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The editorial correspondence should be addressed to the Managing Editor, *Asian Biotechnology and Development Review*, Research and Information System for Developing Countries (RIS). Zone IV-B, Fourth Floor, India Habitat Centre, Lodhi Road, New Delhi-110003, India. Telephones: 24682177-80. Fax: 91-11-24682173-74. E-mail: ravisrinivas@ris.org.in Website: http://www.ris.org.in

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Research and Information System
for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

Asian Biotechnology and Development Review
Vol. 20 No. 3, pp 1-2

Editorial Introduction

K. Ravi Srinivas[*]

Welcome to this issue of Asian Biotechnology and Development Review. Translating the potential of biotechnology for societal progress and to achieve other objectives is not an easy task. In this endeavour expertise in biotechnology is necessary but not sufficient. The two articles in this volume highlight this.

The first article deals with growth of agricultural bioinformatics in India and the challenges in applying bioinformatics. It gives an overview of the field and explains why it has become important in agricultural development. Further it discusses the growth of agricultural bioinformatics in India. It outlines the challenges in effective utilization of bioinformatics in India.

The second article discusses an important issue how to bring in relevant changes in health innovation ecosystem to promote innovations that are accessible, affordable and meet the needs of the people. It examines the translation ecosystem and uses state level disease burden to make few suggestions. This is an example of evidence based policy making in health, where evidence provides the rationale for identifying priorities and is used to evaluate many options in decision making to arrive at the right decision. This paper proposes a regional level entity to facilitate technology transfer and innovation.

The perspective piece highlights the ethical issues in human genome editing and challenges in developing a governance regime. While what happened in China indicated that what was technically feasible should not be a reason to pursue certain things, it also drew attention to the fact in case of certain technologies, law is often unable to regulate effectively as it fails to take into account all potential uses or grey areas in governance could be misused. But only a governance regime penalizes such behavior with severe punishments and incorporates principles of anticipatory governance

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[*] Managing Editor, ABDR and Consultant, RIS. Email: ravisrinivas@ris.org.in

as feasible solution. Even as nations grapple with such developments, the long term solution would be to have a global agreement or at least globally accepted and enforceable norms on using genome editing.

The book review touches upon a theme that is familiar to the readers of ABDR. In this issue we have published excerpts from a report published by FAO on agricultural biotechnology in Asia Pacific. RIS prepared this report for FAO as a deliverable of a study commissioned by FAO.

ABDR welcomes articles, opinion pieces, review articles of two or more books/volumes and book reviews. While we do commission articles, unsolicited contributions are accepted, reviewed on a rolling basis.

Your views and suggestions are welcomed.

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Asian Biotechnology and Development Review
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Development of Agricultural Bioinformatics in India: Issues and Challenges

Diwakar Kumar*

Abstract: Agricultural bioinformatics is one of the recent and the fastest emerging disciplines of the science exploiting computational approaches to biology and life sciences. It is facilitated through mathematical algorithms and statistical techniques essential for the development of a required labyrinthine algorithm that can interpret biological data and configure assumptions from biological shreds of evidences. The discipline comprises many quantitative examinations of the knowledge relating to the biological macromolecules, seeking aid from high-end computing systems and progresses further to computer science and communication technology solving arduous conundrums in the respective fields of life science and more precisely in the field of agriculture. India has mainly focused on the technological upgradation but lacks effective policy measures to have shifts from the traditional technologies. The National System of Innovation framework presents the current landscape of agriculture bioinformatics, and can be mapped for research purpose. The framework requires a variety of expertise stakeholders' networks for productive results, which can cater to the present and the future food demands, and can pinpoint needed solutions. This paper discusses the growth of agricultural bioinformatics in India and the challenges in that field.

Keywords: Agriculture Bioinformatics, Biotechnology Information System Network, Distributed Information Centre, Bioinformatics Policy.

Introduction

Agricultural bioinformatics is one of the recent and fast emerging disciplines of science that exploits computational approaches to find solutions and understand organisms (Baxevanis, 2001). Agriculture accounts substantially in India's economic development as it provides food for more than 1.2 billion people and total employment to about 54.6 per cent of the population

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* Center for Studies in Science, Technology and Innovation Policy, School of Social Sciences, Central University of Gujarat, Gandhinagar-382030 diwakar.kumar@cug.ac.in

(Khatkar *et al.* 2016). India holds the second largest agricultural land of about 140 .9 million hectares in the world. The highest food grains production recorded in 2011-12 was approximately 259.32 million tonnes. Food -grains consumption per person in rural areas has been estimated to decline from 15.3 kg per month from 2000 to 13.8 kg per month by 2050, and only a slight decrease from 11.8 to 11.6 kg per month in urban areas. Indian agriculture era can be divided into six phases: green revolution period (1960 to 1969), early green revolution period (1969 to 1976), the period of wider technology dissemination (1975 to 1989), period of diversification (1989 to 1996), post-reform period (1996 to 2005), and period of recovery (2005 to 2011) (ibid). It is obvious that in future growth in agriculture is impossible with adoption of technologies that combine breakthroughs in science such as genome mapping with applications that enhances productivity. Bioinformatics has immense potential to transform agricultural sector given the increasing importance of information for decision making and the technological options that can empower the farmer through Information and Communication Technologies (ICT).

Agriculture bioinformatics is in the phase of expansion in technological upgradation, such as high-end computing systems, high-speed internet for transferring bulk of genome sequences to major research institutions and laboratories, dry lab infrastructure in almost every research institution, etc. The agricultural bioinformatics discipline does not restrict itself to core biology only but fosters interpretation of genomic data taking aid of other disciplines. Bioinformatics adds mathematics and computer science to rectify results gained through such algorithms (Jian Chen, 2005).

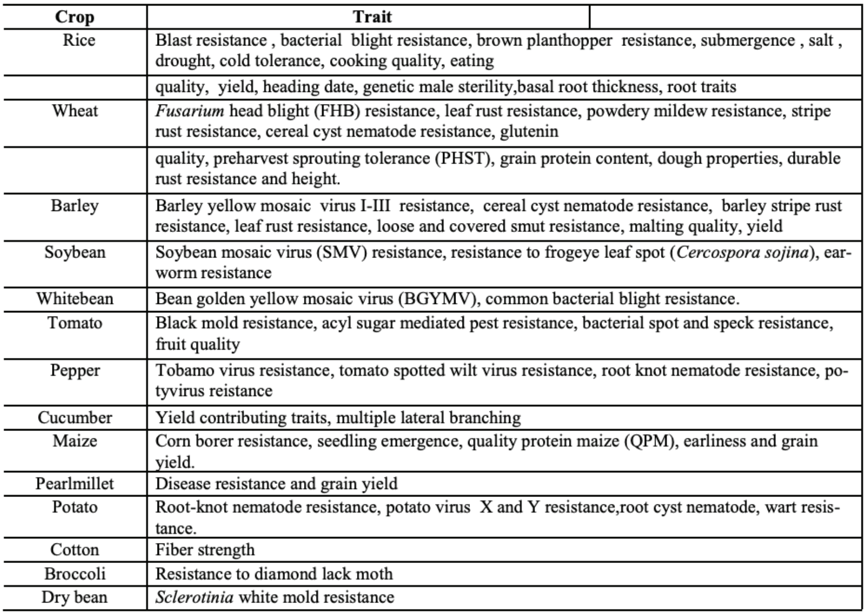
The future of agricultural bioinformatics depends on the development of algorithms that guarantees maximum accuracy as the processed biological data are to be interpreted by the biologist to gain needed information and decipher conjecture from biological data. The informatics section for gene editing is carried by computer-aided learning; this is needed for making necessary tools and software and other programming applications. Such tools and programmed applications play a vital role in the development and implementation of the mathematical algorithms (Kumar, 2017). Agricultural bioinformatics is a very diverse field of study managing a large amount of data in terms of gene sequencing, gene marker, gene mining, etc. Such findings from diverse anatomical disciplines generate biological assumptions which are then used in several research and development activities in the field of agricultural bioinformatics and other related sectors.

The change in the global economy was the major driver to bring in structural changes along with the failure of a small farmer to have a big hand on new technology. The technically sound technologies have their thrust on monocropping having commercial importance. The study of agriculture on the basis of the agroecology brought the concept of biotic and abiotic components. An agroecosystem is composed of crop plants, weeds, livestock, pests, viruses, bacteria, fungus etc. as well as the other non-living agricultural requirements such as air, mineral, water, light, and soil (Miguel, 1995). In the middle of 1990s, the genetic modification in the plants was started to express Insecticidal Crystal Proteins (ICPs), which protect crops attacked by insects. After cloning and sequencing of a gene such modification is applied to crop of commercial importance. There are crops, such as corn, potato, cotton, cabbage, broccoli and soybean, as being the example for using agricultural bioinformatics technologies (Anthony, 2007).

According to one expert, agricultural bioinformatics apparently has been less prioritized in Indian context in comparison to pharma sector and forensic science (Kumar, 2017). Many research institutes lack basic infrastructure, have no specific agricultural bioinformatics policy, and have little collaborations with firms and other research universities for conducting research work. But there are also research institutes that have supercomputers to accelerate agricultural bioinformatics research. In India, genomics and proteomics were mainly used for the discovery of new drug compositions but later the technology and techniques are being used in gene mining, gene editing, gene sequencing for improving crop properties suitable for changes in climatic conditions.

In India major focus in crop improvement is through gene tagging, gene editing, genome sequencing etc. and these are used for improving productivity, resistance to diseases and other biotic and abiotic changes. Bioinformatics is subdivided into three major categories in the field of agriculture — molecular bioinformatics; organal bioinformatics; species bioinformatics (Sharma 2015). Agricultural bioinformatics in India began with the application of green biotechnology and has gained importance in agricultural community.

Table 1: Molecular Breeding Marker Applied in Different Crops



Crop	Trait	
Rice	Blast resistance , bacterial blight resistance, brown planthopper resistance, submergence , salt , drought, cold tolerance, cooking quality, eating	
	quality, yield, heading date, genetic male sterility,basal root thickness, root traits	
Wheat	*Fusarium* head blight (FHB) resistance, leaf rust resistance, powdery mildew resistance, stripe rust resistance, cereal cyst nematode resistance, glutenin	
	quality, preharvest sprouting tolerance (PHST), grain protein content, dough properties, durable rust resistance and height.	
Barley	Barley yellow mosaic virus I-III resistance, cereal cyst nematode resistance, barley stripe rust resistance, leaf rust resistance, loose and covered smut resistance, malting quality, yield	
Soybean	Soybean mosaic virus (SMV) resistance, resistance to frogeye leaf spot (*Cercospora sojina*), earworm resistance	
Whitebean	Bean golden yellow mosaic virus (BGYMV), common bacterial blight resistance.	
Tomato	Black mold resistance, acyl sugar mediated pest resistance, bacterial spot and speck resistance, fruit quality	
Pepper	Tobamo virus resistance, tomato spotted wilt virus resistance, root knot nematode resistance, potyvirus reistance	
Cucumber	Yield contributing traits, multiple lateral branching	
Maize	Corn borer resistance, seedling emergence, quality protein maize (QPM), earliness and grain yield.	
Pearlmillet	Disease resistance and grain yield	
Potato	Root-knot nematode resistance, potato virus X and Y resistance,root cyst nematode, wart resistance.	
Cotton	Fiber strength	
Broccoli	Resistance to diamond lack moth	
Dry bean	*Sclerotinia* white mold resistance	

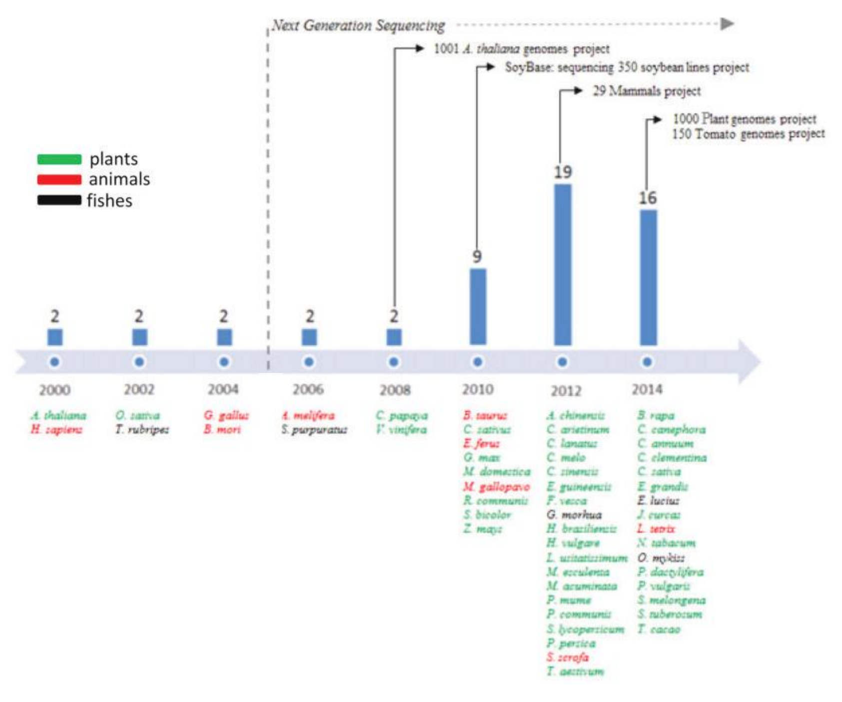
Source: Yadav *et al.* (2015).

Bioinformatics in combination with study of genetic material can result in precise results that enable faster development of varieties (Yadav *et al.* 2015). The genetic material of any plant-crop is a substance that carries all information characteristic to determine its life-cycle. A gene is coded for some specific biological functions; very smallest functional unit of heredity. In agriculture, genetic manipulation begins with a reasonable amount of pure DNA extraction. The required DNA is then cut into pieces so to build a new gene. The needed gene is then placed in the right order and orientation to make the gene functional. Application of bioinformatics in agriculture has led to develop several new products which otherwise would not have been developed.

Development of Bioinformatics in Agriculture

Researches in the field of agricultural bioinformatics gained momentum on account of Human Genome Project, and researches based on bioinformatics and its allied disciplines can be traced back to 1960s when the term bioinformatics was not coined but many projects were undertaken by biologists who were keen to use the available computers and the computational techniques. The first significant project was initiated by Margaret Dayhoff in 1965, and it was she who developed first protein sequence archive named as Atlas of protein sequence and structure (Yadav et al. 2015).

Figure 1: Omics Revolution in the Field of Agriculture Bioinformatics



Source: (Esposito, et al. 2016)

Subsequently, the protein data bank for achieving three-dimensional protein structures could be established in the Brookhaven National Laboratory. It was then researchers like Needleman and Wunsch expanded sequence alignment algorithm during 1970. This was the bottom line in the branch of knowledge in relation to bioinformatics that surfaced the way for customary sequence comparison and database searching practiced by the young biologist. Meanwhile, in 1974, first protein structure algorithm was codified by a pair of scientists, named Chou and Fasman, and that sort of algorithm was primitive by today's standards (Elanchezhian 2012).

With the establishment of the gene banks and development of large data bases, the next phase in agricultural bioinformatics occurred in the 1980s. FASTA, an algorithm developed by William Pearson was the first sequence searching algorithm to be utilised for comparing query sequence of existing database. Basic Local Alignment Search Technique was the improved version of the above algorithm and was proposed by Altschul and coworkers, and, in terms of searching speed, ease of operation and statistical rigor it was excellent.

In late 1980s, commencement of Human Genome Project (HGP) contributed to deployment and development of bioinformatics and bioinformatics became part of the mainstream research in life sciences (Bayat 2002).The rapid developments in ICTs, wide spread availability of internet, the decline in the cost of computing and access to databases and availability of platforms to share and store data in the net contributed to the growth of agricultural bioinformatics. By the end of the last century, the importance agricultural bioinformatics in agricultural R&D was obvious, resulting in more attention and use.

Bioinformatics, however, distinct from computational biology that surrounds all biological areas for example mathematical modeling of an ecosystem, population dynamics, application of game theory in behavioral studies and phylogenetic constructions using fossils records, although it mandatorily does not involve biological macromolecules. In the Indian context, agricultural bioinformatics has restricted itself to gene sequencing, structural and functional analysis of genes and genomes (Xiong, 2006).

Agricultural bioinformatics, an interdisciplinary discipline, is a quantitative analysis of relevant information regarding crop gene in relation to anatomical macromolecule with the pursuance of computational algorithms. Computer science and communication technology then extend further to solve difficult problems in the field of life science, and notably in agricultural bioinformatics. “The genomic sequences are highly encrypted where each code contains information for building and maintaining of functional organisms. The study of information content in genomes is called bioinformatics” (Griffiths *et al.* 2012). Advancement in cell, molecular biology and bioinformatics-based tools and algorithms enabled faster analysis of data and understanding of genes and traits (Thompson, 2011). Genetic diversity in food crops is raw material that would aid in improvising yield. The genetic diversity becomes determinant in increasing protein and vitamin content and fighting pest resistance in food crops. Growing food according to the current level of needs and future demands remains a challenge. The present challenge is tremendous while considering climate change, growing population and regional water shortage in several districts in India (Chand, 2015).

Research Institutes in Agricultural Bioinformatics in India

In Indian context, public funded research institutes and universities are the key actors in the field of agriculture bioinformatics. They have played an important role in collaborating with other research institutions. It is unfortunate for less developed countries like India, which primarily focus on the diffusion of agricultural bioinformatics technology rather than research and development of indigenous technologies catering to the demand of Indian climatic conditions as well as farms; and as a result, it does not receive much acceleration. It becomes necessary for the research institutions to undertake research and develop knowledge and technologies specifically suiting to the geographical locations of the country, especially in the agriculture sector. There remains a possibility where imported technology does not fit into the new local place because of the variance in climatic conditions and other biophysical characteristics. Therefore, it is imperative to develop indigenous technology suiting to the environment. In this regard such institutions focused on innovations to increase technical capabilities in improving food production monitoring with respect to global food production (Cusmano *et al*. 2011).

Initially, bioinformatics in India spread in the early 1980s when the first secretary from Department of Biotechnology (DBT) stressed on the extensive infrastructure and network development. G. N. Ramachandran (GNR) and their colleagues from Madras University who pinpointed the power of accumulating crystal structure data which was then analyzed through programmes run on computers and this enhanced the understanding of proteins. Initial applications of bioinformatics in life sciences opened up new avenues of enquiry. Support from the government was made through the Department of Biotechnology which was set up in 1986. Thus, even as bioinformatics was in its initial days in India, it received the attention and support from the government.

Biotechnology Information System Network (BTISNET) was established by the Department of Biotechnology (DBT) (Bhattacharya, 2011) and the same is depicted in the figure no 2 below.

Table 2: Showing Students Qualified in BINC Examination

Sl. No.	Year of Examination	Total Number of Students Qualified
1.	2007	08
2.	2008	12
3.	2009	30
4.	2018	17

Source*:* BINC, 2009, (DBT, 2019).

Figure 2: Showing locations of Bioinformatics centre in India

Source: (BINC 2009), (DBT 2019)

The spread of network in bioinformatics can be seen on various levels; there are more than 168 centres working on bioinformatics and related aspects. These centres are divided into different categories based on the focused research areas: Centres of Excellence (CoEs), Distributed Information Centres (DICs), Distributed Information Sub-Centres (Sub DICs) and Bioinformatics Infrastructure Facilities (BIF).

This network facilitates in developing a skilled workforce in bioinformatics through M.Sc. and MTech programmes. There are research programmes on bioinformatics to carry out Integrative Graphics Facilities and other research and development projects, these researches are facilitate by DBT through BINC-JRF fellowship and numbers of student qualified in the examinations is depicted in the table no 2. The centres conducts short-term training workshops and seminars for accumulating skilled person under one platform for discussing problems and delivering solutions (Krishnaswamy & Madan, 2016).

Biotechnology Information System Network (BTISNET) established eight Centres of Excellence (CoEs) in agriculture bioinformatics, computational and system biology. These centres have developed infrastructure to give assistance such as lab sharing on the project to project basis, engaging in a collaborative workshop, training programme, partnering in R&D etc. to its neighbouring institutions regarding their research and development (Ramachandran & Arora, 1992). In further expansion to such a network, there is a network of 11 Distributed Information Centres (DICs) and 51 Distributed Information Sub-Centres (Sub DICs) in many research institutions and universities (DBT 2015). The focus of these networks is to facilitate in the research and development to the whole research community of its concern.

To facilitate colleges, Department of Biotechnology (DBT) initiated Bioinformatics Infrastructure Facilities (BIFs) so that the youth can be trained in their curriculum to attract them to bioinformatics. In this regard, 101 educational institutions have been funded and supported through the project so that teaching and learning can be carried out in biology teaching through bioinformatics (BTBI) model to solve hardcore biological problems. National Biotechnology Information System (BTIS) policy document has biotechnology to flourish research, especially in North Eastern parts of India under North East Bioinformatics Network (NEBINET) programme.

Through NEBINET programme, 29 bioinformatics centres got established in eight states among them were: One Distributed Information Centres (DICs) at the North Eastern Hilly University, two Distributed Information Centres (DICs) at the Institute of Bioresources & Sustainable Development and 26 Bioinformatics Infrastructure Facilities (BIFs) at various universities and colleges of the northeast regions (Dharmalingam, 2011).

The National Bureau of Plant Genetic Resources, National Research Centre on Plant Biotechnology, Central Rice Research Institute, Cuttack, Directorate of Rice Research (Indian Institute of Rice Research), Hyderabad, Banaras Hindu University, Central Soil Salinity Research Institute, Karnal, Indira Gandhi Krishi Vishwavidyalaya, Raipur, and University of Delhi-South Campus are the eight centres engaged in a research project to characterize 30 descriptors, including 19 qualitative and 11 quantitative since the last four years. Best variabilities of characters in leaf blade colour stigma colour, have been observed through several centres; where 1548 accessions have been developed while being experimented in different centres of excellence and with different biotic and abiotic traits. Data generated after experimentation forms databases developed across the research institutes in India. There are databases developed by research institutes working in the field of agriculture bioinformatics. The raw data in the form of electronic thesis and dissertation are the most valuable research documents generated after several experiments carried out by M.Sc. students, research scholars and scientists within the laboratory setup of the National Research System of the individual countries (Susmita Das, 2015).

Challenges in Agricultural bioinformatics in India

The emerging discipline “bioinformatics” is the solution for the current demand in the field of agriculture. The discipline can produce novel knowledge when a proper road map is created. The discipline requires a policy ensuring development for the dissemination and application of knowledge, development of a skilled and healthy environment for R&D in the field of agricultural bioinformatics (Kumar, 2017). The sensitive part of any research is its funding mechanism; it hampers innovation to a certain level. Therefore, foremost changes in the policy statement should be to encourage generation of capital that may be created by public-public and public-private partnership, especially in the field of agricultural bioinformatics. Bioinformatics is an emerging phase, which is vibrant. Therefore, it needs sharing of hands in the form of collaborations both in the national and international levels (BITP 2019).

The Biotechnology Information System Network (BTISNet) has developed: Centre of Excellence, Distributed Information Sub-Centre's, and National Virtual Centre for Bioinformatics, Distributed Information Centre's and Bioinformatics Infrastructure Facilities in the allied field of bioinformatics to develop its domain (Krishnaswamy and Madhan Mohan 2016).

Indian biotechnology has a close link with technological development to increase its share, especially in the area of agricultural bioinformatics and therefore there should be strong collaborations for every project regarding agricultural bioinformatics in public sphere (Yadav *et al.* 2015). In near future to strengthen this particular discipline Biotechnology Information System Network can be converted into product organization having a common aim of proper utilization of resources, and its research focusing on individual areas of specializations of constituent centers. It can be reclassified into centres that have a mandate for a particular functional area. Moreover, traditional classifications of DIC, DICS can be replaced into more practical classifications based on more practical situations and work as solution developer centres (Kumar, 2017).

The Indian innovation network collaborates with universities, firms and other public agencies with regard to agricultural bioinformatics that supports production of science and technology within national borders. An important element that has influenced dynamics of technology development is human resource development and socio-cultural environment. Technology policies with respect to economic policies are medium through which the countries maintain its autonomy. The policy decisions have an important impact in developing indigenous technology modification. There is a need for analysis of national response requiring greater attention to factor influencing policy and institutional change (Whittaker, 2003).

Agricultural Bioinformatics Policy in India

Bioinformatics Policy of India (BPI-2004) marked the beginning of the national bioinformatics policy. The focus of such draft was to strengthen national level resources in bioinformatics aiding Research and Development capabilities. It focused on quality human resources and provided means of a training programme for the students, researchers, and scientists pursuing their career in bioinformatics. Such skilled resources can be promoted for researches in the field of agricultural bioinformatics (BPI, 2004).

Researches in the allied sciences using modern biotechnology would support productivity, cost-effectiveness of agriculture and food & nutritional security. The shift in the interrelationship between the government of India, academia, industry and civil society gave rise to the new critical era of science-driven and society relevant innovation in the field of agricultural bioinformatics (DBT, 2019). The advancement in agricultural bioinformatics has propelled scientific revolution creating novel innovation in agriculture bioinformatics, such innovations require a commitment to take the public into confidence to enrich understanding of work.

In this regard, the National Biotechnology Development Strategy from 2015 to 2020 is to establish agriculture biotech partners with State Agricultural Universities (SAU) to carry out research on transgenics in public institutions. It stresses for the formation of a minimum four centers of excellence to work in the area of nutrition sciences of agriculture bioinformatics.

Department of Biotechnology (DBT) has suggested establishing Translational Centres for Agricultural bioinformatics in collaboration with state agricultural universities to carry forward transgenics and validate transgenics developed in state-sponsored toxicological center (NBDS, 2015). There is another important mechanism that would support the diffusion of information when there is lack of institutions and may have uneven distributional consequences. It is a common phenomenon that has been observed that diffusion declines with the social distance suggesting frictions in the diffusion of information regarding agriculture bioinformatics. As there are different groups of people located at different geographical locations and network, therefore targeting procedure would determine how the knowledge is received and by whom (Dillon and Beaman 2018).

Social Networks in Agriculture bioinformatics

The present pattern of agriculture is “Art and science of utilizing advanced technologies for enhancing crop yield while minimizing the potential environmental threat to the planet” (Pratap, 2015). There have been a variety of concepts applied in the form of technologies and innovation to transform contemporary agricultural sciences. The productivity has negatively been affected through depleted lands, soil fertility, environment, health and decrease in biodiversity adding to many socio-economic problems within society. However agricultural bioinformatics researches are needed for the generation of more advanced technologies to change the focus of current, future needs as well as constraints (Pratap, 2015). Niklas Luhmann (Görke and Scholl 2006) looks for the interaction between the social systems comprising organizations or the function system and individuals for bringing in change in technological innovations. The work of the functional system is to efficiently deal with the required legislation, economy, politics, science, and education that play a major role in encompassing social systems.

Weak ties have always remained an important factor in reshaping existing rules that help institutions in gradually building technological trajectory. Such ties cannot make a change in the socio-technical systems as they block the flow of complex knowledge, which shows lack of trust (Reinders, 2011). Technology contributes to building a network between the user and the provider of the knowledge. Agricultural bioinformatics has major contributions from different disciplines, which address production systems from the field. Such contributions from different disciplines produced a more comprehensive system catering environmental, socio-economic and biophysical responses. There are instances where the crop is studied to examine impacts of climate change, policies and alternative technologies. Such an instance depicts that agricultural bioinformatics technologies are still evolving in India and there is a continuous rise in developing new research organizations and generating skilled workforce that can contribute to the community of agriculture bioinformatics. Consequently, technology regime is a set of rules that has its roots in complex engineering skills and is a process used for the production of efficient ways to deal with problems (Geels, 2004).

Conclusion

Agricultural bioinformatics is one of the recent and fast emerging disciplines of science that exploits computational approaches to the responsive biological question. The increase in industrialized agricultural practices have had led to gene erosion and owing to changes in climatic conditions, it is estimated that 16-22 per cent of the gene would soon be eroded. In India, there are some research institutions that have major focus in crop improvement through gene tagging, gene editing, genome sequencing etc. for utilizing them in improving productivity, resistance to diseases and other biotic and abiotic changes, which are a threat for plants to retain their properties in changing climatic conditions and with changing nature of soil content and soil texture. Adoption and diffusion of technology is a process by which technological know-how travels from the introduction of technology to universality. In the Indian context, public funded research institutes and universities are the key actors in the field of agriculture bioinformatics. They have played an important role in collaborating themselves with other research institutions. Weak ties have remained always an important factor in reshaping existing rules that would help institutions in gradually building of technological trajectory. Such ties cannot make the change in socio-technical systems as it blocks flow of complex knowledge, which shows lack of trust.

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Strengthening Regional Capacity Building of Healthcare Translation Ecosystem: A Qualitative Assessment

Tripta Dixit[*]
Smita Sahu[**]
W. Selvamurthy[^]
Sadhana Srivastava[#]

Abstract: The 21st century India is still battling with issues of accessibility, affordability and availability of quality health to masses. It is also facing a myriad of challenges and opportunities for development of indigenous, low cost, and accessible technologies with the influence from cultural diversity, demographic dividend and geographical segmentation leading to varied needs as per the regional conditions of climate, disease prevalence, nutrition and sanitation. Affordable innovative solutions are to be generated and translated to resolve various health issues of diverse India. To understand country's need for attainment of the holistic slogan of 'health for all', a regional (East-West-North-South) analysis was conducted based on the state-level disease burden report 2017. Then the entire translation ecosystem was summarized detailing significance of each stakeholder and regional health-care translation strength to project translation scenario of the country. This paper has emphasized on the essentiality to strengthen translation capacity of each region to meet diverse health-care needs of the people. It has proposed to establish a robust translation ecosystem for innovative indigenous medical technologies by adopting regional establishment of technology transfer entities with focused translation as per the needs of a particular region.

Keywords: Disease burden, translation ecosystem, health-system innovation, technology transfer, regulation

Introduction

The term translation, describes transformation of knowledge through successive fields of researches from a basic science discovery to an effective public health impact; it is a complex process that requires both research

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[*] Scientist B (Innovation and Translation Research Division), ICMR,New Delh, E-mail: tripta.dixit@gmail.com, (Corresponding Author)

[**] Assistant Professor, Amity Science, Technology & Innovation Foundation, Amity University, NOIDA E-mail: ssahu@amity.edu

[^] President, Amity Science, Technology & Innovation Foundation (ASTIF), Director General -Amity Directorate of Science & Innovation, and Chancellor -Amity University, Chhattisgarh, E-mail: wselvamurthy@amity.edu

[#] Scientist F, IPR Unit, ICMR, New Delhi, E-mail: sadhana_s@ymail.com (e.g. bench-work and clinical trials) and non-research activities (e.g. implementation) (Drolet & Lorenzi, 2011). Translational research may have different meanings to different people (Woolf, 2008) different organizational set-ups, but it is seemingly important to almost everyone. Some reported it as unidirectional (NIH, 2007) in which research findings move from the researcher's bench to the patient's bedside and community; some as multidirectional approach, which is a combination of the basic research, patient-oriented research, and population based research, encouraging collaboration among scientists from multiple disciplines with the enduring aim of improving health of the public, followed by support of technology transfer professionals in commercialization of technology.

The dismal state of Indian health-care system is an acknowledged fact with dual burden, of disease (Dixit et al. 2018) and out-of -pocket expenditure (Balarajan, et al. 2011). It states that our rural population is deprived of even the basic primary care of 19th century and a considerable percentage of semi-urban India cannot afford the modern health-care service (Singh & Badaya, 2014). In contrast, we are capable of delivering high-end health-care comparable to any developed nation. India hiked three spots and secured 57th position in global innovation ranking, depicting its innovative potential and promising growth (Cornell University, et al., 2018). This indicates an unceasing zeal of finding new solutions to its problems. Despite being a resourceful country with equipped research infrastructure, manpower, funding support, regulatory support and other concrete efforts, we are unable to provide primitive health-care solutions to the public. The innovative solutions preferably can be biotechnology-based health solutions, which have emerged globally, and contribute much towards growing public and global health needs. These have found tremendous applications in various sectors of life science, and their contribution to health sector has been remarkable as modern biotechnology, which has brought in radical changes in production of new or rare molecules, drugs, formulations, safer viral vaccines, devices, quicker and accurate diagnostic test kits etc. (Henderson, 2005). They have often given solutions for basic problems, are effective in drug delivery approaches, and for new methods for therapeutics, nutritionally enriched genetically modified crops and have been efficient methods for environmental clean-up (Burdi, *et al.,* 2003).Most of the medical technologies employ biotechnology tools and techniques such as molecular diagnostic tools [polymerase chain reaction (PCR) (Heim *et al.*, 2003), recombinant antigens and monoclonal antibodies have been used for this purpose], ELISA etc. This approach has offered modern medical devices for diagnostic and preventive purposes, which include diagnostic test kits, vaccines and radio-labelled biological therapeutics used for imaging and analysis. To meet requirements of basic health problems such as malnutrition, production of nutrient-enriched food such as Golden Rice, Maize, potato and soybean, etc should be explored through biotechnology strategies. This necessitates understanding translation scenario of the country by analysing regional health-care needs to prioritize development of suitable health-care innovative solutions meeting requirement of public health.

Material and Method

To understand the scale of problem and to elucidate the requirement of appropriate basic health solutions and posed challenges for different regions of India (Eastern, Western, Northern, Southern), an analysis was conducted using data of state-level report by the ICMR, PHFI, and IHME (2017) to understand the impact/correlation of nutrition, sanitation, climate and topology of the prevailing disease burden. To simplify observations, maps based on climatic conditions as per Koppen classification and zonal classification systems were altered into just four zones. The selection of states was done with available medical R&D facility and/or up-scaling hotspots to maintain synergy among disease burden and translation capacity of each of the region:

- Eastern region: Odisha, West-Bengal, Jharkhand, Mizoram, Manipur, Nagaland, Meghalaya, Assam, Arunachal Pradesh, Tripura, Bihar
- Western region: Rajasthan, Gujarat, Madhya Pradesh, Maharashtra, Goa
- Northern region: Jammu & Kashmir, Himachal Pradesh, Uttarakhand, Punjab, Haryana, Delhi, Uttar Pradesh
- Southern region: Andhra Pradesh, Kerala, Karnataka, Tamil Nadu, Telengana, Puducherry

Further, using data visualization tool for 'GBD India compare' state-wise data was collected for non-communicable diseases, communicable diseases, nutritional deficiencies, metabolic risks, sanitation risks and diet risks (ICMR, PHFI & IHME, 2017a). The parameters were set to calculate disability-adjusted life years (DALYs) in percentage for both the genders in all age groups. As per the WHO report (2016), DALYs is the summary measure used to give an indication of the overall burden of disease, and thus this parameter was considered for this study. A median was calculated for each parameter taking its highest and lowest values in account.

Simultaneously an attempt was made to summarize healthcare biotechnology translation ecosystem and as per the understanding a connection has been devised, comprising medical R&D institutions, up-scaling hotspots, technology transfer entities and other programmes, regulatory bodies, funding entities and industry (Manufacturing, marketing), Department of Scientific and Industrial research (DSIR) and Scientific and Industrial research organizations (SIRO), MSME/SME/ Start up (Zuniga & Correa, 2013).

This study has taken into consideration only government supported medical R&D institutions, up-scaling hotspots, technology transfer entities and other programmes, regulatory bodies, and funding entities as our emphasis was on translation of indigenous affordable innovative solutions for public health.

The data for the evaluation of each component of translation ecosystem was collected from available literature (Evalueserve, 2008; Anna et al.,2013 NSTMIS, 2015; NSTEDB, 2002). Translation capacity of each component was evaluated diligently from available data and was validated with interpersonal discussions. Similar division of states were done to calculate regional capacity for R&D institutions, up-scaling hotspots and technology transfer entities to observe translation capacity of each region.

Results and Discussion

To simplify our understanding, median was calculated based on DALYs per cent as per state-wise disease burden report for non-communicable (57.11) and communicable diseases (18.1) Also, median was calculated for other associated factors — sanitation (unsafe water & hand washing) (3.41), dietary risk (7.92), metabolic risk (15.59) and nutritional deficiency (4.31).The data was retrieved for each region (Figure 1).

As per the observations based on analysis, an understanding of the regional need has been summarized in Figure 2. This depicts region-wise

Figure 1: Region-wise disease burden (DALYs) influenced by other factors (ICMR, PHFI, IHME 2017)

Disease Burden (DALYs %) in Eastern region

	West bengal	Meghalaya	Tripura	Manipur	Nagaland	Arunachal Pradesh	Chattisgarh	Mizoram	Assam	Odisha	Bihar	Jharkhand
■ Communicable diseases	14.37	15.08	18.34	20.93	21.34	21.98	22.78	23.09	23.14	24.73	25.58	26.32
■ Non-Communicable diseases	62.67	52.27	56.99	58.53	57.23	52.91	50.4	55.5	51.24	52.07	47.61	48.27
■ Nutritional deficiency	4.29	5.34	4.34	2.11	3.29	4.47	4.66	2.99	4.74	4.16	5.55	5.54
■ Sanitation risk	3.06	4.41	4.26	4.29	2.01	3.93	5.74	2.87	5.73	7.44	7.91	9.51
■ Dietary risk	13.05	4.83	8.84	7.54	6.1	4.68	7.88	3.61	6.87	6.97	6.97	6.87
■ Metabolic risk	20.37	9.53	16.36	15.62	12.53	9.9	14.56	8.11	13.27	14.1	11.59	12.29

Disease Burden (DALYs %) in Western region

	Rajasthan	Gujarat	Madhya Pradesh	Maharashtra
■ Communicable	23.5	17.86	22.26	13.7
■ Non-Communicable	49.32	55.66	50.33	63.09
■ Nutritional deficiency	5.14	4.66	5.1	4.27
■ Sanitation risk	4.3	2.57	5	2.56
■ Dietary risk	6.28	10.35	7.7	11.48
■ Metabolic risk	11.01	16.65	13.96	19.29

Disease Burden (DALYs %) in Northern region

	Punjab	Himachal Pradesh	Jammu & Kashmir	Delhi	Haryana	Uttarakhand	Uttar Pradesh
■ Communicable Disease	12.92	13.32	14.26	14.46	16.47	19.94	25.37
■ Non-Communicable Disease	66.02	64.53	61.29	61.24	58.78	55.46	47.88
■ Nutritional deficiency	3.95	3.49	3.85	4.38	4.89	4.11	4.98
■ Sanitation risk	2.35	2.4	2.59	1.38	2.71	2.72	6.12
■ Dietary risk	14.59	7.97	10.43	8.37	9.92	7.37	5.75
■ Metabolic risk	26.13	15.57	17.66	17.63	17.75	14.8	10.74

Disease burden(DALYS %) in Southern region

	Kerala	Tamil Nadu	Karnataka	Andhra Pradesh	Telangana
■ Communicable Disease	7.4	11.79	13.59	15.46	16.37
■ Non-Communicable disease	74.58	65.3	61.97	59.72	59.23
■ Nutritional deficiency	2.47	4.26	4.08	4.44	4.44
■ Sanitation	1.34	2.58	3.26	3.75	4.21
■ Dietary risk	11.24	14.39	9.63	11.51	9.92
■ Metabolic risk	25.2	26.09	19.7	19.11	17.21

need of health-care solutions as per the topology, climate, nutrition intake and sanitary conditions, which ultimately result in dual burden of disease and out-of-pocket expenditure in the region (ICMR, PHFI & IHME, 2017). These results should be treated as preliminary to conduct a pilot study.

An idea has been shaped at R&D lab, up-scaled at translation units and finally manufactured at industry sites. This process is not as simple as it appears; it requires constant funding support and various approvals at almost every stage to take the technology forward. This painstaking process would be a failure if the technology does not see the light of day. The proposed translation ecosystem nexus of health technologies as per our understanding of Indian practice has been depicted in Figure 3. A lead has been generated by medical R&D facility, which would then be assessed for its intellectual property protection. Thereafter, depending upon the stage of development, market potential and regulatory requirements, technology would be up-scaled/matured. Simultaneously, the scouting for continued funding source for every stage of development, potential manufacturer, and potential market has often been carried out. In India, the mechanism

Figure 2: Represents the link between region-wise need of healthcare solutions as per their topology, climate, nutrition intake and sanitary conditions (ICMR, PHFI, IHME 2017)

Disease burden (DALYS %)

North	CD %	NCD%
Punjab	12.92	66.02
Himachal Pradesh	13.32	64.53
Jammu & Kashmir	14.26	61.29
Delhi	14.46	61.24
Haryana	16.47	58.78
Uttarakhand	19.94	55.46
Uttar Pradesh	25.37	47.88

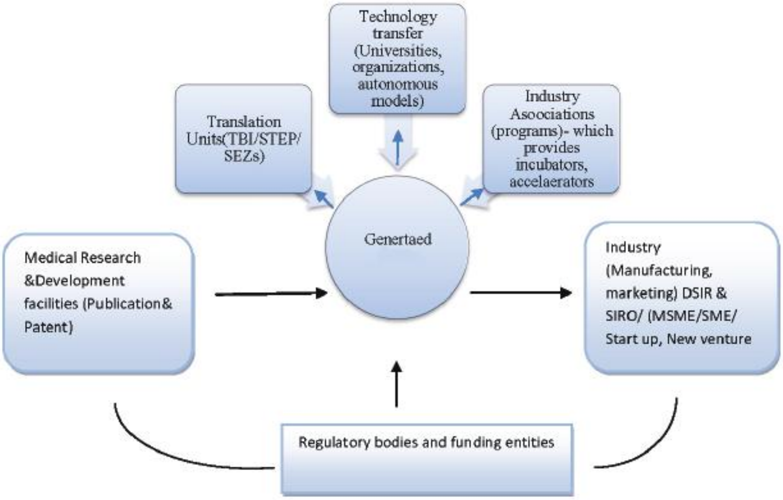
South	CD%	NCD%
Kerala	7.4	74.58
Tamil Nadu	11.79	65.3
Karnataka	13.59	61.97
Andhra Pradesh	15.46	59.72
Telangana	16.37	59.23

Disease burden (DALYS %)

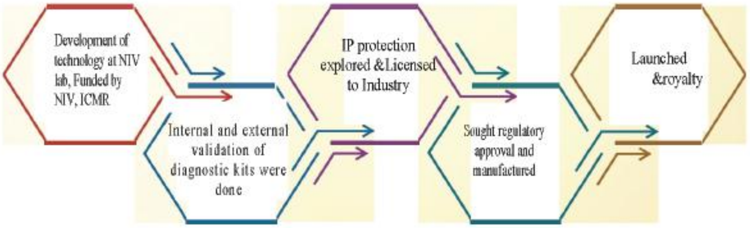
East	CD %	NCD%
Rajasthan	23.5	49.32
Gujarat	17.86	56.66
Madhya Pradesh	22.26	50.53
Maharashtra	13.7	63.09

West	CD%	NCD%
West Bengal	14.37	62.67
Meghalaya	15.08	52.27
Tripura	18.34	56.99
Manipur	20.93	58.53
Nagaland	21.34	57.23
Arunachal	21.98	52.91
Chattisgarh	22.78	50.4
Mizoram	23.09	55.5
Assam	23.14	51.24
Odisha	24.73	52.07
Bihar	25.58	47.61
Jharkhand	26.32	48.27

Figure 3: Nexus of translation ecosystem in India



Box 1 Case Study: Development of IgG assay for detection of Anti-CCHF Bovine



Translational Pathway of diagnostic kit for Crimean-Congo hemorrhagic fever (CCHF) virus

Health Concern: Crimean-Congo hemorrhagic fever (CCHF) is a severe acute febrile illness caused by CCHF virus (CCHFV, family *Bunyaviridae*, genus *Nairovirus*), with overall case fatality rate of 5-50 per cent. Person to-person transmission of CCHFV occurs through direct exposure to blood or other secretions and instances of nosocomial transmission are well-documented and 31 deaths have been reported since 2011.

Among domestic animals; cattle, sheep, and goat play an important role in the natural cycle of the virus. In these animals, CCHFV replicates to high titres in the lung, liver, spleen and reticulo-endothelial system in other

Box 1 continued...

...Box 1 continued

organs but generally causes only subclinical disease and is asymptomatic. Domestic animals are reservoir host for this virus.The disease has been reported from Middle East, Africa & Asia including India. Presence of this disease was first confirmed in a nosocomial outbreak in 2011 that occurred in Gujarat and in 2014 reported in Rajasthan. The virus is transmitted to human either by bite of infected tick or by direct contact with blood or tissues of viremic patients or livestock. Outbreaks of illness are usually attributable to handling infected animals or people. Serological screening of ruminants allows CCHFV affected areas to be identified, as antibody prevalence in animals is a good indicator of local virus circulation. The blood samples drawn from 5,636 domestic animals (cattle, sheep and goat) were picked up randomly across the country, of which 354 animals were found carrying the virus in their blood. Active surveillance may reveal more prevalence of the virus in our livestock. (Isalkar 2018) Therefore, a need is felt to develop a diagnostic test.

Solution: An ELISA based test is developed to detect CCHF virus in cattle and buffalo. It is the first indigenous anti-Crimean-Congo hemorrhagic fever (CCHF) IgG antibody detection kit for cattle and buffalo. The ELISA kit uses inactivated CCHF antigen and hence can be used at any Bio-safety level 2 (BSL2) testing laboratory setting across the country for cattle and buffalo serum samples. This ELISA kit is intended for qualitative detection of IgG antibodies in cattle /buffalo serum samples. The assay is rapid, sensitive, cost effective, user friendly and highly stable at 4°C.

Challenge: Initially the technology faced regulatory hurdles but with a dedicated approach and the support of technology transfer entity following milestones were achieved:

a. First interacted with state FDCA Gandhi Nagar, which suggested getting clarity from CDSCO New Delhi.
b. CDSCO informed that manufacturing license will be provided by state FDCA Gandhi Nagar and added that ‘No Objection Certificate’ for this new diagnostic kit will be required from CDSCO and Ministry of Agriculture, Department of Animal Husbandry & Dairying, New Delhi.
c. A detailed layout of prospective diagnostic manufacturing facility was submitted to FDCA Gandhi Nagar for their approval and request for NOC was sent to CDSCO and Department of Animal Husbandry & Dairying.
d. CDSCO demanded proof of third party validation studies as per CDSCO approved protocol
e. The results were presented before expert scientific committee and on getting approval the NOC for manufacturing was issued.
f. Thereafter, technology was launched in the market.

from up-scaling to commercialization is complex and is not well defined as translation Units (TBI & STEP) (NSTEDB, 2002); technology transfer entities and industry association programmes all are involved in up-scaling and commercialization of the technology to relevant industry for manufacturing and; marketing, they support new venture establishments and start-up formulations. The case study of Crimean-Congo Haemorrhagic Fever (CCHF) virus has shown translational pathway of an ELISA-based diagnostic kit (Box 1).

Components of translation ecosystem

Medical Research and Development

There are numerous Indian research organizations and universities which undertake research work in Medical Science. However, a very few have made remarkable efforts in sustaining the research environment (Ray, et al. 2016), and only just a few institutes have been successful in developing solutions systematically for public use. The aim is not only to foster knowledge creation but also to increase innovation capacity for urgent needs of the society. An interdisciplinary team is required to address the main challenge of technology preparation as the gap lies in 'product engineering', where integration of biotechnology tools, techniques along with engineering applications can be beneficial. Application-oriented institutes and research units addressing affordable health-care solutions are being established but stringent monitoring would be necessary to understand their outputs in terms of successful translation. There are a total of 5710 R&D science and technology institutes (NSTMIS, 2015); out of which approximately 194 are majorly involved in medical R&D. Medical R&D entities involve autonomous medical college research labs, central and state government research labs for basic medical science, applied medical science, translational medical science along with clinical testing labs and other significant organizations involved in medical research and development. A total of 52 centres in Southern region, 57 in Northern region followed by 47 centres in Eastern region and 38 in Western region have been observed accounting for significant medical R&D capacity. Their output should be well understood in terms of successful translation.

Up-scaling hot spots

Once we have a potential idea ready, it needs to be further tested for the claimed response. This is a challenging step as it poses risk of failure and involves constraints such as arranging funds, identifying right partners for testing, seeking regulatory approval if needed for validation studies and lastly, stringent monitoring and improvement of timely results for the desired solution. Having understood the need, government has provided infrastructural support by establishing Science and technology entrepreneurial parks (STEP) (NSTEDB, 2002,), Technology Business incubators (TBI) (NSTEDB, 2002.), Special Economic Zones (SEZ) (NSTEDB, 2002) and other programmes etc. A total of 59 translation units have been identified in Southern region, followed by 17 units in Northern region, and 29 units in Western region and eight in the Eastern region. The design capability needs to be built in country to address gaps of product engineering by clubbing together skilled professionals of the varied fields. STEP[1] can be listed as step one in up-scaling which offers basic amenities where it forges linkages among academic and R&D institutions on the one hand and the industry on the other to promote innovative enterprise through S&T persons. It also provides R&D support to small-scale industry; mostly through interaction with research institutions. For the second stage of up-scaling, the TBIs[2] can be contacted as they provide services to new enterprises (and also to existing SMEs in the region) to facilitate an atmosphere congenial for their survival and growth

Now the question arises that despite these infrastructures why many of the technologies are still unvalidated. This requires a skilled team to identify these leads from inventories, and requiring up-scaling them to meet the existing needs and then commercializing to benefit the public. Another major cause is lack of awareness of their existence which calls for the need for a comprehensive readily available database as authentic directory of validation centres.

Funding entities

India offers a plethora of funding opportunities from government and private players for all stages of technology development and commercialization. To bridge the gap between academia and industry and to promote translation research, funding platforms are being provided in the public-private partnership mode. Funding organizations should encourage more translation research. This would lead to development of numerous commercially viable technologies with societal relevance. We have categorized funding/grant schemes and programmes into : early stage; up-scaling & commercialization; support for IP protection; New Initiatives; International funding. There should be a single platform providing access to all funding schemes pertaining to translation (Table 1).

Regulatory bodies[3,]

The need for regulating health-care sector has been acknowledged with concerns over exorbitant pricing and compromised quality of drugs, vaccines, devices, ayurvedic formulation, etc. The central regulatory bodies are: Department of Health Research, Department of Family &Welfare, and Central Drug Standard and Control Organization to regulate health-care. State-level authorities are: Food and Drug Administration, pollution control boards, biomedical waste disposal, municipal corporation, etc. Other organizations like the Indian Council of Medical Research, Medical Council of India, Department of Ayush, Indian Medical Association, Department of Industrial Policy and Promotion, Narcotic Controls Bureau, Foreign Investment Promotion Board play a crucial role in maintaining regulatory environment. The principal regulator bodies, entrusted with the responsibility of ensuring timely approval, production and delivery of quality affordable drugs for benefiting the public health in India, are listed in Table 2.

Table 1: Illustrates the Types of Funding Support at Various Stages of Translation

Funding support at various translation stages in India				
Innovative ideation and early stage R&D	For technology advancement, validation, scale-up and commercialization	For Intellectual Property protection	New funding initiatives to support Make in India scheme	International funding agencies
Biotech Ignition Grant (BIG) by Biotechnology Industry Research Assistance Council (BIRAC)-Individual Entrepreneurs, Start-ups & Incubates	Social Innovation programme for Products: Affordable & Relevant to Societal Health (SPARSH)	SIPP-Start-up Intellectual Property Scheme	National Initiative for Developing and Harnessing Innovations (NIDHI) by Department of Science & Technology (DST)	Bill and Melinda Gates Foundation,
SRISHTI-Gandhian technology Innovation (GYTI) by BIRAC -for supporting grass-root innovations budding at institutional level.	Small Business Innovation Research Initiative (SBIRI)	Patent Assistance Funding Scheme, BIRAC	Atal Innovation Mission (AIM)	Wellcome Trust
Industry Innovation Programme on Medical Electronics (IIPME)-by BIRAC & Deity (at all three stages)	Biotechnology Industry Partnership Programme (BIPP) -BIPP are such schemes which extend funding support to high risk innovative research by industry and is provided to grantees in a public-private partnership (PPP) mode	Patent Facilitation Cell of TIFAC (PFC-TIFAC)	Impacting Research Innovation and Technology (IMPRINT)	Indo-US Science and Technology Forum

Table 1 continued...

...Table 1 continued

Technopreneur Promotion Programme (TePP) by DSIR	TDB provides assistance in the form of soft loan and/or equity fund under its Seed Support System Scheme.	SIP-EIT Support for International Patent Protection in E&IT (SIP-EIT) – II for Micro, Small and Medium Enterprises and Technology Startup Units	Uchhatar Aavishkar Yojana (UAY),	World Health Organization ,
PRISM (Promoting Innovations in Individuals, Startups and MSMEs)-BY DSIR			New Generation Innovation and Entrepreneurship Development Centre (NewGen IEDC) is a programme launched by National Science and Technology Entrepreneurship Development Board (NSTEDB), DST	Indo-French Centre for the Promotion of Advanced Research (IFCPAR/ CEFIPRA)
			BIRAC has identified the areas of Biopharma including vaccines, bio-agriculture, bio-industrial and bio-informatics for building the national biotechnology capabilities and has initiated several new awards to promote innovations such as SITARE (BIRAC-SRISTI GYTI Awards), BIRAC Hackathons, BIRACTechnology Day Award and BIRAC Innovator Awards	

Table 2: Regulatory Bodies Majorly Involved in Translation of Technologies

S. No.	Regulatory Body	Mandate/Activities
1.	Central Drug Standard and Control Organization	Within CDSCO, DCGI regulates pharmaceutical and medical devices, advised by Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC),as per the Drugs and Cosmetics Act 1945 and its subsequent amendments regulate biological
2.	Department of Ayush	Approvals related to Ayurveda, Yoga, Naturopathy, Unani, Siddha, Homeopathy, SOWA-RIGPA
3.	Clinical Trial registry of India	Set-up by ICMR, keeps a record of all conducted clinical trials conducted in India
4.	Indian Council of Medical Research	Ethical guidelines for stem cell research and Ethical guidelines for biomedical research, CTRI
5.	Department of Industrial Policy and Promotion	Regulates the Intellectual Property protection in country.
6.	Institutional Bio-safety Committee	Interacts within the institution for the implementation of the rDNA Biosafety guidelines.
7.	Review Committee on Genetic Manipulation	Monitors the safety related aspects of activities involving genetically engineering organisms or hazardous micro organisms.
8.	Genetic Engineering Approval Committee	Approval of activities involving large-scale use of genetically modified/ hazardous micro organisms and products thereof in research and industrial production and their safety in terms of environmental protection.
9.	National Biodiversity Authority	Regulates and conserves utilization of biological resources of country.
10.	National Institute of Biologics	Ensuring provision of quality biological drugs i.e In-vitro diagnostics, Vaccines and Biotherapeutics, including therapeutic monoclonal antibodies

Technology Transfer Entities

India has started many innovation oriented activities, many innovation activities to strengthen the innovation ecosystem. An innovative solution is of no significance if it can't be used for solving problems of the masses and to reach out; a defined delivery channel is must, which has often been overlooked. This necessitates the need to establish delivery channels to scout the appropriate technology, appropriate industry partner and transfer of technology in righteous manner abiding by license and other agreements. These delivery channels are technology transfer[4], entities which are very few in number and have committed skilled technology transfer teams which work towards making available solutions in the market. We have observed a total of 24 technology transfer entities related to health technologies with a common objective of bringing affordable solutions to market but with a different mode of working- 15 in Northern region, five in Southern region, three in Western region and one in Eastern region. These are found localized mainly to Northern region and offer services all over the country. We have majorly classified them into three categories: organizations and autonomous model; Universities; Industry association programme. Technology transfer entities involved with medical technologies are listed in Table 3.

Table 3 : Classification of different technology transfer entities involved with medical technologies

At Universities	***Organizations*---and--- *Autonomous Models***		***Industry Associations***
Foundation for Innovative and Technology Transfer	Directorate of Industry Interface & Technology Management (DIITM)	National Innovation Foundation	Global Innovation & Technology Alliance
Industrial Research and Consultancy Centre	Council of scientific and industrial research	Translational Health Science and Technology Institute	

Table 3 continued...

...Table 3 continued

Sponsored Research and Industrial Consultancy	National Research Development Corporation		Health technology accelerated commercialization
Centre for Scientific and Industrial Consultancy	Biotech Consortium India Limited		Accelerated technology assessment &commercialization
Industrial Consultancy & Sponsored Research			National Initiative for Developing and Harnessing Innovations (NIDHI)
			Lockheed Martin India Innovation Growth Programme (Indo-US Science and Technology Forum (IUSSTF))
	Innovation and Translation Research Division		National Bio-design alliance
			Centre for Cellular and Molecular Platforms
			IKP Knowledge park
	Biotechnology Industry Research Assistance Council		Asian and pacific centre for transfer of technology
Technology bureau of small enterprises			

Health-care Industry

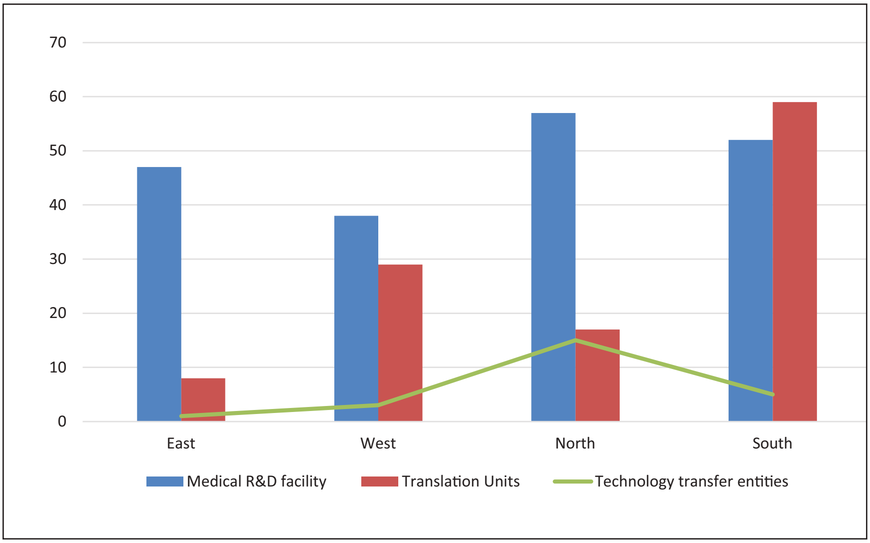
It is the final link of translation nexus as they mass produce the final product for the society. Health-care industry is the largest growing Industry with an expected size of 160 billion (IBEF, 2018). The industry is divided into many segments of which major segments are diagnostics, devices, pharmaceuticals, telemedicine, etc. catering to tangible solutions for the market. Thus, as per relevance and developmental stage of technology, collaborations are made with an appropriate partner either for up-scaling, manufacturing or commercialization. These can be divided into: multinational companies, micro, small & medium enterprises, small & medium enterprises, local manufacturers, and start-ups. The industry also plays important role in R&D. In order to support industry government grants DSIR recognition to Scientific & Industrial Research Organizations (SIRO) and in-house R&D

unit(s) of the company. Now 100 per cent Foreign Direct Investment is encouraging more manufacturing sites in India.

Figure 4 projects region-wise Medical R&D facilities, translation units and technology transfer entities. The ratio of technology transfer entities is significantly low as compared to medical R&D facilities and also the established translation units are majorly centralized in a region. Therefore, a dedicated approach towards grass-root level needs to be adopted. This involves identifying basic day-to-day challenges affecting health and scouting or developing appropriate solutions utilizing folklore knowledge and experience by local manufacturers. These solutions should be well scrutinized to follow the regulatory guidelines for up-scaling and manufacturing. The technology transfer entities shall provide support using

Figure 4: The graph depicting the region – wise ratio of Technology Transfer entities to Medical R&D facilities and Translation Units

	Medical R&D facility	Translation Units	Technology transfer entities
East	47	8	1
West	38	29	3
North	57	17	15
South	52	59	5



their skill-set, network and other resources at each step of translation of these grass-root health technologies. Government has taken a few initiatives in this regard such as establishment of Honey Bee Network (1988-89), Society for Research & Initiatives for Sustainable Technologies & Institutions (SRISTI, 1993), Grassroots Innovations Augmentation Network (GIAN,1997), National Innovation Foundation – India (NIF, 2000)[5].

This approach would help attain Sustainable Developmental Goals in ensuring healthy lives, (3b) towards development of medicine as country's need and timely access to affordable availability of medicines, and (3d) strengthening of health-care innovation capacity and ultimately strengthening country's growth by supporting ' Make in India', with healthy nation and for healthy nationals.

Conclusion

The demand for health solution varies from region to region and requires focused approach for each region. Every technology can have different route of translation. For example— medical device may require less funds as compared to a pharmaceutical composition. Also the regulatory requirements vary for both the segments. Medical device if falls under non-notified category, it will not require any regulatory approval and saves on time whereas a new drug/ vaccine requires to undergo clinical trials in validation and then applying for manufacturing approval. Therefore, the time required for each technology varies. We need to bring all stakeholders together at the common platform to create indigenous affordable innovative solutions and to establish smooth linkage. The translational capacity and successful completion of R&D projects should also be defined by the tangible outcomes and not just publications. The allocated funding support at each stage along with reforming regulatory framework would encourage public-private-partnership and indigenous manufacturing of indigenous innovations. The government has taken many initiatives to strengthen R&D and translation but the technology transfer entities have not received adequate attention which this segment deserves.

The industry, academia, and hospitals face many challenges in translation and require a body to identify issues at the grass-root level to work in synergy with one another and with other dominant factors to bring out the solution as per demands. Current technology transfer entities are majorly centralized in Northern region and are a few in number; thus miscarry the focused approach. They are less connected with local needs and are not much focused on identification of grass -root solutions, and laymen are not capable of realizing what they have and what is market potential. Thus, decentralized approach for regional strengthening of technology transfer entities at different regions is a must. For a healthy nation, the approach of regional developments should be taken up to meet local requirements of low-cost, less-time consuming, point-of-care, operable at low-resource settings and easy to transport indigenous technologies. Regional technology transfer entities shall be encouraged which would scout the possible solutions from R&D inventories, study their stage of development and accordingly direct the path of technology with potential industry, and to be made available to the public.

Endnotes

[1] http://www.nstedb.com/institutional/step.htm

[2] http://www.nstedb.com/institutional/tbi.htm

[3] http://www.cdsco.nic.in/forms/Default.aspx,http://ayush.gov.in/,http://ctri.nic.in/Clinicaltrials/login.php, http://www.icmr.nic.in/,http://dipp.nic.in/English/default.aspx,http://www.dbtindia.nic.in/regulations/, http://dbtbiosafety.nic.in/committee/rcgm.htm,http://envfor.nic.in/division/genetic-engineering-approval-committee-geac,http://nbaindia.org/,http://www.nib.gov.in/,https://en.wikipedia.org/wiki/Foreign_Investment_Promotion_Board,

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Perspectives

Towards an Era of Genetically Modified Humans : Governing Human Genome Editing and Ethics in Decision Making

The basic facts are well known: Dr Jiankui He announced last November, during the Second International Summit on Human Genome Editing at the University of Hong Kong, the birth of the first ever genome-edited human beings. Dr He, who is affiliated to the Southern University of Science and Technology in Shenzhen, edited the genome of two twin girls with the goal to make them immune to HIV infection. Specifically, he disabled the gene called CCR$_5$ that creates a protein that makes it possible for HIV, the virus that causes AIDS, to infect people's cells.

The news shocked the world.[1] Experts and lay people alike appeared horrified that someone had actually created "genetically modified" babies. The reactions were immediate. The conference organising committee, the Shenzhen University, the Chinese Vice-Minister of Science and Technology, groups of prominent Chinese experts and almost any other international experts that was asked, were of the same opinion: that was an unacceptable research development.[2] In terms of both science and ethics, the research has been seriously flawed.

Indeed, there have been a number of obvious problems with Dr He's work that most experts were quick to identify. Firstly, and most importantly, there are too high risks involved with the deactivation of a single gene for this procedure to be routinely used. We simply do not know whether deactivating a gene such as CCR$_5$ will have side effects in the rest of the genome. In fact, there are indications that people who are born with both copies of CCR$_5$ disabled, might be resistant to HIV, but are more susceptible to West Nile virus and Japanese encephalitis. Moreover, genome editing sometimes inadvertently alters genes other than the one being targeted and there is a possibility that only some cells curry the edited gene while others are not. This is called "mosaicism" and can lead to unspecified health complications. Contrary to Dr He's claims that his intervention did not affect other genes in the twins, some experts believe that "mosaicism" could have developed in one of the twins since, it was clear in his presentation that he was able to disable both copies of the target gene in one twin only. It will not be possible to identify the exact effect of the intervention on the health of the twins for many years to come.

Secondly, Dr He did not follow the established obligatory approval processes for medical research. He did not apply for ethics approval at the university that he was working in. On his own admission, he did not do so as he knew that he would have received a negative opinion. His claim that he received ethics approval by the Shenzhen Harmonicare Hospital is disputed by the hospital as untrue. Without approval, his research would not only be unethical but also illegal.

Thirdly, the consent procedure that Dr He followed was deeply deficient. The consent form that he made public was highly technical, did not focus on the risks of the procedure, but instead was very elaborate on intellectual property issues, such as the use of photos and information for publicity reasons. The parents of the twins seem to be of low educational level and have little understanding of what genome editing actually is and what its effects might be.

Fourthly, the specific intervention did not address an unmet medical need. This would have been the necessary prerequisite for attempting such a risky approach that has unclear outcomes for the health and wellbeing of the participants. In case of no other possibility for treatment, high-risk experimental interventions are allowed (with the proper informed procedure) but this was not such a case. The twins were not infected with HIV and a future possibility of infection could have been directly dealt with educational input on safe-sex or anti-viral drugs that are widely used and safe.

There are other faults in Dr He's approach that are important but not as significant as the ones mentioned above. For instance, there was total secrecy surrounding his research and he even ignored the voices of the few colleagues that were told of it and warned him that his intervention was not acceptable. And, although he stated that he regrets the leak of the news before his conference presentation, it appears that there was a well-orchestrated PR campaign, paid by himself, to advertise his research before the conference presentation. The campaign was aimed at opening up commercial possibilities for the companies that Dr He is involved in. He seems to be a co-founder of a number of start-ups relating to genomics research.

At the time of writing this opinion, Dr He is probably under house arrest in Shenzhen. A photo of him "behind bars" in a university accommodation appeared in the local media. A number of disciplinary committees are looking at his work and we will certainly soon hear of disciplinary actions that have been taken against him by his University and the federal authorities.

But, despite the many obvious faults that one can identify in this case, there is still a theme that deserves further discussion. As shocked as the rest of the world was when they heard Dr He's announcement, he himself appeared to be shocked as well by the general reaction. His colleagues that heard about his research the night before the conference announcement over dinner, said that he appeared truly disappointed that there was anything but admiration for his achievements. He apparently believed in all honesty that he would be seen as a "hero" for making a significant step towards the betterment of the human race. And hereby lies the main unresolved topic in this affair: the ethical perspectives that are in conflict in such cases.

We tend to see ethics in disciplinary approaches. From virtue ethics, to deontology and utilitarianism, there is a great number of theories that develop one or the other part of ethical analytical thinking. They aim to work as a compass for decision making but they also represent ideal states of societal functioning. In fact, ethics is not mainly the analysis of individual decision making, but rather the study of the principles on which societies should be organised in and the developmental direction they should take. The actual application of ethics (i.e. applied ethics) has also a number of sub-divisions, from medical, to business, to engineering, etc. to ethics; each one with its own structures and prescriptions. The purpose of the current analysis of the Shenzhen case is not to promote or even develop a specific disciplinary approach – although that would be a worthwhile activity in itself – but rather to identify the ethical trends that are evident in this case.

Dr He is, or was until recently, a typical success story in modern China. Coming from a farming family with very modest means he studied hard to receive a government scholarship that allowed him to study further in the United States, first at Rice and then at Stanford University. At these two top universities, he discovered the potential of genetics research that he very soon applied, upon his return to China, to two genetic testing companies that he founded with the aid of the city of Shenzhen. It should be mentioned that the city of Shenzhen has been actively supporting the development of high-tech commercial organisations and has seen a tremendous economic increase in the last three decades. As is the case with many other young Chinese researchers, ever since his return to China, Dr He has been very active in promoting his commercial activities via his research achievements.

The success story of Dr He is based on the principle of: be there first and leave any questions for later on. It belongs to a highly competitive society that emphasises "success" before anything else. Success, first of the material kind (that is easier to identify) and then of the professional type. In this system, cutting-edge technological developments are considered an end-in-itself, as they can result in straightforward success. Debates on the ethics of these developments do take place but not where they matter most: in the actual centres of technological development. They happen instead in academic circles under strict disciplinary approaches. In this way, there is little questioning of the validity of a cutting-edge technology such as genome editing by its developers. It is meant to be employed in every manner possible, whereby the first to use it, will reap the most benefits.

This is in a nutshell Dr He's approach to his work. He honestly did not see a problem with his work because he equated it with success and noting but success. He was the first one to have successfully created a purpose-built human being that has an improvement over the average person. This by itself was an indisputably unique achievement that should have put his name firmly in the annals of human history. And just in case someone would miss this point, the PR campaign was there to promote it to experts and non-experts alike. If that sounds like "megalomaniac" tendencies, it is probably the case. But even in this confusing state of mind, he is simply following the values of the community he is working in.

In my view, this is by far the most important aspect in this case. Ever since the discovery of techniques to modify the genetic make-up of organisms, we have debates over the risks that these techniques entail. Already in 1975, soon after the introduction of recombinant DNA technology, scientists started an earnest discussion over risks that resulted in the first moratorium (Asilomar conference). Since then, we have witnessed the development of new techniques, the advent of biotechnologies (green, red or blue) and even wider debates on the ethical, legal and social (ELSI) aspects. Specific legislations have been enacted to regulate the use of the new techniques and many guidelines have been established to raise researchers' awareness on the pros and cons. The more effective the techniques become, the more often debates on ELSI are re-enacted.

Genome editing is the most effective technique of genetic engineering developed so far. It is different to the older techniques, only in the sense that is more precise and thus, allows for more efficient modifications. The types of modifications allowed by law or accepted by the common understanding are not different to the ones that have been debated in the past. It is clear therefore that human germline engineering (i.e. altering the human genome) is either legally prohibited or ethically unacceptable, depending on the place of jurisdiction. How come then this happened in such a blatant manner?

The answer is to be found in the timing of the event. It is a pragmatic view to hold that, once a new technology is developed, it will be used in every possible manner whether overtly or covertly. History is full of examples of powerful technologies being developed and even used, against the common wisdom that they could lead to enormous harm. The most obvious example is perhaps that of atom-splitting technologies that still cast a massive dark cloud over humanity. Similarly, since the Asilomar conference, it is a common understanding that genetic modification is a very promising but also enormously risky technology. There is a world-wide implicit understanding (made explicit in the legislation of many countries) that there should be no hidden research using genetic modification techniques on humans. But there is always the possibility, if not certainty, that some researchers will secretly pursue such opportunities. This is what Dr He did as well. He experimented with human germline engineering in secret but with a big difference: he did this in order to get a reputational advantage and not out of fear of the predominant moral stance in his community. In other words, in this case success has been the measure of morality and not the other way around.

This is perhaps the main deliberation point that is still worth pursuing in this debate. Is Dr He alone in this warped view of his work or is it a more widespread belief in the research community? Are we moving towards a dreaded "race to the bottom" when it comes to the ethics of research? These are not idle questions. They have severe repercussions in how international research policy should be planned and executed.

Globalisation has brought immense chances of research cooperation and economic development. Nowadays, there is hardly a major research centre that is not involved extensively in international collaborative research. As a matter of fact, most evaluation assessment guidelines in research put great emphasis on international cooperation. The economic significance of such cooperation runs surely into hundreds of billions of Dollars annually, the exact size being beyond the scope of our argument. The fact is that there is an unstoppable economic trend in international research that we are deeply affected by. What is still unclear is whether we, as international collaborators, share similar aspirations beyond economic success and even more importantly, similar moral values. The "Shenzhen scandal" showed us that there is no common understanding of either. The actual fact that Dr He performed this research and attempted to triumphantly announce it in a global meeting, his surprise to the reaction, but also the initial confusion of the conference participants and the government authorities in how to react, shows that we are far from having a common view of morality.

The solution to this situation is rather straightforward. We cannot have a process of discovery without any discussion on the "rights" and "wrongs" of the process and without sharing the same values as to the "why" we do it. The Human Genome project followed this reasoning when it provided 3 per cent of its budget for ELSI research. Some more big international research projects have followed in these steps with similar initiatives, but the great majority of international collaborations have no such structures. This needs to change if we want to develop a good relationship between science, society and policy. What is being termed "global ethics" encompasses the initiative to explore values systems around the world and compare and contrast individual dominant values that are used as guiding principles in science and technology developments. The ambition here is not to create a "one size fits all" ethics, but to raise awareness of the different perspectives and identify a common understanding of morality in the various research contexts. Such an analysis should be part of every international scientific project and every professional association structure. And it should run concurrently with the scientific research, not beforehand as research needs to follow a certain quick pace, and not after as it might be too late to amend mistakes. A real-time ELSI analysis based on inter-disciplinary and inter-cultural principles is what is really missing.

The ultimate aim is not only to avoid new scandals that take by surprise the society as well as the "wrong doers" themselves, but also to create a stable, consensual decision making in research that has at its heart the benefit of society. This is desirable, doable and, most importantly, necessary.

-Miltos Ladikas
Institut für Technikfolgenabschätzung und
Systemanalyse (ITAS)
Berlin
miltos.ladikas@kit.edu

Endnotes

[1] New York Times, Dec 1, 2018; In China, Gene-Edited Babies Are the Latest in a String of Ethical Dilemmas.

New York Times, Dec 5, 2018; Why Are Scientists So Upset About the First CRISPR Babies?

Science: An 'epic scientific misadventure': NIH head Francis Collins ponders fallout from CRISPR baby study By Jon Cohen, Nov. 30, 2018

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Gene-edited babies: Chinese Academy of Medical Sciences' response and action Published Online November 30, 2018 http://dx.doi.org/10.1016/ S0140-6736(18)33080-0

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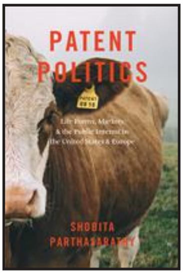
Book Review

Patent Politics: Life Forms, Markets & the Public Interest in the United States & Europe



Shobita Parthasarathy, University of Chicago Press, 2017, 304 Pp, $25.00

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Patent related issues have emerged as an important element in the research and innovation process in its ability to influence knowledge creation, dissemination and exploitation. Recent decades have witnessed the trend for an increasing harmonization of intellectual property systems around the globe, and new institutions of intellectual property protection, in particular through the work of the World Intellectual Property Organization (WIPO) and the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The evolution of the system has seen the generation of diversity regarding different systems' definitions and coverage of intellectual property rights, as well as the harmonization which may be expected to simplify global rules which need to be examined in a specific country context.

Technological advancements in the field of biotechnology such as genetically engineered organisms/crops, embryonic stem cells and more recently CRISPR/Cas9 have posed challenges for traditional patent systems and concerns have arisen about their societal implications and the capacity of existing patent systems to sufficiently address these. There are issues and challenges in the extension of coverage of patent laws in biotechnology advancements, and there are less clarity and understanding on how the property rights regime should look like in the case of such emergent technologies for its responsible development. Shobita Parthasarathy in her book on Patent Politics: Life Forms, Markets & the Public Interest in the United States & Europe takes a critical look at patent systems as a process that goes beyond its applicability in particular cases to delve deeper into investigating "the assumptions, rhetoric, formal rules, informal practices, institutional structures and politics, and organized interests that constitute each patent system's political order, and shape its law and understanding of patents" (p. 9). Instead of merely focusing on the differences in scope of patentability under different patent systems the author adopts a wider perspective in understanding why these differences are there by way of bringing out the moral and ideological underpinnings of the wider set of stakeholders involved in the patent debates.

Theoretically, the patent system is supposed to be non-discriminatory providing "technology-neutral protection" to all kinds of innovation. However, in practice, different fields do work differently in the patent system in the wake of the unique challenges posed to the patent regime by emerging technological developments. The fact that institutional mechanism of patent system to foster science and technology is influenced by national political culture gets masked by the globally harmonized marketplace should be taken into account in analyzing a patent system. This is evident in the life-from patentability witnessed in the biotechnology sector in the recent years. Hence, in order to fully understand divergences in patent system, especially in the field of biotechnology, the author adopts a comparative approach in the exclusive context of the United States and Europe. The book has five chapters excluding the introductory and the concluding chapter.

Defining the public interest in the US and European patent systems the author explains that although efforts for harmonization have been made by the US and Europe, due to differences in political culture and ideology these countries have looked at the issue of governance and public interest in their patent systems in different ways. While Europe has looked at patents as a part of pre-existing moral and social order with the responsibility of protecting public morality, inequity, national security and human rights, the US has emphasized on setting right the conditions for market growth which in turn would take care of public interest. Thus, while the government has assumed a wider role with a responsibility to protect the public interest as it views that interests of the patent holder may not always match the public interest, the US system on the other hand, with its emphasis on procedural objectivity and technical expertise, has assumed a limited role by leaving aside the issue of cost, access and morality of commodification to the market or policy domain. The fact that international negotiations may have erased these differences, the footprints still remains such as the *ordre public* clause in the European Patent Convention (EPC). Although the clause has not prompted enough discussion and there is a lack of clarity with regard to the processes and actors responsible for assessing in the case of violation, according to the author the emerging biotechnological developments and the controversies surrounding them provide scope for revival and reinterpretation of the provisions leading to divergences in understanding of patents system and its governance for public interest.

The issue confronting the questions of life-from patentability which had elicited debate in both the US and Europe has been discussed in detail in the book. Patentability of genetically modified organisms was much debated in the United States in the *Diamond v. Chakrabarty* case in the 1970s on the ground whether such life-form should be treated as a product of nature and thus not patentable or as any other composition of matter. This techno-legal framing of the debate in the US not embracing a metaphysical understanding of genetically modified organisms as life forms in terms of their potentially broad societal and environmental implications got further reinforced with the passage of Bayh Dole Act in 1980. On the other hand, in the European case the issue of patents in genetically engineered organisms was thought about and debated in moral and policy terms. According to the author, although the *ordre public* clause in the EPC served as a tool to discuss moral issue the clause in itself was not able to explain the debate or the final legislation. In fact, the clause was reinterpreted and articulated by the legislators in terms of multiple exclusions to life-form patentability and subsequently legislated upon to incorporate issues of protection of human and animal dignity and impacts of patents on livelihoods of farming and scientific community. These debates in the US and European context also raised concerns globally on the trajectory of emerging scientific and technological development and the governance and regulation of medical and agricultural biotechnology research and development in agriculture and health sector, such as GM foods, embryonic and stem cell research, reproductive technology.

The techno-legal and the socio-economic focus of the US and Europe patent systems respectively gained further traction in the 1980s when patentability concerns were raised on the issue of genetically engineered animals and was criticized by social movements in both the regions. The author opines that the divergence in approaches got further reinforced in the case of genetically engineered animals wherein the patent system of the US and Europe began to recognize different notions of publics and forms of public participation. In the case of the US the expertise barrier was deployed to justify its narrow approach while in the case of pan-European patent system there was a further opening of the patent bureaucracy. The European Patent Office although allowed patent of Oncomouse but it issued a far narrower patent as compared to the original patent application. Also, it took the concerns of public-interest groups seriously and unlike the US patent system considered them as legitimate participants in the European patent bureaucracy. Further, institutional changes incorporating issues of ethics in European patent examination process followed with the creation of the Sensitive Cases, or SeCa, system which was devised to determine application's sensitivity and procedures for additional review in addition to scientific and legal patentability. According to the author, while aspects of procedural objectivity and bioethical concerns have been introduced in the two geographical contexts, the difference in their legal, technology and institutional outcomes could be explained by the divergence in envisioning relationship between government, the market and innovation by the patent system of these two national politics, viz. a *market-making* approach in the case of US and a *market-shaping* approach in the European case.

The book further delves into the patent controversies covering human embryonic stem cells in the US and Europe. The understanding of patent system and its moral underpinnings were further debated in the US and Europe and led to citizen mobilization and government action when patent applications covering human embryonic stem cells were received in the late 1990s. The market-making ideology of the US patent system was questioned by biologists in the case of human embryonic stem cells research, involving the destruction of human embryos. It provided avenues to these scientists to delve into the patent system's barriers and challenge the notion of patents as innovation drivers by putting forth the argument that the human embryonic stem cells patents may actually stifle innovation as observed in the conflict over patenting of complementary DNS (cDNA) developed during the Human Genome Project. On the contrary, Europe initially allowed patents on human embryonic stem cells which got eventually modified in the wake of massive protest leading to the decision of unpatentability if they involved embryo destruction. This also made the European life-from patent challengers more systematic in their approach and established them as stable institutional watchdogs.

A techno-legal governance approach with patents dispute adjudication through courts renders difficulty in terms of understanding of patents as having distributional implications. This has been made evident by the author in patent cases in both human genes and plants in the case of US. Viewing patents as moral and policy object in the pan European patent system distributional concerns were observed to be addressed outside the scope of individual patent decisions. Although socio-economic implications were initially not considered under the *ordre public* clause, other patent-system institutions and the European Parliament began to take an active role addressing distributional concerns. Focusing on the legal dimension of patents controversy related to human genes and plants may contradict the market-making and market shaping approach as the US system prohibited patent on human genes and rejected challenges to plant patents. In Europe patents were allowed on both human genes and plants. Emphasizing on the point that patent controversies related to human genes and plants, when viewed in the broader political and institutional context rather than merely focusing on the legal outcomes, the book elucidates different approaches to patents and their governance in the US and European context and provides a coherent comparative account.

The primary argument put forward in this book, that patent systems are not merely techno-legal documents and that they are shaped by politics and society, has been lucidly explained and analyzed in the case of biotechnology in European and the US context. Focusing on the moral and policy concerns in the patent system provides opportunity to understand values and assumptions underlying patent decision-making process. It also enables to address broader issues related to scientific and technological development trajectory in terms of defining notions of knowledge systems, expertise, publics, posit alternative values for structuring science and technology and, scrutinize our assumptions about evidence-based policy making. Looking at the difference in the political cultures and moral understanding of patent systems of the US and Europe, the author makes a valid suggestion that we need to rethink harmonization efforts of patent systems and international trade agreements. The book makes a clear point that learning to engage with the political dimensions of science and technology policies will be important for better policy making and maximizing public benefits.

As our understanding of journey from lab to land has widened over the years, the saga of institutional development in this journey has also evolved in different geographical boundaries. There are several intricate issues pertaining to technology and patents interface. A systematic discussion on the question of patent rights needs to be seen as one embedded in a dynamic and broad socio-political context and with a bearing on patterns of social relations in the society. National political culture -nation states and national policies -implicated in vision of science and technology development and the way they can be fostered remain important sites for investigation. The book provides a novel comparative analysis on the social, cultural and political factors explaining why controversy surrounding biotechnology patents in the US and Europe rooted in different institutional practices of governance and deliberation has taken different forms. From a comparative standpoint the author has selected the US and Europe – the two leading regions of modern science and technology development. Though both the US and Europe have democratic cultures, they have diverse traditions of engaging publics and experts and managing dissents. Providing evidences drawn from the historical records and interpretive research and analysis, the book provides a rich textured description of the techno-legal orientation of the patent system of the US and a wider conceptualization of patents in the Europe -as innovation and market driver as well as moral and socio-economic objects. On the narrower side, in the comparative standpoint undertaken in the book more can be done to reflect on why patent systems in Europe are permissive about DNA and cloned animals and vice-versa in the case of the US. Based on extensive literature survey, both published and grey, and interviewing large set of stakeholders to uncover the layers of national political cultures vis-à-vis life-form patents in the United States and Europe, the book would serve as a repository of information on patents systems and its modern history.

– Dr. Manish Anand
Fellow, The Energy and Resources Institute (TERI)
Email: manand@teri.res.in

RIS
Research and Information System
for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

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Report

RIS Research on Biotechnology in Asia-Pacific and Report for FAO

RIS has been researching on biotechnology and development issues, particularly on agricultural biotechnologies since mid 1980s. As part of this research RIS has done surveys on biotechnology in different countries, particularly in the Asia-Pacific region. A key objective of such research is to take stock and analyse the impact of policies, while another objective is to do a comparative analysis of policies in different countries/regions and understand the implications of this for policy making. In issues of Asian Biotechnology and Development Review (ABDR) articles on status of biotechnology and biotechnology policies of various countries were published. In 2004 Biotechnology and Development: Challenges and Opportunities for Asia, (editors) Sachin Chaturvedi, S.R.Rao was published by Academic Foundation. In addition to this RIS contributed to various research projects/programs on biotechnology and development issues and outputs from this appeared in publications from, inter alia, OECD.

In 2009 UNESCO office at Jakarta commissioned a study on Status of Biotechnology in Asia-Pacific and RIS undertook the research study. A report based on this was published in 2010. In 2014, a revised version of the report was published as ‘Survey on biotechnology capacity in Asia-Pacific: opportunities for national initiatives and regional cooperation – Report for UNESCO, Jakarta, Sachin Chaturvedi, Krishna Ravi Srinivas, UNESCO Office Jakarta and Regional Bureau for Science in Asia and the Pacific; Research and Information System for Developing Countries 2014 Pp 184 http://ris.org.in/images/RIS_images/pdf/UNESCO%20Biotechnoloy%20Report-web.pdf

In 2017 FAO commissioned a study ‘The status of application, capacities and the enabling environment for agricultural biotechnologies in the Asia-Pacific region’ and RIS undertook the same. Initial findings were presented at the FAO Regional Workshop held at Kula Lumpur in September 2017. RIS completed the study and a report was submitted to FAO. FAO has published this as The "Status of Application, Capacities and the Enabling Environment For Agricultural Biotechnologies in the Asia-Pacific Region Regional Background Study Working Document" The same is downloadable from http://www.fao.org/3/ca4438en/ca4438en.pdf

We thank FAO for this opportunity. RIS continues to work on biotechnology and development issues and details are available at RIS website.

Readers are requested to refer to the full report for references and other details. For further queries on this report or on RIS work on agricultural biotechnology, please write to ravisrinivas@ris.org.in

Executive summary

The share of agriculture in the gross domestic product (GDP) of some countries in the Asia- Pacific region has declined in recent years as their economies transition from agrarian to industrial and service-oriented; however, agriculture is still important in terms of employment and its role as a buffer in phases of deceleration in other sectors. Agricultural biotechnologies have the potential to enhance the contribution of agriculture to these countries' economies.

This study presents overviews of the applications adopted by countries in the Asia-Pacific region and the main gaps in applications, capacities and enabling environments, and makes a few suggestions about what could be done for better utilization of agricultural biotechnologies in the region.

Key findings

The study found that agricultural biotechnologies are well entrenched in the Asia-Pacific region and their use is expanding, as are the capacities and enabling environments needed to support their use.

There are, however, significant differences among countries in their application of biotechnology in all four agricultural sectors: crops, livestock, fisheries and forestry. Small island states and many least developed countries (LDCs), such as Afghanistan and Mongolia, are yet to benefit appreciably from the biotechnology revolution. Multiple factors such as low capacity and the small size of their markets constrain them from reaping the benefits of biotechnology. Some countries, such as Cambodia, the Lao People's Democratic Republic and Uzbekistan, are in the initial stages of applying biotechnology but they have the potential to move forward. A few, such as Sri Lanka and Nepal, have not yet started to apply biotechnology but have the potential capacity and a good policy framework to move ahead. Recent changes in Viet Nam and Myanmar indicate the establishment of an enabling milieu that can take the countries forward in agricultural biotechnology. Larger and emerging economies, such as China, India and the Republic of Korea, are using biotechnology extensively in all four sectors.

State-driven biotechnology policy is evident in Malaysia, the Philippines and Singapore. Similarly, the state is the key player in shaping the destiny of agriculture in the India and the Republic of Korea, although their strategies differ. Australia and New Zealand are the key players in the Pacific region with world-class capacity in biotechnology.

Crops

Resistance to genetically modified (GM) crops in the Asia-Pacific region is weak and is confined to only India and the Philippines. Many countries in the region import GM crops for feed and for industrial purpose, including countries, such as Japan, in which there is no commercial cultivation of GM crops. Many countries permit domestic consumption and trade in GM crops, but limit their commercial cultivation.

Countries have adopted a wide variety of low-, medium- and high-technology applications in crop biotechnology, and newer applications and technologies are pursued with interest. However, in spite of the capacity and need, genetic modification in agriculture is limited to a few crops and a few traits. GM cotton is widely grown across the region, with adoption rates as high as 97 percent in some countries. Although work has been done on developing GM rice, it is yet to be commercialized. Other GM crops are under development but whether many of them will be commercialized is questionable.

More and more countries in the region are adopting high-technology applications. For example, at least six countries are using genome editing and genome mapping, and 15 countries are using marker-assisted selection. Fifteen countries have successfully adopted tissue culture, but its potential is yet to be fully harnessed.

Countries vary widely in terms of capacity to adopt agricultural biotechnologies in the crop sector. Some have exceptionally good capacities while others have low to very low capacities. Australia, China and India have very good or excellent capacity as a result of good availability of human resources, strong public sectors, well-endowed educational systems and strong national innovation systems in agriculture. However, most LDCs and island states have insufficient current capacity to make full use of crop biotechnology. International/regional collaborations can play a key role in enhancing their capacity.

The overall enabling environment is positive, as many countries have policies, regulations and laws favouring development of crop biotechnology. Eleven countries (Australia, Bangladesh, China, India, Iran, Malaysia, Nepal, the Philippines, Republic of Korea, Sri Lanka and Thailand) have specific policies or strategies relating to crop biotechnology. In many others, crop biotechnology is integrated in agricultural development plans, and is actively promoted. However, most of the LDCs do not have a strong enabling environment for crop biotechnology. Most of the countries have biosafety policies or regulations. Incentives and intellectual property protection in many countries, particularly members of the Association of Southeast Asian Nations (ASEAN), also play a vital role in creating a favourable enabling environment.

Livestock

In the livestock sector, major applications of advances in agricultural biotechnologies in the region include exploitation of the genetic association between single nucleotide polymorphisms (SNPs) and meat quality traits; development of effective methods for conservation of avian genetic resources using germ cells; development of an effective method of genome editing in chicken; and functional gene analysis of sexual differentiation of avian species. Australia, China, India, Iran (Islamic Republic of) and

Japan have all employed one or more of these in livestock. China has used knowledge of molecular mechanisms underlying muscle development and intramuscular fat deposition in chickens and protein expression profiles to create new meat-type chicken breeds with quality meat, disease resistance and good feed conversion characteristics. China has sequenced the entire mitochondrial genome of the Datong Yak and has used the CRISPR-Cas9 system to develop transgenic sheep, goats and pigs with traits of interest, including disease tolerance. Australia, China, India, Iran (Islamic

Republic of), Japan, New Zealand and the Republic of Korea are all conducting fundamental research in animal biotechnology. Development of diagnostics and vaccines has enabled the livestock sector meet challenges in animal health, particularly in the case of epidemic diseases.

Countries in the region are diverging in terms of capacity and enabling environment. Most LDCs and island states have low or very low capacities and weak enabling environments. In contrast, some countries, such as Australia, China, Japan and the Republic of Korea, have exceptionally good capacity and very favourable enabling environments. International collaborations and capacity-building initiatives can play a key role in enhancing capacity and contributing to a positive enabling environment. Although not all countries in the region need to be at the forefront of livestock biotechnology, it is important that they at least have some capacities and an adequate enabling environment to allow them to harness livestock biotechnology to address developmental needs and to utilize their animal genetic resources. There is thus a need to address the gaps in capacities and enabling environments between countries in the region.

Forestry

The adoption of biotechnologies in the Asia-Pacific forestry sector is limited, both in terms of the technologies used and the countries using them. Fewer than 15 countries are actively using biotechnologies in the forestry sector. Tissue culture and biopesticides are the most-widely adopted applications. Genetic modification of trees in the Asia-Pacific region is confined to research and development (R&D); there has been only one approval for cultivation of GM trees in the region (*Populus* in China). A few countries are conducting R&D in emerging technologies such as gene editing.

Capacity in research and training in forest biotechnology needs to be enhanced to leverage the full potential of forest biotechnologies in the region. Private-sector involvement also needs to be enhanced. Capacity-building programmes and international collaboration in forestry biotechnology are enabling several countries, including Sri Lanka, Vanuatu and Viet Nam, to harness forestry biotechnology, but such collaborations need to be strengthened and expanded.

Because few countries are engaged in forestry biotechnology, forestry policies generally do not create a positive milieu for forestry biotechnology. The public sector and governments have a key role to play in creating an enabling environment, but only a few countries – e.g. Australia, China, Japan, Republic of Korea and Malaysia – are giving this due consideration.

Fisheries/aquaculture

The fisheries and aquaculture sector in the Asia-Pacific region needs breeding-support and diagnostic tools and vaccines that could be developed using biotechnology, but few countries have the R&D capacity to develop them or the capacity to adopt them. Only eight countries have the capability to undertake R&D and to adopt sophisticated applications such as genome mapping and genome editing. Many others are unable to adopt even low-level technologies, despite an urgent need to do so. The gap between countries in terms of adoption of applications is a cause for concern.

Most of the LDCs lack the capacity to apply even medium-level technologies and have confined themselves to limited use of low-level technologies. Despite their lack of home-grown capacity, countries can benefit from collaborations and regional capacity-building programmes.

Way forward

It is clear that capacity to develop and apply biotechnology in any one sector, e.g. fisheries, cannot be enhanced substantially unless overall capacity in biotechnology is enhanced. This highlights the need for long-term strategies in capacity building. The enabling environment in the region also needs improvement, although it is very good in some countries. In most of the others, the policy thrust is lacking or is found wanting. International collaborations are essential but they are not a substitute for an enabling policy framework, which can create a positive milieu.

3.1 Crops

3.1.1 Introduction

A diverse range of biotechnological applications are in use or under development in the crop sector in the Asia-Pacific region. They range from less-advanced applications such as biopesticides, biofertilizers and tissue-culture techniques to technically advanced applications such as genome editing of crops. There are numerous examples of biotechnologies, many non- GM, that meet the needs of small holders in the region (Ruane *et al.,* 2013). High-level applications are also increasingly used, including genome mapping to assist in developing improved varieties of pulses and molecular breeding for improved wheat quality and for developing maize varieties resistant to head smut (*Sphacelotheca reiliana*) (Varshney, 2017a; Li, 2017a). Medium-level applications, such as tissue culture, have also been widely used and have been successful in many countries, including India and Sri Lanka (John, 2017).

3.1.2 Biofertilizers and biopesticides

Biofertilizers

Nill (2016) defined a 'biofertilizer' as "a microorganism that either mobilizes a soil-borne chemically bound plant nutrient/mineral (i.e. makes the nutrient/ mineral bio-available to crop plant roots) or itself produces (e.g. nitrate from the nitrogen in the atmosphere) a plant nutrient."

The most commonly exploited microorganisms that meet this definition are those that help fix atmospheric nitrogen for plant uptake or solubilize or mobilize soil nutrients such as unavailable phosphorus into plant available forms (FAO, 2011).

An overview of applications of biofertilizers in the region is given in Table 3.1. Biofertilizers are considered suitable for small-scale farmers as they are often cheaper than alternative commercial fertilizers or soil amendments and are easy to use. They are currently used in 19 countries in the region in both conventional and organic agriculture. However, data on use and application of biofertilizers are commonly not available.

Table 3.1. Biofertilizer use in the crop sector in the Asia-Pacific region

Country	**Biofertilzer**	**Crop**	**Other details**
Asia			
Bangladesh	*Rhizobium,Klebsiella pneumoniae,* and *Pantoea agglomeran; Trichoderma harzianum; Azospirillum; Bradyrhizobium*	Lentil, peas, oil crops, soybean; sugar cane, mung bean	Nitrogen fixation bacteria, Isolated from sugar cane
Bhutan	Organic farming		
China	Azolla; algal biofertilizer; biological nitrogen fertilizer, biological phosphate fertilizer and compound bacterial fertilizer, *Rhizobium*,	Rice, sweet corn, tobacco, cassava, wheat, maize, soybean,	
India	Actinobacterial consortium" containing three *Streptomyces* spp; Azotobacters; *Rhizobium; Azospirillum*, Blue Green Algae	Rice, wheat, millets, other cereals, cotton, vegetables, sunflower, mustard, pulses, oilseeds, fodders; maize, sorghum, sugar cane	Increase yield 20–40% for rice, cotton and others
Indonesia	*Rhizobium* sp.; *Bradyrhizobium* sp.; *Azosprillum* sp.; Blue-green algae; azolla-anabena; *Frankia*; mycorrhiza helper bacteria-arbuscular mycorrhizal fungi; PGPR	Legumes; soybean, maize, rice, sugar cane, tree crops, potato, etc.	Nitrogen fixation, yield increase
Iran (Islamic Republic of)	Rhizosphere, cyanobacteria, K- nano fertilizer and N-biofertilizer	Rice, corn, red bean	To increase yield
Japan	Mycorrhizal fungi/nitrogen fertilizers; *Bradyrhizobium*	Leguminous plant; soybean	Increase yield, nitrogen fixation bacteria
Kazakhstan	*Pseudomona, Rhizobium, Azotobacter*	Leguminous crop	Nitrogen fixation
Republic of Korea	EXTN-1; plant growth promotion rhizobacteria (PGPR), phosphate solubilization microbes; nitrogen fixing microbes.	Tomato, lettuce	Promotes growth of lettuce, reduces risk of tomato wilt disease

Table 3.1 continued...

...Table 3.1 continued.

Country	**Biofertilzer**	**Crop**	**Other details**
Malaysia	None that employ biotechnology only naturally occurring organisms are used	N/A	N/A
Mongolia	*Azospirillum*, *Azotobacter* and *Azoarcu*	All cereal crops	Nitrogen fixation bacteria
Myanmar	*Rhizobium*	Wheat; groundnut; sesame	Nitrogen fixation and improve crop production
Nepal	*Rhizobium,* endo-mycorrhiza	Pulse crops	Nitrogen fixation bacteria
Pakistan	BiPower (Produced by NIBGE)	N/A	N/A
Philippines	None that employ biotechnology only naturally occurring organisms are used		
Singapore	Yes	N/A	N/A
Sri Lanka	Many organic and 100% natural biofertilizers are being commercialised in Sri Lanka, but none of the commercialised biofertilizers make use of biotechnology in their process of production	N/A	N/A
Timor-Leste	Nitrogen and phosphorus biofertilizer	Rice	to increase yield
Uzbekistan	*Azotobacter*	wheat	Nitrogen fixation.
Viet Nam	*Burkholderia vietnamiensis* (TVV75); *P. aeruginosa* 23(1–1)	Rice; watermelon;	Pathogen inhibition; siderophores production; gummy steam blight causes by *Didymella bryoniae* and vascular wilt caused by *Fusarium oxysporum*; reduced sheath blight disease caused by *Rhizoctonia solani*; bacterial leaf blight caused by *Xanthomonas oryzae*; fruit rot caused by *Phytopthora capsici*

Table 3.1 continued...

...Table 3.1 continued

Country	**Biofertilzer**	**Crop**	**Other details**
Pacific			
Australia	Yes	Clover, aloe vera, canola, pea, lentil, faba bean, chickpea	Reactive phosphate rock based, magnesium deficiency, potassium deficiency, soil and plant nutrition.
New Zealand	None that employ biotechnology only naturally occurring organisms are used	N/A	N/A

The most common applications are for nitrogen fixation and yield increase. For example, in Bangladesh, *Trichoderma harzianum* is used in crops such as sugar cane and soybean to promote nitrogen fixation, while in China, *Rhizobium* is extensively used in many crops, including rice and wheat. In India, S*treptomyces* spp., *Azotobacter* spp., *Rhizobium* spp. and *Azospirillum* spp. are used on many crops, including rice, and have resulted in yield increases of 20–40 percent in rice, cotton and other crops. In Kazakhstan, *Pseudomonas* spp*., Rhizobium* spp. and *Azotobacter* spp. are used on leguminous crops for nitrogen fixation. In the Republic of Korea, plant-growth-promoting rhizobacteria and nitrogen-fixing microbes are used to boost growth of lettuce and to reduce risk of tomato wilt disease. In Viet Nam, *Burkholderia vietnamiensis* TVV75 and *Pseudomonas aeruginosa* are used on rice and watermelon. In some countries, such as New Zealand and Sri Lanka, biofertilizers are solely naturally occurring organisms.

Recent literature suggests that the potential of biofertilizers is not fully used, and there are issues relating to their regulation and technology (Chandler *et.al,* 2011; Glare *et al.,* 2011; Koul, 2011; Sahayaraj, 2014; Kourti, Swevers and Kontogiannatos, 2016).

Although biofertilizers have been used in many countries for decades, there is little indication of technological development, i.e. there has been little more than selection of superior strains from among wild populations.

Uptake of biofertilizers in Asia faces issues ranging from lack of awareness among farmers to regulatory issues (Singh, Sarma and Keswani, 2016). This has limited their uptake. For example, in 2012–13, India produced only 0.5 million tonnes of biofertilizers, compared with a potential market of 2.5 million tonnes (Hegde 2016). In China, annual output is only about130 000 tonnes (Li, 2017a). This suggests that countries adopt biofertilizers only when the need arises.

Biopesticides

'Biopesticides' are "mass-produced, biologically-based agents used for the control of plant pests. They can be living organisms such as microorganisms or naturally occurring substances such as plant extracts or insect pheromones" (FAO, 2010).

The global biopesticide market is projected to grow by 18.8 percent from 2015 to 2020 and reach US$6.6 billion by 2020. In 2013, the Asia-Pacific region consumed 27.7 percent of global bioinsecticides by volume and 38 percent by value. The biopesticide market in the region is projected to grow 17.8 percent a year between 2015 and 2020 (Mordor Intelligence, 2017), with the market in India forecast to show an even higher growth rate of 19 percent a year over the same period (Ken Research, 2016).

Twelve countries in the region have adopted biopesticides, with biopesticides based on *Bacillus thuringiensis* (*Bt*) being most-widely used (Table 3.2). China is the largest biopesticide market in the Asia-Pacific region, accounting for 35 percent of the overall market, followed by India (Atieno, 2015). The market in China is also expected to be the fastest growing in the region because of increasing acceptance of biopesticide as an alternative to existing chemical pesticides.

Table 3.2. Use of biopesticides in the crop sector in the Asia-Pacific region

Country	**Biopesticide**	**Crop**	**Purpose and other details**
Asia			
Afghanistan	Trichoderma; Madex Plus; Dipel 150 Dust	Vegetables; apple; cabbage	Control colding moth in apple; Fight fungal diseases
Bhutan	Butachlor and Metribuzin; neem oil	All crops	Weed control; pest control

Table 3.2 continued...

...Table 3.2 continued

Country	**Biopesticide**	**Crop**	**Purpose and other details**
Cambodia	Bacillus thuringienis; Trichoderma	Cabbage; all crops	Suits all types of soil
China	Metarhiziumanisopliae CQMa421; *Coniothyrium minitans* CGMCC8325; *Bacillus methylotrophicus* LW-6; sophora alopecuroids alkaloid; D-limonene; terpinen-4-ol;	Cotton, rice plant hopper, rice leaf roller; *Sclerotinia* rot of colza; Citrus canker, *Xanthomonas, oryzicola*, cucumber angular leaf spot; cabbage aphid; powdery mildew of strawberry, early blight of tomato	Disease control; high efficiency; 12 million ha
India	Multiple strains	Basmati rice, cotton, mustard, chickpea and groundnut	Insect resistance
Indonesia	Corn1; Soyabean plus	Corn; soybean	Aluminium tolerance
Iran (Islamic Republic of)	Microbial biopesticides	Crops	
Japan	N/A		
Kazakhstan	*Bacillus thuringiensi; Verticillum lecanii; Cydia pomonella*	Leguminous crop	Protect against bacteria, insect, fungal and viral diseases
Republic of Korea	*Bacillus thringiensis; Beauveria bassiana and Paecilomyces fumosoroseus*	Chinese cabbage; all crops	Targets mite and white fly

Table 3.2 continued...

...Table 3.2 continued

Country	**Biopesticide**	**Crop**	**Purpose and other details**
Malaysia	None that employ biotechnology only naturally occurring organisms are used		
Mongolia	No		
Nepal	*Bacillus thuriengensis*- 8 strains at NAST	Crucifer plants	Insect resistance
Pakistan	*Trichogramma* (egg parasitoid) Fungi (*Trichoderma* and *Gliocladium*) Baculoviruses; Nuclear polyhedrosis virus (NPV) of *Heliothis armigera* NPV of tobacco caterpillar (*Spodoptera litura*) Granulosis virus (GV) *Bacillus thuringiensis* Neem (*Melia azaderechta*) (Biotechnology is not involved to a large extent)	Sugar cane, pulses, cotton, oil seeds,	Pest control; wilt disease treatment; insect control
Philippines	None that employ biotechnology only naturally occurring organisms are used		
Singapore	Yes	N/A	N/A

Table 3.2 continued...

...Table 3.2 continued

Country	**Biopesticide**	**Crop**	**Purpose and other details**
Sri Lanka	Biotechnology-based biopesticides are not yet commercialised in Sri Lanka	N/A	Currently, plant powders, non-volatile and volatile oils, and plant crude extracts are commercially available for management of insect pests and nematodes. Further, several bacterial and fungal biopesticides have shown promising results for the efficient management of plant pathogens in Sri Lanka.
Timor-leste	Yes		
Pacific			
Australia	Yes	The biopesticides are disease-specific and hence can be used on a number of crops	Targets: Crown gall disease, blights (by *Botrytis* spp.), dead-arm of grapevine, *Lepidoptera* larvae, Grey-backed cane grub (scarabs), Locusts and grasshoppers, Redheaded pasture cockchafer, *Helicoverpa* spp.
New Zealand	The exact name of the microorganism they are using is not disclosed online as they are still in the research phase.	Kiwi fruit	*Pseudomonas syringae* pv. *actinidiae* resisitance

Biopesticides face similar challenges to biofertilizers and much of the potential remains underutilized (Singh, Sarma and Keswani, 2016). Despite positive developments in the technologies, significant uptake is still lacking (Glare *et al.,* 2011). In many countries in the region, they are the only biotechnology applications used in crops. Only Australia, China and India are able to leverage them with advanced applications.

Future developments in biofertilizers and biopesticides in the Asia-Pacific region

There are considerable difference across the region in terms of utilization of biofertilizers and biopesticides in crop production. Their use is more widespread in Southeast Asia than in the Pacific island countries. In South Asia, Bangladesh, India, Nepal and Sri Lanka are extensive users, and in Central Asia Iran (Islamic Republic of) has shown much progress. However, overall the current situation is not very conducive to further development and utilization of these technologies.

Options for enhancing use of biofertilizers and biopesticides include:

- Promote their use through technological and policy interventions;
- Invest more in basic research on biopesticides and biofertilizers to develop improved applications that meet the needs of small-scale farmers and that have commercial potential;
- Build capacity in LDCs to effectively utilize biofertilizers and biopesticides.

3.1.3 Tissue culture

'Tissue culture' is "the *in vitro* culture of plant cells, tissues or organs in a nutrient medium under sterile conditions" (FAO, 2010).

The scope for tissue culture is enormous: it can be used for conservation (including *in vitro* regeneration), propagation, in genetic engineering, and for selecting plants for specific characteristics such as insect resistance (Anis and Ahmad, 2016). Tissue culture has been widely used to produce uniform (clonal) crops such as in some horticultural crops, banana and sugar cane.

In India, tissue culture has been used mostly in horticultural, aromatic, medicinal and forestry crops (Hegde, 2016). The country has had some successes in producing banana plants *in vitro*, benefiting small farmers, but has not been successful in using the technique with spices; research is ongoing to introduce it in saffron (John, 2017). According to Anis and Ahmad (2016), "In recent years, there has been an explosion in the number of commercial plant tissue culture units in India. Till date, 95 commercial tissue-culture production units have been recognized by the Department of Biotechnology, Government of India, under the National Certification System for Tissue Culture Raised Plants (NCS-TCP, 2016). The potential for the domestic market is enormous, and by conservative estimates, it is around Rs 2 billion with an annual growth rate of 20 %. The production capacity of commercial tissue-culture units ranges between 0.5 million and 10 million plants per annum with an aggregate production capacity of about 200 million plantlets per year."

In Sri Lanka, tissue culture is a success story, and it is the most-widely used application of agricultural biotechnologies, accounting for 60 percent of their use in the country.

Use of tissue culture in the Asia-Pacific region has been hampered because of the technical difficulties in transfer of the technology from the laboratory to the farmer and because of a lack of extension services to train farmers in handling tissue-cultured plantlets.

3.1.4 Marker-assisted selection

'Marker-assisted selection' (MAS) is the use of DNA sequence markers (molecular markers) to select individual plants or animals that possess gene(s) for a particular performance trait (e.g. rapid growth, high yield, disease resistance) (Nill, 2016).

MAS is made possible by the development of molecular-marker maps, where many markers of known location are scattered at relatively short intervals throughout the genome and statistical associations have been determined between markers and traits of interest. The presence of a marker suggests the presence of the associated gene (FAO, 2010). MAS is widely used in plant breeding in the Asia-Pacific region (Table 3.3).

Table 3.3. Use of marker-assisted selection in the crop sector in the Asia-Pacific region

Country	**Marker**	**Crop**	**Purpose**
Asia			
Bangladesh	SSR	Rice	Rice (diversity analysis of 81 AUS and 26 BRRI developed variety)
Bhutan	Stress tolerance trait	Rice and maize	Stress tolerance
Brunei Darussalam	SSR Marker/ST	Rice	High yield; insect resistance
Cambodia		Rice	Development of markers through molecular breeding.
China	Multi-resistant (CC149); Biotic and abiotic stress resistance; SNPs/indels and candidate genes;	Cotton, wheat, soybean, maize, rice	Increase yield and quality; 4.746 million ha (cotton)
India	Biotic and abiotic stress resistance; SNPs/indels and candidate genes; resistance gene analogs (RGAs) identification	Rice, maize, wheat, bajra, jawar, sorghum, mung bean and rice bean	Fe and Zn concentration; MYMV resistance
Indonesia	TS4	Rice	Broad spectrum resistant Xoo strains
Iran (Islamic Republic of)	RAPD, ALPF, reverse hybrid breeding, haploid breeding, mapping QTLS	Rice, corn, canola, maize	Reverse hybrid breeding, haploid breeding, mapping QTLS
Japan	Biotic and abiotic stress tolerance	Rice	N/A
Kazakhstan	SNP	Wheat	Study genetic diversity in bread wheat
Republic of Korea	SSR; markers resistance to viral dieases	Tomatoes; Korean Chilli Pepper	Pep MoV
Malaysia	SSR markers	Rice	Resistance to brown plant hopper
Mongolia	No	N/A	N/A
Myanmar	SSR or SNP	Rice	Adequate genotyping and phenotyping
Nepal	No	N/A	N/A

Table 3.3 continued...

...Table 3.3 continued

Country	**Marker**	**Crop**	**Purpose**
Pakistan	SSR markers	Wheat, cotton, pulses, potato	Insect resistance
Philippines	DNA fingerprinting for sugar cane. SSRs and SNPs for rice.	Sugar cane and rice	To eliminate susceptibility of sugar cane to downy mildew and smut. Increased root length and biomass in rice
Singapore	SSR markers	N/A	N/A
Sri Lanka	QTL mapping of growth parameters, leaf colour measurements	Rice	Phosphorus deficiency tolerance, salinity tolerance
Thailand	N/A	Cassava; sugar cane	Aroma maker; enhance sweetness
Timor-leste	No	N/A	N/A
Uzbekistan	N/A	N/A	N/A
Viet Nam	SSR markers	Rice Q5DB variety	Saline tolerance
Pacific			
Australia	CRISPR	Wheat	To study control of development, genome integrity, and epigenetic inheritance
New Zealand	For red fleshed apple the red-flesh allele is detected as an additional DNA band on an agarose gel and SNPs for various other traits.	Apple	For pest and disease resistance in the New Zealand apple breeding and also for breeding of red fleshed apples

According to some reviewers, it is an alternative to genetic engineering to produce new crops and for inclusive innovation in agriculture (Haribabu, 2009; Greenpeace, 2014). At least seven countries have at least one project or research initiative in MAS, while India and China have used it extensively (Table 3.4).

Table 3.4. Use of marker-assisted selection to develop varieties with different traits in different crops in India and China

Crop	Trait	India	China
Bean	Disease resistance	1	-
Chilli	Disease resistance	1	-
Maize	Quality protein maize	1	-
Pearl Millet	Disease resistance	1	-
Tomato	Disease resistance	2	-
Rice	Cooking quality		1
	Disease resistance	10	17
	Drought tolerance	3	-
	High yield	-	1
	Flood tolerance	3	-

Source: Varshney (2017b)

Despite progress, its full potential is yet to be fully harnessed in the region, largely because of a combination of lack of capacity and the cost of applying the technology.

3.1.5 Molecular breeding

'Molecular breeding' has been defined as "the utilization of molecular genetics and/or MAS in a breeding programme (e.g. within a seed company or within a university) to select the organisms (e.g. crop varieties) that possess gene(s) for a particular trait (e.g. higher yield, disease resistance)" (Nill, 2016).

Molecular breeding has the potential to enhance breeding for such traits as increased yield and disease resistance, and is relevant for the Asia-Pacific region (Hu, Xiao and He, 2016). Its application has picked up in the region but there are considerable gaps between research and its outcomes; collaborations could play an important role in bridging these gaps (Schafleitner and Karihaloo, 2013).

3.1.6 Genome mapping

At least six countries in the Asia-Pacific region have initiated projects to map genomes of important crops and to identify genes that confer desirable traits. For example, China has completed whole-genome sequencing in major crops, including rice, wheat, cotton, cucumber and tomato (Li, 2017b).

The CGIAR centres, such as the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), are engaged in genome mapping. ICRISAT and its partners have conducted genome mapping in pigeon pea, chickpea, groundnut, longan (*Dimocarpus longan*), adzuki bean, mung bean, pearl millet and sesame (Varshney, 2017b).

The United Nations agencies have an important role in supporting the use of genome mapping, especially through capacity-building and sharing of research outcomes, including data.

3.1.7 Genetically modified crops

According to FAO (2011), "A genetically modified organism (GMO) is an organism in which one or more genes (called transgenes) have been introduced into its genetic material from another organism. The genes may be from a different kingdom (e.g. a bacterial gene introduced into plant genetic material), a different species within the same kingdom or even from the same species. For example, so-called 'Bt crops' are crops containing genes derived from the soil bacterium *Bacillus thuringiensis* coding for proteins that are toxic to insect pests that feed on the crops." (FAO, 2010)

GM crops are perhaps the most-widely adopted and also most controversial application of agricultural biotechnologies. They are being cultivated in eight countries in the region – Australia, Bangladesh, China, India, Myanmar, Pakistan, the Philippines and Viet Nam.

Maize, soybean and cotton are the most-widely grown and tested GM crops. Rice has been tested in five countries but has not yet been approved for commercial cultivation in any country in the region. The current situation on GM crops in the Asia-Pacific region is summarized in Tables 3.5, and 3.6, and in Figures 3.1 and 3.2).

Table 3.5: Cultivation of genetically modified crops in selected countries in the Asia–Pacific region in 2015/2016

Country	GM crops	Area (million hectares)	Quantity	Value (US$)
Australia	Cotton	0.852 (2016)	Cotton: 4.2 million bales (2016)	73 million (2015)
	Canola	N/A	Canola: not available	N/A
Bangladesh	Brinjal (aubergine)	0.0007 (2016)	N/A	N/A

Table 3.5 continued...

...Table 3.5 continued

China	Cotton, papaya, poplar	2.8	N/A	1.0 billion (2015)
India	Cotton	11.2 (2016) (96% of area under cotton cultivation)	35 million bales (2016)	1.3 billion (2015)
Myanmar	Cotton	0.30 (93% of area under cotton cultivation)	N/A	N/A
Pakistan	Cotton	2.9 (2016)	N/A	398 million (2015)
Philippines	Maize	0.812	N/A	82 million (2015)
Viet Nam	Maize	0.035	N/A	N/A

N/A – not available.

Source: ISAAA (2016), GAIN (2016a, 2016b, 2016c), Cotton Australia (2016).

Table 3.6: Status of regulatory approvals and trials of genetically modified crops in selected countries in the Asia–Pacific region

Crop	Australia	China	Bangladesh	Pakistan	Philippines	New Zealand	Republic of Korea	Japan	Thailand	Indonesia	Iran (Islamic Republic of)	India	Malaysia	Viet Nam
Alfalfa	*				*			*						
Canola	*#	*			*		*	*						
Cotton	*#	*#		*#	*		*	*				*#		
Brinjal			*#											
Maize	*	*		*	*#		*	*	*	*			*	*#
Papaya		*#						*						
Potato	*				*		*	*						
Rice	*	*			*			*			*			
Soybean	*	*			*		*	*	*	*			*	*
Sugar beet	*	*			*		*	*						
Sugar cane	*									*				
Capsicum		*												
Tomato		*						*						

*Crop has been genetically modified and a specific trait has been given an environmental and/or food and/or feed approval.
*# the approved crop is under commercial production at present.
Source: ISAAA (2016), GAIN (2016a, 2016b, 2016c)
(See also Table 3.7 in annexure)

Table 3.7: Status of GM crop commercialization and testing research in the Asia-Pacific region

Country	Commercial cultivation	Approved GM events	Field trial	Experimental
Australia	Canola, cotton	Argentine canola (21), alfalfa (3), carnation (12), cotton (24), maize (27), potato (10), rice (1), rose (1), soybean (17), sugar beet (2) and wheat (1)	Bananas, barley, canola, cotton, grapevines, Indian mustard, maize, papaya, perennial ryegrass, pineapple, safflower, sugar cane, tall fescue, torenia, wheat, and white clover	Cowpeas (IR), bananas (FC), barley (AST, MU, FC, Y), canola (FC, Y), cotton (FY), brassica (FC), safflower (MO), sugar cane (FC, SM, HT), wheat (Y, AST, MU, FC), tobacco (MO)
Bangladesh	Aubergine	Aubergine	Aubergine, cotton, potato, rice	Aubergine (IR), jute (BR, FR, IR), kenaf, lentil, mesta, mung bean, oil palm (IP), papaya (VR), rice (AST), tobacco, potato (FR)
China	Cotton, papaya	Argentine canola (12), cotton (10), maize (17), papaya (1), petunia (1), poplar (2), rice (2), soybean (10), sugar beet (1), sweet pepper (1), tomato (3)	Chili, Chinese cabbage, cotton, groundnut, maize, melon, potato, rice, soybean, sweet pepper, tobacco, tomato	Barley, cotton (FQ, VR), hot pepper, maize (AST), papaya (AFR), potato (IR), rapeseed (FR), rice (AST, CQ, IR), sorghum (AST), soybean (IR), sugar beet (AST), wheat (AST, BR, IR, VR)

Table 3.7 continued...

...Table 3.7 continued

Country	**Commercial cultivation**	**Approved GM events**	**Field trial**	**Experimental**
India	Cotton	Cotton	Cotton, aubergine, mustard	Banana (AFR), black gram (FR, HT, IR, VR), bell pepper (MR), brassica (AST, FR, IR), cabbage (IR), cauliflower (FR, IR, PC),chickpea (FR, IR), chilli (FR, IR), cassava (NQ), citrus (VR), coffee (FR), cotton (HT, IR), cucurbits (VR), cucumber (VR), aubergine (AST, FR, IR), ground nut (VR), maize (IR), melon (VR), musk melon (EV), mustard (AST, HT, NQ, PC), mustard green (AST), papaya (VR), potato (AST, IR, MT, NQ, VR), pigeon pea (FR, IR), rice (AST, BR, EV, FR, HT, IR), tobacco (AST, FR, IR, VR), tomato (AFR, FR, IR, VR), wheat (AST, IR)
Indonesia	–	Maize, soybean, sugar cane	Maize (9), soybean (6) and sugar cane (3)	Cabbage (FR), cacao (IR, VR), cassava (SC), chilli (VR), citrus (VR), coffee (FR), maize (IR), oil palm (IR, MO), papaya (AFR), peanut (VR), potato (BR, IR, VR),rice (AST, FR, IR, VR), shallot, soybean (IR, MO, NQ), sugar cane (AST, IR, VR), sweet potato (VR)
Iran (Islamic Republic of)	–	Rice	Rice	Cotton (IR), maize (IR, FR), rice (AST, FR), potato (IR), sugar beet (IR), wheat (FR)

Table 3.7 continued...

..Table 3.7 continued

Country	Commercial cultivation	Approved GM events	Field trial	Experimental
Japan	–	Alfalfa (5), canola (20), cotton (37), maize (198), potato (8), rice (1), soybean (29), sugar beet (3)		
Republic of Korea	–	Canola (14), cotton (29), maize (75), potato (9), soybean (25), sugar beet (1)		
Malaysia	–	Maize (14), soybean (7)	Argentine canola (1), carnation (8), cotton (4), maize (14), soybean (7) papaya	Banana (AFR), chilli (VR), maize (HT, IR), Aubergine (IR), melon (FR), musk melon, oil palm (MO, PI, Y), orchid (AFR), papaya (AFR, VR), pepper (VR), rice (FR), rubber (Y), teak (WQ), tobacco, winged bean (FR)
Nepal	_	_	_	
New Zealand	–	–	Alfalfa (3), Argentine canola (14), cotton (21), maize (27), potato (11), rice (1), soybean (17), sugar beet (2), wheat (1), onion	Onion (HT), potato (BR), sugar beet (HT), brassica (IR)

Table 3.7 continued...

...Table 3.7 continued

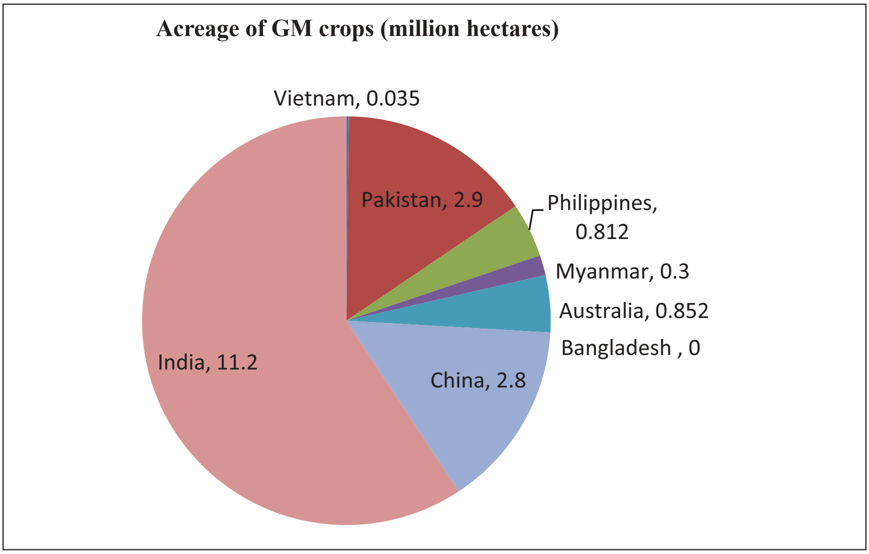
Country	Commercial cultivation	Approved GM events	Field trial	Experimental
Pakistan	Cotton	Maize	Wheat, cotton, maize	Brassica (PC), chickpea (AST, IR), chilli (VR), cotton (IR, VR), cucurbits (VR), potato (VR), rice (AST, BR, FR, IR), sugar cane (IR), tobacco (AST, IR), tomato (IR, PC, VR)
Philippines	Maize	Alfalfa (2), canola (2), cotton (8), maize (52), potato (8), soybean (14), rice (1), sugar beet (1)	Cotton, aubergine, rice, papaya	Abaca (VR), banana (VR), coconut (MO), aubergine (IR), mango (AFR), papaya (AFR, VR), rice (AST, BR, FR, NQ, VR), squash (VR), sweet potato (IR, VR), tobacco (GC), tomato (AFR, VR), yellow ginger (MO)
Thailand	–	Maize (12), soybean (2)	Cotton, rice, tomato, pepper	Cassava, cucurbits (VR), mango, orchids (VR), papaya (IR, VR), pineapple, rice (BR, FR, VR), tobacco, tomato (BR), yardlong bean (VR)
Viet Nam	Maize	Maize (14), soybean (8)		Cabbage (IR), cotton (IR), papaya (VR), potato (VR), rice (NQ, IR) tomato (AST, sugar cane (IR), sweet potato (IR)

Notes : AFR: Altered fruit ripening; AST: Abiotic stress tolerance; BR: Bacterial resistance; CQ: Cooking quality; DR: Disease resistance; EV: Edible vaccine; FR: Fungal resistance; FQ: Fibre quality; HT: Herbicide tolerance; GC: Growth control; IP Industrial product; FC: Food Composition for human and animal nutrition, MU: Micronutrient Uptake; SM: Sugar Metabolism; FY: Fibre Yield; IR: Insect resistance; MO: Modified oil composition; MR: Multiple resistance; NQ: Nutrition quality; PC: Pollination control; PrC: Protein content; SC: Starch composition; VR: Virus resistance; WQ: Wood quality; Y: Yield.

Source: ISAAA (2016), GAIN (2016), Tech monitor (2011)

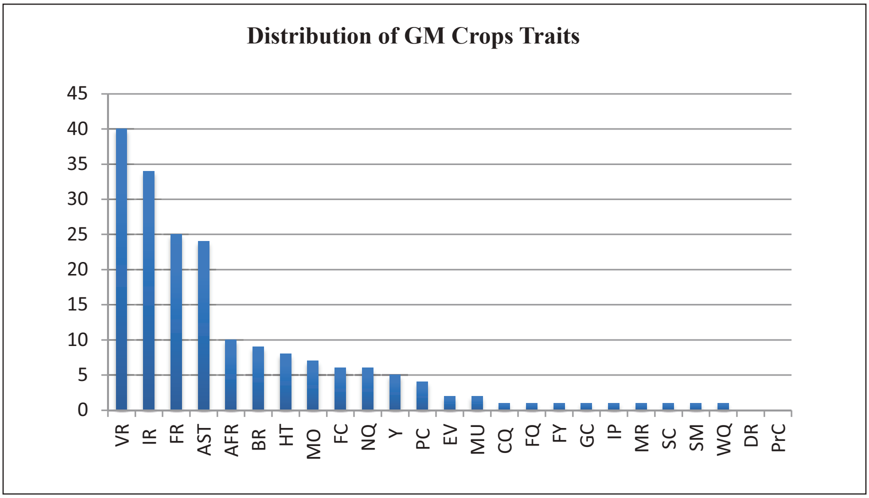
Genome editing is emerging as tool to develop crops with novel traits and is an alternative to genetic modification. However, whether genome editing would be a preferable option for use on food crops depends on public acceptance of genome-edited crops.

Figure 3.1. Area of genetically modified crops grown in selected countries in the Asia–Pacific region



Source: Authors' compilation from various sources

Figure 3.2: Number of cultivars with different GM crop traits



Notes: AFR: Altered fruit ripening; AST: Abiotic stress tolerance; BR: Bacterial resistance; CQ: Cooking quality; DR: Disease resistance;

EV: Edible vaccine; FR: Fungal resistance; FQ: Fibre quality; HT: Herbicide tolerance; GC: Growth control; IP Industrial product; FC: Food composition for human and animal nutrition, MU: Micronutrient uptake; SM: Sugar metabolism; FY: Fibre yield

IR: Insect resistance; MO: Modified oil composition; MR: Multiple resistance; NQ: Nutrition quality; PC: Pollination control; PrC: Protein content; SC: Starch composition; VR: Virus resistance; WQ: Wood quality; Y: Yield.

The current survey found that, although some countries have conducted R&D on GM crops for meeting climate-change challenges, few GM varieties are available to farmers and these are yet to be widely deployed.

Several countries in the region that, until recently confined biotechnological applications to biofertilizers, biopesticides and the like, are showing increasing interest in GM crops. For example, numerous trials have been conducted on a range of crops in Viet Nam, including soybean, maize, cotton, canola, sugar beet and alfalfa, and insect-resistant and herbicide- tolerant GM maize is in commercial production. GM soybean has been approved for use as a food and as a feed. If the other crops tested are approved and commercialized, Viet Nam will be catching up with Australia in terms of the range of GM crops commercialized.

Myanmar has developed and released *Bt* cotton, and this has been adopted by smallholder farmers.

Bangladesh has developed *Bt* brinjal and this is now in commercial production. Although adoption is currently very low, the country is going ahead with ambitious plans on GM agriculture and new varieties are expected to be developed, include of cotton, tomato and rice.

Both Thailand and the Philippines have been investing in R&D in agricultural biotechnology since the 1990s and have adopted regulatory regimes. However, despite many trials, GM crops have not been commercialized in Thailand, although they have been in the Philippines (Larsson, 2016).

Several countries, including Indonesia, Malaysia, New Zealand and the Republic of Korea have approved GM crops, but have yet to start growing GM varieties commercially.

Many countries of the region have approved GM crops for different uses – food, feed and industrial. Thus, even if a country is not growing GM crops commercially, it does not mean that it is not using GM food or GM feed.

3.1.8 Genome editing

According to Genetics Home Reference (2017), “Genome editing (also called gene editing) is a group of technologies that give scientists the ability to change an organism’s DNA. These technologies allow genetic material to be added, removed, or altered at particular locations in the genome.”

A very important issue with genome editing is whether plants developed using genome editing should be treated as GM crops or similarly to crops developed using conventional plant breeding (Wolt, Kan Wang and Yang, 2016; Eriksson and Ammann, 2017).

Twelve countries in the Asia-Pacific region have started using this technology, although many are at the experimental stage (Table 3.8, in annexure). Current projects and initiatives include research on commercially and nutritionally important crops such as rice and cassava (ISAAA, 2017). CRISPR-Cas9 (clustered regularly interspaced short palindromic repeats [CRISPR]- CRISPR-associated protein 9) is the most-widely used technology in the region.

Table 3.8. Use of genome editing in the crop sector in the Asia-Pacific region

Country	Technology	Crop	Purpose
Asia			
Bangladesh			
Bhutan	No	No	no
China	TALEN/CRISPR Cas9	Wheat; rice	Disease resistance
India	Cloning gene 'Pi-Kh' by CRISPR	Rice, wheat	Resistance to blast disease; drought resistance
Indonesia	CRISPR CAS9	N/A	N/A
Iran (Islamic Republic of)	No	N/a	N/A
Japan	CRISPR/Cas9		Japan is also actively involved in the research and development of innovative biotechnologies, such as CRISPR/Cas9.
Republic of Korea	CRISPR CAS9 (No insertion of foreign DNA); CRISPR; CRISPR	*Arabidopsis thaliana*, tobacco, lettuce and rice; apple, grapevine	Physiological; climate-change; under research; to increase resistance to fire blight disease; to increase resistance to powdery mildew

Table 3.8 continued...

...Table 3.8 continued

Country	Technology	Crop	Purpose
Malaysia	CRISPR/Cas is being employed for genome editing in research, however there is no clear indication of its employment in particular crops	N/A	N/A
Mongolia	No	N/a	N/A
Myanmar	CRISPR	Tomato	Improve flavour and quality
Nepal	No	N/A	N/A
Philippines	CRISPR/Cas	Rice	Enhanced rice blast resistance
Singapore	TALEN/CRISPR	N/A	N/A
Timor-Leste	No	N/A	N/A
Uzbekistan			
Pacific			
Australia	CRISPR	Wheat	To study control of development, genome integrity, and epigenetic inheritance
New Zealand	CRISPR/Cas is being employed for genome editing in research, however there is no clear indication of its employment in particular crops		

One purpose for which genome editing could be used is to develop insect-resistant and herbicide-tolerant plants (Lombardo, Coppola and Zelasco, 2015). However, no products based on genome editing have reached the market in the Asia-Pacific region, and hence it is too early to assess the commercial impact of this technology.

3.1.9 Categorization of countries in terms of use of biotechnology applications in the crop sector

The classification of countries according to their use of biotechnology applications in the crop sector is shown in Table 3.9.

Among the ‘Very low use’ category, most countries have not adopted even simple applications such as biofertilizers and biopesticides.

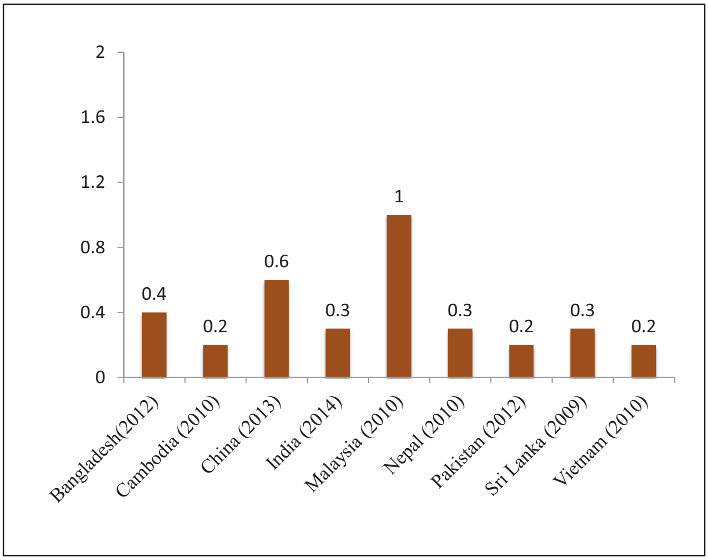
Among the ‘Low use’ countries, adoption of biotechnologies is very limited. However, this does not mean that they have no potential for expanded adoption. For example, although adoption of biotechnologies in Cambodia is currently very low, MAS in rice has a good potential, and the country has benefited from a regional development programme in MAS for rice. However, to adopt such applications, these countries need greater capacities, better policies and a more enabling environment.

Countries in the ‘Medium use’ category show good potential for adoption and application of agricultural biotechnologies. For example, although Sri Lanka has not adopted GM crops, it does have the potential to apply the technology, is making appropriate use of tissue culture and has adopted MAS. Similarly, Myanmar has increasingly adopted agricultural biotechnologies, and has approved growing of GM crops. Nepal has adopted many applications, and has potential to adopt GM crops.

Countries in the ‘High use’ category have adopted a wide range of applications and some of them have approved GM crops for cultivation or have allowed field trials with GM crops (e.g. Bangladesh and Pakistan). For example, Malaysia has adopted crop biotechnologies, has the potential to commercialize GM technology and has approved its adoption. Viet Nam has approved growing of GM crops and is also implementing MAS. Iran (Islamic Republic of) has adopted many applications, including genetic modification of crops and is working on genome editing, as is Pakistan.

‘Very high use’ category countries have the capacity to engage in R&D of high-level technologies and to apply them. In general, they have excellent capacity in biosciences and life sciences. For example, China has adopted low-, medium- and high-level technologies, while Australia, India, Japan, and the Republic of Korea have all adopted high-level technologies and are involved in R&D of emerging applications like genome editing. Singapore has adopted genome editing and, in general, has an excellent capacity in biotechnologies although, as an island state, it has little crop cultivation.

Figure 4.1. Public spending on agricultural biotechnology research and development as a share of agricultural GDP in selected countries in the Asia–Pacific region (percent)



Source: Agricultural Science and Technology Indicators (ASTI) Database, 2016

Table 3.9. Categorization of countries in the Asia–Pacific region in terms of application of biotechnologies in the crop sector

Category	Countries
Very low use	Afghanistan, Brunei Darussalam, Cook Islands, Kiribati, Democratic People's Republic of Korea, Maldives, Mongolia, Marshall Islands, Micronesia (Federated States of), Nauru, Niue, Palau, Samoa, Solomon Islands, Timor-Leste, Tonga, Tuvalu, Vanuatu
Low use	Bhutan, Cambodia, Lao People's Democratic Republic, Uzbekistan
Medium use	Fiji, Indonesia, Kazakhstan, Myanmar, Nepal, Sri Lanka,
High use	Bangladesh, Indonesia, Iran (Islamic Republic of), Malaysia, Pakistan, Philippines, Thailand, Viet Nam
Very high use	Australia, China, India, Japan, Republic of Korea, New Zealand, Singapore

4.1 Crops capacity

4.1.1 Introduction

Capacity for developing and applying agricultural biotechnologies is a key factor in realizing their potential in the crop sector. Capacity includes the capacity to develop applications, capacity to develop human resources, capacity to absorb technologies obtained/transferred from external sources, and capacity for successful commercialization. Even applying a low- level biotechnology requires some capacity.

Among the different components of capacity, the capacity to innovate is very important. Countries that have the capacity to innovate across a range of technologies are able to deploy them in appropriate context and to create a synergy, whereas a country that has limited capacity to innovate can only acquire ready-made technology and deploy it.

Whether a country is able to apply agricultural biotechnologies to meet needs of smallholder farmers depends, *inter alia*, on its capacity to innovate and adopt technologies to meet needs. Since the mid-1990s or so, when the biotechnology revolution in agriculture was taking shape, there has been debate on capacity and capacity building in agricultural biotechnologies, particularly on capacity to develop pro-poor biotechnology (Falconi, 1999; Byerlee and Fischer, 2000; FAO, 2004; Hall and Dijkman, 2006).

Traditional biotechnological applications, such as microbial fermentation, do not require much capacity. However, adoption of a complex set of biotechnologies requires competence in a wide range or areas, including bioinformatics, genomics and GE. For applications such as GM crops, investments in infrastructure, human resources and R&D become essential.

Spending on agricultural research have fluctuated in recent years and has shown marked declines in some countries (e.g. Lao People's Democratic Republic (Table 4.1). Malaysia allocates the largest share of investment to agricultural biotechnologies as a percentage of gross domestic product (Figure 4.1).

Table 4.1. Agricultural research spending by country in the Asia–Pacific region (excluding private for-profit sector), 2000–2014

	Total spending (million 2011 PPP dollars)						
Country	2000	2005	2010	2011	2012	2013	2014
Bangladesh	200.4	158	239	256.4	250.6	N/A	N/A
Cambodia	17.7	19.8	22.4	N/A	N/A	N/A	N/A
China	2614.9	3769.8	7887.5	7768.2	8918.9	9366.2	N/A
India	1927.9	2269.6	2880.5	3194.6	3473.2	3279.4	3360.3
Indonesia	579.6	914.7	1067.7	1182	1282	1585.2	1352.7

Table 4.1 continued...

...Table 4.1 continued

Lao People's Democratic Republic	37.2	21.4	16.2	14.5	12.8	8.8	8.8
Malaysia	91	117	101.6	78.6	83.7	87.9	86.5
Nepal	39.2	29.8	36.5	49.9	53.4	47.9	N/A
Pakistan	235.6	305	291.5	291	332.5	N/A	N/A
Sri Lanka	90.4	59.4	49.2	51.2	46.4	N/A	N/A
Thailand	327	278	439.5	354.4	390	423.6	N/A
Viet Nam	61.6	108.9	136	N/A	N/A	N/A	N/A

PPP – purchasing power parity

Source: Stads, Gert-Jan. 2016

4.1.2 Genetically modified crops

Thirteen of the 43 countries in the region (Australia, China, India, Iran (Islamic Republic of), Japan, Malaysia, Myanmar, New Zealand, Pakistan, the Philippines, the Republic of Korea, Singapore and Thailand) have the capacity to develop GM crops, but the number is likely to increase because countries such as Indonesia, Nepal and Sri Lanka are expected to start permitting or promoting GM crop cultivation in the next few years. On the other hand, the capacity to develop GM crops may be beyond the reach of many LDCs and island states in the region, except perhaps Fiji.

A survey on capacity to develop GM crops has shown that although the private sector is playing the dominant role, the public sector is also crucial. Monsanto and Syngenta and/or their associates are the dominant private-sector players in the region. Among the public-sector players, the Chinese Academy of Sciences (CAS), the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and universities and public institutions are key players.

Australia, China, India, Japan, Malaysia and the Republic of Korea have the greatest capacity to innovate in crop biotechnology, followed by Bangladesh, Iran (Islamic Republic of) and Pakistan, while Myanmar is making strides in crop biotechnology.

In large countries such as Australia, China and India, capacity to develop GM crops is distributed across public-sector institutions and in the private sector. However, in terms of crops and traits, Monsanto and Syngenta are the major players.

In China, the public sector developed *Bacillus thuringiensis* (*Bt*) cotton technology, and was able to compete with Monsanto because of regulations that initially favoured the public sector. However, Monsanto has since emerged as a key player (Linton and Torsekar, 2009). In contrast, in India, Monsanto had the monopoly on *Bt* cotton, although *Bt* cotton developed using technology from the Indian Institute of Technology, Khargapur, was also authorized for release. However, because the Indian Council of Agricultural Research (ICAR) was not able to develop and commercialize *Bt* cotton, and in the absence of an effective competition, Monsanto became the *de facto* lead player in *Bt* cotton commercialization. Indian public-sector bodies have since developed GM mustard and GM chickpea, although the former is yet to be approved for commercial cultivation. The involvement of different agencies such as the ICAR Department of Biotechnology (DBT) and many agricultural universities has created GM capacity in the public sector in India but the public sector has not been able to take advantage of this because of the strength of the private sector in the seed and crop sector.

Iran (Islamic Republic of) has built significant capacity to develop GM crops, with 46 research institutes (Table 4.2) and 42 universities active in biotechnology. Iran (Islamic Republic of) is also one of the few countries engaged in GM rice research.

Table 4.2. Number of academic and non-academic centres of biotechnology in Iran (Islamic Republic of)

Field	Academic	Non-academic	Total
Agriculture and natural resources	11	8	19
Medicine	9	3	12
Pure science	6	2	8
Industry and environment	3	4	7
Total	29	17	46

Source: Authors' compilation based on country survey

Pakistan has more than 10 public-sector institutions involved in crop biotechnology R&D. In 2014, investment in biotechnology R&D was about $40 million.

In Myanmar, the public sector plays the lead role in developing GM crops. The country has only one agricultural university (Yezin Agricultural University), which is the key centre for biotechnology in the country and has developed two *Bt* cotton varieties that have been registered with the

National Seed Committee (OECD, 2014). Although the private sector does not seem to be involved directly in crop development in Myanmar at present, collaborations with the private sector are being developed (ISAAA, 2016).

However, capacity does not translate directly into commercialization of products, particularly GM crops. For example, despite considerable capacity for R&D of GM rice in the region and the progress made in developing GM cultivars, GM rice is nowhere near commercialization on account of factors such as hold-ups in regulatory approval and opposition from civil society.

To sum up, 13 countries in the region have the capacity to develop GM crops, and more are developing the capacity. The private sector is the key player in GM crop development, but the public sector is also significant.

4.1.3 Biofertilizers, biopesticides and tissue culture

Capacity in these three applications is more widespread in the Asia-Pacific than that is that for development of GM crops, as these are relatively low-level technologies. However, lack of capacity is still the major constraint in applying these biotechnologies. While public-sector capacity is well developed in larger countries such as Australia, China and India, and Nepal and Sri Lanka have universities and research centres that have some capacity, the limited market potential of these low-level technologies in many countries may not attract larger players in the private sector to invest or introduce better products. The unevenness in public- sector capacity across the region is also a matter of concern.

4.1.4 Genome mapping and editing

Seven countries in the Asia-Pacific region have the capacity to harness genome editing and genome mapping – Australia, China, India, Japan, New Zealand, Republic of Korea and Singapore. China (through CAS) is one of a few countries in the world to hold patents for this technology. The capacity for these technologies in China has been facilitated by investments in institutes such as the Beijing Genomics Institute and the expertise gained in sequencing genomes. The cost of genome sequencing in China is considerably less than in the United States, and this enables China to use genomics in health and other biotechnology applications. India, Japan, Malaysia and the Republic of Korea also have capacity in these applications. Capacity in genome editing is not the same as that in genome mapping; many countries have capacity in both.

At present, most capacity seems to be in conduct of experimental studies and selected applications in various crops. As no product has been commercialized, it is difficult to assess potential and limitations of current capacity. Another issue is that as genome editing employs a wide range of technologies, capacity to apply one of the technologies does not ensure that the capacity to use all of them is available. There are also legal and ethical barriers to the use of genome editing, although they do not apply to crop-related experimentation or R&D.

To conclude, genome mapping and editing are yet to be established fully as reliable technologies that can deliver exceptional outcomes in crop biotechnology. The potential seems to be immense but so are the uncertainties and other issues such as regulation. Thus, it is reasonable to assume that capacity now available may be constrained by other factors in terms of delivery of applications. Given the 'patent wars' in this technology, as exemplified by claims and counterclaims regarding CRISPR by the University of California, the Broad Institute and others (see, for example, Servick, 2018), it is still not clear to what extent intellectual property rights will be a factor in the application of these technologies.

4.1.5 Marker-assisted selection and molecular breeding

The capacity to apply marker-assisted selection (MAS) across crops is available in many countries, and it is more widespread than the capacity for GM crops or genome editing. Because this is a technology that is non-controversial and can supplement traditional plant breeding, it is an ideal application for countries having strong capacity in plant breeding and in genomics. Nevertheless, the potential of the technology is not used fully in the region. One suggestion is that countries should collaborate in MAS and form crop-specific collaborative projects (Schalfleitner and Karihaloo, 2013).

4.1.5 Publications, impact factor, patents and research collaboration

Publications, patents and research collaborations are indicators of capacity. Table 4.3 gives an overview of the share of the region in global publications and research collaborations related to agricultural biotechnologies.

Table 4.3. Publications related to agricultural biotechnologies by country in the Asia–Pacific region

Country	**Peer-reviewed publication output**	**CAGR (publication output)**	**Percentage of publications from international collaboration**
Asia			
Afghanistan	9	N/A	100
Bangladesh	629	13%	87
Bhutan	10	N/A	100
Brunei Darussalam	16	16%	100
Cambodia	128	14%	98
China	78 263	20%	28
India	24 081	13%	22
Indonesia	629	9%	91
Iran (Islamic Republic of)	6 015	25%	25
Japan*	N/A	N/A	N/A
Kazakhstan	98	30%	91
Democratic People’s Republic of Korea	12	N/A	92
Republic of Korea*	N/A	N/A	N/A
Lao People’s Democratic Republic	41	10%	93
Malaysia	2 645	21%	45
Maldives	3	0%	100
Mongolia	58	27%	100
Myanmar	32	0%	94
Nepal	210	11%	93
Pakistan	2 968	22%	37
Philippines	609	11%	81
Singapore*	N/A	N/A	N/A
Sri Lanka	160	10%	74
Thailand	3 802	10%	60
Timor-Leste	N/A	N/A	N/A

Table 4.3 continued...

...Table 4.3 continued

Uzbekistan	71	12%	75
Viet Nam	729	13%	92
Pacific			
Australia*	N/A	N/A	N/A
Cook Islands	N/A	N/A	N/A
Fiji	20	N/A	100
Kiribati	N/A	N/A	N/A
Marshall Islands	N/A	N/A	N/A
Micronesia (Federated States of)	2	N/A	100
Nauru	N/A	N/A	N/A
New Zealand*	N/A	N/A	N/A
Niue	N/A	N/A	N/A
Palau	2	0	100
Papua New Guinea	116	12%	97
Samoa	5	N/A	100
Solomon Islands	1	N/A	100
Tonga	N/A	N/A	N/A
Tuvalu	N/A	N/A	N/A
Vanuatu	5	N/A	80

CAGR – compound annual growth rate

N/A – not available

* These countries were not covered as the study was restricted to developing countries

Source: CAS-TWAS and Clarivate Analytics (2016)

Although these do not relate to crop biotechnology *per se*, they indicate that the region has significant capacity in the sector, although this is concentrated in only a few countries. Most large-scale science projects are now exercises in collaboration.

Many countries in the region are stepping up their spending in science and technology. For example, Uzbekistan is boosting investments in science and technology, and has ambitious plans to transform itself into an innovation economy. These developments will need to be closely monitored to determine their impact on capacity in biotechnology.

4.1.6 Human resources

Table 4.4 provides estimates of numbers of people involved in the agricultural biotechnology sector in the Asia-Pacific region, compiled from a number of data sources. However, these data come with several caveats. Even OECD does not have recent data on human resources engaged in the biotechnology sector. The data on students and faculty in institutions are often incomplete or not properly segregated. For countries not listed the data available are old or are not from credible sources or have issues with quality.

Table 4.4. Human resources in biotechnology by country

Country	Employment	Education/R&D
Australia	14664 as of January 2017	
Brunei Darussalam	N/A	More than 200 (2015)
China	N/A	More than 1.5 million (2010)
India	N/A	Nearly 71 universities imparting biotech related courses*
Indonesia		Masters 1347 LS, 25 A&V† PhD 410†
Republic of Korea	N/A	Masters 2002 LS, 977 A&V† PhD 902 LS, 299 A&V†
New Zealand		In 2011, 474 organizations were involved in biotechnology in some way. The industry employed 1 900 people in 2011, with 57 percent having a bachelor's degree or higher
Pakistan	N/A	More than 15 institutions involved in Biotechnology, with approximately 3500 students enrolled in PhD and MSc/ MTech courses (2014)
Sri Lanka	As of 2014: Total: 576 Universities: 221 Research: 61 Other: 294	
Thailand	N/A	24 universities across the country have the combined capacity to train approximately 7 000 students in biotechnology-related subjects (2015)

LS – Life sciences; A&V – Agriculture and veterinary.

***Source**s*: From various sources including * DBT (2018), † OECD and data compiled for country reports

4.1.7 Issues regarding capacity in crop biotechnology

The response to the questionnaire from FAO identifies lack of funds and lack of infrastructure as the major constraints in the capacity to develop and apply crop biotechnology in most countries surveyed. However, there are other emerging issues that require attention include:

1) the widening gap between countries and regions and across technologies;

2) underutilization of capacity in technologies such as biofertilizers and GM crops because of regulatory constraints and policies;

3) the inability to leverage public-sector capacity to develop and commercialize products; and

4) the overall capacity to apply and benefit from S&T.

These need to be examined on a country-by-country basis to determine what action is required to build the region's capacity in biotechnology and how FAO can best contribute.

4.1.8 Categorization of countries in terms of capacity

The classification of countries in terms of their capacity to develop and utilize biotechnology applications in the crops sector is shown in Table 4.5.

Table 4.5. Categorization of countries in the Asia–Pacific region in terms of capacity to develop and apply biotechnology in the crop sector

Category	Countries
Very low capacity	Afghanistan, Brunei Darussalam, Cook Islands, Kiribati, Democratic People's Republic of Korea, Maldives. Mongolia, Marshall Islands, Micronesia (Federated States of), Nauru, Niue, Palau, Samoa, Solomon Islands, Timor-Leste, Tonga, Tuvalu, Vanuatu
Low capacity	Bhutan, Cambodia, Lao People's Democratic Republic, Uzbekistan
Medium capacity	Fiji, Indonesia, Kazakhstan, Myanmar, Nepal, Sri Lanka
High capacity	Bangladesh, Indonesia, Iran (Islamic Republic of), Malaysia, Pakistan, Philippines, Thailand, Viet Nam,
Very high capacity	Australia, China, India, Japan, Republic of Korea, New Zealand, Singapore

Countries in the 'Very low capacity' category lack human resource, have weak educational and R&D infrastructure and have very limited public-sector involvement in crop biotechnology. Although some of them work with regional institutions and participate in collaboration, their scope is limited because they do not have a strong national research and innovation system in agriculture and they have been users/adopters of technologies rather than innovators. Moreover, capacity in agricultural training is limited.

Countries in the 'Low capacity' category also lack adequate human resources, do not have strong public-sector engagement in crop biotechnology and have little or no involvement of the private sector in crop biotechnology. They do benefit from international collaboration and networks but their engagement in them is more as recipients than contributors to the scientific research.

Countries in the 'Medium capacity' category have reasonably good capacity in terms of human resources, have a strong public-sector capacity in crop biotechnology, actively participate in regional networks and collaborate with institutes such as the CGIAR centres. They also have a vibrant private sector active in crop technologies or applications such as tissue culture and biofertilizers. Their national innovation system in agriculture has a good capacity in biotechnology.

Countries in the 'High capacity' category have good capacity in terms of human resources and have public and private sectors active in crop technologies, ranging from developing new varieties to R&D in crop biotechnology, backed by favourable policies. These countries have benefited from international collaboration, and are active in international research projects. Some of them benefit from being members of regional groups, such as ASEAN, that promote biotechnology.

Countries in the 'Very high capacity' category have excellent capacity in terms of educational institutions, giving training and conducting R&D, and have a strong national innovation system in agriculture with significant capacity in crop biotechnology. Their public and private sectors are strong in R&D, with capability to turn outcomes of R&D into products and services for wider adoption. They benefit from international collaboration and are contributors to global research networks. They are leaders in agricultural biotechnology in the region, with continuing emphasis on enhancement of their capacity.

5.1. Crops Enabling Environment

5.1.1 GM crops

The enabling environment for GM crops is positive across the region, and in recent years has become attractive. Bangladesh, Myanmar and Viet Nam have seen particular improvements in their enabling environments. Countries like Thailand that have not permitted commercial cultivation of GM crops have created an environment that enables trade and consumption of GM crops. Many countries in the region have been able overcome the issue of trade and standards emerging as a barrier to trade in GM food, although the global situation is complex.

Resistance or objections to cultivation of GM crops has been vociferous in some countries, resulting in moratoriums and similar measures, such as delaying permission to cultivate GM crops, but these have not deterred R&D or plans to promote GM crops. Private-sector investment in GM crops is significant across the region except in a few countries, such as Iran (Islamic Republic of). The fact that multinational corporations are willing to become visible in the region through joint ventures, licensing agreements and undertaking R&D is proof that the enabling environment is conducive. However, issues such as low yield in GM crops, lack of access to seeds and concerns about safety of GM food may impact negatively on the enabling environment.

One way to assess the enabling environment is to examine whether R&D and commercialization of GM crops is established or increasing. Tables 3.1 to 3.8 (Tables 3.2, 3.3 and 3.7) show an increasing number of trials, crops and traits in many countries in the region, indicating a conducive enabling environment, although not all the trials result in approval for cultivation. Given the huge investments in the R&D and infrastructure, it is likely that the enabling environment that has been created will continue to flourish unless there is a disruption such as a major backlash against GM crops or abrupt changes in policies.

Despite a favourable enabling environment, the region has not produced many GM varieties of crops that meet the specific needs of smallholders and that are suitable for climate-change mitigation/adoption. Developing such varieties may need an initiative similar to the Water Efficient Maize for Africa initiative (see https://wema.aatf-africa.org/). However, given the diversity in needs, including country-specific needs, a better solution might be to replicate the Green Revolution model in a mission mode wherein CGIAR institutes work with national-level institutions and state-level institutions such as state agricultural universities.

Such initiatives would create a more favourable response to GM crops from smallholders, the key stakeholder of the agriculture in the region.

5.1.2 Biofertilizers, biopesticides and tissue culture

The enabling environment for biofertilizers, biopesticides and tissue culture is broadly positive. The issue here is more of capacity and regulation than of policies as such.

Regulations in some countries are not conducive for the development of biopesticides, while in the case of biofertilizers the primary constraint is underutilization of capacity because of lack of adequate attention in policy. Thus, the current enabling environment for these needs to be examined and adjusted to be more conducive to innovation to make these applications more suitable for smallholders.

5.1.3 Marker-assisted breeding and molecular breeding

The enabling environment for both marker-assisted breeding and molecular breeding is positive and improving as more countries adopt these applications. Here the issue is more a matter of lack of capacity and the need to identify the right solution rather than policy *per se*. Collaboration, particularly at the regional level, could strengthen the current enabling environment.

5.1.4 Genome editing and genome mapping

Genome editing and genome mapping are emerging technologies and not all countries have competence in them. The enabling environment is positive in those countries that do have competence. However, these technologies have raised many ethical and moral issues, such as such as whether to regulate their products as GMOs or as non-GMOs. As such, maintaining a positive enabling environment requires that these issues be addressed, particularly the ethical and regulatory concerns.

For example, if Europe decides to treat genome-edited cultivars as GMOs and the United States opts to treat them as non-GMOs, this will affect trade and cultivation and hence the enabling environment in the region. In the case of genome mapping in crops and plant genetic resources, the enabling environment is positive but the Nagoya Protocol on Access and Benefit Sharing must be taken into account if the mapping involves access and benefit-sharing.

Labelling of GM foods and products has not been a major issue in the region, and most countries do not have norms mandating labelling and/or segregation of GM and non-GM produce and processed food. Although there have been a few instances of mixing of GM and non-GM produce/ food, these have not disrupted overall trade and consumption.

Despite the positive enabling environment, there seem to be no plans at present in the region to use these technologies for developing varieties to benefit smallholders; even applications regarding climate change do not appear to be a priority.

5.1.5 Biosafety regulation in crop biotechnology

Most countries in the region are Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, the major international convention relevant for crop biotechnology. As a result of efforts of the United Nations Development Programme (UNDP) and the UNEP Global Environment Facility (GEF) in capacity-building programmes and regional programmes on biosafety, most countries in the region have biosafety guidelines, rules and regulations, even in the absence of any biotechnology activity. OECD guidelines and documents have also played an important role in shaping the biosafety regulatory framework in the region, as have the United Nations Industrial Development Organization (UNIDO), FAO, UNEP and others, such as the International Centre for Genetic Engineering and Biotechnology. This has ensured that frameworks are compatible with global norms.

Some countries have comprehensive legislations while many have guidelines and rules. As most of the countries are Parties to the WTO Agreements, the TBT/SPS Agreements are binding. This means that countries cannot arbitrarily use national standards. Thus, biosafety regimes are part of the enabling environment in the region and they add credibility and acceptability to biotechnology policies.

Most countries in the Asia-Pacific region have functional regulatory frameworks for crop biotechnologies, and have specific laws and rules covering field trials, commercialization and post-approval follow ups (Table 5.1). These laws and frameworks have been devised taking into account specific needs and technological developments.

Table 5.1. Overview of biotechnology regulation in the Asia–Pacific region

Country	CPB member	Regulation	Labelling	Biosafety rules and institution(s)
Australia	Non-party	Process-based	Mandatory labelling based on product content (1% threshold)	Office of the Gene Technology Regulator
China	Party (2005)	Process-based	Mandatory for 17 products from corn, soybean, cotton, canola and tomato	National Biosafety Committee of China
India	Party (2003)	Process-based	No mandatory labelling	Genetic Engineering Appraisal Committee
Indonesia	Party (2005)	Process-based	Mandatory for packaged foods; introduced but not implemented (5% threshold)	National Biosafety Commission on Genetically Engineered Products
Japan	Party (2004)	Process-based	Mandatory labelling based on product content (5% threshold)	Ministry of Agriculture, Forestry and Fishery and Ministry of Environment
Republic of Korea	Party (2008)	Process-based	Mandatory labelling based on product content (3% threshold)	Korea Biosafety Clearing House
Malaysia	Party (2003)	Process-based	Mandatory labelling based on product content (3% threshold)	National Biosafety Board
New Zealand	Party (2005)	Process-based	Mandatory labelling based on product content (1% threshold)	Environmental Protection Agency
Pakistan	Party (2009)	Process-based	No legislation on labelling	National Biosafety Committee of Pakistan
Philippines	Party (2007)	Product-based	No labelling policy in place	National Committee on Biosafety of the Philippines
Singapore	Non-party	Process-based	No labelling policy in place	Genetic Modification Advisory Committee

Table 5.1 continued...

...Table 5.1 continued

Thailand	Party (2006)	Process-based	Mandatory labelling for corn and soybean products based on product content (5% threshold)	National Biosafety Committee
Viet Nam	Party (2004)	Process-based	Mandatory; introduced but not implemented (5% threshold)	Ministry of Natural Resources and Environment

CPB – Cartagena Protocol on Biosafety

Source: Gain (2016a, 2016b, 2016c), APCTT (2011), Biosafety clearing house (2016) and country papers prepared for this review

There have been criticisms about regulatory regimes in a few countries. In future, the challenges could come from new technologies, such as gene drives and genome-edited crops. In many countries, regulation is entrusted to an agency or ministry. Current capacity seems to be adequate for GM crops in the pipeline, as they are based on genetic modification technology.

5.1.6 Intellectual property rights and incentives for innovation

There is no uniformity in intellectual property protection for plant varieties, even among members of ASEAN (Table 5.2).

Table 5.2. Law governing intellectual property rights in ASEAN countries

Countries	**Year Joined WIPO**	**Year Joined WTO-TRIPs**	**Latest version of IPR laws**			
			Patent	***Copyright***	***Trademark***	***Plant variety protection***
Cambodia	1995	2004	2003	2003	2002	-
Indonesia	1979	1995	2001	2014	2001	2000
Lao People's Democratic Republic	1995	2013	2011	2011	2011	-
Malaysia	1989	1995	2006	2006	2002	2004
Myanmar	2001	1995	1946	1911	1989	-
Philippines	1980	1995	1998	2013	1998	2002
Thailand	1989	1995	1999	2015	2000	1999
Viet Nam	1976	2007	2009	2009	2009	2004

ASEAN – Association of Southeast Asian Nations

IPR – intellectual property rights

WIPO – World Intellectual Property Organization

WTO-TRIPS – World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights

Source: OECD (2017)

In crop biotechnology, the most relevant intellectual property protection modes are patents and plant variety protection. However, not all countries in the region provide for both patents and plant variety protection.

As most countries in the region are members of the WTO, implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is mandatory. Some countries have opted for TRIPS Plus norms on account of bilateral trade agreements and other factors.

With the exception of India, all major countries in the region with high capacity for R&D in crop biotechnology (Australia, China, Japan, New Zealand, the Republic of Korea, Singapore and Viet Nam) are also members of the International Union for the Protection of New Varieties of Plants (UPOV) (UPOV, 2017). Some members of UPOV offer both patent and plant variety protection but countries that are party to the 1978 Act of UPOV need not.

Many other countries, including India, Indonesia, Malaysia and Thailand, are not the members of the UPOV. They do, however, have plant variety protection laws and regulate seed trade. Although many have not joined UPOV, as Parties to TRIPS countries have to provide for IP protection for plant varieties. India, for example, opted for a *sui generis* system for plant variety protection and farmers' rights (Kanniah and Antons, 2017). Eleven countries are discussing with UPOV the development of national laws based on the UPOV convention or have initiated the process of acceding to the UPOV convention (UPOV, 2017). However, this does not mean that they will join UPOV or change their laws to adhere to the UPOV.

For countries with little innovative capacity, joining UPOV is more a symbolic gesture, indicating their willingness to provide plant variety protection similar to that offered in developed countries. For example, Myanmar and Viet Nam have revamped their national laws on the plant variety protection and seeds. Such changes are gradually transforming intellectual property (IP) landscape in the region.

Given that many countries have legislation that protects plant varieties, the intellectual property rights scenario is positive and contributes to enhancing the enabling environment. In some jurisdictions (e.g. India), patenting of plant varieties, seeds and life forms *per se* is prohibited, explicitly or otherwise. However, for genetically modified microorganisms, which are used in biotechnology applications, patent protection is available in many countries, including China, India and Japan. This is an important incentive for production of biopesticides and biofertilizers.

Translating R&D to a commercial product is fraught with risks such as failure to get clearance for cultivation/commercialization and obsolescence. Since IP rights are incentives for innovation, many multinational corporations consider the status of such rights in their decision-making. Given the shift from the public sector to the private sector in crop biotechnology, IP rights have a crucial role in ensuring that the enabling environment is conducive for R&D and commercialization. However, some people claim that strong IP rights create constraints to access and make seeds of GM crops unaffordable. Despite such controversies, governments have continued to support the development of agricultural biotechnologies.

What is remarkable is that many countries have started considering incentivizing innovation in addition to providing for IP protection. These incentives are provided in many ways, ranging from tax concessions, incentives to commercialize products and special schemes to promote start-ups, to schemes to encourage techno-entrepreneurship, acquisition of technology and incentives to commercialize/scale up (OECD, 2017). Although the OECD publication lists only developments in Southeast Asia, the proliferation of incentives to innovate is found across the region. Some countries have set up agencies to promote innovations in biotechnology, such as the Biotechnology Industry Research Assistance Council in India.

To sum up, the availability of IP protection and incentives in many countries in the region has contributed to developing a positive enabling environment for crop biotechnology.

5.1.7 Policy and strategy in developing the enabling environment

Eleven countries in the Asia-Pacific region have explicit policies or strategies on biotechnology, but in many countries, agricultural biotechnology is a part of the national developmental strategies in agriculture, and many countries in the region have policies with specific objectives in agriculture (OECD, 2017).While China promotes biotechnology through special programmes, India offers a range of programmes and policies ranging from incentives to R&D to support for start-ups through the Department of Biotechnology and institutions/entities promoted by it. Malaysia promotes biotechnology through the Malaysian Biotechnology Corporation, which was set up by the government, and many programmes. Singapore's focus on life sciences and health technology has created a policy environment to attract investment, human resources and research. Thailand has a national strategy on biotechnology that identifies sectors that need focus, and the Republic of Korea is promoting biotechnology through policies and strategies.

Small countries cannot afford such grand-scale initiatives and have used traditional tools of policymaking and promotional strategies. The rapid growth of agricultural biotechnologies in the region is proof that these policies and strategies have worked, but the performance has been uneven.

To develop workable strategies and execute a plan requires capacity and investment. While there are lessons that can be learned from case studies of successes in policy and strategy, the diversity in size of economies, capacities and needs demands diversity in policy frameworks and strategies. Supporting this will require an in-depth analysis of existing policies and their performance.

To sum up, countries in the region have adopted various approaches to promoting biotechnology, and the enabling environment is largely positive. However, it is less so in most

LDCs because either they lack policies or their underdeveloped national innovation systems act as a constraint.

5.1.8 Collaborations and capacity building

Collaborations and capacity building have an important role in creating an enabling environment, particularly in small countries where capacity is limited. This study shows that collaborations are crucial for several countries but there are few collaborations or crop-specific projects across countries or the regions. Moreover, there are few examples of the private sector actively partnering with the public sector to meet the needs of the small-scale farmers. However, precise information on collaborations and cooperation across institutions is difficult to access.

Capacity-building initiatives have worked well in biosafety and in regulatory capacity, but many of these were part of projects that ended a long time ago. In the absence of further capacity building, many guidelines and regulations are old. In addition, capacity building in biosafety has not been of much benefit in countries that do not have any significant capacity in biotechnology or R&D. Nevertheless, collaborations and capacity building in the region will continue to be important for an effective enabling environment.

5.1.9. Categorization of countries in terms of enabling environment

The classification of countries in terms of their enabling environment for development and utilization of biotechnology applications in the crops sector is shown in Table 5.3.

Table 5.3. Categorization of countries in the Asia–Pacific region in terms of enabling environment for developing and applying agricultural biotechnologies in the crop sector

Category	**Countries**	**Remarks**
Low	Afghanistan, Brunei Darussalam, Cook Islands, Kiribati, Democratic People's Republic of Korea, Maldives. Marshall Islands, Micronesia (Federated States of), Mongolia, Nauru, Niue, Palau, Samoa, Solomon Islands, Timor-Leste, Tonga, Tuvalu, Vanuatu	Mostly LDCs/island states in the Pacific. Little or no activity in crop biotechnology.
Very low	Bhutan, Cambodia, Kazakhstan, Lao People's Democratic Republic, Uzbekistan	Need to develop and enhance enabling environments to harness crop biotechnology.
Medium	Fiji, Indonesia, Myanmar, Nepal, Sri Lanka,	Potential to move to next category if enabling environment is enhanced, but constraints such as lack of funding may limit progress.
High	Bangladesh, Indonesia, Iran (Islamic Republic of), Malaysia, Pakistan, Philippines, Thailand, Viet Nam	Have potential and have invested in enabling environment and made changes in policies. Should aim at identifying gaps in enabling environment to move to the 'Very high' category.
Very high	Australia, China, India, Japan, Republic of Korea, New Zealand, Singapore	Have excellent enabling environments backed by policies but will have to support the enabling environments on a sustained basis and make them more attractive to remain in the same position and to move ahead.

Guidelines for Contributors

1. ABDR is a refereed multi-disciplinary international journal. Manuscripts can be sent, preferably as email attachment, in MS-Word to the Managing Editor, Asian Biotechnology and Development Review, Research and Information System for Developing Countries (RIS), Core 4B 4th Floor, India Habitat Centre, Lodhi Road, New Delhi 110003, India (Email: ravisrinivas@ris.org.in; Tel. +91-11-24682177-80; Fax: +91-11-24682173/74). Submissions should contain institutional affiliation and complete mailing address of author(s). All submissions will be acknowledged on receipt.
2. Manuscripts should be prepared using double spacing. The text of manuscripts should not ordinarily exceed 7,000 words. Manuscripts should contain a 200 word abstract, and key words up to six.
3. Use 's' in '-ise' '-isation' words; e.g., 'civilise', 'organisation'. Use British spellings rather than American spellings. Thus, 'labour' not 'labor'.
4. Use figures (rather than word) for quantities and exact measurements including percentages (2 per cent, 3 km, 36 years old, etc.). In general descriptions, numbers below 10 should be spelt out in words. Use thousands, millions, billions, not lakhs and crores. Use fuller forms for numbers and dates— for example 1980-88, pp. 200-202 and pp. 178-84.
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References: A list of references cited in the paper and prepared as per the style specified below should be appended at the end of the paper. References must be typed in double space, and should be arranged in alphabetical order by the surname of the first author. In case more than one work by the same author(s) is cited, then arrange them chronologically by year of publication.

All references should be embedded in the text in the anthropological style–for example '(Hirschman 1961)' or '(Lakshman 1989:125)' (Note: Page numbers in the text are necessary only if the cited portion is a direct quote).

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The following examples illustrate the detailed style of referencing:

(a) Books:

Hirschman, A. O. 1961. *Strategy of Economic Development*. New Haven: Yale University Press.

(b) Edited volumes:

Shand, Ric (ed.). 1999. *Economic Liberalisation in South Asia.* Delhi: Macmillan.

(c) Articles from edited volumes:

Lakshman, W. D. 1989. "Lineages of Dependent Development: From State Control to the Open Economy in Sri Lanka" in Ponna Wignaraja and Akmal Hussain (eds) *The Challenge in South Asia: Development, Democracy and Regional Cooperation*, pp. 105-63. New Delhi: Sage.

(d) Articles from Journals:

Rao, M.G., K. P. Kalirajan and R. T. Shand. 1999. "Convergence of Income across Indian States: A Divergent View". *Economic and Political Weekly,* 34(13): pp. 769-78.

(e) Unpublished Work:

Sandee, H. 1995. "Innovations in Production". Unpublished Ph.D thesis. Amsterdam: Free University.

(f) Online Reference:

World Health Organisation. 2000. "Development of National Policy on Traditional Medicine". Retrieved on March 31, 2011 from http://www.wpro.who.int/sites/trm/documents/Development+of+National+Policy+on+Traditional+Medicine.htm

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Core IV-B, Fourth Floor
India Habitat Centre
Lodhi Road, New Delhi-110 003
Ph.: +91-11-24682177-80
Fax: +91-11-24682173-74
Email: dgoffice@ris.org.in
Website: www.ris.org.in