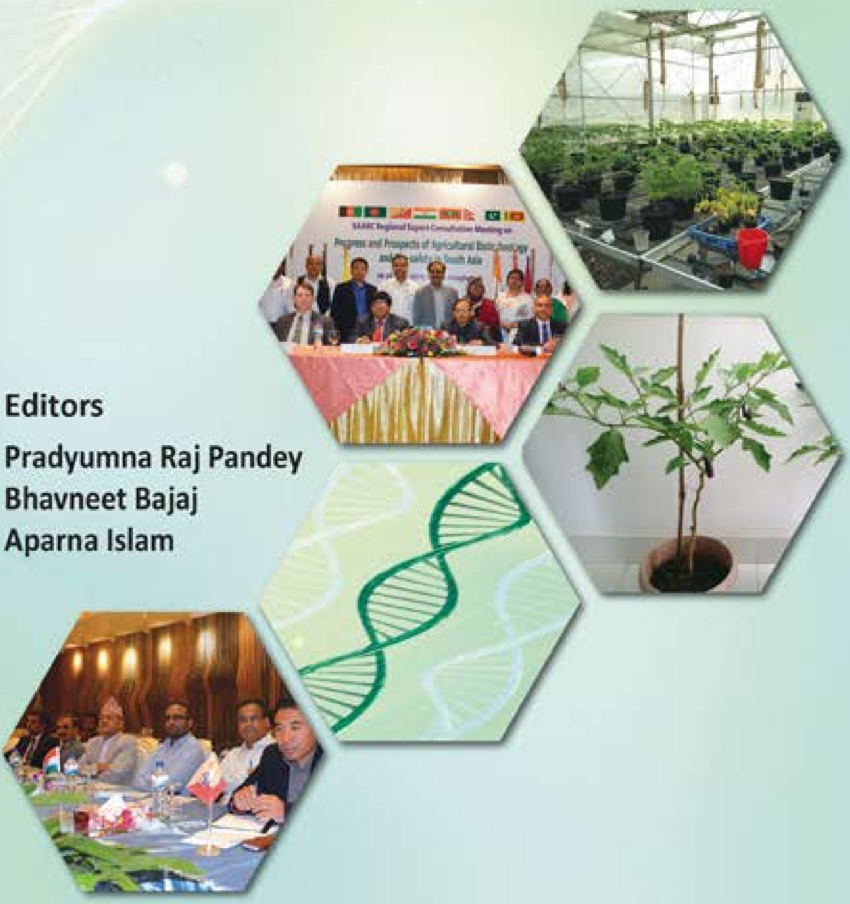
Agricultural Biotechnology and Biosafety in South Asia:
Progress and Prospects



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SAARC Agriculture Centre
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SOUTH ASIA BIOSAFETY PROGRAM

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SAARC Regional Expert Consultation Meeting on the Progress and Prospects of Agricultural Biotechnology and Biosafety in South Asia, 18-20 June 2019, Dhaka, Bangladesh

Editors

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Foreword

Around 25% of the world's population but hardly 2% of global income, South Asia faces a number of challenges to end hunger, ensure food security, promote sustainable agriculture, and achieve the Sustainable Development Goals by 2030. With more than 50% of the region's around 1.8 billion people engaged in agriculture, which is dominated by small, resource-poor farmers with an average holding size of less than 2 hectares, South Asia's development trajectory for poverty reduction and food security continues to rely on ways in which agricultural research and policy is supported and shaped, both nationally and regionally. In this backdrop, Agriculture is increasingly a global enterprise, with the movement of produce, seeds, and commodities between countries providing an essential mechanism to ensure access to adequate food and nutrition. This increasing reliance on agricultural trade means that, in order to ensure that agricultural biotechnology can contribute to achieving food and nutritional security, harmonization of the biosafety rules and regulation among the SAARC countries is needed. As a first step in facilitating harmonization of biosafety requirements, it was realized that to have a regional consultation meeting among the SAARC Member States. As a result, SAARC Agriculture Centre (SAC), Dhaka, Bangladesh in collaboration with South Asia Biosafety Program (SABP), Bangladesh and ILSI Research Foundation, Washington D.C., USA organized the SAARC Regional Expert Consultation Meeting on "The Progress and Prospects of Agricultural Biotechnology and Biosafety in South Asia" on 18-20 June 2019 in Dhaka, Bangladesh. This book "Agricultural Biotechnology and Biosafety in South Asia: Progress and Prospects" is a collection of papers contributed by experts from SAARC Member States.

I would like to take this opportunity to express sincere appreciation to Dr. Pradyumna Raj Pandey, Senior Program Specialist (Crops), SAARC Agriculture Centre and his team for their hard work to put together several papers and prepare the manuscript in this form. I am confident that this compilation will facilitate further research and development in Agricultural Biotechnology and Biosafety in South Asia.

Dr. S.M. Bokhtiar
Director
SAARC Agriculture Centre

Foreword

The United Nations' Sustainable Development Goals envision a world free from hunger and malnutrition by 2030. As of 2017 however, 821 million people are estimated to be chronically undernourished and more than 90 million children under five are dangerously underweight. Climate change and its associated abiotic and biotic stressors are a serious threat to ensuring the sustainable production and distribution of nutritious foods, and its adverse impacts are felt most acutely by resource poor, smallholder farmers like the majority in South Asia. Countries around the world are pursuing agricultural innovation agendas with the goal of helping farmers meet the increasing global demand for sustainably-produced food, feed and fiber in the face of an increasingly challenging landscape. To succeed, technologies will need to be adapted, developed and integrated into food production systems to make better use of agricultural lands, with an emphasis on conservation and stewardship of natural resources. Biotechnology is one such technology.

The ILSI Research Foundation's mission is to bring scientists together to improve environmental sustainability and human health. As the implementing organization for the South Asia Biosafety Program, we work closely with governments in the region to help strengthen institutional governance of biotechnology. Functional, transparent and scientifically sound regulatory processes for agricultural biotechnology are foundational to ensuring that new products are developed and deployed within a system that carefully considers human health and the environment.

As part of our efforts to assist governments in South Asia achieve their policy goals for biotechnology and biosafety, the ILSI Research Foundation has convened a series of consultations under the auspices of the South Asia Biosafety Program. These consultations have identified the need for capacity building and information exchange across the region, and for further efforts to harmonize the technical aspects of biosafety risk assessment and regulation in order to minimize disruptions to agriculture trade in the region.

We are proud to have partnered with the SAARC Agriculture Center to support the "Regional Expert Consultation Meeting on the Progress and Prospects of Agricultural Biotechnology and Biosafety in South Asia," which took place in Dhaka, Bangladesh on June 18-20, 2019. This consultation provided an important forum for countries to learn from each other's experiences with biotechnology and biosafety risk assessment and regulation, and to consider efforts to move forward with regional coordination and harmonization. The resulting publication will serve as a valuable resource to countries in the region, and to organizations like ours working in partnership with governments in South Asia to advance the functional implementation of biosafety processes so that agricultural innovations can be developed, assessed and deployed to the benefit of farmers and consumers.

I want to thank Dr. Shaikh Mohammad Bokhtiar for his valuable cooperation and leadership of the SAARC Agriculture Center. I would also like to gratefully acknowledge Dr. Pradyumna Raj Pandey, Dr. Vibha Ahuja and Dr. Aparna Islam for their work in organizing the consultation, as well as Dr. Bhavneet Bajaj for her contributions to preparing the proceedings. I am confident that this will be the first of many such publications that will help lay the foundation for continued cooperation on biosafety risk assessment and regulation in South Asia.

Dr. Morven A. McLean
Executive Director
ILSI Research Foundation

Foreword

South Asia comprises 21% of the world's population within 3% of the world's area. Achieving food and nutritional security for the region is therefore a great challenge. About 70% of this population is engaged in agriculture, working relentlessly to achieve food security. However, agriculture is facing serious, interconnected challenges, including the constant threat of pests and diseases, increasingly severe consequences of climate change, and other forms of environmental degradation and land use changes. These challenges have an intricate relationship with the economic development of South Asia. To overcome these, scientists, agriculturalists and policy-makers need to develop and deploy adaptive strategies to meet the food and nutrition requirements of the region. Viewing the severity of these challenges, there is no doubt that we need innovations in agriculture, including the development and deployment of modern biotechnology if we are to enable continued food and nutrition security in South Asia. In the South Asian Association for Regional Cooperation (SAARC) region, such efforts are already in place to support sustainable agricultural growth.

The potential of modern biotechnology has been recognized in the Convention on Biological Diversity (CBD) in 1993, which also recognizes the need to ensure that these technologies are developed with appropriate oversight to ensure the conservation and sustainable use of biodiversity. In 2000, to advance this goal and to provide a clear pathway for the safe development and deployment of biotechnology and transboundary movements, the Cartagena Protocol on Biosafety (CPB) to the CBD was finalized. The CPB has been ratified by all eight SAARC countries which have subsequently developed national biosafety regimes and made progress in the research and development of agricultural biotechnology.

The South Asia Biosafety Program (SABP) was established in 2005 to assist the governments in strengthening institutional governance of biosafety. Primarily focused in Bangladesh and India, SABP has also supported regional coordination and harmonization throughout the SAARC region. Every year, the SABP organizes the South Asia Biosafety Conference, an annual conference where policy-makers and researchers of the region meet and share experiences. In these conferences, it was recognized that, despite common outlook on agriculture and facing similar challenges, the progress and development of biotechnology and biosafety varies among the eight SAARC member countries. As a first step towards facilitating harmonization of these biotechnology and biosafety requirements, it is important to have a regional consultation meetings between the governments and biosafety experts of these countries.

In this context, SABP, together with the SAARC Agriculture Centre (SAC) and the ILSI Research Foundation, have joined hands to promote biosafety harmonization among the SAARC countries. As an initial step, we have co-organized the “Regional Expert Consultation Meeting on the Progress and Prospects of Agricultural Biotechnology and Biosafety in South Asia” in Dhaka, Bangladesh in June 2019.

I am very pleased to see the book Agricultural Biotechnology and Biosafety in South Asia: Progress and Prospects as a valuable output from that regional meeting. This book will be immensely useful to understand the regional perspective and possible areas of harmonization in agriculture and biosafety regulations in South Asia. I would like to express my sincere appreciation to Dr. Pradyumna Raj Pandey, Dr. Bhavneet Bajaj, and Dr. Aparna Islam for their hard work in preparing this publication. This book is a valuable contribution to pave the pathway toward harmonized biosafety regimes in South Asia.

Dr. Andrew F. Roberts
South Asia Biosafety Program Lead and
Deputy Executive Director
ILSI Research Foundation

Acronyms and Abbreviations

ACD	Analytical and Certification Division
ADS	Agriculture Development Strategy
AFP	Antifungal protein gene
AFU	Agriculture and Forestry University
AI	Artificial Insemination
APAARI	Asia-Pacific Association of Agricultural Research Institutions
ARS	Agricultural Research System
BAFRA	Bhutan Agriculture and Food Regulatory Authority
BARC	Bangladesh Agricultural Research Council
BARI	Bangladesh Agricultural Research Institute
BCC	Biosafety Core Committee
BCC	Biotechnology Coordination Committee
BCCI	Department of Public Health and Bhutan Chamber of Commerce and Industries
BCH	Biosafety Clearing House
BINA	Bangladesh Institute of Nuclear Agriculture
BIS	Bureau of Indian Standards
BR	Bangladesh Biosafety Rules
BRRI	Bangladesh Rice Research Institute
BSTI	Bangladesh Standardization and Testing Institute
Bt	*Bacillus thuringiensis*
CAC	Codex Alimentarius Commission
CARP	Council for Agricultural Research Policy
CBD	Convention on Biological Diversity
CDB	Cotton Development Board
CEMB	Centre of Excellence for Molecular Biology
CFT	Confined field trial
CIMMYT	International Maize and Wheat Improvement Center
CIP	International Potato Center
CPB	Cartagena Protocol on Biosafety
DFTQC	Department of Food Technology and Quality Control
DLC	District Level Committee
DLO	Department of Law and Order

DNVGL	Det Norske Veritas and Germanischer Lloyd
DoA	Department of Agriculture
DoE	Department of Environment
DoFPS	Department of Forests and Park Services
DOL	Department of Livestock
DoT	Department of Trade
DRC	Department of Revenue and Customs
eDNA	Environmental DNA
ELISA	Enzyme-linked Immunosorbent Assay
EPA	Environmental Protection Act
ERA	Environmental Risk Assessment
FAO	Food and Agriculture Organization of the United Nations
FBC	Field Level Biosafety Committee
GDP	Gross Domestic Product
GE	Genetically Engineered
GEAC	Genetic Engineering Appraisal Committee
GEF	Global Environment Facility
GHI	Global Hunger Index
GI	Glycemic Index
GM	Genetically Modified
GMO	Genetically Modified Organism
GNHC	Gross National Happiness Commission
IBC	Institutional Biosafety Committee
IBSC	Institute Biosafety Committee
ICAR	Indian Council of Agricultural Research
ICPs	Insecticidal Cry proteins
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
ILSI	The International Life Sciences Institute
IPH	Institute of Public Health
IPPC	International Plant Protection Convention
IRRI	International Rice Research Institute
ISAAA	Acquisition of Agri-biotech Applications
ISSR	Inter Spaced Sequence Repeats
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture

JICA	Japan International Cooperation Agency
KASP	Kompetitive Allele Specific PCR
LMO	Living Modified Organism
MAHYCO	Maharashtra Hybrid Seeds Company
MAS	Marker-assisted selection
MOA	Ministry of Agriculture
MoAF	Ministry of Agriculture and Forests
MoALD	Ministry of Agriculture and Livestock Development
MOEFCC	Ministry of Environment, Forest and Climate change
MoEST	Ministry of Education, Science and Technology
MoFE	Ministry of Forest and Environment
MoFSC	Ministry of Forest and Soil Conservation
MoICS	Ministry of Industry, Commerce and Supply
MoMDE	Ministry of Mahaweli Development and Environment
MoST	Ministry of Science and Technology
mtDNA	Mitochondrial DNA
NARC	National Agricultural Research Centre
NARC	Nepal Agricultural Research Council
NATP	National Agricultural Technology Project
NBB	National Biosafety Board
NBC	National Biodiversity Center
NBC	National Biosafety Committee
NBC	National Biotechnological Center
NBCL	National Biotechnology Central Laboratory
NBF	National Biosafety Framework
NBRDC	National Biotechnology Research and Development Centre
NCA	National Competent Authority
NCB	National Committee on Biosafety
NCC	National Coordinating Committee
NEC	National Environment Commission
NFTL	National Food Testing Laboratory
NGO	Non Governmental Organization
NIAB	Nuclear Institute for Agriculture and Biology
NIBGE	National Institute for Biotechnology and Genetic Engineering
NIGAB	National Institute for Genomics and Advanced Biotechnology

NPTC	Network Project on Transgenic in Crops
NPTII	Neomycin phosphotransferase II
NSF	National Science Foundation
NTBs	Non Tariff Barriers
NTCCB	National Technical Committee on Crop Biotechnology
NWFPs	Non-Wood Forest Products
OFRD	On-Farm Research Division
OIE	World Organization for Animal Health
PBRs	Plant Breeder Rights
PCR	Polymerase Chain Reaction
QCQD	Quality Control and Quarantine Division
RCGM	Review Committee on Genetic Manipulation
RDAC	Recombinant DNA Advisory Committee
rDNA	Recombinant DNA
RNR	Renewable Natural Resources
SAARC	South Asian Association for Regional Cooperation
SABP	South Asia Biosafety Program
SAC	SAARC Agriculture Centre
SARS	SAARC Standards
SARSO	South Asian Regional Standards Organization
SBCC	State Biotechnology Coordination Committee
SCA	Sectoral Competent Authorities
SLR	Sri Lanka Rupees
SPS	Sanitary and Phytosanitary
SSR	Simple Sequence Repeats
STCs	Sectoral Technical Committees
TAC	Technical Advisory Committee
UNCED	United Nations Conference on Environment and Development
UNEP	United Nations Environment Program
USAID	United States Agency for International Development
WGHROB	Working Group on Harmonisation of Regulatory Oversight in Biotechnology
WGSNFF	Working Group on the Safety of Novel Foods and Feeds
WHO	World Health Organization
WTO	World Trade Organization

Contents

Synopsis on Progress and Prospects of Agricultural Biotechnology and Biosafety in South Asia

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1. Introduction

Harmonization for biotechnology regulation began in 1986 from the governments in North America and Europe through announced regulatory frameworks for biotechnology. Later in 1986, the governments in North America and Europe began to coordinate efforts on technical harmonization and they considered recombinant DNA safety. Likewise, OECD working groups on biotechnology also initiated efforts on harmonization of regulatory oversight in biotechnology with environmental risk assessment; biology documents for crops, trees and animals; trait documents for insect resistance, herbicide tolerance; technical documents for low level presence, etc. Moreover, OECD established working group on safety of novel foods and feeds for food safety assessment and Crop Composition Documents.

The Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity is an international treaty governing the movements of living modified organisms (LMOs) resulting from modern biotechnology from one country to another. It was adopted on 29 January 2000 as a supplementary agreement to the Convention on Biological Diversity and entered into force on 11 September 2003. In accordance with its Article 36, the Protocol was opened for signature at the United Nations Office at Nairobi by States and Regional Economic Integration Organizations from 15 to 26 May 2000, and remained open for signature at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001. Until March 2018, a total of 171 countries have ratified the Protocol, including the SAARC countries. (http://bch.cbd.int/protocol/parties). In line with obligations under the Protocol, and their domestic needs, SAARC member countries have subsequently developed national biosafety regime.

South Asia is home to nearly 40% of the world's poor and 35% of the world's undernourished population[1] (World Bank, 2019). This is one of the least integrated regions and intra regional trade among SAARC countries exists only less than 5%. According to World Bank (2019), it is due to Non Tariff Barriers (NTBs) and Sanitary and Phytosantary measures. For example, complicated custom clearance requirements, visa requirement, congested

1 https://data.worldbank.org/region/south-asia?view=chart

port, etc. are the major NTB in South Asia. In addition, political factors like territorial dispute between member states also one of the major factors of NTB in South Asia (Singla, 2016). It is estimated that, if barriers are gradually removed, intra-regional trade in South Asia could increase from the current $28 billion to $100 billion. In order to reduce the trade barrier in South Asia, an instrumental regional organization, named as South Asian Regional Standard Organization (SARSO) was established on 25 August 2011 and operated from 3rd April 2014 in Dhaka, Bangladesh as a special body of SAARC. The main aim of SARSO is to facilitate fast track harmonization of standards, reduction of NTBs and promote trade in South Asia.

2. Harmonization Status for Biotechnology Regulation in South Asia

SAARC member countries have common international commitments, policy goals and similar needs and perspectives related to agriculture. SAARC countries are already well aligned for harmonization in shared international commitments and agricultural challenges. This provides a foundation to consider harmonization and establishing harmonized assessment methods through test protocols, Confined Field Trial (CFT) requirements and review criteria for risk assessment. It could lead to mutual recognition of data and greatly facilitate harmonized decisions between countries and even mutual recognition of decisions among the SAARC countries.

In Bangladesh, biotechnology is being used in agricultural sector for increasing nutritional value of crops and developing tolerant crop varieties for biotic and abiotic stresses. Bangladesh became one of the members of Genetically Modified Organisms (GMO) village in 2013 through the introduction of Bt brinjal, the first GMO crop in Bangladesh. Many GMO crop varieties are in the pipeline. As a signatory to Cartagena Protocol on Biosafety, the country has already introduced substantial national legislation and some legislations are being revised and updated.

Bhutan has adopted a precautionary policy concerning GMOs, with the aim to protect, conserve and safeguard the biodiversity in the country and promotes organic agriculture. Research and development of GMO/LMO using modern biotechnology is not conducted in Bhutan as GMOs are currently prohibited for cultivation in Bhutan. However, possibility of introducing GMO in Bhutan would be through trade of food and feed. Traditional biotechnologies such as tissue culture are considered by the government agencies, private companies and institutions for plant propagation. Food and feed derived from GMOs in non-viable forms are permitted after safety assessment by Biosafety Technical Working Group. As of now, Bhutan has not received any application to import food and feed derived from GMO.

India has initiated the harmonization in the subject through development of the SAARC Standard on 'Principles for the Risk Analysis of Foods Derived from Modern Biotechnology'. During the initial phases of the work item and in line with the practices for development of SAARC standards, a comparative analysis of the National Standards of SAARC member states and other international standards was carried out. However, this standard does not address environmental, ethical, moral and socio-economic aspects of the research, development, production and marketing of GMO foods. The standard is based on principles of the risk assessment, risk management, risk communication, consistency, capacity building and information exchange and review processes.

Bt cotton is the first and only commercial GM crop in India, that made big impacts on cotton yield and total cotton production and provided economic benefits to farmers. Bt brinjal was the next GM crop which was declared environmentally safe by Genetic Engineering Appraisal Committee (GEAC) but did not get approval for commercial release from Indian Government. At present, decision on environmental release of hybrid GM mustard, developed for the purpose of enhancement of production of Indian mustard, is pending and GEAC has advised to generate more data on environmental safety. Besides these three, there are several GM crops which are at different stages of development and evaluation. Recombinant DNA (rDNA) and GMOs including GM crops are regulated by the Environmental Protection Act (EPA) rules 1989 under EPA 1986 of Government of India, and the GEAC under the Ministry of Environment, Forestry and Climate Change (MoEFCC) is the apex regulatory authority. India has a three tiered regulatory system for GM crops. Recombinant DNA Advisory Committee (RDAC), constituted by Department of Biotechnology (DBT) under Ministry of Science and Technology, performs advisory role; Institute Biosafety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM) under DBT, and GEAC perform regulatory roles; and State Biotechnology Coordination Committee (SBCC) and District Level Committee (DLC) are constituted by each state for monitoring of GM crops. Promising GM lines, selected under glasshouse condition, undergo three stages of field trials, ie 'Event Selection Trial', Biosafety Research Level-I and Biosafety Research Level-II, before being considered for environmental release.

Nepal is far behind on implementation of biosafety and genetic engineering. Because of open border both in south and north, there is a high risk of GMOs and their products entering the country. Low productivity and insecure food and nutrition in the country demand the adoption of genetic engineering technology that could develop high yielding, nutrition dense and climate resilient genotypes. GMOs are poorly understood by consumers, farmers, policy makers and agriculturists. Research should therefore be started on

GMOs after establishing controlled environments and developing manpower. Biosafety framework and biotechnology policies are in place however, further acts, policy, regulations, directives and guidelines on genetic engineering and their products are necessary to be developed. Advantages of genetic engineering have not been experienced so far by farmers, consumers and researchers. Initiatives need to be taken to establish facilities so that research could be carried out on GMOs.

Pakistan is facing shortage of trained manpower to carry out biosafety studies. Efforts are being made to improve it through the introduction of biosafety courses in universities. Workshops, seminars and training courses are being held by Pakistan Biosafety Association on a regular basis. This provides an opportunity to bring scientists and health care workers from all corners of Pakistan under one roof to discuss the major challenges to Biosafety in Pakistan. This also provides an opportunity for international partners in the field to share their experiences and develop networking with regional scientists. The biotech companies have been hesitating to introduce their new technologies and investment due to non-existence of Plant Breeder's Rights, the enactment of PBRA will revolutionize the Biotech Cotton seed industry. There is still no mechanism for monitoring and evaluation of GM cotton after release which is yet to be developed. Regular funding for the operations of NBC, establishment of national biosafety laboratory, masses' awareness, capacity building and lack of government inter-agency coordination are some other challenges that need to be addressed for the development of a strong regulatory regime.

Whereas, in Sri Lanka numerous institutions have carried out biotechnology related studies but research on GMOs is limited to laboratories or confined places. There is no commercial level production of GMOs in the country. Existing rules and regulations do not allow importation of GMOs into the country and if food or feed are of GM nature they must be labelled. Multiple policies including the National Biosafety Policy and the National Biosafety Act are at different stages of development and yet to come into effect. The Policy on National Biotechnology has been unveiled by the National Science Foundation of Sri Lanka. Biosafety Act is yet to be enacted and regulations are yet to be formulated. Establishment and operation of competent authorities and sectoral committees on GMOs in the country is needed. Likewise, some other related policies are found to be incomplete and not fully implemented. Control of import, labelling and sale of genetically modified foods in Sri Lanka is also needed to be regulated properly. Insufficient technical capacity and a functional administrative and operational system in the country have delayed establishment of Biosafety regulation in Sri Lanka.

3. Conclusions

In South Asia, there is an opportunity to harmonize the biosafety regulations based on existing similarities in national policies, technical documents, and commonalities between countries in the region. Moreover, harmonization efforts on biotechnology and biosafety in SAARC countries have been trying to address the principles as evidenced in their shared international commitments related to agricultural biotechnology, Convention on Biological Diversity, Cartagena Protocol on Biosafety and agreements on World Trade Organization (WTO). In South Asia, harmonization has taken many forms, such as adopting similar processes and standards, mutual acceptance of decisions, Food Safety and Environmental Risk Assessment, etc. However, the implementation has become more challenging in most of the South Asian countries. The application of biotechnology is an important part of agriculture in South Asia, however it is only approved by Bangladesh, India and Pakistan.

On the other hand, there are opportunities to harmonize field trial protocols and confinement measures through data collected from field trials and it can be harmonized among the SAARC countries. It could be used to support regulatory applications in multiple SAARC countries. During a CFT, the physical environment (agroclimate) differentiates one site from another and biotic environment is tightly controlled to allow comparison of control and test plants. Therefore, CFTs conducted in one SAARC country are likely to be directly relevant to other countries based on agroclimate similarities.

4. Recommendations

The SAARC member countries must go ahead with the harmonization of standards, to form regional SAARC standards for the principles and guidelines for risk assessment of foods derived from modern biotechnology. In this case, Bureau of Indian Standards (BIS), India has already led the work and is in process of developing the SAARC standard on 'Principles for risk assessment of foods derived from modern biotechnology', by taking assistance from the corresponding CODEX guideline, CAC/GL 44-2003. India is also in the process of developing two more standards on 'Guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants' and 'Guidelines for the conduct of food safety assessment of foods produced using recombinant-DNA micro-organisms' which are based on the relevant CODEX guidelines, CAC/GL 45-2003 & CAC/GL 46-2003, respectively. It is believed, this will pave way for keeping all the SAARC Member States at the same manner and confidence with reference to dealing with GM food safety as these standards are being developed based on globally accepted CODEX guidelines on the subject.

In addition, following recommendations would be worthwhile for harmonizing biotechnology and biosafety regulations in South Asia.

- SAARC and other regional organizations should continue to support consultations and dialogues related to regional harmonization of biotechnology and biosafety.
- There is a need to support the development and maintenance of web portals to facilitate exchange of information between and among SAARC member countries related to biosafety, which helps for free exchange of biosafety and biotechnological information within SAARC countries.
- SAARC should explore opportunities to provide a platform for hosting the data collection and associated regulatory applications submitted to member countries, including the possibility of a database or repository for data.
- SAARC needs to continue to explore regional standards related to biosafety through SARSO, including food safety assessment standards, environmental risk assessment standards, risk assessment standards for micro-organisms and standards for conducting detection testing.
- It is good to support developing the SAARC standard on 'Principles for risk assessment of foods derived from modern biotechnology', by taking assistance from the corresponding CODEX guideline, CAC/GL 44-2003.
- Support is also required for access and benefit sharing standard of GM germplasm and genes within SAARC Member States.
- There is a need to develop SAARC standard for biosafety and genetic engineering.
- SAARC should conduct more programs for capacity enhancement and prepare a road map in biotechnology and biosafety sector.

5. References

Papers presented in SAARC Regional Expert Consultation Meeting on the Progress and Prospects of Agricultural Biotechnology and Biosafety in South Asia, jointly organized by SAARC Agriculture Centre (SAC), Dhaka, Bangladesh and The ILSI Research Foundation, Washington D.C., USA on 18-20 June 2019 in Dhaka, Bangladesh.

Global Status, Needs and Possible Areas of Harmonization in Agriculture and Biosafety Regulations in South Asia

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1. Biotechnology and Biosafety

Biotechnology aims to improve living organisms or its product for human benefit. This is done through genetic modification. The techniques which encompasses genetic modification range from breeding procedures, like artificial insemination and hybridization, to advanced techniques, like genetic engineering, gene editing etc. Since the discovery of the structure of DNA and development of recombinant DNA technology, the objectives of biotechnology can now be achieved more accurately. Modern biotechnology allows for the precise manipulation of the genetic structure of individual living cells that results in generating Living Modified Organisms (LMOs) or, more popularly known as Genetically Modified Organisms (GMOs). Despite the potential for modern biotechnology to address pressing challenges, concerns have been raised about its potential effects on human health and ecosystems. Because both biotechnology and agriculture are global enterprise, it is obvious that GMOs would be traded across borders. Therefore, the concerns over GMOs have implications for the economy and trade.

In order to ensure that the products of modern biotechnology are safe for humans and the environment, biosafety procedures and assessment methodologies have been developed at both the national and international level. The Convention on Biological Diversity (CBD) clearly recognizes the potential of modern biotechnology, and also recognizes the need to ensure conservation and sustainable use of biodiversity. In 2000, to advance this goal and to provide a clear pathway for the safe development and deployment of biotechnology, the Cartagena Protocol on Biosafety (CPB) to the CBD was finalized. Till date 171 countries (http://bch.cbd.int/protocol/ parties/ updated: 2018-03-05) have ratified or acceded to the CPB. The CPB addresses the potential risks posed by GMOs in terms of safe transfer, handling and use of GMOs subject to transboundary movement. The protocol describes two sets of procedures. One deals with transboundary movement of LMOs for direct introduction into the environment, and the other deals with transboundary movement of LMOs to be used as food or feed or for processing. Both the procedures stand on scientifically sound risk assessment data generation so that it gives the recipient countries and consumers the information they need to make informed decisions about whether they want to accept GMOs.

The CPB is not the only international arrangement relevant to the use of biotechnology. There are several international instruments and standard setting processes that address various aspects of biosafety. The World Trade Organization (WTO), limits the ways that trade can be restricted, but allows restrictions for protection of agriculture, human and animal health and protection of the environment. The way these restrictions are implemented is addressed under the Sanitary and Phytosanitary (SPS) agreement and the Technical Barriers to Trade (TBT) agreement. These agreements recognize three standard setting bodies that set technical standards and methods: Codex Alimentarius, World Organization for Animal Health (OIE), and International Plant Protection Convention (IPPC) and these standard setting bodies have issued guidance documents addressing the use and evaluation of biotechnology.

2. Global Experience with Biotechnology and Biosafety

Between the first commercial cultivation of biotech crops in 1996 and the twentieth year of cultivation in 2016, more than 2 billion cumulative acres of biotech crops have been cultivated globally (ISAAA, 2017). Among the 24 biotech cultivating countries, 19 are developing economies and the number of acres under production of biotech crops in the developing world has exceeded production in industrial countries since 2012. A large proportion of maize, soya, canola and cotton production globally is derived from biotech crops each year (ISAAA, 2017).

The global adoption of this technology has been accompanied by the development of national regulatory frameworks to ensure that the use of biotechnology in food and agriculture is assessed to prevent any unwarranted harm to human health or the environment. The development of these frameworks has been supported by a variety of harmonization efforts and international agreements intended to protect agricultural trade, and to ensure shared understanding of technical and regulatory requirements related to food safety and environmental risk assessment of biotechnology. Some of these efforts are reviewed briefly here.

2.1. The Organization for Economic Cooperation and Development

The Organization for Economic Cooperation and Development (OECD) began work on harmonization for biotechnology in the late 1980s. Over the last thirty years, these efforts have evolved into two separate working groups, the Working Group on Safety of Novel Foods and Feeds, which focuses on producing technical documents in support of food and feed safety assessment for biotechnology and other novel products, and the Working Group on

Harmonization of Regulatory Oversight in Biotechnology, which produces technical documents focused around facilitating harmonization in environmental risk assessment. The OECD has advanced many of what are now considered the core concepts in biosafety, including the idea of comparative assessments based around familiarity with existing crop plants and their traits, and the need for case-by-case risk assessments that incorporate information on the crop, the introduced trait and the receiving environment.

2.2. The Cartagena Protocol on Biosafety

Finalized in 2000 after more than 8 years of negotiations, and entering into force in 2004, the Cartagena Protocol on Biosafety (CPB) is a protocol underneath the Convention on Biological Diversity. The objective of the CPB is to ensure "…an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms 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.[1]" The preamble to CPB recognizes that agricultural biotechnology has great potential to promote human well being, if developed safely, and also recognizes the need to support both environmental protection as well as agricultural trade. To this end, Articles of the CPB address transboundary movement of "living modified organisms" (LMOs) for release into the environment and for direct use in foods, feeds or for processing, as well as providing guidance on the handling, transport, packaging and identification of LMOs during transboundary movements. Annex III of the CPB provides information on risk assessment, and represents a reasonably concise, consensus view of some important principles for ERA, including both case-by-case risk assessment as well as comparative assessment. The Protocol deals with measures, policies and procedures to assess and minimize GMO related risks; capacity building for compliance of the regulations; the Biosafety Clearing-House (BCH), and public awareness and participation etc.[2].

2.3. Codex Alimentarius Guidelines on Foods Derived from GE Plants

The Codex Alimentarius (Codex) is a joint project of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) and is recognized by the World Trade Organization as one of three standard setting bodies. Codex has produced guidelines relevant for addressing the safety

1 https://bch.cbd.int/protocol/text/

2 CBD and UNEP. 2003. Biosafety and the Environment: An introduction to the Cartagena Protocol on Biosafety.Secretariat of the Convention on Biological Diversity (CBD) and the United Nations Environment Programme (UNEP), Montreal, Quebec, Canada, p. 16.

assessment of foods and feeds derived from GE plants. This includes CAC/GL 44-2003 "Principles for the Risk Analysis of Foods Derived from Modern Biotechnology," and CAC/GL 45-2003 "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants." Together these guidelines represent an internationally agreed set of processes and considerations for food safety assessment of biotech crops.

3. Biotechnology and Biosafety in South Asia

The countries of South Asia host a great diversity of geography and cultures but have similarities in agriculture. Livelihood security, food security and nutritional security is largely dependent on agriculture. Within the eight countries that make up SAARC, around 24% of the global population are contained in just 3.5% of the global land area. While taking advantage of the human resources, this densely populated region has to confront hunger and poverty. Unfortunately, 17-30% of populations within SAARC countries are unable to meet the minimum daily recommendation for caloric intake. This is because the 1.9 billion residents of South Asia are challenged to produce sufficient food to ensure adequate nutrition on less than 2 million square miles of total area[1]. The agricultural land is challenged by issues of land degradation and climate change as well as the encroachment of urban development. While agricultural yield is challenged with ever evolving diseases and pests. Many of these factors are interconnected and have effect beyond political boundaries. This creates further complexity in agricultural challenges. Nevertheless, agriculture dominates the livelihood of this vast population. Therefore, the economic sustainability and growth of this region is deeply connected to agriculture. For most SAARC countries, the population remains predominantly rural, ranging from 66% in Pakistan to 86% in Nepal and remain involved with cultivation. Except for Maldives, the GDP is largely dependent on agriculture for these countries. Though agriculture has a high proportion as a share of GDP (up to 40%), but farm sizes are generally small and support up to five laborers per hectare. In one hand, large populations and on the other hand small land area thus small economy pose challenges in agriculture and economic growth[2].

Improving the lives of these smallholder farmers, while improving farm income and food production requires the development and deployment of new technologies. Considerable improvement has been achieve through improvement of germplasm and adaptation of various agriculture practices.

1 http://worldpopulationreview.com/countries/saarc-countries/

2 Pandey, P.R. and Bhandari, H. (eds.). 2018. Rice Technological Innovation and Value Chain Development in South Asia: Current Status and Future Directions: SAARC Agriculture Centre, p. 165.

But the population is increasing, so as the demand for food. On the other hand, crisis of resources, like land, water etc is increasing too. To combat these hurdles improved and advanced technologies are needed. This includes agricultural biotechnology (GE crops)[1]. The potential of genetic engineering is immense. To ensure that the development of GE crops is conducted in a way that allows farmers to benefit from these technologies while maintaining adequate protections for human health and the environment requires appropriate biosafety measures. For this reason all the countries of this region have developed national biosafety system covering all the aspects of the Protocol.

4. Progress of Biotechnology and Biosafety in South Asia

In 2019, three of the eight SAARC countries are producing biotech crops. Biotech cotton is being grown in India and Pakistan while Bangladesh is cultivating Brinjal. In both cases, the plants have been engineered to express proteins from the soil bacterium *Bacillus thuringiensis* (Bt) to confer resistance to certain insect pests.

Biotech research is going on in seven of the eight SAARC countries. In Bhutan, GMO research and development, cultivation and release is prohibited. However, all the eight countries have endorsed the CPB. In line with obligations under the Protocol, and their domestic needs, SAARC countries have subsequently developed national biosafety regime. The development and implementation of biosafety regime varies widely, but some countries have developed and published biosafety framework; rules & regulations; act and policies. For implementation of these, guidance documents addressing both food safety assessment and environmental risk assessment has also been made. Moreover, addition of biosafety regime development, biotechnology policies has been updated to accommodate GMO research and development. The institutions involved with biotechnological research have Institutional Biosafety Committee (IBC) to look after these works within the institutes. The national biosafety committee looks after the importation and import of GE organisms including crops, food and feed. Initiatives for capacity building, awareness program and Biosafety Clearing House (BCH) are also present in several of SAARC countries. However, progress in these regards varies. Several projects and programs, like Biosafety Implementation Project, South Asia Biosafety Program (SABP) (Box 1.1.) funded by various donors, like United Nations Environment Programme (UNEP), Global Environment Facility (GEF), United States Agency for International Development (USAID) are assisting SAARC countries to implement these initiatives.

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1 https://www.sac.org.bd/sac-vision-2020/

Box 1.1. South Asia Biosafety Program (SABP)

***Objective of SABP**:* Facilitating the implementation of transparent, efficient, and responsive regulatory frameworks for products of modern biotechnology in South Asia

Commencement: February 2005

Focal areas: The collaboration between SABP and the Government of Bangladesh SABP has two key focal areas:

(1) Supporting the development of a robust regulatory system, and

(2) Technical capacity building in biosafety risk assessment and risk management in areas that are identified as priorities by the Government of Bangladesh for GE crops and foods.

Activities:

Assistance in regulatory document development, like, Standard Operating Procedures (SOPs), Guidelines for Environmental Risk Assessment (ERA) of Genetically Engineered Plants, User's Guide to Biosafety Regulatory Process for GE Plants in Bangladesh etc.
Training and workshops for both researchers and biosafety practitioners for capacity building
Organizing conferences and supporting participation for network development and knowledge enhancement
Biosafety research grants program to develop baseline data for comparative analysis during risk assessment
Newsletter publication

***Policy Harmonization and SABP**:*

As coordination among the various international regimes can greatly strengthen biosafety while reconciling the legitimate interests of trade, biosafety and other sectors SABP starts to work on this issue. The best place to discuss this is at the assembly of policy makers and researchers. One such place is South Asia Biosafety Conference (SABP). In 2017, at the 5th SABC workshop participants agreed that it made good sense to begin with regional harmonization of food safety assessment guidelines. Later on SARSO begins with comparison of principles for the risk assessment of GE derived foods. Harmonization of other parameters that function at ERA will give coordination remaining assessment process to have mutual respect of data and will favors data transportability. To achieve this in the South Asian countries a regional expert consultation meeting on the "Progress and prospects of agricultural biotechnology and biosafety in South Asia" was arranged with collaboration with SAARC Agriculture Center and ILSI Research Foundation.

5. Prospects of Biotechnology and Biosafety for South Asia

With urgent challenges facing agriculture, and an already large and growing population, it is expected that agricultural biotechnology will have a role to play in meeting future food security challenges in South Asia. Although different countries in the region have different priorities for agricultural development, there is a lot of common ground on which to build to achieve technical harmonization for agricultural biotechnology. All eight countries in SAARC have ratified the CPB, and seven of eight belong to the World Trade Organization. Agricultural trade between SAARC countries necessitates a common understanding of both environmental risk assessment and food safety assessment for foods derived from GE plants. Efforts in this area have already been under discussion in a variety of forums, including ongoing efforts associated with the annual South Asia Biosafety Conference, as well as activities supported by the United National Environment Program (UNEP). At the middle of 2019 a workshop was held entitled "The Regional Workshop on Harmonization of Biosafety Regulatory System", which was organized by the Department of Environment (DoE), Ministry of Environment, Forest and Climate Change (MoEFCC) of the Government of Bangladesh with the support of UNEP-GEF Biosafety Implementation Project. The issues that were recognized for harmonization are regional BCH for information sharing and capacity building on biosafety risk assessment and management. But harmonization in policies is a prerequisite to achieve these. In this background SABP is working. Moreover, the shared priorities embodied in the mission of SAARC to foster cooperation and trade in South Asia, and specifically the SAARC Agriculture Center's mission to support the development of agriculture to meet the needs of South Asia's farmers and consumers suggest that there is the potential for progress on the harmonization of biotechnology and biosafety regulation.

Globally the regulation on biosafety and its assessment are conducted as per Codex Guideline. For this reason, South Asian countries share similarity in both, regulation and assessment criteria. In case of assessment, they are of two types, e.g. food safety assessment and environmental safety assessment. And both of these are under the 'Comparative Approach' concept as per Codex Guideline[1]. As a result, both assessments require common information, for example, biological Information of organism like taxonomy, hybridization, weediness, origin of species, diversity, compositional information; information on intended traits etc. Interestingly worldwide, this information is found to be the same. Consequently, several consensus documents have been developed with comprehensive technical information needed for the regulatory assessment. In case of Confined Field Trials (CFTs) assessment, main issue is performance at the field. During a CFT, the physical environment (Agroclimate) differentiates one site from another. But within SAARC countries, one country is likely to be directly relevant to other countries based on agroclimate similarities (https://ilsi.shinyapps.io/

[1] MOEFCC (2014), A Multi country comparison of information and data requirements for the environmental risk assessment of genetically engineered plants, Ministry of Environment, Forest and Climate Change, Government of India, p-19.

ilsi_webtool/). The above discussion shows that there is huge scope for harmonization. A proof of this is the review of food safety assessment guidelines for foods derived from GE plants produced in India and Bangladesh. Review found a high degree of agreement between these documents and existing Codex Guidelines. This suggests, unsurprisingly, that the technical aspects of biosafety assessment in South Asia are well aligned with internationally developed norms. This suggests that the potential for technical harmonization is high. In this backdrop, the present consultation meeting was conducted to find our opportunity of the harmonization recognizing the need.

5. References

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Progress and Prospects of Agricultural Biosafety in Bangladesh

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Abstract

Bangladesh is an agrarian country and the agriculture sector plays an important role in the economic development as well as food security. Significant success in the agricultural sector of the country has been achieved in the last 30 years through innovation of modern varieties of crops and development of production strategy by affiliated institutions and universities under the Bangladesh Agricultural Research Council. Despite this success in agricultural production, the country is facing multiple problems. Bangladesh is perennially suffering from increased population, reduction of agricultural land, increasing demand for varieties of food or diversified food stuff, flood, drought and natural disaster, etc. Traditional technology is not enough for solving future problems in agricultural production. This problem may be minimized by introduction and utilization of modern biotechnological tools and strategies in the agricultural sector. Biotechnology is being used in agricultural sector for increasing nutritional value of crops and biotic and abiotic stress tolerant crop varieties. With this purpose in view, for safe utilization of biotechnology, relevant policies should be formulated for probable success of this technology. Bangladesh became one of the members of Genetically Modified Organisms (GMO) village in 2013 through the introduction of Bt brinjal, the first GMO crop in Bangladesh. More GMO crops are in pipeline. As a signatory to Cartagena Protocol on Biosafety, the country already introduced substantial national legislation in this regard. Some legislations are being revised and updated. This paper is intended to serve as a resource for other stakeholders interested in understanding the agricultural biotechnology associated with biosafety regulation in Bangladesh.

Key words: Agricultural biosafety, Bangladesh, progress, prospects.

1. Introduction

Jonathan Swift said “that whoever could make two ears of corn, or two blades of grass, to grow upon a spot of ground where only one grew before, would deserve better of mankind....” Agricultural research is working with this manner. Bangladesh is a densely populated country with 1291 persons per Km^2 and it is projected to reach about 186 million by 2030 and 202 million by 2050 (https://www.worldometers.info/world-population /bangladesh-population). The projections show that Bangladesh will have deficit productions of wheat, potato, pulses, vegetables, meat, egg and freshwater fish by 2030 (Islam and Talukder 2017). The agricultural arable land is shrinking at an alarming rate due to urbanization, roads, infrastructure, etc. The country is most vulnerable to climate change with risks from floods, droughts and sea level rise, all potentially impacting adversely on agricultural production. Agriculture sector is going to face serious natural problems that warrant special attention to this sector. Biotechnology can play an important role to address the above issues. Significant initiatives have been taken by the Government of Bangladesh to promote biotechnological research and infrastructure development in the country for enhanced productivity, quality and value of products, stability of production systems and environmental conservation leading to sustained food security, poverty alleviation and livelihood security. There are a series of issues to be addressed in assessing the benefits and risks involved in the use of modern biotechnology. In order to ascertain the risks and benefits, it is important to distinguish between technology-inherent risks and technology-transcending risks (Salimullah and Islam 2016). Recently, Ministry of Environment, Forest and Climate Change, Bangladesh is determined to implement action plans on biosafety according to the provisions of the Cartagena Protocol (Bangladesh Sangbad Sangstha 2019). Researchers and policy planners should have adequate knowledge about regulatory process for applications involving genetically modified plants. As part of South Asia, present status of agriculture, agricultural biotechnology and regulatory process in Bangladesh are highlighted in the present paper.

2. Agricultural Scenario and Current Status of Agricultural Biosafety and Biotechnology in Bangladesh

2. 1. Agricultural Scenario

Agriculture is the backbone of Bangladesh's economy and continues to be the dominant driving force for growth and development of the national economy. It is the single largest contributor to national economy and the largest source of employment. It comprises 14.23% of the country's GDP and employs around 40.6% of labour force. The intensity of cropping was reported to be 195% and food grain production at 38141.00 thousand metric tons by Bangladesh Bureau of Statistics (2019). Agricultural land is an important natural resource. The availability of agricultural land has been declining at the rate of 1% per year and at least one quarter of the country's agricultural land has been lost over the last 30-40 years due to urbanization, building of new infrastructure such as roads, and implementation of other development projects (Hossain et al. 2017). About fifty percent of the land is under cultivation (Table 1). The land-man ratio is decreasing at an alarming rate; the estimated per capita arable land stands at 0.05 ha only.

Table 1: Current land use in Bangladesh

Land Use type	'000' ha	%
Total land area	14763.16	100
Net cropped land	7955.47	54
Forest	2578.14	17
Not available for cultivation	3596.36	24
Cultivable waste	231.98	2
Fallow land	402.43	3

Sources: BBS. 2019

Bangladesh is presently facing several challenges for achieving sustainable agriculture and food security including rapid population increase, shrinking agricultural lands and natural resources etc. Climate change and natural hazards make the situation worse. The opportunity of bringing more lands under cultivation is lacking. There will be a serious gap between demand and supply if the current rate of productivity and production continues. Therefore, the increase in productivity and production rate in all agricultural sub-sectors is of prime importance to meet future demand.

The National Agriculture Policy 2018 was formulated with the aim of ensuring profitable agriculture, nutrition and food security in Bangladesh. The main goal of the policy is to ensure food security and socio-economic development through productivity of crops, boosting production and raising farmers' income, diversifying crops, producing safe foods and developing marketing system, profitable agriculture and use of natural resources. To enable constructive changes in the agriculture sector, Ministry of Agriculture (MOA) has been implementing different development projects/programmes in the field of agricultural research and education including agricultural extension and training, marketing of agricultural products, agricultural support and rehabilitation, innovation, procurement and management of agricultural input and equipment, seed production, storage and distribution, extension of irrigation facilities, fertilizer management activities, farm mechanization and crop storage etc.

2. 2. Agricultural Biotechnology and Biosafety

Over the past two decades, the advancements made in modern agricultural biotechnology have opened new frontiers in agricultural production with rapid progress in developed countries. 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, thereafter, tissue culture research laboratories were set up in different universities and research and development organizations. Intensive work on plant tissue culture has resulted in development of plant regeneration and micro-propagation protocols in several crops, forest plants, ornamentals, fruit trees and vegetables. Besides these, research on transgenic plant development and production of high yielding and pest/insect resistant varieties through genetic engineering, and biochemical study programmes of some key crop plants have also been initiated at several laboratories. Bt brinjal, the first genetically engineered (GE) crop was introduced in the country in 2013. It is expected that Golden Rice will be released shortly. Research activities on other GMO crops like Bt cotton, virus-resistant tomato, salt-tolerant rice, late blight-resistant potato etc. are in progress at different research institutes and universities. The jute genome project earned Bangladesh the pride of being the first country to sequence the whole genome of jute and sequencing of *Macrophomina phaseolina*. In February 2016, Wheat blast devastated more than 15,000 hectares of wheat in eight districts and decreased 16% of the total wheat production in the country. Department of Biotechnology of Bangabandhu Sheikh Mujibur Rahman Agricultural University sequenced the whole genome wheat blast fungus. Currently research on genome editing of the S-genes in wheat by using CRISPR/Cas9 technique to develop new blast-resistant wheat varieties for Bangladesh is on-going. Researchers at the Department of Biochemistry and Molecular Biology of University of Dhaka are screening some salt tolerant transgenic rice lines in greenhouses at the Biotechnology Division of Bangladesh Rice Research Institute (BRRI). Some lines that were found to be saline tolerant at the seedling stage have been selected for reproductive stage characterization. The Plant Breeding and Biotechnology laboratory of the Department of Botany, University of Dhaka, has been working since 2009 to develop peanut resistant to fungal diseases (*Arachis hypogaea* L.). Transformation experiments in two varieties of peanut, namely, Dhaka-1 and BINA Chinabadam-4, were performed using *Agrobacterium* strains LBA4404 containing antifungal protein gene (AFP) and marker gene neomycin phosphotransferase II (NPTII). Research on development of virus resistant tomato is going on at the Biotechnology Division of Bangladesh Agricultural Research Institute (BARI). Chickpea has the pod borer problem, which is causing as much as 48% yield loss. Like the brinjal, a pod borer resistant Bt chickpea was developed by the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) in the hope of reducing the damage of intensive use of pesticide to the environment. Pulse Research Centre of BARI is expected to start research on Bt chickpea. Besides Golden Rice, the Plant Breeding Division of BRRI is working with the International Rice Research Institute (IRRI) to develop zinc (Zn) and iron (Fe) enriched transgenic rice variety, for which the National Committee on Biosafety (NCB) already has approved the importation of seed for trials. The Biotechnology Division of BRRI is also researching development of non-transgenic low glycemic index (GI) rice variety, a salt-tolerant rice variety, and an antioxidant-enriched black rice variety. To develop abiotic stress tolerant rice variety transfer of salinity and drought tolerance gene *OsNHX2* in rice cultivar through *Agrobacterium*-mediated transformation technique is going on at the Biotechnology Division of Bangladesh Institute Nuclear Agriculture (BINA). Bangladesh initiated work in the field of biosafety in the 1990's with an objective to protect human and animal health and biodiversity from the potential adverse effects of the products of modern biotechnology. The economic potential of modern biotechnology in agriculture, health, energy, and the environment are well recognized. However, there are concerns that the GMOs derived from biotech may pose risks to human health and the environment. Moreover, mixing of genes from unrelated organisms might create an imbalance in the natural integrity of the living world. The Government of Bangladesh seeks to move forward in developing and commercializing biotechnology and to address the potential risks arising from any kind of use of GMOs with utmost importance. The Cartagena Protocol on Biosafety (CPB) ensures basic guarantees for all stakeholders. The CPB was adopted by the international community in Montreal on 29 January 2000 in order to fulfill one of the important objectives of the Convention on Biological Diversity (CBD), 1992: the conservation and sustainable use of biological diversity. Bangladesh signed the Protocol on 24 May 2000 and ratified it on 5 February 2004. The Ministry of Environment, Forest and Climate Change (MOEFCC) is the designated National Competent Authority and the Focal Point for implementing the Protocol. The biosafety system in Bangladesh has been built upon transparent procedures for receiving applications, evaluation and decision making. A mechanism for monitoring, enforcing and a system for providing information to the stakeholders as well as public awareness and participation has also been incorporated in the national biosafety framework.

3. Biosafety Regulatory Policy and Framework in Bangladesh

Bangladesh has published various regulations, policies, and other documents on biotechnology such as the National Biotechnology Policy, 2012, Action Plan of the National Biotechnology Policy, 2014, National Biosafety Framework (NBF), 2007, Biosafety Guidelines of Bangladesh, 2008, and Bangladesh Biosafety Rules, 2012, the Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2012; the Guidelines for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants, 2016; and the User's Guide to Biosafety Regulatory Process for Genetically Engineered Plants in Bangladesh, 2017 etc.

3. 1. Bangladesh Biosafety Guidelines

Biosafety Guidelines of Bangladesh were formulated by the Ministry of Science and Technology in 1999 and published in 2000. The Biosafety Guidelines were updated by the Ministry of Environment and Forest (Now

Environment, Forest and Climate Change) considering Cartagena Protocol on Biosafety during 2004-2006 and published in 2007. Revision of Biosafety Guidelines of Bangladesh 2018 is in process.

Scope and Objective: Biosafety guidelines are applicable to all research and development activities of modern biotechnology conducted in laboratories of the government research institutes, state enterprises, universities, international organizations located in Bangladesh, private companies or non-governmental organizations. It applies to lab experiment and field trial, trans-boundary movement, transit, handling and use of all GMOs/ living modified organisms (LMOs) that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Contents: The Guidelines comprise four chapters -Scopes and Objectives of Biosafety Guidelines, Institutional Arrangements, General Provisions on Biosafety (risk assessment and risk management) and Physico-chemical and Biological Containments: Procedures and Facilities. In annexure, it contents Guidelines for Classification of Microorganisms according to their Risk Potential, Good Laboratory Practice (GLP), Good Industrial Large-Scale Practice: The GILSP concept, List of Organisms according to Different Risk Groups, Framework for Risk Assessment, Information needed in Trans-boundary Movement of GMO/LMO, Information required Concerning GMOs/LMOs Intended for Direct Use as Food or Feed, or for Processing under Article 11 of Cartagena Protocol on Biosafety, Biohazard Communication, Glossary of the Terms used in Biosafety Guidelines etc.

Regulatory Committees under the Biosafety Guidelines of Bangladesh: The NCB headed by the Secretary, MOEFCC, as the final decision-making body on approving biotechnology applications. The NCB includes 21 members from various ministries such as the Ministry of Science and Technology, MOA, Ministry of Fisheries and Livestock, and heads of national research institutes and departments. Other important committees include the: 1) Biosafety Core Committee (BCC), headed by the Director General of the Department of Environment (DOE) which provides the NCB with technical comments and recommendations on GE applications, and advises on other GE issues; 2) Institutional Biosafety Committee (IBC), which evaluates and monitors research and development activities in research institutions; and 3) Field Level Biosafety Committee (FBC), which monitors field trials for GE plants, animals, or fish.

A national technical committee will review the dossier and submit any recommendations or concerns to the NCB. Afterward, in most cases, the NCB will send the dossier to the BCC for further review and to recommend a decision. The NCB provides a final decision on the GE application. If approved, four copies of the permit will be issued.

3. 2. The National Biosafety Framework

The National Biosafety Framework (NBF) developed in 2007 provides a basis for administrative system and regulatory regime to be developed for adequate level of protection in the environment and human health against uses of GMOs resulting from modern biotechnology. It contains six chapters:

Chapter 1 includes introductory issues, such as, project background, process of developing the NBF and relationship of the NBF with the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD).

Chapter 2 reviews the existing national policies relevant to biotechnology and biosafety and proposes an outline of a new national policy on biosafety for addressing biosafety concerns arising from the application of modern biotechnology and use of GMOs in the country.

Chapter 3 includes a review of present laws and regulations with potential relevance to biosafety and argues for adoption of a new regulatory regime for biosafety.

Chapter 4 proposes structure of the administrative system for biosafety related activities in the country.

Chapter 5 highlights the proposed monitoring and enforcement system and suggests potential regulatory basis in this regard.

Chapter 6 describes the tools and mechanisms for public information, education and awareness building on biosafety issues and public participation in the decision-making process on any GMO related issues.

3. 3. Bangladesh Biosafety Rules, 2012

Bangladesh Biosafety Rules (BR), 2012 provides regulations on the approval process for 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. It has 13 numbers of Rules on import, export or any other kind of uses of GMOs.

Main Features of Biosafety Rules:

- Thirteen number of Rules
- Restriction on import, export or any other kind of uses of GMOs
- Notification for transboundary movement or any other uses through the respective ministries

- Biosafety Guidelines of Bangladesh has been appended as part of the Rules
- Oversight on Risk Assessment and Management is assigned to various committees already formed
- Overall coordination in implementation of the Rules is assigned to DOE
- Crucial Decision and Policy Making Job assigned to MOEFCC

3.4. The Biotechnology Policy, 2012

On May 15, 2014, the Ministry of Science and Technology gazetted the 'Work Plan for the National Biotechnology Policy 2012'. It 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.

The strategies of work have been categorized as of short (2 years), mid (5 years) and long (10 years) terms, in order to achieve sustainable development in different branches of biotechnology. Increase in agricultural production, ascertaining food security, poverty alleviation and upgrading standard of living will take place by implementation of the Work Plan.

Table 2. Priority research activities (Plant biotechnology)

S No.	Activities	Short	Mid	Long	Implementing agency
1	Developing standard of tissue culture/ micro propagation method, for prompt preparation of high quality and disease-free seed/ sapling of crop plants, bamboo, timber.	√	√	√	MOA and biotechnology related concerned Ministries, research institutions, public- private universities/ institutions.
2	Selection/ reproduction of very important crops (paddy, wheat, pulse, oil seed, etc.) by marker, for specific use.	√	√	√	
3	Developing nutritional value of crops; producing transgenic plants which are resistant to insects and diseases, abiotic stress tolerant and harmonious to climate change.	√	√	√	
4	Identification, differentiation and determination of characteristics of necessary gene, in order to develop variety of plants by transfer of gene.	√	√	√	
5	Determination and conservation of molecular characteristics of plant (including medicinal plants) genetic resources and necessary microorganisms in agriculture sector.	√	√	√	
6	Revealing genome of important crops and forest grown plants for specific use.	√	√	√	
7	Introduction, evaluation and testing of transgenic crops.	√	√	√	
8	Identifying plant diseases at molecular level.	√	√	√	

Source: Ministry of Science and Technology, 2014

The Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants was published in 2012 and is consistent with Codex standards. Bangladesh Standardization and Testing Institute (BSTI) has the lead in assessing the safety of GE foods derived from GE plants. The Guideline for the Environmental Risk Assessment (ERA) of Genetically Engineered Plants, published in 2016, is used for planning and conducting an environmental risk assessment in support of an open release of a GE plant in Bangladesh. The User's Guide to Biosafety Regulatory Process on Genetically Engineered Plants in Bangladesh, published in 2017, guides the user through the process of submitting an application to the biosafety regulatory system.

4. Updates on Important Agri-biotech Products in Bangladesh

4.1. Bt Brinjal

Birnjal is an important vegetable in Bangladesh grown all over the country throughout the year and is liked by all. It is the second most important vegetable in terms of acreage and production after potato and plays a significant role in Bangladeshis' daily diet, livelihood and farm income. The biggest constraint to brinjal production not only in Bangladesh, but throughout Asia is chronic and widespread infestation by the brinjal fruit and shoot borer (BFSB), *Leucinodes orbonalis* Guenée. Bt Brinjal Event EE-1containing the *cry1Ac* gene was developed at Maharashtra Hybrid Seeds Company (MAHYCO), India and underwent considerable safety assessment in accredited laboratories to ascertain its toxicity and allergenicity. BARI started transgenic studies supported by a USAID funded project since 2005 through the introgression of *cry1Ac* gene (from *Bacillus thuringiensis*) into 9 brinjal varieties. On completion of required agronomic, compositional and biosafety studies, the government issued a notification for official release of four varieties of Bt brinjal on 30 October 2013. After field release of four varieties, trials continued their field performance. Trials by On-Farm Research Division (OFRD) of BARI, established that the performance of Bt brinjal was far superior to non-Bt brinjal with respect to fruit and shoot infestations. Fruit infestation by BFSB for Bt varieties varied from 0.00 to 0.37% while 39.00 to 49.79% was observed in non-Bt varieties. In case of shoot infestation, it varied from 0 to 0.22% in Bt varieties and 29.36 to 37.87% in non-Bt varieties at different trials during 2017-18 (On Farm Research Division, 2018). Bt brinjal has been increasingly adopted by Bangladeshi farmers since its release in 2013 with distribution for limited scale cultivation to 20 farmers in 2014 to adoption by an estimated ~17% of 150,000 brinjal farmers in Bangladesh in 2018 (Shelton et al., 2018). This was made possible through (i) building institutional/human capacity to carry out product stewardship, post-release monitoring of crop performance, impact on farming community/environment; (ii) training farmers on good stewardship practices to promote durability of technology; (iii) strengthening extension systems/communication efforts to promote science-based public awareness of GM crops. A study was conducted by BARI scientists in 35 districts during the 2016–17 cropping season using 505 Bt brinjal farmers and 350 non-Bt brinjal farmers. It was observed that net returns per hectare were Tk. 179602/ha for Bt brinjal as compared to Tk. 29841/ha for non-Bt brinjal. This study also indicated that farmers saved 61% of the pesticide cost compared to non- Bt brinjal farmers, experienced no losses due to BFSB, and received higher net returns (Rashid et al. 2018). A book on 'Success story on Bt Brinjal Bangladesh' was published by Asia-Pacific Association of Agricultural Research Institutions (APAARI), Thailand where it is mentioned that Bt brinjal can be emulated for ensuring food and nutritional security, improving the livelihoods of smallholder farmers and protect the environment in other developing countries (Asia-Pacific Association of Agricultural Research Institutions, 2018). BARI applied to release three more varieties which are under consideration of BCC. As the first GE crop in Bangladesh, emphasis should be given on stewardship, farmers' awareness for using non-Bt brinjal as refuge, controlling other pests and labeling. Bt brinjal plays a vital role in the future of biotechnology. The success of this first crop has set the stage for others to come.

4.2. Golden Rice

Rice is a staple food in Bangladesh and people depend on rice for 70% of their daily calorie intake. Rice does not contain any beta-carotene. Dependence on rice as the predominant food source, therefore, necessarily leads to Vitamin A deficiency, most severely affecting small children and pregnant women. Consumption of only 150 gram of Golden Rice a day is expected to supply half of the recommended daily intake of vitamin A for an adult.

GR2-E BRRI dhan29 Golden Rice was developed and selected at IRRI from cross between GR2-E Kaybonnet Golden Rice and BRRI dhan29. The Kaybonnet was modified through *Agrobacterium*-mediated transformation of beta-carotene gene (ZmPSY1) from maize using plasmid pSYN12424. Event GR2E was uniquely identified using a multiplex PCR method employing three primers named ZD-E1-P1, ZD-E1-P2 and ZD-E1-P3. BC_5F_5 progenies of GR2E were imported from IRRI, Philippines. A contained trial was conducted in Aus 2015 comprising 170 lines. A total of 30 materials were selected and advanced to conduct a confined field trial (CFT) in Gazipur during Boro 2015-16. Then eight best materials were advanced for multi-locational CFTs during Boro 2016-17. One material, very similar to BRRI dhan29 in grain type and plant height but 1-2 days late in maturity containing 24% amylase was selected and advanced for multi-locational CFT during Boro 2017-18. To confirm that BRRI dhan29 GR2E rice was substantially equivalent agronomically to the recurrent parental line, BRRI dhan29, grain yield and other phenotypic measurements were collected from confined field experiments at five locations during both the 2017 and 2018 boro rice growing seasons in Bangladesh. A total of 15 agronomic parameters were recorded and of these, three were significantly different between GR2E BRRI dhan29 and non-transgenic control BRRI dhan29. Across all locations and years, the GR2E entry was consistently about 1–2 days late to flowering and time to maturity compared to the BRRI dhan29. While grain yield of GR2E was 13.3 percent higher than BRRI dhan29 in 2017, and approximately 3.8 percent lower than control BRRI dhan29 in 2018, in the combined analysis over seasons and locations yield differences were not statistically significant. The combined analysis of the agronomic and phenotypic data generated over locations and growing seasons for GR2E rice and its non-transgenic control supported the conclusion that the genetic modification resulting in event GR2E did not have an unintended effect on plant growth habit and general morphology, vegetative vigour, or grain yield. From the data and observations, there were no indications that GR2E rice exhibited any fitness advantage that would make it more invasive or persistent in the environment, or have altered susceptibility to pests or diseases, than conventional rice. GR2E introgression line IR112060 GR2E:2-7-63-2-96 can be used for the purposes of breeding advancement as well as variety release in future based on its consistent performance across locations and seasons. There were no sequence homology structural alerts for potential toxicity and allergenicity of the ZmPSY1 protein. Acute oral toxicity studies did not result in mortality or other evidence of toxicity to male and female mice that were administered doses at 100 mg/kg. Nutritional composition of GR2E like fibre, polysaccharide, ash, crude fat, protein, minerals, carotenoids and straw composition were analyzed, and it revealed that every compositional component was very similar to control event except carotenoid. As the gene is endosperm specific so, it expresses only in grain, not in other parts of the plant. BRRI submitted application for the environmental and food safety assessment of GR2E Golden Rice to MOA's National Technical Committee on Crop Biotechnology (NTCCB) on 26 November 2017 and forwarded it to MOEFCC (NCB) on 4 December 2017. BCC and NCB reviewed the application on 3 April 2019 and 28 May 2019, respectively.

4.3. Late Blight Resistant Potato

Potato is the second most important food crop of Bangladesh, next to rice, in respect of production. At present, Bangladesh ranks seventh in the world for potato production, while it ranks third in Asia. Late blight is a serious and worldwide devastating disease of potato. Every year it causes tremendous yield loss. All the commercial varieties of potato at present in Bangladesh are susceptible to this disease. In Bangladesh, farmers usually spend Tk. 80 -100 billion per year in spraying of fungicides to protect the major tuber crop, potato to control late blight disease caused by *Phytophthora infestans*, a fungus. According to Food and Agriculture report 2017, around 25-57% potato yield loss occurs annually in Bangladesh even after fungicide application which indicates that presently used fungicides are not working properly. BARI started transgenic studies on late blight resistant potato since 2005 in Bangladesh with the help of USAID supported ABSP II project.

The RB gene was identified in the wild diploid potato species *Solanum bulbocastanum* and introduced into cultivated US late blight (*Phytophthora infestans*) susceptible potato variety Katahdin (*S. tuberosum*) at Wisconsin State University, USA using biotechnological approaches. In Bangladesh, most of the potato varieties are very susceptible to late blight. Among the varieties Cardinal and Diamant are very popular and thus these two varieties were introgressed with RB gene from two RB hybrid clones (SP951 and SP904) following conventional breeding (hybridization) and transformation (molecular breeding). Hybridization was done in 2006 at Lembang Horticultural Research Institute, Indonesia and transformation was done at the Wisconsin State University, USA in 2007. RB potato was field tested under confined condition for seven consecutive seasons from 2008-09 to 2014-15. Compositional analysis with non-transgenic was done at Dhaka University. Effect of RB gene in the soil was also studied by the BARI scientists. Multi-locational CFTs were conducted in six agro-ecological zones of BARI research stations. In the 2015-16 seasons a multi-locational CFT regulatory trial was also conducted at the same six locations with selected hybrid clones to meet the regulatory requirements for deregulation of the variety with RB gene. By this time, DNA samples of D951-137 were sent to Michigan State University (MSU), USA for molecular analysis where backbone sequence was found in the line along with RB gene which was not acceptable in any transgenic crop. As per suggestion from MSU, backcrossing was done with Diamant to get about 25% backbone-free lines. There is a plan to conduct confined field trial with minitubers derived from TPS (true potato seed) obtained from the crossing during the winter season of 2018-19.

Besides the single RB gene, Tuber Crops Research Centre (TCRC), BARI and MSU, USA are working jointly to develop 3-R-gene GM potato variety for late blight disease resistance. Three R genes viz. Rpi-mcq1, Rpi-blb2 and Rpi-vnt1.1 have been isolated from *Solanum mochiquense, Solanum bulbocastanum and Solanum venturii*, respectively. The Simplot Plant Science plasmid along with nptII selectable marker gene has been used to develop the GM Diamant event. Transgenic events have been developed through *Agrobacterium*-mediated gene delivery system. At MSU, sixteen superior 3-R-gene events using the CIP construct were identified. These events are under trial for efficacy test against the *Phytophthora infestans* isolate US-23 again at MSU. The best performing events from Simplot Plant Sciences will be imported in Bangladesh during August-September, 2019 for contained, confined and regulatory field trials at BARI.

4.4. Bt Cotton

The textile industry has played an important role in Bangladesh's economy for a long time. Currently, the textile industry in Bangladesh accounts for 45% of all industrial employment and contributes 5% to the total national income. The industry employs nearly 4 million people; of which women represent a higher proportion. The basic raw material of textile sector is cotton. Bangladesh is the second highest consumer of raw cotton and the highest importer of raw cotton in the world. Annual requirement of raw cotton for textile industry of Bangladesh is approximately 5.5-6.0 million bales. Around 3% of the national requirement is fulfilled through local production. Cotton Development Board (CDB) has developed intensive programs to produce quality seed combining advanced biotechnology tools with traditional knowledge. The CDB has initiated collaborative research with foreign cotton seed producing companies to develop a GE cotton variety for commercial release. Bt cotton developed by Hubei Provincial Seed Company, China containing the cry1Ab gene, was approved by NCB of Bangladesh for contained trial in December 2014. Bt cotton hybrid seed of variety HSC-4 was obtained through the Material Transfer Agreement between Hubei Provincial Seed Company and Cotton Development Board. Following the Biosafety Guidelines of Bangladesh, Bt cotton contained trial was initiated in July 2015. Bt cotton gene was identified by PCR and Bt protein was detected through Lateral Flow Immuno Strip test. For the bioassay of Bt Cotton, mass rearing of cotton bollworm (*Helicoverpa armigera*), trials in net cage and trials using plastic pots were done. The presence of Bt gene and Bt protein in cotton plats were confirmed, however, the cotton plant did not show any resistance against bollworm. As such, CDB has taken initiative to introduce Bollgard II Bt cotton hybrids developed by MAHYCO, in Bangladesh and obtained permission from NCB in February 2017. After having permission from the NCB, MAHYCO did not agree to share the Bt Cotton Seeds for regulatory trials in Bangladesh. The CDB has signed MOU with JK AgriGenetics Ltd. to introduce Bt cotton hybrids containing truncated *cry1Ac* gene and obtained permission from NCB in October 2017. Contained trials with two Bt hybrids, JKCH 1947 Bt and JKCH 1050 Bt were initiated on 7 August 2018 at the greenhouse of Biotechnology Division, BARI.

5. Harmonization Efforts

5.1. Food Safety Assessment

The Codex guideline for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Plants (CAC/GL 45-2003) was adopted in 2003. According to the Codex guideline, the purpose of the GM food safety assessment is to identify new or altered hazards relative to the conventional counterpart, which is the benchmark for what is regarded as safe. The Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2012 were developed by the Department of Environment. The Bangladesh Agricultural Research Council (BARC), in collaboration with the Bangladesh Standards and Testing Institution (BSTI), DOE, the Institute of Public Health (IPH), the Directorate General of Food, and other relevant stakeholders, undertook the initiative to develop these guidelines to establish the safety assessment procedures for foods derived from GE plants, also taking into consideration the International Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. As the apex body for the National Agricultural Research System, BARC has much of the expertise necessary for both the development and safety assessment of agricultural products of biotechnology. The objective of the guidelines is to provide a system to ensure that foods derived from GE plants are as safe as existing foods in Bangladesh.

5.1.1. Framework for Safety Assessment

Safety assessment is designed to identify whether a hazard, nutritional or other safety concern is present and if present, to collect and analyze information on its nature and severity following a structured and integrated approach performed on a case-by-case basis. The safety assessment of foods derived from GE plants follows a stepwise process aided by a series of structured questions. Factors like identity, source, composition, effects of processing/cooking, transformation process, the recombinant-DNA, protein expression product of the novel DNA, possible secondary effects from gene expression or the disruption of the host DNA or metabolic pathways, potential intake and dietary impact of the introduction of the GE food etc. are taken into account for safety assessment.

5.1.2. Core Information

Description of the GE plant, description of the unmodified host plant and its use as food, description of the donor organism(s), description of the genetic modification (method of genetic modification, potentially introduced genetic material) must be provided.

5.1.3. Molecular Characterization of the GE plant

The molecular-genetic characterization of the modified plant should be sufficient to demonstrate that the introduced DNA has been stably incorporated into the plant's genetic material (nuclear genome or a plastid genome) and that the introduced DNA (or trait) is inherited over multiple generations in a predictable manner.

5.1.4. Safety Assessment

Assessment of Possible Toxicity: Toxicological testing is required for substances of unknown safety that are introduced into the food supply. *In vitro* nucleic acid techniques enable the introduction of DNA that can result in the synthesis of new substances in plants. These include the protein expression product and other substances, which may be generated as a result of enzymatic activity of the protein expression product. The new substances can be conventional components of plant foods such as proteins, fats, carbohydrates, vitamins, which are novel in context of that GE plant.

Assessment of Possible Allergenicity: The primary consideration in allergenicity assessment of a newly expressed novel protein in a food derived from a GE plant is the prevention of unexpected exposure of sensitized individuals to food allergens. All newly expressed proteins in GE plants that could be present in the final food need to be assessed for their potential to cause allergic reactions. This requires consideration of whether a newly expressed protein is one to which certain individuals may already be sensitive as well as whether a protein new to the food supply is likely to induce allergic reactions in some individuals. Information on the source of the introduced gene, amino acid sequence similarity with known allergens and pepsin resistance etc. are considered.

As scientific knowledge and technology evolves, other methods and tools may be considered in assessing the allergenicity potential of newly expressed proteins as part of the assessment strategy.

5.1.5. Compositional Analysis

For GE plants without purposefully altered nutritional properties, compositional analysis is part of the weight-of-evidence approach for evaluating whether there were any unanticipated consequences of the genetic modification. Data should be provided on the levels of key nutrients and antinutrients present in the edible portions of the plant (e.g., seed or grain), including other plant parts (e.g., forage) that may be used as feed for livestock. The compounds chosen for testing should be those recognized as key nutrients and antinutrients for the plant species (e.g., those identified in international consensus documents on nutrient properties, where applicable).

5.1.6. Intended Nutritional Modifications

Foods derived from GE plants that have undergone modification to intentionally alter nutritional quality or functionality need to be subjected to additional nutritional assessment to assess the consequences of the changes and whether the nutrient intakes are likely to be altered by the introduction of such foods into the food supply.

5.1.7. Unintended Effects

Unintended effects can result from the random insertion of DNA sequences into the plant genome which may cause disruption or silencing of existing genes, activation of silent genes, or modifications in the expression of existing genes. Unintended effects may also result in the formation of new or changed patterns of metabolites. The assessment for unintended effects considers the agronomic/phenotypic characteristics of the plant that are typically observed by breeders in selecting new varieties for commercialization.

5.2. Environmental Risk Assessment

The Guidelines for the Environmental Risk Assessment (ERA) of GE plants were gazette in 2016. Bangladesh, the regulation of GE plants is encoded in the Biosafety Rules, promulgated under the Environment Conservation Act, 1995 and elaborated in the Bangladesh Biosafety Guidelines. The NCB is responsible for making decisions regarding the use of GE plants, while the BCC provides the NCB with technical advice and analysis, including environmental risk assessment.

General Considerations in ERA

In order to conduct an environmental risk assessment for the release of a GE plant, it is first necessary to have a thorough understanding of what plant is being assessed.

Description of GE plant: A description of the GE plant being presented for risk/safety assessment needs to be provided. It should include - name of the GE event, unique event-specific identifier, name of the non-transgenic host plant or non-modified counterpart or parental plant, pedigree map of the GE plant, purpose of the genetic modification, intended use, geographical areas within Bangladesh to which distribution of the product is intended.

Description of the Non-transgenic Host Plant or Non-modified Counterpart or Parental Plant: Information on taxonomy, geographic origin and domestication of the plant, reproductive biology, naturally occurring crosses, cultivation in Bangladesh should be included.

Description of the Donor Organisms: Information must be provided on the donor organism(s) and, when appropriate, on other species related to the donor.

Description of the Genetic Modification(s): Consistent with the Bangladesh Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2012, detailed information is required on the genetic modification to allow for the identification of all genetic material potentially delivered to the host plant and to provide all relevant information required for the analysis of the data supporting the characterization of the DNA inserted in the plant.

Molecular Characterization of Transgene(s): A comprehensive molecular and biochemical characterization of the genetic modification needs to be carried out. The requirements below are consistent with the Bangladesh Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants, 2012.

Phenotypic and Agronomic Characteristics of the GE Plant: Information must be provided on the phenotype of the GE plant, including any observation of unintended or unanticipated characteristics.

Cultivation Practices: Information must be provided on any predictable impacts on existing agronomic practice that could arise as a consequence of cultivation of the GE plant and that would have a potential effect on the biodiversity of the receiving environment.

Impact on Non-target Organisms: For those GE plants that have a target organism, including insect resistant or nematode resistant plants expressing a pesticidal protein or molecule, or in cases where the introduced trait is known to have toxic activity, the potential for adverse environmental impacts on non-target organisms should be evaluated.

Post-release Environmental Monitoring: The need for post-release environmental monitoring will be determined on a case-by-case basis, considering familiarity with the plant species and trait.

Instructions on Data Quality: The quality of data submitted with the application should be equivalent to that submitted for peer-reviewed scientific publications. Applicants should clearly describe experimental procedures followed in developing data, including methods, reference materials, quality control and quality assurance procedures, statistical analyses, together with bibliographic references as appropriate. Statistically valid experimental designs and protocols should be employed in generation of all field trial data, and trials should be conducted in a manner consistent with the proposed agricultural practices for the GE plant.

5.3. Import of Agricultural Biotechnology for Food, Feed and Processing

The importation of LMOs for direct use as food, animal feed or for processing (FFPs) is considered under Article 11 of the Cartagena Protocol on Biosafety.

Process Description: An applicant would apply for an import permit through the NCB. The NCB would forward the application, along with technical information to the BCC for their review. The BCC has 60 days to review the application and provide questions to the applicant. A BCC report is then sent back to the NCB, which has 30 days to review the results and issue a decision on the importation of the LMO for use in FFP.

Regulatory Process Outline Expected (Timeline: 90 Days): 1. The application is received by the NCB and reviewed for completeness. A letter acknowledging receipt is sent to the applicant. 2. The application is forwarded to the BCC. The application materials are reviewed in the context of the Bangladesh Guidelines for the Safety Assessment of Food and Feed derived from GE Plants by the BCC and any additional technical experts invited by the BCC for the purposes of the review. 3. The BCC forwards a recommendation to the NCB, which takes a decision on the importation. 4. The decision is communicated back to the applicant, along with any conditions associated with an import approval. The decision will indicate the scope of the approval (e.g. whether it encompasses a single importation, or multiple importations, the duration of the approval etc.).

Submitting Applications: The importer should submit applications for CFTs to the Ministry of Environment. The receiving official at the Ministry of Environment is the Secretary, who serves as the chair of the NCB. Two copies of the application should be sent through mail. The ministry may request additional copies. An electronic copy should also be sent to secretary@moef.gov.bd. The application should be addressed to: Chairperson, National Committee on Biosafety (NCB), Ministry of Environment, Forests and Climate Change (MOEFCC) Bangladesh Secretariat Dhaka-1000. The applicant should expect to receive a letter confirming the receipt of the application from the office of the Secretary. The applicant will be notified of a decision by the Member Secretary of the NCB. Review of the application is expected to take 90 days.

Renewal Applications (Pending revision to the Biosafety Guidelines): For continuations of previously approved field trials, following the same protocols, an expedited review process may occur. If the trial is reviewed by the BCC without any objection then permission to continue the trial may be granted by the Department of Environment, subject to review by the NCB.

6. Challenges and Way Forward for Agricultural Biosafety

Labeling: As per Biosafety Guidelines and Rules of Bangladesh, any GMO products should be labeled properly. Moreover, labeling was incorporated in the notification of Bt brinjal release. But farmers are not interested to label in most cases, although scientists of BARI advocated farmers for labeling. Practically it is difficult to label for each brinjal fruit by the farmers. Considering the socio-economic condition of the farmers, more discussion is needed to address this issue to find out a feasible way for labeling.

Intellectual Property Rights: Bangladesh lacks effective legislation or enforcement mechanisms to protect intellectual property rights. The gene (s) of the GMO products like Bt brinjal, Bt cotton, LBR potato, Golden Rice etc. developed by the multinational company. So, it is troublesome to Bangladesh to claim a right in the intellectual property. There is need to develop transgenic products indigenously in future.

Low Level Presence: Currently, there are no regulations or policies that address any unintended low level presence of GM crops.

Export of GMOs: As per Biosafety Guidelines, an exporter needs to apply for GE product approval. Regulations should be clearer for export of GM products.

Capacity Building: Biosafety is a new area in the country and there is a need for skilled manpower in this context.

Unreasonable Opposition to Biotechnology: A group of civil society stands against biotechnology, especially GMOs. Communication with relevant stakeholders is needed to create an enabling environment for biotechnology. There is a need for a multi-stakeholder process or dialogue to ensure public acceptance for crop biotechnology and in evolving enabling policies.

Delays in Regulatory Approvals: Compared to non-GMO crops, GMO crops take much more time to be released. It takes time to obtain permission to carry out GM research.

In our country, regulatory procedure is variety based. Many countries deregulated the event rather than variety. There may be a discussion on this issue in future.

Post-release Monitoring: It plays a crucial role in environmental risk assessment and management. It should be undertaken to gather information on long-term effects of GMOs on the environment.

7. Conclusion

The global community, including Bangladesh, by adopting the 2030 Agenda for Sustainable Development, has prioritized food security through the second Sustainable Development Goal, or SDG 2, which aims to “end hunger, achieve food security and improved nutrition, and promote sustainable agriculture” by 2030. Biotechnology may contribute in sustainable crop development, but it cannot solve all the problems associated with agricultural production, it has the potential to address specific problems like increasing crop productivity; diversifying crops; enhancing nutritional value of food; reducing environmental impacts of agricultural production through development of crop resistance to biotic and abiotic stresses and promoting market competitiveness. The government is taking keen interest in this area in terms of policy planning, institutional development and funding. Some research programmes are supported by the government. Biosecurity and bioterrorism are rapidly emerging issues, and need to be taken care of in the interest of sustainable research, human health and environmental safety. Biosafety regulations should be updated as per future requirements of the country.

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Current Status of Agricultural Biosafety in Bhutan

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Abstract

The agriculture of Bhutan is mainly based on traditional production techniques and traditional biotechnology is modestly used in Bhutan to address the issues on crop and livestock production. Bhutan acknowledges the benefits offered by modern biotechnology and any other novel technologies for mankind, however, modern biotechnology applications are currently not practiced in Bhutan. Bhutan is well aware that global adoptions of Biotech crops and import of product derived from modern biotechnology are increasing since its conception.

Biosafety Act of the country prohibits any activities involving viable Genetically Modified Organism (GMO)/Living Modified Organism (LMO). The Biosafety Act is framed after careful consideration and in harmonization with the existing laws/policies of the country. As such Bhutan has established regulatory measures like administration of biosafety, laboratory detection of GMOs, capacity building for inspectors, routine surveillance, and permitting and inspection systems. Bhutan has also established a GMO safety management system with administrative procedures for application processing, safety assessment by a Biosafety Technical Working Group and has developed the required guidelines and protocols to implement Biosafety activities in Bhutan.

Key words: Act, BAFRA, Bhutan, GMO

1. Introduction

Bhutan Agriculture and Food Regulatory Authority (BAFRA) was established under the Ministry of Agriculture and Forests to implement sanitary, phytosanitary and biosecurity measures effectively to protect the health and life of humans, farming systems and the environment including the national biodiversity from risks of entry, establishment and spread of exotic pests, diseases and invasive alien species thereby promoting trade and ensuring healthy ecosystem. Currently, BAFRA has two Divisions viz., Quality Control and Quarantine Division (QCQD) and Analytical and Certification Division (ACD). There are four sections (Plant, Livestock, Food and Biosafety) under QCQD and two sections (Certification and Standards Sections) and the National Food Testing Laboratory (NFTL) under ACD. Analytical Services related to food is provided by NFTL, while quarantine samples from live animals are analyzed at the National Centre for Animal Health under the Department of Livestock.

Bhutan ratified the Cartagena Protocol on Biosafety in August 2002 and as an obligation to the protocol, Bhutan developed the National Biosafety Framework (NBF) in 2006.

With the help of funding support from United Nations Environment Program (UNEP) and Global Environment Facility (GEF) the framework was operationalized through the National Biosafety Framework Project in the year 2010 under BAFRA, as it is the national competent authority for implementing biosafety activities. The project was implemented between July 2010 and November 2014.

1.1. Vision of BAFRA

To safeguard national biosecurity and ensure safe food for all.

1.2. Mandate of BAFRA

i. Provide regulatory services to protect the health of animals, humans and the environment

ii. Implement national biosecurity measures

iii. Ensure safety and quality of food including novel food (GMO)

iv. Facilitate trade and market access through inspection and certification services

v. Provide food testing services for regulatory and general purposes

vi. Promote research on biosecurity and food Safety

vii. Enhance collaboration with relevant domestic and international organizations

2. Institutional Architecture and Linkages

Bhutan Agriculture and Food Regulatory Authority, Ministry of Agriculture and Forests is governed by the Management Board under the Chairmanship of Minister for Ministry of Agriculture and Forests (MoAF) and Secretary for MoAF as Vice-Chair. The Board members comprises of heads from the Department of Agriculture, Department of Livestock, Department of Forests and Park Services, Policy and Planning Division, Department of Public Health, Department of Trade, Department of Revenue and Customs, and Bhutan Chambers of Commerce and Industries. The Management Board of BAFRA was established keeping in view the overriding prerequisite for broad representation from across the Renewable Natural Resources (RNR) as well as from relevant organizations of other ministries to act as a consultative, advisory and coordinating body to make BAFRA an efficient and a competent regulatory body.

BAFRA also work closely with Department of Industries, Office of the Consumer Protection, Department of Agriculture Marketing and Cooperatives, National Organic Program and Food Corporation of Bhutan Ltd., Office of the Attorney General, Department of Law and Order, National Environment Commission, National Biodiversity Center and Bhutan Standards Bureau.

At an international level, BAFRA has developed Institutional linkages with Export Inspection Council of India, Department of Agriculture Extension of Bangladesh, Korea Research Institute of Bioscience & Biotechnology and in particular with Korea Biosafety Clearing House and Det Norske Veritas and Germanischer Lloyd (DNVGL) for certification. In addition, BAFRA also functions as national contact point to Codex Alimentarius Commission, the International Plant Protection Convention, International Health Regulations, Sanitary and Phytosanitary Agreement of WTO and International Network of Food Safety Authorities.

3. The Agriculture Sector in Bhutan

The existing food production and marketing is largely subsistence, traditional and localized. Agriculture, livestock and forestry provide livelihoods to more than 58% of the total population, contributing to 16.52% to the total economy (National Statistics Bureau, 2017). Agricultural food production is diversified, and the main crops cultivated are maize, rice, buckwheat, barley and millet reflecting the staple diet of the Bhutanese people. The main horticultural produce includes vegetables, fruits and nuts which are available seasonally. Livestock rearing is also an integral part of the farming system in Bhutan; it is not only useful for animal products but also for manure; often used as a relatively cheap alternative to chemical fertilizers. The diversity of food items of the Bhutanese is also enhanced by a wide variety of wild vegetables, medicinal plants and Non-Wood Forest Products (NWFPs) collected from nature.

4. Global Acreage of Genetically Engineered Crops

The International Service for the Acquisition of Agri-biotech Applications (ISAAA) report 2017 states that the global biotech crop areas has increased by 3 percent or 4.7 million hectares and since 1996 till 2017 biotech crop area have increased by 2.3 billion hectares. It has been also stated that 67 countries adopted Biotech crops since 1996 with 24 countries planting and 43 importing GM crops. Major GM crops grown are Canola (10.2 Mhas), Maize (59.70 Mhas), Cotton (24.21 Mhas) and Soya beans (94.10 Mhas). This indicates that GM is a fast growing technology due to its economic benefit. Both in the developed and developing world, significant yield increases were achieved through the cultivation of GM crops over the non-GM crops and five major countries that grow GM Crops are USA, Brazil, Argentina, Canada and India. Currently, GM varieties of soybean, maize, cotton, canola, sugar beet, alfalfa, papaya, squash, potato, Apples, Eggplant and pineapple are commercially available.

5. Biotechnology and Biosafety in Bhutan

Currently, there is no specific department for biotechnological research and development in Bhutan. However, some conventional biotechnological applications are used in various departments within the Ministry of Agriculture and Forests to address the issues on crop and livestock. In crops, the use of biotechnology is centered in genetic diagnosis mainly on rice, citrus and tissue culture for the propagation of disease-free crops and ornamental plants (Yaganagi and Yangzom, 2013).

As per the report 'Updated National State-of-the-Art Report on Biotechnology', in Bhutan conventional biotechnologies are applied mostly in two fields;

i. Plant biotechnology (Plant tissue culture, Medicinal & Aromatic Plants, Crop breeding)
ii. Animal biotechnology (Vaccine production, Semen production and artificial insemination)

Organizations under MoAF that use biotechnology applications are National Seed Centre, National Livestock Breeding Programme, National Centre for Animal Health and Renewable Natural Resources Research Centers.

In Bhutan, the understanding of and familiarity with GMOs is quite new and there is an ongoing effort to increase the general awareness of the public along with capacity building of BAFRA to regulate GMOs and its products. BAFRA conducted surveys to understand the level of awareness on biosafety targeting the public, scientific community and hoteliers in 2011 and 2013. The surveys revealed that general awareness of modern biotechnology is low in Bhutan. A very small segment of the general literate public is aware of the scientific issues. One of the possible reasons could be the lack of ongoing scientific research and GM technology adoption in the country.

6. Biosafety Policy

Bhutan has adopted a precautionary policy concerning Genetically Modified Organisms (GMOs), with the aim to protect, conserve and safeguard biodiversity in the country and promote organic agriculture. Research and development of GMO/LMO using modern biotechnology is not conducted in

Bhutan as GMOs are currently prohibited for cultivation. However, the government agencies, private companies and institutions apply traditional biotechnology for minor tissue culture activities. The agriculture of Bhutan is mainly organic farming based on traditional production techniques.

The cultivation import and distribution of genetically modified crops are currently prohibited in Bhutan (Biosafety Act, 2015) and the possibility of introducing GMO in Bhutan would be through trade of food and feed. However, genetically modified (GM) foods and feeds in non-viable forms are permitted after safety assessment by Biosafety Technical Working Group and approved by the National Biosafety Board, while the environmental release of viable genetically modified organisms (GMOs) is completely prohibited. Ensuring the safety of imported GM food in the market is the responsibility of BAFRA, especially given Bhutan's reliance on significant imports to meet food requirements.

The Biosafety Act of Bhutan 2015 describes the framework for the regulation of GMOs and their products and is complemented by corresponding regulations and guidelines. Some of the salient features of the Biosafety Act of Bhutan are as below;

The prohibitions in the Biosafety Act are:

i. Import of any GMOs and any other genetically modified biological material capable of reproducing;
ii. Transit of GMOs capable of reproducing;
iii. Intentional introduction of GMOs capable of reproducing into the environment;
iv. Any use, including contained use of GMOs capable of reproducing; and
v. Research and development that involves GMOs capable of reproducing

The exemptions in the Biosafety Act are:

i. Traditional and domestic methods of animal and plant breeding;
ii. Traditional and domestic exchange and sale of local seeds, plants, and livestock;
iii. Gene sequencing, tissue culture, and other similar methods, which do not involve the use of modern biotechnology; and
iv. Products derived from genetically modified organisms for pharmaceuticals for human and veterinary use.

Biosafety legislation was framed after careful consideration of other existing legislations described below and being a landlocked country with an open and porous border, Bhutan's prime concern is the safety of its citizens and its pristine environment; but at the same time, increasing food security and ensuring food-sufficiency are critical objectives of Bhutan.

i. Ministerial Notification 2000

Bhutan adopted a precautionary approach in 2000, whereby all imports of GMOs into the Kingdom were banned through a ministerial decree issued by the Ministry of Agriculture. This was the first initiative taken by the government to ensure that GMOs are not introduced into the Kingdom.

ii. Food Act of Bhutan 2005

The Food Act of Bhutan 2005, Chapter VII; Section 59 and 60, mandates the regulation of food business pertaining to genetically modified foods.

iii. National Biosafety Framework of Bhutan 2006

As an obligation to the Protocol, Bhutan developed the National Biosafety Framework (NBF) in 2006. With the help of funding from the United Nation Environment Program (UNEP) and Global Environment Facility (GEF), the Framework was operationalized through the National Biosafety Framework Project (NBFP) in 2010 under BAFRA. BAFRA was designated as the National Competent Authority for the implementation of all biosafety related activities in the Kingdom.

iv. Seed Rules and Regulations 2006

Chapter 4, Section II Clause (c), Import of seed, states that "import of genetically modified seeds has to comply with the national regulatory framework on biosafety".

v. National Environment Protection Act 2007

The National Environment Protection Act 2007, Chapter 5; Section 72 mandates the establishment of regulatory controls over import and use of GMOs including living modified organisms and products containing GMOs.

vi. Constitution of the Kingdom of Bhutan 2008

The Constitution states that every Bhutanese is a trustee of the Kingdom's natural resources and environment for the benefit of the present and future generations and declares it the fundamental duty of every citizen to contribute to protect, conserve, and prevent all forms of ecological degradation including noise, visual and physical pollution. This Article mandates the adoption and support of environment-friendly practices and policies.

vii. Economic Development Policy 2010

The Policy promotes Bhutan as an organic brand and focuses on the production of high-value organic produce.

viii. Biosecurity Policy of Bhutan 2010

The Policy designates BAFRA as the competent authority to coordinate all biosecurity-related activities. The Biosecurity Policy of Bhutan aims to achieve Gross National Happiness by ensuring the protection of the Bhutanese people, the biological resources, plants and animals from the harmful effects of pests and diseases, invasive alien species, GMOs, toxic chemicals and food additives.

ix. Ministerial notification 2011

A notification was issued by the MoAF banning import, transit, release, research and contained use of GMOs/LMO escapable of reproducing in the Kingdom.

7. Biosafety Administration Structure

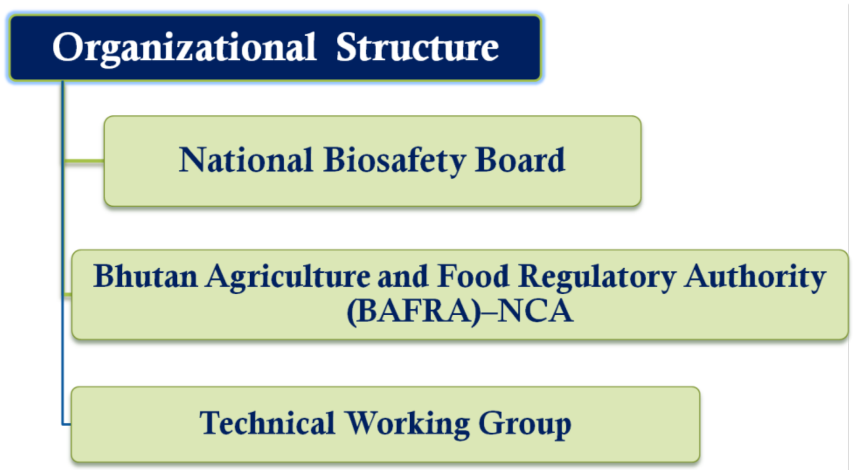

Figure 1: Organizational Structure of Biosafety in Bhutan

Source: Prepared as per the Biosafety Act 2015

Figure 1 represents organizational structure of biosafety administration in Bhutan. The National Biosafety Board is the highest decision-making body for issues related to biosafety. The Board exercises the jurisdiction and powers and discharges the mandates conferred or imposed by the Act. BAFRA is the national competent authority for the implementation and enforcement of activities related to biosafety. Biosafety Technical Working Group comprises officials from relevant agencies and their main role is to advise on technical and scientific aspects related to biosafety. Biosafety Technical Working Group is also entrusted with conducting risk assessment of GM food.

8. National Biosafety Board (NBB)

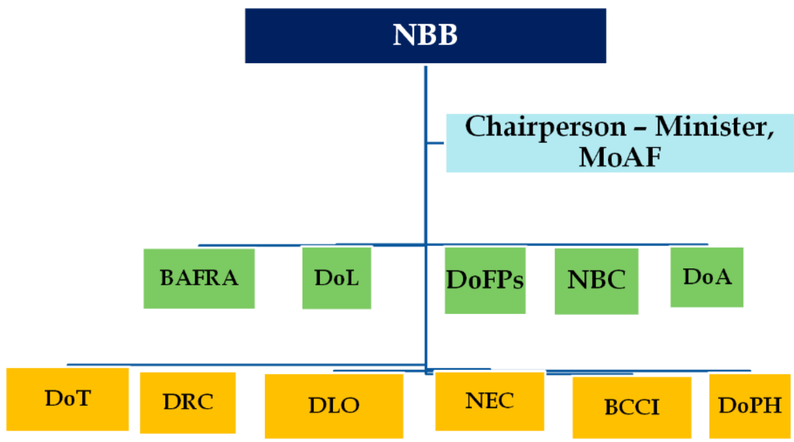

Figure 2: National Biosafety Board

Prepared as per the Biosafety Act, 2015

Figure 2 represents the formation of National Biosafety Board (NBB) where green represents members from Ministry of Agriculture and Forests and yellow represents members from outside of the Ministry. NBB comprises of members from Department of Livestock (DOL), Department of Forests and Park Services (DoFPS), National Biodiversity Center (NBC) and Department of Agriculture (DoA). From outside the Ministry, we have members from Department of Trade (DoT), Department of Revenue and Customs (DRC), Department of Law and Order (DLO), National Environment Commission (NEC), Department of Public Health and Bhutan Chamber of Commerce and Industries (BCCI) representing private sectors.

9. Biosafety Initiatives

In an effort to implement Biosafety activities in the country, Bhutan has developed guidelines and manuals that are in line with international best practices such as;

i. Guidelines for handling applications for GMO/LMO and their products
ii. Guidelines for inspection and monitoring of GMO/LMO
iii. Guidelines on environmental risk assessment of GM plants
iv. Risk assessment of food and feed products derived from GM plants
v. GMO detection method and protocols

vi. Laboratory manual for the detection of GMO
vii. Manual for training workshop on GMO/LMO-handling application and inspections
viii. Draft Biosafety Communication Strategy
ix. Draft Biosafety Incident Management Plan

BAFRA conducts regular GMO surveillance as a part of monitoring program to regulate the presence of GMO in Bhutanese market focusing on GM elements in feed, corn, soya, rice and brinjal by using test kits and PCR methods.

10. Conclusion

The agriculture of Bhutan is mainly organic farming based on traditional production techniques.

Royal Government of Bhutan has adopted a precautionary policy concerning GMOs, with the aim to protect, conserve and safeguard the biodiversity in the country and promotes organic agriculture. Research and development of GMO/LMO using modern biotechnology is not conducted in Bhutan as GMOs are currently prohibited for cultivation in Bhutan. However, possibility of introducing GMO in Bhutan would be through trade of food and feed. Traditional biotechnologies such as tissue culture are engaged by the government agencies, private companies and institutions for plant propagation.

Food and feed derived from GMOs in non-viable forms are permitted after safety assessment by Biosafety Technical Working Group. As of now Bhutan has not received any application to import food and feed derived from GMO.

11. Acknowledgement

The author would like to acknowledge the resources and information obtained from the archives of Bhutan Agriculture and Food Regulatory Authority, Ministry of Agriculture and Forests, Thimphu.

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Status of Development of Genetically Modified Crop and its Regulatory System in India

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Abstract

Bt cotton, the first and only commercial GM crop in India, made big impacts on cotton yield and total cotton production, and economic benefits to cotton farmers. Bt brinjal is the next GM crop which was declared environmentally safe by Genetic Engineering Appraisal Committee (GEAC) but did not get approval for commercial release from Indian Government. At present, decision on environmental release of hybrid GM mustard, is pending and GEAC has advised to generate more data on environmental safety. Besides these three, there are a number of GM crops which are at different stages of development and evaluation. Recombinant DNA (rDNA) and genetically modified organisms (GMOs) including GM crops are regulated by the Environmental Protection Act (EPA) rules 1989 under EPA 1986 of Government of India, and the GEAC under the Ministry of Environment, Forestry and Climate Change (MoEFCC) is the apex regulatory authority. India has three tiers regulatory systems for GM crops. Recombinant DNA Advisory Committee (RDAC), constituted by Department of Biotechnology under Ministry of Science and Technology, performs advisory role; Institute Biosafety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM) under DBT, and GEAC perform regulatory roles; and State Biotechnology Coordination Committee (SBCC) and District Level Committee (DLC) are constituted by each state for monitoring on GM crops. Promising GM lines, selected under glasshouse condition, undergo three stages of field trials, 'Event Selection Trial', Biosafety Research Level-I and Biosafety Research Level-II, before being considered for environmental release.

Keywords: Bt cotton, GM crops, India, regulatory framework

1. Introduction

The knowledge-driven new horizon that has been created in the Indian economic landscape, towards which researchers, investors and entrepreneurs are venturing, is biotechnology. India's varied agro-climatic zones, rich bioresources, diverse gene pool, traditional knowledge base and specific skill sets provide biotechnology sector a wealth of material for cutting edge research programs. India's sixth Five Year Plan (1980-1985) has identified biotechnology as a means to address the developmental needs of its agriculture and health sectors. Since then an unprecedented growth in biotechnology has been recorded with an abundance of government initiatives (Sharma et al., 2003).

The Indian biotechnology industry can be grouped under the sectors-biopharmaceuticals, bioservices and bioinformatics, bioagriculture, and bioindustries (Figure 1). Biopharmaceuticals, comprising vaccines, therapeutics and diagnostics, constitutes the largest biotechnology sector in India, both in terms of domestic and export revenues, and it accounted for 62% of Indian biotechnology market share in 2009. Bioservices is the second largest sector, and growth of this sector can be attributed to the fact that India has become a popular destination for clinical trial, contract research and manufacturing activities. Bioinformatics deals with creation and maintenance of extensive electronic databases on various biological systems, and also interpretation and analysis of data generated by whole genome sequencing efforts. The third largest sector of Indian biotechnology is bioagriculture, which can be segmented into transgenic crops, biopesticides, biofertilizers, and plant tissue culture. Bioindustrial sector predominantly consists of enzyme manufacturing for detergents, textiles, food, leather, paper and pharmaceuticals (Malhotra et al., 2012).

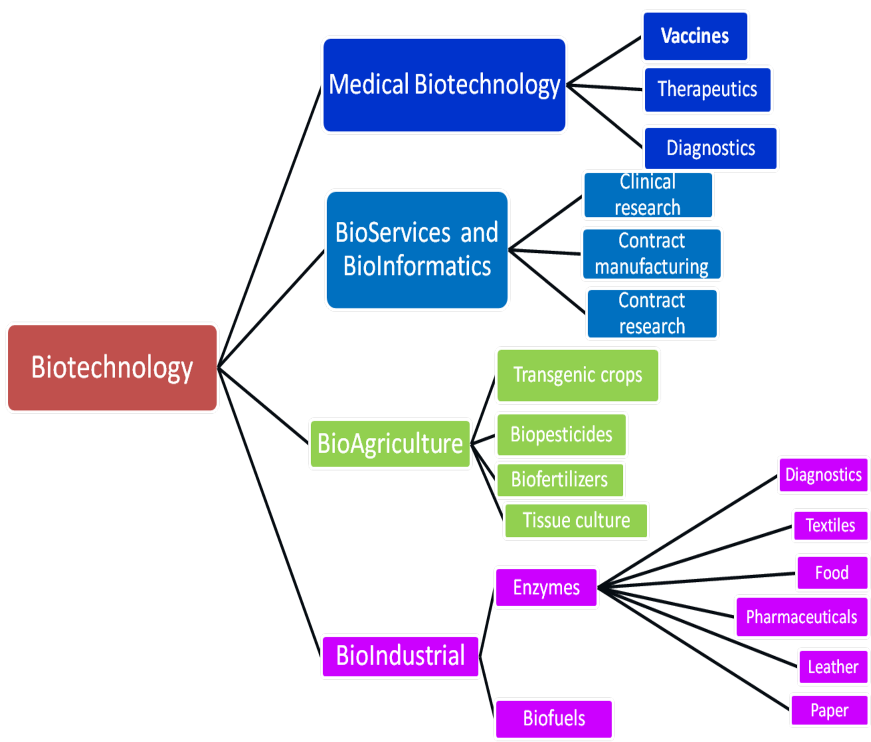

Figure 1. Different Indian biotechnology sectors.

2. Status of GM Crops in India

During 1980 to 2000, cotton farmers were facing yield crisis in cotton production due to high susceptibility to Lepidopteran insect-pests commonly known as bollworm complex consisting of cotton bollworm (*Helicoverpa armigera*), pink bollworm (*Pectinophora gossypiella*) and spotted bollworm (*Earias vitella*) (Karihaloo and Kumar, 2009). Occurrence of the cotton bollworm outbreak was to the extent of epidemic nature in cotton-growing areas across India from 1978 to 2001 (Dhawan et al., 2004). Thus, *Helicoverpa armigera* became the most damaging insect-pest causing devastating losses of cotton up to 80% resulting in frequent crop failures. Controlling of cotton bollworm was required excessive and indiscriminate spraying of chemical insecticides which has led to the development of high level resistance in insect pests (Ramasundaram and Gajbhiye, 2001). In cotton alone 9400 M tonnes of insecticides were used in 2001 which accounts for 46% in total insecticides used (Kranthi, 2012). The indiscriminate usages of chemical insecticides led to detrimental consequences on human health and environment (Abhilash and Singh, 2009).

The soil-borne bacterium, *Bacillus thuringiensis* (*Bt*), that produces insecticidal Cry proteins (ICPs) were commonly used as a biological pesticide to control borer insect-pests. Isolation of *cry* genes paved way for the genetic modification through plant transformation techniques. In USA, insect resistant transgenic cotton plants expressing *Bt* proteins were first commercialized in 1996 ('Bollgard I' by Monsanto, USA). Monsanto offered to share *Bt* cotton technology to the public sector institutions of the Government of India in the early 1990s. The technology transfer offer contained a package comprising two constructs with *cry1Ac* and *cry1Ab* genes, transgenic cotton seeds of Coker-312 variety containing *cry1Ac* gene (Choudhary et al., 2014). However, after the failure of the negotiation efforts, the public sector organization, Indian Council of Agricultural Research (ICAR) initiated development of indigenous insect resistant *Bt* cotton funded by World Bank under National Agricultural Technology Project (NATP). Meanwhile, Indian private sector seed company Mahyco initiated development of insect-resistant *Bt* cotton hybrid varieties in collaboration with Monsanto. In 1996, Mahyco imported seeds of cotton variety, Coker-312, containing *cry1Ac* gene from Monsanto. The gene (*cry1Ac*) was introgressed into elite Indian cotton cultivars by conventional breeding (Karihaloo and Kumar, 2009). Risk assessment studies and limited field trials were conducted during 1996 and 1998. Multi location field trials were conducted at 40 locations in nine states during 1998 and 2000 to assess the insecticidal efficacy and other agronomical parameters of insect resistance and its interaction with the environment, which was followed by large-scale field trials at 10 locations in 6 states. All the biosafety issues like food and feed safety, gene flow, cross-pollination, effect on non-target beneficial organisms and impact on soil micro organisms, etc. were carefully examined during these trials (Manjunath, 2004). ICAR also validated the safety, efficacy and performance of *Bt* cotton hybrids under its All India Coordinated Cotton Improvement Project (AICCIP) in 2001. In 2002, the Ministry of Environment and Forests (MoEF) approved the commercial release of three Mahyco bred *Bt* cotton hybrid varieties, MECH 12, MECH 162 and MECH 184, based on the reports of large scale evaluation at multi locations for the efficacy against the target pest, environmental implications, and agronomical performance across cotton-growing areas (Jayaraman, 2002; Mayee et al., 2002). Subsequently, three new cotton events, BG-II© *Bt* cotton expressing *cry1Ac* and *cry2Ab* developed by Mahyco, Event-1 *Bt* cotton expressing *cry1Ac* developed by JK Seeds and GFM event expressing *cry1Ab* and *cry1A* developed by Nath Seeds, were approved for commercial cultivation in 2006. Later on, one more event, MLS-9124 expressing *cry1c* developed by Metahelix Life Sciences, was approved for commercial cultivation in 2009 (Choudhary and Gaur, 2015) (Table 1). You can insert small table inside the text.

Table 1. Commercialized *Bt* cotton events in India

S N	Gene(s)	Event	Developer	Year of approval
1.	*Cry1Ac*	Mon-531	Mahyco/Monsanto	2002
2.	*Cry1Ac* & *Cry2Ab2*	Mon-15985	Mahyco/Monsanto	2006
3.	*Cry1Ac*	Event-1	JK Agri-Genetics	2006
4.	Fused *Cry1Ab* & *Cry1Ac*	GFM Event	Nath Seeds	2006

Development of *Bt* cotton was an important breakthrough in Indian agriculture. Adoption of *Bt* cotton by Indian cotton farmers was phenomenal. *Bt* cotton acreage had been increased from 0,029 Mha in 2002 to 10.6 Mha in 2011, whereas total cotton area increased nominally from 8.7 Mha in 2002 to 12.1 Mha in 2011 (Figure 2). *Bt* cotton revived the ailing Indian cotton sector by doubling cotton production and thereby providing benefits to cotton farmers. Cotton yield increased from 308 kg/ha in 2002 to 496 kg/ha in 2011, and total cotton production increased from 15.6 million bales in 2002 to 35.6 million bales in 2011 (James, 2012; Kathage and Qaim, 2012; Malhotra et al., 2012). In 2014, 7.7 million cotton farmers adopted *Bt* cotton representing 95% of estimated 12.25 million cotton farmers in India. Acreage of *Bt* cotton in India reached to a record 11.6 million hectares out of 12.25 million hectares of total cotton area (Choudhary and Gaur, 2015). *Bt* cotton also contributed substantially in reducing pesticide usage. The insecticide usage for the control of bollworms declined from 9410 metric tons in 2001 to 121 metric tons in 2013 (Kranthi, 2014). *Bt* cotton has been a major contributor to cotton export from India, which increased from 0.9 million bales in 2005 to 23 million bales in 2012. World cotton production was 120 million bales and India contributed one fifth of the global total in 2012. India's share in the world cotton production increased substantially from 12.5% in 2002 to 25% in 2013. In fact, it is due to *Bt* cotton, bio-agriculture has become the fastest growing sector of biotechnology industry in the year 2010 registering a growth rate of 37% and accounting for 14% of total biotechnology revenues. It ranked third among the Indian biotechnology sectors with a total turnover of Rs. 1,936 crore in 2009 (Malhotra et al., 2012; Srivastava and Kolady, 2016).

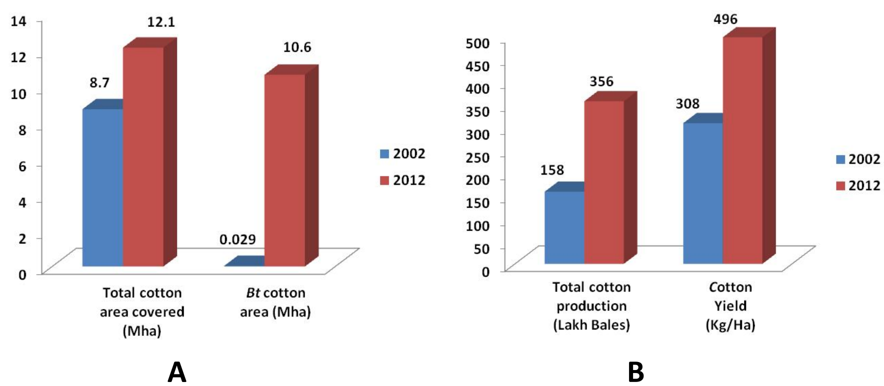

Figure 2. Change in acreage and production of cotton in India since the introduction of *Bt* cotton. A: Increase in area under *Bt* cotton and total cotton during 2001-02 to 2010-11. B: Increase in cotton yield and production during 2001-02 to 2010-11. This figure is not readable, simple bar graph might better, increase font size, year writing style not acceptable, check units in both graphs

Subsequent to commercialization of *Bt* cotton, Mahyco developed *Bt* brinjal event, EE-1, against brinjal shoot and fruit borer (BSFB) in collaboration with University of Agricultural Sciences, Dharwad, Tamil Nadu Agricultural University, Coimbatore and ICAR-Indian Institute of Vegetable Research, Varanasi (Table 2). BSFB is the main insect pest causing 60-70% crop damage, and farmers resort to repeated insecticide sprays incurring huge expenditure. Development of BSFB resistant brinjal cultivar by conventional breeding is not yet successful as no resistant germplasm source is available. Mahyco's *Bt* brinjal Event EE-1 had been subjected to rigorous biosafety regulatory processes encompassing all aspects of food and environmental safety and, socio-economic assessment. GEAC approved environmental safety of Event EE-1 in 2009. However, Indian Environmental Ministry imposed indefinite moratorium on the commercial release of *Bt* brinjal Event EE-1 for conducting more research on safety and biodiversity (Choudhary et al., 2014).

Table 2. Status of GM crops pending approval for field trials and commercial release in India

Crop	Organization	Gene(s)/Trait(s)	Status
Cotton	Mahyco/Monsanto	*cry1Ac*- cry2Ab & *CP4EPSPS*/IR&HT	Applied for environmental release in 2013, withdrawn in 2016
Brinjal	Mahyco	*cry1Ac*/IR	Under moratorium
Mustard	Delhi University	*barnase*, *barstar*/AP	Environmental safety trials
Maize	Monsanto	*cry2Ab2* & *cryA.105* and *CP4EPSPS* /IR&HT	BRL-II stage
Brinjal	Bejo Sheetal/IARI	*cry1Aabc*/IR	BRL-II stage
Chickpea	Sungrow Seeds	*Bt*/IR	BRL-I stage
Rice	Mahyco	NUE	BRL-I stage

(AP, agronomic performance; HT, herbicide tolerance; IR, insect resistance; NUE, nitrogen use efficiency)

The next GM crop for which approval for commercial release is awaited in India is GM mustard developed by Prof. Deepak Pental of Delhi University (Table 2). The Dhara Mustard Hybrid 11 (DMH 11) is GM mustard (*Brassica juncea*) hybrid developed by expressing *Barnase*, *Barstar* and *Bar* genes. DMH11 was developed by crossing between two GM mustard lines, Varuna, expressing *Barnase* and *Bar* genes, as female parent and Early Hira 2 (EH2), expressing *Barstar* and *Bar* genes, as male parent. *Bar* gene was used to facilitate hybrid seed production. Delhi University submitted an application to GEAC in 2015, along with complete safety assessment data, requesting for approval for environmental release of DMH 11. GEAC uploaded the safety assessment data on its website for public feedback. After assessing the safety assessment data and public feedback GEAC advised the developer to conduct more tests to further investigate on environmental bio-safety, especially effects on beneficial insect species (Jayaraman, 2017).

Apart from these GM crops for which approval for environmental release is pending, there are quite a few GM crops which are at advanced stages of development and evaluation (Table 2). Mahyco, in collaboration with, Monsanto, has developed Bollgard®II (BG®II) Roundup Ready Flex, country's first stacked trait cotton event expressing three genes, *cry1Ac* and *cry2Ab* to confer insect resistance, and *CP4EPSPS* gene to impart herbicide tolerance and sought approval from GEAC for environmental release in 2013. Subsequently, it withdrew application due to conflict with Indian Government over patent and royalty issues (Choudhary and Gaur, 2015). GEAC approved BRL-II trial of BSFB resistant *Bt* brinjal of Bejo Sheetal Pvt. Ltd. and insect resistant and herbicide tolerant maize of Monsanto India Pvt. Ltd., and BRL-I trials of *Bt* chickpea of Sungrow Seeds and nitrogen use-efficient (NUE) rice of Mahyco in 2014 (Table 2). Different institutes of ICAR are engaged in development of GM crops. ICAR started 'Network Project on Transgenic in Crops (NPTC)' in 2005 to develop GM crops in different ICAR institutes, State Agricultural Universities and Universities. Sixteen institutes under Crop Science Division of ICAR are developing GM crops on 15 field crops targeting seven traits, and seven ICAR institutes of horticultural crops are working on 11 crops targeting six traits. The list of GM crops which are at advanced stage of development in different ICAR institutes is mentioned in Table 3.

Table 3. GM crops at advanced stage of development in different institutes of Indian Council of Agricultural Research (ICAR)

Crop	Institute	Trait	Stage of development
Rice	Indian Institute of Rice Research	Drought tolerance	Event Selection Trial
Sorghum	Indian Institute of Millets Research	Insect resistance (stem borer)	BRL-1
Chickpea	Indian Institute of Pulses Research	Insect resistance (Pod borer)	Event Selection Trial
Pigeonpea	Indian Institute of Pulses Research	Insect resistance (Pod borer)	Event Selection Trial
Sunflower	Indian Institute of Oilseed Research	Resistance to sunflower necrosis disease	Event Selection Trial
Castor	Indian Institute of Oilseed Research	Insect resistance (Foliage feeder)	Event Selection Trial
Tomato	Indian Institute of Vegetable Research	Drought tolerance	Event Selection Trial
Tomato	Indian Institute of Vegetable Research	Insect resistance (Fruit borer)	Event Selection Trial
Brinjal	Indian Institute of Vegetable Research	Insect resistance (Shoot & fruit borer)	Event Selection Trial
Potato	Central Potato Research Institute	Virus resistance (Leaf curl virus)	Event Selection Trial
Potato	Central Potato Research Institute	Late blight resistance	Event Selection Trial

3. Regulatory System

Recognizing the potential importance of biotechnology, the Government of India had set up the National Biotechnology Board in 1982 and issued a set of biotechnology safety guidelines in 1983 to undertake biotechnology research in Indian laboratories. The National Biotechnology Board was up graded to Department of Biotechnology (DBT) under the Ministry of Science and Technology in 1986. During its formative years DBT in collaboration with other government departments, formulated framework for the evaluation and eventual clearance of GM crops for field cultivation. However, in order to address the biosafety issues, biodiversity and environmental risks, the responsibilities to overlook research and product development involving genetically modified organisms (GMOs), were assigned to Ministry of Environment, Forestry and Climate Change (MoEFCC) based on Government of India Rule (Allocation of Business) 1961. Initially, GMOs and GM crops were being regulated under the Environmental Protection Act (EPA) 1986, commonly referred as EPA 1986. As no provision was made for GMOs and GM crops in EPA 1986, they were regulated under the legislative provision of 'hazardous substance' of EPA 1986. Later on MoEF formulated and notified rules, known as EPA Rules 1989 under EPA 1986, by an Administrative Order for diverse activities related to GMOs and GM crops including, manufacture, use, import, export and storage, etc. (Chimata and Bharti 2019; Choudhary and Gaur, 2015).

The EPA Rules 1989 formulated definition for gene technology and genetic engineering. As per the Rules "Gene Technology" means the application of the gene technique called genetic engineering, include self-cloning and deletion as well as cell hybridisation. "Genetic engineering" was defined as the technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self-cloning) as well as modification of an organism or in a cell by deletion and removal of parts of the heritable material (Chimata and Bharti, 2019).

The rules 1989 also defined the regulatory bodies and their responsibilities (Table 4). The Recombinant DNA Advisory Committee (RDAC) reviews the developments in biotechnology globally and recommends suitable safety regulations for India in research involved recombinant DNA technology. Institutional Biosafety Committee (IBSC) is constituted by the host institute where the genetic engineering work takes place. Review Committee on Genetic Manipulation (RCGM) of DBT under Ministry of Science and Technology, and Genetic Engineering Appraisal Committee (GEAC) of MoEFCC are the key regulatory bodies. RCGM provides guidelines specifying regulatory procedures to be followed in research involved genetic engineering and guidelines for the contained field experiments involving GMOs. GEAC is responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment including experimental field trials. There are two state level regulatory bodies namely, State Biotechnology Coordination Committee (SBCC) and District Level Committee (DLC). SBCC, headed by the Chief Secretary of the State, has powers to inspect, investigate and take punitive action in case of violations in statutory provisions. The Committee reviews the safety and control measures in the various industries/ institutions handling genetically engineered Organisms/Hazardous microorganisms. DLC monitors the safety regulations in installations engaged in activities involved GMO research. DLC regularly submits the monitoring reports to the SBCC. Hence, regulatory system in India is comprised of three different functions, advisory, performed by RDAC; regulatory, performed by IBSC, RCGM and GEAC; and monitory, performed by SBCC and DLC (Chimata and Bharti, 2019; Warrier and Pandey, 2016).

Table 4. Different committees involved in advising, regulating and monitoring GM crop development in India

Committee	Function	Administrating agency
Genetic Engineering Appraisal Committee (GEAC)	Regulatory	Ministry of Environment, Forest and Climate Change (MoEFCC)
Recombinant DNA Advisory Committee (RDAC)	Advisory	Department of Biotechnology (DBT), Ministry of Science And Technology (MoST)
Review Committee on Genetic Manipulation (RCGM)	Regulatory	Department of Biotechnology (DBT), Ministry of Science And Technology (MoST)
Institutional Biosafety Committee (IBSC)	Regulatory	Registered Institutions, Universities and Private Companies
State Biotechnology Coordination committee (SBCC)	Monitoring	Concerned State Governments
District Level Committee (DLC)	Monitoring	Concerned State Governments

(Source: Chimata & Bharti, 2019)

The Recombinant DNA Advisory Committee (RDAC), constituted by DBT, had formulated ‘Recombinant DNA Safety Guidelines’ in 1990 to regulate rDNA technology in medicine and agriculture as per the EPA Rules 1989. These guidelines were revised as ‘Revised Guidelines for Safety of Biotechnology’ in 1994. Realizing the need for comprehensive guidelines for transgenic plants in the mid-nineties, DBT framed and released comprehensive guidelines for GM crops in 1998 referred to as ‘Revised Guidelines for Research in Transgenic Plants’ and ‘Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts’ to regulate GM crops and products (Choudhary et al., 2014). To ensure the safety of products derived from genetic engineering, several safety guidelines had also been formulated. Contained use of genetic engineering products is defined in Recombinant DNA Safety Guidelines, 1990 & 1994; Revised Guidelines for Research in Transgenic Plants, 1998; and Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017. Contained field trials involving GMOs are regulated by 'Guidelines for Conduct of Confined Field Trials of Regulated GE Plants, 2008', 'Standard Operating Procedures (SOPs) for CFTs of Regulated GE Plants, 2008' and 'Guidelines for Monitoring of Confined Field Trials of Regulated GE Plants, 2008'. Guidelines and protocol for the safety assessment of foods and feeds derived from genetically engineered plants were drawn out in 2008. Environmental safety assessments are controlled by the Guidelines for Environmental Risk Assessment (ERA) of GE Plants, 2016, Risk Analysis Framework, 2016 and ERA of GE Plants: A Guide for Stakeholders, 2016.

The process of GM crop development in India needs approval from various agencies at different stages. Each Institute/Organization/University has to formulate own IBSC to review, approve and monitor all the rDNA related works including GM crops development. IBSC is chaired by Head of the Institute/Organization/University, and members include subject specialist DBT nominee and a recognized medical practitioner. To initiate a new rDNA work or a new project on GM crop development the concerned researcher has to seek approval from IBSC, which is empowered to give approval up to glasshouse evaluation. IBSC sends periodically information on rDNA related research works of the institute to RCGM. Initially GM crops are characterized and evaluated under glasshouse condition. Researchers do trait evaluation and detail molecular characterization of glasshouse grown transformants and select a few best performing events based on repeated glasshouse trials. The next step is 'Event Selection Trial' under confined field condition. Initially, researcher seeks permission from IBSC to apply for 'Event Selection Trial'. Once permission is granted, then the concerned researcher applies to RCGM in prescribed format along with detail information on trial site and trial plan. RCGM examines the application and forwards it to GEAC for consideration. GEAC convenes meetings periodically, examines al the applications and the decision is conveyed to the researcher through RCGM. At present, researcher has to get 'No Objection Certificate' form the state where he plans for conducting the trial. Once one or two promising events are identified the next step is 'Bio-safety Research Level-I' (BRL-I) trial at two locations for two years. Researcher has to generate complete bio-safety during BRL-1 trial. The last step before making application requesting environmental release is multilocation BRL-II trial (Chimata and Bharti, 2019).

4. Challenges and Wayforward

It has been 17 years since commercial cultivation of *Bt* cotton in 2002, and since then no other GM crops are approved for cultivation in India despite involvement of 12 public funded Institutes and universities and 16 different private sectors in GM crop development in 18 different crops (Giri and Tyagi, 2016). High cost of development, especially bio-safety evaluation, over stringent regulatory regimes, controlled by different authorities, and vociferous anti-GM crop propaganda are responsible for preventing successful exploitation of GM crops technology in India. If India has to harness the benefits of GM technology it is highly imperative that Indian Government unveils favourable policy decisions and takes proactive steps, like sustained fund support, purchasing license and/or 'freedom to operate' for modern technologies, and popularising GM crops among common people through mass media etc. Indian researchers engaged in GM crop development are to show competency by developing more and more promising GM crops targeting traits of national importance, which will help creating enabling environment in near future.

5. Conclusion

World has witnessed overwhelming acceptance of GM crops in the last two decades. Twenty eight countries have adopted GM crops across the globe and its cultivation covered an area of 181 million hectares. Soybean, maize, cotton and canola accounted for 90% of all biotech crop hectarage in the world. In India, *Bt* cotton is the only GM crop under cultivation, covers 95% of the total cotton growing area. Applications for environmental release of two other GM crops, Bt brinjal and GM mustard hybrid, were being considered by Indian Government. *Bt* brinjal got biosafety clearance but environmental release is pending due to indefinite moratorium in 2010. Biosafety of GM mustard hybrid is still under consideration. Apart from these three, there are a number of GM crops which are at different stages of development and evaluation by both public and private funded Institutions.

6. Acknowledgements

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Progress and Prospects of Agricultural Biotechnology and Biosafety in Nepal: Present Status, Challenges and Way Forward

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Abstract

Genetic engineering has been considered as the most advanced technology for increased productivity. However, issues have been raised against this technology and their products pertaining to risk to humans and biodiversity. To minimize the risk associated with Genetically Modified Organisms (GMOs), the Government of Nepal approved the National Biosafety Framework comprising Biotechnology Policy in 2006. Both framework and policy need to be implemented more effectively. None of the GMOs and their products has been reported in Nepal and most of the legal documents have a provision of regulating GMOs and allowed for research. Tissue culture (particularly micro-propagation) and DNA marker technology have been utilized to advance agriculture in more than 15 institutes. The major challenge in biotechnology research is dependency for requirements of biotechnological research including genetic materials on foreign countries. Policy restricts the direct entry of GMOs and their products; however there is high risk of entry of GMOs and their products from India and China. Genetic engineering has been poorly understood by most of the Nepali people and therefore, education or training is the prime concern for initiating R&D on GMOs. Research on GMOs should be started in confined areas (controlled structures) along with developing a clear roadmap for research and development using genetic engineering.

Keywords: Agricultural biotechnology, GMO, biosafety regulation, biotechnology policy, food safety

1. Introduction

Agriculture remains the life of Nepali people. Until 1980s Nepal was a food self-sufficient country. As population has increased and different agricultural technologies made available, Nepal has become a food and nutrition insecure country. The government of Nepal has given high priority to agriculture since the third Five Year Plan (1975-80) to address food and nutrition security. About 71,387 tons of food in 2015 was deficit in Nepal and 35 districts (MoAD, 2016) are food deficit. Nepal ranked 72nd among 119 countries in Global Hunger Index (GHI) with GHI value of 21.1 (https://www.globalhungerindex.org/nepal.html). Nepal is rich in agrobiodiversity; however, she depends about 95-100% on foreign germplasm for agricultural research (Joshi et al., 2016). With the objective of increasing productivity and sustainable management of agrobiodiversity, Government of Nepal has approved many international movements, agreements, and developed and introduced different agricultural technologies.

The Convention on the Biological Diversity (CBD) was ratified by Nepalese parliament on 23 November 1993 and enforced in Nepal since 21 February 1994. As a party to CBD, Nepal has made its commitment to biosafety by signing the Cartagena Protocol on Biosafety on 2 March 2001. The main objective of the protocol is to pay special attention to the transboundary movement of GMOs, produced by using modern biotechnology, because of its trade between nations, and regulate the export and import of such goods only based on the advanced informed agreement. Nepal also ratified ITPGRFA in January 2007 and became a party on 19 October 2009. Signatory countries are obliged to create the proper policy and legal conditions to implement the treaty effectively.

Nepal is located between India and China (Figure 1) with a total area of 147181 km^2. Topographically there are three Agro-ecological zones, 35% is mountain, 42% is hill and 23% is lower flat land, also known as Tarai. The total cultivated agricultural land is 30, 91,000 ha (21%) and 10, 30,000 ha (7%) is uncultivated agricultural land. The best strategy for increased food production is vertical expansion for which genetic enhancement is needed. Biotechnology has the potential to address problems not solved by conventional agricultural research. In addition, biotechnology may speed up research processes and increase research precision. Owing to the development of biotechnology in the global scenario and richness of diversity in plant genetic resources in Nepal, there is a great potential of using biotechnology tools for increasing food production and promoting sustainable agriculture. Tissue culture has been applied in agriculture since 1989 and DNA marker technology since 2000 (Joshi 2017) in Nepal. Genetic engineering, though one of the most debatable technologies is considered most important for food and nutrition security. There are many things to do for making the environment conducive for research on genetic engineering and biosafety framework is one among them.

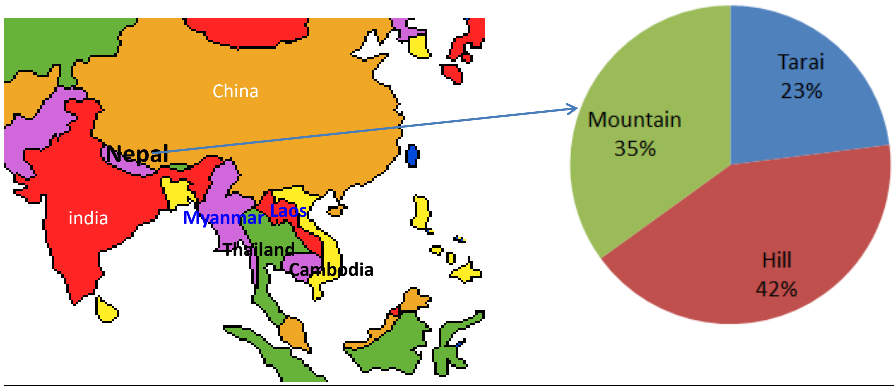

Figure 1. Location of Nepal in South Asia and areas under three agro-ecological zones.

Source: MoAD, 2014

2. Agricultural Scenario and Status of Agricultural Biosafety and Biotechnology

2.1. Agricultural Scenario

Despite many efforts, the rate of country's economic growth has remained slow (<4% after 2007), and the Human Development Index (0.574) and Gender Inequality Index (0.480) were below the South Asian average in 2017 (UNDP, 2018).The population growth rate is 1.4% per year with a growth rate of 5.9% per year for principal agriculture production (Figure 2). The economy of Nepal is very much dependent on the use of natural resources, including agricultural lands, forests, water resources and protected areas. Share of agricultural sector in the national GDP (NRs. 1,789,767 million) is 32.6% (MoAD, 2014). Agriculture is the primary occupation for a vast majority of the people and remains the country's principal economic activity. About 21% (3.2 million hectares) of the total land area of Nepal is used for cultivation and the principal crops are rice (45%), maize (20%), wheat (18%), millet (5%) and potatoes (3%), followed by sugarcane, jute, cotton, tea, barley, legumes, vegetables and fruits (MoAD, 2014).

Agriculture in Nepal is characterized by very small land holdings scattered to different plots, where high input agriculture is difficult to adopt. Land size owned by farmers is the most important economic asset for food and nutrition security. Sixty five percent of the population in Nepal is engaged in Agriculture (MoAD, 2014), though the average size of land owned by the household is only 0.7 ha (CBS, 2013). Holding without land is 3% and 10% of the land-owning households have less than 0.1 ha and 53% of the land-owning households have less than 0.5 ha (CBS, 2013).

The practices of agriculture (cultivation of crops) range from 60 M to 4700 M altitude in Nepal (Joshi et al., 2017). Nepal experiences a wide range of climatic variation and broadly there are three agro-ecological zones, namely High Hill (mountain agriculture), Mid Hill (Temperate agriculture) and Tarai (Tropical agriculture) (Figure 3). High Hill is located in more than 2,000 m altitude and covers an area of 51,817 km^2. Only 9% of the area is used for agriculture and the rest belongs to other categories. Hence, only a small proportion of the population dwells in this zone. The agriculture is livestock based with little cropping. Conditions are extreme and food deficits are common.

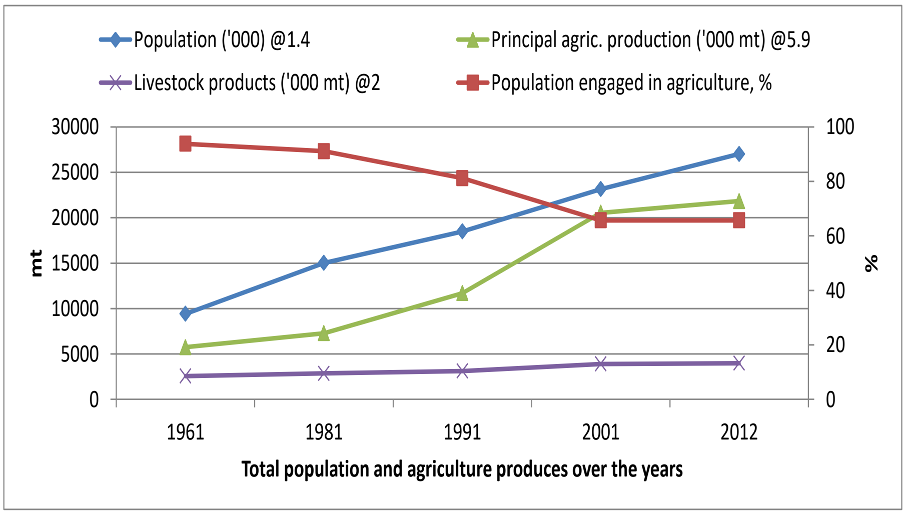

Figure 2. Total population and agriculture production over the years.

Source: MoAD, 2013

Mid Hillis located between 330-2,000 m altitudes and covers an area of 61,345 km^2. It has around 42% of the agricultural land. The area is characterized by high ridges and steep slopes around numerous streams giving rise to many microclimates. The Hill accounts for about 50% of the population. Tarai is located in less than 330 m altitude and covers an area of 34,019 km^2. Around 66% of the total land is under cultivation. Since, this zone alone produces 60% of the total food production in the country it is known as the granary of Nepal. About 45% of the total population dwells in Tarai. Over 33% of the arable land is irrigated.

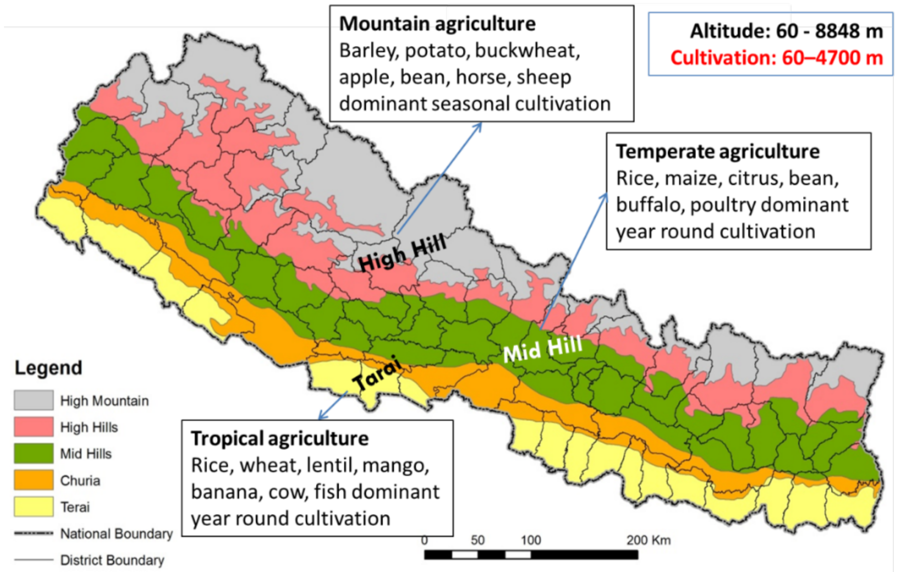

Figure 3. Three agro-ecological zones based agriculture and dominant crops and livestock in Nepal.

Source: Joshi et al 2017

2.2. Agricultural Biosafety

Biosafety Guidelines 2004 have been developed and these guidelines focus on regulating laboratory safety and GMO safety. These guidelines point out the step by step processes for release of GMOs or their products in the environment by taking due precaution, prior to releasing GMO or products. Further progress for the implementation of this guideline is not available. National Biosafety Framework 2006 authorizes the concerned agencies for regulatory measures and guidelines to avoid or minimize potential risks of genetically modified (GM) plants and their products, GM microorganisms and their products and GM animals and their products. Though, it has not been effectively implemented. Probably this situation occurs because of non-existence of any GMOs and their products in the country. Nepal's biosafety policy is to contribute to poverty alleviation through the development and application of biotechnology in sectors where comparative benefits can be achieved.

2.3. Agricultural Biotechnology

Existing agricultural biotechnology tools that are being used in Nepal are depicted in Figure 4. There are three broad categories under modern biotechnology. Among these, tissue culture is the popular one and both private sector and public sector institutes are using this technique. DNA marker technology is limited only to assess genetic diversity. Most of the Master and

PhD level students of agricultural science include marker technology for their thesis. Results of markers profiles have not been further used in breeding and crop improvement program. Some of the products of biotechnology that farmers are getting benefits are virus-free potato, banana and greening free citrus saplings. DNA marker-based products mainly in rice, wheat and potato have been tested and evaluated in collaboration with IRRI, CIMMYT and CIP. After extensive testing, IRRI bred rice varieties tolerant to submergence (Swarna Sub-1 and Samba Masuli Sub-1) and drought tolerant varieties (Sukha Dhan 1 to 6) were released in Nepal. These rice varieties were developed following Marker Assisted Selection (MAS) in IRRI. Biotechnological tools are also used in livestock and fish research and details of tools and species are given in Table 1.

Among the modern biotechnological tools, artificial insemination (AI) was the first tool used in Nepal in1952 followed by tissue culture in 1976 (Figure 5). Major initiatives are sand rooting in 1988, virus-free potato production in 1989, DNA marker technology in 2002, GMO testing in 2005, biosafety and policy formulation in 2006 and conservation biotechnology in 2012. Different approaches have been applied for conservation of agricultural genetic resources in Nepal and they are categorically explained in Figure 6.

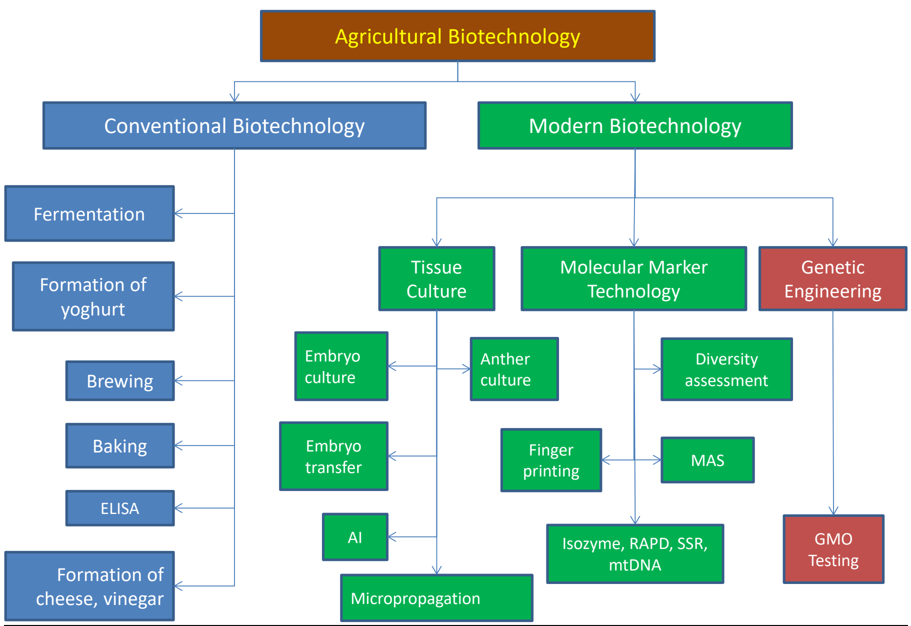

Figure 4. Agricultural biotechnological tools using in Nepal under conventional and modern biotechnology.

Adapted: Joshi, 2017

Table 1. Biotechnological tools and their application in different species in Nepal

SN	Biotechnological tool	Applied species
Crop		
1.	Anther culture	Rice, wheat
2.	Micropropagation	Sugarcane, potato, banana, citrus, cardamom
3.	MAS	Rice, wheat, maize, potato, buckwheat,
4.	RAPD	Wild buckwheat, tite buckwheat, cardamom chayote, finger millet
5.	SSR	Rice, barley, maize, upland rice, wheat, finger millet, rice bean, citrus, bean, jute, soybean
6.	GMO testing	Maize, soybean
7.	Isozyme	Mango, barley, rice, pigeon pea, taro, swertia, tite buckwheat, citrus, wild rice
8.	KASP	Rice
9.	Embryo rescue and culture	Wheat x maize, rice, buckwheat
10.	DNA bank	Rice, wheat, rice bean, maize, chayote, garlic, cardamom, mango, buckwheat, finger millet
11.	Tissue bank	Potato, sweet potato, citrus, cardamom, sugarcane
Livestock and fish		
12.	Marker based disease diagnosis	Farm animals and poultry
13.	Embryo transfer	Cattle
14.	mtDNA	Cattle, buffalo, goat, sheep, yak, pig, poultry
15.	RAPD	Poultry
16.	SSR	Buffalo, wild buffalo, cattle, fish
17.	Isozyme	Fish, goat
18.	AI	Cattle, sheep, pig, buffalo, goat
19.	eDNA	Fish
20.	Cryo bank	Cattle, goat, pig

Source: Joshi et al., 2009; Joshi, 2017; NAST and MoEST, 2008

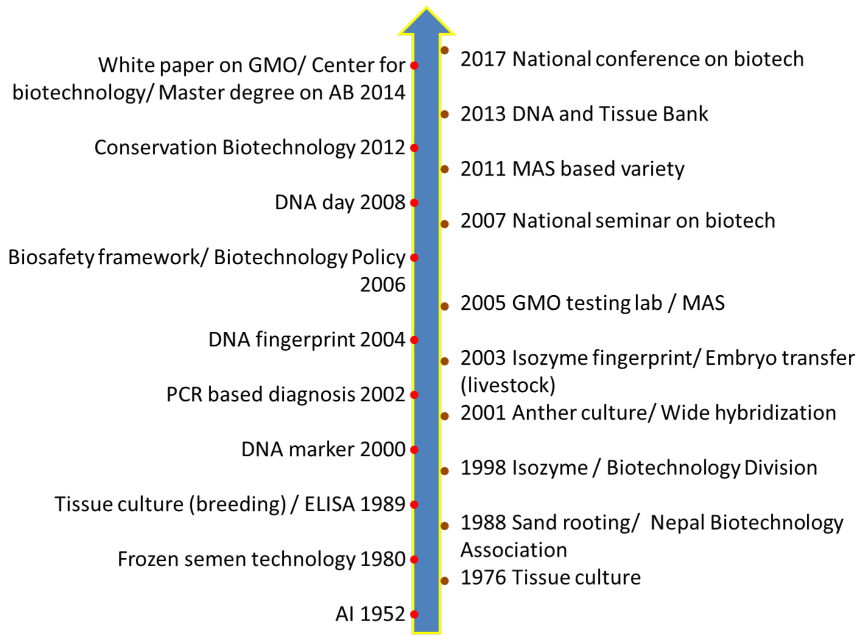

Figure 5. Major biotechnological events in Nepal.

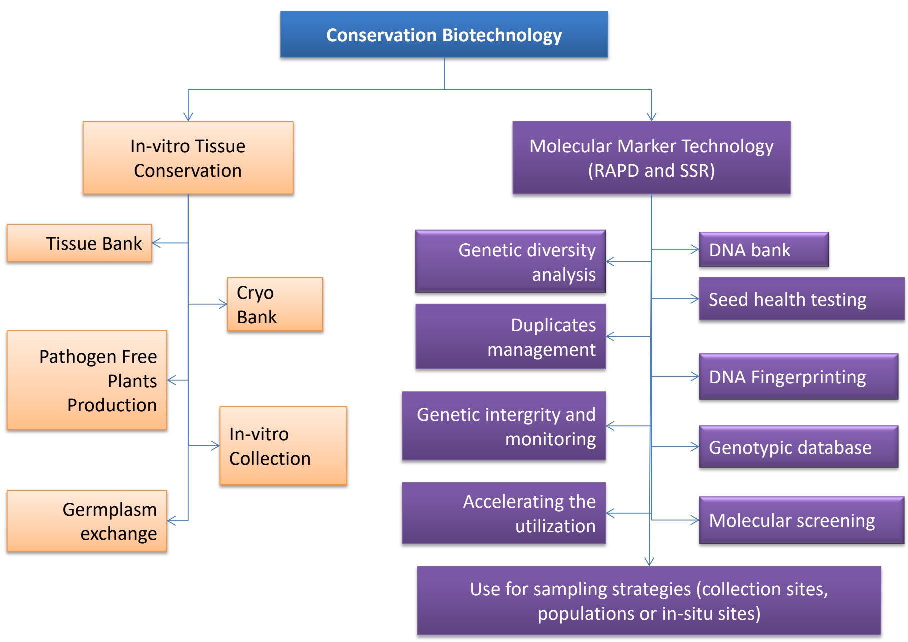

Figure 6. Potential use of biotechnological tools for conservation of agro biodiversity.

Source: Joshi, 2017

There are more than 15 policies, acts, regulations and strategies and action plans that have considered biotechnology as an important tool for effectively and efficiently achieving the targets. Eleven such legal documents have mentioned GMOs (Figure 7). All these documents have provisions of regulating GMOs and their products. There is no restriction for research on GMOs and their products. Nepal Agricultural Research Council's (NARC) Vision 2011-2030 has considered biotechnology as one of five broad based thematic areas of interventions. In Biotechnology Policy 2006 (MoEST, 2006), increment of production and productivity through the biotechnological research, development and technology transfer 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. The National Wetland Policy 2002 has emphasized on taking concrete steps in banning unwarranted entry of alien GMOs.

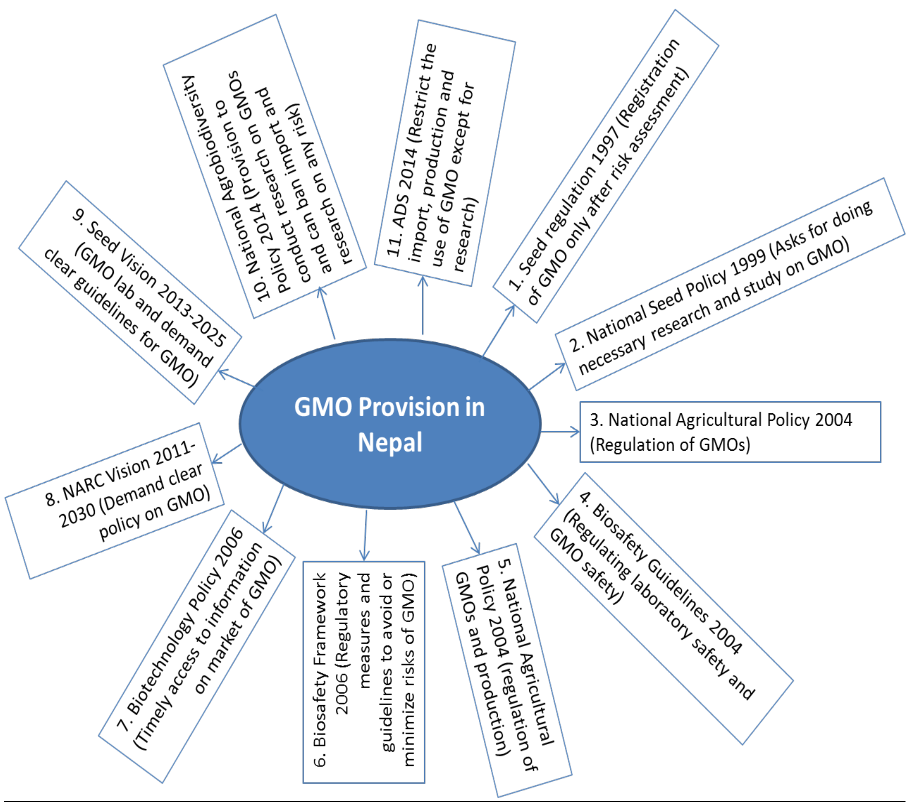

Figure 7. Legal documents about GMOs along with provisions.

The objectives of Biotechnology Policy 2006 are to (i.) Conduct study and research to develop GMOs and transgenic plants employing genetic engineering and tissue culture technology; (ii.) Obtain permission to import

GMO and transgenic seeds only after verification report of authorized government agencies on biosafety through study and research activities; and (iii.) Formulate biosafety regulation as suitable to the situation in Nepal.

Biotechnology Coordination Committee (BCC), National Biotechnology Research and Development Centre (NBRDC), and National Biotechnology Central Laboratory (NBCL) have been visualized in the policy. Under NBRDC, a Biotechnology Scientific Committee will be established. Other provisions are to establish one-window system for transportation, import and export of biotechnology-based production; to set up a fund at national-level in order to promote research and development of biotechnology; to obtain membership of the International Centre for Genetic Engineering and Biotechnology (Nepal is a signatory country now) and establish relation with regional and international organizations.

3. Biosafety Regulatory Policy and Framework

A regulatory mechanism has been developed on biosafety in line with CBD to manage or control the risks related to hazardous chemicals and GMOs. National plan of action for biotechnology was formulated as part of Biotechnology Policy 2006. This plan is not in existence anymore. In the past, it was planned to establish a National Biotechnology Center to promote research and development in agriculture, health, environment and industry by Nepal's Ministry of Science and Technology, but it could not be implemented.

Currently, there are Biosafety Guidelines 2004 (MoFSC, 2005) and National Biosafety Framework 2006 (MoFSC, 2006) in Nepal for regulating GMOs and their risk. 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 on March 2001.

National Biosafety Framework 2006 authorizes the concerned agencies to develop regulatory measures and guidelines to avoid or minimize potential risks of genetically modified (GM) plants and their products, GM microorganisms and their products and GM animals and their products. The framework is applicable to the development, production, contained use, field test, intentional introduction into the environment, and importand export of GMOs that may have an adverse effect on the conservation and sustainable use of biological diversity, and environment taking also into account the risks to human health. The framework covers the existing or potential use of GMOs in laboratory or in an open space; human health, biodiversity, natural environment, agricultural products, foods and drinking products, animal feed and areas of sewerage management; regulation of experiment, flow of information, review, assessment of risks including socio-economic and ethical effects; monitoring of import and export, laboratory and field test; research and development in academic and industrial sectors; safety of the place where functions relating to GMOs are carried out; public participation on the issues of modern biotechnology and biosafety.

Scope of risk assessment is risk to environment from the use of GMOs, and risk from the consumption of food containing GMOs. The risks of GMOs or products thereof have been classified into four levels as follows:

Level 1: No risk to human health, biological diversity and environment.

Level 2: Low risk to human health, biological diversity and environment.

Level 3: Medium risk to human health, biological diversity and environment.

Level 4: High risk to human health, biological diversity and environment.

The technical framework of biosafety mainly covers the scientific research and testing of seed, plants, food, feed and animals with GMOs, which may be imported or produced within the country. The tests aim to identify the components of GMOs and identify whether the tested GMOs pose any adverse risks to biological diversity and human health. On these grounds, decision will be made whether to allow or restrict the import of the tested GMOs.

The provisional mechanism in the framework is depicted in Figure 8. Nepal has made provision of National Focal Point of CBD and Biosafety Clearing House (BCH), for Ministry of Forest and Soil Conservation (MoFSC). In addition, Government of Nepal also formed National Biosafety Committee (NBC)/ National Competent Authority (NCA) and six Sectoral Competent Authorities (SCA) for effective monitoring and regulation of GM products. These competent authorities are supposed to fulfill the procedures in respective sectors as per prescribed process for the response of civil society and other stakeholders. The SCA evaluates a proposal on GMOs and products thereof, and the risk assessment report in consultation with experts. Any tests of the GMOs must be carried out in an accredited laboratory. The SCA submits its comments to the NCA. It is mandatory to submit biosafety report for registration of GMO seed and labeling of GMOs.

The functions of the NBC are to draft policies, guidelines, legislations, and cooperate with national and international bodies on biosafety, establish standards and procedures for risk assessment and labeling of GMOs, make decisions on all proposals on GMOs and products thereof. The NCA determines the biosafety standard and the GMOs Free Zone can be declared by publishing in the Nepal Gazette.

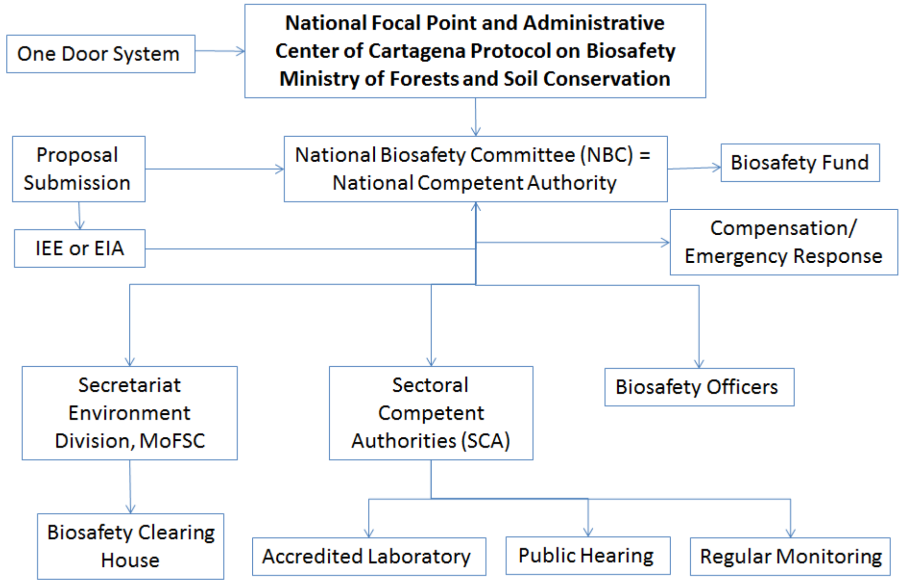

Figure 8. Biosafety working mechanism envisaged in National Biosafety Framework 2006.

Source: MoFSC, 2006

4. Updates on Important Agri-biotech Products

GMOs have not been registered, introduced and grown in Nepal (Thapa, 2013). Research on genetic engineering (GMO, recombinant DNA technology) has not started yet. Many interactions and discussions though have been taking place across the country since 2000. Many tissue culture and DNA marker based agricultural products are available. Neither GMO nor GM foods are reported in the country. Some level of understating and efforts on following agri-biotech products are given below.

a. Bt Cotton: Because of being a non-food crop and being widely grown in India, many growers and agriculturists are in favor of Bt cotton in Nepal. Bt cotton is considered safer than using pesticides. However, research has not been initiated.

b. GM Mustard: There have been no discussions on GM mustard.

c. Golden Rice: It is the most discussed GMO in Nepal. Some efforts were made to initiate research on it, but due to opposition and lack of proper policy, no progress was made.

d. Late blight resistant potato: Late blight is one of the most devastating diseases of potato. Therefore, considerable efforts are being made to develop late blight resistant potato using conventional breeding. There have been no discussions or activity regarding research on developing GM potatoes resistant to the disease.

e. Iron fortified rice: World Food Program has initiated an awareness program in Nepal and it is expected that project on iron fortified rice will be implemented in 2019.

5. Harmonization Efforts

Harmonization is the process of minimizing conflicting standards which may have evolved independently. The goal is to find commonalities and provide a common standard. All stakeholders in Nepal (Figure 9) are working closely with regards to biosafety. Regular discussions and interaction meetings are held to harmonize policy and regulation. Regular reviews of existing policy and regulation and subsequent revisions accordingly in the new documents are being practiced in Nepal. Currently, there are many acts and policies under formulation and revision, therefore, these acts and policies are not contradictory to the National Biosafety Framework.

a. Food Safety Assessment: Department of Food Technology and Quality Control (DFTQC) is the organization for regulating food safety in the country. Expert teams regularly monitor the food quality based on existing guidelines. However, they do not have any lab and policy for GMO testing. Formally, foods have not been so far tested whether they are GMO based. Currently, Food Act is under revision and it is expected to cover GMOs.
b. Environmental Risk Assessment (ERA) has not been started because of non-existence of GMOs. Ministry of Forest and Environment (MoFE), Ministry of Agriculture and Livestock Development (MoALD) and NARC are the relevant ministries and research organization for ERA. Forest Act 1993 and Environment Protection Act 1997 have provisions for environment impact assessment but do not contain regulations for GMOs.
c. Import of Agricultural Biotechnology for Food, Feed and Processing: There is no legal provision for importing any agricultural biotechnology products for food, feed and processing. Import export act also needs to be revised for inclusion of GMOs.
d. Food and Feed Products derived from Biotechnology: Food and feed products derived from technologies other than genetic engineering are being regularly imported following provision in regulation. Food related acts and policies need revision for inclusion of GMOs.

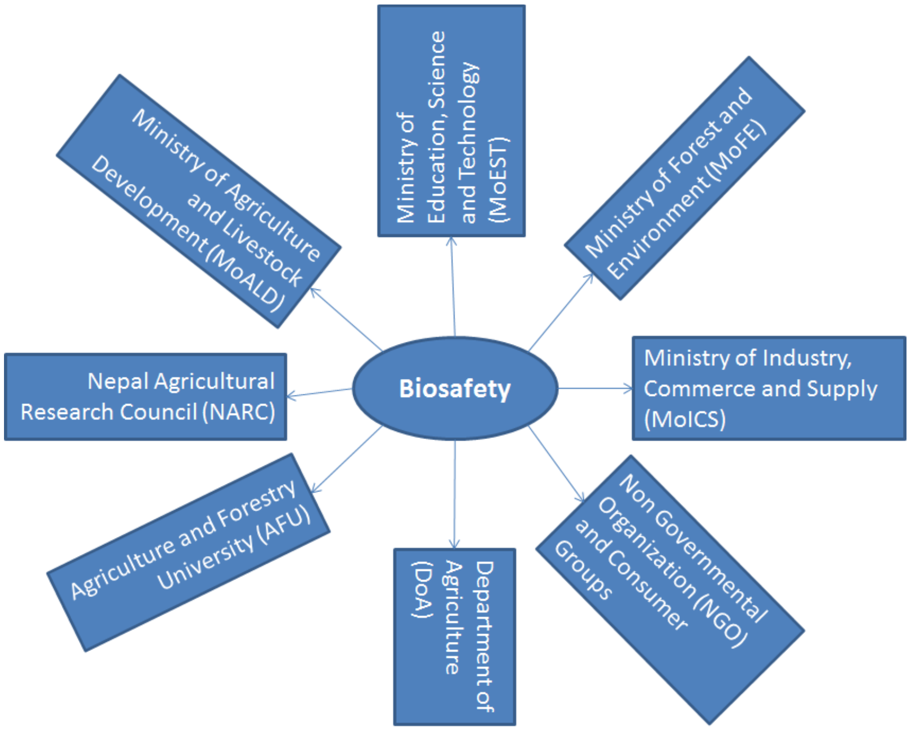

Figure 9. Responsible organizations related to biosafety and working on harmonizing polices and agreements.

There are, however, some acts, policies, regulations and guidelines which were formulated before the Biosafety Framework. For example, acts relating to export, import, plant protection, food, feed, drug, national parks and wildlife protection, and aquatic animal protection have been formulated and enacted before the emergence of issues of modern biotechnology. The Seed Act need to be harmonized with GMOs related policies and guidelines.

6. Challenges and the Way Forward of Agricultural Biosafety

Everything for biotechnology research needs to be imported from outside the country and it therefore becomes very costly. Nepal is very rich on agricultural genetic resources; however, their use in R&D is very poor. Both Biotechnology Policy and Biosafety Framework have not been effectively implemented. Biosafety covers only the GMOs but there are many cases of eroding local diversity through modern varieties. Farmers and consumers still have not experienced the benefits from biotechnological products. Steps should be taken to educate the public and make them aware of benefits and potential risks of GMOs. There is a high demand of budget for developing infrastructure and capacity development. Mechanism is necessary to setup one window system for the transport, import and export of biotechnology products especially GMOs. Before releasing any GMOs for certain areas, all the local genetic resources should be conserved. Another challenge is the implementation of Biosafety Framework and Biotechnology Policy, and initiation of research on genetic engineering as these framework and policy are under the Ministry of Forestry and Environment, and Ministry of Education, Science and Technology respectively, but MoALD and NARC are the implementing organizations.

Road map for overall development of agricultural biotechnology in the country is given in Figure 10. Awareness programs need to be extensively organized across the country. There should be enough facilities and capable human power. All necessary acts, policies, regulations and guidelines should be in place. Evidences with respect to risk and advantage of genetic engineering should be generated within the country. Major focus on developing trained human resources, well-equipped laboratories and operational procedures is needed. Strong support is necessary from respective quarantine and custom offices along with strengthening such offices. At the regional level, access and benefit sharing standards for GM germplasm should be developed. An information portal for free exchange of biosafety and biotech information within South Asian Association for Regional Cooperation (SAARC) needs to be developed. Provisions should be made to use GMO related data generated by other countries. SAARC standard for biosafety and genetic engineering needs to develop along with the provision of capacity enhancement and SAARC road map preparation.

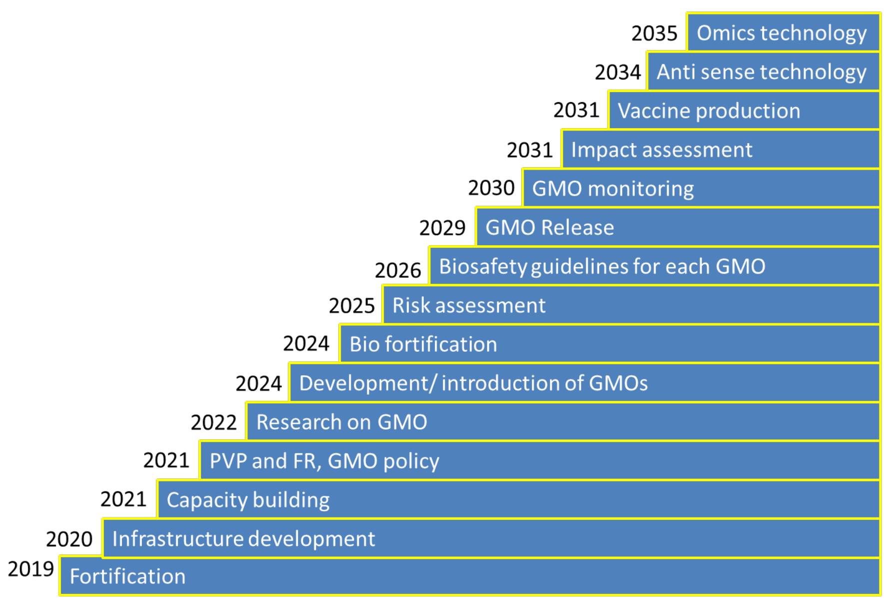

Figure 10. Roadmap for advancing agricultural biotechnology in Nepal.

7. Conclusion

Nepal is far behind on implementation of biosafety and genetic engineering. Because of open border both in south and north, there is a high risk of GMOs and their products entering the country. Low productivity and insecure food and nutrition in the country demand the adoption of genetic engineering technology that could develop high yielding, nutrition dense and climate resilient genotypes. GMOs are poorly understood by consumers, farmers, policy makers and agriculturists. Research should therefore be started on GMOs after establishing controlled environments and developing manpower. Biosafety framework and biotechnology policies are in place however, further acts, policy, regulations, directives and guidelines on genetic engineering and their products are necessary to be developed. Advantages of genetic engineering have not been experienced so far by farmers, consumers and researchers. Initiatives need to be taken to establish facilities so that research could be carried out on GMOs.

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Progress and Prospects of Agricultural Biotechnology and Biosafety Regulations in Pakistan

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Abstract

Pakistan started working on modern biotechnology in the 1980s. Currently, there are more than 40 biotech centers/institutes in the country. However, very few centers have appropriate physical facilities and well-trained manpower to develop genetically modified (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) stress resistance genes have already been incorporated in some crop plants. Despite acquiring capacity to produce transgenic plants, no GM crops except cotton, either produced locally or imported, have been released commercially in the country. GM cotton was granted approval for commercial release in the year 2010 and Pakistan is ranked as having the 7th largest area under GM crops cultivation in the world. Concerted and coordinated efforts based on biotechnology are being undertaken for improvement in the livestock sector as well. Pakistan is a signatory to the World Trade Organization, Convention on Biological Diversity (CBD) and Cartagena Protocol on Biosafety (CPB). The country has ratified both CBD and CPB. National Biosafety Guidelines were promulgated in April 2005 under which a three-body regulatory system comprising Institutional Biosafety Committee (IBC), Technical Advisory Committee (TAC) and National Biosafety Committee (NBC) were established. National Biosafety Centre was set up for the implementation of National BiosafetyRules-2005. Forty-five Bt- cotton varieties and three GM events have been approved for commercial cultivation so far. Several GM events in other crops are waiting for their commercial release. Work related to DNA fingerprinting of quality traits in livestock and important field crops is in progress also. Shortage of trained human resource for biosafety studies, monitoring and evaluation are some of the issues being faced after the release of GM cotton in the country.

Key words: Biotechnology, biosafety, GM crops, Pakistan

1. Introduction

The agriculture sector, being the backbone of the country's economy, continues to be the largest sector and a dominant driving force for the growth and development of national economy of Pakistan.

The major crops grown are wheat, rice, cotton, sugarcane, and maize. Gram and other pulses, oil seeds, and fodder crops are also grown in different parts of the country on sizeable areas. In Pakistan, the average yields of the crops, despite the Green Revolution era, are still low compared to many other countries. A large gap exists between the potential and realized yield for almost all the major crops. With a few exceptions, the average yield of most of the crops is either stagnant or has even declined during the last decade, while input costs and amounts of fertilizers, pesticides, etc. have continued to increase. The agricultural production system in the country can operate on sound scientific and stable bases only if farm technology is kept in tune with the changing environmental and socio-economic conditions through an efficient and dynamic agricultural research system. Biotechnology is one of the recently emerging sciences that has developed very quickly in different areas affecting human life. It shows a huge potential in helping mankind solve problems that are difficult to deal with using traditional methods. In agriculture, biotechnology has been applied in different fields including the production of genetically modified (GM) crops. Biotechnology has considerable potential for promoting the efficiency of crop improvement, food production, and poverty reduction, especially in developing countries like Pakistan.

1.1. Historical Perspective of Agricultural Biotechnology in Pakistan

The advent of traditional biotechnology in Pakistan dates to 1970 when work was initiated in the Botany Department of Peshawar University. Professor Dr. Ihsan Ilahi established a plant tissue culture facility for medicinal plants *Rauwolfia serpentine* (Akram and Ilhai, 1986), Papaver (Ilahi and Ghauri, 1994), and some others. Later the areas of biofertilizer (Biological nitrogen fixation and mycorhizza, 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 National Agricultural Research Centre (NARC), Islamabad. These activities continued for decades in those centers and a few products derived from this work, like virus free potato seeds and multiplication of healthy banana, sugarcane by NARC have been commercialized (Zafar, 1997). 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 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). Keeping in view the rapid pace of advancements in S&T taking place around the world, the GoP initiated the process of formulating its new S&T policy in 2009 later named National Science, Technology & Innovation policy (ST&1-2011) of Pakistan (www.pcst.org). This policy also placed biotechnology and genetic engineering among the priority areas. This policy has been vetted by the Law and Justice Ministry and was officially launched in November 2012. It is pertinent to note that the recent devolution process did not affect the Ministry of Science and Technology as science and technology was designated a federal subject.

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, Centre of Excellence for Molecular Biology (CEMB) at University of Punjab, Lahore was established which undertook the first project on gene cloning in Pakistan. CEMB is also credited for development of first GM crop rice in Pakistan. However, this crop could not be advanced further due to nonexistence of biosafety regulations and export reservations at the time. In 1986, the Government of Pakistan approved the establishment of National Institute for Biotechnology and Genetic Engineering (NIBGE) which was formally inaugurated in 1994 at a cost of US $1.2 million. Both CEMB and NIBGE have a well-developed infrastructure for modern technology in accordance with international standards. Modern biotechnology played a crucial role when cotton crop faced the menace of leaf curl virus (CLCV) in 1992. The viral genome was sequenced. This helped in the recognition of new CLCV strains (Burewala, Shahdadpur strains) that were created as a result of recombination of original strain (Multan strain). Sequencing studies facilitated in understanding the evolutionary mechanism of virus.

In the year 2001 and 2002, the establishment of National Biotechnology Commission and Higher Education Commission played an important role in the promotion of modern biotechnology in both universities and research institutes that were working on conventional technologies. Several new academic (Commission on Science and Technology for Sustainable Development in the South (Pakistan) , National University of Sciences and Technology (Rawalpindi, Pakistan) , Fatima Jinnah University) and research institutes were set up. In the year 2007 at the Federal level, National Institute for Genomics and Advanced Biotechnology (NIGAB) was established at National Agricultural Research Centre, Islamabad with the mandate of working on cutting edge technologies related to plant and animal biotechnology. Currently, there are more than 40 centers in the country engaged in research using techniques offered by modern biotechnology.

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, maize, cotton) is expected in the near future.

1.2. Current Status of GM Research in Pakistan

The first project on cloning of insect resistance genes from bacteria was taken up by CEMB, Lahore (1984-94). This group collected 600 isolates of *Bacillus* from various parts of the country, characterized and isolated useful genes for genetic transformation. Currently, CEMB is employing locally cloned *cry1Ac* genes, herbicide resistance EPSPS, and many other genes for abiotic stress tolerance (cemb web). NIBGE, Faisalabad, also developed capability for gene cloning and vector construction. Three to five genes for CLCV resistance have been cloned, but these failed to produce resistance when tested against mutated Burewala strain (Asad et al., 2003). NIBGE has also succeeded in cloning a novel gene from Australian web spider (*HvT*). This was employed to develop insect resistant transgenic tobacco. A group in NIBGE is also developing cDNA libraries of cotton and *Calotropis*. Genes for long fibre length (>34mm) from *Calotropis* have been transformed into cotton and evaluated (Indrais et al., 2011).

Pakistan celebrated the year 2010 as a landmark with the commercial release of insect resistant GM cotton. Nine varieties harboring *cry1Ac* gene were granted approval for cultivation and with this, Pakistan joined the GM crop growing countries club as the 26^{th} country. The area under approved Bt cotton is continuously increasing and Pakistan has the 7^{th} largest area under GM crop cultivation globally (*ISAAA,* 2016). Currently, one non-patented event MON531 and local event CEMB-II are authorized for cultivation in the country. Also, some local events for Bt and herbicide tolerant genes have been generated by CEMB and NIBGE and are under evaluation. Initially another event GFM Cry1Ab/Ac was commercialized in the year 2010, but it could not be realized on ground due the reason that event was harbored in exotic hybrid cotton and seed import could not be accomplished under the existing cotton seed import rules of country.

Gene cloning and transformation for a number of other traits is being carried out by other institutes (Table-1). Genes for disease resistance (*chitinase*), drought tolerance (*DREB, AtNHX1, AVP1*) herbicide resistance (EPSPS), cold tolerance (DREB, ipt) have been transformed into groundnut (Iqbal, et al., 2011), wheat, maize and tomato at NIGAB, Islamabad. A few novel genes for salt tolerance from *Salicornia,* synthesis of synthetic genes have also been done at NIGAB (work under publication).

Table-1. Crops undergoing transformation in Pakistan.

Crop	Institute
Cotton	CEMB, Lahore; NIBGE, Faisalabad
Brassica	IBGE, Peshawar; KIBGE, Karachi; ABR/AARI, Faisalabad
Wheat	NIBGE, Faisalabad; F.C. College, Lahore; CABB/UAF; NIGAB, Islamabad
Potato	NIBGE, Faisalabad; QAU, NIGAB, Islamabad
Ground Nut	NIGAB; Islamabad
Chickpea	NIGAB, Islamabad, QAU, Islamabad
Sugarcane	NIBGE, Faisalabad
Tomato	NIGAB; Islamabad; QAU, Islamabad
Chili	NIBGE, Faisalabad; Quaid-i- Azam University, Islamabad
Soya bean	NIBGE, Faisalabad
Maize	CEMB, Lahore

Source: NBC, Pakistan EPA,2010-2018..

1.3. Role of Biotechnology in Improvement of Livestock Sector

Breeding of dairy cattle in Pakistan involves programs based on the international trade of semen from elite bulls with high genetic merit for the dissemination of alleles associated with positive economic traits, such as increased milk yield. The dissemination of such traits is beneficial for animal production, but the simultaneous dissemination of genetic defects is not. Holstein-Friesian breed is widely disseminated throughout the country, with regional populations genetically linked because of the international trade in semen, embryos and live animals. Therefore, defective alleles occurring within widely used breeding lines are likely to be present in the Pakistani Holstein-Friesian and crossbred population.

Inherited disorders are of major importance in Holstein Friesian cattle a breed that now dominates the world dairy industry due to high milk production. The important inherited disorder BLAD was disseminated globally in 1992 by this breed and reported in Pakistani Holstein Friesians in 2008. However, a range of inherited disorders for example citrullinemia, deficiency of uridine monophosphate synthase and bovine hereditary zinc deficiency recognized internationally are still in need to be explored in this breed in Pakistan. The current research activities at, NIGAB NARC, Islamabad are focusing on identification of animals that have greater production potential and are free from genetic anomalies. Similarly, molecular characterization of pathogens belonging to food animals and identification and development of immunogenic proteins for the development of diagnostics and vaccines against selected pathogens (Foot and Mouth disease Virus , Peste des Petits Ruminants and Avian Influenza etc).

2. Biosafety Regulations in Pakistan

Biotechnology applications, specifically in using genetically modified organisms (GMOs) must be accompanied by a systematic risk assessment and management. The Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD) set the framework on transboundary movement of living modified organisms (LMOs), which required countries ratifying the protocol as state parties. On June 5, 1992, Pakistan signed the CBD when it was opened for signature at the United Nations Conference on Environment and Development (UNCED), Rio de Janeiro, Brazil. After 2 years, Pakistan ratified the CBD on July 26, 1994. Pakistan also signed the Cartagena Protocol on Biosafety in 2001, but could not deposit the instruments of ratification until, May 2009. The ratification of Nagoya-Kuala Lumpur supplementary protocol on Liability and Redress to CPB in accord with article 18(1) is still pending.

Pakistan Biosafety Rules were promulgated in September 2005 (http://www.environment.gov.pk). Exercising the powers conferred by Section 31 of the Pakistan Environment Protection Act (XXXIV of 1997) the Ministry of Environment (MOE), Government of Pakistan made the rules, called Pakistan Biosafety Rules 2005 (14), and these biosafety rules were promulgated in April 2005. Currently after 18th Constitutional Amendment, Ministry of Climate Change is the custodian of Pakistan Biosaftey Rules-2005.

National Biosafety Guidelines were prepared through a national forum participated by all of the stakeholders and experts, including academic institutions, research and development organizations, industry, non-governmental organizations (NGOs), human rights societies, and international experts like United Nations Environment Program/Global Environmental Facility (UNEP/GEF) consultant Julian Kinderlerer, from the United Kingdom. These guidelines have been prepared keeping in view the guidelines prepared by the United Nations Industrial Development Organization (UNIDO), Food and Agriculture Organization (FAO) of the United Nations, World Health Organization (WHO), UNEP, and all the developed and developing countries, with modification to suit our unique and specific socioeconomic and geographic environment. After passing through several developmental stages (Table 2), this document was presented to the MOE in January 2000. Enactment of these biosafety guidelines has come into force with the promulgation of Pakistan Biosafety Rules 2005.

Table 2. Development of National Biosafety Guidelines/Rules in Pakistan

Sr. No.	Date	Main Activity/development
1	March 1994	Preparation of Voluntary Code of Conduct for release of GMOs into the environment
2	September 1996	Establishment of Biosafety Committee to prepare NBG (National Biosafety Guidelines)
3	January 1998	Constitution of National Biosafety Expert Committee (NBEC) to review
4	June 1998	1st meeting of NBEC and constitution of a subcommittee
5	June 1998	1st meeting of subcommittee of NBEC held at MOEnv
6	November 1998	2nd meeting of subcommittee of NBEC held at CEMB
7	January-June 1998	2nd,3rd, and 4th NBC meeting and 3rd NBEC meeting at Ministry of Environment
8	July 1999	Biosafety Guidelines submitted to NBEC
9	January 2001	National consultative workshop to update Biosafety Guidelines by NBEC
10	January 2002	Meeting of NBEC
11	May 2002	Briefing to Minister (Environment) on Biosafety Guidelines
12	June 2004	Draft safety rules prepared by Pakistan EPA (Pakistan Environment Protection Agency)
13	January 2005	Briefing to Prime Minister of Pakistan on the Biosafety Guidelines/Rules
14	January 2005	Prime Minister directs an inter-ministerial meeting to review comments/suggestions received
15	February 2005	Circulation of biosafety rules and inter-ministerial meeting to review comments/suggestions received
16	April 2005	Pakistan Biosafety Rules 2005 [S.R.O336(1)/2005 and file 2(7)95-Bio]
17	May 2005	National Biosafety Guidelines [Notification No. F.2 (7) 95-Bio]
18	2010-2011	Establishment of Ministry of Climate Change, as custodian of Biosafety Rule implementation

Source: Zafar, 2007

2.1. Biosafety System of Pakistan

Prior to the devolution of Federal Ministries in 2010 and 2011, the Pakistan Biosafety system was defined by two instruments. The Pakistan Biosafety Rules and the Biosafety Guidelines. These were implemented in response to the signing of the Cartagena Protocol on Biosafety by Pakistan.

2.1.1. Biosafety Rules, 2005

The Pakistan Biosafety Rules were notified in 2005. The Rules are applicable to three broad, frequently overlapping categories of organisms and activities;

a. Live, microorganisms and cells and
b. Import, export, sale, manufacture and storage of microorganisms and gene technological products for research whether conducted in laboratories of teaching and research, research and development institutes or private companies involved in the uses and applications of GMOs and products thereof.
c. All work involved in field trial of GM plants animals (including poultry and marine and purchase of LMOs, substances or cells and products thereof for commercial purposes.

The Rules establish a three-tiered hierarchy of governing bodies designated to administer the Biosafety Rules. The NBC and the TAC are Federal-level committees and the third tier comprises all the IBCs that have been created within various institutions that are engaged in regulated biotechnology activities. At present, there are 41 notified IBCs in the country and more than 500 cases for approval have been submitted.

The focus of the NBC is to establish national policies on biosafety; authorize commercial release of, and trade in crops and products derived through biotechnology; ensure regulatory compliance; coordinate with trading partners on issues relating to products of biotechnology and provide information (except for confidential business information) to developers and the public. The function of the TAC is to provide the technical information needed by the NBC to effectively do its job including evaluation of applications for field trial licenses and provide recommendations to the NBC regarding the issuance of licenses and to monitor new technological developments to assess biosafety risks. IBCs are responsible for day to day research activities within their institutions including monitoring ongoing research projects and ensuring that required records are kept; inspecting lab facilities and containment measures; coordinating with NBC to provide guidance and training to researchers and establishing institutional emergency response plans.

The central regulatory mandate of the Biosafety Rules is that any commercial activity (import, export, sale, purchase, or trade) involving a LMO or a product made from one requires a license. Similarly, the deliberate release of an LMO into the environment such that the organism is not contained as in the case of a field trial, also requires a license. Contained use meaning laboratory research performed inside a physical structure limiting the LMOs contact with the environment and the public must also be licensed. The unintentional release of an LMO is always a violation of the rules.

The NBC issues licenses to conduct these regulated activities under authority granted through the National Environmental Protection Act. Specifically, the license is issued pursuant to section 14 of the Act, dealing with hazardous substances that states:

"No person shall generate, collect, consign, transport, treat, dispose, store, handle or import any hazardous substance except under a license issued by a Federal Agency"

Licenses are renewable in two-year increments, but may be revoked by the NBC under three circumstances (1) if new evidence is found demonstrating harmful effects of the genetically engineered organism covered by the license (2) if the genetically engineered organism causes unexpected environment or health injury or (3) if the license holder is not in compliance with any federal requirements or conditions. Applicants whose license applications are denied may reapply, after six months if they present new information relative to the environmental risk of the organism.

2.1.2. National Biosafety Guidelines

The National Biosafety Guidelines (the Guidelines) were finalized in May 2005, by the Pakistan EPA, following a multi-stakeholder consultation process including representatives from academia, research and development centers, industry, and NGOs. The purpose of the Guidelines is to provide guidance for conducting laboratory and field research using GMOs and for the commercial release of GMOs as well as to establish regulatory processes consistent with the forms necessary for the implementation of these processes, along with instructions for completing the forms. In addition, the Guidelines clarify the roles played by the three authorities responsible for the regulation of biotechnology the IBCs, the TAC and the NBC.

3. Status of Bt Cotton

Following approval by NBC, MOEnv and other regulatory agencies, the Punjab Seed Council has approved 8 varieties and one hybrid with Bt genes for general cultivation in Punjab. Pakistan joined the club of GM cotton growing counties with the release of nine varieties (eight open pollinated varieties and one hybrid cultivar) in 2010. All Bt varieties harbor Monsanto's event MON531 not under patent protection in Pakistan except for hybrid GN-2085 which contains Chinese Patented event in Pakistan. Currently, 45 Bt gene harboring cotton varieties have been given approval for commercial cultivation. About 95% of cotton growing area is covered by these varieties harboring *Bt* gene. Terms and conditions has been in progress with Monsanto for the introduction of Bollgard-II™ event (MON15985) in Pakistan.

In the year 2017, CEMB signed agreements with 17 national seed companies on public-private partnership basis for the commercialization of indigenous transgenic events (CEMB-II and Klean cotton). Field trial permissions have been granted for Klean cotton by NBC while CEMB-II has been commercialized in the country already. Local private sector like Four Brothers Limited has emerged as a potent developer for number of transgenic cotton technologies which might be realized in very near future in addition to multinational seed companies.

Along with this, the law for Plant Breeder's Rights Act (PBRA)—2016 has been enacted in the country. It is expected that this decision will pave the way for establishment of viable biotech cotton seed industry in Pakistan.

4. Challenges and the Way Forward

The country is facing shortage of trained manpower to carry out biosafety studies. Efforts are being made to improve it through the introduction of biosafety courses in universities and degree awarding institutes (Quaid-i-Azam University, NIBGE, NIGAB/NARC). Workshops, seminars and training courses are being held by Pakistan Biosafety Association on a regular basis. This provides an opportunity to bring scientists and health care workers from all corners of Pakistan under one roof to discuss the major challenges to Biosafety in Pakistan. This also provides an opportunity for international partners in the field to share their experiences and develop networking with regional scientists. The biotech companies have been hesitating to introduce their new technologies and investment due to non-existence of Plant Breeder's Rights, the enactment of PBRA will revolutionize the Biotech Cotton seed industry. There is still no mechanism for monitoring and evaluation of GM cotton after release which is yet too developed. Regular funding for the operations of NBC, establishment of national biosafety laboratory, masses' awareness, capacity building and lack of government inter-agency coordination are some other challenges that need to be addressed for the development of a strong regulatory regime.

4.1. Biosafety Clearance House

Under Article-20 of the CPB , it is the obligation of member states to establish a Biosafety Clearance House (BCH) to (a) facilitate the exchange/sharing of scientific, technical, environmental, transboundary movement and legal information on GMOs and (b) assist members to implement protocol. The Information in BCH also includes the final decisions taken by member states regarding the import and release of GMOs. BCH is a web portal system and it is meant for monitoring GM materials across the boundaries only. The procedures for notification have been set forth in the articles 8-10 of CPB.

Pakistan has not established an in-country BCH yet which is a key consideration in the current Biosafety Regulatory Framework even after several years of ratification of the CPB. As a result of this, there is no information available in the country on the genetic nature of imported commodity items, for example, soybean products. Recently, NBC prepared a project proposal for the establishment of BCH Cell at NBC which is good sign for biosafety regulation in the country.

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The Progress and Prospects of Agricultural Biosafety in Sri Lanka: Present Status, Challenges and Way Forward

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Abstract

Sri Lanka is a Member State of the South Asian Association for Regional Cooperation (SAARC) and a biodiversity hot spot in the world. The three major components of the economy of Sri Lanka are agriculture, industry and services. Major problems to be addressed in the agriculture sector can be divided into technology development and adoption, resource constraints, socio-economic and policy related, marketing and processing. Biotechnology related tools can be used directly or indirectly to solve these problems to a considerable extent. A number of research institutes in the country carry out biotechnology related research on many agricultural crops. Sri Lanka signed the Cartagena Protocol on 24 May 2000 and ratified it on 28 April 2004. The National Biosafety Policy of Sri Lanka was developed by the National Science Foundation of Sri Lanka in 2010. The objective of this policy was 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. The National Biotechnology Policy would also enable regulation of the trans-boundary movement through formulation of relevant policies, regulations, technical guidelines and establishment of management bodies and supervisory mechanisms. Based on this policy a National Biosafety Framework was established by the Ministry of Mahaweli Development and Environment (MoMDE), Sri Lanka, including relevant stakeholders in 2005. Through this National Biosafety Framework, Biosafety Act of Sri Lanka was developed and the act to be enacted in the parliament of Sri Lanka. This will be followed by the development of regulations. The Ministry of Health in Sri Lanka is also developing a biosafety and biosecurity policy document with participation of relevant stakeholders. There is a need to establish and operate competent authorities and sectoral committees on Genetically Modified Organisms (GMOs) in the country. Insufficient technical capacity and a functional administrative and operational system in the country have delayed the proper establishment of biosafety regulations in Sri Lanka.

Key words: Biotechnology Policy, Biosafety, Sri Lanka, regulations

1. Introduction

Sri Lanka, a member state of the South Asian Association for Regional Cooperation (SAARC), is located in the Indian Ocean southwest of the Bay of Bengal, between latitudes 5° and 10°N, and longitudes 79° and 82°E. The total land area is 65,610 km^2 and the population is around 21,670,000. The climate is tropical, and the country experiences two main rainy seasons based on two monsoons, North Eastern monsoon and South western monsoon. In 2018, the GDP of Sri Lanka, at current market price, was Sri Lankan Rs. Billion 14,450. The unemployment rate is 4.4 per cent and the per capita income is US $3,991 (Central Bank of Sri Lanka, 2018). The three major components of the economy of Sri Lanka are agriculture, industry and services and their percentage share of the GDP at current market prices are 7.0%, 30.4% and 53.6%, respectively in the first quarter of 2018 (Department of Census and Statistics, 2018).

2. Agriculture Sector in Sri Lanka

Sri Lanka is recognized as a biodiversity hotspot in the world. Agriculture sector in Sri Lanka consists of non-plantation crops sector (rice, vegetable crops, fruit crops, and other field crops), plantation crop sector (tea, rubber, coconut, sugarcane, export agricultural crops, Palmyra, and cashew), forestry sector, livestock and poultry sector, fisheries and aquaculture sector, and floriculture sector. 27% of the total workforce engages in agriculture-related activities and the total no. of employment in the agriculture sector was 2,140,185 in 2018 (Department of Census and Statistics, 2018). 24.36% of the total exports are from the agriculture sector of the country (Sri Lanka Customs, 2017). In 2018, the growth rate percentage of 16.6 was observed in the agriculture sector. Paddy sector has contributed the most (65%) followed by vegetable (17.7%), other field crop (13.8%) and fruit (12.1 %) sectors (Central Bank of Sri Lanka, 2018).

Major problems found in the agriculture sector of Sri Lanka are categorized into the following: 1. Technology development and adoption related (Inadequate availability of new high yielding varieties, inadequate availability of information on new technologies at village level, low productivity due to rain-fed cultivation in marginal lands, poor land preparation and crop management resulting in low yields, high incidence of pests and diseases, lack of soil fertility improvement practices and low levels of inputs, particularly fertilizer, improper ground water management practices, inadequate farm mechanization, inadequate extension staff and mobility), 2. Resource constraints (inadequate availability of quality seeds, high price of hybrid seeds, unavailability of water during critical growth periods, lack of input supply mechanism at village level. 3. Socio-economic and policy related (trade policies on the importation of lentils and other food commodities, giving high priority for self-sufficiency in rice and neglecting other field crop production, lack of farmer group activities, and 4. Marketing and processing associated (lack of organized marketing systems and storage facilities, low farm-gate price and profitability, inadequate processing facilities and agro-based industries). Out of these problems, biotechnology related tools can be used directly or indirectly to solve problems such as inadequate availability of new high yielding varieties, low productivity due to rain-fed cultivation in marginal lands, high incidence of pest and diseases, inadequate availability of quality seeds, high price of hybrid seeds, unavailability of water during critical growth periods, lack of soil fertility improvement practices and low levels of inputs uses such as fertilizers.

3. Agriculture Biotechnology in the Country

Biotechnology is one of the main technologies used in agricultural sector. Biotechnology can be defined as "use of living systems and organisms to develop or make useful products, or any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use" (UN Convention on Biological Diversity, Art. 2). 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 are shown in Table 1.

Table 1. Investment on biotechnology in Sri Lankan Agriculture

Total investment*	Amount
Agriculture Research at Current Market Price (SLR. mn.)	1,247
Agriculture Research at Current Market Price (US $ mn.)	8
Agricultural Biotechnology Research at Current Market Price (SLR. mn.)	34
Agricultural Biotechnology Research at Current Market Price (US $ mn.)	0.22

SLR = Sri Lanka rupees

(Source: Niranjan, 2018, Central Bank of Sri Lanka, 2018)

*Average Exchange Rate in 2017 to US$ = 152.4575. Agricultural sector includes agriculture (plantation &non-plantation), forestry, and livestock & Fisheries Sectors. Capital investment in agricultural biotechnology is not covered.

4. Institutes that Engage in Biotechnological Research in Sri Lanka

Crop biotechnologies have shown rapid progress over the last two decades in some areas such as tissue culture-based techniques (micro propagation, somatic embryogenesis), mutagenesis, genetic modifications, Marker-assisted selection (MAS), disease and pest diagnostics and gene editing etc. In Sri Lanka, most of the government universities engage in biotechnology related research while a few private institutes also conduct degree and non-degree courses related to biotechnology. Among the government research institutes, Research Stations of the Department of Agriculture, Sri Lanka carry out considerable research on biotechnology. Among the other government institutes, Rubber Research Institute, Tea Research Institute, Coconut Research Institute, Sugarcane Research Institute, Research Division of the Department of Export Agriculture, National Aquatic Research Authority, Veterinary Research Institute also have biotech based research in their programmes.

Most of the research carried out by these institutes include, gene pyramiding for pest and disease resistance in plants using molecular markers and subsequent development of lines /varieties. incorporation of flood resistant/ drought resistant/ salt tolerant genes to popular varieties through MAS, molecular marker development for biotic/ abiotic resistant gene tagging, tissue culture development with or without mutations, anther culture development, embryo rescue, germplasm characterization /DNA fingerprinting, diversity analyses of crops/ varieties/ accessions and land races with ISSR and SSR markers, transgenic plant development for virus resistance, molecular detection of pests and plant pathogens and diversity analyses of pathogens. However, the success stories on novel technologies such as gene editing are yet to be unveiled in Sri Lanka. Some important developments in the area of biotechnology, which have taken place during the last four decades in Sri Lanka are listed in Table 2.

Table 2. Developments in biotechnology and biosafety related activities in Sri Lanka.

Period/Year	Activity
Late 1970s	Initiation of tissue culture for orchids at the Royal Botanical Garden
1983	Establishment of tissue culture division at the Coconut Research Institute, Formation of a Biotechnology Group of Scientists at the Sugarcane Research Institute
1987	Establishment of the first biotechnology laboratory at the Plant Genetic Resources Centre of the Department of Agriculture with Japan International Cooperation Agency (JICA), Initiation of *in-Vitro* conservation of vegetative propagated crops
1987-96	Training of four Sri Lankan scientists on biotechnology at Universities of Riverdale, USA; Nottingham, UK; Bath, UK; Tsukuba and Kyoto, Japan
1992	Establishment of a steering committee for biotechnology by the National Science Foundation 1994. Establishment of the Virus Indexing Centre of the Department of Agriculture
1997	Identification of biotechnology as a thrust area for development by Ministry of Science and Technology (MoST)
2002	Signing of the Cartagena Protocol on 24 May 2000 by Sri Lanka

Period/Year	Activity
2002	Identification of biotechnology as a thrust area by the Ministry of Environment and Natural Resources, Identification of national priorities on agricultural biotechnology by the Council for Agricultural Research Policy (CARP) of the Ministry of Agriculture
2003	Identification of areas of research in biotechnology by National Science Foundation
2004	Ratification of the Cartagena Protocol on 28 April 2004by Sri Lanka.
2009	Formulation of National Biotechnology Policy by National Science Foundation & National Science and Technology Commission, Establishment of the National Committee on Agricultural Biotechnology at CARP
2010	Cabinet Approval to the National Biotechnology Policy
2014	Drafting of The Biosafety Act (MoMDE)
2019	Undertaking of Initiatives for the development of guidelines and training Manuals for Environmental Risk Assessment, Risk Management and Risk Communication of GE mosquitoes and insects by the National Science Foundation
2019	Drafting of a National Policy on Biosafety and Biosecurity by the Ministry of Health in consultation with other relevant agencies

(Source: Niranjan, 2018, Central Bank of Sri Lanka, 2018)

5. GMOs/ LMOs in Sri Lanka

Sri Lanka does not produce genetically engineered (GE) crops or animals. Though some GE related research is carried out at the laboratory level, no commercial level development of GE crops or animals has taken place in Sri Lanka. Sri Lanka does not allow import of GE food, crops, or animals into the country. Sri Lankan trade regulations require mandatory labelling of GE ingredients, GE-free certification for imported goods, and approval of imports for food products containing more than 0.5% (by volume) of GE-derived ingredients. Food that has GE content of less than 0.5% is exempted from these regulations, provided that the presence of such GE content is considered technically unavoidable and the organisms have been subject to a scientific risk assessment (www.gain.fas.usda.gov).

6. National Policy on Biotechnology

The National Science Foundation (NSF) of Sri Lanka established a Steering Committee for Biotechnology in 1992 to promote and support biotechnology related research in universities and research institutions. In 1997, the MoST of Sri Lanka identified biotechnology as a thrust area for development in the country. Funds were made available from a loan from Asian Development Bank for the development of human resources and capabilities in some selected universities and research institutes of Sri Lanka (National Science Foundation, 2010).

The NSF of Sri Lanka unveiled the National Biotechnology Policy of Sri Lanka in 2010. The objective of this policy was to ensure that the risks likely to be caused by modern biotechnology and its products will be minimized and protection of biodiversity, human health and environment will be maximized. The National Biotechnology Policy will regulate the transboundary movement through formulation of relevant policies, regulations, technical guidelines and establishment of management bodies and supervisory mechanisms. This policy covers all biotechnology areas, 1. All areas of agriculture, livestock, fisheries, forestry, human and animal health, food production, energy and environment, 2. All research and development in biotechnology, 3. All promotional and regulatory activities for product development and commercialization, 4. All measures to ensure public health and environmental safety with regard to biotechnological applications in Sri Lanka (National Science Foundation, 2010). The policy aims to position all biotechnologies, including agricultural, medical, environmental, energy and industrial as key contributors in enhancing the quality of life of the citizens and to support the national development of Sri Lanka through economic advancement. The policy aims to ensure an economic, legal and a regulatory framework to facilitate development and co-ordinate multidisciplinary research, product development and commercialization in biotechnology, provide an institutional framework i.e. Apex Body for national decision-making, coordinating, monitoring biotechnology research and development , promoting, networking, funding and performance managing in biotechnology. It will enable promotion of applications of all biotechnologies with adequate consideration to ethical and biosafety issues, support for research and development as well as human resource development in biotechnology, guidance for the judicious use of biodiversity in innovations in all biotechnologies to ensure the sustainable use of environment and biodiversity, safeguarding intellectual property rights and traditional knowledge in development and application of all biotechnologies, nurturing and promotion of public-private cooperation and collaboration in developing biotechnology based industries for the development of the country. The National biosafety policy aimed at drafting and enacting the new regulations for approving authority(composition, powers and duties), procedure for granting approval, monitoring mechanism and powers vested in it, enforcement powers, offences and related aspects(National Science Foundation, 2010).

7. National Biosafety Framework

Sri Lanka signed the Convention on Biological Diversity in 1992 and ratified it in 1994. Sri Lanka also signed the Cartagena Protocol on 24 May 2000 and ratified it on 28 April 2004. Cartagena Protocol ensures an adequate level of protection in handling, use and transfer of GMOs. The MoMDE of Sri Lanka acts as the national focal point for the Convention on Biodiversity and the Cartagena Protocol on Biosafety in Sri Lanka. In order to implement the Cartagena Protocol in the country, MoMDE formulated the National Biosafety Framework under the National Policy on Biosafety and it was approved by the Cabinet of Ministers of Sri Lanka in 2005.

The Biosafety Framework is based on a precautionary approach with the following two objectives, 1. To provide an overview of current situation in the country that was assessed during the National Biosafety Framework development project and identify what is currently taking place in Sri Lanka (i.e. policies, legislation, administrative system etc.). 2. To identify what is still needed to be done to complete the National Biosafety Framework (the required legislation, still needs to be drafted/ adopted, filling the gaps in the administrative or enforcement systems etc.). Under the National Biosafety Framework, the national coordinating committee (NCC) has been established representing the biosafety related sectors and institutions of the country. Thus, the MoMDE, the Ministry of Justice, the Ministry of Health, the Ministry of Agriculture, the Ministry of Animal Production and Health, Department of Wildlife Conservation, Forest Department, Department of Agriculture, Department of Fisheries represent NCC (www.ilsirf.org).

8. National Biosafety Act

The Biosafety Act of Sri Lanka was drafted in 2014 by the MoMDE under the National Biosafety Framework and arrangements have been made for enactment of the Act in the parliament of Sri Lanka. For the finalization of the Act and related activities, the MoMDE has implemented a National Biosafety Project called “Implementation of the National Biosafety Framework in accordance with the Cartagena Protocol on Biosafety” for which funding support is obtained from the Global Environment Facility (GEF) and technical support from the Food and Agriculture Organization of the United Nations (FAO). This project is represented by many relevant agencies. The Biosafety Act will regulate and monitor the applications of modern biotechnologies, including all “GMOs”, “LMOs”, and products that would affect food consumption, research, commercial production, and imports and exports. This Act will include detailed procedures for approval, monitoring, and enforcement of penalties for violations related to GMOs and LMOs.

9. Biosafety Regulations

Based on the Biosafety Act, biosafety regulations are being developed under the National Biosafety Framework in Sri Lanka. Biosafety regulations and guidelines shall be applicable to all research and development activities of modern biotechnology conducted in laboratories of government research institutes, state enterprises, universities, international organizations, private companies or non-governmental organizations. They shall also be applicable to laboratory and field trials, transboundary movement, transit, handling and use of all GMOs/LMOs that may have potential adverse effects on the conservation and sustainable use of biological diversity of the country and constitute risk to human health. Country specific guidelines for import of GMOs and products, internal transport and release of GMOs and products, for the production of GMOs and for the safe use of rDNA technology in the laboratory will be included in these regulations (www.ilsirf.org).

10. Other Acts Relevant to Biosafety Aspects in Sri Lanka

According to the Food Act No 26 of 1980 of Sri Lanka, regulations under section 32 Food (control of import, sale and labelling of genetically modified foods) and regulations published in Gazette No 1456/22 – August 03, 2006 on GM Food regulation no person shall, import, store, transport, distribute, sell or offer for sale any genetically modified organism as food for human consumption; any food containing or consisting of genetically modified organisms; any food produced from or containing ingredients produced from genetically modified organisms without the approval of the Chief Food Authority (Director General of Health Services, Sri Lanka). GM food regulation labelling requires the inclusion of the statement "Genetically modified' in package or at retail sale. The following acts of Sri Lanka also show direct or indirect scope for biosafety aspects in the country; Animal Diseases Act No 59 of 1992 (Department of Animal Production and Health, Sri Lanka), Animal feed Act amendment No. 12 of 2016 (Department of Animal Production and Health, Sri Lanka), Customs Ordinance, Sri Lanka Customs, Consumer Affairs Authority Act 09 of 2003 (Consumer Affairs Authority, Sri Lanka), Fauna and Flora Protection Ordinance, 2 of 1937 (Department of wild life, Sri Lanka), Fisheries and Aquatic Resources Act (Department of Fisheries and Aquatic Resources), Plant Protection Act No. 35, 1999, Quarantine and Prevention of Diseases Ordinance , 1987. (Department of Health, Sri Lanka), Seed Act of No. 22 of 2003 (Department of Agriculture, Sri Lanka), Sri Lanka Accreditation Board for Conformity Assessment Act 32 of 2005, Science and Technology Development Act No. 11 of 1994 (Director, National Science Foundation, Sri Lanka).Plant Protection Act, No 35 of 1999, which provides the legal provisions to prevent the entry, establishment and spread of any pest and disease or their causative agents, which are injurious to plant health or destructive to plants in Sri Lanka. These provisions can be used not only to prevent the entry of plants and animals, but to prevent the import of any genetically modified plasmids that could be potentially harmful to plants. In the Plant Protection Act GMOs and LMOs are being mentioned. Labelling provisions of the Consumer Affairs Authority Act No,9 of 2003 can be used to label all goods with GM.

11. National Policy on Biosafety and Biosecurity

The Ministry of Health in Sri Lanka has taken initiatives to draft a National Policy on Biosafety and Biosecurity, emphasizing laboratory biosafety. The policy has been drafted and is to be submitted to higher authorities for further processing.

12. Major Problems and Way Forward

The Policy on National Biotechnology has been unveiled by the National Science Foundation of Sri Lanka. Biosafety Act is yet to be enacted and regulations are yet to be formulated. Establishment and operation of competent authorities and sectorial committees on GMOs in the country is needed. Some other related policies are found to be incomplete, or still at various stages of development or implementation. Control of import, labelling and sale of genetically modified foods in Sri Lanka is also needed to be regulated properly. Insufficient technical capacity and a functional administrative and operational system in the country have delayed establishment of Biosafety regulation in Sri Lanka.

13. Conclusion

Numerous institutions in Sri Lanka carried out biotechnology related research. Research on GMOs is limited to laboratories or confined places in Sri Lanka. There is no commercial level production of GMOs in the country. Existing rules and regulations do not allow importation of GMOs into the country. If food or feed are of GM nature they must be labelled. Multiple policies including the National Biosafety Policy and the National Biosafety Act are at different stages of development and yet to come into effect.

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Harmonization in Regional Standards on Safety of GM Foods

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Abstract

This article is an endeavour to bring forward a case study of the harmonization efforts initiated by India to formulate a regional SAARC standard on risk assessment of foods derived from modern biotechnology, commonly known as genetically modified (GM) foods. The Bureau of Indian Standards (BIS), which is the national Standards Body of India is one of the 8 members of the South Asian Regional Standards Organization (SARSO) and is developing a SAARC standard on 'Principles for the Risk Analysis of Foods Derived from Modern Biotechnology'. This standard is based on the corresponding CODEX Guideline CAC/GL 44-2003 with which it is harmonized and thus paves way for its easier acceptance among SAARC states while the regional standard is being developed.

Keywords: Genetically modified (GM) foods, BIS, SAARC, CODEX, food safety assessment.

1. Introduction

For many foods, the level of food safety generally accepted by the society reflects the history of their safe consumption by humans. It is recognized that in many cases the knowledge required to manage the risks associated with foods has been acquired in the course of their long history of use. Foods are generally considered safe, provided that care is taken during development, primary production, processing, storage, handling and preparation. The hazards associated with foods are subjected to the risk analysis process to assess potential risks and, if necessary, to develop approaches to manage these risks. While risk analysis has been used over a long period of time to address chemical hazards (for example residues of pesticides, contaminants, food additives and processing aids), and it is being increasingly used to address microbiological hazards and nutritional factors, the principles were not elaborated specifically for whole foods.

The risk analysis approach can, in general terms be applied to foods, including foods derived from modern biotechnology. However, it is recognized that this approach must be modified when applied to a whole food rather than to a discrete hazard that may be present in food. In view of above, it becomes extremely important that the standards are harmonized in the region to bring uniformity and confidence in trade. Standardization is the process of formulating and applying rules for an orderly approach to a specific activity for the benefit and with the cooperation of all concerned, and in particular for the promotion of optimum overall economy taking due account of functional conditions and safety requirements. It is based on the consolidated results of science, technique and experience. It determines not only the basis for the present but also for future development, while keeping pace with technological developments world over. The evolution of the concept of standardization has helped in codifying the existing knowledge and in bridging international barriers, it being a dynamic activity.

2. South Asian Regional Standards Organization (SARSO)

The South Asian Regional Standards Organization (SARSO) is a specialized body of South Asian Association for Regional Cooperation (SAARC) aimed to achieve and enhance coordination and cooperation among SAARC Member States in the fields of standardization and conformity assessment and to develop harmonized standards for the South Asian region to facilitate intra-regional trade and to have access to the global market. The Member States of SAARC are Afghanistan, Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka. The agreement on the establishment of SARSO entered into force with effect from 25 August 2011 after ratification by all Member States of SAARC.

The National Standards Bodies of the SAARC Member States participate in the development of SAARC Standards (SARS) through the Sectoral Technical Committees (STCs). The SARS are developed through consensus and are drafted in accordance with the editorial rules of the SARSO Directives. In accordance with the ‘SAARC Agreement on Implementation of Standards’, the approval of a SAARC Standard implies that member states have an obligation to give it the status of a National Standard.

3. Initiative by India

Bureau of Indian Standards, the National Standards Body of India has paved way to furthering regional standardization in the area by taking cue from the following Indian Standards which specify the basic principles and guidelines for risk analysis of foods derived from modern biotechnology:

a) IS 15887 : 2010 Principles for the risk Analysis of Foods derived from modern biotechnology

b) IS 15888 : 2010 Guideline for the conduct of food safety assessment of foods derived from recombinant - DNA plants

c) IS 15889 : 2011 Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA micro-organisms

It is important to note that all these Indian Standards are harmonized versions of the relevant CODEX guidelines/ standards, which are internationally followed.

4. The CODEX Guidelines Involved

The Codex Alimentarius, or "Food Code" is a collection of standards, guidelines and codes of practice adopted by the Codex Alimentarius Commission (CAC). The Codex Alimentarius is a collection of internationally adopted food standards and related texts presented in a uniform manner. These food standards and related texts aim at protecting consumers' health and ensuring fair practices in the food trade. The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade.

The following CODEX Guidelines form the basis for the current task of harmonizing the regional standards on GM food safety:

i) CAC/GL 44-2003 Principles for the risk analysis of foods derived from modern biotechnology (Amendments 2008, 2011) – Already under development

ii) CAC/GL 45-2003 Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants

iii) CAC/GL 46-2003 Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA micro-organisms

5. Draft SAARC Standard Being Developed by India

India has initiated the harmonization in the subject through development of the SAARC Standard on 'Principles for the Risk Analysis of Foods Derived from Modern Biotechnology'. During the initial phases of the work item and in line with the practices for development of SAARC standards, a comparative analysis of the National Standards of SAARC Member States and other international standards was carried out by the designated Project Leader. During the analysis, it was observed that Bangladesh had also used the CODEX guideline, CAC/GL 44-2003 for developing their national standard on the subject.

This standard being developed covers principles for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology. However, this standard does not address environmental, ethical, moral and socio-economic aspects of the research, development, production and marketing of these foods. Further, this standard also does not address animal feed and animals fed such feed except in so far as these animals have been developed by using modern biotechnology.

This standard is based on the following principles:

i) Risk Assessment
ii) Risk Management
iii) Risk Communication
iv) Consistency
v) Capacity Building and Information Exchange
vi) Review Processes

Risk assessment is designed to identify whether a hazard, nutritional or other safety concern is present, and if present, to gather information on its nature and severity. It includes a comparison between the food derived from modern biotechnology and its conventional counterpart focusing on determination of similarities and differences.

Risk management covers measures for foods derived from modern biotechnology should be proportional to the risk, based on the outcome of the risk assessment and, where relevant taking into account other legitimate factors, relevant for the health protection of consumers and for the promotion of fair practices in food trade. It also highlights that different risk management measures may be capable of achieving the same level of protection with regard to the management of risks associated with safety and nutritional impacts on human health, and therefore would be equivalent. The uncertainties identified in the risk assessment should be accounted for and appropriate measures implemented.

6. Way Forward

The SAARC member countries must go ahead with the harmonization of standards so as to form regional SAARC standards for the principles and guidelines for risk assessment of foods derived from modern biotechnology. Bureau of Indian Standards (BIS), India has already lead the work and is into the process of developing the SAARC standard on 'Principles for risk assessment of foods derived from modern biotechnology', by taking assistance from the corresponding CODEX guideline, CAC/GL 44-2003. India is also in the process of developing two more standards on 'Guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants' and 'Guidelines for the conduct of food safety assessment of foods produced using recombinant-DNA micro-organisms' which are based on the relevant CODEX guidelines, CAC/GL 45-2003 & CAC/GL 46-2003, respectively. It is believed this will pave way for keeping all the SAARC Member States at the same frequency and confidence with reference to dealing with GM food safety as these standards are being developed based on globally accepted CODEX guidelines on the subject.

7. References

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CAC/GL 76-2011 Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology. *Published by Codex Alimentarius Commission.*

IS 15887 : 2010 Principles for the Risk Analysis of Foods derived from modern Biotechnology. *Published by Bureau of Indian Standards.*

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Proceedings of SAARC Regional Expert Consultation Meeting on "The Progress and Prospects of Agricultural Biotechnology and Biosafety in South Asia"

The SAARC regional expert consultation meeting on "The Progress and Prospects of Agricultural Biotechnology and Biosafety in South Asia" was organized in Dhaka by SAARC Agriculture Centre (SAC), Dhaka, Bangladesh in collaboration with South Asia Biosafety Program (SABP), Bangladesh and ILSI Research Foundation, Washington D.C., USA on 18 June 2019 to 20th June 2019.

In the inaugural session on 18 June 2019, Mr. Kamalaranjan Das, Additional Secretary (Research Wing), Ministry of Agriculture, Government of the People's Republic of Bangladesh graced the occasion as the Chief Guest, while Dr. M. Shahidur Rahman Bhuiyan, Senior Food Security and Agricultural Policy Advisor, USAID was present as the Special Guest. Dr. Pradyumna Raj Pandey, Senior Program Specialist, SAARC Agriculture Centre and one of the programme coordinator delivered his welcome speech to the international and national participants for the Regional Expert Consultation Meeting. During his welcome address, he briefed about the SAARC activities, objectives of the meeting, expectation from country nominated focal persons. The keynote lecture was delivered by Dr. Andrew F. Roberts, Deputy Executive Director, ILSI Research Foundation, USA, to set the tone for the policy dialogue for the event by introducing the importance of harmonization within South Asia Countries. The Chief Guest of the inaugural session Mr. Das mentioned that the Government of Bangladesh recognizes the potential of agriculture biotechnology, formulated the National Biotechnology Policy, and published in 2018 with the aim to ensure profitable agriculture, nutrition and food security in Bangladesh. The special guest, Dr. Bhuiyan explained various activities of USAID along with the activities of SABP. The inaugural session concludes with the vote of thanks by Dr. Aparna Islam, Country Manager, SABP Bangladesh and one of the coordinators of this program. She explained the activities of SABP and continual activities of harmonization within South Asian countries.

Mr. Md Samsul Haque, Director General, SAARC and BIMSTEC, Ministry of Foreign Affairs, Government of Bangladesh as the chief guest of the Concluding Session assured the continuous support to SAC activities from the Government of Bangladesh. Dr. Syed Humayun Kabir, Ex-Director General, SARSO Secretariat, Dhaka, Bangladesh chaired the session as the Special Guest. He talked about the initiative Bangladesh has taken in SARSO to have harmonization in policies including in agriculture and biotechnology. Dr Pradyumna Raj Pandey expressed his sincere thanks to all participants from the Member States of SAARC, local participants, colleagues of SAC, SABP and ILSI Research Foundation for their significant contributions to make a successful and fruitful program at the end of the program. Among the participants, Bangladesh, Bhutan, India, Nepal, Pakistan and Sri Lanka are participating as national focal point expert from the Member States of SAARC. Besides, more than 30 professionals belonging from national, regional and international organizations located in Dhaka attended the meeting.

Objectives of the Dialogue

1. To share information on the current status of agricultural biotechnology and biosafety regulations in South Asian countries.
2. To explore mechanisms to promote harmonization, including a regional biosafety platform.
3. To identify areas where SAARC countries can adopt harmonized polices that will provide benefit to farmers and consumers through access to food and technologies.

Salient Achievements

The three-day consultation meeting realized the importance of biotechnology and biosafety and harmonization of standards among the SAARC Member States. Participants realized and committed to improve policies and create enabling environment towards harmonization in agricultural biosafety in their own country. They agreed to establish the professional as well as knowledge driven platform for biosafety in South Asia and publish current research and development of biosafety and biotechnological advancement in South Asia through SAC publication.

Recommendations

1. Need to develop the SAARC standard on 'Principles for risk assessment of foods derived from modern biotechnology', by taking assistance from the corresponding CODEX guideline, CAC/GL 44-2003.
2. Access and benefit sharing standard of GM germplasm and genes within SAARC Member States.
3. There should be information portal, which is free exchange of biosafety and biotechnological information within SAARC countries.
4. It is need to develop SAARC standard for biosafety and genetic engineering.
5. More programs for capacity enhancement and SAARC road map in this sector.

Lessons Learned

The consultation meeting realized the importance of harmonization of standards among the SAARC member states so as to form regional SAARC standards for the principles and guidelines for risk assessment of foods, feeds and products derived from modern biotechnology. Therefore, keeping all the SAARC member states at the same frequency and confidence with reference to dealing with GM food safety as these standards are being developed based on globally accepted CODEX guidelines on the subject.

Concept Note

Regional Expert Consultation Meeting on the Progress and Prospects of Agricultural Biotechnology and Biosafety in South Asia

Jointly organized by

SAARC Agriculture Centre (SAC), Dhaka, Bangladesh,

The ILSI Research Foundation, Washington D.C., USA

and

South Asia Biosafety Program (SABP)

18-20 June 2019, Dhaka, Bangladesh

1. Introduction

The economic development of most of the South Asian countries, including the SAARC region is deeply connected to developments in agriculture. However, as we close the second decade of the 21st century, agriculture is facing serious and interconnected challenges, including the constant threat of pests and diseases, increasingly severe consequences of climate change, other forms of environmental degradation and land use changes. These challenges will require concerted efforts by scientists, agriculturalists and policy makers to develop and deploy adaptive strategies to meet the needs of South Asia's farmers as they labor to meet the food and nutrition requirements for the nearly 2 billion people who inhabit the region. Innovations in agriculture, including the development and deployment of modern biotechnology, are essential to the success of these efforts and scientist at research institutions and universities, both private and public, in the SAARC region are working relentlessly in this regard.

The Convention on Biological Diversity (CBD), which came into force in 29 Dec 1993 clearly recognizes the potential of modern biotechnology, and also recognizes the need to ensure that these technologies are developed with appropriate oversight to ensure the conservation and sustainable use of biodiversity. In 2000, to advance this goal and to provide a clear pathway for the safe development and deployment of biotechnology, the Cartagena Protocol on Biosafety (CPB) to the CBD was finalized. Till date 171 countries (http://bch.cbd.int/protocol/parties/ updated: 2018-03-05) have ratified or acceded to the Protocol, including the SAARC countries. In line with obligations under the Protocol, and their domestic needs, SAARC countries have subsequently developed national biosafety regime.

Agriculture is increasingly a global enterprise, with the movement of produce, seeds, and commodities between countries providing an essential mechanism to ensure access to adequate food and nutrition. This increasing reliance on agricultural trade means that, in order to ensure that agricultural biotechnology can contribute to achieving food and nutritional security, harmonization of the biosafety rules and regulation among the SAARC countries is needed. As a first step in facilitating harmonization these biosafety requirements, it is important to have a regional consultation meeting among the governments and biosafety experts of these countries.

2. Objectives

4. To share information on the current status of agricultural biotechnology and biosafety regulations in South Asian countries.
5. To explore mechanisms to promote harmonization, including a regional biosafety platform.
6. To identify areas where SAARC countries can adopt harmonized polices that will provide benefit to farmers and consumers through access to food and technologies.

3. Methodology:

- Organize the expert consultation meeting on the Progress and Prospects of Agricultural Biosafety in South Asia in collaboration with ILSI Research Foundation and the South Asia Biosafety Program.
- Agricultural Biotechnology and Biosafety experts from NARS or extension Systems (Ministry/Department of Agriculture/Food Technology and Quality Control) of SAARC Member States will be selected through SAC.
- Organize field visit for the participants to show the improved technologies of Agricultural Biotechnology and Biosafety for South Asia.
- Compilation of papers will be edited and published by SAC and ILSI Research Foundation.
- SAC and ILSI Research Foundation in coordination with other potential development partners will jointly explore the possibility to develop and implement further possible projects on Agricultural Biotechnology and biosafety in South Asia.

4. Expected outputs

- Improved policy and enabling environment towards harmonization in agricultural biosafety
- Established professional as well as knowledge driven platform for biosafety in South Asia
- Publish current research and development of biosafety and biotechnological advancement in South Asia.

5. Target Participants: 25 (tentative)

- 8 Agricultural Biotechnology and Biosafety experts from SAARC Member States (Ministry/Department of Agriculture/Food Technology and Quality Control/ NARS or extension Systems/ Competent National Authorities and National Focal Points) (1 each from 8 SAARC Ministry/)- coordinated by SAC
- 10 from local participants (DoE, MoEFCC, BARC, MoA, Bangladesh)
- 3 from SAC, Dhaka
- 4 from SABP

6. Venue: Dhaka, Bangladesh

7. Date: 18-20 June 2019 (03 days)

8. Collaborating Institutions

a. SAC, Dhaka, Bangladesh
b. ILSI Research Foundation, Washington D.C., USA
c. South Asia Biosafety Program (SABP)
d. Ministry of Agriculture, Government of Bangladesh
e. Ministry of Environment, Forest and Climate Change, Government of Bangladesh

9. Outline of the country paper/presentations

Title: Progress and Prospects of Agricultural Biosafety in South Asia: Present Status, Challenges and Way Forward in SAARC (Respective SAARC Member States)

1. Abstract (for paper only)
2. Introduction

3. Agricultural scenario and current status of agricultural biosafety and biotechnology in the region
4. Biosafety regulatory policy and framework for each SAARC country
5. Updates on important agri-biotech products in the SAARC region
    a) Bt Cotton
    b) GM Mustard
    c) Golden Rice
    d) Late Blight Resistant Potato
6. Harmonisation Efforts
    a) Food Safety Assessment
    b) Environmental Risk Assessment
    c) Import of agricultural biotechnology for food, feed and processing
    d) Food and feed products derived from biotechnology
7. Challenges and Way forward of Agricultural biosafety
8. Conclusion
9. References (for paper only)

10. Coordinators

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Program

Day 1 (18.06.19) 10:00-10:30	Registration
10:30-11:45	**Inaugural Session**
10:30-10:40	Welcome address: Dr. Pradyumna Raj Pandey, Senior Program Specialist (Crops), SAARC Agriculture Centre (SAC)
10:40-11:10	Keynote Lecture: " ***GlobalStatus and Need of Harmonization Biotechnology and Biosafety framework*** " **-** Dr. Andrew F. Roberts**,** Deputy Executive Director, ILSI Research Foundation
11:10-11:20	Address by Special Guest: Dr. M. Shahidur Rahman Bhuiyan, Senior Food Security and Agricultural Policy Advisor, USAID
11:20-11:35	Address by Chief Guest: Mr. Kamalaranjan Das, Additional Secretary (Research Wing), Ministry of Agriculture, Government of the People's Republic of Bangladesh
11:35-11:45	Vote of Thanks: Dr. Aparna Islam, Country Manager, SABP
11:45-12:30	Group Photo and Hi-Tea

Technical Session 1 - Day 1 (18 June 2019)	
12:30-18:30	**Technical Session I: Status of Agricultural Biotechnology and Biosafety Regulatory System in SAARC Countries** **Chair: Dr. Andrew F. Roberts**
12:30–13:00	**Afghanistan:** Country paper presentation
13:00-13:30	**Bangladesh:** Country Paper presentation
13:30-14:00	**Bhutan:** Country Paper presentation
14:00–15:00	**Lunch**
15:00-15:30	**India:** Country paper presentation
15:30 - 16:00	**Maldives:** Country Paper presentation
16:00-16:30	**Tea Break**
16:30-17:00	**Nepal:** Country Paper presentation
17:00-17:30	**Pakistan:** Country Paper presentation
17:30-18:00	**Sri Lanka:** Country Paper presentation
18:00-18:30	**Open Discussion**
19:00-21:00	**Workshop Dinner**

Technical Session 2- Day 2 (19 June 2019)	
09:30–10:50	**Technical Session II: Possibilities of Harmonization in Agricultural Biotechnology and Biosafety Regulatory System in SAARC Countries** **Chair: Dr. Pradyumna Raj Pandey**
09:30-10:00	Bangladesh's Positions on the Issues of Harmonization in Biosafety
10:00-10:30	Bureau of Indian Standards: Update on the Status of Regional Food Safety Standard
10:30-10:50	Regional Perspective and Possible areas of Harmonization in Agriculture and Biosafety Regulations
10:50-11:30	**Tea Break**
Technical Session 3- Day 2 (19 June 2019)	
11:30-13:00	**Technical Session III: Case Study: Fall Armyworm** **Chair: Dr. Vibha Ahuja**
11:30-12:00	Background on Fall Armyworm
12:00-12:30	Regional Harmonization for Pest Control Strategy
12:30-13:00	Open Discussion
13:00-14:00	**Lunch**
Technical Session 4- Day 2 (19 June 2019)	
14:00–15:00	**Technical Session IV: Mechanism for Regional Harmonization** **Chair: Dr. Syed Humayun Kabir, Ex-DG, SARSO**
14:00-14:20	SARSO as an Instrument for Regional Harmonization
14:20-14:50	Possible Harmonization Between India and Bangladesh: A Case Study
14:50-15:15	Open Discussion
15:15-15:30	**Tea break**

15:30-17:00	**Concluding session**
15:30-15:50	Recommendation on Harmonization in Agriculture and Biosafety Regulations Dr. Andrew F. Roberts
15:50-16:00	Address by Special Guest: Dr. Syed Humayun Kabir, Ex-Director General, SARSO Secretariat, Dhaka, Bangladesh

16:00-16:15	Address by Chief Guest: Director General, SAARC and BIMSTEC, Ministry of Foreign Affairs, Government of Bangladesh
16:15-16:20	Vote of Thanks: Dr. Pradyumna Raj Pandey, Senior Program Specialist (Crops), SAARC Agriculture Centre (SAC)

Day 3 (20 June 2019)	
07:30–13:00	**Field visit: BARI**

Participant List

Annexe 1: List of Participants

	Country	Name and designation
1.	**Bangladesh**	**Dr Mst. Dilafroza Khanam** CSO and Head, Biotechnology Division, BARI Mobile : 01931124138 Email : khanammarry@gmail.com
2	**Bhutan**	**Mr. Jambay Dorji** Sr. Planning Officer/Focal for Biosafety (GMO) Bhutan Agriculture and Food Regulatory Authority Ministry of Agriculture and Forests Thimphu: BHUTAN Mobile: +975-17618686 Email: jamsdor77@gmail.com
3	**India**	**Prof. Debasis Pattanayak** Pr. Scientist NIPB New Delhi Email: debasispattanayak@yahoo.co.in Mobile: +91-9910014695
4	**India**	**Dr. Anil Kapri** Scientist-C Food & Agriculture Department BUREAU OF INDIAN STANDARDS 9, Bahadur Shah Zafar Marg, New Delhi - 110002, INDIA Phone: +91 11 23230131, 3375/Ext. 8439 |+91 11 23231128 Email**:** anilkapri@bis.gov.in

	Country	Name and designation
5	**Nepal**	**Dr. Bal Krishna Joshi** Senior Scientist Nepal Agricultural Research Council (NARC) Mobile : +977 9863020222 Email : joshibalak@yahoo.com
6	**Pakistan**	**Dr Ghulam Muhammad Ali** Director General, National Agriculture Research Center (NARC), Islamabad Email: drgmali5@gmail.com Phone: +9251-9255028 +92-300-5565559
7	**Sri Lanka**	**Dr. D.M.J.B Senanayake** Director (Acting and Principal Scientist (Biotechnology) Rice Research and Development Institute, Bathalagoda, Sri Lanka 00-94-718003289 jsenanayake@gmail.com
	Program Coordinator, SAC	**Dr. Pradyumna Raj Pandey** Senior Program Specialist (Crops) SAARC Agriculture Centre, Dhaka, Bangladesh
	Program Coordinator, SABP	**Dr. Aparna Islam** Country Manager, South Asia Biosafety Program (SABP), C/o CIMMYT, House-10/B, Road-53, Gulshan-2, Dhaka-1212, Bangladesh, Cell: 01817114304 G-mail: aparnaislam@southasiabiosafety.org
	Keynote speaker	**Dr. Andrew F Roberts**, Deputy Executive Director ILSI Research Foundation, USA
	Speaker	**Dr. Vibha Ahuja** Biotech Consortium India Ltd. India
	Speaker	**Mr. Ramesh Khadka** Deputy Director, SARSO, Dhaka
	Speaker	**Dr. Joseph Huesing** USAID

	Country	Name and designation
	SAC	**Dr. Nasreen Sultana** Senior Program Specialist (Horticulture) SAARC Agriculture Centre, Dhaka, Bangladesh
	SAC	**Dr. Ashis Kumar Sanmanta** Senior Program Specialist (Livestock) SAARC Agriculture Centre, Dhaka, Bangladesh
	SAC	**Dr. Rudra Bahadur Shrestha** Senior Program Specialist (PS PD) SAARC Agriculture Centre, Dhaka, Bangladesh
	Local participants	
1.	Dr. Md. Harunor Rashid, PSO, BARC, Bangladesh	
2.	Dr Rakha Hari Sarker Professor and Chairman, Department of Botany, University of Dhaka, Dhaka-1000, Bangladesh. E-mail: rhsarker2000@yahoo.co.uk	
3.	Professor Mohammad Nurul Islam, Department of Botany, University of Dhaka, Dhaka-1000, Bangladesh. E-mail: mnurul@du.ac.bd	
4.	Professor Dr. Md. Shahidul Islam, Department of Biotechnology Bangladesh Agricultural University, Mymensingh-2202, Bangladesh E-mail: m.s.islam@bau.edu.bd	
5.	Dr. Mohammad Al-Forkan, Professor and Founder Chairman Department of Genetic Engineering and Biotechnology, University of Chittagong, Chittagong-4331, Bangladesh. Cell: (0088)-01819383213; 01554327785. Email: alforkangeb@gmail.com; alforkancu@hotmail.com	
6.	Dr. Md. Tofazzal Islam, Professor, Department of Biotechnology, Bangabanhu Sheikh Mujibur Rahman Agricultural University, Gazipur-1706, Bangladesh E-mail: tofazzalislam@yahoo.com	
7.	Dr. Enamul Haque, CSO, Bangladesh Rice Research Institute (BARI) BARI Road, Joydebpur, Gazipur.	
8.	Dr. M. A. Yousuf Akhond, PSO Bangladesh Agricultural Research Institute (BARI) Joyebpur, Gazipur-1701.	
9.	Dr. Md. Abdul Kader, PSO, Bangladesh Rice Research Institute (BRRI), Joydebpur, Gazipur-1701.	

	Country	Name and designation
10.	Mr. ANM Iftekhar Alam, National Institute of Biotechnology (NIB), Ganakbari, Ashulia, Savar, Dhaka-1349.	
11.	Dr. Ibrahim Md. Saiyed, Country Manager Healthier Rice Program, IRRI, Dhaka	

Photo Gallery

Dignitaries during the opening ceremony of the Regional Expert Consultation Meeting on the Progress and Prospects of Agricultural Biotechnology and Biosafety in South Asia during Opening Ceremony.

Dr Pradyumna Raj Pandey, Senior Program Specialist and Coordinator of the program handing over the crest to the chief Guest of the opening ceremony Mr. Kamalaranjan Das, Additional Secretary (Research Wing), Ministry of Agriculture, Government of the People's Republic of Bangladesh.

Guests and Participants of the Regional Expert Consultation Meeting on the Progress and Prospects of Agricultural Biotechnology and Biosafety in South Asia during closing session.