultry producer and the exports are increasing to the Asian and Middle East countries.

To enhance animal health and productivity through a multi-pronged approach, the research in the areas of breeding, reproduction technologies, nutrition and health care is being and would continue to be supported by the system.

Genomics and genetic characterization

Application of Genome-Wide Marker-Assisted Selection for enhancement of production, feed conversion ratio and disease resistance in indigenous stocks of livestock and poultry, namely, cattle, buffalo, sheep and pigs, and chicken. The document has listed the following specific areas under animal sciences.

- Animal reproduction and transgenics
- Sperm sexing technique for enhancing productivity
- Biopharming for therapeutic proteins specifically in purification of recombinant proteins
- Production of biologicals for embryo transfer technology
- Generation of transgenic animal model for disease resistance
- Development of new tools for detection of silent heat and pregnancy in cattle
- Major multi-centric programme on generating transgenic animals in livestock

Nutrition

- Metagenomics of gastrointestinal tract of livestock and poultry and identification of metabolic pathways for re-engineering in culturable microbes
- Feed and fodder enrichment by lignin degrading enzymes and plant breeding strategies
- Methane mitigation strategies
- Nutrigenomics for optimization of feed formulation

Animal food safety

- Affordable animal products including designer egg/meat with adequate food safety and longer shelf life
- Predictive microbiology approaches aimed at ensuring safety of animal products
- Simple and rapid assays for detection and quantitative estimation of incriminating factors such as pesticide, heavy metals, veterinary drugs and other toxic residues in animal feed and products

Aquaculture

Aquaculture plays a vital role in India as it has a coastline of over 8000 km, an Exclusive Economic Zone of over 2 million sq. km. India, currently is ranked second in global fish production, inland capture and aquaculture, and seventh in marine capture production. Fisheries sector in India, is a predominant employment provider to millions of people. However, sustainable productivity and management had been a concern. The strategy would leverage biotechnology research to address the concerns and enhance aquaculture productivity thereby contributing to food security. The research programme would focus on improving feed and nutrition, aquatic health and breeding techniques for obtaining desired and disease resistant traits.

Larval feed and nutrition

Live feed plays an important role in early developmental stages of the finfish and shellfish larvae and is an essential part of mariculture operations.

Health

Health of the aquatic animal largely depends on the health of the aquaculture environment. Development of healthy brood stock of all cultivable fin and shell fishes is very important.

Breeding and genetics

DNA marker technology is being used in various species for trait characterization related to growth, disease resistance and salinity tolerance and could be exploited for enhancing productivity.

Products and processes from medicinal and aromatic plants

Contrary to the popular belief, even today 80 per cent of the Asian and African populations relies on medicinal plants for their primary health care needs. Medicinal and aromatic plants are increasingly gaining attention among the urban population as chemical drugs are posing severe challenges in terms of development, safety, resistance and cost. India possesses an unmatched heritage represented by its ancient systems of medicine, which are a treasure house of knowledge for both preventive and curative healthcare. The positive features of the herbal medicine, namely, their diversity and flexibility; accessibility; affordability; a broad acceptance by a section of the general public; comparatively low cost; a low level of technological input and growing economic value have great potentials to make them providers of health care that the larger sections of our people need.

Biotechnological capabilities offer unique opportunities to advance our knowledge on medicinal and aromatic plants. The Indian strategic policies have been supporting the salient aspect of the Indian medicine system through research opportunities aimed at understanding the mechanism of action of medicinal plant-based drugs, understanding the biosynthesis pathways for commercial application, botanical pesticides and insecticides and studies on genetic diversity.

3.2 Capacity Development

Biotechnology, as a discipline, is highly dynamic and rapidly evolving. Recognizing the importance of capacity and competence building, the Strategy document priorities the following for facilitating training, education and research aspirations of students, faculty and other biotech professionals.

- Specialized training programmes for professionals - to facilitate technology competence and for updating professional skills required in the dynamic system
- New career options for students - aimed at motivating young minds towards biotechnology for a career and to make higher education, enterprise driven and interdisciplinary approach.
- Faculty improvement programme - for continuous improvement, lateral growth and for recognition of the dedicated services rendered
- Attracting skills - for imbibing the overseas talent (scientists and post docs) in our development process

Instruments for Implementation

- Overseas and national fellowships for working professionals for specialised skill training in interdisciplinary and translational research
- Overseas exchange and clinical training programmes
- Overseas associateship for UG and PG teachers
- Promote bioscience and biotech higher education and research programme in engineering system
- Dual degree M.Sc./MBA in agribusiness, pharma business and bioenterprise management
- Support for integrated and interdisciplinary PG and Ph.D. programmes
- Graduate research fellowships including summer training
- Polytechnic schools for skill development
- Recognition of promising star colleges and nurturing them
- Establishment of European Molecular Biology Laboratory (EMBL) like centres in the country
- New scheme to be launched to increase mobility of industry professionals into academic institutions and *vice versa*
- Career development and distinguished awards for teaching faculties
- Prestigious positions such as 'Science Chairs' for best brains in India and from overseas
- Establish a National Council for Biosciences and Bioengineering to provide outstanding training to trainers, linked to advanced technology platform in universities and inter institutional centres

3.3 Infrastructure Development

DBT has a key role to play in creation of infrastructure for successful commercialization of technologies, emanating from hard-core research (DBT, 2015). Thrust will be on:

- Translational capacity to be embedded in all major research centres and programmes
- Support for business incubation infrastructure, technology validation and scale-up infrastructure
- Technology management, professional development and licensing of technologies for accelerated commercialization
- Technology repository for depositing technologies developed indigenously and for global acquisitions
- Nurturing bioentrepreneurship

Instruments for Implementation

- Strengthen and create technology incubators to provide technology incubation, validation and scale up support to enterprises
- Technology development centres within existing academic institutes
- Establish/strengthen/encourage domain specific 'Innovation Accelerators' and 'Translational Accelerators' accessible to public institutions and SMEs to successfully incubate discoveries, and take them through the validation stage, and package them for transfer and licensing. The translational accelerator would offer support for preclinical work, clinical trials, field trials of modified crops/ organisms, compliance with regulatory requirement and production as per Good Manufacturing Practices (GMP) standards
- Through the Biotechnology Industry Research Assistance Council (BIRAC), create and sustain 'Translational accelerators' in key locations. The facility is to include validation and transfer centre for facilitating technology licensing
- Work through BIRAC for nurturing entrepreneurship, technology acquisition and commercialization
- Over 150 TTOs to be set up, spread across the country in research institutes and universities
- Creation of a scheme to popularize technology transfer training
- Establishment of validation centres for nutrition claims with a focus to collect valid data on the phytochemical components of different Indian foods
- Creating and strengthening infrastructure in the areas of preclinical toxicology and clinical trials in diverse demographical settings
- Creating manufacturing facilities for production of clinical grade material for evaluating promising vaccine candidates through Public-Private Partnership model
- Establishment of Rural Technological Innovation and Application Centre (RTIAC)
- New scheme to be launched, namely, 'Encouraging development and commercialization of inventions and innovations' for DBT scientists of autonomous institutes to explore entrepreneurship

3.4 Communication Strategy

It is important to focus on communication strategies to bring awareness of the modern tools of biotechnology among public and how it could improve our well-being, offer food and energy securities and helps in preserving our environment. This is possible by implementing the following measures.

- Promotion/strengthening of public communication cell
- Establishment of a media resource centre to effectively interface with print and electronic media

3.5 General Awareness

It is important to raise public awareness of the modern tools of biotechnology and how it could improve our well-being, offer food and energy securities and helps in preserving our environment. It is important to engage with not-for-profit and other professional organizations to scientifically articulate the benefits, risks and impacts of biotech products for easy understanding of society.

The scope of biotech is very wide. The application of tools of biotechnology is rapidly growing. Hence inter-ministerial efforts would be coordinated towards conducting public outreach programmes aimed at educating people. Data centres would provide a focal point on information about the various biotechnology research impacts for interested public.

3.6 Policy Advocacy

The debate for establishment of Biotechnology Regulatory Authority of India (BRAI) is highly influenced by the law makers in the Parliament, non-government organizations and media. Establishment of BRAI, as an independent regulatory body will help in taking decisions for release of GMOs for commercial use. This will also help in taking decisions on critical issues like *Bt* brinjal and taking efforts and investments to logical ends.

4. Specific Focus on Research

All the areas like basic and strategic research, applied and adaptive are important to make a system productive and achieve the deliverables. Hence, equal emphasis needs to be given to all those aspects in a big country like India.

4.1 Basic and Strategic Research

These include identifying and cloning new genes, their modifications, transfer to target organisms, transformation systems, identification of desired events and understanding the intricacies related to those aspects. The strategic research also includes to deploy the desired events/gene(s) in correct background, their evaluation and deployment.

Applied Research

Once the gene(s), events and other related information are satisfying, those genes can be transferred to elite backgrounds following MAS/MABC/conventional breeding procedures. Those will also include their evaluation for agronomic traits, molecular characterization and target traits.

4.3 Adaptive Research

This is the most challenging part for the success of the GMO. The proposed GMO should be adaptive and productive in the target region/ecosystem without any cost to the environment, insects, biodiversity and other related issues.

5. Priority Areas of Agricultural Biotechnology

Different sectors/areas of agriculture where biotechnological innovation/tools can be applied include bioprospecting, conservation and sustainable use of bioresources. Along with pursuing basic research, genome sequencing and genomic studies for identification of useful genes, QTLs and validation of their function; developing transgenic crops and crop improvement through MAS for tackling various abiotic and biotic stresses and quality traits are of high priority in the agricultural biotechnology programme.

6. Major Challenges and Opportunities

With some billion-plus mouths to feed, and counting, AB has to be a natural winner in priority terms for a country like India, especially in the era of climate change, degradation of farmlands, increased soil salinity, drop in groundwater, pollution of surface water sources, more frequent droughts and so on.

Advances in gene discovery and genomics have led to the identification of several novel genes that provide excellent opportunities for effectively tackling problems of biotic/abiotic stresses, enhancement of crop productivity, and improvement of their nutritional quality.

These scientific advances help in accelerating pre-breeding germplasm enhancement for eventual crop improvement through effective molecular breeding. Along with pursuing basic research, QTLs and validation of their function, developing transgenic crops and crop improvement through marker aided selection for tackling various abiotic and biotic stresses and quality traits are of high priority in the agriculture biotechnology programme of the department. The strengths of the technology provide an opportunity to solve those problems.

7. Future Outlook

Policies for agriculture itself have to deal with a multitude of new and emerging issues, and decision making is further complicated by influential legal binding instruments negotiated globally, nationally and bi-nationally. Yet it is important that appropriate, effective and legitimate policies are adopted and implemented. Coordination between ministries and local governments is a key to success of developing and implementing policies. The policies need to be more inclusive and responsive to deliver benefit to the resource poor farmers and reduce the risk while taking care of their livelihood.

7.1 Short-term Plan

The short-term plan for AB should be to bring all the GMOs available to a logical end, bring a more transparent regulatory system and deploy the available gene(s) using MAS/ MABC and release them for the benefit of resource poor farmers, *Bt*-cotton being a successful example.

7.2 Medium- and Long-term Plan

For the medium- and long-term plan, there has to be significant funding, collaboration and focussed research to understand the mechanisms and gene function, their identification and cloning, and further use. The international/ national policies should also support the researchers, developing countries and resource-poor farmers.

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Country Status Report - Iran

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1. Introduction

Agricultural biotechnology (AB) is experiencing rapid progress in the Islamic Republic of Iran (Iran). Iran considers modern biotechnology important to its social and economic development and thus issues relating to modern biotechnology are included in policies, plans and research activities. Iran has experienced remarkable advances in the R&D of AB during the last few decades. Both traditional and modern biotechnologies have been explored to meet the agricultural needs of about 77 million people living in Iran. The country proved its commitment to biosafety issues by joining the Convention on Biological Diversity (CBD) in August 1996. Iran has set targets for biotechnology development, including becoming the regional leader in biotechnology and tenth in the world, and increasing its share of the global biotechnology market to 3 per cent by 2025 from its present estimated share of around 0.62 per cent. The current status on the national policies, strategies that regulate the biotechnological developments in the country, capacity development, budget allocation for biotechnological research, challenges and opportunities for research are detailed in the present report (Table 1).

Table 1. Basic Information

Indicator	Details
Value of GDP (Trillion IRR) IRR= Iranian Rial	14827*
Value of GDP (Billion USD)	439.51**
Value of agriculture GDP (Trillion IRR)	16@
Value of agriculture GDP (Million USD+)	489.93
Agriculture GDP as per cent of GDP	10.08***
Total investment in agricultural research (Billion USD)	~0.42
Total investment in agricultural research (Trillion IRR+)	13.72
Total Investment in AB Research (Billion USD)	~0.2
Total Investment in AB Research (Trillion IRR+)	6.53

*Source: World Bank (*2017; **2017a; ***2017b) @ Trading Economics (2017); + 1 USD=32658 IRR*

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2. National Policies

2.1 Current National Policies on Agricultural Biotechnology and Policies for Enhancing the Livelihood of Farmers through Agricultural Biotechnology

Certain national policies were formulated in the country to meet the following requirements.

- Capacity to generate, adapt, and/or negotiate access to biotechnology innovations
- Capacity to generate good quality animal and plant germplasm where biotechnology can be used
- Ability to identify and prioritize critical problems affecting the rural poor that may be addressed by biotechnology
- Existence of a technology and information delivery system
- Existence of a rational (science-based), transparent and expedient biosafety regulatory system
- Ability of the public sector and the international agricultural research centers to negotiate and promote private-public partnerships in an environment where biotechnologies for resource poor farmers can be considered public goods (Ghareyazie *et al.,* 1999).

The key initiatives undertaken by Iran in developing and implementing the systems to comply with the provisions of the biosafety protocol has been recently reviewed by Esmailzaeh (2013) and are detailed below:

2.1.1. Convention on Biological Diversity, August 1996

Iran joined the CBD in August 1996. According to Paragraph 8 of this Convention, Iran commits to the creation and maintenance of tools necessary for supervising, managing and controlling risks in the use or release of Living Modified Organisms (LMOs) resulting from modern biotechnology with regards to human health and the environment.

2.1.2 National Biotechnology Committee, 2000

National Biotechnology Committee (NBC) was established in 2000 as part of the Ministry of Science, Research and Technology to discuss and make decisions on different issues, such as the country becoming a Party to the Cartagena Protocol. As a result of the committee's efforts, the Islamic Consultative Assembly of Iran, the Iranian Parliament, ratified the Protocol on Nov. 20, 2003.

2.1.3 Cartagena Protocol on Biosafety, 2001

Iran signed the Cartagena Protocol on Biosafety on April 23, 2001 and in Nov. 2003, the Islamic Consultative Assembly of Iran ratified the protocol, while it came into force on Feb. 18, 2004.

2.1.4 National Biotechnology Strategy, 2004

National Biotechnology Strategy, a ten-year plan for the development of biotechnology, was developed and ratified by the Cabinet of Ministers on May 5,2004. The development of biotechnology should be in accordance with the environmental regulations of the country, aiming at the protection of genetic reserves and accompanied by the observance of biosafety laws within the framework of global protocols as acceptable to the country. The plan includes the development of biotechnology in the following areas: health and medicine, agriculture (e.g. plant, livestock and marine life), industry and mining, the environment, and, bioethics. A Biotechnology Development Council (BDC) was established in 2005 to lead the biotechnology development, promote the private and the public sector, and, raise public awareness on biotechnology.

2.1.5 Biosafety Clearing-House (BCH)

The National Institute of Genetic Engineering and Biotechnology (NIGEB), affiliated with the Ministry of Science, Research and Technology (MoSRT), has been responsible for Iran's BCH since 2004. NIGEB's activities to promote information sharing, public awareness and public education include:

- Registering and updating required information on the BCH website
- Providing a mailing list of relevant stakeholders and disseminating biosafety news
- Publishing biosafety bulletins

2.1.6 National Biosafety Council (NBSC), 2005

The NBSC was approved by the Cabinet in 2005, which includes the Minister of Science, Research and Technology; Minister of Health and Medical Education, the MoA; and the Head of the Environmental Protection Organization (EPO).

2.1.7 National Biosafety Framework (NBF), 2006

A draft National Biosafety Law was developed by a committee comprising experts from the MoSRT and the EPO. This draft law was assessed during a series of meetings by the National Coordinating Committee of the NBSC. After being approved by the Cabinet of Ministers, Iran's Parliament ratified the draft law on July 29,2009.

2.1.8 The Biosafety Law, 2009

The Biosafety Law came into force on Aug. 27, 2009, under which all issues related to the production, application, release, transport and use of LMOs are addressed. Article 4 of the Biosafety Law, deals with issues related to modern biotechnology, with regards to regulating LMOs as referred to in the Protocol.

2.1.9 Draft of the Executive Regulations of the Biosafety Law, 2013

A draft of the executive regulations of the Biosafety Law was developed by a specialized committee of the NBSC to facilitate the implementation of the Biosafety Law, and clarify the relationship between the legislative duties and executive bodies. It specifies all the details and processes related to field trials, production, release, import and export, transport, purchase and sale, distribution, consumption and use of LMOs and their products. It was approved by NBC on April 7, 2012 and came into force on July 10, 2013.

Implementation of Policies

2.2.1 Responsible Government Bodies

Institutes responsible for implementing various biotechnological capacities are enlisted hereunder.

Biotechnological capacity	Institute
Capacity to generate, adapt, and/or negotiate access to biotechnology innovations	1. Agricultural Research, Education and Extension Organization (AREEO) 2. Agricultural Biotechnology Research Institute of Iran (ABRII) : Iran is basically working on developing tools that are significant to the field of biotechnology, especially for developing crops that are able to tolerate abiotic and biotic stresses. This institute has different departments of Genomics, Microbial Biotechnology, System Biology, Nuclear Agriculture, Bioinformatics, Nanotechnology, Tissue Culture and Gene Transformation, Molecular Physiology.
Capacity to generate good quality animal and plant germplasm where biotechnology can be used	1. Agricultural Biotechnology Research Institute of Iran (ABRII) 2. Iranian Research Institute for Plant Protection (IRIPP) 3. Iranian Fisheries Science Research Institute (IFSRI) 4. Animal Science Research Institute of Iran (ASRII) 5. Persian Gulf Biotechnology Research Center (PGBRC) 6. Iranian Research Organization for Science and Technology (IROST)

Biotechnological capacity	Institute
Ability to identify and prioritize critical problems affecting the rural poor that may be addressed by biotechnology	1. AREEO 2. The High Council of Science, Research and Technology (HCSRT)
Existence of a technology and information delivery system	1. AREEO - Extension Division
Existence of a rational (science-based), transparent and expedient biosafety regulatory system	1. Iran's National Biosafety Committee (NBSC) 2. National biosafety organizations
Ability of the public sector and the international agricultural research centers to negotiate and promote private-public partnerships in an environment where biotechnologies for resource poor farmers can be considered public goods	1. AREEO 2. HCSRT
Biosafety Law, 2009	1. The Minister of Agriculture: Production of LMOs in the agricultural sector and natural resources 2. The Minister of Health and Medical Education: Health and safety of food, cosmetics and medical materials 3. The EPO: Wild life and evaluation of the environmental risk assessment based on scientific documents provided by an applicant
NBC, 2005	The EPO was designated as the secretariat of the NBC Ministerial Biosafety Committee was also established to implement biosafety regulations in the relevant executive bodies (Esmailzaeh, 2013)

2.2.2 Effectiveness of the Policy

The policies were moderately and sometimes highly effective to reach the considered goals. However, improvement in the system is needed for monitoring and controlling biosafety issues. Moreover, international collaborations with partners needs to be expanded by seeking new partners.

After the inception of biotechnological research, Iran has improved its production of recombinant bio-pharmaceuticals, recombinant vaccines (*e.g.* human and animal vaccines), biofertilizers, animal cloning, stem cell technologies, and research on production of transgenic plants and animals. The fundamental and strategic policies of Iran on the development of modern biotechnology, helped in the development of recombinant DNA technology and the LMOs, while protecting the environment from any harmful effect of this technology.

Statistically by 2011, Iran became the first country in the region and 14th in the world to publish scientific articles on biotechnology (Esmailzaeh, 2013). Iran was the first Islamic country to officially release any biotech crop plant (an insect resistant transgenic rice variety). The Ministry of Health has also declared the GM rice as safe. Work is in progress for the release of several domestically produced transgenic crop plants namely, 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. Attempts were also made 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 *A. lagopoides*. Iran has not only produced GM crop plants, but also is producing transgenic animals. In January 2010, birth of the first transgenic animals in any Islamic country was accomplished at the Royan Research Institute in Isfahan. The two goats produced through GE for pharmaceuticals in their milk are called 'Shangool' and 'Mangool'.

Production of new cultivars through modern biotechnology in the country has also succeeded in the following case:

(i) 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.

(ii) Identification and isolation of candidate genes for *Fusarium* head-blight resistance and molecular breeding for improved *Fusarium* head-blight resistance in wheat.

(iii) Production and evaluation of high-yielding doubled-haploid wheat and barley lines with resistance to yellow rust.

(iv) Introduction of kallar grass (*Leptochloa fusca*) as an ideal crop for fodder production and bioreclamation of salt affected soils.

(v) Production of biofertilizer prepared from N-fixing microalgae in rice fields.

(vi) Identification of candidate genes involved in saline and drought tolerance in *Sueada aegyptiaca*, sugar beet, and wheat using proteomics techniques.

There are several ongoing projects in the field of molecular farming as well. The following are some examples:

(i) Cloning and expression of the tissue Plasminogen Activator (tPA) gene in tobacco for stroke treatment. The 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.

(ii) 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 per cent. The ultimate goal is to produce a plant antibody against MUC1 and prevent cancer development.

(iii) Successful cloning and expression of a tobacco recombinant camelid single-domain antibody.

(iv) 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.

2.3 Capacity Development

2.3.1 Existing Capacity Level

AREEO with 19 nation-wide research institutes including multidisciplinary and crop-based research centers; 34 provincial research and education centers; 360 research stations, farms and bases; 34 agricultural extension directorates; 1,213 district extension centers; 23 research incubation centers and 142 knowledge-based enterprises is considered the largest national agricultural research system (NARS) in the region. Over 10,000 employees including nearly 3,000 scientists are working at AREEO's research and education institutions (AREEO, 2017).

In Iran, by 2011, number of post-graduate students studying in various biotechnology-related fields rose upto 5,000; and research centers working on issues related to modern biotechnology increased to 120 universities, 40 institutes and 200 companies (Esmailzaeh, 2013).

2.3.2 *Required Capacity for Future*

- Strengthened policy enabling environment, establishment of a political and economic framework (including the legislative and regulatory framework) suitable to ensure good performance in agriculture
- Organizational dimensions of capacity development, being mainly conceived as operational support to the functioning of organizations and institutions that affect the performance of the agricultural sector
- Development of individual capacities, which are related to promotion of skills and knowledge of people involved in agricultural and rural development: farmers, fishermen, herders, rural producers, distributors, rural service providers, technicians, traders, food inspectors, etc

2.4 Partnership

2.4.1 *Existing Major Partnerships*

- Food and Agriculture Organization (FAO)
- Japan International Cooperation Agency (JICA)
- Asia-Pacific Association Agricultural Research Institutions (APAARI)
- Centers of the Consultative Group of International Agricultural Research (CGIAR)
- International Center for Agricultural Research in the Dry Areas (ICARDA)
- International Center for Maize and Wheat Improvement (CIMMYT)
- International Rice Research Institute (IRRI)
- International Crops Research Institute for the Semi-Arid Tropics (ICRISAT)
- International Society for Horticultural Science (ISHS)
- International Seed Testing Association (ISTA)
- International Institute of Sugar Beet Research (IISBR)
- The Organization for Economic Co-operation and Development (OECD)
- International Union of Forest Research Organizations (IUFRO)

2.4.2 *Scoping of New Partnerships*

- WorldFish
- International Water Management Institute (IWMI)
- Association of Agricultural Research Institutions in the Near East and North Africa (AARINENA)
- International Center for Tropical Agriculture (CIAT)
- International Livestock Research Institute (ILRI)

2.5 Funding Mechanism

Funding for agricultural research in Iran has principally been provided by the national government, supplemented to a minor degree by internally generated resources and funds from the private sector. In 2004, 88 per cent of the combined budget of 71 government and non-profit agencies was derived from the Iranian government, 6 per cent was generated internally by agencies, and the remainder was raised by public and private enterprises. Negligible additional funding was contributed by foreign donors and international development banks (ASTI, 2008). There is lot of business potential for the AB products in Iran. For example, production of date palm seedlings using tissue culture is one of the successful agribusiness sectors by the Rana Agro-industry Company; a producer and distributer of date palm seedlings in the southern part of Iran. Production of Pistachio seedlings using tissue culture is a major project of the Ministry of Jihad-e Agriculture and the main aim is to develop areas cultivated with high-quality pistachio with increased yields.

3. National and Institutional Strategies

3.1 National Strategies for Research & Development

- Financial sustainability of research
- Expanded access to new technology, knowledge and best practices through enhanced research and extension services
- Doubling the efforts to develop applied research in agriculture
- Supporting science-based companies who are involved in agriculture research process
- Collaboration with private sector and food industries to cover the whole value chain of the research in agriculture with emphasis on some small crops that usually is not well-known to people
- Launching some collaboration and partnership with recognized and leading institutions around the word to scale up the present situation of agriculture research

3.2 Capacity Development

- Planning and institutional capacity to formulate suitable policies, plans, researches, strategies, studies and insurance schemes for sustainable agricultural development
- Capacity development through short and long training courses, which are provided with leading scientific faculty
- Participating in the UNEP-GEF capacity-building project on "Building Capacity for Effective Participation in the BCH" in Farsi, in August 2009. The following biosafety workshops were organized:
  - (i) Biosafety Analysis of Transgenic Plants, Feb. 25 -March 2, 2005
  - (ii) First International Congress of Bioethics, March 26-28, 2005
  - (iii) First International Workshop on Biosafety and Risk assessment for the Environmental Release of GMOs, Nov. 12-16, 2005
  - (iv) Second International Congress of Bioethics, Feb. 5-7, 2011
  - (v) First International Workshop of Bioethics and Ethical Aspects of Biosafety, Nov. 20-22, 2011, with NIGEB, in collaboration with the International Centre for Genetic Engineering and Biotechnology (ICGEB)
- Signed a memorandum of understanding with ICGEB in 2012 for the establishment of the regional center for bioethics and biosafety.
- Establishing national BCH website and publishing booklet on "UNEP-GEF Project on Building Capacity" are the other modes of effective participation for capacity development (Esmailzaeh, 2013).

3.3 Infrastructure Development

- Enhanced investment to improve agricultural infrastructure, including the development of complementary economic activities such as processing industries, rural industries and the introduction of modern services in rural areas
- Improvement of productive infrastructure
- Promoting the development of soil and water infrastructure related enhancing irrigation and drainage system
- Supporting the sustainable utilization of fishery resources, enhancing their facilities and infrastructure
- Development of infrastructure of agricultural, livestock and fisheries complexes
- Providing infrastructure for food security and improving value added of agricultural sector based on the sustainable development

3.4 Communication Strategy

- Considering some international centers/institutes not only as general assets but also companies, which we can have long run communication to provide best solution to our agricultural challenges
- Increasing technical, economic, and financial capacities of cooperatives, facilitating their access to resources, information, technology, communication systems
- The following tools are applied to inform the public on the advantages and risks of modern biotechnology:
  (i) using the media and the press (radio, television, newspapers, magazines);
  (ii) interviews with experts; publication of articles, films, *etc.*
  (iii) establishing a national biosafety information centre;
  (iv) informing through labels (in particular on GM food items);
  (v) holding conventions suitable for different groups;
  (vi) holding training workshops suitable for different groups;
  (vii) preparing bulletins, pamphlets and posters for different groups of people;
  (viii) creating biosafety courses for different biotechnology majors;
  (ix) preparing information compact disks for the use of the public;
  (x) creating an MS biosafety major in the educational system of the country.

3.5 General Awareness

Several dissemination activities are undertaken with stakeholders to enhance awareness. For instance NIGEB's activities to promote information sharing, public awareness and education include: (i) registering and updating required information on the bch website; (ii) providing a mailing list of relevant stakeholders and disseminating biosafety news; (iii) publishing biosafety bulletins; (iv) translating protocol articles into farsi; (v) compiling, publishing and translating a brochure on the introduction of the BCH and (vi) participating in various national and international biosafety seminars and workshops.

Following may be the strategies for further enhancing general awareness. Authorised information must be up to date, precise, useful, scientifically valid, serious, appropriate, relevant, simple and easy to understand. People involved in the act of informing should be well-informed and honest in speech and act. Materials should be made available in adequate quantity to the public in a comprehensible form, avoiding unnecessary technical information. To choose better methods, experts in teaching and training, psychologists and sociologists must be involved. Individuals and interested institutes should have access to all biosafety decisions and the information based on which such decisions have been made. Information on biosafety issues should be performed under the supervision of the secretariat of the National Biosafety Committee.

3.6 Policy Advocacy

Communication with private companies and NGO's who can convey governmental policy amongst farmers as well as experts who are dealing with agricultural activities. This can happen by establishment of Participatory Variety Selection (PVS), for spreading some high yielding varieties through the country. Providing enough subsidies for hiring and applying some new technologies such as seed certification and multiplication.

4. Specific Focus on Research

Research category	Focus area
Adaptive	Domestication of new technologies according to the necessities of the agricultural sector in Iran.
Applied	Transferring the exisiting technologies to farmers which have been concluded from previous researches in Iran
Basic	Tracking the updated technologies prevalent in leading and well-known institutes around the world and providing enough facilities for domestic scientists who eagerly want to adopt and use those technologies
Strategic	Government and the Ministry of Agriculture will issue the global programme and strategy consistent with other policies in agricultural activities

5. Priority Areas of Agricultural Biotechnology

5.1 Different Sectors/Areas of Agriculture where Biotechnological Innovations/ Tools can be Applied

(i) Increasing the productivity of agricultural crop production to enhance food security and improve resilient livelihood in different parts of the country.

(ii) Increase of income of farmers, nomads and rural population as well as sustainable development of villages and poverty alleviation.

(iii) Modernization of productive systems

5.2 Priority Areas in Plant, Animal, Aquatic Biotechnology for Low- and High-Tech Biotechnology

(i) Enhance agriculture, its role for the economy and its contribution to combat poverty.

(ii) Achieve national food security, food self sufficiency and food safety.

(iii) Improve agricultural productivity.

(iv) Enhance commercialization as identified in Vision 2025, the 5th Five-Year National Economic, Social and Cultural Development Plan (5th FYNDP). Broad Policies of Expediency Council for Agriculture and Water, MTP for Aquaculture & Fisheries and NAP on Desertification and Drought.

(v) Promote sustainable development of natural resources through desertification control, reduction of overgrazing, limiting irresponsible fishing practices, mitigating effects of climate change.

(vi) Improve disaster risk management linked to natural calamities (including transboundary animal diseases)

(vii) Increase the role of non-governmental and private sector.

"Vision 2025", adopted in January 2009 by the Supreme Leader of the Islamic Republic of Iran, is the overall framework that defines long-term policy directives in all areas-Broad Policies for Agriculture, adopted by the Expediency Council of the Islamic Republic of Iran in July 2005 (dated 11/04/1384 H, according to the Iranian calendar);- Broad Policies for the Water Sector that the Expediency Council of the Islamic Republic of Iran approved in December 1998 (dated 10/23/1377 H according to the Iranian calendar- The 4th FYNDP (2005-2009), which has been extended in its applicability until March 2011; and the 5th FYNDP (March 2011-March 2016) (CPF, 2012).

6. Major Challenges

- Insufficient funding
- Imposed Sanction

- Low amount of sabbatical opportunities for medium career scientists to attend in pioneer agricultural research centers
- Lack of clear protection of IPR legislations in the field of agriculture in Iran
- Biosafety aspects of agricultural research are not well known in the country

7. Future Outlook

7.1 Short- and Medium-term

- Applying updated agricultural technologies, which is in line with increasing food security
- Increasing and boosting of knowledge-based companies on agriculture, technologies related to Biological fertilizers
- Animal vaccines
- Diagnosis kits
- Biological inhibitors
- Molecular agriculture
- Livestock, poultry and aquatic vaccines
- Plant production and reproduction
- Animal production and reproduction (Bioeconomy in Iran, 2018)

7.2 Long-Term

- Provide food security and improve resilience livelihoods in Iran
- Sustainable agriculture - Rehabilitate natural resources, promote rural development, contribute to competitiveness and stimulate non-oil exports

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Country Status Report - Sri Lanka

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1. Introduction

Agriculture plays an important role in improving the livelihoods of the Sri Lankans. Sri Lankan agricultural sector broadly consists of six sub-sectors including non-plantation crops (rice, vegetable crops, fruit crops, and other field crops), plantation crops (tea, rubber, coconut, sugarcane, export agricultural crops, palmyra, and cashew), forestry, floriculture, livestock and poultry, fisheries and aquaculture. From the Sri Lankan perspective, the term 'biotechnology' is defined as "all technologies involving the use of organisms, cells, and biomolecules, leading to industrial, agricultural, medical, energy, and environmental applications" (NSF and NSTC, 2009). Biotechnology includes the traditional processes used in the manufacturing industries to modern processes such as recombinant Deoxyribose Nucleic Acid (DNA) technology, genomics, proteomics, and bioinformatics. The vision of the current national policies on biotechnology is to enhance the quality of life of all Sri Lankans regarding health, food security, a clean environment, and socio-economic development through the ethical, effective, and safe use of biotechnology.

The workforce participated in agriculture-related activities (Department of Census and Statistics, 2017), to the tune of 27 per cent and contributed to 24.36 per cent of the total exports (Sri Lanka Customs, 2017). The contribution of agricultural sector to the Sri Lankan economy, research investment on agriculture and biotechnology, and the positioning of biotechnology in the Sri Lankan agriculture is given in Table 1.

Table 1. Basic Information

Indicator	**Details**
Value of GDP (Trillion SLR) SLR= Sri Lankan Rupee	13.29[*]
Value of GDP (Billion USD)	87.18[**]
Value of agriculture GDP (Billion SLR)	178.27[@]
Value of agriculture GDP (Billion USD[+]) 150.768	1.18
Agriculture GDP as a percentage of GDP (%)	7.71[***]
Total investment in agricultural research (Million SLR)	~ 1247
Total investment in agricultural research (Million USD[+])	~ 8.27
Total investment in agricultural biotechnology (AB) research (Million SLR)	~ 34.00
Total investment in AB research (Million USD[+])	~ 0.25

Source: World Bank ([*]2017; 2017a; 2017b); [@]Trading Economics (2017); [+]1 USD=150.768 SLR

Dr Frank Niranjan is Senior Scientist, SLCARP, Colombo. He obtained his PhD from the University of Peradeniya, Sri Lanka. Dr Niranjan's research interests include, returns to investments in agricultural research, impact assessments on technologies, research management, vulnerability and impact related to climatic change. His experiences include country coordinator and research team leader for international organizations. He has several national and international papers in refereed journals, policy briefs and books to his credit. Dr Niranjan's future area of work will be on cultivation and agro-tourism.

2. National Policies

2.1 Current National Policies on Agricultural Biotechnology and Policies for Enhancing the Livelihood of Farmers through Agricultural Biotechnology

During the last three decades, AB has provided a platform to most countries to address poverty alleviation, job creation, and food security to improve people's quality of life. The chronological development of biotechnology in Sri Lanka is provided below:

Late 1970's	Initiated tissue culture for orchids at the Royal Botanical Garden
1983	Established Tissue Culture Division at Coconut Research Institute (CRI); Formed a biotechnology group of scientists at the Sugarcane Research Institute (SRI)
1987	Established the first biotechnology laboratory at the Plant Genetic Resources Centre at the Department of Agriculture (DOA) with JICA and initiated *invitro* conservation of vegetatively propagated crops
1987-96	Trained four scientists on biotechnology at Universities of Riverdale, USA; Nottingham, UK; Bath, UK; Tskuba and Kyoto, Japan
1992	Established a Steering Committee for Biotechnology by the National Science Foundation (NSF)
1994	Established the Virus Indexing Centre of the DOA
1997	Identified biotechnology as a thrust area for development by Ministry of Science and Technology; Developed human resources and capabilities with Asian Development; Bank assistance and initiated financial support by NSF, Council for Agricultural Research Policy (CARP), and National Research Council (NRC)
2002	Identified biotechnology as a thrust area by Ministry of Environment and Natural Resources and identified national priorities on AB by CARP of the Ministry of Agriculture
2003	Identified areas of research in biotechnology by NSF
2009	Formulated National Biotechnology Policy (NBP) by NSF and National Science and Technology Commission (NSTC) and established the National Committee on Agricultural Biotechnology at CARP
2010	Granted cabinet approval to the NBP

In addition, some of the important events of Sri Lanka joining the conventions, agreements or promulgation of national policies of biotechnology are mentioned below:

2.1.1 The Convention on Biological Diversity (CBD)

Sri Lanka signed the Convention in June, 1992 and CBD Article 8 was ratified in March, 1994 that deals with *in-situ* conservation and regulates, manages or controls the risks associated with the use and release of Living Modified Organisms (LMOs) resulting from biotechnology, which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

2.1.2 The Cartegena Protocol on Biosafety

Sri Lanka signed the protocol in 2000, which was ratified in 2004.

2.1.3 National Biosafety Framework (NBF)

The NBF was prepared in April 2005. The overall objective of the framework is to ensure that the risks likely to be caused by modern biotechnology and its products will be minimized and biodiversity, human health and environment will be protected in a maximum way, regulating the transboundary movements through formulation of relevant policies, regulations, technical guidelines and establishment of management bodies and supervisory mechanisms.

The NBF described the requirement of National Policy on Biosafety, new law and enforcement system, system to handle notifications or request for authorizations, monitoring and enforcement, mechanism for promoting and facilitating public awareness and participation. The NBF provided guidelines for the import of Genetically Modified Organisms (GMOs), internal transport and production of GMOs (ILSIRF, 2005).

2.1.4 National Policy on Biosafety – 2005

The objective is to ensure adequate levels of protection for the safe use of modern biotechnology based on the precautionary principle.

2.1.5 National Laws & Regulations on LMO's /GMO's

- Food Act No 26 of 1980, Regulations under section 32
- Food (Control of Import, Sale and Labeling of Genetically Modified Foods) Regulations (Gazette No. 1456/22, Aug. 3, 2006)

2.1.6 National Biotechnology Policy (NBP) – 2009

The Cabinet of Ministers adopted the policy in 2010, which highlighted the need for the promotion of biotechnology and support for Research & Development (R&D) in various government institutions. Following are the policy statements prepared by the NSF and NSTC in 2009:

(i) The present and all future governments shall make a strong commitment to biotechnology and biotechnology industry and an Apex Body called National Biotechnology Council (NBC).

(ii) Biotechnology and all related activities shall always safeguard the human health, the environment, and protect our rich biodiversity.

(iii) A comprehensive mechanism of funding for biotechnology R&D and product development shall be established through a public-private partnership.

(iv) Human resource development required for national biotechnology objectives shall be the responsibility of the state and supported by the industry.

(v) A national strategy to address ethical issues and public awareness related to all biotechnology activities among the community at large, policymakers, legislators, administrators, and private sector shall be developed.

(vi) Technology and expertise acquisition through strong international linkages with institutions at the leading edge of their fields shall be established.

(vii) A positive atmosphere conducive to growth and innovation shall be created by establishing administrative, legislative, and regulatory mechanisms for the procurement and sourcing, development and commercialization of biotechnology.

(viii) Institutions that are currently/could be involved in biotechnology, research, and development including industry shall be assisted to evolve into a network of national Centers of Excellence (CoE).

(ix) Industrial opportunities for agricultural, medical, bioindustry, energy, and environmental biotechnologies shall be improved and created.

(x) Biotechnology industries shall be developed by establishing one or more biotechnology parks with state-of-the-art research and incubator facilities under the auspices of the NBC.

2.1.7 GM Food Regulation

No person shall, import, store, transport, distribute, sell or offer for sale of the following without the approval of the Chief Food Authority (Director General of Health Services)

- any GMO as food for human consumption
- any food containing or consisting of GMOs

- any food produced from or containing ingredients produced from GMOs
- Approved products should be placed in the market with appropriate labeling, which include the statement "GM" in package or retail sale (ILSIRF, 2017)

2.1.8 Global Environment Facility/Food and Agriculture OrganizationProject

This four-year project is operative for implementation of the NBF in accordance with the Cartagena Protocol on Biosafety. The objective is to strengthen Sri Lanka's regulatory, institutional and technical capacities for the effective implementation of the NBF. It has four components, namely, (i) strengthening policy, institutional and regulatory frame work for biosafety; (ii) enhancing system for risk assessment, risk management and risk communication; (iii) Developing technical capacity for detection and identification of LMOs and strengthening biosafety related infrastructure; and (iv) knowledge development, public awareness and participation (ILSIRF, 2017).

2.1.9 Biosafety Bill

The main objective is to ensure that applications (uses, development, research, productions, marketing and other commercial applications, handling, transport, import, export, sale, including contained use and re-export, transfer, disposal and release) of any LMOs are undertaken in a manner that prevent/reduce risks to biological diversity and human health.

2.2 Implementation of Policies

The NBP of the Government of Sri Lanka drives the development of biotechnology industry in the country with sustainable financial commitment, consistent policy, and private sector partnership. The National Focal Point and Competent Authority for the CBD and the Cartagena Protocol on Biosafety is the Biodiversity Secretariat, Ministry of Mahaweli Development and Environment. The Sectoral Competent Authorities are Department of Agriculture, Department of Animal Production and Health (DAPH); Department of Health; Department of Fisheries and Aquatic Resources; Ministry of Industry and Commerce; Department of Wildlife Conservation. Several policy thrust areas identified by the National Policy are as below (NSF & NSTC, 2009):

Policy Thrust I: Establishment of an apex body, the NBC

Policy Thrust II: Establish an innovative sustainable funding mechanism for biotechnology

Policy Thrust III: Establish an environment conducive to innovation, product development and commercialization

Policy Thrust IV: Enact legislative reforms and compliances

2.3 Capacity Development

Based on a Memorandum of Agreement between SLCARP and Indian Council for Agricultural Research (ICAR), India, MSc and PhD scholarships are awarded to scientists in the National Agricultural Research System (NARS).During 2000-2007, of the total of 56 MSc scholarships, 21.4%, and of the 43 PhD scholarships, 14% were awarded to NARS to undertake research on AB (SLCARP, 2012). The NARS comprised institutes of DOA; CRI; Department of Export Agriculture (DEA); Tea Research Institute (TRI); Rubber Research Institute (RRI); Hector Kobbekaduwa Agrarian Research and Training Institute (HARTI); DAPH; SRI; Royal Botanic Gardens (RBG); National Aquatic Resources Research and Development Agency (NARA); Council for Agricultural Research Policy (CARP); Ministry of Agriculture (MOA); and Institute of Post-harvest Technology (IPHT). In addition, many scientists working at Fruit Research and Development Institute (FRDI), RRI, CRI, SRI, and DEA undertook tissue culture activities.

The existing and required capacity of biotechnologists in various research institutes in the NARS is presented in Table 2. Some scientists undertake tissue culture techniques only, for *e.g.* thise in FRDI, RRI, CRI, SRI and DEA.The herbarium in DNBG currently has capacity in plant molecular science, and requires floristic biotechnology in future. At the CC, only two technical officers are available to undertake biotechnological research, while the Breeding Division of the VRI has not been functioning since researchers have left the institute. Presently, no scientist is working on biotechnological research in the livestock sector.

Table 2. National requirements for biotechnologists

Research institutes in the NARS	Capacity of biotechnologists	
	Existing capacity as on 31-12-2017	Required capacity by 2025
Rice Research and Development Institute (RRDI)	2	6
Horticultural Crops Research and Development Institute (HORDI)	0	3
Field Crops Research and Development Institute (FCRDI)	1	4
Fruit Research and Development Institute (FRDI)	5	8
Plant Genetic Resources Centre (PGRC)	3	6
National Plant Quarantine Service (NPQS)	3	5
Tea Research Institute (TRI)	7	10
Rubber Research Institute (RRI)	8	8
Coconut Research Institute (CRI)	2	3
Sugarcane Research Institute (SRI)	2	2
Palmyrah Research Institute (PRI)	0	1
Department of Forest (DF)	1	2
Department of Export Agriculture (DEA)	4	10
Department of National Botanical Gardens (DNBG)	1	10
Cashew Cooperation (CC)	0	2
National Aquatic Resources Research and Development Agency (NARA)	5	10
Veterinary Research Institute (VRI)	0	1
Total	**44**	**91**

2.4 Partnership

2.4.1 Existing Major Partnerships

During late 1970s, tissue culture for orchids was established at the Royal Botanical Garden. Coconut tissue culture division was established in 1983 and at present the first tissue culture coconut plant was introduced to the field by the CRI. Biotechnology scientists group was formed at the SRI during 1983-84. The first biotechnology laboratory was established at PGRC of the DOA in 1987, with the assistance of Japan International Comprehensive Agency (JICA). Four scientists were trained in biotechnology at Universities of Riverdale, USA; Nottingham, UK; Bath, UK; and Tsukuba and Kyoto, Japan during 1987-96. Thereafter, several scientists were trained at SLCARP under the ICAR-SLCARP project. In 1994, the Virus Indexing Centre of DOA was established, and later, biotechnology laboratories were established at RRDI, FCRDI, HORDI, and recently at FRDI.

2.4.2 Scoping of New Partnerships

Sri Lanka is searching partnerships regionally and globally in terms of R&D in AB. A regional network should be established apart from organizing international training courses/workshops in biotechnology. Access to new publications through databases in biotechnological advances should be established.

2.5 Funding Mechanism

Establishment of an innovative sustainable funding mechanism for biotechnology was identified in the NBP. Public investment for agricultural research is ensured through Treasury to individual research institutes in the NARS. Allocations for biotechnological research have been made available based on research priorities. Private sector agricultural companies have allocated some amount for biotechnological research. The private sector should be further encouraged and motivated through soft loans, tax credits, and tax exemptions to invest in biotechnology R&D. Some private sector companies involved in AB research are, Serendib Horticulture Technologies Private Limited, CIC Agriculture Private Limited, and Hayleys Agriculture Holdings Private Limited.

3. National and Institutional Strategies

3.1 National Strategies for Research and Development

- Establishment of an apex body, called as NBC
- Establish an innovative sustainable funding mechanism for biotechnology
- Establish an environment conducive to innovation, product development, and commercialization
- Enact legislative reforms and compliances

3.2 Capacity Development

- Include biotechnology and other related subjects to secondary and undergraduate curricula
- Promote post-graduate research and training (local and overseas) in biotechnology in universities, research institutes, and at the industry level
- Attract young scientists to biotechnology through grants, special internships, scholarships, and fellowships
- Career opportunities should be provided to scientists working in universities and research institutes in biotechnology-related jobs
- Strengthen the existing capacity of biotechnology by providing collaborative programmes overseas
- Coordinate short-term training in biotechnology in local and international context

3.3. Infrastructure Development

The NBC, which is the apex body in Sri Lanka, and Centers of Excellence (CoE) in biotechnology in public and private institutions were established. Financial support should be guaranteed while promoting collaborative activities and research with national and international organizations. A coordinating office should be established to check whether the research activities undertaken are in line with the identified research priorities of biotechnology. Research institutes, universities, and private sector organizations should be assisted to become CoE in biotechnology. It is also decided to establish biotechnological parks in the country.

3.4 Communication Strategy

The biotechnological R&D activities are performed at research institutions and university faculties in the NARS, and in the private sector organizations. These research activities are based on research priorities formulated by the NCB at the CARP. NBC, as the apex body, should drive policies, facilitates, and coordinate and monitor all activities related to biotechnology research, promotion, and application. A communication strategy should link all the above institutes to develop biotechnology in the country.

3.5 General Awareness

- Include biotechnology into school curriculum through National Institute of Education and university curriculum through University Grants Commission
- Identify scientists and other experts who are capable of communicating the message of biotechnology to the public
- Training of trainers at NSF, CARP, research institutes, universities, and other places and provide financial support to disseminate information

- Create public awareness on the national biosafety
- Provide training materials to training programmes on biotechnology
- Initiating an Information center on biotechnology

3.6 Policy Advocacy

It is advised to sustainably use biodiversity for biotechnology, to promote manufacturing of bioproducts and also encouraged to improve traditional biotechnological processes. It is planned to establish a national data bank or information center for biodiversity.

4. Specific Focus on Research

Specific focus has been given to categorize research projects conducted since 2000 in research institutes belonging to the NARS. This has indicated the distribution of research projects among adaptive, applied, basic, and strategic research areas in the following manner.

Adaptive research	Applied research	Basic research
Non-plantation sector		
Marker Assisted Selection (MAS) for bacterial leaf blight resistance and quality improvement	Molecular detection and identification of fungi, bacteria and viruses; mutations with tissue culture on fruits; molecular characterization of crop germplasm; cryopreservation of embryos/embryo culture; virus indexing; antibody production	Embryo rescue technique of chilli, rice; gene mining, tagging; DNA fingerprinting; mutagenesis; genetic transformation of tomato; gene expression studies; gene pyramiding; genetic engineering/Transgenic approaches
Plantation sector		
Vegetative propagation using infertile ovary culture; somatic embryo genetic cultures; validation of an embryo culture protocol; use of Double Haploid (DH) technology; tissue culture; MAS; hybridity confirmation	Molecular characterization of germplasm; genome mapping; new genotype development; molecular detection and identification of pathogens; *In vitro* culture; cryopreservation of embryos	DNA fingerprinting; gene mining
Fisheries sector		
In vitro propagation of aquatic plants	Molecular identification	
Forestry sector		
Tissue culture		
Floriculture sector		
In vitro propagation; Tissue culture		Genetic transformation; Genetic improvement

5. Priority Areas of Agricultural Biotechnology

National research priorities for AB were identified by the SLCARP National Committee on Agricultural Biotechnology for the period of 2017-2021 for non-plantation sector, plantation crop sector, livestock and poultry sector, fisheries sector, export of agricultural crops, floricultural crops, other crops and organisms, and others (SLCARP, 2017).

5.1 Non-plantation (Food) Crop Sector

- Molecular characterization of genetic resources of important food crops
- Gene/QTL mapping and MAS for important traits on yield, biotic and abiotic stresses, and nutritional qualities
- Use of novel molecular techniques for crop improvement
- Development and application of disease diagnostic tools for major food crops using molecular tools
- Production of high quality and disease-free planting materials of major food crops
- *Invitro* conservation (cryopreservation and tissue culture) of crop germplasm

5.2 Plantation Crop Sector

- Genetic characterization of crop germplasm
- MAS for crop improvement (yield, biotic and abiotic stresses with special reference to heat and drought)
- *In vitro* conservation (cryopreservation and tissue culture) of crop germplasm
- Mass production of planting material using *in vitro* techniques
- Detection and identification of pathogens of economically important diseases and pests
- Production of disease-free high-quality planting material

5.3 Livestock and Poultry Sector

- Development and application of biotechnologies related to animal feed and nutrition
- Molecular identification and quantification of mycotoxins producing microorganism in poultry feed
- Intestinal microbe population identification in poultry
- Improvement of nutrient availability of animal feed through manipulation of rumen microbes
- Micropropagation of hybrid grass varieties
- Improvement of molecular technologies for disease diagnosis for viral, bacterial, fungal, and parasitic diseases
- Vaccine production for viral, bacterial, and parasitic diseases for emerging needs

5.4 Fisheries Sector

- Development of biotechnological protocols for marine micro algae propagation
- Extraction of bioactive compounds from marine micro algae and other marine organisms
- Development of resistant brood stocks of shrimp for white spot disease using molecular markers
- MAS for selected aquatic plants of ornamental value: *Cryptocoryne* (leaf color and leaf shape) and *Anubias* (leaf shape)
- Stock identification for economically-important marine food fish using molecular tools
- Development of barcoding database for endangered, endemic, and threatened fish species
- Molecular identification of antimicrobial resistant pathogens along fish product supply chain (especially targeting export industry)
- Molecular identification of parasites in food fish (targeting export industry)
- Molecular characterization of lactic acid bacteria and other commercially important microorganisms applicable in the processing industry

5.5 Export of Crops

5.5.1 Agricultural Crops

- Molecular characterization of important export agricultural crops
- Pest and disease diagnosis of cinnamon using molecular techniques
- Molecular evaluation of germplasm and Geographical Indicator fixing in black pepper and coffee
- Development of biotic and abiotic tolerant varieties of pepper and Arabica coffee using reverse genetics approaches

5.5.2 Floricultural Crops

- Production of commercially viable new varieties through genetic engineering in orchids, anthurium, and other indigenous species
- Quality indexing for the planting material during import and export
- Mass production of planting material via *in vitro* techniques in orchids, anthuriums, ornamental flowering plants and foliage
- Pest and disease diagnosis of ornamental crops through molecular techniques

5.6 Other Crops and Organisms

- Commercial propagation of oil palm and bamboo using *in vitro* techniques
- Screening and improving microorganisms and their products, either for direct consumption as food or in agro-industries for sustainable agriculture

5.7 Others

- Policy research to enhance the application of biotechnology in agriculture
- Application of genetic engineering tools to achieve resistance for biotic and abiotic stresses
- Bioprospecting for agricultural use
- DNA fingerprinting/bar-coding of important plants and varieties

6. Major Challenges and Opportunities

Generally, in agriculture sector, access to new technologies is limited to scientists and academics to upgrade their knowledge in molecular biology techniques, new inventions, and refinement in cost-effective methods in biotechnology. Partnership programmes with prominent international centers of excellence in relevant fields of biotechnology to scientists are limited. Knowledge of scientists on international treaties related to biotechnology is inadequate, which may affect negatively in their scientific career. Collaborative research and development are limited among scientists and academics leading to more effective output and outcome; funding agencies should consider this in granting either foreign or local research funds. A Package of product development is essential to transfer, and commercialization to a private sector should be taken as an important point (Fernando, 2016). Challenges and opportunities related to biotechnology research by sector are summarized below (Herath, 2016; Krishnarajah, 2016; Perera, 2016; Senanayake, 2016; Senaviratne, 2016; de Silva, 2016).

Challenges	Opportunities
Lack of trained researchers and technical staff is the major challenge faced by all the sectors.	

Challenges	Opportunities
Non-Plantation Sector	
High cost of equipment and chemicals; delay in procurement of chemicals	Awareness on biotechnological tools; availability of basic biotech facilities; interest among undergraduate students; inclusion of biotech courses at undergraduate and postgraduate levels
Plantation Sector	
Under investment; research in isolation and lack of multidisciplinary approach; lack of industry focus; lack of central facilities for sequencing and genotyping; delay in procurement of chemicals	
Floriculture Sector	
High cost of equipment and chemicals; techniques in producing novel plants need to be refined; lack of adaptive or applied research; weak linkage between public-private partnership, research in isolation	Awareness on biotechnological tools; methods already developed can be exploited; rich biodiversity
Forestry & Livestock Sector	
Under investment; lack of industry focus	
Fisheries Sector	
	Staff with post-graduate training; Supporting staff; biotechnology/molecular biology laboratories; tissue culture laboratories

7. Future Outlook

The NBP outlines the future outlook on biotechnology, published by the NSF and NSTC in 2009. These can be categorized as short-, medium-, and long-term interventions to improve the status of biotechnology in Sri Lanka.

7.1 Short-term

- Create public awareness on biotechnology by incorporating more lessons on biotechnology in school curriculums, conducting seminars, workshops, industry visits, exhibitions and promoting write ups in newspapers
- Establishment of centers of Excellence for biotechnology, which is already achieved

7.2 Medium-term

- Gradual increase of research investment should be done by the Government through Treasury allocations, and budgetary allocations through Annual Action Plans of research institutions in NARS. Further, capital budget allocations should be increased gradually to infrastructure development, especially equipment and laboratory set-ups.
- Increase opportunities for biotechnology-related industries and entrepreneurship in all six sectors in agriculture by providing tax concessions and exceptions.

7.3 Long-term

- Undertaking the development of human resources is essential to improve the capacity of biotechnology, which is possible by offering training in foreign universities for MSc and PhD candidates. Further, the capacities should be enhanced by offering middle-level training for technicians and other support staff in research institutes and university laboratories.

- Sustainable utilization of biodiversity resources should be maintained with R&D, while utilization of endemic species in the country should receive special attention.
- Establishment of biotechnology parks to represent all six sectors in agriculture.

8. Conclusions

- It is essential to increase international collaborations through training courses and research projects in AB. As a result, new PhD, MSc, and short-term training programmes for scientists should be initiated; and training programmes for supporting staff at laboratories should also be arranged for capacity development. Infrastructure development should be undertaken through these collaborations.
- Sri Lanka should link with regional networks to increase the access to advanced biotechnological tools and increase the number of latest scientific publications on the subject. The public-private partnership should be promoted with practical implementation, and more emphasis should be given to increase annual recurrent and capital budgets of institutions on biotechnology.
- The national research programme should base on research priorities identified by the CARP. NBC should involve practically to drive policies, facilitate, coordinate, and monitor all activities related to biotechnological research. NRC is responsible for effective implementation of the NBP through regulations, strategies, and action plans. A meta-analysis is suggested to draw baseline in agricultural biotechnological research and its advancement in Sri Lanka.

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Country Status Report -Nepal

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1. Introduction

In Nepal, biotechnological research started in 2003. However, progress is very slow due to lack of sufficient infrastructure, manpower, awareness among people and various other reasons. Today's need is to take forward the field of agricultural biotechnology (AB) together with other allied fields of these cutting-edge technological inventories for improving the country's economy. The present report is a compilation of information on the status of biotechnological research in Nepal (Table 1).

Table 1. Basic Information

Indicator	Details
Value of GDP (Billion NPR) NPR= Nepalese Rupee	2599*
Value of GDP in USD (Billion USD)	24.47**
Value of agriculture GDP (Billion NPR)	254.67@
Value of agriculture GDP in (Billion USD+)	2.46
Agriculture GDP as per cent of GDP	27.04***
Total investment in agricultural research (Billion NPR)	~2.45
Total investment in agricultural research (Million USD+)	~23.75
Total investment in AB research (Million NPR)	~49.48
Total investment in AB research (Million USD+)	~0.48

*Source: World Bank (*2017; **2017a; ***2017b); @Trading Economics (2017); + 1 USD=103.15 NPR*

2. National Policies

2.1 Current National Policies on Agricultural Biotechnology and Policies for Enhancing the Livelihood of Farmers through Agricultural Biotechnology

Following are the policies of Nepal that have addressed in varying degrees the growing field of AB.

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2.1.1 National Seed Policy, 1999

Government of Nepal formulated the National Seed Policy in 1999, which focuses on seven areas of seed sectors in Nepal, namely, variety development and maintenance, seed multiplication, quality control, increased involvement of private sector, seed supply, institutional strengthening and biotechnology.

2.1.2 National Agricultural Policy, 2004

This umbrella policy of the overall agriculture sector intends to regulate the use of genetically modified organisms (GMOs) and production. The productivity of the overall agriculture sector is expected to increase through the suitable agricultural (bio) technologies.

2.1.3 Biosafety Guidelines, 2004

The guidelines are focused on regulating laboratory safety and GMO safety. This has come up with an agreement with the Nepal government ratifying the Cartagena Protocol on Biosafety 2000 in March 2001.

2.1.4 National Biosafety Framework, 2006

It authorizes the concerned agencies for regulatory measures and guidelines to avoid or minimize potential risks of genetically modified (GM) plants, microorganisms, animals and their products.

2.1.5 Biotechnology Policy, 2006

Increment of production and productivity through the research, development and technology transfer of biotechnology is expected. Identified priority areas are tissue culture and plant improvement. This does not specifically spell more on agriculture biotechnology, rather is an umbrella policy for similar works across several other sectors (NAST and MOEST, 2008).

2.1.6 Nepal Agricultural Research Council (NARC) Vision 2011-2030

Biotechnology has been given due priority for advancing agriculture. It is mentioned that the scope for developing new biotechnology products that involve licensing, and hence royalties, should be explored. Biotechnology is one of five broad thematic areas envisioned in NARC's vision. Within this area, there are two sub-themes, namely, improvement of crops and horticulture, and improvement of livestock and fisheries. Many different interventions related to biotechnology are proposed in the vision.

2.1.7 National Agrobiodiversity Policy, 2014

It has provision on receiving permission from authorized agency to conduct research on GMOs and government can ban import and research on any GMO having potential risk to alter diversity and negative impact on environment.

2.1.8 National Biodiversity Strategy and Action Plan (NBSAP) 2014-2020

Priority is given to biotechnology for effective management and utilization of biodiversity including agricultural biodiversity. The NBSAP provides a guiding framework for the management of Nepal's biodiversity. It has been prepared to meet the national needs for managing biodiversity on a sustainable basis for the benefit of present and future generations, and also to fulfill the country's international obligations. It has a 35 years long-term vision and also includes specific short-term strategies and priorities for action set to achieve up to 2020 AD.

2.1.9 International Treaty on Plant Genetic Resources for Food and Agriculture and Multilateral System (ITPGRFA-MLS) Implementation Strategy and Action Plan (IMISAP) 2018-2025

Biotechnology is considered as one of the tools to manage and conserve Agricultural Plant Genetic Resources (APGRs).

2.2 Implementation of Policies

2.2.1 Government Bodies Responsible for Implementation of Each Policy

The main implementing bodies for various policies related to agriculture biotechnology are given in Table 2.

Table 2. Various agriculture biotechnology policies and implementing agencies in Nepal

Policy	Agencies
National Seed Policy	Seed Quality Control Centre (SQCC), Nepal Agricultural Research Council (NARC) and Ministry of Agriculture, Land Management and Cooperative (MoALC)
Biosafety Framework	Ministry of Science and Technology (MoST), Ministry of Forests and Environment (MoFE), Nepal Academy of Science and Technology (NAST) and NARC
National Agriculture Policy	SQCC, NARC and MoALMaC
Biotechnology Policy	MoST, NAST, MoALC and NARC
NARC Vision	NARC
National Agrobiodiverity Policy	MoALC, NARC, SQCC
NBSAP	MoFE, MoALC and NARC
IMISAP	SQCC, MoALC and NARC

2.2.2 Effectiveness of the Policy

While other countries including our neighbors have made or are making impressive progress in biotechnology, Nepal has not yet made much headway in this field. Some work has been initiated using the biotechnological tools for the improvement of crops, animals, industrial microorganisms and also to combat environmental pollution problems.

The programme on modern crop biotechnology in Nepal was initiated since 2000 (Joshi, 2017). Since then, a number of decent research laboratories were spread in different universities and R&D organizations. In addition, presently few Non-Government Organizations (NGOs) are also working on plant and animal molecular research as well. Protocols on plant regeneration and micropropagation have been developed on different crops, forest plants, ornamental and fruit trees as well as vegetables. Marker-aided selection and molecular characterization by Random Amplification of Polymorphic DNA (RAPD), Simple Sequence Repeats (SSR), isozymes, mitochondrial DNA, and whole genome studies are being undertaken in different plants, fish and animal species (Kunwar *et al.,* 2000; Takeda *et al.,* 2004; Joshi *et al.,* 2009; Gorkhali *et al.,* 2011, 2014, 2015, 2016, Joshi 2017a,b,c; Joshi *et al.,* 2017). Research on use of DNA probes for the diagnosis of diseases and DNA fingerprinting of various animals and crops are in progress.

In animal biotechnology, modern biotechnology programmes including Embryo Transfer (ET) technology and Artificial Insemination (AI) have been initiated and successfully implemented. Recently vaccine has been developed against Rabies, Peste des Petits Ruminants (PPR) *etc.* Developments in fish biotechnology include induced breeding techniques in carp, rainbow trout, and others; production of all monosex population (all males and all females) in tilapia and silver carp by sex reversal. In the field of industrial biotechnology, Nepal is yet to make real breakthrough. Some achievement has been made in the field of biogas production from animal excreta and bioconversion of agricultural residues to feed, food and fertilizers. In case of environmental biotechnology, mostly traditional techniques are being used for waste treatment and pollution control. Modern biotechnological methods are yet to be applied.

2.3 Capacity Development

2.3.1 Existing Capacity Level

NARC has good facilities for basic biotechnological work, namely, tissue culture and PCR. All equipment for these works is very conventional. There are about 15 staff working on AB, in the areas of diversity assessment of agricultural genetic resources using different kinds of DNA markers. In addition, screening for molecular markers for different biotic and abiotic stresses, is also getting momentum.

2.3.2 Required Capacity for Future

Development of manpower on advanced biotechnology, namely, bioinformatics, genetic engineering, genomics, sequencing, molecular breeding, gene/Quantitative Trait Locus (QTL) tagging and mapping, antisense Ribonucleic Acid (RNA) technology, metabolomics and MAS, vaccine production, *etc.* The second requirement is establishment of advance lab and supplies of different modern equipment to existing labs. Third one is establishment of mutation breeding garden along with chemical and reagents production lab.

2.4 Partnership

2.4.1 Existing Major Partnerships

Major partnerships are among NARC, SQCC, MoALC, NAST and Consultative Group on International Agricultural Research (CGIAR) institutes. The partnership between NARC and CGIAR is mainly for supply of genetic materials and training. NARC has good collaboration with SQCC, different research and universities of Japan, Korea, India, England, USA, Australia, China, Germany, *etc.*

2.4.2 Scoping of New Partnerships

Partnerships are necessary in different dimensions of AB *e.g.* technology transfer (sequencing, mutagenesis, molecular breeding, bioreactor, genetic engineering, vaccine production, *etc.*), funding (for establishment of lab and supplies) and capacity (short, medium and long-term trainings). Agrobioversity available in the country has been poorly used in R&D. This part should be taken with due consideration for developing new partnership along with contribution on organic agriculture. NARC is ready to develop partnerships with different organizations for advancing AB in the country.

2.5 Funding Mechanism

Funding priorities have been increasing on AB at national and institutional levels but at a slower pace. Main funding mechanism for NARC is given in Figure 1.

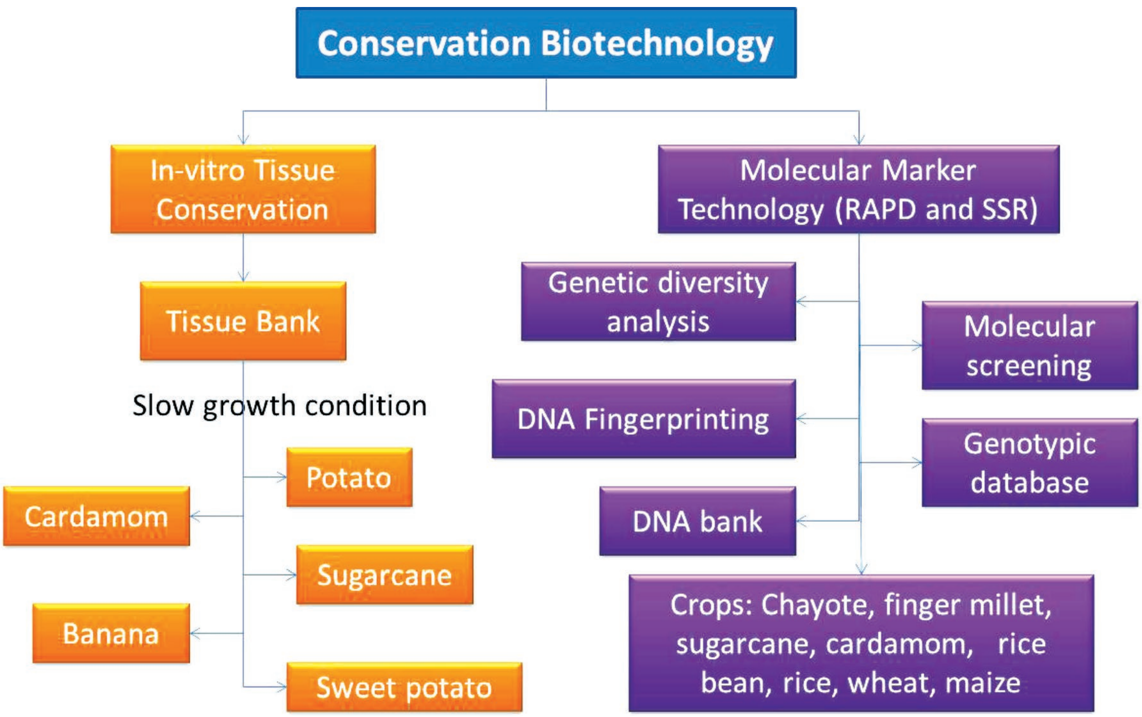

Figure 1. *Current status of conservation biotechnology in Nepal*

3. National and Institutional Strategies

There is no separate strategy for R&D, capacity development, infrastructure development, communication strategy, general awareness and policy advocacy. Followings are the general strategies for crop sciences, animal science and fish.

One of the national strategies is policy dialogue on linking science policy with agricultural development policy. A team of experts is formed to advise and formulate policies in biotechnology and the application of biotechnology as well as the production and release of GMOs. A regulatory mechanism has been developed on biosafety in line with Convention on Biological Diversity (CBD) to manage or control the risks related to hazardous chemicals, GMOs in biotechnology. Some of major strategies are NBSAP, Agriculture Development Strategy (ADS) and IMISAP in the country.

Establishment of a central laboratory is the institutional strategy for national funding mechanism and use of advance tools and technologies. Promotion of appropriate biotechnologies for the conservation and utilization of crops, plant and animal genetic resources are highlighted. A National Genebank has been established along with tissue bank and DNA bank. A national agrobiodiversity database including genotypic data is in the process of development. Mechanism to setup one window system for the transport, import and export of biotechnology products especially GMOs are in discussion. Major strategy is maximizing the positive effects and minimizing possible negative effects of biotechnology. Further discussion is planned for identification of scope and priority areas on R&D of biotechnology that can provide cost-effective solutions.

4. Specific Focus on Research

Applied AB is the major focus area of NARC. Micropropagation and DNA technologies are the major subject of interest to develop profitable agriculture in Nepal. Some of specific focus include virus indexing in potato, large cardamom, banana; MAS in major cereals, vegetables and fruit species, genetic diversity assessment and fingerprinting of indigenous crops, livestock, fishes, microorganisms and insects; banking of DNA and tissue; screening of germplasm against biotic and abiotic stresses; disease diagnosis; laboratory strengthening and manpower development. The priority areas of NARC are illustrated in Figure 2.

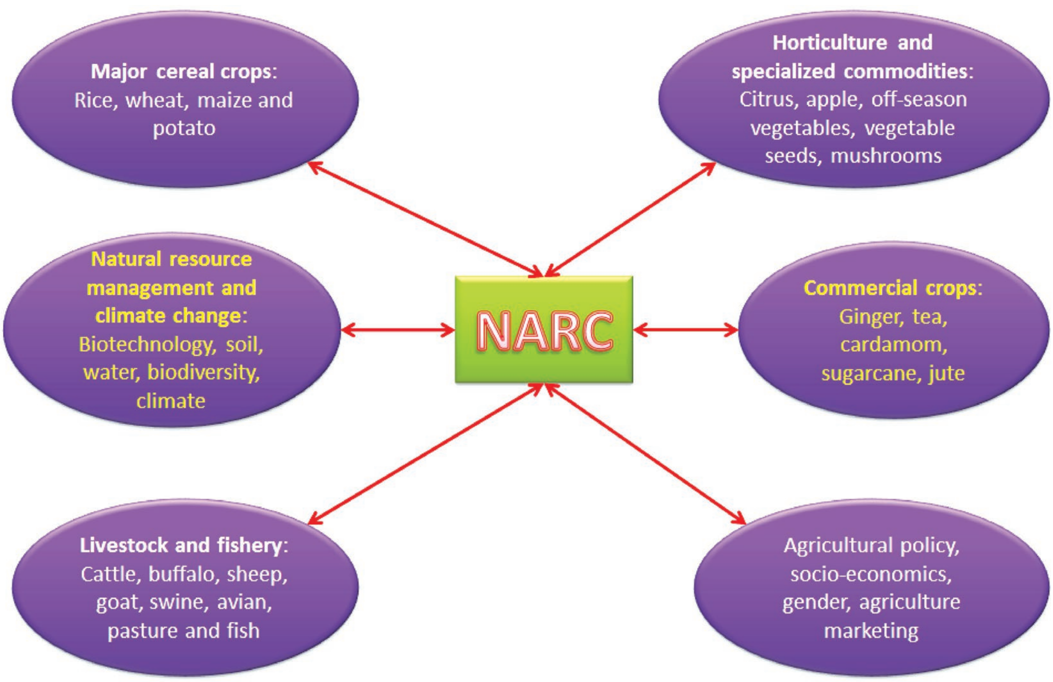

Figure 2. *The priority areas of NARC*

5. Priority Areas of Agricultural Biotechnology

There are many priority areas on the use of biotechnology for agricultural R&D in Nepal. Some of them are already in practice and others are planned for future. Priority areas are given below under six major sectors.

5.1 Agriculture and Food

Major priority areas under this sector are tissue culture, biopesticides, biofertilizer, natural products in healthcare, animal feeds/supplements, fish, crop and animal improvement, decorative flowers/plants, herbs and mushrooms, identification and isolation of genes to use in molecular hybridization, studies on polymorphism, molecular mapping of endangered and commercial species, selection of gene for breeding programmes and development of diagnostic kits (MAS) for improvement of livestock and crop productivity, DNA profiling, diagnosis of diseases *etc.*

5.2 Animal Science

In Nepal, among the animal biotechnologies, the application of assisted reproductive biotechnologies such as AI, oestrous synchronization and ET is commonly used. These techniques can bring about faster genetic gain. Molecular markers for genetic diversity studies are also used widely, but MAS for genetic improvement is yet to be initiated, however, identification of trait- specific markers has already initiated in chicken in-research level. Biotechnologies to improve animal nutrition through feed additives such as amino acids and enzymes are applied, especially in monogastric livestock, whereas use of other additives such as probiotics has been initiated in research level. Advanced technologies such as cloning and transgenesis are hardly used in the country as the national policy is still not clear for this aspect.

5.3 Animal Health Care

In order to cure normal and chronic diseases, communicated through genetic impairment or external effect and to make timely identification of pathogen, the knowledge of modern biotechnology shall be utilized. Emphasis shall be in the areas of diagnostics, vaccines, veterinary drugs, immunology and therapeutics, ET and gene therapy. Similarly, molecular based serological techniques using monoclonal antibodies and recombinant antigens as well as PCR-based methods are being used for diagnosis of diseases and epidemiological studies in the country, together with conventional and recombinant vaccines for controlling diseases.

5.4 Industry

Programmes shall be operated to maximize development and competitiveness of the industries established in areas of food processing, forest based-products including the area of chemical and accomplish a significant achievement through biotechnology-based research. The important sectors shall be food and industrial enzymes, fermentation products, bioenergy, biofuel and bioconversion.

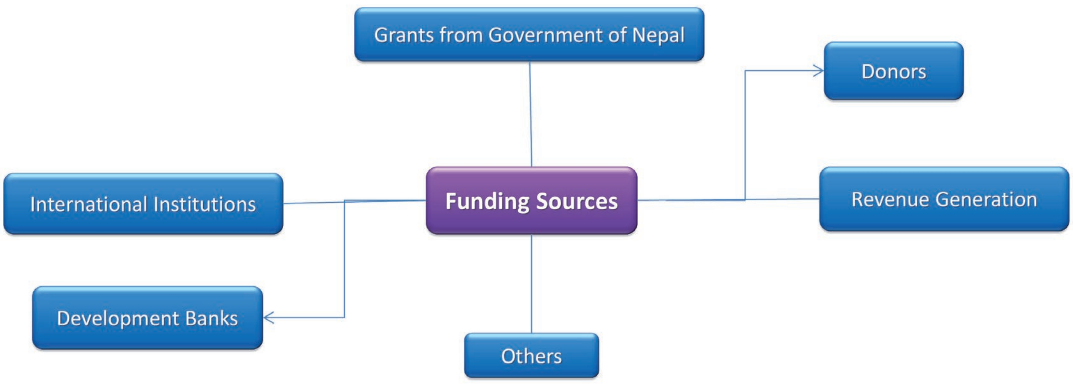

Figure 3. *Flow diagram - Main funding mechanism for NARC*

5.5 Environment and Biodiversity

For achieving clean environment and conservation of agricultural biodiversity, priority should be on development of biological control agents, urban waste management, industrial waste treatment and development of monitoring tools and biosensors.

5.6 Human Resource Development

Initiative is required to develop suitable human resource in the field of biotechnology and retain the existing human resource and attract the new-comers. Priority is given for the introduction of biotechnology and bioinformatics at the graduate and post-graduate levels in universities. Scientists will be imparted with necessary short-term and long-term training on professional and innovative skills. Efforts shall be made to establish cooperation on study and research amongst national and foreign universities/ institutions in the field of biotechnology. Scholarships for Masters and PhD in Science and Technology shall be made available in biotechnology and sectors related thereto. The programmes and systems for the promotion of entrepreneurship shall be developed by National Biotechnology Research and Development Centre, and Ministry of Environment, Science and Technology.

6. Major Challenges and Opportunities

6.1 Challenges

- There is a wide gap between technology generation in tissue culture and its dissemination to the clients or the farmers. Several protocols have been developed for tissue culture propagation for more than 100 plant species in Nepal, but very few of them have been widely used by the farmers
- There is no other technique available today to control viral diseases on plants except thermo-therapy and meristem culture. Economically important plants such as potato seeds, citrus saplings, banana and cardamom should be first cleaned from the viruses and then rapidly multiplied by tissue culture and distributed for planting in safe areas
- There is acute lack of national programme on biotechnology
- Biotechnology programmes are usually dependent on the initiative of a few foreign-trained scholars and enthusiast scientists at home
- The limiting factors both for private and government sectors are lack of qualified and properly trained research and development manpower
- The availability of quality infrastructure relevant to biotechnology research is negligible
- Lack of public sector-private enterprise links, university-industry interaction, and university-university cooperation also limits the scope of biotechnology on its application in agricultural research

6.2 Opportunities

- Different types of agricultural genetic resources and diverse climatic variation are the main opportunities for biotechnological work in Nepal
- Many students are more interested on biotechnology
- Many technologies are available and some of them can be directly used for benefit

7. Future Outlook

7.1 Short-Term Strategies

The targets are use of latest serological techniques like Enzyme Linked Immunosorbent Assay (ELISA), Double Antibody Sandwich, Dot Immunobinding Assay and tissue culture for virus indexing and cleaning of germplasms especially in potato, sugarcane, citrus, banana and cardamom. Developing and standardizing efficient micropropagation protocols for economically important vegetative propagated crop and flowering plants are also in demand. Other working areas within few years are anther culture, embryo culture and protoplast culture, development of hybrids, biochemical and molecular characterization, marker aided selections and marker aided backcrossing, biopesticide and biofertilizer, information collection, retrieval and dissemination, preparation of diagnostic kits for indexing serious diseases in plants and animals, and preparation of the vaccines for animals, and biofortification.

Similarly, in animal biotechnology, AI in different species to be widely used for dissemination of superior male germplasm as the opportunity for increased productivity (Gorkhali and Sapkota, 2017). In order to improve the effectiveness of this technique, cryopreservation techniques for semen need to be improved on quality and keep-ability of semen. In addition, progesterone monitoring and estrous synchronization techniques need to standardized in order to improve the conception rate.

In case of animal nutrition and production, wide use of improved microbial cultures such as fermentation adding useful bacteria need to implemented to increase the quality of silage and digestibility of other feeds. Similarly, effectiveness of the pre- and pro-biotics in Nepalese context needs to be assessed.

7.2 Medium-Term Strategies

Include the setup of biotechnology information centre and establish a computer link with institutions, sand rooting and commercial production of tissue culture plantlets for exports (*eg.* banana, carnation, chrysanthemum, lily etc), studies on vaccine production for major diseases of livestock and poultry, screening and development of cost effective molecular tools to reduce the genetic disease burden and increased the production, production of disease free potato seeds, citrus, banana and cardamom and use its geographical advantage to produce and sell them in massive scale, tissue culture vaccines production to immunize the livestock population and protect them from deadly diseases, and metabolic assisted breeding. Medium-term plans on conservation biotechnology are given in Figure 4.

In case of animal reproductive physiology, complementary technologies such as multiple ovulation and ET and sexing of semen and embryos are to be initiated for medium and long-term strategies.

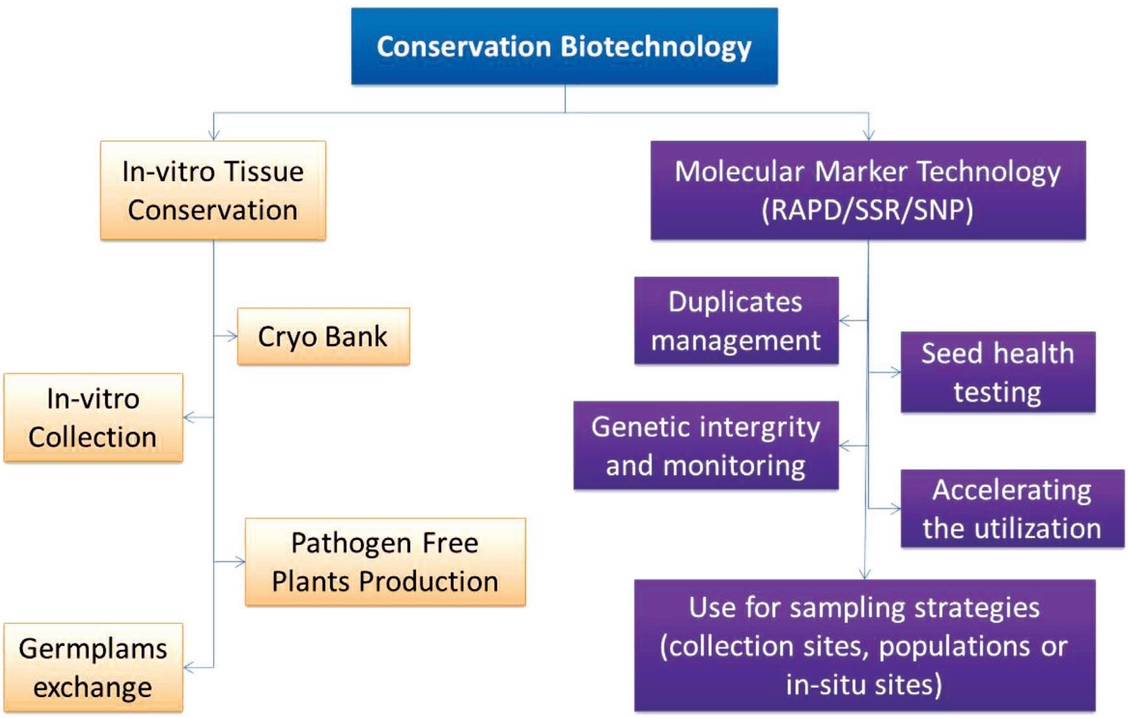

Figure 4. *Medium-term future plan on conservation biotechnology (Source: Joshi 2017a, 2017b)*

7.3 Long-Term Strategies

The major plans include initiation of research on genetic engineering in confined area, production of secondary metabolites from cell culture, resistance breeding against insects, diseases and stresses, gene tagging and mapping including QTL, gene pyramiding, sequencing of indigenous genetic resources, use of bioinformatics system, viruses and vaccines control system, and microorganisms use in agriculture (Figure 5).

Conservation of genetic resources and diversity especially for the endangered and/or extinct animals cryopreservation techniques (cell lines culture) would be strengthened. Similarly, transgenic animals and gene transfer, "Knock-in", "Knock-out" should also be introduced in order to improve the productivity as well as to promote gene(s) related to economically important traits.

Animal nutrition aspect is lagging behind in implementing biotechnological techniques. The following are the untouched research areas under this discipline, which is very advanced in neighboring countries:

- Inhibit pathogens, increase immunity (long-term)
- Growth promoters; Metabolic modifiers (long-term)
- Recombinant somatotropin, repartitioning agents
- Single cell proteins
- Genetic manipulation of plants to increase digestibility, reduce anti-nutrients and to decrease P&N excretion (phytate, amino acids)
- Genetic manipulation of rumen microbes for improved fermentation, metabolism and utilization
- Use of microorganisms including recombinant DNA technology such as recombinant bacteria for enzyme and hormone production for increased productivity or decreased environmental impact

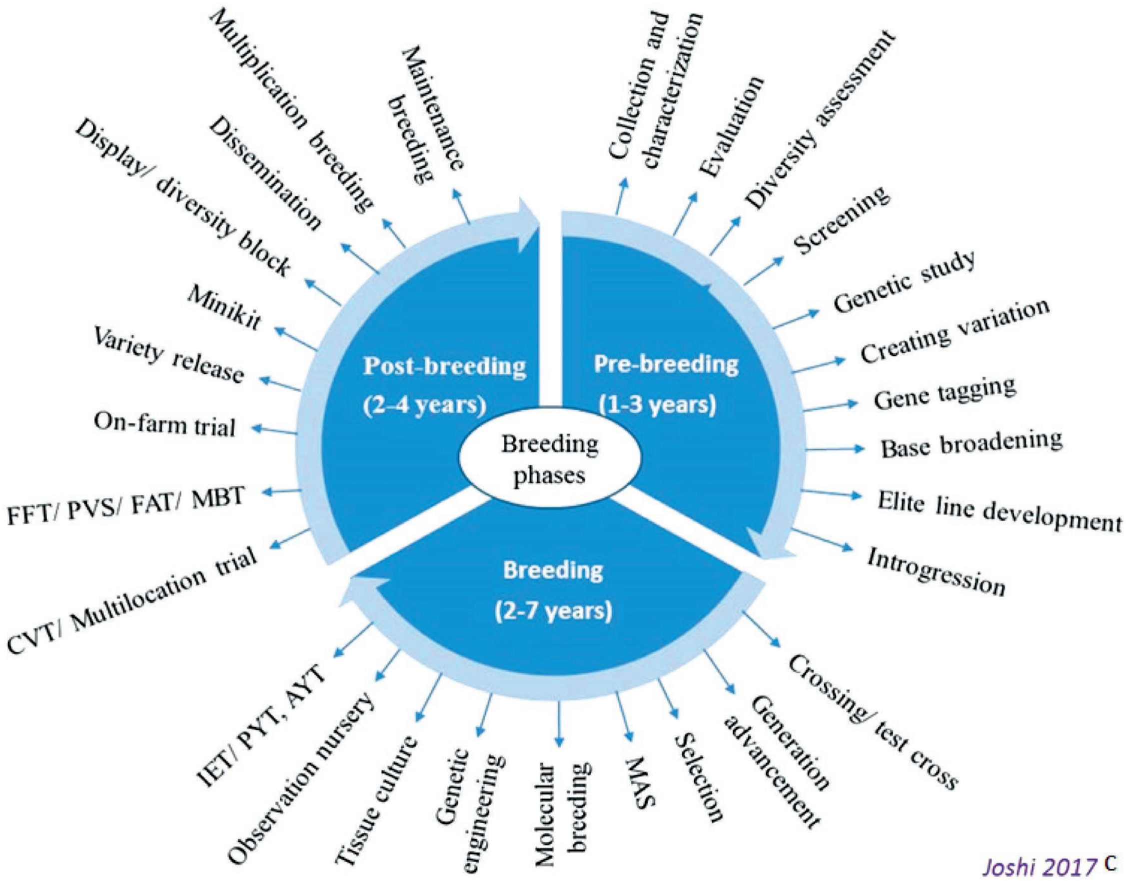

Figure 5. *Priorities and activites for crop breeding*

8. Conclusions

Biodiversity conservation is an essential element of human development and security. Agriculture, forestry, fisheries and livestock contribute significantly to national economies and employment. Achieving development goals requires creative use of both existing and new resources. Nepal, being one of the world's richest biodiversity zones/areas, has ample opportunity for the development in this field. Keeping in view the critical role played by the scientific and technical personnel in the development of biotechnology, all possible academic and training programmes in the field of biotechnology and bioinformatics need to be encouraged. For front line research in modern biotechnology, selected laboratories in some existing R&D organizations and academic institutions need to be strengthened with modern laboratory facilities.

The present level of livestock and fisheries production can be significantly improved through application of classical breeding and modern biotechnology for improvement of breeds and nutrition, protection of health and conservation of genetic resources of animals and fishes. In addition, feed development and microbial upgradation, improved digestibility and bioavailability can be addressed through gene base technology.

Many policy and strategy documents of Nepal have considered the application of AB for over all agricultural development. The National Policy on Biotechnology needs to be reviewed in consultation with other relevant ministries for updating, harmonization and standardization of the policy in line with the fast development in this field. Biotechnology has been considered to overcome the consequences of abiotic and biotic stresses, basically developing climate resilient varieties. Biotechnology can play significant role in food and nutrition security through increased agricultural production, nutrition-dense production and diversified production by adopting new biotechnological tools. For this, there is need for the development of human resources and infrastructure. The country too needs to keep biotechnological research on the priority. Strong linkages and collaboration with national and international institutions are equally important for proper use of biotechnology in agricultural research and development. Bilateral and multilateral collaboration of the local R&D organizations with advanced laboratories of the world needs to be encouraged to gain access to cutting-edge research in this emerging field and for training, expert service and facility development in areas of national interest.

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Country Status Report – Pakistan

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1. Introduction

Productivity gained in the last 20 years through biotech crops proves that conventional crop technology alone cannot allow us to feed the immense increase in population. In 20 years, an accumulated 2 billion ha of biotech crops globally have been grown, commercially comprising soybean (1.0 billion ha), maize (0.6 billion ha), cotton (0.3 billion ha) and canola (0.1 billion ha). Biotech products derived from this 2 billion ha significantly contributes food to the current population of 7.4 billion people. Hence, feeding requirement of the world, which is continuously increasing and predicted to be 9.9 billion in 2050 and 12.3 billion in 2100 is indeed a daunting task. Of the total number of 26 countries planting biotech crops in 2016, 19 were developing countries and seven industrial countries. Total global area under Genetically Modified (GM) crops is more than 180 million ha with 28 countries growing GM crops.

Pakistan has made significant progress in the development and usage of biotechnology, having grown GM cotton on 2.9 million ha, seventh in global ranking and more than any Islamic country (ISAAA, 2016). The details on various national policies, their implementation, different national and institutional strategies for the development of biotechnological research in Pakistan, budgetary allocations, challenges and opportunities are discussed in the present report (Table 1).

Table 1. Basic Information

Indicator	Details
Value of GDP (Trillion PKR) PKR= Pakistani Rupee	31.96*
Value of GDP (Billion USD)	304.95**
Value of agriculture GDP (Trillion PKR)	2.28@
Value of agriculture GDP (Million USD+)	2.17
Agriculture GDP as per cent of GDP	19***
Total investment in agricultural research (Billion PKR)	8.09
Total investment in agricultural research (Million USD+)	7.69
Total investment in agricultural biotechnology (AB) research (Billion PKR)	4.05#
Total investment in AB research (Million USD+)	3.85#

*Source:*World Bank (*2017;** 2017a); ***MoF, 2017; @Trading Economics (2017); +1 USD=105.22 PKR*
 # 50% of Agricultural research investment

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2. National Policies

2.1 Current National Policies on Agricultural Biotechnology and for Enhancing the Livelihood of Farmers through Agricultural Biotechnology

The national policies related to AB in Pakistan, which are in place for the enhancement of livelihood of farmers, are listed below along with their objectives.

2.1.1 Seed (Registration) Rules, 1987

It assesses the suitability of varieties for registration in regard to *inter alia*, distinctness, uniformity, stability and value for cultivation and use based on recommendations of the Provincial Government. It also recommends for registration of new varieties and areas for their suitability.

2.1.2 Seeds (Truth-in-Labeling) Rules, 1991

Controlling and regulating the quality of seeds of various varieties of crops.

2.1.3 Pakistan Fruit Plants Certification Rules, 1998

Controlling and regulating the quality of nursery plants of various horticultural crops.

2.1.4 Pakistan Biosafety Guidelines/Rules, 2005 (GoP, 2005)

The Biosafety rules and regulations are covered for release of modern biotechnology products and to establish standards and procedures for risk assessment and labelling of Living Modified Organisms (LMOs), substances or cells and products. The rules are applicable to the following three broad, frequently overlapping categories of activities/organisms:

- Manufacture, import and storage of microorganisms and gene technological products for research whether conducted in laboratories of teaching and research, research and development (R&D) institutes or private companies involved in the use and application of Genetically Modified Organisms (GMOs) and products thereof
- All works involved in the field trial of genetically manipulated plants, animals (including poultry and marine life), microorganisms and cells and
- Import, export, sale and purchase of LMOs, substances or cells and products thereof for commercial purposes

The Rules established a three tiered hierarchy of governing bodies designated to administer the biosafety guidelines. The National Biosafety Committee (NBSC) and the Technical Advisory Committee (TAC)-Federal Level Committees and the third comprises all the Institutional Biosafety Committees (IBSC)-created with various institutions. The NBSC focuses on national policies on biosafety, authorizes commercial release and trade in crops and products derived through biotechnology, and ensures regulatory compliance. TAC provides the technical information needed by the NBSC to do its job, evaluate applications for field trial licenses and monitor new technologies. IBSCs are responsible for day to day research activities within their institutions.

2.1.5 National Science, Technology and Innovation Policy (ST&I-2011)

Keeping in view the rapid pace of advancements in Science and Technology(S&T) taking place around the world, Government of Pakistan (GoP) initiated the process of formulating its new S&T policy in 2009, later named as National Science, Technology & Innovation Policy (ST&I-2011) of Pakistan (PCST, 2018). This policy has been vetted by the Law and Justice Ministry and was officially launched in November, 2012 and placed biotechnology and genetic engineering among the priority areas.

2.1.6 The Seed (Amendment) Act, 2015 (NAP, 2018)

It revised the document of Seed Act, 1976 (Punjab Code, 2018) and regulates the GM crop varieties, along with other objectives.

2.1.7 Pakistan Biosafety Ordinance, 2015

Revised document of Pakistan Biosafety Rules is yet to be approved by the Cabinet.

2.1.8 Plant Breeders Rights Act, 2016

Protects the breeder's rights on crop variety developed and regulates the GM crop varieties, along with other objectives. The first National Science and Technology (S&T) policy of Pakistan was formulated in 1984. The subjects of Molecular Biology and Genetic Engineering were placed in priority research areas. Later, in 1997, some modification was made and the National Technology Policy was launched maintaining an emphasis on biotechnology as one of the priority areas (Zafar, 2002). The other policies include Cotton Vision, 2010, Cotton Vision, 2015 and now the new Cotton Policy, 2030, later of which is under formulation. Similarly, the Agriculture Policy of GoP also recognized the importance and application of biotechnology in improving this sector.

2.2 Implementation of Policies

Part of the challenge stems from the need for regulatory framework for introducing biotech products and technology for humans, plants and animals. Pakistan has ratified the Cartagena Protocol of Biosafety (CPB) with a framework for handling GMOs as a mark of progress on this front. The regulatory guidelines are built upon a three-tier system-composed of the NBSC; a TAC; and IBC, according to USDA GAIN report on Pakistan. Under the existing biosafety regulatory regime, NBC has been created for the approval of various GMOs, lab genetic manipulation experiments, import and transportation of GM related material, snap checking, *etc* (Table 2). The constitution of IBSC is mandatory. Currently, 41 IBCs have been registered in the country. However, several institutes are yet to establish their IBCs. Two Monitoring Committees, one each for pests and weeds have also been created.

Table 2. Approval of GM cases with NBC/Pak-Environmental Protection Agency

IBSCs	42 notified (Public + Private sector, National & MNCs)
TAC	20 Meetings (Last meeting on Feb. 8, 2017)
NBC	17 Meetings
Submission/Approval status	
Cases submitted	155
Cases notified	118
Labs+ GH + Field studies	109
Commercial approvals	
Deregulated/Exempt	31 (Bt-Cotton)

2.2.1 Government Bodies Responsible for Implementing each Policy

Name of the policy	Implementation agency
Seed (Registration) Rules, 1987	Federal Seed Certification and Registration Department
Seeds (Truth-in-Labeling) Rules, 1991	
Pakistan Fruit Plants Certification Rules, 1998	Ministry of National Food Security and Research
Pakistan Biosafety Guidelines/Rules, 2005	Ministry of Climate Change, Government of Pakistan
National Science, Technology and Innovation Policy (ST&I-2012)	Pakistan Council for Science and Technology in collaboration with Ministry of Science & Technology
The Seed (Amendment) Act, 2015	Ministry of National Food Security and Research
Pakistan Biosafety Ordinance, 2015	Environment Protection Agency of Pakistan, under the Ministry of Climate Change, Government of Pakistan.
Plant Breeders Rights Act, 2016	Ministry of National Food Security and Research

2.3 Capacity Development

2.3.1 Existing Capacity Level

Institute	Infrastructure	Areas
National Institute for Genomics and Advanced Biotechnology (NIGAB), National Agricultural Research Council (NARC), Islamabad	Developing	Agriculture and livestock
National Institute for Biotechnology and Genetic Engineering (NIBGE), Faisalabad	Established	Agriculture, health, industry, environment
Center of Excellence in Molecular Biology (CEMB) Punjab Univ., Lahore	Established	Agriculture, health, industry
Agricultural Biotechnology Research Institute (ABRI), Ayub Agriculture Research Institute, Faisalabad	Developing	Agriculture
26 other Biotech centers	Developing	Agriculture

2.3.2 Required Capacity for Future

Agricultural biotechnology is included as one of the economic drivers in Medium Term Development Framework and Vision 2025 documents of Planning Commission of Pakistan. Agri-biotech has potential to address issues of innovation in agriculture for realizing efficiency, equity and environment. Major investments have been made by GoP over the years. However, there is a need to fill the gap and develop mechanisms for commercialization and thus creating impact on uplift of socio-economic conditions of the end-users (farmers). Few areas are given below, which are either neglected altogether or need strengthening.

(i) **Strengthening of Agro-genomics Centre to act as national depository/supplier for developing desirable (designer) transgenic GM crops and animals :** PARC is the apex agricultural R&D body in the country. The agri-biotechnology programme of NARC is among the pioneers of agri-biotech research in Pakistan. Recently, this effort has been strengthened by establishing an exclusive centre on AB (plants and animals) named NIGAB. There is an urgent need to reinforce these efforts by providing expertise and new knowledge.

(ii) **Establishment and capacity building of National Biosafety Centre for evaluation of GMOs in the country :** This will allow indigenous development and import of GM crops/seeds in the country and their release in the environment. At present country is lacking this facility.

(iii) **Development of national centre for molecular diagnostic and recombinant livestock vaccines :** Livestock contribution to agri GDP is on constant rise. However, productivity is low and diseases are taking heavy toll. There is a strong need to develop an exclusive centre for animal vaccines of international standard.

(iv) **Development of agricultural bioinformatics centre in PARC for retrieving/dissemination of recent knowledge :** There is need to upgrade the existing facilities of Directorate of Publications to an international standard to be a hub of all bioinformatics activities. This is important for knowledge dissemination and retrieval.

(v) **Establishment of a permanent body/cell in ministry and/or PARC and capacity building in Agri-biotech area to negotiate/import GM crops/seed (Issue of royalties, technology fee, license fee impact etc.) :** Biotech crops are now gaining ground in the country due to large acceptance in the region (China, India). A specialized body is required to deal with the complex issues of material transfer agreement, plant breeders' rights, patents, royalties etc.

(vi) **Development of agri biotech (tissue culture) park in collaboration with private sector :** True potential of tissue culture technology for mass production of vegetative grown plants in horticulture and floriculture (banana, potato, dates, sugarcane etc) is yet to be realized. This technology is simple and contributes in an effective manner in shortest possible time. There is a need to establish tissue culture parks at NARC and at regional centre in collaboration with Zarai Taraqiati Bank Limited and private sector. Infrastructure will be required for this purpose in the initial phase. Later, the project will be entering into self-generating income mode.

2.4 Partnership

2.4.1 Existing Major Partnerships

Pakistan has put in significant research efforts in seed and livestock development at various agriculture universities, institutes and departments. Pakistani researchers and scientists are currently collaborating in life sciences with their counterparts in the US and China. Crops like cotton, rice, wheat, corn, potato and groundnut are being developed locally or with the collaboration of Chinese and US seed companies. The leading biotech institutes in the country are listed in Table 3.

Table 3. Major biotech institutes in Pakistan

Agricultural Biotechnology Research Institute (ABRI), Ayub Agriculture Research Institute (AARI), Faisalabad	Department of Plant Breeding & Genetics, Pir Mehr Ali Shah Arid Agriculture University, Rawalpindi
Atta-ur-Rahman School of Applied Biosciences, National University of Sciences and Technology (NUST), Islamabad	Faculty of Biological Sciences, Forman Christian College, Lahore
CEMB, Lahore	Faculty of Biological Sciences, Quaid-i-Azam University, Islamabad
Centre of Agricultural Biochemistry and Biotechnology (CABB), University of Agriculture, Faisalabad	Four Brothers Seeds Corporation Pakistan Pvt. Ltd., Multan
Crop life Pakistan, Karachi	Institute of Biochemistry and Biotechnology, University of Veterinary and Animal Sciences, Lahore
Department of Bioinformatics & Biotechnology, Government College University, Faisalabad	Institute of Biotechnology and Genetic Engineering (IBGE), University of Agriculture, Peshawar
Department of Bio-Sciences, COMSATS Institute of Information Technology, Islamabad	Institute of Molecular Biology & Biotechnology, Bahauddin Zakariya University, Multan
Department of Biotechnology, Abdul Wali Khan University, Mardan	Jullundur (Pvt.) Ltd., Arifwala
Department of Biotechnology, Balochistan University of Information Technology, Engineering and Management Sciences, Quetta	NIBGE, Faisalabad
Department of Biotechnology, Sindh Agricultural University, Tandojam	NIGAB, P-NARC, Islamabad
Department of Plant Breeding & Genetics, Muhammad Nawaz Sharif (MNS) University of Agriculture, Multan	

2.4.2 Scoping of New Partnerships

PARC, while expanding its scope regarding coordination of agricultural research, notified a National Coordinator for Biotechnology to be posted under Plant Sciences Division at PARC Head Quarters, Islamabad. The National Coordinator (Biotechnology) will liaise closely with relevant R&D establishments for facilitating planning and coordination of research programme(s) for creating synergies. Activities would include (i) developing short and long-term R&D agenda; (ii) maintaining professional contacts; (iii) assisting policy makers and (iv) organizing events to increase interaction, knowledge sharing and human resource development.

2.5 Funding Mechanism

The following are the predominant sources of funding for biotechnological research activities in Pakistan:

(i) Public Sector Development Program (PSDP) of Ministry of National Food Security and Research
(ii) PSDP of Ministry of Climate Change
(iii) Research endowment funds of PARC, Pakistan Science Foundation
(iv) Higher Education Commission (HEC) and other similar sources from Universities
(v) Provincial annual development programmes
(vi) Donors' grants and Technical Assistance

3. National and Institutional Strategies

3.1 National Strategies for Research and Development

The advent of traditional biotechnology in Pakistan dates back to 1970 when work was initiated in the Botany Department of Peshawar University. Professor Dr Ihsan Ilahi established a plant tissue culture facility for the medicinal plants like *Rauwolfia serpentina* (Akram and Ilhai, 1986), papaver (Ilahi and Ghauri, 1994), and many more. Later the areas of biofertilizers (biological nitrogen fixation and mycorrhiza *etc.*) and biopesticides (neem extracts and biocontrol methods) along with tissue culture of vegetatively grown crops (banana, date palm, potato, sugarcane and many other horticultural plants) were initiated in various university departments and research organizations in the public sector including NARC, Islamabad. These activities have been continued for decades in those centers and few products delivered from this work, like virus-free potato seeds and multiplication of healthy banana and sugarcane by NARC, have been commercialized (ILSIFR, 2012). Similarly, many production units of biofertilizers in both the public and private sectors are operating in the country (Hafeez, 2009, Hafeez and Hassan, 2012). Likewise, biocontrol for insects in sugarcane fields is expanding with the help of the sugar industry and represents a recognized success story. Most of the departments are still pursuing research and development in the above stated sectors.

The importance of modern biotechnology was formally recognized in 1981 when the first training course on recombinant DNA technology was organized at the Nuclear Institute for Agriculture and Biology, Faisalabad. This workshop recommended the establishment of an exclusive National Centre of modern biotechnology. In 1983-84, CEMB at University of Punjab, Lahore was established, which undertook first project on gene cloning in Pakistan. CEMB is also credited for development of first GM rice crop in Pakistan. However, this crop could not be advanced further due to non-existence of biosafety regulations and export reservations at that time. In 1986, the GoP approved the establishment of NIBGE, which was formally inaugurated in 1994 at a cost of US $1.2 million. Both CEMB and NIBGE have well-developed infrastructure for modern technology according to international standards.

Modern biotechnology played crucial role when cotton crop faced the menace of *Cotton leaf curl virus* (CLCV) in 1992. The whole viral genome was sequenced. This helped in the recognition of new CLCV strains (Burewala, Shahdadpur strains) resulted as recombination of original strain (Multan strain). Sequencing studies have facilitated the understanding of the evolutionary mechanism of virus.

More than 200 life sciences departments are engaged in genomics and biotechnology research at various Pakistani universities (Haq, 2012). Pakistan has been a Science Watch rising star for several years for research papers in multiple fields, particularly in biological sciences. Publications by Pakistani research teams have increased four-folds in the last decade, and the majority of publications from major universities are in life sciences.

3.2 Capacity Development

The number of biotechnology institutes for capacity building has been grown significantly since 1990. Currently, there are more than 50 academic institutes that awards MS, MPhil and PhD degrees in the field of biotechnology. More than 20 institutes are focusing in the field of conventional and 10 on modern plant biotechnology. Six institutes are conducting work on modern animal biotechnology in the country. A reasonable number of biotechnologists pass out from local institutions and complete their higher degrees from abroad. Their skills have to be sharpened by providing employment in various national and international centers of excellence.

Research work is being done in major centers to find and isolate desirable genes for plant transformation under different projects. The year 2010 proved to be landmark in the history of Pakistan when legal approval was granted for the commercial cultivation of Bt cotton in Pakistan. The commercial release of few more GM crops and varieties (sugarcane, groundnut, cotton) is expected in the near future.

Pakistan is building the capacity of its young scientists in the legislative, regulatory, and policy areas related to AB, biosafety and nanotechnology. A small project has been funded in agricultural nanobiotechnology related to the use of nanoparticles for plant genetic engineering utilizing a Bio-Rad biolistic gene gun at NIBGE, Faisalabad.

While the universities have stepped up their research programmes in life sciences as a result of the higher education reforms undertaken in the last decade, it's still a major challenge to translate the academic work into tangible benefits in terms of improved human health and higher crop and livestock yields in the country.

3.3 Infrastructure Development

In the year 2001 and 2002, the establishment of National Biotechnology Commission (NBC) and HEC played an important role in the promotion of modern biotechnology in both of Universities and research institutes working on conventional technologies. A number of new academic (COMSATS, NUST, Fatima Jinnah University) and research institutes were set up. In the year 2007 at Federal level, NIGAB was established at NARC, Islamabad with the mandate of working on cutting edge technologies related to plant and animal biotechnology. Currently, there are 38 centres in the country working on modern biotechnology as well as more than 50 academic institutes awarding MSc, MPhil, PhD degrees in biotechnology. The infrastructure needs of the centres have sufficiently been taken care off.

3.4 Communication Strategy

The Pakistan Biotechnology Information Center (PABIC), established in June 2006, has a strategic initiative to promote communication and knowledge about biotechnology in Pakistan. It aims to produce better-informed citizens who would be able to make informed decisions about aspects of biotechnology. PABIC supports the establishment of an active network of science communicators of 27 institutes in Pakistan who gather and exchange experience and communication strategies with each other. Working groups are set up to draw up a catalogue of Best Practices, incorporating the success formulae for communication in the life sciences especially in biotechnology related research. The internet platform of PABIC contains educational materials about biotechnology-related research and links for target groups, and categorized by level of knowledge. Most of the publications and educational materials provided by International Service for the Acquisition of Agri-biotech Applications (ISAAA) (translated in Urdu version) can be downloaded from the website (ISAAA, 2018). In addition, it also contains a large virtual library with illustrative materials that can be downloaded free of charge. Pakistan publishes its newsletter "Arisen" (both in English and Urdu) in printed form, covering the biotechnological developments (Navarro, 2008).

3.5 General Awareness

Lack of awareness about biotechnology regulatory laws remained the major reason for slow development of biotechnology in Pakistan. Various interest groups, civil societies, Non-Governmental Organizations (NGOs), regulators and research experts keep on writing in the papers on the pros and cons of GMOs and biotechnology laws passed by the government. They have created various email/apps groups to have dialogue and create awareness. Apart from that, research duplications, lack of coordination among the ongoing research activities at various biotech centers, failure in targeting priority research areas, lack of industry link with biotech research are still issues being faced.

The PABIC was established at Latif Ebrahim Jamal National Science Information Center, University of Karachi under the patronage of ISAAA and National Commission on Biotechnology. The initiative of the establishment of PABIC is an attempt to initiate multidisciplinary research and enhance the awareness and appreciation of biotechnology at the local and international levels.

Pakistan has several good institutions currently working on various aspects of biotechnology. There are number of universities, which offer various degrees in this discipline. However, there is lack of appreciation of biotechnology at the public and industrial levels. Coordination and exchange of information among institution and practitioners of biotechnology is less than adequate. Therefore, there is a need of a resource center in Pakistan, which can serve as a hub to disseminate information, to support the collaborative efforts and to develop a network of institutions and individuals working in this field.

Aims and Objectives of PABIC

- To launch biotechnology-based information programmes.
- To create awareness in public sector, education sector, and industrial sector.
- To provide first time learning services using the latest learning technologies that can be emulated by educational institute.
- To disseminate information.
- To exchange ideas relevant to judicious use of biotechnological innovations.
- To educate and raise awareness about the biotechnology.
- To focus on presenting / discussing key issues affecting the industry.

3.6 Policy Advocacy

Policy advocacy is done mostly through stakeholder's meetings and seminars/conferences on various policy issues from time to time. Experts from various fields of knowledge and GOs, NGOs, Civil Society, business community representatives, scientists and policy makers sit together and reach out at a consensus for formulation as well as implementation of the policies.

4. Specific Focus on Research

The major focus of biotechnology work in Pakistan is on adaptive and applied work. The basic and strategic work is done at a very low level in some specific institutes, like NIBGE and CEMB.

5. Priority Areas of Agricultural Biotechnology

5.1 Plant Biotechnology

5.1.1 Major thrust of Biotechnology Research following areas:

- Higher productivity
- Enhanced nutritional status
- Value addition to crops as therapeutics

Within the ambits of these thrust areas, the following priority areas are being addressed:

5.1.2 Stability against Stresses

Insect pests and diseases still continue to cause heavy crop losses. Focusing on specific crops and problems, transgenic and/or marker assisted selection approaches shall be developed and used to evolve stress tolerant crop varieties.

5.1.3 Yield Enhancement

Three approaches are contemplated to raise the genetic ceiling to yield *viz*., (i) exploitation of hybrid vigor, (ii) search for and use of still unexploited, yield related gene blocks (QTLs), and (iii) engineering of biosynthetic pathways of starch, protein and oil. Whereas male sterility by anther/ pollen specific expression of toxin/ protoxin genes would be engineered to extend hybrid technology to non-hybrid crops like Brassica, marker associated gene blocks relating to yield shall be identified using QTL techniques in landraces and progenitor species of crop plants. Manipulation of key/rate-limiting enzymes in the pathways of starch *etc.* will be attempted for achieving new yield thresholds. Development of map based and marker assisted technologies for precision breeding in crop plants like rice, wheat, Brassica, chickpea, *etc.* special focus on designer crop plants that carry specifically selected genes with traits that allow them to thrive in particular environment or produce valued consumer characteristics through the application of structural/ functional genomic approaches.

5.1.4 Nutritional Quality Improvement

Exotic and indigenously identified candidate genes to be exploited to enhance the level of essential nutrients such as iron, zinc, vitamins, balanced proteins etc, in major crops correction of ant nutritional factors known to exist in specific pulse and oilseed crops. A time bound mission to be launched.

5.1.5 Edible Vaccines

Edible vaccines are required for diseases, particularly for cholera, hepatitis and rabies would be developed and tested for large scale production.

5.1.6 Genome Editing of Crops

For the speedy development of GM crops, the development of Genetically Engineered (GE) crops is much needed using the 3rd genome editing tools like CRISPR/cas-9. Huge potential exists for major crops like rice and wheat (disease resistance), cotton and sugarcane (disease and insect resistance). Capacity building programmes are in great demand for this technology.

5.1.7 Plant tissue culture

- Developing complete package for improvement of priority crops, namely potato, olive, Pistachio, banana, papaya, grapes, sugarcane, coconut, root stock of fruit trees, date palm, strawberries, ornamental plants, tea, apple, spices, and medicinal plants.
- Continued large scale production of forest tree species.
- Development and use of micropropagation for multiplication of root stocks and scions in selected varieties of fruit crops like mango and hairy root culture for production of secondary metabolites in general and those relevant to food industry.
- Promoting application of tissue culture technology at grass root level and its adoption by the end user.
- Utilization of tissue culture for enrichment of genetic diversity.

5.1.8 Biofertilizers and Biopesticides

Transgenic biofertilizers and biopesticides, particularly botanicals, some of which have already been developed in Pakistan, would be needed to be tested for commercial production.

Bioprospecting and molecular taxonomy: It is expected to complete the prospecting and molecular characterization and documentation of the economically and ecologically important hot spots of biodiversity in the country.

5.1.9 Animal Biotechnology

- Development of recombinant diagnostics and vaccines for major diseases in livestock/fish and establishment of required cell lines and their banking facilities.

- Transgenic animals can be employed either as biofactories for the production of commercial products or as living models for the study of human disease and evaluation of pharmaceuticals. The use of transgenic animals for these purposes can be more economical or in case of human disease and drug models, more realistic than are conventional alternatives.
- Techniques for cloning, both embryonic and somatic, by multiplication of elite animals.
- Development and formulation of improved animal/fish fee.
- Development of genetic markers for animal breeding programmes.

5.1.9 Aquatic Biotechnology

While considerable progress has been made in fish biotechnology in Asia, the following aspects still need to be further strengthened in Pakistan:

- Genetic improvement of cultured fish for improved growth, disease resistance and adaptability to new farming systems.
- Development of low-cost but efficient grow-out diets for cultured fishes using locally available feedstuffs and microbiological processes.
- Utilization of detailed and microbial feed sources for pond cultured fish.
- Production of vaccines and monoclonal antibodies for the prevention and control of bacterial and virus diseases.
- Development of drugs and other biotechnological products from marine organisms.
- Improved availability of mother stocks and seeds, especially of brackish water marine fish and shellfish.

6. Major Challenges and Opportunities

6.1 Challenges

Pakistan, a developing country, is facing multi-faceted challenges including energy crisis, food security, and rapid urbanization in the wake of increasing population and the more global phenomenon of climate change. By 2050, the population will grow to 355 million and already per capita land and water availability has reduced to 0.4 h. and 1000 m^3 compared to 0.7 ha and 7400 m^3 in 1947.

6.2 Opportunities

Like other countries, Pakistan also took bold step towards adoption of modern biotechnology and started to establish biotechnology centers across the country. In all key national science and technology policies, the role of biotechnology as a potential tool for the growth and socio-economic development has been well acknowledged.

7. Future Outlook

7.1 Short-term (2018-2030)

7.1.1 Fast Track Mechanism of Regulatory Processes for Biotech, Crops

Currently, the biosafety scenario of Pakistan is almost de-tracked after 18th Amendment in Constitution. It is the need of times that:

- Biosafety should be declared as Federal subject,
- The time limits specified in the National biosafety guidelines/rules for various committees must be followed strictly,
- On line and time-based web portal system for biosafety regulatory process should be introduced,

- It will be useful to work with some international groups who are working on technologies that do not fall truly under the definition of GM products e.g. Bio-engineering Consortium at Iowa State University is working on the use of genome editing tools causing genetic modifications. Such kind of genetic modification need not to follow the biosafety guidelines and thus, the time period required for commercialization of products will be reduced considerably.

7.1.2 Focused Adaptive Research on Biotechnology

- Assessment of success stories of biotech products should be carried out, keeping in view the local requirements to get the immediate benefits of biotechnology.
- There should be specified biotech institutes working on adaptive biotech research and this should be part of National Biotechnology Policy.
- Enactment of Plant Breeder Rights Law, which will also encourage the multinationals to introduce the success stories in the country.

7.1.3 Formulation of National Biotechnology Policy Prioritizing Crops and Traits, Avoiding Duplication of Research

- NBC should be re-instated
- National dialogue may be initiated for trait/crop prioritization
- National annual biotechnology planning should be conducted

7.1.4 Development of Public-Private Partnerships Based on Biotechnology Interventions

Biotechnology is also a main contributor to Small and Medium Enterprise development by encouraging establishment of Start Up companies. Such an activity can be facilitated by active participation of the government by providing financial support for such companies because of the absence of Venture Capitalists. In order to achieve this, it is suggested that a Venture Capital Fund be established with a contribution from the Government, represented by Ministries such as Ministry of National Food Security and Research and Ministry of Science and Technology, and the private sector, represented by the federal and provincial Chambers of Commerce and Industry. Such a fund would go a long way in commercialization of biotechnology.

7.2 Medium-term (2018-2040)

- Improving nutritional quality of fruit and vegetable like Innate® potato in USA
- Innovative pest control strategies such as RNAi silencing of target genes, sterile insect technology
- Indigenous research and development on new generation technologies (3rd, 4thand further)
- Development of efficient Enzyme Linked Immunosorbent Assay (ELISA) and Polymerase Chain Reaction (PCR) based diagnostic kits for plant diseases
- Artificial insemination has been used widely in cattle, buffaloes and some species of poultry, but to a limited extent in countries for, pigs, sheep, and horses. For that matter, embryo transfer currently has only very limited use in all species. Recently, there have been significant advances in the *In Vitro* Fertilization (IVF) process (especially in cattle), *in vivo* and co-culturing of embryos. Sexing has been done through karyotyping and Y chromosome specific DNA based probes. Embryonic or fetal stem cell has been used in research and therapeutic purposes.
- Genetic improvement of animal breeds through gene assisted selection to improve breeding strategies and development of improved DNA based disease diagnosis, vaccines and therapeutics are the major research areas in biotechnology. Development of PCR, ELISA based diagnostic kits and recombinant vaccine developments are key target areas in present scenario.
- In view of potential applications of nanoscale materials in biotechnology, over 50% of total global funding in the field of nanotechnology is now being directed to explore their applications in biotechnology, *i.e.*, a field generally known as nano-biotechnology. New undergraduate/graduate

degrees and courses are now being introduced worldwide in Nano-biotechnology. Our neighboring countries, like China, India and Iran, have already invested in this technology quite heavily and thus there is a dire need for investment in this emerging technology by appropriate training of manpower and developing institutions with a major focus on nanoscience and technology. In this regard, it is suggested that in Pakistan a National Agricultural Nano-biotechnology institute shall be established.

Keeping in view the importance of biotechnology, following shortcomings should be addressed.

- Human resource development (Technical and scientific staff)
- International trainings (Stem cell culturing, 3D culture, IVF, transgenic animal production, nano-biotechnology *etc.*)
- International collaboration with institutes of high repute
- Provision of Hi-Tech equipment (IVF workstation, laparoscope, stereo-microscope, low pressure sterilizer, dry ice machine)

The above-mentioned areas may be made as part of National Biotech Policy with increased funding on sustainable basis.

7.3 Long-term (2018-2050)

7.3.1 Development of Animal Stem Cell Bank

There is a need to establish a laboratory that will carry out the processing and have storage facilities of canine stem cells with complete standard operating procedures for tissue processing, cell growth and expansion.

All research and development activities will be conducted under sterile conditions, utilizing universal standard techniques and precautions to minimize risk of contamination, infection or pathogen transmission.

Specific cell assays, characterization processes and procedures to assess potential toxicity and consistently assure safety, purity, and potency will be carried out to get a stable finished stem cell product or stem cell derivative.

Since Pakistan is extremely lacking in animal cell culture expertise, active collaboration and joint venture with international organizations such as Animal Cell Therapies Inc, San Diego, CA is strongly suggested.

7.3.2 Development of National Genome Sequence Database on Pattern of NCBI

High quality equipment and manpower are required for the establishment of genetic database in Pakistan.

8. Conclusions

Agriculture plays an important role in the national economy of Pakistan. Adoption of biotechnology, especially in agriculture and livestock sectors is essentially needed to fulfil the food and nutritional requirements of ever increasing population.

Pakistan started working on modern biotechnology in the mid of 1980s. Currently, there are more than 50 biotech centers/institutes in the country. However, very few centers have appropriate physical facilities and well trained manpower to develop GM crops. Most of the activities are focused on cotton among the major crops of Pakistan. Biotic (virus/bacterial/insect) and abiotic (salt, drought, cold) resistant genes have already been incorporated in some crop plants.

Concerted and coordinated efforts based on biotechnology are being undertaken for improvement in the livestock sector as well. Thirty-one Bt cotton varieties and three GM events have been approved for commercial cultivation so far. A number of GM events in other crops are waiting for their commercial release. Regarding livestock sector, Almost 95% of the vaccines for large animals are produced locally in public sector institutes and only Foot and Mouth Disease (FMD) vaccine is currently imported. However, the coverage of these vaccines is fairly low. The FMD of cattle is causing heavy losses every year. Domestic poultry is also not fully vaccinated, however, all commercial poultry farms are 100 per cent vaccinated against the viral diseases.

The future pathways of biotechnology in Pakistan in the context of vision-2050 can be grouped in three categories as short-, medium- and long- term strategies, respectively. Fast track mechanism of regulatory processes for Biotech, crops on Brazil Model, enactment of Plant Breeder Rights Law, indigenous research and development on new generation technologies, adoption of adaptive research, formulation of national biotechnology policy, exploration of new technologies such as nano-biotechnology, innovative pest control strategies, embryo transfer, *in-vitro* fertilization, sexing, cloning, and transgenesis, development of public-private partnerships based on biotechnology interventions and development of National Genomic Database are the suggested future working areas on biotechnology in Pakistan.

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Country Status Report-Lao PDR

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1. Introduction

Agriculture is one of the most important economic sectors of Lao PDR and plays an important role in helping rehabilitating and stabilizing the national economy. Biotechnological tools contribute to increased food production through enhanced plant breeding activities, advanced research in livestock production *etc.* Therefore, it is mandatory to have strong research targets in place and is recommended to have an in-depth analysis on the role of biotechnology in crop production and other allied fields, before deciding on investments in this area. Information on the existing policies that govern the biotechnological research and biosafety issues, budgetary provisions, priority areas for research, challenges and opportunities, funding mechanism *etc.* in the country are reviewed and presented in following sections.

Table 1. Basic Information

Indicator	Details
Value of GDP (Trillion LAK) LAK=Lao Kip	140.75*
Value of GDP (Billion USD)	16.85**
Value of agriculture GDP (Billion LAK)	~ 28.64
Value of agriculture GDP (Million USD+)	3.47
Agriculture GDP as per cent of GDP	16.2***
Total investment in agricultural research (Billion LAK)	~ 119
Total investment in agricultural research in USD (Million USD+)	~ 14.4
Total investment in agricultural biotechnology research in local currency (Billion LAK)	~ 28.29
Total investment in agricultural biotechnology research in USD (Million USD+)	~ 3.42

*Source: World Bank (*2017; **2017a; ***2017b); +1USD=8262.28LAK*

2. National Policies

2.1 Current National Policies on Agricultural Biotechnology and Policies for Enhancing the Livelihood of Farmers through Agricultural Biotechnology

Dr Chay Bounphanousay is Deputy Director General of NAFRI, Lao PDR. He served in various capacities that include, Senior Research Assistant (rice), Associate Coordinator (biodiversity and on farm conservation), Project Leader (rice improvement, regeneration and safety duplication), Coordinatior (mechanization and value adding for diversification of Lowland cropping system and national seed multiplication), Director, Agricultural Research Center and Director, Rice Research Programme. Dr Chay has rich experience of coordinating with several international agencies such as IRRI, JIRCAS and Kasetsart University, Thailand and Global Crop Diversity Trust (GCDT).

2.1.1 Convention on Biological Diversity (CBD), 1996

The Government of Lao PDR acceded to the CBD on Sept. 20, 1996 and completed its National Strategy on Environment to the year 2020 and Action Plan.

2.1.2 Cartagena Protocol on Biosafety (CPB), 2004

CPB was accepted by the Laos government on Nov. 1, 2004. The objective of CPB is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of Living Modified Organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements (LANBF, 2004).

2.1.3 UNEP/GEF National Biosafety Framework (NBF) Development Project, 2004

Lao PDR participated in the UNEP/GEF National Biosafety Framework (NBF) Development project and completed it successfully in December 2004. The NBF was responsible for preparation of biosafety regulations (LANBF, 2004).

2.1.4 Biosafety Law, 2014

A draft Biosafety Law was considered initially at the Lao government meeting on Aug. 30, 2005. The Law was adopted in the 6th Ordinary Session at the 7th National Assembly Congress on Dec. 18, 2013 and promulgated by the President of the Lao People's Democratic Republic on Jan. 28, 2014. Biosafety Law consists of 10 parts and 78 articles and Article 1 deals with the major objectives. This Law determines the principles, regulations and measures on management and monitoring of biotechnology safety in research, development, handling, movement, and the use of Genetically Modified Organisms (GMOs). It also monitors the negative impacts of GMOs on conservation and sustainable use of biodiversity, with a focus on the limitation and reduction of risks to the life and health of human beings, animals, plants and the environment that can be linked at the regional and international levels, and which contribute to the national socio-economic development (LANBF, 2004). Some important articles under the law include:

- **Article 13:** Biotechnological research and development. Promoted for the conservation and sustainable use of genetic resources within priority areas (Genetic Resources; Biotechnology in Agriculture and Forestry; Health; Industrial Processing; Environment) that hold potential for socio-economic development.
- **Article 14:** Biotechnology in Genetic Resources. Priority areas of research and development (R&D) include identification and establishment of a genetic database; *In situ* and *Ex situ* conservation of genetic resources.
- **Article 15:** Biotechnology in agriculture and forestry
- **Article 16:** Biotechnology in health
- **Article 17:** Biotechnology in the processing industry
- **Article 18:** Biotechnology in the environment
- **Article 21:** Biotechnology patents
- **Article 54:** Committee for Biotechnology Safety Administration
- **Article 55:** Location and functions of the National Committee for Biotechnology Safety

The country is also in the process of drafting sub-regulations which will support the implementation of Biosafety Law including environmental release, food and feed (labeling) and contained use.

2.1.5 Agriculture Development Strategy (ADS) 2025

The Ministry of Agriculture and Forestry has developed the Agriculture Development Strategy 2025, and a 'Vision up to 2030', aiming to achieve a number of prominent goals. These include: food and nutrition security, contributing to the SDGs with zero hunger by 2025, suitably commercialized production systems, protection of rural livelihoods and poverty alleviation, and sustainable forest utilization and conservation (MAF, 2015).

2.1.6 Agriculture and Forestry Research Strategy (AFRS) 2025

The AFRS is an instrument of Ministry of Agriculture and Forestry for agriculture and forestry development and for achieving its development goals as outlined in the Agriculture Development Strategy (ADS 2025). The strategic goal of AFRS is to define and articulate how NAFRI intends to carry out research for development and to contribute to achieving the goals of the ADS 2025. Specifically, for food and nutrition security, poverty alleviation through the effective and efficient use of scientific knowledge and research results, increasing sustainable agriculture productivity and sustainable natural resources management. The mission of NAFRI is to provide institutional, human, and scientific resources to the government and to a wider spectrum of stakeholders and development partners, donors, and the private sector for carrying out systematic research for development (NAFRI, 2015).

2.2 Implementation of Policies

2.2.1 Government Bodies Responsible for Implementing Each Policy

(i) Lao National Biosafety Frameworks (LANBF)

LANBF defines responsibilities of implementation of policies. Regulations to implement Biosafety Law includes three frameworks: (1) Framework of Prime Minister's Decree to implement Biosafety Law; (2) Framework of Minister's Decree to implement Biosafety Law; and (3) Framework of Guidelines and Manuals to implement Biosafety Law (LANBF, 2004).

Although responsibilities of implementation of policies are assigned in the National Biosafety Framework, actual implementation is at initial stages. National Biosafety Committee (NBC) authorities and functions and responsibilities to laboratory research are well defined and included in the LANBF. Institutional Biosafety Committee (IBC) consists of institutions and organizations, state or private, engaged, or with the intent to engage, in the purchase, construction, propagation or field release of GMOs or components must each arrange for the establishment of an IBC to serve as the administrative board on matters of biosafety and on compliance with Biosafety Guidelines. Institutions and organizations involved in genetic manipulation work should appoint a Biological Safety Officer (BSO) to the IBC. Alternatively, institutions affiliated with an IBC yet without the services of a BSO may opt to transfer the responsibility of securing a biosafety officer over to the committee. For larger institutions contracting the services of multiple BSOs, the NBC requires that one representative shall be designated and shall serve as the NBC contact or relations officer. BSOs on leave of absence must arrange for competent replacement to take up the forsaken responsibilities. The project supervisor or head researcher should possess requisite thorough understanding of the codes, regulations and laws applicable to genetic engineering and biotechnological work and exhibit an appreciation for the biosafety concerns that underlie the need for such provisions.

(ii) Management and Monitoring National Authorities on Biosafety

The Science Technology and Environment Agency (STEA) is the management and monitoring organization on biotechnology and biosafety at the central level.

(iii) Management and Monitoring Unit at the Ministerial Level

Ministry is required to establish its management and monitoring organization on biotechnology and biosafety unit along with the STEA.

(iv) Management and Monitoring Unit at the Provincial, Municipal, City and Special Zone Level

Provinces, municipality, city and special zone shall establish their own management and monitoring on biotechnology and biosafety units in cooperation with the STEA.

(v) Management and Monitoring Unit at the District and Prefecture Level

District and prefecture shall establish own management and monitoring units on biotechnology and biosafety in cooperation with management and monitoring units at the provincial, municipal, city and special zone level in which they are located.

2.3 Capacity Development

At present, there are very limited number of biotechnology researchers. There is a need for more number of biotechnologists and other staff to meet the requirements of short-, medium- and long-term goals. In addition, there is a need to strengthen the capacities of the existing staff, including laboratory technicians by imparting training (national/international).

2.4 Partnership

Exisiting partnership is with International Rice Research Institute (IRRI), Philippines, Khon Kaen University, Thailand and Tsukuba University, Japan. There is a need to assess Lao PDR's agricultural priorities in the context of using biotechnology to enhance national food and nutritional security. Based on the assessment study, new partnerships need to be identified.

2.5 Funding Mechanism

The Government of Lao PDR has expressed through different policy documents that conservation and utilization of genetic diversity is highly important to improve food security, alleviate poverty, and promote rural development. Some budget allocation for biotechnology research is done from the international projects. For example, in 2007, FAO with the support from the FAO Netherlands Partnership Programme and in collaboration with NAFRI, carried out a plant breeding and associated biotechnological survey in the country. Results of the survey indicated the urgent need for development of a national strategy for short- and medium-term human capacity building; increased allocation of resources for plant genetic resources (PGR) utilization, increased international support to enhance the local breeding programmes by using modern biotechnological tools (FNPP, 2007).

Collaboration between Lao PDR and IRRI started in 1987 and intensified, when the Swiss Agency for Development and Cooperation supported the Lao PDR-IRRI Research and Training Project from 1990 to 2007. The project sought to improve and strengthen the country's rice research capacity and included research support, development, and training. IRRI's work in Lao PDR is currently supported by the International Fund for Agricultural Development, the Bill & Melinda Gates Foundation, the Australian Centre for International Agricultural Research, and the Government of Japan (IRRI, 2016). Further funding mechanisms needs to be worked out based on the assessment study.

3. National and Institutional Strategies

It is mandatory to have strong plant breeding programmes in place and clear goals to be achieved through the application of biotechnologies before start considering the different tools. It is recommended to have an in-depth analysis before deciding on investments in this area. Some alternatives to achieve this are to ensure that any investment made in biotechnology is done in the context of an existing breeding programme and targeting at solving specific problems. This can be achieved by; (i) consulting other countries in the region to learn about their experience in this area and transfer them to Lao PDR as appropriated; (ii) requesting international support to clearly understand the role biotechnology can play to enhance the local breeding programmes; (iii) upgrade the facilities of the current biotechnology laboratories, which are only doing tissue culture work for multiplication, to have them supporting breeding activities (FNPP, 2007).

3.1 National Strategies for Research & Development

Science and technology is promoted to meet demands of agricultural productivity and quality that highlights the strategic areas as following:

- Promote clear and organic agriculture in each local area in order to meet the domestic market demand and export
- Promote production along with marketing and processing

- Turn the population's natural livestock production to farming using scientific techniques of modern technology to uplift the productivity
- Upgrade the existing agriculture promotion and development centers to become comprehensive centers to be capable of demonstrate techniques of agricultural production, grain/seed production to farmers.

3.2 Capacity Development

The Government of Lao PDR, in the past few years, has taken the following steps to enhance the capacity development.

(i) Allocation of funds for R&D activities in 2011-12

(ii) Approved Science and Technology Law in 2013, which indicates 1 per cent of domestic investment to be used for R&D activities

(iii) Establishment of "The Science and Technology Fund" in 2014

As part of capacity building under the Lao-UNEP-GEF INBF project activities, the following two trainings were conducted.

- Trainings on GMO risk assessment and risk management (June 16-27, 2014)
- Hands-on training on detection of LMOs (Quality Assurance and GMO Analysis Using Real-Time PCR) (July 7-18, 2014)

The objective of capacity building programme to implement Cartagena Protocol on Biosafety is to identify specific need of Lao PDR in the following items (LANBF, 2004):

- Institutional capacity building
- Human resources development and training
- Risk assessment and other scientific and technical expertise
- Risk management
- Public awareness, education and participation
- Information exchange and data management
- Scientific, technical and institutional collaboration
- Technology transfer
- Identification of LMOs

3.3 Infrastructure Development

The Ministry of Science and Technology (MOST) is the technical organization, established by Prime Minister Decree number 309 PM dated Sept. 28, 2011, that determines the government administration at the central level, and has the roles as a secretary for the state in developing and macro-administering for the concerning works on science, technology, intellectual property *etc.* throughout the country.

The Biotechnology and Ecology Institute, was established by The Ministry of Science and Technology (MOST) Minister Order number 0036 MOST dated Jan. 18, 2013, which determines the principles concerning the location, functions, duties, scope of rights, organizational structures, principle and operational working approaches of the MOST in order to be a reference in implementing and performing the political movements of their own in order to implement the policies and guidelines of a party and a state; plans, programmes and projects concerning MOST roles on biotechnology and ecology throughout the country (MOST, 2015).

Molecular laboratory facilities for the detection of GMOs was established in July 2014.

3.4 Communication Strategy

Chapter IV of LANBF explains the communication strategy broad. However, specific strategies need to be developed based on priorities and projects in operation.

3.5 General Awareness

(i) **Lao Biosafety Clearing-House :** Established by Article 20 of Cartagena Biosafety Protocol in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs.

(ii) **Mechanisms for Public Education Awareness and Participation (PEAP) :** The public should have biosafety knowledge and skills, to know how to use of living modified organisms and their products in daily life, actively participate and contribute to the conservation and sustainable use genetic resources, taking also into account risks to human health. Conducting dissemination meetings, campaigning, lectures and publishing of information in the mass media, namely newspapers, magazines, radio, television broadcasts and others to raise awareness.

To further raise general awareness, Lao PDR should focus on five areas (LANBF, 2004):

(i) Incorporate biosafety education activities at all levels of general education (formal and non-formal education) as part of environment education curriculum.

(ii) Develop the biosafety awareness activities as part of environment awareness system.

(iii) Develop the biosafety training mechanism.

(iv) Develop the biosafety public participation mechanism in decision making.

(v) Create the biosafety network and to develop the biosafety information provision mechanism.

3.6 Policy Advocacy

The congruent establishment of the 'Policy Think Tank' at NAFRI will play an important role for policy studies and advocacy.

4. Specific Focus on Research

Explore biotechnological interventions to improve rice quality with special reference to grain, cooking, eating and fragrance through marker assisted selection (MAS) and breeding. Conservation of endangered species using biotechnological tools also needs to be focused.

5. Priority Areas of Agricultural Biotechnology

5.1 Application of Biotechnological Innovations/Tools in Different Sectors/ Areas of Agriculture, Including Bioprospecting, Conservation and Sustainable Use of Bioresources

- Application of biotechnological tool for germplasm evaluation, utilization and improvement.
- Lao PDR has recently initiated two biotechnology laboratories on tissue culture located at Rice Research Centre, NAFRI (1998) and STEA (1999). These laboratories concentrate their activities on tissue culture to produce banana, potato, and some flowering plants.

5.2 Priority Areas in Plant, Animal, Aquatic Biotechnology for Low- and High-Tech Biotechnology

The potential areas for these laboratories to work in association with the plant breeding programmes are:

- The challenge Lao PDR breeders are facing today is to improve rice grain quality, mainly cooking and eating quality (softness and aroma). The country has a large number of glutinous rice cultivars with different fragrances. Rice breeding programme by using MAS is important to achieve the target
- Tissue culture to grow genetically pure plants from the improved varieties
- Rapid propagation to produce large number of plants in a short period of time
- Conservation of endangered species by reproducing many plants in safe laboratory conditions, from limited original samples
- Improvement in quality by selecting strains that have particular characteristics.

Externally the above institutes have been working with the Asian subcommittee on biotechnology and the Lao/China Committee on Science, Technology and Development Cooperation.

6. Major Challenges

- Lack of dedicated budget (chemical, reference materials, equipment, trainings and others)
- Limited human resources (knowledgeable persons, risk concern, policy support and others)
- Weak coordination mechanism and information sharing among stakeholders
- Lack of expertise

7. Future Outlook

Future research priorities will help creating and scaling up appropriate and effective technologies that contribute to food and nutrition security, poverty reduction, local value addition, suitable market promotion, and environmental sustainability.

- Strengthening capacities for laboratory staff and risk assessors (concerned stakeholders)
- Integrated implementation of the biotechnology safety on national biosafety activities (*e.g.* National Biodiversity Centre, National Biosafety Regulation - Health, National Biodiversity Strategy and Action Plan (NBSAP) - Environment, National Agricultural Biodiversity Programme-Agriculture, Chemical, Biological, Radiological and Nuclear (CBRN) National Action Plan)
- Development of technical guidelines and manuals for safety of GMOs (release to the environment, contained use and food-feed)
- Raising awareness campaign for the public and concerned stakeholders

In order to deliver the desired results, NAFRI's research areas are grouped into the following six broad thematic areas or strategic research programmes guiding future practice-oriented interventions:

- Sustainable agro-biodiversity programme
- Improved agriculture productivity programme
- Agriculture adaptation to climate change programme
- Agriculture and forestry policy research programme
- Capacity building programme
- Information and Communication programme

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Country Status Report – Malaysia

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1. Introduction

Malaysia, being the world leader in the production of several industrial crops, like oil palm, rubber, cocoa, pepper and tropical timber, coupled with its rich biodiversity and strong information and communication technology (ICT) infrastructure, is driving forward in its goal of biotechnology to improve the nation's food security and economic growth. Key research areas for the agriculture sector in the country are agricultural genomics, tissue culture technology, livestock farming, animal health and nutrition, biopesticides and biofertilizers, extraction of metabolites and nutritionally enhanced agriculture products *etc.* The present report covers the information on the national biotechnology research programme, existing policies that regulate the research on agricultural biotechnology (AB), their implementation strategies, challenges and opportunities.

Table 1. Basic Information

Indicator	Details
Value of GDP (Billion MYR) MYR= Malaysian Ringgit	1352*
Value of GDP (Billion USD)	314.50**
Value of agriculture GDP (Billion MYR)	118.71 @
Value of agriculture GDP (Billion USD+)	27.61 @
Agriculture GDP as percentage of GDP	8.78***
Total investment in agricultural research (Million MYR)	~ 151.80
Total investment in agricultural research (Million USD+)	~ 37.38
Total investment in AB research (Million MYR)	~ 3.30
Total investment in AB research (Million USD+)	~ 0.81

*Source: *World Bank (*2017; **2017a; ***2017b); @8.78% ofvalue of GDP; + 1USD=4.06 MYR*

2. National Policies

2.1 Current National Policies on Agricultural Biotechnology and Policies for Enhancing the Livelihood of Farmers through Agricultural Biotechnology

Dr Mohammad Roff Mohd. Noor is Director General, MARDI, Malaysia. He obtained his PhD in Plant Virology from University of Reading, UK. He is a member of Pesticide Board, PBBM Global Cooperation Board, Animal Feed Board, National Committee on Economic Pests, Evaluation Panel, Research, development and commercialization funding for Agriculture Sector and Scientific Committee and South East Asia Vegetable Conference (SEAVEG) for three consecutive terms. He is responsible for all regulatory matters related to ionizing radiation with the Atomic Energy Licensing Act. Dr Noor is also Chairman, Safety Committee in MARDI and is on Editorial Board, Asia-Pacific Journal of Entomology.

In 2005, the government developed a number of policies, regulations, programmes and initiatives that are aimed to support the biotechnology and bioeconomy development to invigorate Malaysia's economic sector. The AB sector development focuses on technologies, such as genetic engineering, genomics, proteomics and biopharming and transgenic plants and livestock.

2.1.1 National Biotechnology Policy (NBP), 2005

The strongest boost for the biotechnology sector in the country was the launch of the NBP in 2005. The main aim of NBP is to develop biotechnology sector into one of the key economic drivers for the nation, contributing 5 per cent of the nation's GDP by 2020. NBP was designed to provide a comprehensive roadmap that would foster a conducive ecosystem for accelerated growth in the biotechnology industry.

The objective of the policy is to further develop three economic sectors, namely, agriculture, healthcare and industrial manufacturing, as well as support the growth of an enabling ecosystem such as research and development (R&D) and technology acquisition; human capital development; financial infrastructure development; legislative and regulatory framework development; strategic positioning; and government commitments.

2.1.2 Biosafety Act (Established in 2007 and enforced in 2009)

Malaysia currently does not grow biotech or GM crops but it imports GM grains for the use as feed in the poultry and livestock industry. The country also has a number of research projects at public institutes that aim to develop biotech crops such as disease resistant banana, rice, rubber, oil palm, papaya, teak, pineapple, chilli, and orchid. For all these purposes, a legal instrument that regulates LMOs is important. Malaysia is also a signatory to the Cartagena Protocol on Biosafety that requires Parties to have a national legislation framework in place. The Biosafety Law was established in 2007 and came into force in 2009. It's aim is to establish the National Biosafety Board to regulate the release, importation, exportation and contained use of LMOs, and the release of products of organisms, with the objectives of protecting human, plant and animal health, the environment and biological diversity (Laws of Malaysia, Biosafety Act, 2007).

2.1.3 Bioeconomy Transformation Programme (BTP) under the 10th Malaysian Plan, 2012

To complement the NBP, the BTP was launched in 2012 to further accelerate the country's bioeconomy development. Malaysia's bioeconomy agenda is spearheaded by the Ministry of Science, Technology and Innovation (MOSTI). The Programme's core strategies focus on the complete value chain approach to increase multiplier effects for a sustainable economy and create a positive impact on the income and welfare of the people. The BTP is expected to be one of the strategies to transform Malaysia into a high-income nation with activities focusing on agriculture productivity, discoveries in healthcare and the adoption of sustainable industrial processes. BTP targets to secure MYR 48 billion (USD 10.9 billion) of Gross National Income (GNI), create 170,000 new job opportunities and capture an investment of MYR 50 billion (USD 11.4 billion) by the year 2020.

2.2 Implementation of Policies

To achieve the goals of the biotechnology policy, the programmes and activities that are implemented can be divided into two major activities: (i) Research, development and commercialization (R,D&C) and (ii) Industry development services.

2.2.1 Government Bodies Responsible for Implementation

(i) **Ministry of Agriculture and Agro-based Industries (MOA) :** The Malaysian Agricultural Research and Development Institute (MARDI) is involved in livestock, crop biotechnology, horticulture, food technology, genomics, and bioinformatics. Research on rubber, palm oil, cocoa, pepper is conducted by Malaysian Rubber Board, Malaysian Palm Oil Board, Malaysian Cocoa Board and Malaysian Pepper Board, respectively.

(ii) **Ministry of Science, Technology and Innovation (MOSTI) :** There are over 20 agencies and research institutes under MOSTI that deal with biotechnology. The National Institute of Biotechnology Malaysia (NIBM) was inaugurated to lead, coordinate and implement the national biotechnology agenda through research, development, innovation and commercialization activities. There are three institutes under NIBM, namely, Agro-Biotechnology Institute (ABI), Malaysia, Malaysia Institute of Pharmaceuticals and Nutraceuticals (IPHARM) and Malaysia Genome Institute. However, implementation of policies related to AB in MOSTI is carried out by ABI. Some of the other agencies are Malaysian Bioeconomy Corporation, Nuclear Agency, Nano Malaysia, Standard and Industrial Research Institute of Malaysia, Standards Malaysia, Malaysian Technology Development Corporation (MTDC), Malaysian Debt Ventures (MDV) and Technology Park Malaysia (TPM). These institutes and agencies undertake a wide range of activities such as R&D, commercialization, facilitation of biobusiness, project financing, development of industry standards, and provide incubation services related to biotechnology among others.

(iii) **Ministry of Natural Resources and Environment (MNRE):** Forest Research Institute Malaysia is dedicated to research on forestry biotechnology, forest and environment, forest products, forest biodiversity, and natural products.

(iv) **Ministry of Higher Education (MoHE):** There are about 44 universities that offer biobased degree programmes ranging from basic sciences in related to biology to biotechnology, biomedical science, food technology, bioprocess engineering, biochemical engineering, molecular biology, agriculture technology and marine biology among others. These universities also carry out research in these areas (Khairul *et al.*, 2011).

(v) **The Malaysian Biotechnology Corporation (MBC):** Is meant for industrial development services is now renamed as Bioeconomy Corporation. MBC was established to serve as a one-stop agency to facilitate the biotech companies, implement government policies and initiatives, encourage R,D&C of biotech products. It performs its services through the BioNexus Programme. BioNexus status is granted to companies that are involved in the biotechnology businesses and once granted the BioNexus status, they can receive incentives such as tax exemptions, funding, human capital development and product registration/testing assistance, and location advisory, as well as access to expertise in the BiotechCorp network. The number of BioNexus status companies had grown rapidly from about 50 in early 2008 to more than 286 companies by 2017.

(vi) **Technology Park Malaysia (TPM):** TPM is another programme in which technology-based companies, including those in biotechnology are clustered together geographically within the park. The TPM includes incubator and an enterprise complex, which houses technology-based companies, including biotechnology businesses. TPM supports the development of biotechnology products and its subsidiary, TPM Biotech, provides research and production facilities as well as marketing services for biotechnology companies.

(vii) **The Malaysian Industrial Development Authority (MIDA):** MIDA is an agency under the Ministry of International Trade and Industry, is tasked to directly promote the biotechnology policy initiatives as well as incentives offered under the policy's BioNexus Programme at the international level. This promotion is carried out in collaboration with Biotech Corp with the intention of persuading foreign companies to set up their biotechnology businesses in the country (Khairul *et al.*, 2011).

2.2.2 Effectiveness of the Policy

To date, the biotechnology policy contributed an estimated MYR 20 billion to national revenue and MYR 29.1 billion to investments. There is an increase in the number of jobs in the biobased industry by 54,776 in the first phase and 84,000 in the second phase, for a total of 138,776 jobs created. The initiatives by the government and the biotechnology policy have enabled an influx of Foreign Direct Investments in the local biotechnology sector where its value stands at MYR 11.6 billion in 2015. Most of these investments are from the United States, the United Kingdom, Australia, Belgium, Singapore, Taiwan, India, Belgium, Holland, Germany, Denmark, South Korea, Japan, and France. As of Dec 2015, under the BTP there were 48 trigger projects that have taken off and contributed MYR 5.97 billion (USD 1.4 billion) to the GNI, created 23,355 job opportunities, and MYR 18.21 billion (USD 4.1 billion) in terms of investment.

However, the challenge is still huge to become a significant global player and to achieve its targets in 2020. Although Malaysia has all the right policies and initiatives in place but its implementation is slow. In the excitement of developing biotechnology, there is a rush by biotech companies to grab the incentives provided by the government without having a deep understanding of biotechnology and the skills required to carry out bio businesses. There is also a need for further enhancement of the public-private sector collaboration to ensure not only commercialization of biotech products but also efficient transfer of technologies from the public institutes to the stakeholders including farmers.

2.3 Capacity Development

Malaysia's current National Education Policy emphasizes on science and technology in the country's 37 institutions of higher learning. To date, there are 31 universities offering biotechnology programmes with about 3,000 undergraduates studying biotechnology annually. The number is predicted to increase due to high interest among Malaysians to pursue careers in the biotech field. Approximately 23,000 research personnel and more than 5,000 R&D scientists and skilled workforce are expected to be available in the next two years.

Bioeconomy Academy under the Bioeconomy Corporation/Bioeconomy Malaysia plays a vital role in this area. Bioentrepreneurship is also encouraged among graduates to create their own job and to become a job creator. Trainings are conducted by the MTDC and other agencies and universities and positive outcome has been seen through these efforts.

2.4 Partnership

The MBC also organizes the BioNexus Partners (BNP), which is a one-stop access to a network of key facilities, expertise, training and biobased services to support your R,D& C needs. These laboratories are available within Malaysia's renowned institutes of higher learning (13), research institutes (3) and government-linked companies (GLCs, 3). The BNP laboratories have various international and local accreditation including ISO 17025, Good Laboratory Practice (GLP), Association for Assessment and Accreditation of Laboratory Animal Care International, Hazard Analysis Critical Control Point and Good Manufacturing Practice (GMP) ensuring reliability and credibility of data and results generated.

Malaysia is also conducive for foreign companies to expand their biotech business as the cost of operation is competitive and the government offers a wide range of incentives. There are currently a number of companies that have their businesses in Malaysia such as Biocon from India, Verdezyne and Glycos from the USA, Arkema and Metabolic Explorer from France, CJ Bio from Korea, Mitsui from Japan and AJ Pharma from Saudi Arabia.

2.5 Funding Mechanism

There are several ways to fund biotechnology research and its commercialization in Malaysia. Most of the funds are derived from governmental source. Some of the main funding bodies are as follows:

2.5.1 Funds from Government

A comprehensive funding structure and financial incentives to the tune of MYR 2 billion have been allocated under the Ninth Malaysia Plan for R, D&C, strategic technology acquisition, business and entrepreneurship development as well as building of the requisite infrastructure. The funding for R&D in biotechnology is currently provided under existing sources such as the e-Science/smart funds, research funds and the MTDC's R&D commercialization schemes and TechnoFund. The MOSTI, MoHE and MOA are the major fund providers. MDV, a subsidiary of Ministry of Finance (MOF), also has an important role in the development of biotechnology companies, as it offers financing to companies that have received and are in the process of fulfilling their customers' product orders.

2.5.2 Venture Capital

MTDC is a venture capital firm specializing in incubation, seed, start-up, and early stage financing. It was initially established by the government to spearhead the development of technology businesses in Malaysia. Its initial role was to concentrate on the promotion and commercialisation of local research and invest in new ventures that can bring in new technologies from abroad. Under the 10th Malaysia Plan, the role of MTDC had been expanded to create an effective ecosystem for commercialisation of homegrown technologies - to groom a new generation of technopreneurs through comprehensive nurturing services that support them all the way from laboratory ideas to full commercialisation. There are five types of grants available, namely Commercialization of Research & Development Fund, Technology Acquisition Fund, Business Growth Fund (BGF), Business Start-up Fund (BSF), and Business Expansion Fund (BEF).

2.5.3 Cradle Fund

Cradle fund manages the preceding grant that supports commercialization of innovative ideas including those in biotechnology. These grants include U-CIP, which is targeted towards academic community (lecturers, students or researchers) interested in commercializing their technology ideas and R&D, and CIP500 Grant, which helps entrepreneurs to move from seed phase to technology commercialization phase. Through its 13-year history, Cradle has helped fund over 700 Malaysian tech start-ups and holds the highest commercialisation rate amongst government grants in the country.

Other funding body includes grants from MIDA, Malaysia External Trade Development Corporation, Majlis Amanah Rakyat, MIMOS Berhad, Small and Medium Industries Development Corporation and loans from banks such as Agrobank, Bank Kerjasama Rakyat Malaysia Berhad (Khairul *et al*., 2011).

3. National and Institutional Strategies

3.1 National Strategies for Research and Development

3.1.1 Strengthening Knowledge Base

- Develop, acquire specialised skills needed to narrow the research gaps and to drive biotechnology
- Building the nation's human capital through biotechnology education, training and research activities
- Promoting basic research in biotechnology with perceived significant potential impact on future
- Establish strong biotech research teams
- Increase emphasis on research training of young scientists in internationally competitive environments
- Strengthen international networking
- Foster R&D links between institutions of higher learning and private sector
- Align biotech R&D to national growth objectives

3.1.2 Enhancing Agricultural Growth

- Transforming and enhancing value creation in the agricultural sector
- Increase downstream activities on high value-added products
- Capitalizing on the strengths of biodiversity to commercialize discoveries in health-related products
- Nurturing growth opportunities in industrial bioprocessing and biomanufacturing

3.1.3 Enhancing Sustainability

- Embrace green technology
- Utilizing biotechnology in various ways to reduce or mitigate carbon emission

3.1.4 Supporting Services

- Provide the right financial support *via* competitive lab to market funding and incentives to encourage committed participation from academia and the private sector, including GLCs.
- Create an enabling environment with supportive institutional, regulatory and financial framework to facilitate the buildup of a strong and diversified biotechnology industry.
- Establish R&D centers of excellence and accelerate technology development, diffusion and commercialization.

3.2 Capacity Development

Key strategy is to execute the policy over three phases: (i) Phase I, 2005-2010 for capacity building; (ii) Phase II, 2011-2015, transforming science to business; and (iii) Phase III, 2016-2020, ensuring global presence.

3.2.1 Phase I, 2005-2010 (Capacity Building)

- Establishment of the MBC, Advisory and Implementation Councils
- Development of knowledge workers and job supply
- Development of legal and intellectual property framework
- Building of Malaysian branding within the biotechnology industry
- Initial job and industry creation

3.2.2 Phase II, 2011-2015 (Science to Business)

- Development of local expertise
- Development of new products
- Technology acquisition and develop capability in technology licensing
- Intensified investment promotion and branding
- Intensify spinning-off companies
- Knowledge intensive job creation

3.2.3 Phase III, 2016-2020 (Global Presence)

- Consolidation of strengths and capabilities
- Strengthen technology and innovation licensing
- Further develop expertise
- Promote global Malaysian companies (Bioeconomy Corporation, 2017)

3.3 Infrastructure Development

The government has also launched five channels of regional economic growth namely, The Northern Corridor Economic Region, The East Corridor Economic Region, Sarawak Corridor Renewable Energy, Sabah Development Corridor and Iskandar Malaysia. These corridors aim to encourage companies to find new growth opportunities in agriculture and healthcare biotechnology (Low, 2013). All these corridors offer excellent infrastructure and logistics support for industry players. A number of foreign companies are already operating at these corridors. Malaysia has excellent infrastructure including possessing a good transportation network and strong ICT infrastructure.

3.4 Communication and Awareness Strategy

The Malaysian Biotechnology Information Center is responsible for communicating and providing scientifically accurate and fact-based resources to all stakeholders to support the biotechnology sector. The strategies of communication and awareness given below (Arujanan, 2011).

- Training of scientists and media
- Developing modules on science communication for science undergraduate- and graduate students
- Provision of grants to scientists for public awareness programmes
- Creation of more science centers, science museums, and science parks
- Inclusion of modules on science journalism in journalism programmes

3.5 Policy Advocacy

The National Biotechnology Division under the MOSTI is responsible in enforcing the NBP. The strategies of policy advocacy include:

- **Planning Section:** To coordinate and monitor the implementation of the policy thrusts as outlined in the NBP
- **Research and Development Section:** to develop, implement and coordinate R&D and innovations in biotechnology in accordance with the NBP
- **Technology Transfer Section:** To facilitate and coordinate the commercialization of R&D in biotechnology by providing funds to researchers to develop IPs and to facilitate technology transfer
- **Promotion and Communication Section:** To promote public awareness and interest on the importance of biotechnology and disseminate research findings to the industry to encourage innovation in biotechnology (National Biotek Division, 2018)

4. Specific Focus on Research

Biotechnology is envisaged to change the food system in Malaysia, and AB focuses on enhancing food security through ensuring sustainable production, sustainable management of pests and diseases, nutritional security and quality and safe food.

5. Priority Areas of Agricultural Biotechnology

5.1 Optimization of Utilization of Biodiversity and Resources

Using sequencing technology and bioinformatics, valuable information stored within the genome of native flora and fauna biodiversity is decoded and used to decipher important cellular and biosynthetic pathways that are important for : (i) production of valuable health benefiting nutrients; (ii) valuable genes used as markers and (iii) selecting crop varieties with desirable traits for further breeding programmes.

5.2 Screening and Developing New Crop Varieties

Crop varieties which are resistant to plant diseases and pests and climate changes, to be developed. Efforts are being targeted towards deciphering metabolic and cellular pathways to identify valuable marker genes by using omics and genetic engineering tools. These genes can then be used in marker assisted breeding and in genetic engineering to develop transgenic crops that are tolerant to climatic changes such as drought and to combat pest and diseases.

5.3 Precise Selection of Superior or Preferred Livestock Breed

Marker assisted selection technology is being used in precise selection of superior or preferred animal for breeding programmes. This technology is also used to reduce in the number of breeding cycle and time whilst allowing for the selection of precise traits in the animal of choice.

5.4 Enhancing Sustainable Agricultural Practices

Sustainable agricultural practices are adapted through formulating biofertilizers and biopesticides. Emphasis is on converting agro-waste to biofertilizers through innovative bioprocessing to improve crop plants' uptake of nutrients by their interactions in the rhizosphere. Research efforts are also targeted at developing biopesticides such as microbial pesticides, plant-incorporated-protectants and biochemical pesticides, produced through naturally occurring substances that control pests by non-toxic mechanisms.

5.5 High Value Bioingredients/Products

Value addition through frontier technologies such as biofermentation, nutrigenomics for production of high value health products.

5.6 Ensuring High Quality and Safe Food Production through Innovative Biodiagnostic Approaches

Utilizing biotechnological and nano-technological approaches to develop precise and sensitive biodiagnostic tools to detect contaminants, as early warning systems in pest and disease management and for enhancing delivery of fertilizers.

6. Major Challenges and Opportunities

6.1 Challenges

Although biotechnology is an important driver for economic growth and sustainable development in Malaysia, there a set of challenges and issues that need to be addressed, enumerated below.

(i) **Shortage of Homegrown Talents and Expertise:** Human capital availability and quality are critical in the development of the biotechnology industry. To-date we still face shortage in number of qualified experienced researchers or skilled workers. An in-depth and precise understanding about new frontier technologies is still lacking.

(ii) **Government/Institutions/Private Sector Collaboration still Modest:** Collaboration with the private sector is of vital importance for successful technology transfer and to understand the target market, target distribution, sales and marketing strategies. The role of the government is important in establishing a good relationship between the two parties, namely, the generator of knowledge and the user of knowledge.

(iii) **Insufficient Research Funding :** Although there is a steady increase in R&D expenditure in Malaysia from 2000-2012, funds are relatively low when compared to the neighbouring country, Singapore. National Research Foundation in Singapore announced a funding of MYR 57 billion for research activities for the next five years (Arujanan, 2016).

(iv) **Limited number of World Class Companies to Raise Standard and Create Competition:** Malaysian companies are mainly Small and Medium Enterprises, lacking experience, knowledge and competitiveness to penetrate in international markets.

(v) **Modest Public Engagement and Understanding of Biotechnology:** There is a strong need to create understanding of biotechnology among all key stakeholders including policymakers, politicians, farmers, media, and the general public. Science communication needs boosting as it has to be translated in laymen language to transfer the needed information effectively (Berger, 2013; Arujanan, 2016; Arujanan and Singaram, 2018).

6.2 Opportunities

The opportunities of biotechnology expanding in Malaysia are vast (Zurina, 2017) due to the following:

(i) **Conducive Environment:** Malaysia is endowed with a very conducive environment for biotechnology investors. Its political stability coupled with its excellent infrastructure are the positive features for biotechnological investments.

(ii) **Abundant Natural Resources:** Malaysia is one of the world's 12 hotspots of biodiversity as it is richly endowed with diverse flora and fauna that can potentially be developed into various value-added natural products.

(iii) **Enabling Policy and Regulatory Framework:** Malaysia also has its own policy with regard to biotechnology, namely, the NBP and also the Biosafety Act (2007) to monitor issues about modern biotechnology like the GMOs *etc.* Despite the slow-paced global economy, Malaysia has also attracted a lot of biotechnology investments from the private sector.

(iv) **Governmental Support:** Malaysia has strong government support in terms of grants, incentives and establishing infrastructures and research institutions, which houses modern facilities and state-of-the-art equipment for biotechnology research.

7. Future Outlook

Biotechnology in Malaysia has offered great opportunity in supporting and consolidating sustainable development in the sectors of agriculture, environment and bioindustry. The biotech industry has generated a total income of MYR 2.7 billion during 2011-2015, while creating a total of 31,000 job opportunities. Seeing that Malaysia is an agricultural-based country, the involvement of biotechnology needs to be heightened to make Malaysia more competitive in the international arena.

7.1 Enhancing Self-Sufficiency Level (SSL)

One important area where AB can make its mark is to address the country's dependency on food imports and to enhance the SSL. Biotechnological approaches can be applied to breed crops with higher yields, resistant to plant diseases and pests and tolerant to climate changes so as to reduce the trade balance deficit of MYR 17 bil.

7.2 Attract and Develop Talent

Further training of scientists, biotechnologists from the local talent pool required. In addition, there is also a need to attract global experts and leading biotech firms to further boost the biotechnology industry.

7.3 Engrain Sustainability and Importance of Biotechnology in People's Mindset

Awareness programmes should be enhanced to incorporate importance of green initiatives in agriculture.

7.4 Engage the People

Public education and communication are necessary for knowledge sharing on experiences and best practices. It is also needed to seek buy in and also to overcome skepticism and negative feelings over novel biobased products and technologies.

7.5 Capitalizing on the Strengths of Biodiversity

To create national wealth in value-added health-related products and improve livelihood of farmers.

7.6 Further Investment

To identify new and innovative ways of making investments to improve livelihood of farmers.

7.7 Fostering and Strengthening Partnerships and Cross Industrial Relationships

Biobased value chains cut across different sectors and require multi-industry and institute collaboration to develop new applications closer to the needs of consumers.

8. Conclusions

The emerging and rapidly developing area of modern biotechnology is envisaged to become the main driving force needed to revolutionize Malaysian agriculture. Due to the recent advances in modern biotechnology especially in the field of omics, tremendous amounts of information on gene functions are being generated and will continue to increase in the coming years. This in turn will offer greater opportunities for a variety of innovative application of genes for crop improvement, either through transgenic or conventional approaches of plant breeding, and will ultimately contribute to new sources of growth for agriculture. Biotechnology is also redefining the value creation potential of agriculture in Malaysia. Innovative technologies and products will be fundamental to Malaysia's future specially to position Malaysia in the forefront and extend its leadership in global market. By the year 2020, the government envisages that the biotechnology sector will provide employment to 280,000 people and will contribute to 5 per cent of the Nation's GDP that is it is expected to generate MYR 248 billion in revenue. Malaysia has an influential voice among the developing countries as well as in the Islamic world. Malaysia could be a strong partner with other global players in the development of AB and be a powerful, vocal advocate of biotechnology in the international arena. Through the application of biotechnology, the vision of transforming Malaysia's agriculture sector towards becoming a more dynamic and competitive industry can become a reality.

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Country Status Report - Philippines

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1. Introduction

The Philippines started its biotechnology programmes in 1979 with the establishment of the National Institute of Biotechnology and Applied Microbiology at the University of the Philippines (UP), Los Banos (BIOTECH-UPLB), which was later renamed as the National Institute of Molecular Biology and Biotechnology (NIMBB). The Philippines is the first Association of South-East Asian Nations (ASEAN) country to initiate a biotechnology regulatory system, which established the National Committee on Biosafety of the Philippines (NCBP) in 1990. The country's biosafety regulatory system follows strict scientific standards and has become a model for member-countries of the ASEAN seeking to become producers of agricultural biotechnology (AB) crops. The types of research undertaken in the Philippines from 1980 to 1990 were mainly related to conventional biotechnology. With the onset of Agriculture and Fisheries Modernization Act (AFMA) in 1997, modern biotechnology was recognized as a strategy to increase agricultural productivity. The present report is an updated compilation of basic information (Table 1) and about the country's policies that regulate the biotechnological research, budgetary indicators, effectiveness of policies, challenges and priority areas.

Table 1. Basic Information

Indicator	Details
Value of GDP (Trillion PhP) PhP = Philippine Peso	15.81*
Value of GDP (Billion USD)	313.60**
Value of agriculture GDP (Billion PhP)	179.82@
Value of agriculture GDP (Billion USD+)	3.60
Agriculture GDP as per cent of GDP	9.66***
Total investment in agricultural research (Billion PhP)	~16.79
Total investment in agricultural research (Million USD+)	~335.93
Total investment in AB research (Million PhP)	~248.10
Total investment in AB research (Million USD+)	~4.96

*Source: World Bank (*2017; **2017a; ***2017b); @Trading Economics (2017); +1 USD=49.9800 PhP*

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2. National Policies

2.1 Current National Policies in Agricultural Biotechnology and Policies for Enhancing the Livelihood of Farmers through Agricultural Biotechnology

2.1.1 Republic Act 8435/Agriculture and Fisheries Modernization Act (AFMA) of 1997

The Philippines recognized the potential role of biotechnology in agricultural modernization as early as 1997 through this Act, which provided significant funding to the agriculture sector. Ten per cent of the funds for agriculture modernization was allocated for research and development (R&D), four per cent of which was allocated to support the biotechnology programme. The Act contains the goals of the national economy, which are "more equitable distribution of opportunities, income and wealth; a sustained increase in the amount of goods and services produced by the nation for the benefit of the people; and an expanding productivity as the key to raising the quality of life for all, especially the underprivileged" (The Lawphil Project, 1997).

2.1.2 Philippine National Policy Statement on Modern Biotechnology, 2001

This government policy is supportive of biotechnology, and states that it shall "promote the safe and responsible use of modern biotechnology and its products as one of several means to achieve and sustain food security, equitable access to health services, sustainable and safe environment, and industry development" (NCBP, 2018).

2.1.3 Philippine Agricultural and Forest Biotechnology Agenda (PAFBA I), 1995-2000 and PAFBA II, 2002-2010

The R&D areas on biotechnology have evolved for the past decades with DOST-PCAARRD initiatives on the crafting of the Philippine Agricultural and Forest Biotechnology Agenda or PAFBA I (1995-2000) and PAFBA II (2002-2010), which focused on traditional biotechnology and few GM crops (*i.e.* papaya).

2.1.4 Biosafety Regulations

- Biosafety regulatory systems of the Philippines are well-established, complementing the biotechnology policy (Mamaril, 2017). An Executive Order (EO) 430 "Constituting the NCBP and for Other Purposes" was signed on Oct. 15, 1990. It is said to be the first biosafety system in a developing country (Mendoza *et al.,* 2009).
- The Philippines signed the Cartagena Protocol on Biosafety on May 24, 2000. Prior to signing the Protocol, the Philippine biosafety system has been based on voluntary disclosure. Declaration of GMO presence in a product became mandatory after the Philippines ratified the Protocol.
- The Department of Agriculture (DA) Administrative Order No, 8 (AO8) provided "Rules and Regulations for the importation and release into the environment of plants and plant products derived from the use of modern biotechnology", and was signed April 3, 2002. The AO 8 was seen as a formalization of an already existing arrangement between the Bureau of Plant Industry (BPI) of DA and the NCBP (Ochave, 2007) and facilitated the commercialization of GM crops in the Philippines.
- EO No. 514 establishing the 'National Biosafety Framework (NBF)', prescribing guidelines for its implementation, strengthening the NCBP, and for other purposes" was issued on March 17, 2006. The NBF is a combination of policy, legal, administrative and technical instruments developed to attain the objective of the Cartagena Protocol on Biosafety, which the Philippines signed on May 24, 2000, ratified on October 5, 2006 and entered into force on January 3, 2007. The Protocol aims to "contribute in ensuring an adequate level of protection in the safe transfer, handling, and use of Living Modified Organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity."
- Joint Department Circular 1 (JDC 1-2016) gives the rules and regulations for the R&D, handling and use, transboundary movement, release into the environment, and management of GM plant and plant products derived from the use of modern biotechnology (DBM, 2018). It was formulated as a response to the Supreme Court ruling in the *Bt* eggplant case of December 2015. The JDC was issued by the executive departments, namely, Department of Agriculture (DA), Department of Environment and Natural Resources (DENR), Department of Interior and Local Government (DILG), Department of Health (DOH) and Department of Science and Technology (DST).

2.1.5 Harmonized National R&D Agenda (HNRDA) - Agriculture, Aquatic and Natural Resources (AANR) - 2017-2022

The DST, in consultation with government and private R&D institutions, academia, industry and other concerned agencies, prepared the Harmonized National Research and Development Agenda (HNRDA) 2017-2022 (DST HNRDA, 2018) to ensure that results of Science and Technology (S&T) endeavors are geared towards and are utilized in areas of maximum economic and social benefit for the people. Agriculture, aquatic, and forestry biotechnology R&D in the Philippines has recently been reviewed and presented (Ebora, 2015). The HNRDA-AANR 2017-2022 is a product of multi-sectoral consultations. The AANR sector supports the use of advanced and emerging technologies such as biotechnology, genomics, bioinformatics, nanotechnology, nuclear technology, space technology, electronics and automation, and information and communication technology as R&D tools to find S&T solutions to AANR problems or develop new products with significant potential impact to the sector.

2.2 Implementation of Policies

2.2.1 Government Bodies Responsible for Implementing Each Policy

(i) **Agriculture and Fisheries Modernization Act (AFMA):** The DA was authorized to implement the AFMA and its various programmes for agriculture modernization including the use of biotechnology.

(ii) **The Policy Statement of 2001:** The DA, DOST, DOH, DENR, Trade and Industry, and other concerned agencies are responsible to address the current issues associated with the local and global dimensions and trends of modern biotechnology, including its potential health, environmental and social impacts.

(iii) **EO 430:** The NCBP was responsible to formulate and review national policies and guidelines on biosafety. From 1990 to 2002, the NCBP's scope of mandate included R&D in the laboratory, screenhouse and in the field.

(iv) **DA AO8:** Field trials up to commercialization of GM crops came under the purview of DA Bureau of Plant Industry (DA-BPI).

(v) **EO 514:** With the issuance of this EO, the NCBP became a policy making body and technical evaluations came under the purview of Competent National Authorities (CNAs).

2.2.2 Effectiveness of the Policy

In terms of support for biotechnology R&D, the Philippines allocated significant funds for biotechnology R&D. These have resulted in products of conventional biotechnology, which have benefited farmers, consumers and the general public.

There are 12 GM corn transformation events approved for commercial cultivation with valid permits (till December 2018) and comprise five single trait events and seven stacks. Research institutes which are focusing on the development of GM crops of (i) rice are Philippine Rice Research Institute (PhilRice) and the International Rice Research Institute (IRRI); (ii) papaya and eggplant are Institute of Plant Breeding - University of the Philippines Los Banos (IPB-UPLB); and (iii) cotton are Philippine Fiber Industry Development Authority (PhilFIDA) (BPI DA, 2018). Strategies for the efficient commercialization of these in-country developed products need to be improved.

The well-established regulatory systems have resulted in the widespread planting of GM corn in the country. As of March 2016, area planted with GM corn was 656,084 ha, providing enormous economic benefits to farmers (Mamaril, 2017a).

2.3 Capacity Development

2.3.1 Existing Capacity Level

The Philippines has sufficient technical experts in conventional biotechnology. The R&D centers in biotechnology have developed products which are benefitting Filipino farmers. Expertise in crop biotechnology is continuously being built up and is close to attaining the critical mass. However, the Philippines needs to build up expertise in livestock and aquaculture biotechnology.

2.3.2 Required Capacity for the Future

To address future needs, biotechnology centers are being put up in the fields of livestock, crop, and fisheries. This is an initiative of the DA, with its core facilities in the PhilRice in Munoz, Nueva Ecija. It is expected that these centers will complement the biotechnology centers in the UP system.

2.4 Partnership

2.4.1 Existing Major Partnerships

Private-public sector partnerships for biotechnology activities have been practiced. A number of awareness campaigns have been conducted with International Service for the Acquisition of Agri-biotech Applications (ISAAA) and Southeast Asian Regional Center for Graduate Study and Research in Agriculture - Biotechnology Information Center (SEARCA BIC) on the commercialization of biotechnologies (SEARCA BIC, 2018). Collaborations with agencies outside of the country are also being continuously explored, in terms of programme funding and use of technologies.

2.4.2 Scoping of New Partnerships

The Philippines is interested to pursue further collaborations with traditional and non-traditional partners.

2.5 Funding Mechanism

The HNRDA ensures the continued funding for R&D in the field of AB, especially for programmes and projects that address the needs identified in the industry strategic R&D plans and programmes of DOST-PCAARRD.

3. National and Institutional Strategies

3.1 National Strategies for Research and Development

In line with the DOST's mandate of providing central direction, leadership and coordination of the scientific and technological efforts in the country, DOST spearheaded the preparation of a HNRDA 2017-2022. This was done through consultation among government and private R&D institutions, the academia, industry and other concerned agencies. The HNRDA aims to ensure that results of S&T endeavors are geared towards and utilized in areas of maximum economic and social benefit for the people. It integrates the existing R&D agenda of government agencies conducting R&D in AANR sector and inputs from various stakeholders.

3.2 Capacity Development

The country, through its national line agencies such as the Commission on Higher Education, DOST and DA, offers scholarship grants through its Councils and other attached agencies. At the same time several State Universities and Colleges (SUCs) offer biotechnology and/or biotechnology-related curricula such as the UP Systems, Central Luzon State University, Mapua Institute of Technology, Visayas State University, University of Santo Tomas (UST), De La Salle University and Ateneo de Manila University, among others.

There are several capacity building initiatives taken all over the country such as the launching of the association of Filipino Teachers Recognizing the Importance of Biotechnology Education, by UP Diliman; Biotechnology workshops for high school teachers and Information, Education and Communication (IEC) projects of the DOST and the National Academy of Science and Technology for Local Government Units; activities such as film showing, essay writing, quiz, campus journalism and photo contests on biotechnology conducted by institutions such as ISAAA, SEARCA-BIC and the Biotech Coalition of the Philippines (BCP).

With regards to capacity building for the regulation of GM crops and products, CNAs have worked with international groups such as the Programme for Biosafety Systems (PBS). PBS is an international programme, which assists partner governments in the development of evidence based regulatory systems through technical assistance and capacity building.

Recognizing the role of media in influencing the public perception, decision-making, policy environment formulation and dissemination of the benefits of modern biotechnology, efforts are focused on educating the media through study tours, seminars and workshops. Partnerships among various agencies and the media to uphold science for agricultural development are continuously being forged.

Partner agencies such as the PBS, BCP, ISAAA, and SEARCA-BIC organize seminars/workshops tackling emerging issues, risk communication, and biotechnology principles that may be crucial for the regulatory system to keep pace with the dynamic developments in biotechnology.

Capacities of small-scale farmers are also being strengthened as well by providing a venue for farmers to share their success stories and speak of the benefits they gained from biotech adoption, among others.

3.3 Infrastructure Development

The Philippines first established a biotechnology institution in 1979, the National Institute of BIOTECH-UPLB as the country’s R&D organization, which specializes in agricultural, environmental and industry related biotechnology. The institute capitalizes on the use of the country's diverse collection of microorganisms, rich natural resources and agro-industrial waste and by-products to develop and advance alternative technologies and products towards improved agro-industrial productivity.

In 1995, by virtue of the Presidential Proclamation no. 526, the Network of National Institutes of Molecular Biology and Biotechnology was constituted and BIOTECH was renamed as NIMBB (NIMBB, 2018). This network is comprised by the research institutes at the four campuses of the UP system one each in Los Banos, Diliman, Manila and Visayas.

IPB UPLB has embarked on the development of the GM crops, *viz*., delayed ripening papaya, *Papaya ringspot virus* resistant papaya, and *Bt* eggplant. It is also involved in basic research like the expression of coconut genes in corn as a proof of concept for oil biosynthesis.

The Philippine Genome Center (PGC, 2018) was launched by the UP system in collaboration with DOST in 2011. It is a multidisciplinary institution that combines basic and applied research for the development of health and therapeutic products, and improved agriculture and aquatic resources. Its services include the provision of full range of DNA sequencing from high throughput capillary sequencing to medium and high throughput next generation sequencing. The PGC’s Agriculture, Livestock and Fisheries Programme are at the forefront of research towards the genetic improvement of plant varieties and animal breeds using molecular marker-assisted selection and breeding.

The Department of Agriculture - Biotech Programme Office is funding both conventional and advanced AB projects being implemented by DA attached agencies and SUCs. In 2015, the DA has institutionalized its agri-biotech centers by virtue of the DA AO 21 series of 2015. These agri-biotech centers were created to assist agency-members of the DA and other collaborating agencies/institutions/units/offices to conduct agri-biotech researches, acquire relevant biotech tools and to commercialize locally adapted or generated, safe and beneficial technologies and products. The Agricultural Biotechnology Center that was initially located at the PhilRice, Nueva Ecija was then restructured into the Crop Biotech Center, Livestock Biotech Center, and Fisheries Biotech Center.

3.4 Communication Strategy

Science-based information on biotechnology is disseminated through learning events and outreach activities with various stakeholders. Biotech information is being synthesized and packaged by partner institutions and groups such as SEARCA-BIC, ISAAA, BCP, in various formats such as briefing materials like comics, pamphlets and PCAARRD Technology Brief that conform to a specific group of stakeholders. Public engagement for transparent decision making and debate are also being facilitated.

In addition, the country celebrates the National Biotechnology Week (NBW) by virtue of Presidential Proclamation no. 1414 every last week of November. The NBW provides a venue to highlight the importance and potential benefits of biotechnology to agriculture and food security, nutrition and health, sustainable environment, and economic growth. Moreover, the Proclamation constituted a Steering Committee, involving seven Executive Departments of government namely, Agriculture, Education, Environment and Natural Resources, Health, Interior and Local Government, Science & Technology and Trade & Industry, to formulate a plan for the meaningful annual celebration of NBW.

The Biosafety Clearing House or BCH Pilipinas was launched in 2008 (BCH, 2018). It serves as a knowledge and information exchange center to facilitate the implementation of the Cartagena Protocol on biosafety platform. It serves as a 'one-stop-shop', where users can easily search and retrieve biosafety-related information.

3.5 General Awareness

Based on a study by Torres *et al*. (2006), Filipino stakeholders are generally less exposed to sources of information on AB. Stakeholder groups in the study rated their understanding of science only as adequate. In general, the study respondents showed favorable perceptions about AB.

ISAAA conducted a media study from 2000 to 2016. Over 17 years, ISAAA reports that media coverage showed a mature editorial stance that happened gradually over a period. While science-based information to the general public has been good, there is still room for improvement, needing greater efforts in IEC. This was evident in the *Bt* eggplant court case, wherein negative non-scientific perceptions were manifested.

3.6 Policy Advocacy

Science-based information on biotechnology is disseminated through learning events and outreach activities with various stakeholders. Biotech information is being synthesized and packaged by partner institutions and groups such as SEARCA-BIC, ISAAA, BCP, in various formats such as briefing materials like comics, pamphlets and PCAARRD Technology Brief that conform to a specific group of stakeholders. Public engagement for transparent decision making and debate is also being facilitated.

4. Specific Focus on Research

Specific focus of AB is on basic and applied, as well as adaptive and strategic research. Biotechnology as a tool, is used in addressing the problems and gaps identified in the value chain of various agricultural commodities.

5. Priority Areas of Agricultural Biotechnology

Priority areas for R&D in crop biotechnology are germplasm evaluation, conservation, utilization and management; varietal selection and improvement; and production of good quality planting materials. As far as livestock is concerned, the priority biotechnology R&D is on breed development and genetic improvement for meat, dairy, and draft; reproductive biotechniques, nutrition, feeds and feeding system. For aquaculture, disease diagnosis, conservation, utilization and management and improvement of broodstock are the priority areas. Biotechnology techniques are also used in biodiversity-related studies and conservation efforts.

6. Major Challenges and Opportunities

For matters regarding policy, there are a number of biotechnology-related bills that are currently filed in the Philippine House of Representative. These are as follows:

(i) HB 2719: GMO-Free Agricultural Act

(ii) HB 3686: The Philippine GMO Labeling Act, The Right-to-Know-Act

(iii) HB 3810: GM Labeling Act

(iv) HB 2038 & 4214: Establishment of an Abaca Biotechnology Laboratory and appropriating funds thereof.

(v) HB 3798: National Commission on Biosafety of the Philippine Act

Some of these legislative initiatives, either perceived as supportive or against biotechnology and addressing the concerns of the stakeholders, still remain a challenge. However, these could also be viewed as an opportunity to discuss the concerns of various sectors through a healthy and productive dialogue with the general public and policy makers.

Regarding biosafety regulations, there are few challenges such as the involvement of different agencies, which have their own policies, procedures and structures that govern their activities. Initial actions have already been taken to mitigate this issue by developing a harmonized operation manual and simplifying prescribed forms. Similarly, the capability in regulating GM products must be maintained and enhanced as some emerging technologies such as the commercialization of GM animals and New Breeding Techniques (NBT), which might not be covered by the existing biosafety regulations.

On classical technologies, products developed, especially by public institutions, need to be transferred quickly to private sector investors. This would allow scientists to devote limited time and resources in conducting research on more powerful cutting-edge biotechnologies to benefit society. On future needs, the Philippines need to discuss gene editing in the context of research and regulation to maximize benefits while minimizing risk.

7. Future Outlook

With the full support of the government on biotechnology, it is expected that more biotechnological products (both conventional and high end) will be available in the near future. This will be possible if science-based initiatives are in place and be able to satisfactorily address the consensus of all stakeholders. The regulatory system should be able to appropriately adjust to rapid advancement in the technology and its scope and application.

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Country Status Report - Taiwan

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1. Introduction

The island of Taiwan is a natural gateway to East Asia as it is strategically located in the middle of the chain of islands. Though only one-quarter of the land is arable, the subtropical climate permits multi-cropping of rice and growing of fruits and vegetables all year round. The application of biotechnology to agriculture has become a very critical issue to sustain the growth and development of the country and promote the need to continuously improve and develop this sector. In Taiwan, plant tissue culture, applied microbiology and molecular biology, and studies such as gene editing, have been included as the key areas of research under agricultural biotechnology (AB), funded by the government. The current situation of research, application, and commercialization of biotechnology in Taiwan is briefly covered in this report along with the budgetary details (Table 1).

Table 1. Basic Information

Indicator	Details
Value of GDP (Billion NTD) NTD=New Taiwan Dollor	17431[*]
Value of GDP (Billion USD)	572.77[*]
Value of agriculture GDP (Billion NTD)	300.40[*]
Value of agriculture GDP (Million USD[+])	10.01
Agriculture GDP as per cent of GDP	1.72[*]
Total investment on agricultural research (Million NTD)	4307.97[@]
Total investment on agriculture research (Million USD)	143.59[@]
Total investment on agro-techno and biotechnology (Million NTD)	747.72[#]
Total investment on agro-techno and biotechnology (Million USD)	24.92[#]

Source: [*]National Statistics (2017); [@]COA (2017); [#]MOFA (2017); [+]1 USD=30.0025 NTD

2. National Policies

2.1 Current National Policies on Agricultural Biotechnology and Polices for Enhancing the Livelihood of Farmers through Agricultural Biotechnology

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The chronology of AB developments is listed in Table 2, along with the strategies and policies in Taiwan (FFTC, 2005).

Table 2. Chronology of AB developments in Taiwan

1980s	Research on basic applications of molecular biology- gene cloning, transformation, and genetic marker analysis in plants and animals
1982	Biotechnology was included as one of the eight key areas of research by the government- Education or training programmes were initiated
1984	Development Centre for Biotechnology, the first autonomous and non-profit organization, specifically focused on biotechnology research
1990s (mid)	Establishment of important regulations or guidelines concerning biotechnology and biosafety ● National Science Council (NSC): Experimental rules for recombinant DNA ● Council of Agriculture (COA): Guidelines for risk assessment in genetically modified (GM) plants and animals
1994 onwards	● Development of transgenic plants and animals ● DNA-based genotyping for breeding ● Development of biopesticides, biofertilizers, and animal vaccines ● Marketing promoted with the involvement of private companies
1997	National Science and Technology Programme for AB initiated, implemented and coordinated by the NSC, COA, and the Academia Sinica. The main scope includes flowers and ornamental plants, plant bioprotection, aquaculture, livestock and animal vaccines, utilization of plant genomes, environmental biotechnology and medicinal plants.
1999	National Agricultural Biotechnology Programme - The Experimental Rule of Recombinant DNA was issued by the NSC, as well as the guidelines for risk assessment in GM plants and animals by COA.
2003	The amendment of the Plant Variety and Seed Act was promulgated by COA, by taking biotechnology into account.
2005	● Framework for the management of biotechnology and biosafety ● Establishment of Biotech Science Parks

2.1.1 Industrialization Project for Agricultural Biotechnology, 2009

The five-year, NT$ 2.4 billion (US$ 81 million) project for AB, unveiled by the government in 2009, was a joint effort involving Academia Sinica, COA, NSC, Ministry of Economic Affairs (MoEA), Ministry of Education and Ministry of Health and Welfare (MOHW). During the project period, publication of more than 600 research papers and 300 patents was achieved, and provided training for over 16,000 individuals and promoted 279 technology transfer agreements with licensing fees reaching NT$ 220 million. Some of the successful technology developments include a banana-based pig vaccine, muscle building fish feed, a new breed of Oncidium orchid, biogas power generation using animal effluent and a fluorescent pink ornamental fish (Taiwan Today, 2013).

2.1.2 Taiwan Biotech Industrialization Take-off Action Plan, 2013

In June 2013, the Taiwan Biotechnology Take-off Diamond Action Plan was renamed as the Taiwan Biotech Industrialization Take-off Action Plan, and formally implemented (BPIPO, 2014).

Recently, through governmental forces, firm-structured and production industrial clusters are formed. Alongside, governmental policy and resources also foster commercialization of technological innovation and results in the forms of governmental projects, driving continuous growth to knowledge-based agricultural businesses that is centered by technology, resources and services, such as biotechnology testing and Farming Model Factories.

2.1.3 Intellectual Property Rights Protection Laws (Asiabiotech, 2005)

Taiwan has signed Intellectual Property Rights (IPR) agreements with many industrialized countries, and is rapidly establishing international links in terms of IPR promotion and education to enhance local citizens' awareness of IPR. The government hopes to be able to guide corporations in becoming familiar with IPR for knowledge management and improve the way the business sector handles IPR-related legal conflicts, in order to strengthen Taiwan's IPR protection environment, which has Patent Law, Trademark Law, Copyright Law, Integrated Circuit Layout Protection Law, Trade Secrets Act, Guidelines for Ownership and Use of the Scientific Technological R&D Results of the Government, and Foundation Law for Technology Development.

2.1.4 New Agricultural and Bio-economic Development Agenda

Figure 1 depicts the Taiwans' recent agricultural and bio-economic development agenda, which proposes following execution strategies:

(i) Strengthen international competitiveness in relation to agro-bio economic and technology power

- Develop raising technology, consolidate interdisciplinary research (COA; Ministry of Science and Technology-MOST; MOEA)
- Promote Industry-Government-Academic exchanges and cooperation (COA, MOST)

(ii) Construct agriculture and bio-economic industrialization developing environment positing competitiveness

- Complete establishment of regulations and mechanisms to industrial development (COA, MOEA, MOHW, Environmental Protection Administration)
- Reinforce international agro-techno industry analysis and global IP roadmap (COA, MOEA)
- Strengthen industrialization promotion and extend industry clusters (COA, MOEA)

(iii) Nurture Industry-Oriented Interdisciplinary and Diversified Human Recourses Base

- Enhance nurturing interdisciplinary human resource courses on new technology (COA, MOEA)
- Enhance nurturing industrial legal and marketing human recourses (COA)

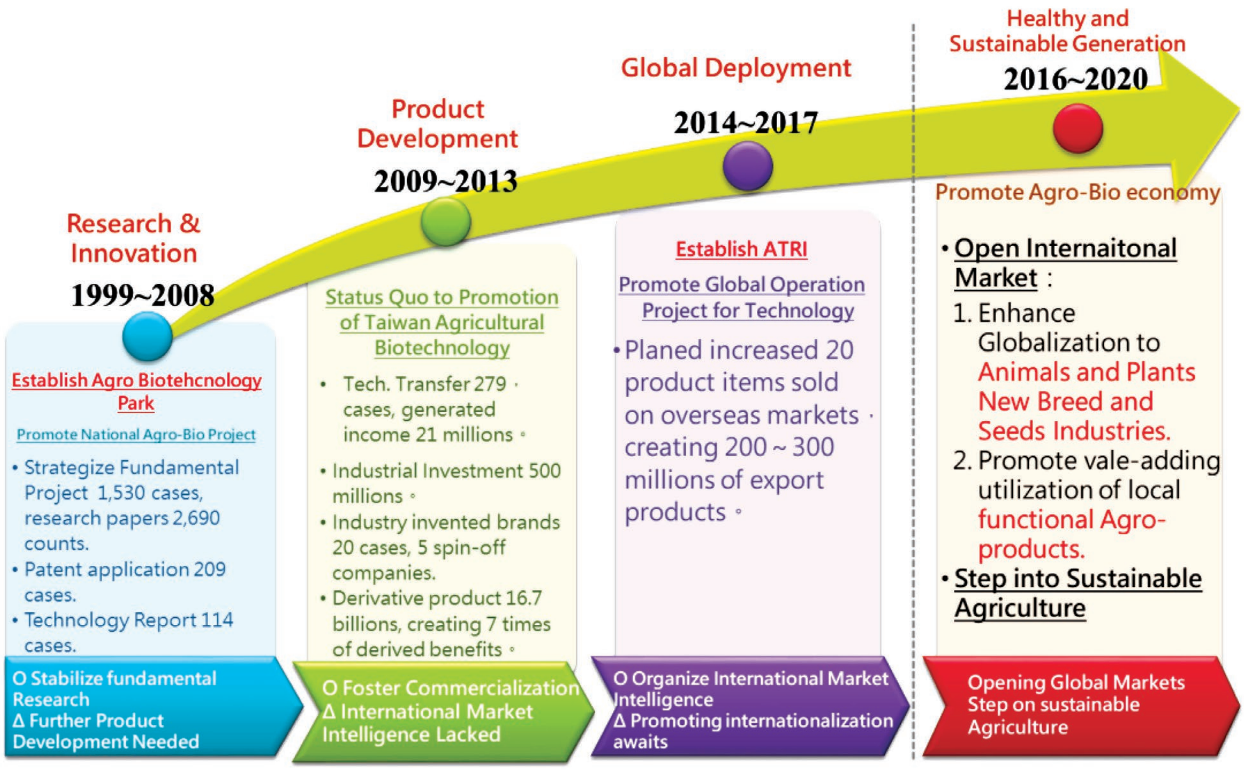

Figure 1. *Status Quo to promotion of Taiwan AB*

(iv) Promote Globalization of Agriculture and Bio-economic Industries

- Construct international capacity, develop global service network
- Implement international cooperation, boost international connection to industries [COA, Ministry of Foreign Affairs (MOFA), MOEA]

2.2 Implementation of Policies

2.2.1 Government Bodies Responsible for Implementation

The COA is the competent authority on agricultural, forestry, fishery, animal husbandry and food affairs in Taiwan. Under the council there are several departments that are responsible for implementation. In addition, the government established the "Biotechnology and Pharmaceutical Industries Programme Office (BPIPO)" under the Ministry of Economic Affairs to serve as an integrating arm, implementing and promoting policies concerning the development of biotechnology industry in Taiwan. BPIPO's services include: (i) to promote government biotech-related policies; (ii) to act as the window for international exchanges; (iii) to provide information related to investment incentives; (iv) to provide relevant legal information; (v) to provide relevant documents for the setting up of companies and factories; (vi) to assist in business operational planning and raising of capital (Asiabiotech, 2005). BPIPO acts as single contact window for domestic and international biomedical-related industries, acting as one stop window; promoting industrial investment and integration, assisting biotechnology, pharmaceutical, medical device industry development and upgrade (BPIPO, 2018).Taiwan's agricultural industry, with its high level of agricultural expertise resulting from a century of accumulated research and technical advances, is advancing toward a technology-intensive model characterized by academic-public-private collaboration with the support from MOFA. The sector is ready to embrace the era of smart agriculture by using biotech resources to create value-added products (NSPP, 2018).

2.2.2 Effectiveness of the Policy/Programme

Some of the successful technology developments of the ROC government-backed five-year national AB development programme are listed below (FFTC, 2005; Taiwan Today, 2013):

(i) The world's only fluorescent pink lionhead fish.

(ii) Banana-based pig vaccine.

(iii) Muscle building fish feed.

(iv) New breed of *Oncidium* orchid.

(v) Biogas power generation using animal effluent.

(vi) The orchid industry in Taiwan produced tissue culture products to a greater extent and the main categories of orchids produced include *Phalaenopsis, Oncidium, Cymbidium, Dendrobium* and *Paphiopedilum*.

(vii) Taiwan Banana Research Institute produces more than one million Cavendish banana plantlets produced by tissue culture each year with resistance to *Fusarium* wilt of banana, commonly known as Panama disease. Feasibility of using tissue culture to generate variation for selection of commercially acceptable wilt resistant cultivars in banana is being explored.

(viii) Taiwan Agricultural Research Institute (TARI) transferred some of their know-how in developing biopesticides to different companies, that are being marketed in different names, such as "Dr. Root" (Vesicular-Arbuscular Mycorrhizal Fungi, VAMF) by Tai-En Co.; "Mycovam" (VAMF) by the Taiwan Biological Research Co.; "Ai-gen-how" in Chinese); VAMF by the Lei-ju Co., and "Agroguard" (Bacillus) by the Taiwan Biological Research Co.

(ix) GM products: Transgenic papaya resistant to *Papaya ringspot virus* was developed by the National Chung-Hsing University during mid-1990s. It passed the environmental risk assessment in 2000, but needs to go through the food safety assessment before marketing.

(x) Several transgenic crops, including rice, broccoli, potato and tomato, are now under the process of environmental risk assessment performed at TARI and Asian Vegetable Research and Development Center (AVRDC), but has yet to go through food safety assessment.

(xi) Transgenic eucalyptus, created by the Forest Research Institute, was under field evaluation according to the guideline during 2005.

(xii) In animals, the transgenic ornamental fish containing fluorescent gene developed by a private company, and the duplicated goats derived from somatic cell cloning, developed by the Livestock Research Institute and the National Taiwan University, are two examples of outstanding achievements. Although many of these genetic engineering products are ready for application, so far none of them has been commercialized or marketed.

2.3 Capacity Development

During 2009-2012, Taiwan's Development Programme of Industrialization for Agricultural Biotechnology (DPIAB) promoted the publication of more than 600 research papers and 300 patents, provided training for over 16,000 individuals and promoted 279 technology transfer agreements with licensing fees reaching NT$ 220 million (Taiwan Today, 2013).

2.4 Partnership

Taiwan International Agricultural Development Company (TIADC) invested in Pingtung Agricultural Biotechnology Park (PABP) of the COA. The PABP established in 2006, is now spread in 233 ha of land area, of which over 90 per cent has been leased by investing firms. It has succeeded in attracting over 100 agribusinesses forming industrial clusters that include natural products, aqua breeding, husbandry materials and animal health, agro-bio materials, biotechnical service, and energy-saving and ecological agro-production system. Recently, PABP received approval from the Executive Yuan for an expansion plan, and it is anticipated that the 165.41 ha expansion project will be completed by the end of 2019. Along with other construction such as multi-functional warehousing and services zone (including the industrial talents training center for agro-biotechnology), PABP will create an agribusiness cluster of over 180 firms. Therefore, this investment by the TIADC in PABP has significance as an indicator for Taiwan's global innovative agribusinesses industrial cluster (COA, 2013).

2.5 Funding Mechanism

The five-year, NT$ 2.4 billion (US$ 81 million) project, a joint effort involving Academia Sinica, COA, National Science Council, Ministry of Economic Affairs, Ministry of Education and MOHW, was unveiled in 2009 by the ROC cabinet. In addition, the DPIAB office has assisted in initiating 378 matchmaking sessions for local firms and facilitated R&D spending by related sectors topping NT$ 464 million during 2009-2013, with total economic benefits estimated at NT$ 16.7 billion (Taiwan Today, 2013).

3. National and Institutional Strategies

3.1 National Strategies for Research and Development

3.1.1 Agricultural and Biotechnology Research

(i) **Agricultural Genome for Industrial Applications:** Developing foresighted technology on genome, through enlarged application to genome technologies, supporting potential industries' development; using SNP molecular-marker and mapping and genome testing, *etc.*, establishing genome and genetic recourse database usable for agriculture, livestock and fishery farming on selecting new breeds with respect to market demands shortening breeding schedule.

(ii) **New Breeds and Seeds of Animals and Plant:** Promote global development of new animal breed, plant cultivar and seed, escalating efficiency on plant cultivation, improving overseas market efficacy for breeds and raising international Technical Assistance Facility/International Seed Testing Association (ISTA) certification rates.

(iii) **Animal and Plant Health Management:** By equipping Organization for Economic Cooperation and Development (OECD) and Good Laboratory Practice (GLP) toxicology testing capacity, thus improving efficiency on plant protecting biological agent safety testing; strengthen fishery farming biological agent on reducing incidence rate for sea water farmed animals, and developing fish meal alternatives to ensure qualitative and quantitative excellency of Taiwan agricultural products, properly secure safety to environmental and agricultural products.

(iv) **Regenerated Recourses Cycling Application:** Improve technology on reusing regenerated recourses, developing biomedical industrial added value, substitution to animal feeds, environmental friendly bioenergy development and developing livelihood products, *etc.*

3.1.2 Industrialization Fostering Measurement

(i) **Reinforce International Agro-Techno Industry Analysis and Global IP Road-Mapping:** Collect international intelligence of analyzed industry subject and future development trend of markets. Auditing proper essential elements and operation model for the targeted industry using industrial environment and characteristics combined with business's needs. Assisting on plan improvement to technology research and strategy development to IP road-mapping through information exchange and communications with research team.

(ii) **Construct Industrialization Promoting Platform to Enhance Promoting Power:** Integrating resources including Agricultural Incubation Center, New Business Development, Industry Consultation and Agriculture Biotechnology Park, providing complete and consistent industrialization services, offering 4 in 1 incubation for new businesses venture and existing corporations to accelerate development of agro-businesses and improve competitiveness to agricultural and biotechnology Industry.

(iii) **Nurturing Industry-Oriented Interdisciplinary Human Resource Development:** Arrange training camp for agricultural and biotechnology new business, providing mentoring courses from technology assessment, professional competence training, organization development, business group composition, financial evaluation, corporate operation to production/marketing/HR/RD/finance systematically, accompanied with practical exercise finding potent subject products to finish commercialization and corporate evaluation plan (Business Plan).

(iv) **Foster International Development to Industry:** Foster Taiwan Pavilion, Taiwan Excellence Awards in international competitions or exhibitions, assisting Taiwan agro-businesses to enlarge and enter into international markets, driving visibility and status of our country. On the other hand, utilizing interdisciplinary horizontal alliance, transferring internationally innovative technology to agro-businesses internationally recognizable, establishing agro-business, at which recourses are provided by peasants; value adding, mass production and packaging are conducted by domestic firms, that finally execute marketing under internationally known bran, pushing products to global market to accelerate international development to domestic agricultural products.

3.2 General Awareness

Exhibitions are one of the means of creating awareness about biotechnological developments of the country and one such 'Asia Agri-Tech (AAT) Expo & Forum' was conducted at Taipei, Taiwan in 2017. This Expo attracted more than 20,000 visitors from 36 countries, and the total sales were estimated to be approximately 17 million US dollars. It was an exclusive trade show representing Taiwan's premier, international and professional B2B trading platform that focuses on the state-of-the-art technologies for the field of agriculture in Asia. With the rising issues of climate change and food safety, the agricultural business opportunity has expanded potentially as well as the development of IoT and biological technology. The AAT brings together manufacturers, wholesalers, and retailers to exhibit their products in general (AgEvents, 2018).

The annual AAT is concurrently held with the 'Livestock & Aquaculture Taiwan (LAT) Expo & Forum'. The 2nd edition will take place at the Taipei World Trade Center, Hall 1 on July 26-28, 2018. This three-day trade show contains a series of conference and business match making programme and will reveal the strengths and competitiveness of Taiwan's supply chain (AAEF, 2018).

4. Major Challenges and Opportunities

4.1 Challenges

Following the international developing trends, many countries like Japan and China channelized great fund in R&D of agricultural genomics technology. Developed countries (*e.g.* European Union, Japan) make efforts to develop intelligent agriculture and show great progress with the technique. Further, the following issues may become the main potential obstacles for commercialization of GM products (FFTC, 2005):

(i) Incomplete framework of law and regulation system for transgenic animal and fish.

(ii) There is a need for stronger connection between laboratories and factories *i.e.* between the researchers and producers, in order to speed up commercialization and marketing in this field.

(iii) Most of the companies are small and medium enterprises (SMEs), thus may have limited competition ability due to the higher production cost and low R&D budget.

(iv) There is a strong need for more public communication and education about biotechnology products.

(v) There is a need for more traditional nursery companies to join the GMO business as their experience in marketing will be very helpful for the development of GMO business.

(vi) There is a strong need to increase international cooperation either in research or business aspects.

4.2 Opportunities

(i) Taiwan has a variety of land types, from the ocean to the mountains, and it harbours rich biodiversity, which is the basis for the development of AB.

(ii) Since 1999, a considerable amount of energy in the use of microorganisms has been accumulated by focusing on AB as a key research project.

(iii) AB combined with Taiwan's foundation of electronic Information and Communication Technology (ICT), opportunity of cross-domain linkage exists to create greater technological advantages and diversified industrial energy.

(iv) The government strongly supports biotechnology and gradually improves the industry environment (such as talents, regulations, investment environment, and internationalization).

5. Future Outlook

Observing global developmental trends, in the coming 20 years, issues such as aging population, food safety, environmental changes and sustainable development will emerge worldwide. European and American countries are introducing bioeconomy as core replying policies. Taiwan as well could take agricultural and bioeconomy as replying plan, such as developing modernized biotechnology to tackle insufficient arable land per capita, climate changes and lack of resources; promoting healthy agriculture to cope with aging population, over-priced medical cost and food safety; achieving intelligent industry in response to aging rural and inadequate global competitiveness; stepping in sustainable agriculture to face environmental damages and problems on waste recycling. In this context, the following short and long term goals are set.

5.1 Immediate and Short-term Goals

(i) Develop next generation genomics foresight technology and enhance molecular markers application to agriculture, forestry and livestock, to increase efficiency of breeding.

(ii) Execute global development of new animal species, plant varieties and seedlings, and build a production and marketing alliance to scale up the management projects, and improve the international competitiveness.

(iii) Reinforce the animal and plant health management to retain the fine qualities of agricultural products, completing environment and agricultural product safety.

(iv) Accelerate the value-added functional agricultural products and produce agricultural products in wide variety for competitive advantage to assure national health protection.

(v) Promote application technology of cyclic regeneration to increase resource mobility, and create the new chance for cyclic symbiosis in agriculture industry development.

5.2 Long-term Goals

Long-term goals are set to overcome the environment challenges and trends, and sustain next generation industry for the future of agriculture. It is expected to expand safe, non-hazardous recycling agriculture to improve people's welfare.

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Country Status Report - Thailand

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1. Introduction

Agriculture in Thailand is highly competitive, diversified and specialized and its exports are very successful internationally. The Government of Thailand has been promoting growth and fostering developments in biotechnology, in an effort to transform Thailand into the center of excellence in biotechnology in Asia. Factors such as limited availability of agricultural land, water shortages, the low-yielding crops, and pest problems are being addressed by researchers to develop innovative agricultural technologies through extensive research and development (R&D) activities. Thailand's biotechnology development will improve significantly if capital and financing mechanisms, along with standard system and regulations are improved. The country's emphasis is on application of core technologies such as genomics, bioinformatics, plant and animal breeding by means of molecular markers to accelerate development in the priority areas of agriculture/food, medical care and environment protection, new knowledge creation for the development of value-added products, as well as for knowledge-based policy and strategic planning. In addition to being consistent with the national agenda and government policy directions, the national goals for biotechnology development are also derived from consideration to other dimensions. The present status of the country in the above-mentioned areas of biotechnological research along with related policies, their implementation, budgetary allocations, (Table 1) future outlook and priorities are compiled in this report.

Table 1. Basic Information

Indicator	Details
Value of GDP (Trillion BAHT) BAHT = Thai BAHT	15.45*
Value of GDP (Billion USD)	455.22**
Value of agriculture GDP (Billion BAHT)	134.30@
Value of agriculture GDP (Billion USD+)	4.12
Agriculture GDP as per cent of GDP	8.70%***
Total investment in agricultural research (Billion BAHT)	~17.66
Total investment in agriculture research (Million USD+)	~541.80
Total investment in agricultural biotechnology (AB) research (Million BAHT)	~335
Total investment in AB research in USD (Million USD+)	~10.28

*Source: World Bank (*2017; **2017a; ***2017b); @Trading Economics (2017) +1 USD=32.5951 Thai BAHT*

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2. National Policies

2.1 Current National Policies on AB and Policies for Enhancing the Livelihood of Farmers through AB

Thailand's national policies on AB work in parallel with global, regional and national development in formulating the policy framework. Currently no genetically engineered (GE) crops have been approved for cultivation and no field trials have been undertaken. Thailand does not engage in the development or production of GE animals. Agriculture research system in Thailand, the development, policies, institutions, investment patterns, and impact assessment have recently been reviewed (Suphannachart, 2015). List of policies on biotechnology that are formulated from time to time are given below.

2.1.1 The 6th National Social and Economic Development Plan (1987-1991)

The efforts put to implement the plans and their achievements have induced structural change in the Thai economy from a dominant agricultural to a more industrial-oriented economy (NESDB, 1987-1991).

2.1.2 The National Biotechnology Policy Framework (2004-2009)

The goals of biotechnology development in Thailand (2004-2009) by the year 2011, were that biotechnology would play a vital role in the country's development in line with government policy and the national agenda, which encompasses sustainable competitiveness, healthcare for all, equitable income distribution and a self-sufficient economy. The emphasis was on applying core technologies, *e.g.* genomics, bioinformatics, plant and animal breeding by means of molecular markers to accelerate development in the following areas: agriculture/food, medical care and environment protection, new knowledge creation for the development of higher value-added products, as well as for knowledge-based policy and strategic planning. The core technologies are also to help promote biotechnology business, including high-end products with high value and new types of services where modern technology is required.

Recognizing the potential of biotechnology development in Thailand, the timeframe was shortened to 6 years (2004-2009) so as to harness benefit from biotechnology development at a faster pace. Accordingly, the Secretariat to the National Biotechnology Policy Committee, published the 2 National Biotechnology Policy Framework (2004-2009), for enhancing Thailand's biotechnology position (NCGEB, 2005).

2.1.3 National Economic and Social Development Plan (2012-2016)

The vital role of advanced technologies, including Information and Communication Technology (ICT), biotechnology, nanotechnology, as well as cognitive science, in economic and social development, and human life was well recognized (NESDP, 2012-2016).

2.1.4 Eighth National Research Policy and Strategy (2012-2016)

Five national research strategies were identified and the policy has taken the importance of participation from all relevant parties in both the central and regional sectors into consideration. The fourth Research Strategy on "Development of innovation and research personnel potential and capability" deals with the biotechnological innovations. It is also related to and in compliance with the 11th National Economic and Social Development Plan (2012-2016). National Research Council of Thailand (NRCT) has integrated regional research data, issues and problems together with the country's changing situations and challenges in the formulation of the present research policy and strategy (NRPS, 2012-2016).

2.1.5 Ninth National Research Policy and Strategy (2017-2021)

At present, the NRCT is in the process of undertaking the Ninth National Research Policy and Strategy (2017-2021), which will get consistent with government policy, 20-year National Strategy (2017-2036), the 12th National Economic and Social Development Plan (2017-2021), together with current economic, social and political changes inside and outside the country. It is envisaged that concerned authorities will use the Ninth National Research Policy and Strategy for a research guideline and framework for the preparation and evaluation of research proposals, as well as stimulating the private sector to increasingly invest in research for helping the development of the country (NRPS, 2017-2021).

2.1.6 National Science, Technology and Innovation Policy and Plan (2012-2021)

The conceptual framework of the National Science, Technology and Innovation Policy (STI) and Plan 2012-2021 identifies challenging issues impacting the development of science, technology and innovation that better serve the needs of Thailand's economy and society throughout the next decade. The Policy and Plan outlines the ways in which Thailand can benefit from STI in preparation for confronting domestic, regional and global challenges (STI, 2018).

2.1.7 National Guideline for Capacity Building in Science, Technology and Innovation Competitiveness Biotechnology Development Policy Framework (2012-2021)

The Government launched the Biotechnology Development Policy Framework 2012-2021, with the collaboration between the STI Policy Office and National Center for Genetic Engineering and Biotechnology (BIOTEC). This multi-billion Baht plan aims to promote sustainable growth in the biotechnology industry through research funding, strategy mapping and investment incentives. Under this policy framework, a strong emphasis will be placed on enhancing R&D in the private sector and utilizing the intellectual capital created from the biotech revolution to strengthen the country's overall competitiveness (TIR, 2017; STI, 2018a).

Four strategic sectors have been prioritized within the framework (BIOTEC, 2018), which include food and agriculture, medicine and health, bioenergy and biobased industry due to their social and economic importance, their ability to excel through the application of biotechnology, and their potential benefits to community economic development.

Targets of Biotechnology Policy Framework (2012-2021)

- Increase competitiveness by advancing science and technology in areas where Thailand has a comparative advantage and/or strong capacity
- Increase wealth and reduce inequality by creating jobs
- Increase quality of life by strengthening economic, social, health and environmental security and promote life-long learning
- Foster sustainable development by helping to realize economic development objectives that safeguard environmental quality and conserve natural resources
- Strengthen national security by increasing self-reliance in strategic sectors such as energy and healthcare

2.1.8 National Biosafety Guidelines for Genetically Modified Organisms(GMOs) R&D in Thailand

National biosafety guidelines were formulated for laboratory testing, field testing and planned release of GMOs since 1992 by BIOTEC under Ministry of Science and Technology (MOST). The National Biosafety Committee (NBC) was established in 1993 to serve as a coordination body with Institutional Biosafety Committee (IBC), to develop national biosafety guidelines, oversee imports of living organisms, review and direct research methodologies, *etc.* The NBC is no longer active and hence, the review of biosafety issues for GE plants and animals is currently being conducted by the Technical Biosafety Committee, an adhoc technical advisor of BIOTEC. About 36 IBCs were established by different research institutes throughout the country (BIOTEC, 2018). Regional IBC networks have been created to encourage communication and sharing of experiences between its members.

2.2 Implementation of Policies

2.2.1 Government Bodies Responsible for Implementing Each Policy

Four main government agencies, listed below, are involved in the regulation of AB.

(i) **Department of Agriculture (DOA), Ministry of Agriculture and Cooperatives (MOAC):** The MOAC encourages crop varieties improvement, minimize agricultural losses through agricultural machinery and post-harvesting R&D including research collaboration among government, private firms, universities, entrepreneurs and research institutes. In addition, the National Bureau of Agricultural Commodity and Food Standards under MOAC represents the Thai Government in negotiating all Sanitary and Phytosanitary issues in international organizations (*e.g.* Codex, International Plant Protection Convention and World organization for Animal Health, *etc.*), including food safety in GE products (Preechajarn, 2017).

(ii) **National Centre for Biotechnology and Genetic Engineering (BIOTEC), MOST:** The BIOTEC is one of the centres of the National Science and Technology Development Agency (NSTDA), which supports and transfers technology for the development of industry, agriculture, natural resources and environment. Specifically its R&D on food, plant and animal uses biotechnology to improve yield and quality.

(iii) **Ministry of Natural Resources and Environment (MONRE):** The Office of Natural Resources and Environmental Policy and Planning is a national focal point on Convention on Biological Diversity (CBD) and Cartagena Protocol on Biosafety; drafting Biosafety Act and Biodiversity Act.

(iv) **Food and Drug Administration (FDA), Ministry of Public Health (MOPH):** The FDA under the MOPH enforces the food safety under Food Act. It regulates and monitors the trade and use of GE food including labeling.

2.2.2 Effectiveness of the Policy

In spite of the benefits derived from implementation of policies, key strategic areas remain the same for further improvement. Application of genomic technology, genetic engineering and cell factory systems in combination with other technologies along with conventional plant breeding is required to enable improvement of crops and livestock, agricultural inputs and value added products.

2.3 Capacity Development

2.3.1 Existing Capacity Level

Biotechnology companies in Thailand have a variety of competitive advantages including intellectual property protection and a robust and technically-equipped workforce. Currently, 24 universities across the country have the combined capacity to supply approximately 7,000 students with a biotechnology background each year (Thailand Board of Investment, 2018).

2.3.2 Required Capacity for Future

(i) Physical infrastructure such as biology research institutes, centers for excellence, pilot plants and regional bioparks.

(ii) Personnel development and capacity building for biotechnology and related fields including professional researchers, biotechnology business managers, IP managers and local researchers generated from the Royal Golden Jubilee PhD programme and multi-disciplinary study programmes.

(iii) Critical investment and biotechnology development fund established through a public-private partnership to provide capital for biotechnology entrepreneurs.

(iv) Streamlined regulation and investment policies advance more efficient policies, regulations and standards to eliminate bottlenecks impeding progress in key areas such as GMOs, biosafety, bioethics and IP management. Seek tax deductions for R&D expenses related to the Framework's strategic sectors. Structure government procurement processes to support markets for biobased products.

2.4 Partnership

2.4.1 Existing Major Partnerships

The government and organizations supporting the growth and competitiveness of biotechnology industry in Thailand include the Department of Agriculture (DOA), Ministry of Agriculture and Cooperatives (MOAC);

National Science and Technology Development Agency (NSTDA), Ministry of Science and Technology (MOST); Ministry of Natural Resources and Environment (MONRE); Food and Drug Administration (FDA), Ministry of Public Health (MOPH). The NSTDA has four national research centers (i) National Center for Genetic Engineering and Biotechnology (BIOTEC); (ii) Thailand National Metal and Materials Technology Center (MTEC); (iii) National Electronics and Computer Technology Center (NECTEC) and (iv) National Nanotechnology Center (NANOTEC) and one Technology Management Center (TMC). The NSTDA provides technical assistance and R&D grants to both public and private sectors in the industry.

Further, the Thailand Science Park (TSP); Research and Development Certification Committee Secretariat (RDC); Thailand Center of Excellence for Life Sciences (TCELS); Thailand Institute of Scientific and Technological Research; The Venture Capital Industry in Thailand are also contributing to biotechnological development in Thailand (Thailand Board of Investment, 2018a).

2.5 Funding Mechanism

The main funding mechanism on agricultural R&D in Thailand is from the NRCT and Agricultural Research Development Agency, which focus on research projects applied for commercial, public, policy usages and innovation (NRCT, 2016). The National Innovation Agency focuses on food processing research. The Board of Investment of Thailand (BOI) is creating a positive environment for local and international industries by promoting R&D investment projects. BOI provides maximum benefit privileges to biotechnology-related investments. The critical investment and biotechnology development fund is also established through a public-private partnership to provide capital for biotechnology entrepreneurs. BOI investment incentives for biotechnology companies in Thailand include a tax exemption on import duties on machinery, an 8-year exemption of corporate income tax, an additional 5-year 50% reduction of corporate income tax on net profit, a 10-year double deduction on transportation, electricity and water supply costs, and a deduction from net profit of 25 per cent of investment in infrastructure installation and construction cost (TIR, 2017).

3. National and Institutional Strategies

3.1 National Strategies for Research and Development

Research activities are focussed on genomic technology, genetic engineering and cell factory systems in combination with other technologies along with conventional plant breeding to enable the following:

(i) **Crops and livestock improvement:** Increase productivity, pests and disease resistance, and research on emerging industrial demands such as development of high-starch and fine pellet cassava or high-protein and antioxidant-rich rice, and adaptation to changing climatic conditions, *e.g*. developing drought-resistant rubber. In case of livestock, genetic development can generate more productive and faster-growing farm animals such as high-meat content pigs, higher yields of healthy piglets per mother and dairy cows that remain productive in warmer climates.

(ii) **Agricultural inputs' improvement:** Diversify and increase productivity of microorganism for soil nourishment by modifying organic fertilizers, pesticides and livestock food supplements to reduce antibiotics, and by developing easy-to-use vaccines and test kits for accurate disease diagnosis.

(iii) **Value-added products:** Increase agricultural and food production value by utilizing farm wastes as inputs for other industries. Such waste could aid in the production of sweeteners, bioenergy, biopolymers and other biochemical products as well as food supplements such as dissolvable fibers, low-calorie food, fat substitutes and biochemical substances (BIOTEC, 2018a).

3.2 Capacity Development

To enable the Thai government's move to smart growth and Thailand 4.0, the government has adopted a policy to reform the agriculture sector to ease problems faced by Thai farmers and to support national development by transitioning to "smart farming" and "precision agriculture". During 2005-2008, more than 80 extant businesses incorporated biotechnology R&D in their work processes and there were 50 new emerging biotechnology companies in Thailand.

Government agencies and universities provide supporting services to stimulate biotechnology businesses. R&D infrastructures such as Biopark in the expansion phase of TSP became operational after 2010. The NSTDA, NCGEB, TCELS, and BOI under the direction of the Ministry of Industry are major agencies committed to strengthening Thailand's competitiveness in biotechnology (Chanvarasuth and Indaraprasirt, 2009). TSP is a key hub for R&D where specialists and researchers from industry, academia and NSTDA collaborate to further inspire and stimulate the formation and growth of knowledge-based businesses. A network of 1,600 full-time researchers and technicians, of which around 400 hold doctorate degrees, can be found at TSP.

3.3 Infrastructure Development

Government and organizational support for infrastructure is provided through the NSTDA, which is home for four national research centers (BIOTEC, MTEC, NANOTEC, and NECTEC) and one TMC. The NSTDA acts as a bridge between the requirements of academic research and innovation in the industry. TMC also provides important support in biotechnology through its Technology Licensing Office, which is responsible for the licensing of intellectual property (TIR, 2017).

TSP, the first technology and innovation hub of Thailand, with state-of-the-art R&D infrastructure in an atmosphere that supports an innovation-driven ecosystem, is helpful for those who are engaged in scientific and technological research. The park offers a full range of value-added services to support technology businesses including rental space for laboratories, vacant land for the construction of research centers and pilot plants, testing service centers and banking services. Over 80 companies have already set up their laboratories at TSP, of which 30 per cent are international companies such as Sumitomo, Zoetis and Haydale. Many leading Thai companies such as Betagro, SCG, PTT, and Mitr Phol are also represented (SlideShare, 2017).

3.4 Communication Strategy

There is need to increase community access to biotechnology by simplifying research products and developing technologies appropriate to their localities. Pilot farms with community participation and local administration leadership need to be established, and support to these farms through existing mechanisms such as technology assistants, local/village agricultural technology transfer centers and local universities is required.

3.5 General Awareness

Consumer knowledge and acceptance of products from agriculture biotechnology needs to be enhanced.

3.6 Policy Advocacy

Strategy: Apply genomic technology, genetic engineering and cell factory systems in combination with other technologies along with conventional plant breeding for crops and livestock cultivation improvement, agricultural inputs' improvement and development of value-added products.

There has been little policy and regulatory progress in the area of AB since the Cabinet agreed to revoke the ban on biotech field trials in December 2007.

4. Specific Research Focus

- Accelerate R&D for crop/livestock strains of desired qualities
- Improve inputs such as high-performance microorganism strains for organic fertilizer and livestock feed supplements
- Initiatives to stimulate funding for R&D within the food sector, both to stimulate innovation and to enhance basic science research, could be derived in part from agricultural and food export taxes

5. Priority Areas of Agricultural Biotechnology

5.1. Different sectors/areas of agriculture where biotechnological innovations/ tools can be applied

(i) **Food and Agriculture:** Advance market competitiveness and strengthen agricultural sustainability by increasing quality, productivity and innovation while reducing costs.

(ii) **Medicine and Health:** Advance wellness, improve self-reliance and increase competitiveness in medical and healthcare fields, where Thailand has a comparative advantage

(iii) **Bioenergy:** Increase energy security by developing alternative energy sources without compromising food production or environmental sustainability

(iv) **Biobased Industry:** Increase industry commitment to environmental protection through more resource efficient production and stimulating innovation in fields where Thailand holds a comparative advantage

5.2 Priority areas in Plant, Animal, Aquatic Biotechnology for Low- and High-tech Biotechnology

Advance market competitiveness and strengthen agricultural sustainability by increasing quality, productivity and innovation while reducing costs. Increase biotechnology's role in crops and livestock cultivation, especially through their inputs (e.g. fertilizer, herbicide, pesticide and feed) to raise food production efficiency and to contribute to environmentally responsible and sustainable agricultural production. Crop productivity can be achieved through management technology gains and the application of biotechnology to improve yields up to a crop's maximum genetic potential. Increase agricultural quality and productivity to yield a 50 per cent increase in the sector's value chain through genetic improvements, quality and safety controls, nutrient labeling and product diversification and innovation.

6. Major Challenges and Opportunities

6.1 Challenges

The Policy Framework's key factors in the development of Thailand's biotechnology include

- Establishment of a public-private research matching fund for demonstration plants.
- Tax benefits allowing 300 per cent annual deductions for research and technology development expenses.

6.2 Opportunities

Thailand offers a number of outstanding opportunities for companies in the biotech industry as given below:

(i) **Skilled Labour:** Thailand boasts a robust and technically-equipped workforce, which is well supported by numerous trainings and development programmes conducted by government agencies and organizations.

(ii) **Access to Markets:** The reduction of tariff and non-tariff barriers articulated in free trade agreements between Thailand and India, China, Japan, Australia and Association of Southeast Asian Nations (ASEAN) extend trade opportunities with neighboring countries. Thailand has the advantage because of bilateral and multilateral collaboration, excellent infrastructure, abundant raw materials, skilled labor, government support, and the central location among ASEAN countries with close proximity to India and China (Thailand Board of Investment, 2018a).

7. Future Outlook

Thailand is among the world's top ten exporters as a result of increase in high-valued agriculture and food products. There are three major segments in this industry in Thailand, namely, medical biotechnology, agriculture-biotechnology, and cosmetic-biotechnology, which have been growing significantly and still have considerable potential for future growth.

7.1 Medium-Term (5 years)

- Thailand achieves higher competitiveness in global food and agriculture markets and the product market value increases 30 billion Baht per year due to increase in production efficiency and innovation
- A 30:70 private-public investment ratio in biotechnology R&D
- Thai biotech business expansion across the Asian Economic Community

7.2 Long-Term (10 years)

- A 50:50 private-public investment ratio in biotechnology R&D

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Country Status Report – Vietnam

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1. Introduction

Vietnamese agricultural sector identified biotechnology as a key strategic spearhead to deal with the problems of developing sustainable agriculture to ensure national food security, thereby contributing to the world's food security. Biotechnology in Vietnam's agricultural sector has achieved significant success, which include the application of gene technology in selecting varieties that have high yield and good quality and are resistant to diseases; cytological technology in propagation of promising varieties in both crop and animal sectors; creating biological products such as biofertilizers and biopesticides, biomaterials in treating aquaculture environment *etc.* In the present report, attempts are made to understand the existing policies/regulatory procedures of the country that govern the biotechnological research, financial indicators, (Table 1) implementing agencies, priority areas of research and opportunities for international collaboration.

Table 1. Basic Information

Indicator	Details
Value of GDP in local currency (Trillion VND) VND= Vietnamese Dong	5007.90*
Value of GDP (Billion USD)	223.86**
Value of agriculture GDP (Trillion VND)	768.23@
Value of agriculture GDP (Billion USD+)	32.97
Agriculture GDP as per cent of GDP	15.34***
Total investment in agriculture Research (Billion VND)	~ 1400
Total investment in agriculture Research (Million USD+)	~ 60.07
Total investment in agricultural biotechnology (AB) research (Billion VND)	~ 150.00
Total investment in AB research (Million USD+)	~ 6.43

*Source: *VnEconomy (2017); **World Bank (2017); ***GSO (2017); @15.34 percent of value of GDP; + 1USD=23303 VND*

2. National Policies

2.1 Current National Policies on Agricultural Biotechnology and Policies for Enhancing the Livelihood of Farmers through Agricultural Biotechnology

Dr Pham Van Toan is the Vice President of VAAS, Vietnam. Dr Pham post graduated in Germany. He served in various capacities as Head of Department of Agricultural Microbiology, Vietnam Agricultural Science Institute and at Soil and Fertilizer Research Institute; Director, Office for Biotechnology Programme in the agriculture and Director of Post Graduated Training Department, VAAS. Dr Pham's interests include research on biofertilizers, organic fertilizer, biocontrol of plant diseases and GMOs. He has several national and international publications to his credit. Dr Pham is also the Member of Biosafety Committee and the Food, Feed Safety Committee of Ministry of Agriculture and Rural Development.

2.1.1 The Action Plan to Promoting the Development and Application of Biotechnology for National Industrialization and Modernization (Decision No. 188/2005/Qd-Ttg of Prime Minister on July 22, 2005)

General objectives are creating, receiving, mastering the key biotechnology areas and applying successfully in the fields of agriculture, fisheries, healthcare, industrial processing and environmental protection; creating new bioproducts such as plant varieties, animal breeds, microorganisms, industrial processing products with high yield, high quality, competitiveness and high economic efficiency; forming and developing the small and medium bioindustry enterprises for the production and commercialization of biotechnological products for consumption and export (Vanbanphapluat, 2018).

The objectives of 2020 are as follows:

(i) To train scientific and technological human resources in the biotechnology domain with high qualifications and good qualities capable of creating and mastering technologies in the field of biotechnology in service of economic development, social and environmental protection.

(ii) To build a number of advanced and modern centers for scientific research and technological development on international standard biotechnology.

(iii) To form and develop a bioindustry capable of producing key and essential products for the national consumption.

2.1.2 The Key Programme for the Development and Application of Biotechnology in Agriculture and Rural Development up to 2020 (Decision No. 11/2006/QD-Ttg of the Prime Minister on January, 12. 2006)

The general objective is to develop new plant varieties, animal breeds, microbial strains, and biological products with high yield, good quality and economic efficiency, enhancing the quality and competition of the agricultural products, increasing the agriculture, forestry, aquatic processed products (Faolex, 2006).

The outlook of 2020 are:

(i) To achieve progress in AB in Vietnam at par with the level of advanced countries in the region.

(ii) To create crop varieties by methods of biotechnology so as to cover 70 per cent of total cultivation area. GM crop will share 30-50 per cent of area cultivating new crop varieties. A 70 per cent demand for high quality seedlings will be covered by micropropagation. Biological products (biocontrol and biofertilizer) will be applied in 80 per cent area of vegetable cultivation. Main demand of the country on veterinary vaccine will be covered.

(iii) Biotechnology will share over 50 per cent of contribution of science and technology to agriculture growth.

2.1.3 Scheme Development and Application of Biotechnology in the Field of Processing Industry until 2020 (Decision 14/2007/Qd-Ttg of the Prime Minister on January 25, 2007)

Overall objectives are to research and create biotechnological advances in the country, applied widely and effectively in the field of food processing industry to enhance the quality and competitiveness of processed products to better serve the needs of domestic consumption and export and setting up the production in industrial level of enzyme (including recombinant enzymes), proteins, organic acids, amino acids, microbial products including genetically modified organisms (GMOs), the active ingredient, biological additives, biofuels *etc.* to meet the needs of the processing industry and better to serve the industry, agriculture, fisheries and health (Faolex, 2007).

To research and create advanced biotechnologies in the country in combination with importing modern biotechnologies from foreign countries for wide and effective application to food processing and consumer goods production in order to raise the quality and competitiveness of processed products and better meet the domestic consumption and export demands.

2.1.4 Scheme on Development and Application of Biological Technology in the Fisheries Sector to 2020 (Decision No. 97/2007 / Qd-Ttg of the Prime Minister on June 29, 2007)

The general objectives are to create new aquatic animal breeds of high yield and quality and biotechnological preparations for aquaculture development. To research into and apply post-harvest and processing technology, raise the proportion of aquatic and marine products processed by biotechnology, improve the competitiveness of these products on the market and better serve consumption and export demands (Faolex, 2007a).

Outlook of 2020:

(i) To bring aquatic biotechnology up to the level of advanced countries in South-East Asia.

(ii) Establishing the network of medium and small-sized aquatic biotech - enterprises in the disease prevention and aquatic product processing.

(iii) To ensure 100 per cent of the demand for high-quality and disease-free breeds of key reared aquatic animals (black tiger prawn, sutchi catfish, tilapia, giant river prawn, sea crab, snapper, porgy, cobia, grouper and clam) suitable to different ecological areas.

(iv) To increase the yield of key reared aquatic animals by 30 per cent based on biotechnology development and application in the fisheries domain.

2.1.5 Approving the Master Plan on Biotechnology Development and Application in Vietnam up to 2020 (Decision No. 14/2008/Qd-Ttg Dated January 22, 2008 of the Prime Minister) (FAO, 2018)

(i) To research, develop, and apply biotechnology in a wide and effective manner to production and life.

(ii) To build bioindustry into a hi-tech economic sector capable of producing key and essential products and greatly contributing to national economic growth.

(iii) To concentrate resources on and diversify forms and the effectiveness of investment in biotechnology, form and develop a biotechnology market.

2.2 Implementation of Policies

2.2.1 Government Bodies Responsible for Implementing Each Policy

Table 2. Ministries responsible for implementation of policies related to biotechnology and biosafety

Ministry	Responsibilities
Ministry of Science and Technology (MOST)	Elaborating and setting up the master plan on biotechnology development in Vietnam up to 2020
	Elaborating and setting up the network planning and capacity building of biotechnology research institutes, centers and laboratories in Vietnam
	Elaborating and setting up the “Promoting international cooperation and integration in biotechnology research, application and development” and the scheme on "Perfecting the system of legal documents, mechanisms, policies and institutions on biotechnology”
Ministry of Natural Resources and Environment (MNRE)	Elaborating and setting up the scheme on development and application of biotechnology in the field of environmental protection
Ministry of Agriculture and Rural Development (MARD)	Elaborating and setting up the key programmes on biotechnology development and application in the field of agriculture and rural development up to 2020
Ministry of Fisheries	Elaborating and setting up the scheme on development and application of biotechnology in the aquaculture up to 2020
Ministry of Industry	Elaborating and setting up the scheme on development and application of biotechnology in the processing industry
Ministry of Education and Training (MOET)	Elaborating and setting up the programmes on training human resources for biotechnology in Vietnam

2.2.2 Scientific Research and Technological Development

During 2007 to 2017, some new plant varieties of rice, maize, tea, coffee, and potato were created by using biotechnological methods and nationally recognized and permitted for cultivation in Vietnam in field trials. Many biological agents were developed for biocontrol of plant and animal diseases; and biofertilizers, or biopreparations for soil improvement, environmental treatment and animal feed. The bioproducts have been scaled up through effective pilot production and transfer into production, some of which have been registered in the list of fertilizer or plant protection agents permitted to commercialization in Vietnam. Micropropagation of flowers, potatoes and forestry trees is established on an industrial scale and provided millions of seedlings for production each year.

In order to promote the development and application of genetically modified (GM) plants in Vietnam, the MARD has granted permits for the field testing of GM maize and recognition of test results. On that basis, the MNRE has reviewed and issued the biosafety certificate for four transgenic events of maize. Till now, the MARD has approved eight GM maize varieties for cultivation and at the same time approved the food and feed safety for 20 corn and soybean events.

In the field of animal breeding, molecular and gene technology has been used to identify effective genetic source (genes of high economic value, disease resistance and abiotic tolerance) for the breeding of cows, pigs, chickens. Reproductive technologies have improved the reproductive efficiency of pigs and cows.

In the fisheries sector, during 2007-2014, new fish and shrimp breeding techniques and technologies were applied to produce pathogen-free and fast growing breeds. Vaccine and biopreparations were developed to control fish and shrimp diseases as well as the biopreparations to treat the environment of fish and shrimp racing or improve the feed quality or feeding efficiency (Vietnamnet, 2018).

2.2.3 Capacity Building

Biotechnology human resource training has been carried out in various forms, which include post-graduate training abroad, short-term training in foreign countries, domestic training by topic and short-term technician training. Qualified students in good numbers have been assessed and selected for biotechnology training. Up to 2015, Vietnam sent 499 students for doctoral and master programmes abroad and carried out the short-term training for 1,504 technicians in the field of AB.

During the past 10 years, the MARD has invested in 17 laboratories in different research institutions and universities to strengthen the infrastructure in biotech research and development (R&D), which includes the laboratory for GMO detection.

2.2.4 International Cooperation

During 2006-2015, international cooperation in the field of biotechnology and biosafety management was implemented with a strong and positive contribution in training the human resources, developing the legal documents of GM crops *etc.* The cooperation includes sending experts to biotech leading countries like United States, China, Japan, Germany, the Netherlands, Australia, Spain, Russia, Israel, the Philippines and India to learn the application and development of biotechnology, the policy, organization and management of biosafety and build cooperation programme for research and training as well as holding media conferences on achievements and application of modern biotechnology in agriculture, the policy on biotechnology management and biosafety of GMOs.

2.2.5 Information and Communication

Modern means of propaganda and dissemination of knowledge are important to understand the true, accurate, and multidimensional achievements of biotechnology in the world by the managers, scientists and citizens and gain the ability to put them in use in Vietnam. Information and communication was diversified across multiple communication channels like website, television, radio, newspaper, conferences and seminars. In cooperation with foreign organizations [Crop Life Asia Business Forum, The International Service for the Acquisition of Agri-biotech Applications (ISAAA), Programme for Biosafety

Systems (PBS), International Life Sciences Institute] a series of conferences, seminars and workshops were organized in Vietnam to present the achievements of modern biotechnology, the safety of GM crops and the new knowledge of biotechnology.

2.3 Capacity Development

2.3.1 Existing Capacity Level

Biotechnology laboratories in Vietnam belong to different ministries and local people committees. At present Vietnam has 12 university and 44 research institutes working in area of biotechnology with more than 5,000 scientists and technicians. Seven national key biotech laboratories are already established, which include two laboratories of gene technology, one laboratory of animal cell technology, one laboratory of plant cell technology, two laboratories of enzyme, protein technology and one laboratory of microbial technology for industrial production.

2.3.2 Required Capacity for Future

Although enough focus was given on the infrastructure development and training of human resources for biotechnology, the progress made in biotechnology research, development and the bioindustry is still on a low profile. Hence, human resources training and strengthening of laboratories should be continued.

2.4 Partnership

2.4.1 Existing Major Partnerships

During 1990-2005, major participation in biotechnology R&D was mainly between the research institutions and universities. However, when the key programme on biotechnology development and application was implemented, private sector companies, and international organizations were involved in the biotech development and application.

2.4.2 Scoping of New Partnerships

According to the master plan for bioindustry development up to 2030, the bioindustry enterprises include domestic public and private bioindustry enterprises and international bioindustry enterprises.

2.5 Funding Mechanism

2.5.1 Public Funding

The government will support for the R&D, capacity building, international cooperation and information, communication on biotech development and application. The government will also review and supplement mechanisms and policies to encourage enterprises to invest in industrial-scale production and commercialization of biotech products according to the market mechanism.

2.5.2 Private and Other Sources

These will make new investment and upgrade bio-industry enterprises in research, development and production of biotech products to meet the needs of the economy and exportation.

3. National and Institutional Strategies

3.1 National Strategies for Research and Development

The key programme for the development and application of biotechnology in agriculture including fisheries sector will be continued up to 2030. It concentrates on the R&D of new plant varieties, animal and aquatic breeds, tolerance to abiotic stress, resistance to disease, high yield and quality, creating and developing bioproducts used in sustainable plant, animal and aquatic production, harvest and post- harvesting.

On April 21, 2017, the Prime Minister of Vietnam approved the master plan for the bioindustry development up to 2030 (Decision No. 553/QĐ-TTg of the Prime Minister), which aims to concentrate the resources on investment for developing the bioindustries, renewing mechanisms and policies, taking advantage of international cooperation and support for creating favorable conditions for enterprises to invest in production of biotechnology products in the fields of agriculture, industry, medicine and environmental protection. The bioindustry enterprises in the agricultural sector will concentrate on production of plant varieties, animals and aquatic breeds, production of organic fertilizers, biofertilizer, biopesticide, bioinsecticides, biopreparation used in environmental treatment, animal feeds, vaccines, biomedical to control animal and aquatic diseases and the biological products for food, feed preservation and processing as well as bioproducts for control of residues or prohibited substances in food and feed (ThuVienPhapLuat, 2017).

3.2 Capacity Development

On December 25, 2015, the Prime Minister of Vietnam approved the plan for the training of science and technology human resources (*Decision No. 2395/QĐ-TTg of the Prime Minister)* aimed to contribute to improving the professional qualifications, knowledge, management skills, researching, mastering the hi-tech of human resources and to form a working team of highly qualified scientific and technological experts in science and technology to meet the requirements of country's socio-economic development. It is presumed that by the end of 2025, about 350 experts and 130 research groups will be trained abroad in order to form a contingent of scientific and technological experts with professional qualifications and form the strong research groups capable to solve the tasks. Post-doctoral training for 300 scientists in abroad and training for 500 technological managers within the country in the area of modern biotechnology is expected to be completed by 2025 (ThuVienPhapLuat, 2015).

3.3 Infrastructure Development

The Prime Minister of Vietnam approved the plan of setting up a network for research institutes, research centers and biotechnology laboratories up to 2025 (Decision No. 1670/QĐ-TTg of the Prime Minister on November 28, 2015) to create mutual links for mutual assistance, capacity building and efficiency in research, application and development of biotechnology (ThuKyLuat, 2015).

The Institute of Biotechnology (IBT) of the Vietnam Academy of Science and Technology (VAST) is a national leading research institution in the fields of biosciences and biotechnology. Its main activities are R&D in genetics, animal and plant biotechnology, biotechnology of microorganisms, proteins and enzymes, environmental biotechnology, marine biotechnology, biomaterials technology, bionanotechnology, medical biotechnology, bioinformatics and related fields.

By 2020, Vietnam will invest and develop three national biotech centers based on the IBT of the VAST, the IBT Hue University and the Center for Biotechnology Ho Chi Minh City. Further, the government plans to develop 10 national key laboratories for gene technology (2), plant cell technology (2), animal cell technology (1), enzyme and protein technology (2), microbial technology (1), stem cell technology (1),biomedical medicine (1), as well as strengthening at least 20 biotechnology laboratories of institutes and universities. The national key laboratories of institutes and universities will continue consolidating, developing and intensifying in-depth investment in networking from the central to local levels for the performance of their functions and tasks.

3.4 Communication Strategy

(i) Promote information, communication and education to raise awareness among all sectors of people about the important role of biotechnology in the socio-economic development and in the agricultural sector.

(ii) Organizing the dissemination of the policy and action plan of the government to create a strong change in the awareness of all sectors and people on the function and role of biotechnology and bioindustry for the industrialization and modernization of the country.

(iii) Disseminating the results of biotechnology research, development, technology transfer and introduction of models of bioindustry enterprises.

(iv) Propagate and encourage the use of domestic bioproducts and build Vietnam's trademark of bioproducts.

3.5 General Awareness

In Vietnam, biotechnology is identified as an essential and important prerequisite for achievement of national goals. Since 1995, biotechnology is one of the government's first priorities for scientific research and now becomes one of the four leading technological areas that play an important role in the national industrialization and modernization.

3.6 Policy Advocacy

For biotechnology development and application, Vietnam government will review and supply mechanisms and policies to encourage enterprises to invest in the production and commercialization of biotechnology products. It includes:

(i) Preferential policies for investment and establishment of bioindustry enterprises as well as preferential policies for the tax of land use, supporting for loans and technology transfer.

(ii) Preferential policies on enterprise income tax, export tax, import tax, high-income tax, personal income tax and other forms of tax preferences for enterprises, organizations and individuals having the activities of producing and trading bioproducts in Vietnam.

(iii) To mobilize resources and create favorable conditions to attract new domestic and foreign investments in biotech research, development or technology transfer and upgrade bioindustry enterprises.

4. Specific Focus on Research

Basic research concentrates on gene and cell technologies such as gene mapping, genomics, gene expression for establishing the scientific background for development of GM crop and microorganism. Applied research in biotechnology is mainly to create new plant varieties, animal, aquatic breed with good agronomic characteristics (high yield, good quality, biotic and abiotic stress tolerance or resistance), develop new techniques for plant, animal, aquatic disease diagnosis and bio preparation for disease control, enhance the nutrition uptake by plan or nutrition digestion by animal as well as apply and develop the propagation industry in whole country to meet the demand of high quality and disease free seedlings.

Vietnam has the policy to increase international cooperation in the field of AB through developing the bilateral and multilateral cooperation programmes and projects with biotechnologies in developed countries in order to make the fullest use of the intellectual properties.

5. Priority Areas of Agricultural Biotechnology

According to the key programme for the development and application of biotechnology in agriculture including fisheries sector, plant, animal, aquatic and microbial biotechnology will be the priority areas of Vietnam AB. Regarding the conservation and sustainable use of bioresources, finger printing (molecular makers) will be used in the evaluation, characterization and utilization of plant, animal, aquatic genetic resources for breeding and better use of local plant, animal, aquatic genetic resources.

6. Major Challenges and Opportunities

6.1 Challenges

In the past, biotechnology in Vietnam primarily focused on development of new plant varieties, animal and aquatic breeds, biopesticides, biofungicides, biofertilizers, tissue culture seedlings and some other products used for the control of animal and aquatic diseases. There are no successful results in the development of GM forest and industrial crops. Biotechnological research should be expanded in the fisheries sector.

6.2 Opportunities

The capacity building in biotechnology in Vietnam is improved but yet to meet fully the demand on the research, development and application of biotechnology in the agriculture. Vietnam government already approved plan for biotechnology capacity building, plan for bioindustry and will continue the "Key programmes on biotechnology development and application in the field of agriculture, fisheries" up to 2030. This is a good opportunity for biotechnology development and application in Vietnam.

7. Future Outlook

By 2020, different ministries (MARD, MOST, Ministry of Trade and Industry) will complete the targets assigned under different policies, namely, "Master plan on biotechnology development in Vietnam up to 2020", the "Key programmes on biotechnology development and application in the field of agriculture and rural development up to 2020", the scheme on "Development and application of biotechnology in the aquaculture up to 2020" and the scheme on "Development and application of biotechnology in the processing industry", and if needed, would be extended up to 2030.

The "Master plan for the bioindustry development up to 2030", the "Plan for training of science and technology human resources" and the "Planning of the network for research institutes, research centers and biotechnology laboratories up to 2025" are in vogue and would be completed by 2025 and 2030, respectively.

8. Conclusions

Biotechnology is identified as an essential and important pre-requisite for achievement of national goals of Vietnam and is one of the four leading technological areas that play an important role in the national industrialization and modernization.

In the last 10 years, in Vietnam, AB contributed actively in the development of agriculture sector. Priority is given for biotechnology development, application and the government encourages all domestic, international organizations and enterprises to do the research, development and application of biotechnology in agriculture sector.

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Country Status Report - Papua New Guinea

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1. Introduction

Agriculture in Papua New Guinea (PNG) has a huge untapped potential for application of biotechnology, which needs to be explored through a multi-pronged strategy involving modern and improved agricultural technologies. PNG is a nation, rich in genetic resources, which include cultivated varieties, landraces, genetic stocks, wild and weedy species, trees and shrubs. These resources provide unique opportunity not only for improving productivity but also for creating more desired diversity and using these for alternative purposes. However, without the application of some aspects of biotechnology, it is not possible to explore this opportunity for deriving such potentially available benefits.

The National Agricultural Research Institute (NARI) supports crop improvement initiatives at all stages, from laboratory research to field trials to commercialization and the delivery of technology. Importance of biotechnology policy is emphasized in this report in order to enhance food and nutritional security by compiling the status of agricultural biotechnology (AB) highlighting PNG-specific needs. While presenting the indicators, it is pertinent to mention that the agricultural GDP is slightly underestimated as large part of domestic food production, which does not pass through formal markets, is not captured. Total investment in agricultural research includes investment into research and development (R&D) organizations that also deliver on extension and other services in the sector. Based on a current survey on investment in agricultural research by APAARI/IFPRI in 2018, the estimate on investment for AB research is only based on authors' personal experience (Table 1).

Table 1. Basic Information

Indicator	Details
Value of GDP (Billion PGK) PGK= Papua New Guinean Kina	67.24*
Value of GDP (Billion USD)	21.09
Value of agriculture GDP (Billion PGK+)	1.02
Value of agriculture GDP (Billion USD)	3.19
Agriculture GDP as percent of GDP	17.81***
Total investment in agricultural research (Million PGK)	~40.50@
Total investment in agricultural research (Million USD+)	~12.95
Total investment in AB research (Million PGK)	~0.20
Total investment in AB research (Million USD+)	~0.06

*Source: World Bank (*2017; **2017a; ***2014); +1 USD=3.1276 PGK*

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2. National Policies

2.1 Current National Policies on Agricultural Biotechnology and Policies for Enhancing the Livelihood of Farmers through Agricultural Biotechnology

PNG does not have any existing national policies, laws or other legislative instruments that govern AB in general or its the use for enhancing the livelihood of farmers. In the past, there have only been attempts made to develop policies and relevant legislations as part of managing PNG's substantial biological diversity.

2.1.1 Convention on Biological Diversity (CBD), 1993

In 1993, the PNG Government ratified the CBD. PNG was part of a multi-country United Nations Environment Programme-Global Environment Facility (UNEP-GEF) funded project during 2002-2005, aimed at assisting countries to develop a National Biosafety Framework, which was an obligation under the Cartagena Protocol on Biosafety.

2.1.2 PNG Biosafety Framework, 2005

The PNG Biosafety Framework was completed in 2005, followed by the accession of the country to the Cartagena Protocol on Biosafety in 2006. The PNG Biosafety Framework has five key elements (CBD, 2018).

- National Biosafety and Biotechnology Policy
- Regulatory Regime (Biosafety and Biotechnology Bill)
- System to handle notifications and requests
- System for follow-up actions such as monitoring and enforcement
- System for public information and participation

2.1.3 Draft Biosafety and Biotechnology Policy and the Draft Biosafety and Biotechnology Bill, 2006

A draft Biosafety and Biotechnology Policy and the Draft Biosafety and Biotechnology Bill were produced as part of the UNEP-GEF project but by the end of the project in 2006, both documents had not been endorsed by PNG National Executive Council to be tabled and approved in Parliament.

2.1.4 National Biodiversity Strategy and Action Plan (NBSAP), 2007

As part of the obligation to the CBD, the country developed the National Biodiversity Strategy and Action Plan (NBSAP) that was finalized in October 2007 (NBSAP, 2007). The NBSAP is the roadmap to the sustainable use and management of the country's biological resources. It has nine broad programmes that are designed to achieve the six main goals of the strategy. The NBSAP contains some strategies with relevance to biotechnology and biosafety.

The programme 'Policy and Legislation' includes activities to obtain:

- Parliamentary approval of Biosafety Policy and Bill
- Implement Biosafety and Biotechnology Policy and Law

The programme 'Research and Information on Biodiversity' contains strategies to:

- train personnel in the field of plant and animal molecular genetics (especially DNA barcoding) through developing a strategic partnership with reputable international institutions, and
- establish a molecular genetics laboratory at the University of PNG and other Universities or research institutions.

2.2 Implementation of Policies

Conservation and Environment Protection Authority (CEPA) is the government body that is responsible for the implementation of CBD and related national policies, legislations and strategies. CEPA was established under the Conservation and Environment Protection Act, 2014 (CEPA Act) and took over the role formerly undertaken by the Department of Environment and Conservation as PNG's environmental regulator.

As mentioned above, draft policies and regulatory frameworks in relation to biosafety and biotechnology have to date not been tabled to Parliament, making it difficult to apply and use the full range of biotechnological advances for improving productivity and efficiency of agricultural production in the country.

2.3 Capacity Development

One of the major obstacles in progressing with the development and implementation of relevant policies, laws and associated enforcement mechanisms in AB or biotechnology in general is the lack of capacity in policy development and legislative process, shortage of expertise in advising policy makers on the technical details of a policy and funding to engage in relevant stakeholder consultations. Hence, capacity development and associated funding support is required at various levels in the future. PNG is reliant on support from external donors and funding bodies to progress in the areas of AB policies and application.

2.4 Partnership

PNG receives support from a wide range of international partners. As mentioned above, the UNEP supported PNG with the development of the Biotechnology and Biosafety Framework. PNG is also a member of the Asia-Pacific Economic Cooperation (APEC) and has been participating in the High Level Policies Dialogue on Agricultural Biotechnology (HLPDAB) since the inception in 2001 and implemented several projects (Table 2).

Table 2. Projects implemented as part of the HLPDAB

Project title	Project number	Proposing economies	Project years
Workshop on public perception of AB	DAB 01 2007	Canada	2007-2008
Bilateral exchanges to strengthen AB policy environments in APEC Economies (Phase II)	DAB 01 2008T	United States	2008-2009
Low level presence of products of AB in agricultural shipments - towards an alignment of APEC Member Economy Policies	DAB 01 2010T	United States	2010-2011
Plant biotechnology life cycle		United States	September 14-15, 2014, Beijing, China
Fostering the benefits of innovation in plant breeding and science communication		United States	April 2015, Manila, Philippines
Strengthening innovation and cooperation among APEC economies to advance science and facilitate trade	HLPDAB 01 2016T	United States	2016
Innovations in plant breeding: Leveraging innovation for economic development through enabling policy environments		United States	August 1,2018 (Proposed)

PNG will host the 2018 APEC cycle and aims to maintain coherence with the previous hosts on policy dialogue, and consistent with the current 2016-2018 HLPDAB Strategic Plan as endorsed by Senior Officials Meeting.

PNG has presented its initial indications of the HLPDAB agenda for the during the APEC Food Security Week (FSW) 2018, at Can Tho, Vietnam, in August 2017. Consistent with the strategic objectives of APEC Food Security Road Map 2020 and HLPDAB Strategic Plan 2016-2018, and in trying to maintain coherence to and continuation of themes that were identified by Philippines 2015 and Peru 2016, the following themes were presented:

- Update and exchange of information on policy issues, challenges and lessons learnt on the application and use of agricultural biotechnology (AB) for sustainable agricultural and fisheries production to enhance food and nutrition security, trade and marketing of products derived from AB.
- Potential of AB for climate smart agriculture to enhance the adaptation, mitigation and resilience of food farming systems and value chains to sustain production, productivity and income and improve food and nutrition security under climate change conditions.
- Update on regulatory issues and challenges for AB focusing on the harmonization of regulatory process between economies to speed up the import approval process for the trading of products derived from AB.

The HLPDAB work for 2018 will contribute towards enhancing food security through smart innovative agriculture. PNG would, therefore, propose the following consolidated themes through two Concept Notes in 2018:

- Towards alignment of national regulations on labelling of food products derived from the application of modern biotechnology to be consistent with international standards and guidelines to reduce technical barriers to trade and enhance food security in APEC economies I (depends on the passing of the Biosafety and Biotechnology Bill in Parliament).
- Use of advanced breeding methods and pests and disease diagnostics to enhance and sustain food production under changing climatic conditions.

While PNG is actively participating in the policy dialogue regarding AB, more initiative and stronger action needs to be taken to translate those high level discussions into national policies and associated laws and regulations.

2.5 Funding Mechanism

At present any funding that has been provided towards the development of policies in biotechnology has come from donors or external funding bodies. Departments in the PNG government are chronically underfunded and do not have the required level of technical expertise to progress with relevant policies on biotechnology and biosafety.

So far, there is no interest by the private sector to engage in discussions, dialogue or to engage in public-private partnerships in the area of policy development in biotechnology and biosafety.

3. National and Institutional Strategies

3.1 National Strategies for Research and Development

In the absence of National Policy Frameworks on AB or biotechnology in general, there are also no national strategies developed for PNG. The PNG National Agricultural Research System comprises number of organizations that are involved in agricultural research for development, and most of them use some AB tools and methods as part of their work (Table 3). None of the institutions have any particular strategy for any areas of AB. Table 3 shows the list of organizations and the main biotechnology applications used in the past and at present.

3.2 Capacity Development

Currently, very few avenues exsit in the country to develop skills and competency in AB. The country has only six universities and two of them are conferring degrees in Agricultural Sciences. Only the PNG University of Technology (UoT) has 'Agricultural Biotechnology' included as a subject in its 4-year Bachelor of Science in Agriculture programme. The UoT also offers Masters and PhD programmes in Agricultural

Table 3. Biotechnology applications in PNG agriculture research for development organizations

Name of the Organization	Biotechnology applications
NARI	• Micropropagation (potato, sweet potato, taro, yam, cassava) and *in vitro* conservation • Molecular and serological diagnosis of plant viruses and phytoplasma (PCR, ELISA, LAMP) • Barcoding for insect pests • DNA fingerprinting • Biopesticides (entomopathogenic fungi for control of sweet potato and taro pests)
Kokonas Indastri Koporesen (Coconut R&D)	• Micropropagation of coconut
Coffee Industry Corporation	• Micropropagation and somatic embryogeneisis of coffee • Molecular diagnosis of coffee pests
New Britain Palm Oil Ltd Biotechnology (private sector)	• Commercial clonal micropropagation of oil palm • Somatic embryogenesis and haploid breeding
Oil Palm Research Association (OPRA)	• Molecular diagnosis of pests and diseases • Clonal micropropagation
University of Technology Biotechnology Centre	• Molecular and serological diagnostics of plant viruses • Micropropagation of PNG staples • Gene expression analysis • Plant transformation • Biopesticides (entomopathogenic fungi) • DNA fingerprinting • Host-pathogen interaction in eaglewood
University of Papua New Guinea (School of Natural and Physical Sciences)	• Assessing chemical and molecular diversity in rare and valuable medicinal plants • Bioprospection of available biodiversity for useful active compounds with medicinal properties
University of Goroka (Centre for Natural Resources and Research Development)	• Bioprospecting of mushrooms

PCR: Polymerase Chain Reaction, ELISA: Enzyme Linked Immunosorbent Assay, LAMP Loop Mediated Isothermal Amplification

Sciences with applied AB tools featuring in some student projects depending on the funding availability. Overall, the capacity at the Department of Agriculture to provide capacity building in AB is very limited due to only few academic staff having necessary qualifications, limitations in funding and facilities. Current available manpower with the skills and competencies in AB have obtained their qualifications while pursuing higher degree studies overseas supported through various scholarships provided by development partners such as Department of Foreign Affairs and Trade, New Zealand Agency for International Development and Japan International Cooperation Agency.

3.3 Infrastructure Development

Existing infrastructure for conducting research using AB applications and tools are limited to a few laboratories as part of agricultural research establishments by the organizations listed in Table 3. Most of the agricultural research organizations in PNG have at least one purpose-built tissue-culture facility. However, a number of those facilities are defunct, either due to lack of skilled staff, high maintenance cost, breakdown of equipment and lack of funding to replace and maintain equipment and infrastructure. The UoT, NARI and OPRA have laboratories that allow use of basic molecular-based tools for disease diagnostics, plant breeding and diversity studies. There is a general need to improve the standards of the laboratories and upgrade them with more advanced equipment to meet accreditation requirements.

3.4 Communication Strategy and General Awareness

Agricultural research organizations or universities do not have any communication strategies to raise awareness on or promote the use of AB. Over the years, some limited awareness of biotechnology issues in the community was raised through programmes conducted by UoT Biotech Center, NARI and the CEPA but limited to urban population and schools. Such initiatives can be improved by well funded and coordinated awareness programmes as well as inclusion of biotechnology in secondary school curricula and expansion of university curricula.

3.5 Policy Advocacy

Policy advocacy has only been sporadic over the past few years and within the country limited to highlighting the need for development of relevant legislative and policy frameworks in media articles. This was mostly done by NARI, which has also been participating in regional initiatives such as the Pacific Island Biotechnology Working Group meeting in 2005. This was supported by Technical Center for Agricultural and Rural Cooperation (CTA) and facilitated by the SPC. The Working Group developed a range of recommendations in relation to biotechnology issues in the region including, policy, public awareness, regional cooperation, capacity building, science development and commercialization. The aim was for those recommendations to be considered in the Pacific Plan 2020. NARI also participated in the APAARI Expert Consultation on Biotechnology, Biosecurity and Biosafety in 2011, which generated a number of recommendations that would also inform policy makers. The APEC meeting hosted by PNG in 2018 and the HLPDAB will offer further opportunity to raise issues on the need for national legislation, relevant policies and strategies to progress in PNG in the area of AB.

4. Specific Focus on Research

The use of AB in the country is limited to application of biotechnology tools and methods developed elsewhere. Given the current status of capacity, infrastructure and policy support, this will likely to continue into the foreseeable future.

5. Priority Areas of Agricultural Biotechnology

There are growing opportunities for use of biotechnological innovations and tools in agricultural research to address the constraints and opportunities in agriculture sector development, as given below.

5.1 Plant and Animal Genetic Resources (PGR & AGR)

PNG has a large agrobiodiversity and is a center of diversity for a number of crops such as banana, breadfruit, sugarcane, sweet potato, taro, yam and many of the leafy vegetable species. There are also large number of local fruit and nut species with a potential for further domestication and commercialization. The major priorities are:

- Genetic diversity assessments and gene discovery research using DNA fingerprinting innovations
- DNA fingerprinting tools for establishment of core collections and inventories of this diversity for future use.
- Similar work needs to be done for local animal genetic resources with focus on poultry, pigs and goats to inform future genetic improvement of livestock resources.

5.2 Crop Improvement and Seed Systems

Biotechnological applications and tools will continue to be important for:

- Micropropagation as most staple crops in PNG are vegetatively propagated. It will have an increasing importance for the provision of pathogen-tested planting materials (*e.g.* potato and sweet potato). Besides, clonal propagation for establishing plantations of promising lines or cultivars of important agricultural crops will become important.

- Development of micropropagation techniques to support growing industries, *e.g.* galip nut (*Canarium indicum*), eagle wood including somatic embryogenesis, organogenesis, *etc.*
- Application of marker technologies to support marker-assisted breeding, mutation studies and dihaploid production for biotic and abiotic stresses in major staple crops.
- Application and/or adaptation of markers for sex determination (*e.g.* galip nut) and paternity testing in self- and cross-incompatible crop species such as sweet potato, cocoa, *etc.*

5.3 Pest and Disease Diagnostic and Management for Crops and Livestock

- Use of available diagnostic technologies based on PCR, Reverse transcription PCR (RT-PCR), serological tests, LAMP for detection, surveillance and monitoring of endemic and incursions of exotic pests and diseases
- Genetic diversity assessments using DNA fingerprinting for pest and disease populations
- Indexing of PGR for safe exchange of germplasm

5.4 Priority Areas in Plant, Animal, Aquatic Biotechnology for Low- and High-Tech Biotechnology

PNG has a large biodiversity, which is largely unexplored for natural products and biologicals that could be turned into a commercial value. Bioprospecting has been done for use for medicinal purposes but not for applications for food, nutrition and agricultural production. Recently, a large international agricultural supplies company has shown interest to work with PNG agricultural research institutions for bioprospecting to identify a) Genes and proteins; b) Chemicals (small molecules); c) Biologicals (*e.g.* microbes) that can be further developed into novel plant protection tools for economic pests and diseases worldwide. Application of advanced biotechnological tools in screening for genes and proteins and how they can be incorporated in target crops would be part of this work, offering opportunities to PNG scientists to increase their capacity in this area of work. Other areas of interest include further exploration and production of biopesticides using biotechnology innovation and tools.

6. Major Challenges and Opportunities

6.1 Challenges

The major challenge in PNG for the use of biotechnology innovations and tools are capacity gaps at various levels. At the national level, there is a lack of guiding laws, policies and strategies that would provide the legislative, regulatory and enabling environment to promote AB innovations. Similar to that at the institutional level while recognizing the value of AB tools and its use, application is only adhoc and dependent on external donor funding. In general there is shortage of skilled and competent scientific and technical staff in agricultural research institutions, and capacity building again relies on external funding for scholarships to go for higher degree studies abroad and maintenance and upgrading of in-country research facilities.

Another challenge is the absence of adequate laws and policies, which hampers the provision of intellectual property rights arising from application of AB, *e.g.* in priority areas of bioprospecting, gene and protein discovery, use of overseas PGR collections for crop improvement using biotechnology tools *etc.* PNG is a signatory to the CBD but has not yet ratified the Nagoya Protocol.

6.2 Opportunities

On the other hand, there are many opportunities where application of AB innovations would greatly assist in addressing agricultural production problems, *e.g.* a commercial approach to micropropagation to respond to the growing need of pathogen-tested quality planting material for crops of economic importance such as coconut, sweet potato, taro, banana, coffee and cocoa. There are also many issues unique to PNG or

Pacific Islands crops (taro, sweet potato, Pacific yams, banana, indigenous fruits, nuts *etc.*), the agricultural systems and the agro-ecological environments in the region, which are very different to the neighboring Asian region. This will require dedicated research at the national level as research into such crops or associated issues are of little interest or priority to other countries where biotechnological capacity is much more advanced. In order to support this, partnerships and collaborations with organizations in the wider Asia-Pacific Region would greatly assist in that endeavor.

7. Future Outlook

Looking back over the past 10-12 years, a previous report (not published) compiled for the Biotechnology Working Group that met in Fiji (supported by CTA) in 2005 gave a very similar status on biotechnology in PNG, as is reported here. There has been little change since and in the short- and medium-term, there is unlikely any major shift to be expected in the future for the use and application of AB innovations and tools. However, the pool of young scientists and technicians with skills and competencies in various biotechnological tools and applications is growing steadily. This trend now needs to be supported with mobilizing funding to establish and improve on existing facilities and laboratories as well as research projects and studies that allow for the application of those skills. Ideally, this work should be conducted within the country but other options such as working with experts from other countries through staff exchange or short-term training course abroad would also be the useful interventions.

The long-term aim should be to engage with policy makers for the development and implementation of relevant national laws, policies and strategies with adequate budget support to help the country take better advantage of advanced AB innovations and tools in the future for the accelerated agricultural development. In that context, in 2005, the idea of establishing a Center of Excellence was suggested as one option to move forward in the area of AB. The Center could be cross-institutional, drawing expertise from different agricultural research organizations in the country to attain focus. This center can be supported by the PNG government and other funding bodies and will be an attractive option for collaboration and cooperation with other organizations that have a strong focus on AB in the region or at the international level.

8. Conclusions

PNG is yet to develop a significant capacity for developing and using AB innovations and tools. Capacity development is required at all levels including at national level, the mainstreaming of AB in secondary school and higher education curricula, the development of institutional strategies and mobilizing funding to support relevant research interventions. The country can be benefitted from increased collaborations and networking in this area with other countries in the Asia-Pacific region.

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Country Status Report- Samoa

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1. Introduction

The Samoan islands nation is blessed with a large area of arable land suitable for agricultural development, but less fortunate as it has no known minerals or oil deposit. The country relies on exports for foreign exchange where fish and agriculture if combined, contributes more than 50 per cent of the total export annually. Tissue culture is the only agriculture a biotechnology (AB) tool employed by the Ministry of Agriculture (MoA) and Fisheries Crops Division for *in vitro* conservation and mass propagation of disease-free planting materials of selected commercial crops. During the past 20 years, conventional participatory plant breeding approach, which involved the development of complementary regional and national breeding programmes, was used. The main objective was to provide Samoan taro growers the option of growing new improved taro varieties resistant to taro leaf blight disease through population breeding and mass recurrent selection. The present status report highlights the latest updates on agricultural biotechnological research and biosafety issues pertaining to the country, including the budgetary indicators (Table 1).

Table 1. Basic Information

Indicator	Details
Value of GDP (Billion Samoa Tala) WST = Samoan Tala	2.133*
Value of GDP (Billion USD)	0.86**
Value of agriculture GDP (Billion WST)	~0.232
Value of agriculture GDP (Million USD+)	0.91
Agriculture GDP in per cent of GDP	10.4***
Total investment in agricultural research (Million WST)	~0.90
Total investment in agricultural research (Million USD+)	~0.36
Total investment in AB research in local currency (Million WST)	~0.60
Total investment in AB research (Million USD+)	~0.24

*Source: World Bank (*2017; **2017a; ***2017b); +1 USD=2.5338 WST*

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2. National Policies

2.1 Current National Policies on Agricultural Biotechnology (AB) and Policies for Enhancing the Livelihood of Farmers through AB

AB in Samoa, as in most Pacific Island countries, is almost non-existence and its utilization is very low. The only form of biotechnology that does exist is tissue culture, which is considered as a low-tech biotechnology. There is no policy directly related or in place to support AB in Samoa but there are regulations, ordinance, or biosafety legislation put in place by the MoA to regulate highly toxic pesticides and chemicals, even GM products, to prevent them from being introduced into the country. These are given hereunder.

2.1.1 National Biodiversity Strategy and Action Plan, 2001

Samoa's National Biodiversity Strategy and Action Plan (NBSAP), endorsed in 2001, provides the overarching policy context for biosafety matters. The following are the three themes under which objectives directly relevant to biosafety initiatives are listed in Table 2.

Table 2. Samoa's NBSAP with themes and objectives relevant to biosafety

Theme #	Objective #	Action
1. Mainstreaming Biodiversity	3. Legislation	To develop appropriate legislation on biosecurity to include risk management on GMOs, invasive alien species and effective border control
5. Biosecurity	1. Policy and legislation	To develop policy and actions for the management of biosafety issues
7. Agrobiodiversity	2. Research and development (R&D)	To assess the impacts of new technologies (genetic expressions, living or GMOs and genetically engineered organisms) on agrobiodiversity

2.1.2 Strategy for the Development of Samoa (SDS), 2002-2004

The vision of the SDS (2002-2004) aims an improved quality of life premised on a competitive economy with sustained economic growth, improved education, enhanced health standards and strengthened cultural and traditional values. The policy contains a number of strategic outcomes relevant to biosafety including: improving health standards; enhancing agricultural opportunities; and improving infrastructure and services (include the environment) to enhance Samoans' quality of life (SPREP, 2018).

2.1.3 National Biosafety Policy for Samoa (NBPS), 2004

The NBPS aims to ensure that Samoan people can make informed decisions in relation to modern biotechnology in a way that supports, rather than constrains, economic growth and health standards, while not diminishing cultural and traditional values. In 2003, the National Coordinating Committee established a Drafting Team to write biosafety policy. Following consultations with stakeholder representatives *via* the National Coordinating Committee, the Minister of Natural Resources and Environment (MNRE) approved the NBPS as an annex to the NBSAP in April 2004. The NBPS puts in place a structure to enable the development of an implementing legal regime and technical and administrative systems. It aims to ensure an adequate level of protection in the safe transfer, handling and use of GMOs resulting from modern biotechnology that may have adverse effects on conservation and sustainable use of biological diversity.

2.1.4 National Biosafety Framework (NBF), 2004 (Draft)

Samoa's NBF is a combination of policy, legal, administrative and technical instruments to ensure adequate level of protection for the safe transfer, handling and use of GMOs. It aims to safely manage GMOs that may have adverse effects on conservation and the sustainable use of biological diversity, also taking into account possible risks to human health (SPREP, 2018).

2.1.5 Biological Diversity Protection Bill, 2004 (Draft)

The Draft Bill implements all operative provisions of the Cartagena Protocol. It provides a regulatory and administrative framework for GMOs; procedures relating to the importation of GMOs; other dealings with GMOs such as export, transit, use for food, fee and processing, contained use and unintentional and illegal releases and transboundary movements; facilitate the application of the benefits of modern biotechnology in Samoa; aims to protect Samoa's biological diversity and to regulate the development, use, handling, and transboundary movement of GMOs and the applications of modern biotechnology. The main objectives of the bill are to: (i) manage importation, development, field testing, fermentation, release, or export of GMOs (ii) protect Samoa's biodiversity, environment, and people from adverse effects from GMOs (c) manage import and release of organisms that are not GMOs and are also not found in Samoa (SPREP, 2018).

The Draft Bill created a National Competent Authority (NCA), which has representatives of relevant Ministries, the commercial sector and community. The NCA is chaired by either the MNRE or the CEO of MNRE.

2.1.6 Biosafety (Genetically Modified Organisms) Regulations, 2004 (Draft)

The Draft Biosafety (GMOs) Regulations provide further details about the administrative procedures set by the Draft Bill. It provides for basic matters such as forms and fees for notifications for transboundary movement of GMOs. The Draft Regulations also provide for independent review of the NCA's decisions. It's a supporting regulation to the Draft Biological Diversity Act for transboundary movements of GMOs (SPREP, 2018).

2.1.7 Agricultural Sector Plan (ASP) Strategic Policy, 2016-2020

Samoa has a medium-term (five year) Agricultural Sector Plan (ASP) covering the period 2016-2020. The plan provides an essential underlying supporting structure to guide all programmes and actions from stakeholders to improve food, nutrition and income security, thereby improving the livelihood of all Samoan people. The main focus of the ASP 2016-2020 is to strengthen government partnerships with private sectors, Non-Government Organizations (NGO) and Development Partners in supporting agricultural development and innovation to promote health, prosperity and job creation. The major driving force behind the Sector Plan is to improve the welfare of all Samoans through more effective use of the country's natural resources.

The ASP consists of two volumes, which provide the strategic policy framework as a roadmap for the plan and the implementation and monitoring framework, which provides a clear indication of the roles and responsibility of lead agencies. The Strategic Policy Objectives are:

- To ensure a priority focus agriculture sector operating within a stable and coherent enabling policy and legislative framework.
- To ensure an increase stable supply and consumption of domestically produced nutritious products for both rural and urban communities.
- To enhance private sectors capacity in improving production, productivity, product quality, value addition and marketing.
- To strengthen capacities in rural communities, land owners, farmers and fishers to use natural resources in a sustainable way and increase sector resilience to natural disasters and climate change.

These objectives were translated into more specific plans of action as an essential step towards practical implementation. The ASP's priority area is to establish detailed monitoring framework for effective implementation of the plan and to facilitate corrective action, if any problems are encountered and improve project coordination among all executing agencies for effective utilization of Samoa's capital resources.

2.2 Implementation of Policies

MNRE is the designated national focal point for the Biological Diversity Protection Bill, 2004, (draft), which will coordinate and support biosafety procedures and implementation of biosafety policy. MNRE implements NBPS and also NBF.

2.3 Capacity Development

2.3.1 Existing Capacity Level

Assessing the capacity of the staff is one of the critical factors in the existing structure. There is shortage of qualified staff in certain fields like pest and disease management, tissue culture experts (molecular biologists), plant breeders, animal breeders/geneticists and agricultural engineers. This reservoir of skills has to be established to minimize dependence on expatriate contractors. There is also need to impart hands on training and education to the existing technical staff in knowledge management and other technical aspects.

There is also a need to establish inter-regional fora to coordinate and support the Pacific region and specifically Samoa's national agricultural research capacity building through support from several Agricultural Research Organizations and Institutes in Asia, where Asia-Pacific Association of Agricultural Research Institutions (APAARI) can play a vital role in facilitating and coordination. The Crops Division is now reviewing the existing human resource structure of the four sections within the division to strengthen their capacity to ensure the smooth and successful implementation of the project activities. For research, advisory and development sections, to review their staff portfolio, their roles, functions, work plan, and their capacity to absorb project activities. Staff appraisal and capacity building are required in areas of high importance like pathology, tissue culture, and agricultural engineering for the improvement of agricultural production and modern technologies to assist the poor resource farmers in rural communities.

2.3.2 Required Capacity for Future

Provision of formal and informal trainings, short-, medium- and long-term trainings to the existing staff is the priority. They may be attached to the universities or research institutes for improving their biotechnological skills.

2.4 Partnership

2.4.1 Existing Major Partnership

Listed below are the key partners, including government ministries and other organizations, working together with the MoA in the ASP. The lead agency is the MoA and Fisheries (MAF, 2018), which has Crops Division, Livestock Division, Fisheries, Quarantine, Policy and Planning, and Corporate services.

Government Ministries

(i) Ministry of Natural Resources & Environment (MNRE)

(ii) Ministry of Commerce, Industry and Labors (MCIL)

(iii) Ministry of Foreign Affairs and Trades (MFAT)

(iv) Ministry of Health (MOH) - Non Communicable diseases and Nutrition

(v) Ministry of Education, Sports and Culture (MESC) - School Feeding Programme

(vi) Ministry of Women, Communities and Social Development (MWCSD)

(vii) Scientific Research Organization of Samoa (SROS)

(viii) Development Bank of Samoa (DBS)

(ix) Ministry of Finance (MOF)

Non-Government Organizations

(i) Women in Business and Development Incorporation (WIBDI)

(ii) Matuaileoo Environment Trust Incorporation (METI)

(iii) Samoa Federated Farmers Incorporated (SFFI)

(iv) Samoa Farmers Association (SFA)

(v) Samoa Association of Manufacture Enterprises (SAME)

(vi) Samoa Chamber of Commerce and Industries (SCCI)

(vii) Small Business Enterprise Centre (SBEC)

Other Development Partners

(i) Australian Agency for International Development (AusAID)/Australian Centre for International Agricultural Research (ACIAR)

(ii) New Zealand Horticultural Research Centre

(iii) China - Samoa Agriculture Technical Aid Project

(iv) World Bank - SACEP Project

(v) Secretariat of the Pacific Community (SPC)

(vi) Food and Agriculture Organization (FAO)

Samoa is rebuilding its taro production base following the development and introduction of varieties resistant to taro leaf blight with the help of AusAID. The opportunity to improve rural livelihoods through taro exports would be effective by exporting quality consignments, without any contamination with pests of quarantine concern.

2.4.2 Scoping for New Partnership

Agricultural research in Samoa is long way to go and APAARI is a platform to facilitate and coordinate short-term visit to several national and organizations in agricultural research in Asia for short-term training and consultation on skill development, knowledge management, exchange and communication linking biotechnology in areas of agronomy, post-harvest, tissue culture and pest/disease management.

2.5 Funding Mechanism

The total estimated cost to implement the ASP in the current five year calendar of the MoA ending in 2020 is over 116.8 million WST (PAPFNet, 2018), where 57 per cent of the total costs of operation is from the core funds of the Ministry. The remaining balance of 43 per cent is expected to be shared among other key partners, other NGOs and DPs.

Samoa needs to develop agriculture biotechnology policy for the next five-year sector plan focusing on capacity building, education and facilities. This will support financial proposal when DPs approach for assistance and financial support for capacity building in areas of AB.

3. National and Institutional Strategies

At present, biotechnology in Samoa is at very low level and it is very clear from the current national ASP that there is no policy or activities related to AB as it is not considered very important. However, there is a need to draw the attention of policy makers to design a policy for conventional biotechnology in the next Sector plan. Priority areas should be tissue culture, biofertilizers, biopesticides, bioherbicides and marker assisted breeding.

3.1 National Strategy for R&D in AB

The vision of the SDS 2002-2004 aims an improved quality of life premised on a competitive economy with sustained economic growth, improved education, enhanced health standards and strengthened cultural and traditional values. The policy contains a number of strategic outcomes relevant to biosafety including: improving health standards; enhancing agricultural opportunities; and improving infrastructure and services (include the environment) to enhance Samoans' quality of life. Various strategies have been identified to implement the objectives defined under NBPS, 2004 (SPREP, 2018).

3.1.1 Short-term strategies (1-3 years)

- Strengthen the capacity of MNRE to implement the policy
- Increase public awareness and participation
- Develop a regulatory regime
- Set up administrative systems

3.1.2 Long-term strategies (3-5 years)

- Strengthen the capacity of all stakeholders to implement the Policy
- Improve administrative systems
- Strengthen institutional systems
- Increase public awareness and public participation

3.2 General Awareness

Modern biotechnology and biosafety are complicated issues and are new to most people and difficult to understand. Public awareness and participation are essential elements for the success of a biosafety framework. It is important to work with stakeholders, including the community, to raise awareness about, and increase participation in, biosafety issues. The Government of Samoa is committed to building community support for the NBF and its implementation. Stakeholders should participate in the administrative systems through membership of the NCA. Community support and understanding will be increased through public awareness activities. Local scientific and educational institutions, such as the National University of Samoa, the University of the South Pacific and Nuu Research Station, also have a vital role to play through contributing, and developing their technical expertise. Participation of stakeholders outside Samoa, namely donor agencies, bilateral partners and regional organizations, will help in supporting Samoa's biosafety efforts and forge links with international know-how (SPREP, 2018).

4. Priority Areas of Agricultural Biotechnology

4.1 Crop Improvement

Virus indexing and PCR diagnostics are the vital areas of application of biotechnological tools for the viral disease detection and mass propagation of pathogen-free planting materials. The use of molecular marker for genepool management and DNA fingerprinting of several root crops is another area, which is possible through collaboration with other overseas Institutes, located in Australia and the Secretariat of the SPC. Tissue culture technology is another important area to improve agricultural productivity through the production of high quality planting materials that are pathogen-free for the benefits of farmers in the country and in the Pacific region. Therefore, the following areas are prioritized:

- *In vitro* conservation and micropropagation of important food and cash crops of the country
- Disease diagnostics
- Mass propagation techniques *i.e.*, bioreactor for rapid mass propagation
- Molecular marker technologies
- MAS to support conventional plant breeding

4.2 Animal Health and Production

- Artificial insemination (AI) for cattle and sheep

4.3 Food Technology and Post-Harvest Technology

- Analytical services for food nutritional analysis
- Soil sampling for soil nutrient determination
- Fresh agricultural produce for value addition

5. Major Challenges and Opportunities

5.1 Challenges

- Introduction of GM food products or food crops
- Food and human safety is of vital importance
- Lack of policy on intellectual property rights
- No programme in place for the use and management of high biotechnology
- Capacity building and human resources development is very limited
- Lack of facilities and high maintenance cost of the existing facilities
- Lack of partnership from developed or industrial countries that are advanced in biotechnology
- Lack of awareness programmes for farmers and other stakeholders on the pros and cons of GM and biopesticides for human and environmental safety

5.2 Opportunities

- Samoa is well-supported by APAARI and other agricultural research organizations in Asia, in low-tech biotechnologies, short-and long-term hands-on training and knowledge management.
- There are financial opportunities or assistance from DPs for agriculture biotechnology capacity building.
- Review and development of new biosafety policy by the MoA.

6. Conclusions

Agriculture biotechnology has played a vital role in genetic resources management particularly in *in vitro* conservation, genotypic and phenotypic characterization of crops, and the use of molecular technologies for diseases diagnostics and the production of pathogen free planting materials. For example, banana growers in Samoa are now able to plant disease-free Cavendish banana imported as tissue cultured meristems from South Africa.

Samoa has become a country partner of the APAARI network that creates an opportunity to explore the potential benefits of information sharing, education, quality training and the use of technologies for the improvement of agricultural production and increase income generating farmers through access to quality seeds and planting materials.

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Appendix I

Technical Programme

Day 1: May 29, 2018

08:00-09:00	**Registration**	
09:00-10:30	**Opening Session**	
09:00-09:05	**Welcome Address**	**Ravi Khetarpal**, APAARI, Thailand
09:05-09:10	Remarks	**Siriporn Boonchoo**, DOA, Thailand
09:10-09:15	Remarks	**Andrew Alford**, ACIAR, Australia
09:15-09:20	Remarks	**Rajeev K. Varshney**, ICRISAT, India
09:20-09:28	Remarks	**Trilochan Mohapatra**, ICAR, India
09:28-09:35	Remarks	**Yusuf Zafar**, APAARI, Thailand
09:35-09:55	Inaugural Address	**Chung-Hsiu Hung**, COA,Taiwan
09:55-10:00	Vote of Thanks	**Rishi K. Tyagi**, APAARI, Thailand
10:00-10:30	***Tea/Coffee Break and Group Photograph***	

Technical Session I
Partnership and Investment in Agricultural Biotechnology

Co-Chairs	**Chung-Hsiu Hung**, COA, Taiwan and **Trilochan Mohapatra**, ICAR, India
Rapporteurs	**K.S. Varaprasad**, Ex-ICAR, India and **Martina Spisiakova**, APAARI, Thailand

10:30-10:50	ACIAR for Promoting Partnership and Investment in Agri-biotechnology in Asia-Pacific	**Andrew Alford**, ACIAR, Australia
10:50-11:10	Current Status and Long-term Investments in Agricultural Biotechnology for Sustainable Development in Asia-Pacific	**Rhodora Aldemita**, ISAAA, Philippines
11:10-11:30	Agricultural Biotechnology for South-South Cooperation	**Sachin Chaturvedi**, RIS, India (Skype presentation)
11:30-11:50	FAO's Role in Agricultural Biotechnology	**Amgalan Ariunbold**, FAO-RAP, Thailand
11:50-12:05	**Discussion**	
12:05-13:05	***Lunch (Greenery Café, Ground Floor)***	
13:05-13:25	Role of Biotechnology in Improving Productivity for Rice Producers in Asia from IRRI's Perspective	**David Johnson**, IRRI, Philippines
13:25-13:45	Advances in Genomics Research and Molecular Breeding in Dryland Crops through Partnership for Achieving Food and Nutritional Security	**Rajeev K. Varshney**, ICRISAT, India

13:45-14:05	Agricultural Biotechnology in 21st Century – USDA's Perspective	**Russell Nicely**, US Embassy, Thailand
14:05-14:25	National Broodstock Improvement Network (NBIN)	**Cherdsak Virapat**, NACA, Thailand
14:25-14:40	**Discussion**	
14:40-15:00	***Tea/Coffee Break***	

Technical Session II
Public-Private Partnership in Agricultural Biotechnology

Co-Chairs	**Yusuf Zafar**, APAARI, Thailand and **Siriporn Boonchoo**, DOA, Thailand
Rapporteurs	**Anuradha Agrawal**, NBPGR, India and **Martina Spisiakova**, APAARI, Thailand

15:00-15:15	Agricultural Biotechnology Park in Public-Private Partnership	**Su-San Chang**, PABP, Taiwan
15:15-15:30	*Success of *Bt* Brinjal in Bangladesh	**Rafiqul Islam**, Ex BARC, Bangladesh
15:30-15:45	Success of GM Maize in Philippines	**Reynaldo V. Ebora**, PCAARRD, Philippines
15:45-16:00	Investing in Agricultural Biotechnologies in the Pacific: Striving for an Effective Broad Stakeholder Alliance	**Jan Helsen**, SPC, Suva
16:00-16:15	**Discussion**	
16:15-16:30	Leveraging Funds for Basic Research in Agricultural Biotechnology: the ICGEB Experience	**Martina Viviani**, ICGEB, Italy
16:30-16:45	Opportunities for Funding: Grant and Partnership Programs in Biotechnology for Agricultural Development	**Tracy Powell**, USAID, USA
16:45-17:00	Challenges in Globalization of Agricultural Biotechnology – Private Sector's Perspective	**Siang Hee Tan**, CropLife Asia, Singapore
17:00-17:15	Investments in Livestock Biotechnology and Scoping Partnership	**Md. Kamarudin Isa**, Malaysia
17:15-17:30	Building-up the Partnership for Using Biotechnological Tools for Sustainable Conservation and Utilization of Bioresources – Role of Bioversity International	**Zongwen Zhang**, Bioversity International, China
17:30-17:45	**Discussion**	
18:15-20:30	***Social Dinner (Greenery Café, Ground Floor)***	

**To avoid repetition, the paper on "Success of Bt Brinjal in Bangladesh" is not included in his book, as it has been published separately in detail as other document.*

Day 2: May 30, 2018

Technical Session III
Country Status Reports on Agricultural Biotechnology

Co-Chairs	**M. Roff Bin Mohd Noor**, MARDI, Malaysia and **Rajeev Varshney**, ICRISAT, India
Rapporteurs	**K.S. Varaprasad**, Ex-ICAR, India and **Geraldine Nemrod**, APAARI, Thailand

	South and West Asia	
09:00-09:15	Bangladesh	**Md Harunur Rashid**, BARC, Bangladesh
09:15-09:30	Bhutan	**Wangda Dukpa**, DOA, Bhutan
09:30-09:45	India	**Trilochan Mohapatra**, ICAR, India
09:45-10:00	Iran	**Fariborz Ehteshami**, AREEO, Iran
10:00-10:15	Sri Lanka	**Frank Niranjan**, SLCARP, Sri Lanka
10:15-10:30	Nepal	**B.N. Mahto**, NARC, Nepal
10:30-10:45	Pakistan	**M. Kamal Sheikh**, PARC, Pakistan
10:45-11:00	**Discussion**	
11:00-11:15	***Tea/Coffee Break***	

Technical Session III
Country Status Reports on Agricultural Biotechnology (contd.)

Co-Chairs	**Gerry Jayawardena**, SLCARP, Sri Lanka and **B.S. Dhillon**, PAU, India
Rapporteurs	**Frank Niranjan**, SLCARP, Sri Lanka and **M. Kamal Sheikh**, Pakistan

	South-East Asia	
11:15-11:30	Lao PDR	**Chay Bouphanousay**, NAFRI, Lao PDR
11:30-11:45	Malaysia	**M. Roff Bin Mohd Noor**, MARDI, Malaysia
11:45-12:00	Philippines	**Reynaldo V. Ebora**, PCAARRD, Philippines
12:00-13:00	***Lunch (Greenery Café, Ground Floor)***	
13:00-13:15	Taiwan	**Ruey-long Chen**, Taiwan
13:15-13:30	Thailand	**Danai Narkprasert**, Thailand
13:30-13:45	Vietnam	**Pham Van Toan**, VAAS, Vietnam
13:45-14:15	**Discussion**	
14:15-14:45	***Tea/Coffee Break***	

Technical Session III
Country Status Reports on Agricultural Biotechnology (contd.)

Co-Chairs	**Pham Van Toan**, VAAS, Vietnam and **K.S. Varaprasad**, Ex ICAR, India
Rapporteurs	**Wangda Dukpa**, DOA, Bhutan and **Geraldine Nemrod**, APAARI, Thailand

	The Pacific	
14:45-15:00	Papua New Guinea	**Birte Komlong**, NARI, PNG
15:00-15:15	Samoa	**Tolo Iosefa**, MOAF, Samoa
15:15-15:30	**Discussion**	

Technical Session IV A: World Café Discussion
(a) Priority Research Areas; (b) Capacity and Infrastructure Development; (c) Public Awareness; (d) Policy Advocacy; (e) Possible Partnership

Moderator	**Rishi K. Tyagi**, APAARI, Thailand	
15:30-17:30 (about 20 min. for a group of 7-8 participants on each table)	**Host/Facilitator:**	
	Table 1. Research	**Anuradha Agrawal**, NBPGR, India and **Geraldine Nemrod**, APAARI, Thailand
	Table 2. Capacity Building	**Martina Spisiakova**, APAARI, Thailand and **Celilu Bitong**, APAARI, Thailand
	Table 3. Infrastructure Development	**Frank Niranjan**, SLCARP, Sri Lanka and **Norah Omot**, APAARI, Thailand
	Table 4. Public Awareness	**M. Kamal Sheikh**, PARC, Pakistan and **Fai Collins**, APAARI, Thailand
	Table 5. Policy Advocacy	**K.S. Varaprasad**, Ex-ICAR, India and **Tarathip Sanboonkrong**, APAARI, Thailand
	Table 6. Possible Partnerships	**Birte Komolong**, NARI, PNG and **V.K. Sah**, APAARI, Thailand
	Compilation of Recommendations: (by all Hosts/Facilitators of each table; and finally to be handed over to Anuradha Agrawal and Martina Spisiakova)	

Day 3: May 31, 2018

Technical Session IV B
Recommendations of World Café Discussion

Co-Chairs	**Reynaldo V. Ebora**, PCAARRD, Philippines and **Jan Helsen**, SPC, Suva
Rapporteurs	**Frank Niranjan**, SLCARP, Sri Lanka and **Fai Collins**, APAARI, Thailand

9:00-9:15	Compilation and Presentation of Recommendations	**Anuradha Agrawal**, NBPGR, India **Martina Spisiakova**, APAARI, Thailand
9:15-9:30	**Discussion**	

Technical Session V
Panel Discussion on Partnership and Innovative Funding Mechanism for Priority Areas in Agricultural Biotechnology to achieve SDGs

Co-Chairs	**Trilochan Mohapatra**, ICAR, India and **Su-San Chang**, PABP, Taiwan
Rapporteurs	**Frank Niranjan**, SLCARP, Sri Lanka and **K.S. Varaprasad**, Ex ICAR, India

09.30-10:50	Perception of Panellists (8 min each)
	Cherdsak Virapat, NACA, Thailand
	Roland Schafleitner, WorldVeg Centre, Taiwan
	Tracy Powell, USAID, USA
	Tin Htut, MOALI, Myanmar
	Anil Kumar Anal, AIT, Thailand
	Wen-Chin Yang, ABRC, Taiwan
	Karsidete Teeranitayatarn, IED, Thailand
	Shiv Kant Shukla, BCIL, India
10:50-11:00	**Discussion**
11:00-11:20	***Tea/Coffee Break***

Plenary Session

Co-Chairs	**Su-San Chang**, COA, Taiwan, **Siriporn Boonchoo**, DOA, Thailand, **Birte Komolong**, NARI, PNG, **Ravi Khetarpal**, APAARI, Thailand
Rapporteurs	**Rishi K. Tyagi**, APAARI, Thailand and **Geraldine Nemrod**, APAARI, Thailand

11.20-12:00	Presentation of Recommendations of Technical Sessions/World Café Discussion	Technical Sessions I: **K.S. Varaprasad** Technical Session II: **Anuradha Agrawal** Technical Session III: **Wangda Dukpa** *Technical Sessions IV: **Anuradha Agrawal** and **Martina Spisiakova** Technical Sessions V: **K.S. Varaprasad**
12:00-12:05	Brief Remarks by the Co-Organizers	**Su-San Chang**, PATB, Taiwan (on behalf of COA) **Siriporn Boonchoo**, Thailand (on behalf of DOA)
12:05-12:30	Remarks by the Co-Chairs	**Birte Komolong**, NARI, PNG **Su-San Chang**, COA, Taiwan **Ravi Khetarpal**, APAARI, Thailand
12:30-12:35	Vote of Thanks	**Rishi Tyagi**, APAARI, Thailand
12.35-13.35	***Lunch (Greenery Café, Ground Floor)***	

**Presented during Technical Session IV B*

Appendix 2

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