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Asia-Pacific Biotechnology Report 2010

Survey on Biotechnology Capacity in Asia-Pacific: Opportunities for National Initiatives and Regional Cooperation

Sachin Chaturvedi

Krishna Ravi Srinivas

A report prepared for UNESCO Office, Jakarta

RIS
Research and Information System for Developing Countries

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Executive Summary

Biotechnology in the Asia-Pacific is well established and is advancing to next stages. While the development is not even and the gap among countries is increasing, there are many positive trends. Strong support from the states has continued and such support in future is important. Agricultural biotechnology has become the most widespread application, industrial biotechnology and medical biotechnology are becoming important sectors in some countries. There are many positive factors that are in favor of strong and sustained growth of biotechnology in AP. These include economic growth in AP, well developed human resources, support from state, growing market, the increasing innovative capacity of industry, the emphasis on research in basic life sciences in some countries. On the other hand as not all countries are doing well in biotechnology development, sustaining the growth would need changes and course corrections in the policies and strategies. Besides this, regional, bilateral and multilateral initiatives in capacity building are essential for biotechnology to grow further in many countries that lack the indigenous capacity in many areas including regulating biotechnology.

The biotechnology industry has grown rapidly in the recent years and is diversifying into new areas. Some countries in AP are capable of harnessing the developments in post human genome mapping biology. They are adopting many strategies including developing biotechnology clusters, focusing on niche areas, enhancing human resources to become competitive in medical biotechnology. While the industry lags behind the biotechnology industry in USA or Europe, in terms of size and revenue, there is ample scope for countries and firms to identify sectors/niche areas and develop their capabilities and competitive advantages in them. Biotechnology can play an important role in socio-economic development. This is recognized by many countries but development of strategies to achieve this with specific goals in key sectors like health, agriculture are found wanting in most countries. Many countries have to strengthen their national innovation systems and enhance their capacity to translate research into products.

Biosafety is an area in which there is enormous scope for progress. Development of regulatory regimes in all countries that are using biotechnology is necessary partly to fulfill obligations under Cartagena Protocol, where it is applicable and partly to ensure that biotechnology regulation enhances credibility and acceptability of biotechnology.

To sum up biotechnology revolution in AP is well established by now and has entered the crucial phase now. It can grow further and sustain the momentum if the constraining factors are eliminated or minimized while the positive factors are supported further and necessary changes in policies and strategies are made. This report maps the contours and directions of biotechnology development in AP, identifies the strengths and weaknesses and suggests measures to be taken the governments, donors, multilateral and UN agencies and industry to ensure that the AP region benefits most from biotechnology.

Chapter 1: Asia-Pacific Economic Development and Emergence of Biotechnology

Introduction

The Asia-Pacific region (AP) has achieved remarkable economic success in last few decades. This has happened as AP has largely transformed itself to the technology-driven economic powerhouse with rapid adoption and diffusion of new technologies. Among these new technologies, biotechnology with its wide ranging applications in agriculture, health and industry, is considered as a major technology that can further economic and social development.

At a larger level, the effects of such revolutions have generally occurred in three main stages.[1] First, technological change often raises productivity growth in the innovating sectors; second, falling prices encourage capital deepening and, finally, there can be significant reorganization of production around the capital goods that embody the new technology. One of the important features of the biotechnology revolution has been the expansion of the biotechnology industry across the developed countries, particularly by transnational companies (TNCs) and market oriented penetration of new product and processes in the AP countries and other developing countries. The adoption of ICT has catalysed the diffusion of biotechnology. These countries have strengthened their strategies for commercialisation of biotechnology leading to a many fold growth in the AP biotechnology industry.[2]

In most of the AP economies the State has played a catalytic role in the adoption and development of the technology. Since most of the AP economies adopted the export led growth model, adoption of new standards and technology was duly rewarded through the various programmes of the governments. Hobday (1995) has shown how various economies followed specific educational and investment programmes to gain technological competence and not through the other established route of substantial government subsidies to promote 'leapfrogging" into high technology industry.

As we would see in the forthcoming chapters, AP is all set to make a major global impact in biotechnology. As the country reports would show, most of the AP economies have realised these pre-conditions for technology development. Accordingly in biotechnology sector, a similar trend is emerging with countries developing their strategies in which state plays an important role as a catalyst and facilitator and are also making use of cluster and regional innovation cluster models for fostering innovation.[3] Many economies within AP are pursuing a pro-active strategy for development and adoption of biotechnology.[4] Several developing countries in AP, including Peoples Republic of China, Singapore, India, Indonesia, Malaysia, Philippines and Thailand have begun to invest heavily in biotechnology.[5] They are closely following the OECD members in AP, viz. Japan and South Korea in terms of investments and allocations. In some countries the second and third generation biotechnology is in place and these countries are part of the global biotechnology revolution.

However, most of the AP countries are assessing potential advantages with biotechnology and its impact on the trade and economy and this technology is capital-intensive and requires many pre-conditions for its development. This is a major challenge with most of the economies in the region. Since biotechnology development is more with-in the private sector, it is highly proprietary in nature.[6] The evolution of harmonized intellectual property rights regime, through the WTO, has further intensified the magnitude of challenges that these economies are facing.[7] This has further constrained the space available to the developing countries for relevant policy formulations.

The dilemma is on allocation of scarce physical and financial resources between overall developmental goals verses R&D for innovation and adoption of technologies. Further, the challenges range from the growth prospects of the industry to a stronger regime of intellectual property protection. Food insecurity, malnutrition, communicable and non-communicable diseases are major problems, which need immediate attention. At another level, questions are being asked about the long-term implications of genetic engineering on the environment, in other words the biosafety issues.[8]

1.1 Economic Growth in Asia-Pacific

The Asia-Pacific region (AP) has established itself as a major source for global economic development. As is clear from the Table 1.1, members from ASEAN, China, India and others from South Asia have consistently shown high growth rates which are very different from the OECD members based in Asia and Pacific. China with consistently high GDP growth rate from 8.4 per cent to 10 per cent in 2003 and 13 per cent in 2007 has almost amazed everyone. In 2008, China exhibited a growth rate of 9 per cent. Similarly, India with 4.4 per cent in 2000 has reached 9.6 per cent in 2006, and 7.1 per cent in 2008. Most of the ASEAN members like Cambodia, Indonesia, Malaysia, Philippines and Vietnam have also shown high growth rates. In case of Lao PDR, the growth rate has gone up from 5.8 per cent in 2000 to 8.3 per cent in 2006 and 7.5 per cent in 2008. Similarly, Indonesia has gone up for the same period from 4.9 per cent to 5.5 per cent and 6.1 per cent in 2008. This sharp growth in the region has provided strength in terms of prudent fiscal policies and ambitious social expenditure policies. One of the positive features of this growth rate is the fact that it has bolstered the magnificence in the domestic demand. This may provide well needed boost to the internal expansion and thus may sustain the growth process on its own.

Sustenance in adverse circumstances in the AP economies shows their great resilience and potential to be anchors for global economic growth, particularly India and China both are likely to play this important role. Their continuous growth may provide a stabilisation role in their respective sub-regions. India which grew at 9 per cent in 2007 ended with 7.1 per cent growth in 2008 and is likely to be close to 6 per cent in 2010, despite of more than 30 per cent shrinkage in the export market.[9] Similarly, China was at 13 per cent in 2007 and 9 per cent in 2008. It is expected to have GDP growth rate 8.4 per cent in 2010.

In the South Asian region, Bangladesh, Pakistan and Sri Lanka all achieved GDP growth of about 6 per cent in 2008. Only exception in this region was F, which due to several internal challenges could end up only with 5.6 per cent in 2008.

Among the South-east Asian countries, the rate of GDP growth dropped from 6.5 per cent in 2007 to 4.3 per cent in 2008.[10] In this sub-region, the countries that relied heavily on manufacturing exports to the developed countries were the worst affected ones. They included Cambodia, the Philippines and Singapore. In case of Singapore, the slow down was the most severe as the GDP growth rate declined from 7.7 per cent in 2007 to 1.2 per cent in 2008. This region also had a major gain due to continuously high commodity prices. The beneficiaries included Malaysia, Lao PDR, Indonesia and to some extent Vietnam. These economies have also been adversely affected with high food and fuel prices, tighter international credit conditions and weaker foreign demand.

According to IMF (2009) Australia and New Zealand will see negative output growth but are expected to return to positive growth towards the end of the next year with their strong policy response to financial sector and exchange rate depreciation. Similarly, South Korea and Japan are also likely to rebound only by middle or end of 2010.[11]

Table 1.1: Real GDP Growth Rates Across AP Economies

Countries	2000	2001	2002	2003	2004	2005	2006	2007	2008
China	8.4	8.3	9.1	10	10.1	10.4	11.6	13	9
Republic of Korea	8.5	3.8	7	3.1	4.7	4.2	5.1	5	2.5
Bangladesh	5.9	5.3	4.4	5.3	6.3	6	6.6	6.4	6.2
Bhutan	7.2	6.8	10.9	7.2	6.8	7.1	8.5	21.4	5
India	4.4	5.8	3.8	8.5	7.5	9.4	9.6	9	7.1
Nepal	5.9	4.7	0.2	3.8	4.4	2.9	4.1	2.6	5.6
Pakistan	3.9	2	3.1	4.7	7.5	9	5.8	6.8	5.8
Sri Lanka	6.1	-1.5	4	5.9	5.4	6.2	7.7	6.8	6
Cambodia	8.4	7.7	7	8.5	10.3	13.3	10.8	10.2	7
Indonesia	4.9	3.8	4.3	4.8	5	5.7	5.5	6.3	6.1
Lao PDR	5.8	5.7	5.9	5.8	6.9	7.3	8.3	7.9	7.5
Malaysia	8.9	0.5	5.4	5.8	6.8	5.3	5.8	6.3	5.4
Philippines	4.4	1.8	4.5	4.9	6.4	5	5.4	7.2	4.6
Singapore	10.1	-2.4	4.2	3.5	9	7.3	8.2	7.7	1.2
Thailand	4.8	2.2	5.3	7.1	6.3	4.5	5.1	4.9	2.6
Viet Nam	6.8	6.9	7.1	7.3	7.8	8.4	8.2	8.5	6.2
Australia	3.4	2.1	4.2	3	3.8	2.8	2.7	4.2	2.4
Japan	2.9	0.2	0.3	1.4	2.7	1.9	2	2.4	-0.7
New Zealand	3.8	2.4	4.7	4.4	4.4	2.7	2.7	3	-0.8

Source: UN ESCAP (2009).

However, specific measures taken by several AP countries in terms of providing fiscal stimulus for supplementing private sector efforts for economic revival are being looked at with great hope. Singapore has provided almost $14 billion, Indonesia ($ 6.1 billion), Philippines ($ 6.5 billion), Thailand ($ 3.3 billion), Malaysia ($ 2 billion) and Vietnam ($ 1 billion).[12] China leads the AP economies with a stimulus package of $ 584 billion while South Korea has provided fiscal stimulus of equivalent to around 4 per cent of its GDP. The AP economies may also have to grapple with decline in private capital inflows, which have played an important role in expansion of frontier technologies in the region.

Net private capital inflows are expected to become negative in 2009, driven by sharp retrenchments in bank lending and portfolio flows through even more resilient foreign direct investment (FDI) flows.[13]

However, despite this major economic expansion the Asia Pacific region is home to a major portion of the poor in the world and some countries rank at the bottom of the Human Development Index. In terms of the indicators like Maternal Mortality Index (MMI), Infant Mortality Index (IMI) some countries are at par with sub-Saharan Africa. Any technology policy endeavours, and for that biotechnology policies cannot be divorced from the developmental needs and aspirations of the millions who live in the region.

Biotechnology is needed and should be given priority not just because it is a cutting edge technology but because it can be part of the broader development strategy and can help countries in achieving developmental objectives. Although this is obvious, linking biotechnology with developmental goals and measuring its impacts or contributions are not easy. There are conceptual and methodological issues and there are also issues of technological choices and alternative options to achieve the same objective. The developments in Asia Pacific indicate that the linkages are not clear and often claims are contested.

Since biotechnology program objectives need to be very clear, the developing countries might even have to plan for manpower with super-specialization to attend the high priority areas defined by the relevant public policy. An attempt is being made in Table 1.2 to capture these different attributes in one matrix to determine the position and direction of biotechnology policy in different countries. This is specifically attempted for agricultural sector but may be extended to others with change in biotechnology attributes and policy targets[14]. The factors determining economic cost would largely remain the same. The matrix consists of the major crops in a given developing country on the vertical axis, while the aggregate cost values for R&D, IPR protection, biosafety enforcement, infrastructure, distribution cost and cost for human resource development all on the horizontal axis. These costs may be involved in introducing any of the biotechnological traits such as pest resistance, drought resistance and productivity improvement etc. in the ordinary varieties of different crops listed on the vertical axis. These crops are generally important for food and nutritional securities or exports of developing countries.

Table 1.2: Biotechnology in Developing Countries: Matrix for assessing Technology Direction and Cost of Adoption

	Biotechnology Traits (Economic Cost)	Productivity Improvement (RPBIDH)	Pest Resistance (RPBIDH)	Drought Resistance (RPBIDH)	Enhancing Shelf Life Value (RPBIDH)	Reducing Post Harvest Losses (RPBIDH)	Nutritional Improvement (RPBIDH)
Food Grains							
Cereals							
Rice							
Wheat							
Coarse cereals							
Pulses							
Gram							
Non-Food grains							
Oilseeds							
Groundnut							
Rapeseed							
Fibers							
Cotton							
Jute							
Mesta							
Plantation crops							
Tea							
Coffee							
Rubber							
Others							
Sugarcane							
Tobacco							
Potato							
Note: Economic Cost constitutes RPBIDH.							
R: R & D Allocation; P: Patent (IPR) Protection; B: Biosafety Enforcement; I: Infrastructure; D: Distribution Cost; H: Human Resource Development							
Source: Chaturvedi (2002).							

1.2 Definition of Biotechnology and Statistical Measurement

In the AP region, though there are many economies which have invested heavily across various sectors of biotechnology but do not have precise numbers on public investment with statistics to assess returns on their financial expenditures, impact of policies on foreign direct investment and even on regulatory policies etc. The importance of evidence-based policy making is extremely important, especially for developing countries with limited resources, so as to ensure optimum utilisation of resources and reasonable prioritisation of R&D expenditure. It is in this context that AP requires a clear policy on definition of biotechnology and its measurements, both for assessing its impact on

domestic economy and also for identifying complementarities for best possible utilisation of resources. It is for this, that AP economies would have to place their biotechnology numbers together.

In order to collect policy relevant statistics, it is of utmost important to have a precise definition of biotechnology. The OECD has evolved a broad definition of biotechnology. This is in two separate categories one is a one-line definition and the other gives details of various sectors covered under biotechnology. The one-line definition is, "The application of science and technology to living organisms as well as parts, products, models thereof, to alter living or non-living materials for the production of knowledge, goods and services." Although the single definition defines the purpose of biotechnology, the list based definition is essential for identifying modern biotechnology. In the OECD report (Biotechnology Statistics 2009) includes data for countries which used the same definition of biotechnology.

Once collection of statistics is undertaken, the next point is how convergence should be achieved in terms of methods of collection, authentication and curing of data across countries. What actually should be given? Whether the OECD definition is enough to articulate our developmental needs and policy perspectives? We do not say that it is not appropriate. But beyond OECD what is that topping, value addition, what other parameters we should have. For example, inclusion of biofertilisers into the definition of biotechnology is a major policy dilemma. Whether there is a scope within the OECD definition for that? If we do not include such industries, sometimes the policy-makers say that the pure recombinant DNA industry is very small, so, why are you spending? There are many perspectives possible on this.

A related issue of importance is to focus on what all are the indicators which should be selected for this exercise and what may be the best modality to collect them. It would be best to have the statistics collected through a governmental agency or it should be collected by somebody else who will cooperate with the government at a close level.

In the AP context or in the context of developing countries in general, we need to be very cautious of the definition so that large number of developing countries may join this initiative with comparable numbers. The OECD effort and the interests of developing countries would have to be consciously harmonized. While harmonizing with OECD definition and the indicators, one should see what is OECD Plus, the plus for AP countries. One crucial difference is that there is lot of public funding and that there is a lot of potential, as has been rightly identified in several studies about biotechnology applications. One thing was also clear that in developing countries agri-food sector occupies the centre-stage for policy makers because of obvious concerns related to food security and other public policy concerns in the agricultural sector.

1.3 ABIDI

In this context, the launching of the Asian Biotechnology, Innovation and Development Initiative (ABIDI) in January 2007 at New Delhi assumes significance. This was hosted by RIS with support from the Government of India, Department of Biotechnology. At

this event, some AP based think-tanks, research institutions, agencies and governments came together to launch an exercise for data collection and for evolving a common approach on definition of biotechnology. The Second meeting of this group was organised at Kathmandu, in March 2009, which was hosted by the Government of Nepal, Ministry of Agriculture.[15]

In the meeting issues related to collection of statistics, using a common methodology to collect data and analyze them was discussed. The OECD experience was also debated. Many participants agreed that there was an urgent need to bring in coherence and clarity in data collection, information sharing and analyze the data and in using them for policy purposes. It was decided that these would be taken up in a greater detail in the next meeting to be held in Sri Lanka in 2010.

1.4 Framework of the Study

This study would highlight some of these issues and related issues, in light of national and regional efforts for capacity building in the realm of biotechnology, across various sectors. After tracking down the dynamics of economic growth in AP, with a focus on recession, we looked into the issues in measuring and assessing impacts of biotechnology. The Chapter 2 would look into the interplay of various economic sectors with technological advancements in the region. This chapter also culls out broad trends in the biotechnology capacity across the AP economies with comparative tables and supporting write-up. The following chapters provide country specific details while the last chapter presents broad policy recommendations for enhancing biotechnology capacity in the region. The last Chapter draws the broad conclusions and presents the way forward.

Conclusion

The Asia-Pacific region is an economic power-house and is home to some of the countries that are moving fast in the biotechnology revolution. Although the countries have invested heavily in biotechnology, particularly in agri-biotechnology and medical biotechnology there are issues like technology assessment and, making the best utilization of resources including human resources.

AP is a major source for global economic development and is also one of the fastest growing markets in the world. The high growth achieved during the past decade may not be sustained at the same level in the coming years. Still countries in AP will continue to achieve significant growth. The fiscal stimulus provided in the current global economic crisis and slow down is likely to provide an impetus for economic revival and growth. The lessons learnt from the 1997-98 financial crisis are important for countries that bore the brunt of that crisis. Although AP has done commendably in terms of economic growth, in terms of Human Development Index there is a lot to be done. The variation across countries in this indicates that the gap among countries has not been bridged by the economic growth. Hence it is important that biotechnology strategy should strive to achieve developmental goals also. Linking biotechnology with broader goals in other sectors is vital for enhancing credibility and acceptability of biotechnology.

Capacity building is an important issue that deserves more attention now. Some countries (e.g. New Zealand, Korea, Singapore) have explicitly identified biotechnology as a source of economic development and have tried to integrate that into the overall development strategy. But as all countries are not equally strong and capable in all sectors, it is sensible to identify areas of potential growth and focus on niche areas than spreading the resources thin by trying to do anything and everything in biotechnology. In most countries biotechnology is strongly supported by the state. Many countries have invested heavily in creating infrastructure, offered incentives to industry and start ups and have expanded the capacity in human resources development. While the state supported measures are necessary, they themselves may not be sufficient to spur biotechnology revolution. Countries would need to do a SWOT analysis of their biotechnology strategies and reorient their strategies.

The collection of statistics, measuring the biotechnology sector and other issues in analyzing the data deserve more attention now. Some of the countries (e.g. Japan, South Korea) are members of OECD. OECD had come out with definitions and methodology for data collection and analysis. This exercise was started on a small scale and had proved that it was possible to apply the definitions and methodologies in many countries which were in different stages of development. So countries in AP can undertake a similar exercise and collect statistics periodically and analyze them. Such an exercise will go a long way in assessing the trends and impacts of biotechnology through indicators.

Strong economic growth, coupled with a fast growing market and better capacities in human resources, infrastructure and capabilities in R&D, and state support are some of the factors that favor biotechnology revolution in AP. Despite the variations among countries in using biotechnology and in development of biotechnology strategies, biotechnology has come to stay and will play an important role in socio-economic development in AP. The question now is what the strategies to make it more relevant are and how to ensure that the momentum is maintained.

Chapter 2: Expanding Contours of Biotechnology Revolution in Asia-Pacific: An Overview

Biotechnology is a technology that has enormous implications for countries in the Asia-Pacific as it has wide ranging applications in agriculture, health and industry. For many countries in the region, agriculture is a crucial sector in terms of contribution to GDP, employment, livelihood and food security. For a region endowed with rich biodiversity and forest resources, biotechnology offers enormous scope in overcoming declining productivity in agriculture, developing varieties that are more suited to biotic and abiotic stresses, increasing the potential for value addition and reduction in use of pesticides.[16] Although many countries in the region started using biotechnology in the early 1990s the use of biotechnology has been uneven and as a result they are unable to reap the benefits of biotechnology revolution.

The AP economies would have to think of relying more on path dependency model as technological convergence emerge as a major policy option with the increasing use of information and communication technologies in life sciences. The birth of nanobiotechnology is one of the developments that have significant implications for humankind[17] particularly for the AP economies as several of them have invested heavily in ICT. In all the advance areas of biotechnology research like mapping of the genome of crops like rice, using information from human genome project and multiplying tissue culture results all require application of ICT. For countries in the Asia and Pacific, the implications of this convergence will be immense. The Rand Corporation report points out the technological capabilities of some countries in Asia to apply and benefit from this convergence.[18] . Some countries in AP can derive advantage from the Bio-driven convergence (see Box 2.1).

The convergences can result in novel technologies and applications across sectors ranging from health to transport. For example use of nanotechnology to develop low-cost water purification systems that can be used in remote/rural areas is an application that can eliminate deaths on account of diarrhea and improve infant mortality rate (IMR).

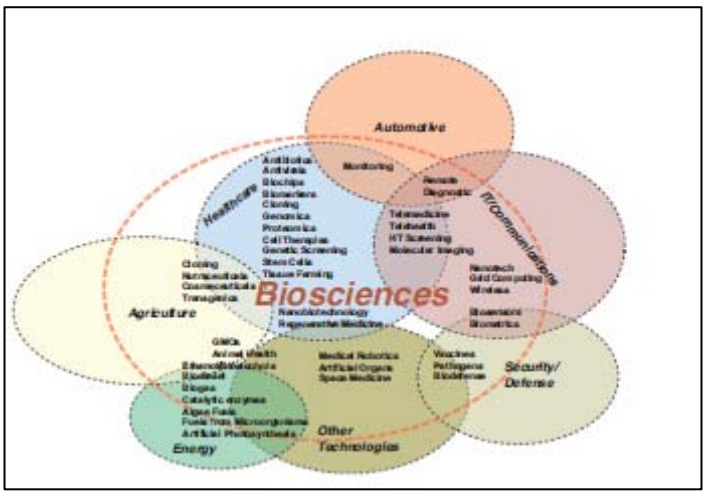
However, tapping the potentials of these technologies may need a well planned strategy to direct the R&D in converging technologies to solve problems and to develop appropriate technologies. Biotechnology is a key technology in this convergence. Hence it is important that countries in AP evolve suitable plans to realize the potentials. This calls for Technology Assessment, directing research and development for fulfilling some specific objectives and rapid diffusion of technologies. In many of the AP countries state is playing a critical role in promoting biotechnology. The states should also incorporate the technological convergence dimension in their national biotechnology plans.

Box 2.1: Bio-driven Convergence

In the recent literature on technological trends the idea of Bio-driven Convergence is referred to. Bio-driven convergence means confluence of many technology platforms,

although they may seem to be unconnected. Examples include tissue engineering, telemedicine, remote diagnosis, use of biosensors, biochips, personalized medicine. The relevance of Bio-driven convergence may seem to be far fetched as most of these technologies are under development and/or not yet commercialized on a large scale. It may also appear that these are not of much relevance to countries in AP as many countries have not even realized the potential of first generation biotechnology. However in view of declining costs in computing, developments in fields like synthetic biology and the expertise being gained by some countries in AP in different technologies it is better to have a realistic assessment of the potentials of Bio-driven convergence. That bio-driven convergence will have its impacts in agriculture and health is obvious. But what is interesting is that the convergence opens up new avenues for resource utilization in biofuels, biomarkers can be widely applied in both agriculture and health and setting up of DNA data banks/gene banks can facilitate better utilization of human genetic resources for development of medicine. Although it is premature to lay out a time frame in which this convergence will have a wider impact, the increased use of telemedicine, biomarkers and investments and research in fields like tissue engineering indicate that within the next two decades some significant applications will be developed and deployed. Some countries in AP like Japan will be able to use the convergence as they have well developed industry and R&D system in many of the disciplines that form the backbone of this convergence. Country like India can leverage its expertise in bioinformatics while Korea and Singapore may be able to do well in niche areas like tissue engineering. Although most of the expectations/predictions on this convergence may not materialize and some applications will raise questions about privacy, regulation, the convergence is likely to have significant impact in application of biotechnology and genetic engineering.

Figure 2.1: Bio-driven Convergence



Source: Chips, Clones, and Living Beyond 100 How Far Will the Biosciences Take Us? Paul J. H. Schoemaker, .Joyce A. Schoemaker, . FT Press 2009

2.1 Technology and Industrial Growth Strategies

Globally the biotechnology industry is dominated by firms in North America particularly USA and Canada (See Table 2.1) and Europe. As the table below indicates the AP region is a distant third in the global biotechnology industry. In all parameters North America is leading. The share of AP in the global revenue is less than 10 per cent. Thus the industry in AP has a long way to go when compared to USA or Europe. Canada is also doing well in terms of all parameters.

Table 2.1 Global Biotechnology Industry at a Glance (2005)

	Global	**US**	**Europe**	**Canada**	**Asia-Pacific**
Revenues ($m)	84872	68400	13352	2692	3970
R&D Expense ($m)	31806	30000	6309	915	488
Net Income (loss) ($m)	-694	-3600	-2645	-722	-6
Number of Companies					
Public	798	386	181	82	149
Private	3616	1502	1563	322	615
Total	4414	1888	1744	404	764

Source: Ernst & Young (2008). Beyond Borders Global Biotechnology Report.

As discussed earlier, with ongoing economic turmoil, investments in R&D and innovation are crucial and therefore AP economies would have to continue supporting R&D and innovation policies across key growth areas for AP economies. This may require intensive R&D collaborations among member countries. There are several studies which have demonstrated that a large share of industrial growth in the OECD countries have come from technological innovation.[19] This is evident through new technological capabilities leading to changes in products and processes coming through the learning and translation of good practices.[20]

Some countries in the AP region have evolved policy measures (See table 2.2) and are investing heavily in this and are competing with other major players like USA and Europe for their share in the global market. We find that governments in Korea, Singapore, Japan, India and China are investing heavily in biotechnology. In India many states have either a biotechnology policy or are encouraging special biotechnology zones, modeled after Information Technology Parks. The use of clusters and regional clusters for developing biotechnology in Korea and Japan, for example, is based on the success of clusters like Silicon Valley.[21] In India the emergence of Bangalore as a major hi-technology cluster with electronics, software, ITES, biotechnology and biopharmaceutical industries is a much cited and studied phenomenon.[22]

Table 2.2: Evolution of Biotechnology Policy in Asia-Pacific

Australia	National Biotechnology Strategy	2000
Bangladesh	National Biotechnology Policy	2006
Cambodia	No national policy as such	
China	First policy in 1990, most programs are under 863 plan	1990
India	First Policy in 1983 later the National	1983

	Biotechnology Strategy in 2007	
Indonesia	First policy in 1990, Subsequent Policy in 2004	1990
Japan	Bio-Strategy in 2002 – focus on 4 sectors	2002
Korea	National Bio Industry Action Plan	2004
Laos PDR	No National Policy	
Malaysia	National Biotechnology Policy	2005
Nepal	National Biotechnology Policy	2006
New Zealand	National Biotechnology Strategy	2003
Pakistan	There is no comprehensive National Strategy	
Philippines	No Comprehensive National Strategy	
Singapore	No specific National Biotechnology Policy, Biotechnology promotion as part of the Economic Strategy with thrust areas	2006 Science&Technology Plan
Sri Lanka	Policy is being evolved	
Thailand	National Strategy with specific objectives	2004
Vietnam	No national strategy	

The research suggested that industrial technological development should not be viewed as a process that can be promoted easily and quickly by investing in new equipment or buying imported technology. It requires conscious investments by firms in their own technology capability. Technology capability being defined above refers to the skills, knowledge and experiences need to operate imported technology efficiently. The research also found that enterprise in newly industrialized countries in East Asia had built up relatively good technological capabilities in a spectrum of industries compared to international standards and that this was a major factor in their rapid export growth and technological upgrading.[23]

Within the biotechnology sector one comes across different sectoral experiences. Japan and USA are competitors in high-technology sectors and have their respective strengths in innovative capacities and catering to the global markets and also in basic research. But the growth paths and trajectories of biotechnology industry in USA and Japan are very different. Venture capital played an important role in USA while in Japan, the biotechnology firms were mostly spun out from industrial conglomerates. Right from the beginning, biotechnology patents in USA were broadly focused while in Japan scope of patentability was narrow and broad claims were disallowed.[24] Thus, the biotechnology industry's evolution in USA and Japan is a study in contrasts.[25]

The biotechnology industry in Korea did not follow the path of the industry in USA and without the state's support and guiding role, the industry would not have reached this

stage. In India, the state support for the industry was vital for its growth and diversification. In fact over the years the Indian government had continued and increased its support to the development of biotechnology by investing in infrastructure, human resource development, various incentives for commercialization, schemes for applied R&D and by a consistent policy framework. In all these cases the linkages with other sectors were established and biotechnology fitted well within the overall industrial development strategy. In other words, the hand of the state directed the rapid development of biotechnology. But in case of most countries in AP this did not happen. Even when the state wanted to direct and set the direction for the industry to grow, biotechnology did not grow rapidly. In fact there were many false starts that were followed by stagnation or incremental growth. While potential applications were identified and some promising beginnings were made, the pace did not gather momentum to reach the next stage but faltered along the way. We analyze this elsewhere. But the point we want to emphasize is, biotechnology is not an inappropriate technology, nor is a technology that will become irrelevant rapidly. In fact it is a technology that can enable leap frogging.

Table 2.3: Biotechnologies with a High Probability of reaching Markets by 2030

Agriculture	Health	Industry
Widespread use of marker assisted select (MAS) in plant, livestock, fish and shellfish breeding	Many new pharmaceuticals and vaccines, based in part on biotechnological knowledge, receiving marketing approval each year	Improved enzymes for a growing range of applications in the chemical sector.
Genetically modified (GM) varieties of major crops and trees with improved starch, oil and lignin content to improve industrial processing and conversion yields.	Greater use of pharmacogenetics in clinical trials and in prescribing practice, with a fall in the percentage of patients eligible for treatment with a given therapeutic.	Improved micro-organisms that can produce an increasing number of chemical products in one step, some of which build on genes identified through bioprospecting.
GM plants and animals for producing pharmaceuticals and other valuable compounds.	Improved safety and efficacy of therapeutic treatments due to linking pharmacogenetics data, prescribing data and long-term health outcomes.	Biosensors for real-time monitoring of environmental pollutants and biometrics for identifying people.
Improved varieties of major food and feed crops with higher yield, pest resistance an stress tolerance developed through GM, MAS, intragenics or cisgenensis	Extensive screening for multiple genetic risk factors for common diseases such as arthritis where genetics is a contributing cause.	High energy-density biofuels produced from sugar cane and cellulosic sources of biomass.

More diagnostics for genetic traits and diseases of livestock, fish and shellfish	Improved drug delivery systems from convergence between biotechnology and nanotechnology	Greater market share for biomaterials such as bioplastics, especially in niche areas where they provide some advantage.
Cloning of high-value animal breeding stock.	New nutraceuticals, some of which will be produced by GM micro-organisms and others from plant or marine extracts	
Major staple crops of developing countries enhanced with vitamins or trace nutrients, using GM technology	Low-cost genetic testing of risk factors for chronic disease such as arthritis, Type II diabetes, heart diseases and some cancers	
	Regenerative medicine providing better management of diabetes and replacement or repair of some types of damaged tissue.	

Source: OECD (2009).

By and large, in most countries, the application of biotechnology varies from sector to sector. For example in Japan limited application of agricultural biotechnology is there while industrial biotechnology has received major attention. Similarly, in Korea and Singapore medical biotechnology has attracted major attention of policy makers. In Thailand, it is agricultural biotechnology which has emerged as very important for increasing exports of agricultural products. In case of India and China, cross-sectoral priorities are being addressed through biotechnology. To what extent all these ambitious objectives will be achieved and whether Japan could repeat the miracle it did in automobiles and electronics in biotechnology is not yet known. It is well known that even Europe is struggling hard to keep the pace with USA in biotechnology and is trying its best to catch up with USA.[26] But in a globalised world, it is possible to identify niches and increase the competitive advantage in them. Similarly, it is also likely that advantages like cheaper labor cost, availability of trained human resources, extensive state support will help the countries in AP to overcome some of the factors that inhibit their growth. Realizing this, countries like Korea, Singapore and New Zealand are welcoming influx of human resources in biotechnology, while India and China are relying both on numbers and in the quality of human resources.

Most countries have evolved attractive policies to attract FDI investment in biotechnology and relaxed norms of equity ownership and whole range of incentives are offered. In terms of investment, R&D the region lags behind both USA and Europe and Canada is another competitor. The E&Y survey indicates that in terms of R&D expenditure, both in absolute terms and in proportion to the turnover, USA is leading and

the AP region lags behind. It is true that the biotechnology sector in USA is not a profit making machine and historically biotechnology industry has continued to incur loses. But what would sustain, the momentum are the innovative products and the confidence in the industry. Does this mean that biotechnology industry in AP will always lag behind and remain in the third place? It need not be so. Because the experience shows that the first mover advantage is not permanent and countries do catch up and reduce the gap to reach the higher rungs in the ladder.

In medical biotechnology the success of Korea in vaccines is a case in point. Korea developed and successfully commercialized Hepatitis B vaccine. This is a product development that resulted in a cheaper vaccine that could compete globally.[27]

While biotechnology has firmly established itself in AP, more has to be done for ensuring its rapid expansion. In context of new technologies particularly, biotechnology, most of the national initiatives are focused on the issue of innovation system and the capacity to adapt and absorb technology as the deficiencies of earlier models of linear technology transfer are emerging as major impediments in the technological and thereby economic growth. Thus technology can no longer be viewed as tools, techniques and processes that should be transferred and applied but seen as an important component of a broader framework of technology transfer and application, particularly in LDCs.[28]

The importance of evolving the regional plan for capacity development in the realm of biotechnology would have to be strongly embedded in the national strategies of various AP economies. Some states give incentives and concessions to biotechnology industry, encourage FDI and develop special clusters or biotechnology zones for integrating research, commercialization and technology development. Japan's approach is a classic example of using regional clusters and drawing on the capabilities of Centers of Excellence to support biotechnology. Singapore's BioPolis is another example of technology facilitation by the state. Investment in this way helps in stimulating further investment in a high-end technology sector by the private companies.

South Korea too is using the concept of clusters for biotechnology. India is another country that is investing heavily in biotechnology infrastructure and enhancing the capacity of its universities and research centers. It is also establishing Centers of Excellence through newly announced *National Biotechnology Strategy*. In all these countries the linkages with other innovative sectors are established. Thailand is another country that has a policy with specific goals and linkages. Hence one can reasonably expect that these measures will bear fruit in the medium term while in the long term countries have to re-work and adjust the policies and strategies taking to account the global trends, the national biotechnology landscape and the goals achieved and gaps remaining (if any). Compared to Africa and Latin America, biotechnology in AP is more wide spread and well entrenched. But there is no case for complacency as the progress is uneven and many countries have a long way to go. More importantly the innovation potential of Brazil, and South Africa and some other countries in Africa and LA cannot be under estimated. The possibility of Brazil and South Africa emerging as potential competitors in some sectors cannot be ruled out. Regional clusters can play an important

role in development of and sustaining the biotechnology industry but as recent research shows non-local sources of knowledge are also equally important.[29]

In our view these national plans and strategies should be studied for their effectiveness and assessed. Since biotechnology is more than 15 years old in many countries, the time has come to evaluate the experience so far and find out what has worked and what has not. Obviously there is no magic plan that would deliver results every where. But a comprehensive study of experience so far viz. a viz. the expectations will be of immense use for national governments, international agencies and funders. We suggest that such a study while focusing on biotechnology should also try to address broader and relevant issues.

While the number of firms cannot be the sole indicator of the biotechnology industry, it does give an idea. In many countries industry is in nascent stages while in some there is a well diversified biotechnology industry. As the individual country reports indicate the trajectory of biotechnology development is not uniform. Some countries have made rapid progress in the last decade while some have not been able to do so. For example in India, China, and Korea the industry has not only grown rapidly in terms of numbers and also has become a diversified industry. The table below provides some ideas about the status of the industry.

Table 2.4: Industry Size/No. of Firms

S.N.	Country	No. of Firms	Description
1	Australia	527	Majority in health biotechnology
2	Bangladesh		Nascent Stage
3	Cambodia		Industry in nascent stage
4	China		Mostly in public sector
5	India	325	Majority in biopharma sector
6	Indonesia		Industry in initial stages
7	Japan	1007	Market size $19.5 billion
8	Korea	773	
9	Laos PDR	None	
10	Malaysia	65	
11	Nepal		Nascent stages
12	New Zealand	168	
13	Pakistan		Industry in nascent stages
14	Philippines	24	
15	Singapore		Well developed
16	Sri Lanka		Industry in nascent stages
17	Thailand	200	
18	Vietnam		No biotechnology industry

2.2 Agricultural Biotechnology

The achievements of agricultural biotechnology in AP are mixed. The productivity in agriculture has increased but gaps remain and more importantly biotechnology has succeeded in enhancing productivity and yields in some crops like cotton but in crops like

rice, the results are not expected soon. Some of the predictions made in 1980s and the expectations that biotechnology will be the next Green Revolution that will transform the agriculture and enormous gains in productivity are being keenly awaited. There is fast expansion in global R&D share of developing countries, which has expanded from 45 per cent in 1981 to 56 per cent in 2000.[30] According to IAASTD (2009), China and India account for 31 per cent of total agriculture R&D expenditure by the developing countries. Most of this expenditure has focused on agricultural productivity and quantitative gains. The rise in budgetary allocations by China and India is an outcome of growing government participation in the agriculture research related activities. The commercialisation strategies proactively engaged private sector entities atleast for the first generation biotechnology development. As is clear from Table II.2 total public agriculture research expenditure in China went up from US $ 1049 million to US $ 3150 million in the period 1981-2000 and in case of India from US $ 533 million to US $ 1858 million in the same period. Here the data is adjusted for inflationary changes at the dollar value of year 2000.[31] This had Chinese share in the global total at 14 per cent while India stood at 8 per cent. The share of Asia-Pacific as a whole in the global agriculture R&D increased from 20 per cent to 33 per cent in the period 1981 to 2000. In the same period, share of Latin America and Caribbean declined from 13 per cent to 11 per cent and for Sub-Saharan Africa from 8 per cent to 6 per cent.[32]

Table 2.5: Total Public Agricultural Research Expenditures by Region, 1981, 1991 and 2000

	Agricultural R&D Spending			**Shares in Global Total**		
	1981	**1991**	**2000**	**1981**	**1991**	**2000**
	(million 2000 international dollars)			**(per cent)**		
Asia & Pacific	3047	4847	7523	20	24.2	32.7
China	1049	1733	3150	6.9	8.7	13.7
India	533	1004	1858	3.5	5.0	8.1
Latin America & Caribbean	1897	2107	2454	12.5	10.5	10.7
Brazil	690	1000	1020	4.5	5.0	4.4
Sub-Saharan Africa	1196	1365	1461	7.9	6.8	6.3
West Asia & North Africa	764	1139	1382	5.0	5.7	6.0
Developing countries, subtotal	6094	9459	12819	45.4	47.3	55.7
Japan	1832	2182	1658	12.1	10.9	7.2
USA	2533	3216	3828	16.7	16.1	16.6
Subtotal, higher-income countries	8293	10534	10191	54.6	52.7	44.3
Total	15197	19992	23010	100	100	100

Source: IAASTD (2009).

Several of the developing countries, in fact, have now embarked on the path of employing the second generation of biotechnologies. The ability to use stem cell research is a case in point. Many of these developing countries were earlier being advised to attempt simpler techniques of plant tissue culture, meristem and organ culture in order to achieve rapid vegetative propagation[33]. The global synergies, appeared over the years

have helped in bridging the so-called gap between North and South over biotechnology. In India itself now there are seven lines of stem cell on which research is on by a private firm. In Singapore, a public research institute has finished the gene sequencing of fugu fish, which has homologies to human genome. In China also Beijing Genome Institute (BGI) has full genomic knowledge about a rice variety.

In agricultural biotechnology Thailand strives to use biotechnology to move up the ladder in value addition and in increasing exports. In Malaysia the continued support for biotechnology is evident in the importance given to it in the Eight Five Year Plan and the increase in budgetary allocations. In Thailand and the Philippines, commercialization in agricultural biotechnology is remaining as a major challenge. In the Philippines, the less controversial technological choices like biofertilizers and biopesticides have been given due importance. The Bangladesh strategy also addresses similar approach towards agriculture biotechnology. But in many other countries, particularly in LDCs the linkages are weak or biotechnology is not well integrated in the overall development framework.

What needs to be pointed out is that at least, some governments have realized that biotechnology in their countries should become a global industry and that would be possible only if they necessary infrastructure for research centers and institutes is developed. Although this race to globalize and do world class science is welcome, it is possible that in that case the real applications of biotechnology may end up with products and services that cater to global markets or industries in advanced countries than with products that cater to the needs of small and medium farmers or health needs of the poor. Hence it is suggested that an assessment of the policies and programs can be done to identify how best they can meet the needs of groups like small and medium farmers.

In case of agricultural biotechnology, this is all the more obvious because varieties cannot be developed in one place and simply be planted all over the region. Traits that confer specific benefits have to be incorporated into varieties and hybrids that have some advantages and more suited to meet the local/national needs. This leads to the question of the capacities and capabilities of National Agricultural Research Systems (NARS) in using biotechnology and their capacity to develop transgenics for crops that are important for a particular country. Recent research raises some questions about the role of public sector in this and the scope for developing new strategies[34]. It is well known that while Green Revolution was led by public sector, gene/genomics revolution would not be so.[35] One of the options then would be to promote more collaboration with international research centers. But the budget for such centers is not increasing and the CGIAR system itself has not been well funded now. The countries can use bilateral assistance to strengthen NARS and use this to support biotechnology research. This will work only if the assistance is on a long-term basis because biotechnology research needs support for many years to establish itself and reach the critical stage. Hence in our view, the time has come to review policies on NARSs and study the linkages between NARS and biotechnology in AP region.

Involving users, i.e. farmers and developing appropriate products for them is important. Agricultural biotechnology can be a tool for empowerment if the needs of the farmers are

assessed and technology is applied to solve real world problems. The Cassava Biotechnology Network is a successful example of the new approach in which farmer is not a recipient of charity or is offered something for free. Rather the innovation is developed to overcome some of the problems farmers face in cultivating and using Cassava. Tissue culture techniques were taught to farmers including women and they were encouraged to use their traditional knowledge about the local varieties and choose the best from them for reproduction. The technology was made available and local materials were used. As a result farmers set up units to produce high quality Cassava stakes and these were not unaffordable. [36]. Development of pro-poor transgenics in AP will make biotechnology more relevant and will enhance the credibility and acceptability of biotechnology in agriculture (See Box 2.2).

At the outset, some very basic propositions would have to be raised about the additional inputs being expected from biotechnology, which are other than the traditional techniques already available. Since most of the countries have witnessed Green Revolution there is already a decent R&D set up and network of extension agencies is working. It is equally important to identify possible areas of research where blending of the two streams of technologies can be achieved. The hybridisation techniques and other agricultural practices may well supplement the biotechnology methods[37]. This would not only augment the technical capabilities but would also help in reducing the capital cost which generally goes up with adoption of biotechnology. Thus the biotechnology revolution in agriculture will have to be both an evolution and revolution in AP. It will build upon the Green Revolution even as it strives to overcome some of the problems that have resulted due to Green Revolution and the pressures on resources like land, water on account of increases in population, urbanization, deforestation and industrialization. When the potential impacts of climate change are also taken into account, the challenges ahead are very evident.

Box 2.2: Pro-poor Transgenics

A question that is often posed is whether biotechnology can be used to develop pro-poor transgenics that meet the needs of poor and marginal farmers and whether such transgenics can be accessed by them at affordable prices. The question is a relevant one because often, and, not without reason, it is pointed out that most of the GM crops do not have traits that meet the explicit needs of poor and marginal farmers and they tend to make them rely on trangenics produced by agro-MNCs. For example Roundup Ready resistance may be beneficial to farmers but that is not the most appropriate trait the farmers need from crops. It has been pointed out while the possibilities exist so far we have not seen them being realized.[38]. According to one commentator

"This is not surprising because the range of products already developed – the first generation of GM crops – are neither the crops nor the traits that are most important for poverty reduction and food security. Herbicide tolerance and insect resistant traits reduce costs and increase returns to labour rather than land and are thus suited for labour scarce environments. This is particularly the case for RR soy, which does not have significant yield benefits in most situations. Bt cotton, by contrast, does have significant yield benefits. The consensus view among economists and GM critics alike is that a pro-poor research agenda would target staple food crops, particularly those of the poorest people (cassava, millets, rice, wheat and white maize) and traits that increase production (yield potential, yield stability and environmental constraints such as salinity and drought"[39]

A recent study on a public-private partnership to develop Bt Brassica under a consortium arrangement gives some interesting ideas about development of Pro-poor Transgenics.[40]

The Collaboration for Insect Management for Brassicas in Asia and Africa (CIMBAA) is a consortium in which there are six research partners, four public partners and there is one private partner (Nunhem Seeds) http://www.cimbaa.org

The project focuses on cabbage and cauliflower and the objective is to develop varieties with insect resistant traits and the varieties will be locally adaptable and will provide sustainable pest control strategy. In this project Integrated Pest Management (IPM) practice is also integrated in the development stage itself so that an effective IPM strategy can be formulated. Although there were two options – development of hybrids or open-pollinated varieties, the decision was in favor of hybrids as open-pollinated varieties may face problems in fulfilling biosafety norms, although they would permit re-use of farmer saved seed.

The patent owner (Bayer Crop Science) in the consortium, made available the Bt technology, without charging a technology fee. The ownership of the technology and the biological material will be transferred to one of the public partners in the consortium. The technology will be licensed on a non-exclusive basis to many seed companies without any technology fee. The seed companies are free to choose/develop their own lines and markets. Thus Nunhem Seeds is not the only seed company that can get the license to use the technology. The availability of funds from non-private sector in the project helps the private sector partner in reducing its investments in the development of technology.

For the private sector partner access to elite germplasm is important. With this germplasm the company can do value addition in seeds like seed coating. It can use the germplasm with this and use its network of distributors to reach a wider market. Thus in this case the trait and its ownership are less important than superior germplasm. Although the study on this project has raised some questions about participation of farmers in this project, it is clear that there are alternative ways of approaching and solving problems in accessing patent protected technology and biosafety concerns. Still it is clear that intellectual property rights is an important issue in accessing and using technologies to develop transgenics and there are no easy answers to this.

Whether it is the Generation Challenge of CGIAR or consortium arrangements mentioned above, Freedom to Operate and access to patented technologies is a central issue in development of transgenics. The development of pro-poor transgenics is likely to be hampered by high cost of acquiring the licenses or the germplasm and the technology fee may be another factor that will increase the overall cost.

Still countries should not give up on pro-poor transgenics. Instead they should try solutions ranging from using competition policy to thwart attempts by monopolies, seeking alternatives to both technology and germplasm from other sources, encouraging public-private partnerships to reduce overall costs in development of technology.

It is suggested each country can identify two or three such crops for experimenting with pro-poor transgenics. These projects may be undertaken jointly by two or three countries and involvement of CGIAR centers can be encouraged. Since CGIAR centers and other institutions like Agricultural Universities are good sources for germplam involving them will be all the more desirable.

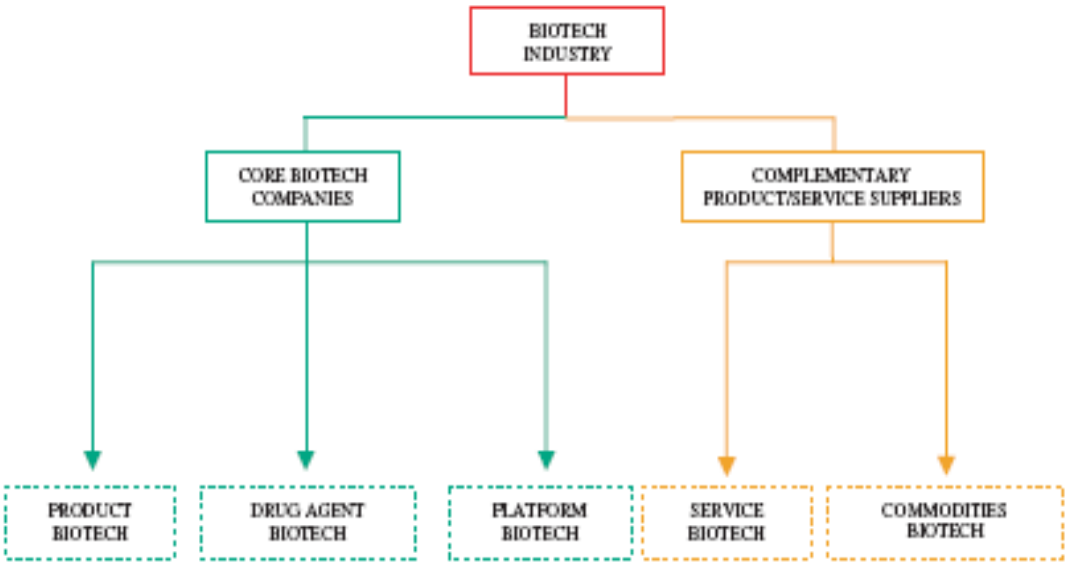
Countries can seek the assistance of organizations like PIPRA, CAMBIA in intellectual property rights issues and in access to technologies. Some times the technology may be available under humanitarian license or a similar license. PIPRA can help in getting access to technologies developed by its member institutions and in negotiating licenses. CAMBIA can help is locating patent free technologies or technologies which are in public domain as patents have expired.

The development and deployment of pro-poor transgenics will enhance the acceptability of biotechnology besides meeting the needs of poor and marginal farmers.

2.3 Medical Biotechnology

Medical biotechnology is becoming an important application of biotechnology thanks to developments in life sciences and ICTs. But not all countries in AP are capable of investing in a big way in medical biotechnology although the innovations in this can be applied widely. Korea, India, Japan, Singapore and China have given importance to medical biotechnology. Thailand is another country that is giving importance to this sector but its main focus is on integrating this with medical tourism. Medical biotechnology industry can be broadly classified as two sub-sectors, one dealing with biopharmaceuticals, new drugs and the other diagnostics, bio-devices. Biopharmaceuticals is a growth industry in Asia. With some of the key patents going off the patent protection in the next decade, the competition in the biopharmaceutical market has really intensified.

Medical biotechnology in the post-genomic life sciences, which involves using knowledge from different disciplines and hence the medical biotechnology industry needs firms with specialized functions and expertise in particular domains. They are broadly classified into two types – Core biotech companies, and, complementary/product service suppliers. The taxonomy is as below



As there is a need for different competencies, it is not necessary that a single firm should do all the related activities. This gives enormous scope for outsourcing including Contract Research (CR). In fact some countries in AP have a competitive advantage in doing contract research and in conducting clinical trials. Given the knowledge-intensive nature of medical biotechnology and the need to integrate different domains of knowledge to develop new products, the availability of trained human resources is a key factor for development of this sector. Recognizing these countries in AP has invested heavily in training and development and in establishing centers of excellence or specialized research institutes. Japan for example has many Centers of Excellence (COE) on specific technologies. Singapore has established BioPolis to act as a global hub for bio-medical technology and life sciences research. India and China have strengthened their R&D system besides setting up many institutes for biotechnology and genomics research. Several strategies are adopted to woo the talented persons as Singapore announced fellowships while New Zealand relaxed immigration norms for professionals in biotechnology.

Although medical technology is relatively a hi-technology industry it offers immense scope for development of diagnostics, vaccines and other health products including bio-generics that would meet the needs of the people in AP countries. Unlike agricultural biotechnology, in this sector, the private firms are the major player and private sector investment in R&D is higher than that of public sector. The synergy between public and private sector in this is important. The public sector can focus on basic research while

applied research and commercialization can be done by private sector. In some applications like stem cell therapy some countries in AP are competing well with USA and Europe. For example India has emerged an important country in the global stem cell landscape.[41]. Korea is progressing despite some set backs on account of fudged results. In medical technology there is enormous scope for public-private partnerships to develop products, offer services and commercialize technologies. India can combine medical tourism with development of biomedical technology.

For many firms in AP region in biopharmaceuticals the advantage lies is in lower cost of production than in innovation. Although AP region can boast of many pharmaceutical firms that can produce new drugs and perform R&D for drug discovery, in terms of revenue and R&D expenditure the USA and Europe based firms are much ahead. Similarly in medical biotechnology innovation using genomics USA is the front runner. Countries like Japan and Singapore are trying to catch up with USA in this.

A factor that could affect the diffusion of innovations in this sector is IPRs. Stronger IPRs can become a barrier in technology development and transfer. So it is essential that public policies to promote technology in this sector should strive to strike a balance between the incentives for innovation and accessibility and affordability of the innovations. As the Korean example of vaccines indicates the need for a pragmatic approach is obvious. Public policies that strive for the golden mean in promoting innovation, ensuring access and affordability, and incentives for industry to invest are essential. It is up to each country to craft a specific innovation policy in this sector. A country can identify a sector like biopharmaceuticals or CRO and craft an innovation policy for that sector. CROs can be encouraged to move up in the ladder of value addition and work with public sector universities.

In our view countries in AP need to do a SWOT analysis and identify areas where they can compete well and explore niche areas where they have distinct advantages. The scope for setting up agencies to promote regional innovation activities and partnerships can be explored.

2.4 Regulation of Biotechnology

Biotechnology regulation is a contentious issue. There are different models of risk assessment and regulations. There is no single model that can be considered as universally applicable and valid for all technologies for all time to come. Countries which swear by science and technology do not follow same norms of risk assessment or adopt uniform regulatory regimes.[42] Although the differences between USA and Europe in agricultural biotechnology are well known, what is important is that countries in Europe do not apply the same norms in health sector biotechnology or in agricultural biotechnology. This is not an unexpected phenomenon, because countries have evolved different styles of regulation over the years in consonance with their administrative and political frameworks. Countries in AP thus need not simply ape USA or Europe and should strive to develop regulatory regimes that are suited to their needs. But in a world of globalized science and technology, the regulatory convergence is not likely to occur even when the same sciences and technologies are applied. In other words, while science

and technology may be universal, regulatory regimes will not be universal, nor will be based on the same principles of risk assessment and regulation. So even when countries have ratified Cartagena Protocol it is not necessary that all those countries will have identical regulatory regime. There are three broad models of regulation – 'liberal science-based' regulation, 'precautionary science-based regulation', and 'social values-based' regulation and states shape policies on agricultural biotechnology regulation by incorporating parts of these models in many ways.[43] . The countries in AP can share their experiences and learn from others experiences and thereby save costs in regulation and also use the data available for technology evaluation (See Box 2.3)

In the decades to come, developing an appropriate regulatory framework will be a major challenge for countries in AP because of the nexus between trade and bio-safety on one hand, and, the issues raised by technological convergence and new technologies like nanotechnology. For example risk assessment of nano-particles is a major issue and as of now there is no universally applied methodology in this. When nanotechnology is being applied in medicine new issues will arise like regulating nanobiotechnology medical devices. Similarly in agricultural biotechnology while old issues like labeling of GM products will continue new issues like regulation of health-foods, neutraceuticals, and plant derived vaccines will have to anticipated. By and large, there is no resistance to agricultural biotechnology in AP as in many countries in Europe. But this does not mean that there is 100 per cent acceptance for GM food. The controversy over export of rice with traces of GM from USA to Japan and the subsequent rejection is a pointer. In fact if countries begin to apply either labeling or criteria like 1 per cent or 2 per cent GM is allowed the implications of these for trade are important. Hence it is essential that countries are prepared well to face the regulatory and trade challenges.

Box 2.3: Regulation: Sharing and Learning from Each Other

The cost of field trials and biosafety regulation are increasing. Conducting field trails and subsequent approval is often challenged and the rationale behind the approvals is questioned. Although the technology may be universal, the conduct of trials and regulatory practices vary. While the need for conducting trials at the national level is a necessity, there is enough scope to share and learn from other countries. Although the local conditions will vary, the parameters of the trials and the questions to be addressed can often be similar. For example in testing for gene flow, the methodology can be same even when the crop is tested at different environments. Countries conduct many trials, accumulate enormous data and often the results are not shared with other countries. For many countries that lack the capacity to conduct trials extensively, asking the right questions and designing trials that are appropriate to the risks to be assessed would go a long way in assessing risks and benefits with relevant data, instead of going for too many trials with too many questions to be tested for. We are not advocating abandoning of science based risk assessment here. We are pointing out the need to conduct appropriate trials. Even before conducting trials meta-analysis of results from studies done elsewhere can give some insights about the potential risks and can be helpful in designing trials. For example if majority of the studies show that gene flow beyond the expected threshold is a recurring feature in case of a transgenic, then the question of gene flow to wild relatives

has to be addressed and the implications of this gene flow in actual cultivation has to be examined all the more carefully.

The generally accepted view is that each transgenic has to be evaluated on a case to case basis.[44]. This is because it is better to proceed with caution than to extrapolate from similar trails elsewhere and decide on that basis. As countries conduct more trials and as more independent studies are done on environmental and other effects of transgenics, data and more information accrues and is used by the respective governments or agencies. Even if the general behavioral traits are known, regulators demand testing for potential environmental effects which is understandable. But there is no methodological uniformity in this and countries adopt different methods. In fact issue becomes controversial when some stakeholders argue that a particular risk is not studied or is understudied. The controversy over impacts of transgenics on Monarch Butterfly is an well known example for this. In fact often what are the right questions in risk assessment itself is a contested one.[45]

In this context the suggestion made by Nuffield Council of Ethics in its 2003 report on sharing of methods and results of environmental risk assessments between countries with similar agricultural environments is an idea that is worth trying in AP[46].

The report took the view such a sharing among/between countries with similar agricultural environments could reduce costs of trails for any one country. Logical extrapolation of previous findings can help in better design of trials and in better understanding of data/results. Combined with the extrapolation from studies elsewhere and data on hand from local field trials will help in identifying issues for further investigation. At present there is no global data base that provides data on various field trails and performance of released varieties in different environments although FAO has taken an initiative in this. Its site gives details about field trials, traits and other details.[47]. This is necessary but not sufficient for the purpose we are discussing. It is suggested that countries in AP can work on a comprehensive data base on trials already done, crops released and their performance and trails in progress with access to results/data on trials and data on performance besides a comprehensive collection of methods used and summaries of meta-analysis already done.

This exercise can be undertaken as a part of the capacity building exercise. On a regional level one country can undertake to develop and maintain this database.

Countries in AP are in different stages when it comes to biosafety and regulation. As the table below indicates some have well developed regulatory system while some are in the initial stages of developing appropriate regulatory regimes.

Table 2.6: National Initiatives in Asia –Pacific on Biosafety

Country	Details
Australia	Gene Technology Act 2000, Labeling for GM food
Bangladesh	No stand alone policy, Framework developed under UNEP-GEF project
Cambodia	National law and regulation in progress

China	National regulation in place
India	No GM labeling, regulatory regime is in place and under revision
Indonesia	Regulation in place
Japan	Regime in place for import and export of LMOs
Korea	Bioethics and Biosafety Act 2004, regulation of LMOs
Laos PDR	Draft law yet to be approved
Malaysia	Biosafety Act of 2007
Nepal	National Biosafety Framework 2007
New Zealand	Biosafety regulations in place
Pakistan	National Biosafety Guidelines 2005
Philippines	No holistic framework
Singapore	Regulatory regime for research on GMOs and biosafety
Sri Lanka	Biosafety framework evolved , GM labeling regulation 2007
Thailand	No comprehensive Act, only rules are in place
Vietnam	Initial stages of development

2.5 Capacity Building and Regional Cooperation in Biotechnology

Most of the multilateral and regional institutions have played an important role in developing a pan-Asia-Pacific approach for promoting agriculture innovation and for strengthening R&D endeavors. Regional institutions like the South Asian Association for Regional Cooperation (SAARC), Association of South-East Nations (ASEAN) and Asia-Pacific Economic Cooperation (APEC) have launched several R&D collaboration programs along with manpower training and skill up gradation initiatives.[48]

There are regional institutions like IRRI, ICRISAT and ICGEB which have also played an important role. Rockefeller Foundation has been one of the major funding agencies for rice biotechnology research. It had supported (till 2000) research in both basic science and applied research on rice including research on rice genome mapping.[49] It has been one of the supporters of the Golden Rice research project right from the beginning.

In 2008 it reaffirmed its commitment to the project by indicating that it would fund IRRI for working on regulatory measures relating to Golden Rice in Bangladesh, India, Indonesia, and the Philippines. The continued support is part of the Rockefeller Foundation's overall support for biotechnology which extends to a similar support to initiatives in Africa. ICRISAT is one of the CGIAR centers and is located in India. Its focus is on crops for semi-arid regions and developing appropriate varieties and technologies. In biotechnology ICRISAT is working closely with the Government of India and other national governments. It has established The Centre of Excellence in Genomics to provide high-throughput, low-cost genotyping services for research and breeding and this will enable National Agricultural Research Systems (NARS) to do genotyping. Another initiative that has been started with support of DBT, India is Platform for Translational Research on Transgenic Crops (PTTC) for evaluating new options in agricultural biotechnology.[50]

Another CGIAR institution, the International Rice Research Institute (IRRI) has been involved in rice research for almost half a century. Its approach includes biotechnology and it supports both basic and applied research in this. Its involvement with biotechnology started in 1978 with tissue culture. IRRI's biotechnology program is also engaged in human resources development and has imparted training to plant breeders and other scientists from developing countries.

ICGEB is an initiative sponsored by UNIDO for application of biotechnology in developing countries to solve their problems. Its headquarters are in Trieste and the Centre in India (New Delhi) is the centre in Asia. ICGEB works on biomedicine, crop improvement, environmental protection/remediation, and biopharmaceuticals and biopesticides production. It is involved in human resources development through PhD and Post-Doctoral fellowships. It is collaborating with enzyme to develop a new and improved treatment for Malaria.

UNESCO and the Ministry of Agriculture, Government of Bhutan, organized a Training workshop in molecular propagation of medicinal plants in Bhutan. Laboratory experiments covering basic biotech techniques in micro-propagation were also undertaken during the training course. UNESCO supported the government of Maldives in their efforts of taking protective measures against the threats to the country from global ecological degradation, and pursuing environmentally-friendly lifestyles with the aid of modern technology as has been faithfully outlined in the Government's 7th National Development Plan. UNESCO organized a training course on conventional and molecular fish disease diagnosis. Researchers from Marine Research Centre, Maldives spend 17 days at the UNESCO MIRCEN (Microbial Research Centre) at the Karnataka Veterinary, Animal and Fisheries Sciences University College of Fisheries, Bangalore, India receiving training on use of equipment for health management of captive aquatic animals, and use of biotechnology techniques in fish disease diagnosis. UNESCO and the National Science Foundation, Sri Lanka organized a symposium on Science Journalism. UNESCO supported 4th Conference on Biotechnology and the Development in Nepal, in collaboration with RIS and Nepal Government.

There are also regional initiatives in improving infrastructure for betterment of agricultural production. The Greater Mekong Sub-region (GMS), initiated by the Asian Development Bank is an innovation in international cooperation especially in infrastructure development and benefit sharing. The unique features of the GMS are its geography (with each country sharing atleast three border areas) economics (bordered by China and Thailand) and sponsorship (ADB from national allocations).[51]

In Asia, the regional cooperation in science and technology has also been catalyzed by countries like Japan, which are keenly supporting active networks within the region. The Official Development Assistance (ODA) being extended by Japan is aptly analyzed.[52] The findings have shown that till now the focus of Japanese assistance is on ethical issues within biotechnology. However, it is being argued that Japan should consider redesigning the ODA as an instrument for meeting the larger economic needs in the AP region with the help of biotechnology. The response to these global developments from the AP

countries is at different levels. Largely it has remained confined to joint technology development programs, in case of ASEAN, and issuing statements of intentions in case of SAARC. These groupings have yet to reach at the stage of commercialization of frontier technologies. One basic difference, which stands very clear, among these groupings is the very raison d'être for cooperation. Where EC wants to retain its comparative advantage in the higher band of technologies, groupings like SAARC are looking for complementarities to overcome the high cost of R&D for ensuring success of policy programs such as food security. The urge to establish SAARC gene bank probably emphasizes that point only. The example about island communities and UNESCO's efforts behind MIRCEN network signifies the same spirit. The central issue however, is that after creation of infrastructure services and policy framework for promotion of biotechnology, AP countries have to focus on strengthening the implementation of biosafety guidelines affiliated with the commercialization of biotechnology products. The challenge is to ensure the working of the regulatory regime not only at the level of research laboratories but also at the operational levels such as trade, quarantine and embarking points. This again requires specialized training of personnel who are manning these entry points. In case of AP countries, regional cooperation at the level of trade groupings like SAARC and ASEAN may play a vital role in evolving and implementing the biosafety guidelines. Since geographical conditions and biological vegetation are almost same, regional cooperation may facilitate emergence of harmonized approach towards biotechnology.

The importance of co-operation for technology development is well acknowledged in the literature. The Green Revolution would not have been possible had there been no co-operation. In case of biotechnology it is clear from our surveys that there had been many co-operative initiatives in the countries in AP region. Bilateral and multi-lateral efforts have played an important role in development of technology in this region.

But a closer look reveals that while they are necessary they themselves are not sufficient enough to spur a biotechnological revolution or sustain it. They succeed well if they are integrated into a broader policy framework or national biotechnology strategy. Otherwise they remain confined to one institution or one technology and the linkage between them and the overall policy framework is missing. For example Pakistan and Indonesia had benefited from bilateral and multilateral initiatives in co-operation but these initiatives have had very limited impact on the overall development of biotechnology in these countries. The absence of a strategic framework, lack of funding for biotechnology, and the limited scope of most of the initiatives are some of the factors that constrain the country from deriving the best from such initiatives. In case of Sri Lanka FAO had played an important role in formulating the National Strategy and in capacity building. Similarly UNEP has played an important role in bio-safety issues. Rockefeller Foundation, US AID, ADB are some of the other institutions that have helped growth of biotechnology in the region. But it is up to the national governments to come out with a policy and regulatory framework and make the best use of these initiatives.

Strangely the co-operation between or among the countries in this field are limited and perhaps there are more multilateral initiatives than bi-lateral initiatives. As countries are

at different levels of economic development and application of biotechnology, it can be argued that the scope for such a co-operation is limited. It is also true that countries often lack the financial and other resources to engage in such a co-operation in a big way. But the question is, if there can be regional trade agreements and trade blocs why can't there be a regional co-operative effort in biotechnology too. South East Asian countries like Vietnam, Laos, and Cambodia can learn many lessons from the experiences of Thailand and South Korea. Similarly, Indonesia can benefit immensely from the technological leadership and dynamism of the biotechnology sector in those two countries if there is a long-term co-operation program with well thought-out plans and programs. In the case of SAARC there is little that has been done in this. India's stride in biotechnology offers many a lesson to Bangladesh, Sri Lanka and Nepal. Yet under SAARC there are no significant initiatives in this.

Regional co-operation does not necessarily mean that it is one-way traffic in the sense that one country helps the other(s) and there are only donor(s) and recipient(s). The scope for regional co-operation in joint research, development of technology and transfer of technology should be envisaged and some common themes for such a research can be identified. For example, in SAARC rice biotechnology is one theme that is of importance to India, Pakistan, Sri Lanka and Bangladesh. Biotechnology for plantation crops is a theme that can be jointly explored by India and Sri Lanka. Besides this specific crop/theme focused regional co-operation there should be co-operative efforts at the Pan AP level in sectors like health, industrial application of biotechnology, second/third generation bio-fuels using biotechnology.

The uneven development of human resources in biotechnology is a case for concern. As biotechnology is knowledge intensive industry the availability of trained and qualified personnel is essential for growth and development of industry and capability to use biotechnology. Development of human resources in basic science and applied research is a necessary condition for sustaining biotechnology development in any country. The table below provides an overview of the situation in different countries and further analysis is provided in the subsequent chapters.

Table 2.7: Human Resources

Country	**Details**
Australia	8820 in industry & academic institutions
Bangladesh	Limited
Cambodia	No industry – very few in academic institutions
China	Well developed in both basic & applied research
India	61 universities offer PG/PH.D courses
Indonesia	5 public sector organizations, 3 private sector
Japan	Well developed – strong base in basic and applied
Korea	approx.20000 persons in industry, strong academic research
Laos PDR	Limited human resources`
Malaysia	Fast growing industry and emphasis on education & research
Nepal	Limited human resources
New Zealand	Demand more than supply, relaxed norms for foreigners

Pakistan	29 centers/departments, industry nascent stage
Philippines	<1000 in biotech R&D firms,
Singapore	about 12000 employees, strong research base
Sri Lanka	<300 researchers mostly in govt. sector
Thailand	plans to develop human resources in a big way
Vietnam	Limited human resources

The biotechnology revolution is expanding as well as deepening. Technological convergence is giving a new impetus to this. Countries in AP are in different stages of development in harnessing biotechnology. There are many positive developments and some of the trends are disquieting. In our view, the time to assess the direction and trend of the biotechnology revolution in AP has come and relevant measures have to be taken. One important lesson is that in a globalised world where science and technology is also globalised, countries should be aware of both the threats posed by and the opportunities provided by this globalization. By and large, states in AP have been positive supporters of biotechnology and this is likely to continue in future also.

2.6 Conclusion

The contours and direction of biotechnology in AP are clear. In terms of growth and innovation agricultural biotechnology is the most well developed biotechnology in AP. Medical biotechnology is taking roots in some countries and in some countries like Singapore it is emerging as the significant application of biotechnology. There are enough indications that biotechnology industry is growing in all countries, albeit in different paces. While the continued support of the state for biotechnology is necessary, the importance of strengthening national innovation systems need not be over-emphasized. For countries that have a weak and under-funded innovation system in agricultural research, optimum utilization and benefiting from agricultural biotechnology will be difficult. In medical biotechnology, many states have realized the importance of supporting research in basic life sciences and have invested heavily in supporting it or in developing the right infrastructure. Development of biotechnology clusters is becoming an important phenomenon in some countries. The biotechnology clusters and regional initiatives in some countries (e.g. New Zealand) are expected to add momentum to development of biotechnology in AP. Thus biotechnology in AP is entering a crucial phase and the path ahead is full of many opportunities and challenges.

Regulation of biotechnology has emerged as an important issue. Most of the nations in AP are either signatories to the Cartagena Protocol or have taken steps to implement it in the national regulatory framework. Some countries like Sri Lanka are moving closer to implementing a national biosafety framework. In this area i.e. regulation and biosafety, capacity building is vital and there is ample scope for regional and multilateral collaboration. A well-developed and coherent regulatory framework is essential for

development of biotechnology industry in any country. Countries should realize this and ensure that appropriate framework is in place as early as possible. Although collaboration in developing regulatory framework and capacity is welcome, ultimately the framework should be credible and relevant to the needs of the country implementing it.

Although there are many multilateral initiatives in biotechnology in AP, these are not sufficient, considering the needs of the countries and for the growth of biotechnology. The scope for more initiatives, particularly in human resources development and collaborative regional research has been highlighted in this report. Here too, such efforts have paid a rich dividend and have been part of the initial initiatives in establishing biotechnology. Issues like technology convergence and the challenges posed by globalised science and technology need to be understood and appropriate policies have to be developed by countries in AP.

Due to lack of reliable data and problems in accessing and analyzing the data and information it is difficult to make a comprehensive analysis and comparative study of the information and data available from different sources. The issues relating to data collection and methodology have been highlighted elsewhere. Still from the data and information available it is possible to make some preliminary inferences.

The biotechnology industry is growing but it is nowhere near the size and diversified nature of the industry in USA or Europe. The number of firms involved in R&D is increasing but still small. The number of firms dedicated to R&D is very less. Most of the biotechnology firms are small and medium enterprises in terms of employment although the value addition per employee is likely to be higher than that of other industries. As the country chapters indicate industry has grown through different stages and in some countries like Vietnam and Sri Lanka it is in nascent stages. In countries like Japan, Korea and Australia the industry is trying to catch up globally and has strong roots. Venture capital is an important source in Japan and New Zealand but in many countries there is no venture capital investment in biotechnology. International collaboration and technology partnerships are becoming important in countries like Korea, Malaysia, Japan and Singapore. The strong support from the state through various schemes, incentives and investment in infrastructure is giving the biotechnology industry, the much needed impetus. But this alone cannot sustain the industry in the long run particularly in sectors where innovation is the important source for growth. Hence the strengthening of national innovation systems, more collaboration with academic institutions/universities, improving the capacity to develop novel products and capitalizing upon/ building on research and development in basic sciences are necessary for the industry to grow and sustain. Focusing in niche areas/technologies like stem cell technology, and use of medical tourism, attracting foreign talent are some of the strategies that are put to use by the industry and government.

The biosafety regulation in AP is a cause of concern as many countries have not implemented national regulatory frameworks. Some countries have them in place for many years and are in the process of revising them (e.g. India) or have revised them (e.g. Japan). But in some countries there is lack of clarity in issues like labeling of GM foods,

regulating agricultural biotechnology and this will affect the growth of biotechnology. Most countries in AP are signatories to the Cartagena Protocol and have taken steps to adhere to it.

In terms of human resources the countries in AP are in different stages of development. Countries need to do more in this and strengthen the national innovation systems. Countries like Thailand, China, and India have invested in their tertiary educational system to develop appropriate human resources in biotechnology. But for many countries the dependence on public sector research institutions in agriculture/agricultural biotechnology is heavy as there is no significant activity by the private sector in this. The lessons from the Green Revolution are relevant here. Without sustained efforts including bilateral/multilateral support and collaboration in capacity-building these countries will not be able to build up a critical mass in human resources and other capacities to benefit from biotechnology.

Many countries have developed biotechnology strategies or policies on promoting biotechnology. Some countries have no specific policy but indicate the importance of biotechnology in their development/ Science and Technology policy. The biotechnology strategies with specific objectives and focusing on particular areas bring in needed clarity and induce the private sector to identify sectors for investment. The absence of a policy or strategy may indicate that while the government is not averse to biotechnology, it has no special plan to promote it. Hence it is essential that countries develop coherent and appropriate policy frameworks/ strategies to promote biotechnology.

Technology convergence, declining investment in public sector R&D for agriculture, intellectual property rights, public acceptability and attitude towards biotechnology are some of the issues that deserve attention from governments and policy makers.

To sum up, while it is necessary to learn from the past, it is equally important to think about new approaches and initiatives in the future to sustain the biotechnology revolution in AP.

Country Reports

Chapter 3: Australia

Introduction

Australia has developed a reputation for itself in the field of biotechnology and now is one of the major centres for biotechnology in the world after United States, Canada, Germany and the United Kingdom. Realising the importance of biotechnology well ahead of many others the Australian government attempted to plan and promote biotechnology development through the setting up of the Biotechnology Australia in 1999. Subsequently it came out with National Biotechnology Strategy in July 2000. The key objective of the National Biotechnology Strategy is to provide a framework for Government and key stakeholders to work together to ensure that developments in biotechnology are captured for the benefit of the Australian community, industry and the environment, while safeguarding human health and ensuring environmental protection.

This agency was supported with $ 30.5 million for a period of three years (2001-04). The Strategy received a further $66.5 million in 2001, with funding for the Biotechnology Centre of Excellence, the Australian Stem Cell Centre, and additional funding for the Biotechnology Innovation Fund (BIF). The Strategy and Biotechnology Australia were again funded $20 million in July 2004 to continue the National Biotechnology Strategy and Biotechnology Australia until 2008. Further funding was also provided to extend support for the Australian Stem Cell Centre until 2010-11.[53] The Australian Government is considering an independent review of both these initiatives. In addition to the Australian Government's contribution to biotechnology, State and Territory governments also commit substantial resources to the development of biotechnology. In addition to all this are the benefits that biotechnology developments receive from governments other programmes in health, agriculture, environment, industry and education portfolios.

3.1 Programme Framework and Funding

3.1.1 National Biotechnology Strategy

The National Biotechnology Strategy of Australia was launched in July 2000 with the objective of providing a framework for Government and key stakeholders to work together to ensure that developments in biotechnology are captured for the benefit of the Australian community, industry and the environment, while safeguarding human health and ensuring environmental protection. The Strategy addressed six key themes with specific objectives and activities to achieve them. They included (a) biotechnology in the community which had to focus on establishing and providing channels for credible sources of information on biotechnology; (b) ensuring effective regulation comprising setting up of an Office of the Gene Technology Regulator (OGTR) in collaboration with the Department of Health and Ageing (DoHA) apart from Ecological Risk Programmes for providing information on risks associated with GMOs; (c) biotechnology in the economy to provide support for industry development through NBS funding and for establishing a peak industry body called AusBiotech and National Stem Cell Centre (NSCC); (d) Australian biotechnology in the global market, with NBS funding for supply chain management of GM and non-GM products in partnership with industry; (e) improving access to Australian biological resources across States and Territories; and (f)

resource coordination among Commonwealth Biotechnology Ministerial Council (MinCo), Australian government, State & Territory Biotechnology Liaison Committee (BLC) and an independent advisory body on biotechnology – the Australian Biotechnology Advisory Council (ABAC). Following the 2004 US Bio conference, a National Approach Work Programme was agreed by the Australian Government to build on national strengths in biotechnology collaboratively to avoid duplication and dilution of effort.

3.2 National Bioinformatics Strategy

Bioinformatics has been identified as a Priority Goal within the National Research Priorities. For the period 1999 to 2006, the Australian Government has provided or committed around USD 60 million to specific bioinformatics activities, and around USD 80 million overall to more generic types of infrastructure and project support.[54]

3.3 Biotechnology Industry

There is steady expansion of the private sector in Australia. In 1999 there were 170 private firms. This number increased. In 2008, there were more than 505 firms providing employment to nearly 7000 people.[55] The Australian Government, through the Office of the Gene Technology Regulator and Food Standards Australia New Zealand ensures that all food products that reach consumers (including imports) are biologically safe to consume.

The Industry comprises a range of companies, from start-ups to more developed companies selling products in Australia and overseas, operating in applications of biotechnology including health, industrial processing, agriculture and environment. The total number of firms operating in applications of biotechnology in 2006 was 527 out of which 353 were dealing with Health Biotechnology (Table 3.1). A total of 384 firms were dedicated only to biotechnology which is about 73 percent. In 2006, the number of people employed in Biotech R&D firms was about 18,700.[56]

Table 3.1: Break up of Firms dealing in Biotechnology Applications

Biotech Application	No. of Firms
Health	353
Agriculture	185
Natural Resources	22
Environment	85
Industrial Processing	90
Bio-Informatics	84
Others	48

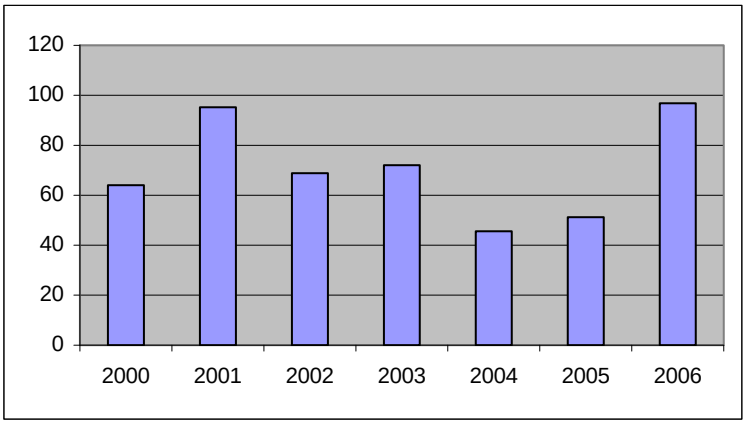
Note: A given firm can deal in more than 1 application.
Source: OECD (2009).

An estimated 8,820 persons were employed in 72 publicly listed biotech companies in 2006-07 whose turnover in the same year was about USD 2300 million. Six companies had a market capitalization of over USD 100 million at the end of 2008.[57]

3.4 Innovation and Patents

Patents are very important indicators of success in the biotech sector because of the importance of intellectual property as the foundation of inherent value in this sector. Over the period 2000-2005 the trend in US biotech patents granted to Australian inventors has been shifting gradually downwards, however in 2006 there was a sharp upward turn (fig. 3.1).

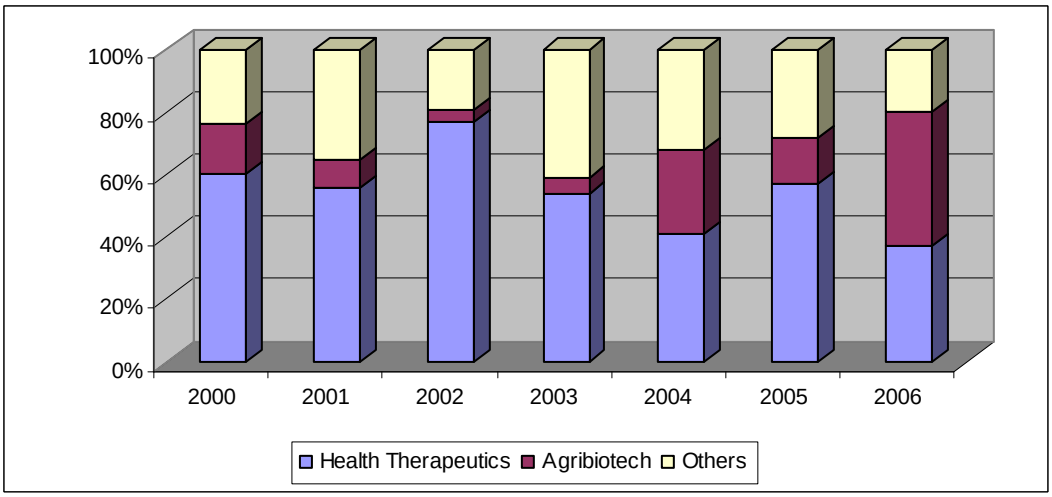
Figure 3.1: No of US Biotech Patents granted to Australian Inventors



Source: Thorburn and Hopper (2007).

The Health Biotech patents were completely dominant before 2004 but from that year onwards the number of Agri-Biotech patents has been increasing (fig. 3.2).

Figure 3.2: Breakup of US Biotech Patents granted to Australian Inventors into Biotech Applications 2000-2006



Source: Thorburn and Hopper (2007).

A total of 297 biotech PCT patent applications were filed by Australia in the period 2004-2006 making the share of Australia in total biotech PCT patents 2.1 percent.[58]

3.5 Regulation of Biotechnology

3.5.1 Office of the Gene Technology Regulator

The Office of the Gene Technology Regulator is an Australian Government agency, located within the Government Department of Health and Ageing. The Gene Technology Act 2000 establishes a statutory officer, the Gene Technology Regulator, to make decisions regarding 'dealings' with GMOs, including research, manufacture, production, experiment trails, commercial release and importation. The Regulator has the responsibility for identifying, assessing and managing potential risks to human health and the environment that may be posed by gene technology. Therefore, the regulator will not issue a license for a GM dealing until satisfied that the health and safety of the people and environment are protected. The Act also establishes a public record of GMOs and GM products approved in Australia (the GMO record). The GMO Record is available on the OGTR web site and lists of all GMOs approved by the Regulator and all GM product approved by other product regulators. The Regulator has extensive powers to monitor and enforce the law. Anyone who does not adhere to license conditions, or follow directions from the Regulator to take measures to protect human health and safety and the environment from risks posed by gene technology, could face criminal penalties, including fines and imprisonment. Marketability and agriculture trade issues that may be posed by gene technology are excluded from the scope of the assessment of the Regulator.

3.5.2 Food Standards Australia New Zealand

The agency Food Standards Australia New Zealand ensures the safety of all consumable foods, including imports, by developing effective food standards for Australia and New Zealand. For Australia, FSANZ develops food standards for the entire food supply chain, from primary production through to manufactured food and food retail outlets.

3.5.3 GM food Labeling

The Standard for Labeling GM food came into force in December 2001. It requires any food, food ingredient or processing aid produced using gene technology and containing novel DNA of novel protein to be labeled as 'genetically modified'. The standard also allows 1 percent unintentional presence of GM food or ingredient in a final food.

3.6 Conclusion

Australia has a vibrant biotechnology industry and a supporting policy milieu including financial support from the federal government and state and territory governments. The presence of a developed regulatory regime is another feature that will help growth of biotechnology in Australia. Agricultural biotechnology and health biotechnology are the two most important sectors. In terms of human resources Australia can draw on the well developed tertiary education sector including the universities that attract students and faculties from other countries in AP. Hence biotechnology in Australia can be expected to grow further and deepen in the years to come.

Chapter 4: Bangladesh

Introduction

In the recent past, Bangladesh has exhibited a consistently high growth rate of around 6 per cent with increasingly high degree of diversification. In 2008, the growth was around 6.2 per cent which was lesser than 6.6 per cent of 2006, largely due to frequent natural disasters, which adversely affected agriculture growth.

Bangladesh is pre-dominantly an agricultural economy with almost 80 per cent of population dependent on agriculture. The fertile alluvial soil of Ganges-Meghna-Brahmputra (GMB) delta coupled with high rainfall and easy cultivation has made rice as the major food crop which is cultivated throughout the year, apart from other commercial crops like jute, etc.

Bangladesh has launched major efforts for promoting commercialization of biotechnology in the agriculture sector. The National Technical Committee on Crop Biotechnology in the Ministry of Agriculture has approved the import of some biotech products for contained trials; these include Golden Rice, fruit-and shoot-borer resistant Bt eggplant, late blight resistant Potato, insect resistant Bt Chickpea, and ring spot virus resistant Papaya. After successful completion of the contained trials, Bt. Eggplant is currently under limited field trials at Bangladesh Agricultural research Institute (BARI) regional stations; while transgenic potato is awaiting government approval for such trials. There are interesting research projects initiated at the Dhaka University for developing saline resistant rice varieties, which are being field tested at Satkhira. Similarly a large number of jute varieties from the Gene Bank of Bangladesh Jute Research Institute have been screened for cold tolerance. The next phase for these biotech trials will be the approval for multi-location trials in farmers' fields. Bangladesh has also taken initiatives to tap international institutions. It became member of ICGEB in the nineties. It has established a National Institute of Biotechnology with a view to creating a Centre of Excellence in modern biotechnology. Recently one of the leading pharmaceutical firms INCEPTA signed an MoU with ICGEB, Delhi to access recombinant DNA technology for vaccine production to manufacture Hepatitis B in Bangladesh.[59] The largest pharmaceutical company, SQUARE Ltd has also taken up an ambitious programme in modern biotech products.

4.1 Policy Initiatives

Bangladesh had undertaken efforts to consolidate R&D policies in the biotechnology sector through the National Biotechnology Policy, which was a follow up of the work identified by the National Committee on Biotechnology Product Development, 1993. It was in May 2004 that the Government of Bangladesh constituted a National Committee for the formulation of a National Biotechnology Policy. The Committee came out with a draft policy in August of the same year , which was circulated widely for comments and discussion. Finally, the National Biotechnology Policy, prepared by the Ministry of Science, Information and Communications Technology, Government of the People's Republic of Bangladesh and approved by the National Task Force on Biotechnology was

released in July, 2006. The released document was the fifth draft of the policy and covers almost all aspects of biotechnology and its utilization for national development.

Research work in Bangladesh till recently were mostly carried out by individual scientists in a fragmented manner. Previously there was no separate research budget for the purpose. Currently, a separate R & D budget is given by the government for carrying out research work. In addition a special grant of 180 million Taka is provided by the Ministry of Science and ICT every year for R & D in Physical, Biological and Engineering Sciences. However, the annual expenditure per scientist in a year will not exceed $ 500.

The National Policy (2006) envisaged setting-up an autonomous National Commission for Biotechnology (NCBT) with its own Secretariat and independent funding.[60] This is proposed to be the national body with the following responsibilities:

(i) Be the GoB's focal point for promoting and supporting all biotechnology-related activities in Bangladesh through interaction and coordination with relevant government departments, academic and research institutions, and local biotechnology and pharmaceutical industries;
(ii) Formulate and implement Biotechnology-related policies;
(iii) Coordinate and fund Biotechnology research in Bangladesh;
(iv) Support Biotechnology education and training;
(v) Help raise funds from government and private sectors in Bangladesh and from international funding agencies and development partners; and
(vi) Be the reference centre for Biotechnology-related regulatory and intellectual property issues.

However, it was also envisioned that the flagship for research would remain with the National Institute of Biotechnology (NIB). Both NCBT and NIB are expected to work closely for optimum economic returns. It is also proposed that the NCBT and NIB share the same International Scientific Advisory Committee (ISAC) for the first five years.

4.2 Institutional Framework

Since independence, Bangladesh has launched several initiatives for strengthening the institutional framework for academics and education sector. Universities in Bangladesh represent about 75 academic bodies out of a total of about 105 institutions represent the conventional higher education institution (HEI) in Bangladesh. Segmented by management and financial structure, these include 30 public universities, 54 private universities, 1 international university, 31 specialized collages, and 2 special universities. There are specialized universities in both categories offering courses principally in technological studies, medical studies, business studies and Islamic studies. There are two private universities dedicated solely to female students. The number of universities is growing mostly in and around the capital city of Dhaka..[61] However, this is not sufficient as number of applicants for various posts is huge and it does not cop-up with the overall requirements. As a result, more than 50 candidates appear for one seat in a government university. The total capacity of all the government universities will be less than 50,000.

There are several institutions of national importance established in Bangladesh which cover various areas of research. Most of these institutes have been functioning for more than 30 years and the total number of scientists working in different institutes will be nearly 3000. The most important of them are: Bangladesh Atomic Energy Commission (BAEC); Bangladesh Council of Scientific and Industrial Research (BCSIR); Bangladesh Rice Research Institute (BRRI); Bangladesh Agricultural Research Institute (BARI); and Bangladesh Institute of Nuclear Agriculture (BINA). The Sericulture Research Institute (SRI) at Rajshahi has been working on improvement of sericulture production in Bangladesh. Another important institution is the Bangladesh Livestock Research Institute (BLRI) which has launched a modern biotechnology research programme in collaboration with the Bangladesh Agriculture University (BAU). The programme includes embryo transfer technology and multiple ovulation embryo transfer technology. There are two major NGOs also working in the realm of biotechnology, especially tissue culture technology for micro-propagation, they are BRAC and PROSHIKA.

The National Institute of Biotechnology (NIB) under the Ministry of Science and Information and Communication Technology, Government of Bangladesh, was launched in 1999 for carrying out far more focused work in biotechnology research. It was proposed that the NIB would be a national network for contemporary Biotechnology R&D with an intramural research and administrative centre at Savar and extramural research units (within university and research institutes) spread across the country. This institute would have six laboratories working in various areas such as DNA Laboratory, Plant Biotechnology, Animal Biotechnology, Fish Biotechnology, Fermentation and Bioprocessing and Bioenergy and Fertilization. The concept of the institute was developed in 1984 but due to several administrative delays the proposal was finally approved in 1995. At this stage a project proposal was prepared with an estimated cost of 2021.20 lakh taka. The NIB could only be launched in 1999.[62] The NIB is expected to have more than 100 scientists on board working at the above mentioned six laboratories. It has launched various projects on various areas of national requirement. There was one project launched in 2006 which was expected to be over by the end of 2009, developing technology for production of valuable materials including foodstuffs using microbes, and preservation of microbial diversities, which would be of immense economic significance given continuous economic environmental challenges across Bangladesh.

4.3 Biosafety

The Ministry of Science and Technology of Bangladesh formulated Biosafety Guidelines for the first time in 1999. Bangladesh ratified the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity on February 5, 2004, which came into force in May 5, 2004. Being the National Focal Point (NFP) of the CPB, the Ministry of Environment and Forest took the lead in establishing a biosafety regulatory regime. On May 10, 2008, the Department of Environment, Ministry of Environment and Forest issued the Biosafety Guidelines of Bangladesh, and the National Biosafety Framework. However, the regulatory structures as per the policy are yet to be installed; as a result, no biotechnology crop is approved for commercial cultivation.

Bangladesh officially prohibits the importation (for commercial use) of agricultural products containing bioengineered products. On July 19, 2006, the National Task Force on Biotechnology Development (NTFBD) approved a policy framework and issued guidelines for biotechnology. The Biosafety Guidelines of Bangladesh have subsequently been updated by the Ministry of Environment and Forests in conformity with the CPB and were published in the National Gazette in January 2008.[63] In order to implement the biosafety guidelines, the following committees were formed which provided administrative support mechanisms at various levels viz. National Committee on Biosafety (NCB), the Biosafety Core Committee (BCC) and the Field Level Biosafety Committee for monitoring confined field trials. In 2007, Bangladesh developed the National Biosafety Framework (NBF). The Biosafety Framework has been finalized through the process of multi-stakeholder consultation and it lays the foundation for establishing a regulatory regime to ensure safe transfer, handling, transit, trans-boundary movement, development, field trial and commercial release of GMOs. The NBF is complimentary to the national commitments towards implementation of a multilateral environmental agreement like the Cartagena Protocol on Biosafety.

4.4 Conclusion

Bangladesh has made a good beginning in terms of policy and capacity building. It should maintain the tempo and go further in biotechnology development. Bilateral and multilateral support in human resources development will go a long way in realizing the potential of biotechnology. The need for a dynamic biotechnology industry in private sector is obvious as the government and public sector institutions alone will not be able to sustain the biotechnology development in Bangladesh.

Chapter 5: Cambodia

Introduction

Cambodia has consistently shown high growth rate of 6 per cent and above in the recent past. In the fiscal years 2007 and 2008, it exhibited a growth rate of 6.3 per cent and 6.1 per cent respectively. According to ADB Outlook (2009), the growth is likely to decelerate this year due to contraction in demand but may pick up in 2010. The government has made an effort of providing a stimulus package of almost $ 6.5 billion (Rp 73.3 trillion) for boosting support to private consumption through waivers of income and value added taxes through subsidies for cooking oil and generic medicines. The package is likely to boost electricity, housing, construction related activities.[64] However, Cambodia faces the challenge of coping with widespread poverty when more than 55 per cent of the population is living on less than $ 2 a day. The poverty incidence is around 16 per cent in Cambodia.

In the Cambodian economy, the share of agriculture is relatively small at 14 per cent but it employs more than 41 per cent of the population. An estimated 85 per cent of 14 million Cambodians live in rural areas and depend upon agricultural cultivation as their primary means of subsistence or livelihood. This sector has shown an average growth rate of 4.5 per cent in last couple of years. In 2008, this was 4.8 per cent. The proactive measures by the government through subsidies and other support measures, adoption of hybrid seeds and fertilisers have helped in boosting rice production to a great extent, bringing Cambodia to self-sufficiency. In 2008, rice production went up by 5.5 per cent to 38.6 million metric tonnes.[65] Cambodia has developed into a net exporter of rice and corn, and nearly all exports are unofficial border trade with Vietnam and Thailand.[66]

5.1 Specific Initiatives

In order to provide a major fillip to agriculture research, the Government of Cambodia approached the International Rice Research Institution (IRRI) for research assistance on rice, which later on led to the launching of the Cambodia-IRRI-Australia Project (CIAP) in 1989. The efforts through this project laid the foundation stone for the evolution of a national agricultural research system in Cambodia. The mini project graduated to a major institutional building block, as CIAP evolved as Cambodian Agricultural Research and Development Institution (CARDI) took off in 1999. This institute hired almost 40 researchers from many domestic agencies including the Ministry of Agriculture's, Department of Agronomy and Agricultural Land Improvement and Department of Agricultural Engineering.

CARDI's Training and Information Program manages all training activities. Annually the CARDI training program offers 10 to 15 training events, typically attended by over 300 individuals.[67] Resource personnel for training are drawn from CARDI's professional staff, and occasionally are supplemented by individuals from other institutions or organizations external to CARDI. With its links to the international science and agricultural communities, as well as its link to government, CARDI has access to a wide range of expertise and training resources. As a result, Cambodia has a relatively strong

supply system for distribution of standardised seeds and planting material (See Table 5.1).

Table 5.1: Quality Seed and Plant Materials

Category	Classification			
	Foundation seed	**Registered seed**	**Certified seed**	**Graded seed**
A. Seed				
1. Rice	USD 3.13/kg	USD 2.50/kg	USD 1.88/kg	USD 0.50/kg
2. maize	USD 6.25/kg	USD 4.36/kg	USD 3.13/kg	USD 1.50/kg
3. Mungbean	USD 6.25/kg	-	-	USD 1.50/kg
4. Tomato	USD 6.25/g	USD 4.38/g	USD 3.13/g	USD 1.25/g
5. Watermelon	USD 1.25/g	USD 0.94/g	USD 0.63/g	USD 0.31/g
B. Seeding and plant propagation materials (CARDI nursery)				
			Age at 6 months	**Age at 3 months**
6. Mango seedling			USD 3.50/plant	USD 2.5/plant
7. Banana tissue culture plantlet (made available by prior purchase order only)				USD 0.40/plantlet

At this moment, CARDI has a team of highly qualified scientists and engineers in agriculture and socio economic disciplines and is regarded as the leading centre for agricultural research expertise in Cambodia. In 2004, CARDI launched advance research laboratory for conducting biotechnology related research in agriculture. It has been engaged in providing training services for many years and has a well designed and resources training facility located at CARDI. The basic objective of CARDI is "Technology for Prosperity", as a part of which CARDI launched biotechnology research in Cambodia. According to Channa (2006) CARDI has initiated programmes in agriculture biotechnology for achieving greater crop productivity, enhancing resistance to biotic and abiotic stresses and improved agronomic traits. However, due to resource constraints Cambodia relies more on first generation agriculture biotechnology like tissue culture for banana production. In many other areas Cambodia still has to rely on conventional breeding techniques for mass and pure-line selection, conventional crossing, and grafting.[68]

A recent statement made on World Food Day by the Cambodian spokesman of the United Nations World Food Program raised alarm over the fact that 64 per cent of children under five years of age, and 59 per cent of Khmer women, reportedly suffer from iron deficiency or anemia, "which drains them of energy and makes them more susceptible to disease.[69] In a bid to strengthen the Cambodian vegetable industry, improve household nutritional levels and replace imports with local produce, ACIAR has recently supported a three-year project on improvement of vegetable production and post harvest management systems.[70] Cambodian farmers adopt new agricultural technology very well, especially the use of high-yielding hybrid corn seeds.[71] Charoen Pokphand Group (C.P.) from Thailand has successfully introduced hybrid seeds to Cambodia corn growers. Hybrid seeds dominate about 90-95 percent of the total corn area. The market share of

C.P. hybrid seeds is about 70-80 percent, while the balance goes to hybrid seeds from Vietnam and other multinational companies.[72]

5.2 Patents and Publications

Regarding patent regime in Cambodia, laws in patents, Utility Model Certificate and Industrial Design have been in force since January, 2003. Also, laws concerning Marks, Collective marks, Trade names and Acts of Unfair competition have been in force since February, 2002. As for the industrial property statistics, the number of applications filed by residents and non-residents in 2003 is 297 and 1559 respectively while the number of applications granted to the same are 270 and 1548 respectively.

5.3 Biosafety

The objectives of the government in biotechnology and biosafety are:

- Use of biotechnology to reduce the use of chemicals.
- Use of biotechnology to control pollution and to improve environmental health and other aspects of environment.
- Provide capacity for monitoring and enforcement to concerned ministries, NGOs and universities.
- Build capacity in appropriate labs in Cambodia to be able to identify LMOs (Living Modified Organisms).
- Utilize biotechnology to produce protein rich products that could be used as animal feed, organic fertilizers, soil conditioners and soil stabilizers.
- Promote sound genetic manipulation to increase fish and crop production.
- Promote the production of biogas, bio-fertilizers, and energy as a by-product of fermentation processes.
- Establish a national directory of human resources working on subjects concerned with biotechnology and biosafety.
- Develop a biotechnology training program including risk assessment and risk management of LMOs.
- Increase university resources in biotechnology research and development.
- Develop a National Code of Ethics and Guidelines for the use of biotechnologies, LMOs and GMOs.

Cambodia also developed their National Capacity Action Plan to address the objectives of the three UN Conventions (UNCBD, UNFCCC, and UNCCD) and identified 160 priority actions for implementation over a period of 10 years (2007-2016).

5.4 International Agreements

Cambodia signed the Cartagena Protocol on Biosafety in 2003. The progress in relation to the protocol includes adoption of national law on Biosafety (2007), and the extension of the mandate of the National Biodiversity Committee to also cover biosafety issues. Cambodia developed its Guidelines for Risk Assessment and Risk Management of Living Modified Organisms in 2007 and a draft National Action Plan on Biosafety and Biotechnology was developed in 2008. A Biosafety clearing house was thus established with the Ministry of Environment for sharing information with the CBD secretariat and other Parties to the Protocol.

5.5 Conclusion

It is clear that Cambodia has a long way to go in biotechnology. The modest beginning needs assistance from other countries and international agencies. Cambodia is rich in biodiversity and it's plans for biotechnology can focus on increasing agricultural productivity through biotechnology and conservation and sustainable use of biodiversity.

Chapter 6: China

Introduction

Since the 1990s, China has shown keen interest in development and adoption of biotechnology across various sectors. There are several programmes within which biotechnology is being funded by the government. China first incorporated biotechnology in the Seventh Five Year Plan (1986-1990) through the National Biotechnology Policy Outline, issued by the Ministry of Science and Technology (MOST) in 1990. Most of the biotechnology programme of China are under the '863 Plan', which has emerged as China's key initiative in science and technology.

With the continuous expansion of these programmes, China now has more than 150 laboratories and more than 50 research institutions engaged in frontier areas of biotechnology. China is among the few countries of the world, in which R&D expenditure and number of R&D personnel, both have gone up in a major way. In the period 2000-2005, the R&D expenditure went up by 19 per cent while the number of R&D personnel went up by 48 per cent.[73]

6.1 Institutions and Human Resources

S&T activities in higher education institutions are mainly carried out in their R&D institutes. In 2005, the number of R&D institutes of all forms established by higher education institutions was 3936. There are various forms of these institutes, with over 2/3 established independently by higher education institutions, while some were jointly established with other higher education institutions, and some with domestic or foreign enterprises, etc. About 4.1 million personnel were engaged in S&T Programs in 2006 out of which 1.5 million were engaged in Research and Development In terms of the composition of R&D institutes, 78 per cent covered the fields of science, engineering, agriculture and medicine, 22 per cent touched the field of social sciences and humanities. Most of these institutes focus on R&D activities, among which state laboratories, state key laboratories and state specialized laboratories highlight scientific research, while other R&D institutes are engaged in knowledge innovations as well as S&T activities pertaining to technological innovation.

6.2 Programme Framework

Among the major programmes funded by the Chinese government for development of biotechnology, the key ones are National S&T Programme (NSTP), National Natural Science Foundation and some programmes by the Chinese Academy of Sciences (CAS). There are separate programmes being funded by the Ministry of Agriculture and Ministry of Health. The NSTP has three major components which are generally to support biotechnology and other related initiatives. The National Nature Science Foundation of China is another source for supporting biotechnology. The research under programme 863 is on biology and medicine while the National Key Technologies R&D Programme focuses on agriculture alone. The focus under programme 973 is on basic research aspects of biotechnology which is also being supported by the National Basic Research Programme through its grant for protein research projects (Table III.1). The National

Nature Science Foundation of China (NNSFC) provides allocations for capacity building for young scientists and to some extent also support basic research.

6.3 Programme-Specific Expenditure

In 2006, the Gross Domestic Expenditure on S&T Research and Development was Yuan 300 billion out of which Yuan 74 billion was provided by government and Yuan 224 billion by the private sector. Out of this, expenditure on basic research was 15.6 billion yuan, expenditure on applied research was 50.5 billion yuan, and on experimental development was 234 billion yuan, accounting for 5.2 per cent, 16.8 per cent and 78 per cent of the GERD respectively.[74] It can be seen that the proportion of expenditure on scientific research (basic and applied research) to GERD is low in China with 22 per cent in 2006, compared to around 40 per cent of developed countries and emerging industrialized economies.

Table 6.1: Key Biotechnology Supporting Programmes in China

S. No.	Agency	Programme Details	Biotechnology Allocation
(i)	National Hi-Tech R&D Programme	863 programmes	0.81 billion yuan (2006)
(ii)	National Key Technologies R&D Programme	-	2.11 billion yuan (2006)
(iii)	National Basic Research Programme	973 programmes	0.26 billion yuan (2006)
(iv)	National Nature Science Foundation of China (NNSFC)		1.1 billion yuan (2007)

Source: Zhe (2009).

6.3.1 Hi-Tech Research and Development Programme (863 Programme)

This programme was started by the Ministry of Science and Technology in 1987 as a leading science and technology initiative and was termed as the National Hi-Tech R&D Programme. Its generic areas of funding are agriculture, medical, animal and environmental sectors but the programme 863 is also a major programme to support biotechnology and within that medicine related research in China. The budget for this programme in last five years has continuously expanded from $ 55 million to $ 105 million in 2004 and almost the same amount in 2005. In 2006, the total amount was Yuan 3.8 billion. Out of this, only Yuan 810 million (21 per cent) was for biotechnology (Table 6.2).

Table 6.2: Budget of 863 Program and the Share of Biotechnology Programs

Year	Total Budget (million $)	Share of biotechnology Programs
1987-2000	712.5	26%
1998	87.5	22%
1999	100	25%
2000	112.5	25%

2001	206.25	27%
2002	537.5	33%
2003*	384.4	26.8%
2004*	468.75	22.6%
2005*	511.9	18.5%

Source: Xielin and Jinhui (2007) based on Annual Reports on 863 Program, www.863.org.cn, *www.most.gov.cn

6.3.2 National Key Technologies R&D Programme

In this programme, the allocated total budget for Biotechnology is somewhere around Yuan 2.11 billion, out of which 29 per cent was allocated for the development of agriculture biotechnology. This programme provided support to the development of select areas of medical biotechnology as well.[75]

6.3.3 Programme 973

This programme is also termed as National Basic Research Programme. In this programme the primary focus is on protein research and procreation and development of related research projects. The budgetary allocation for this project in 2006 was Yuan 170 million.

6.3.4 National Nature Science Foundation of China (NSFC)

This Foundation is largely working in terms of enhancing basic research capacities in China and also trying to create a strong base of scientists and technical manpower to work at junior level. The scientists have tried to ensure that the system should help in term of tapping the potential of Chinese students. The budgetary allocation for this programme in 2007 was Yuan 3 billion, out of this nearly Yuan 1.1 billion (35 per cent) was for life sciences (Table 6.3). In 2007 more than 4000 projects/fellowships were sanctioned for promotion of R&D in life sciences.

Table 6.3: Budget of NSFC and Expenditure on Life Science and Biotechnology, US $ Mn.)

Year	Total Budget	Expenditure on life science and biotechnology
2001	199.8	66.6
2002	246	82
2003	256.2	85.4
2004	281.2	93.7
2005	337.7	112.6

Source: Xielin and Jinhui (2007) and based on Annual Reports of NSFC from www.nsfc.gov.cn

6.3.5 Innovation Fund for Technology based firms (IFT)

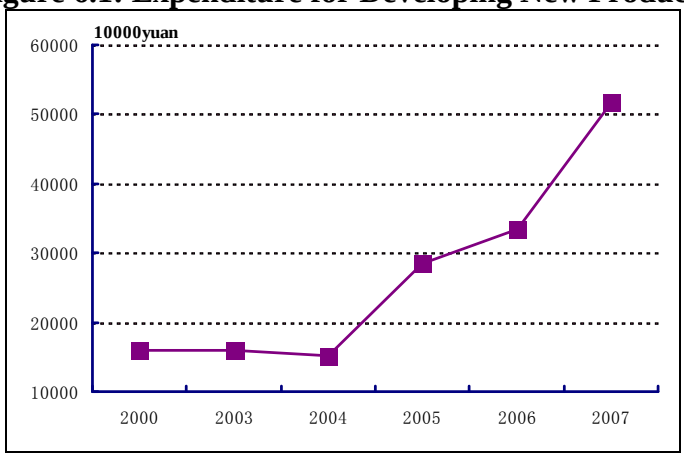
The programme was launched in 1999, under the stewardship of the Ministry of Science and Technology (MOST). The budgetary allocation for this programme has gone up from US $15.4 million in 2001 to US $ 21 million in 2006. This programme has focused on firms dealing with agriculture, medical, animal and environmental biotechnology. The programme requires private sector recipients of this fund to make an equal amount of investment for R&D purposes. These initiatives have provided a major boost to the growth of the private sector.

6.4 Regulatory Regime

6.4.1 Innovation and Patents

Bio-industry has received a major boost from the government as more and more funds are used for developing new products. About Yuan 0.15 billion were invested annually in developing new products and it was not enhanced distinctly from 2000 to 2004. After 2004, the condition was changed markedly and the annual average increasing rate is 53 per cent. In 2007, the funds reached to 0.52 billion, accounting for 59 per cent of the total expenditures on biotechnology activities and revealing the accelerating progress of industrialization (Fig 6.1).

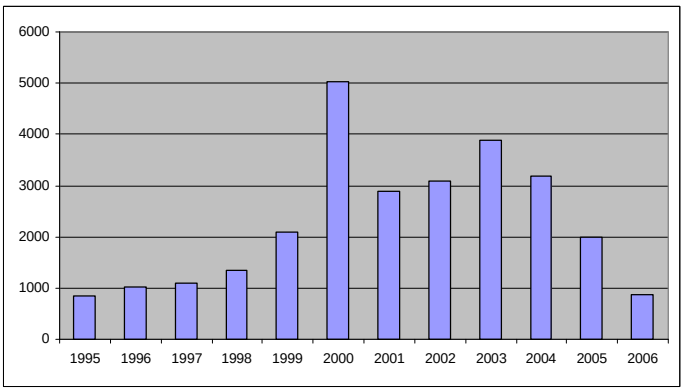
Figure 6.1: Expenditure for Developing New Products



Source: Zhe, Li (2009)

In China, attention on patents as an important index of S&T activities' outcome, especially in relation to demonstrating the contribution of R&D , is growing at a high pace. The number of applications for Biotechnology Patents was just 840 in 1995 after which it increased continuously and reached 5000 mark in 2000 (fig 6.2). However, the number did drop to about 900 in 2006. The increased patents also reveal the industrial progress that is based on the technical advancement.

Figure 6.2: Number of Patent Applications for Biotechnology for 1995-2006



Source: Gangulli, and Prikril (2009).

Number of Biotechnology PCT Patent Applications by China increased to 423 in the period 2004-06 as compared to just 22 in period 1994-96 and with it the Share of China in Total Biotechnology PCT Patents Applications reached to 2 percent.[76]

6.4.2 Biosafety Framework and Policies

While the Ministry of Science and Technology is mainly responsible for biotechnology research, the Ministry of Agriculture is the primary institution in charge of the formulation and implementation of Biosafety guidelines on agriculture biotechnology and their commercialization, particularly after 2000 and the Ministry of Public Health is responsible for food safety management of biotechnology products. The State Environmental Protection Authority has taken up the responsibility of international Biosafety Protocol and most of international activities. China signed the Cartagena Protocol in August 2000 and ratified it in June 2005.

The first biosafety regulation, 'Safety Administration and Regulation on Genetic Engineering', was issued by the Ministry of Science and Technology in 1993. This regulation consisted of general principles, safety categories, risk evaluation, application and approval, safety control measures and legal responsibilities. After the above regulation was decreed, MOST required relevant ministries to draft and issue corresponding Biosafety regulations on biological engineering.

6.5 Private Sector

Against a background of improvement in intellectual property protection, multinational companies have begun moving parts of their R&D operations to China to cut research costs, speed up new products launches and improve market access. 27 of the worlds to 30 multinational pharmaceuticals now have manufacturing and sales operations in China.[77]

6.6 Conclusion

China is fast catching up with other major players like Korea and Japan. The state directed biotechnology development coupled with the drive to expansion of higher education and investment in frontier technologies and support for research in basic life sciences is likely to pay rich dividends in the long run. The presence of a large number of trained and qualified Chinese students and faculty in universities and research centers abroad is a resource pool that China can bank upon to meet its future needs. Thus the biotechnology revolution in China is poised for a leap forward in the years to come.

Chapter 7: India

Introduction

Despite the major financial crisis, India has exhibited strong macro-economic fundamentals. The GDP growth rate in 2008 is at 7.1 per cent, which is better than many other economies. Though, industry's growth rate declined with sharp fall in manufacturing sector 8.2 per cent to 4.1 per cent and services sector (over half of GDP) decelerated from 10.9 per cent to 9.6 per cent. The most disappointing story comes from agriculture sector where growth rate slowed to 2.6 per cent from 4.9 per cent in 2007.

India is among the first few countries in the developing world to have declared the importance of biotechnology as a tool for advancing growth in the agriculture and health sectors. The Government of India established the National Biotechnology Board in 1982 as the apex body to identify priority areas and evolve a long term plan for the development of biotechnology which later graduated to the Department of Biotechnology. The National Biotechnology Strategy was approved by Government of India in 2007-08. The Indian biotech industry is also on a growth curve and the number of companies dealing in biotech applications had increased to 200 in 2005 from just 75 in 1999-2000 generating revenues to the tune of USD 1 billion.[78]

7.1 Institutional Framework and Funding

The National Biotechnology Board was set up in 1982 as in apex agency to spearhead the development of biotechnology in India. It was chaired by a Science Member of the Indian Planning Commission with representation from almost all prominent S&T agencies n the country. The NTBT was formed with the specific purpose of identifying priority areas and for evolving a long term plan for the country. The NTBT, through the " Long Term Plan in Biotechnology for India" in April 1983, spelt out priorities for biotechnology in India in view of national objectives such as self sufficiency in food, clothing and housing, adequate health and hygiene, provision of adequate energy and transportation, protection of the environment, gainful employment, industrial growth and balance in international trade. In 1986, realizing the need for a separate department to promote and direct the development of biotechnology, the Government of India created a new department-Department of Biotechnology (DBT).

Since then DBT has played an important role in development of biotechnology in many ways. It has promoted innovative schemes in human resources development, engaged in promotion of entrepreneurship in biotechnology, and encouraged international collaboration in biotechnology. The policies have undergone changes with shifts in emphasis to new areas and identifying new opportunities. DBT is also actively involved in regulating biotechnology and in granting of approvals for field trials. It has proposed a new regulatory framework for biotechnology and if that proposal becomes a law, India will have a new regulatory body, National Biotechnology Regulatory Authority (NBRA). NBRA would function as a single window mechanism for biosafety clearance of genetically modified products and processes and would replace the Genetic Engineering Approval Committee (GEAC). The mandate of the proposed NBRA is broad and this includes food and recombinant drugs. Besides DBT there are many other departments

and state governments (e.g. Andhra Pradesh, Karnataka, Chattisgarh) that promote and support biotechnology in India. Some states have specific policies and strategies to promote biotechnology. For states like Andhra Pradesh and Karnataka that are leaders in information and communication technologies, biotechnology provides an added advantage in promoting bioinformatics and biotechnology related services. For states that are rich in biodiversity like Kerala, appropriate use of biotechnology can result in value addition and development of new/novel products. However for most states the challenge lies in using agricultural biotechnology to enhance agricultural productivity.

At present, there are seven major agencies in India responsible for financing and supporting research in the realm of biotechnology apart from other sciences. They are:

- Department of Biotechnology (DBT)
- Department of Science and Technology (DST)
- Indian Council of Agriculture Research (ICAR)
- Indian Council of Medical Research (ICMR)
- University Grants Commissions (UGC)
- Department of Scientific and Industrial Research (DSIR)
- Council of Scientific and Industrial Research (CSIR)

DBT, DST and DSIR are part of the Ministry of Science and Technology, while ICMR is with the Ministry of Health, ICAR with the Ministry of Agriculture and UGC with the Ministry of Human Resource Development. Their funding for selected years is given in Table 7.1.

Table 7.1: Budget Allocations of Major Biotechnology Funding Agencies in India (millions of USD PPP)

Agency	1990-91	2000-01	2002-03	2003-04	2004-05
Department of Biotechnology (DBT)	135	160	267	293	358
Indian Council of Agriculture Research (ICAR)	667	1647	1667	1615	1934
University Grants Commissions (UGC)	720	1656	1774	1749	1832
Department of Scientific and Industrial Research (DSIR)	511	1142	1180	1219	1439
Department of Science and Technology (DST)	533	918	1150	1262	1420
Council of Scientific and Industrial Research (CSIR)	484	1073	1145	1184	1399
Indian Council of Medical Research (ICMR)	82	173	185	179	197
Total	**3133**	**6768**	**7368**	**7501**	**8579**

Source: Chaturvedi (2006).

7.2 National Biotechnology Strategy

The National Biotechnology Strategy was approved by the Government of India during the year 2007-08. The cornerstone of the strategy is the focus on building coherence and connectivity between disciplines and to bring together variegated skills across sectors to enhance synergy. The strategy seeks to address a number of challenges relating to the biotech sector in terms of R&D, creation of investment capital, technology transfer, absorption and diffusion, IPR, regulatory issues, building public confidence and tailor-made human capital for all these aspects. The stated vision of the strategy is responsible

use of life sciences and biotechnology to promote balanced growth of all sections of society.

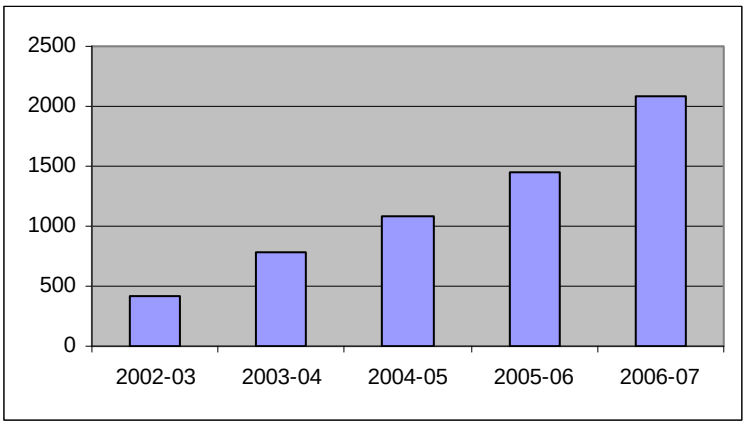
7.3 Human Resources

A total of 11 post graduate courses on biotechnology are being offered at 61 universities across the country and in which 785 students were enrolled in 2007-08. Till 2007-08, 570 students had been awarded Ph.D degrees and 567 students were still enrolled in Ph.D programmes in biotechnology. The number of faculty in these universities is about 350. During the period 2002-07, the faculty associated with 34 of these universities had published 1719 papers in high impact research journals. To provide All-India representation, maintain uniformity and ensure selection of quality students, admissions for PG programmes in biotechnology are done through a Common Entrance Test conducted by JN University at 53 centres across the country.[79]

7.3.1 Biotechnology Industry

The size of Indian Biotech Industry is continuously increasing. The industry has gained momentum and is on a roll. This is further evident from the fact that about 7-8 years back there was no biotechnology industry to speak of in India. The size of the industry was USD 2.08 billion in 2006-07 registering a growth of 31 percent over the previous year's figure (fig 7.1).

Figure 7.1: Growth in Biotech Industry Revenue, 2002-2006 (USD million)



Source: Gupta, (2007).

The biotech sector of India had over 325 companies contributing to the growth of the sector in 2006. Nearly 70 percent of the revenue comes from the biopharma sector followed by bioservices (fig. 7.2).

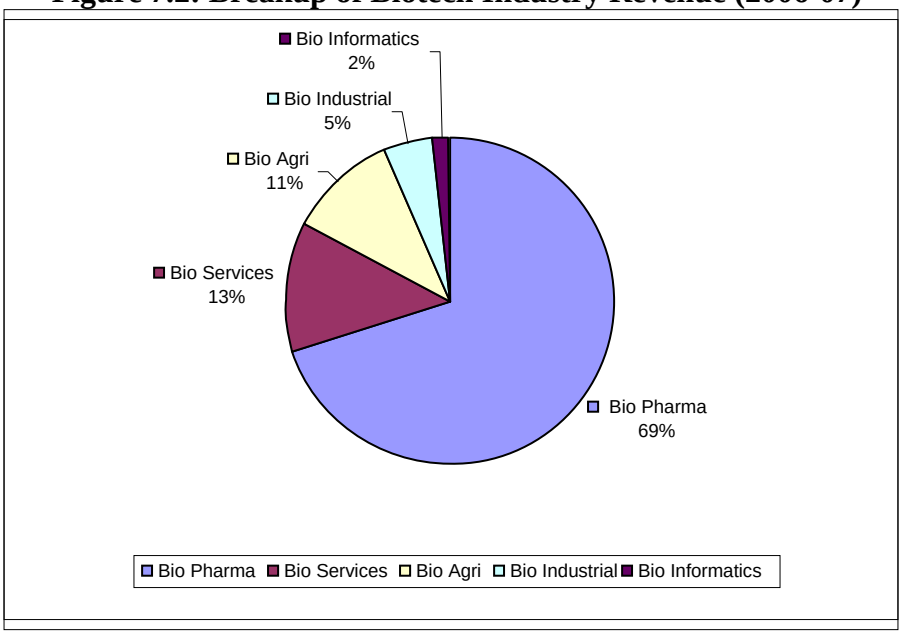
Table 7.2: Biotech Industry Exports vs Domestic Sales, 2006-07 (INR million)

Sector	Exports	Domestic Sales
Bio Pharma	36730	23000
Bio Services	10520	500
Bio Agri	470	8790
Bio Indusrial	450	3500
Bio Informatics	1200	250

Total	**49370**	**36040**

Source: Gupta (2007).

Figure 7.2: Breakup of Biotech Industry Revenue (2006-07)

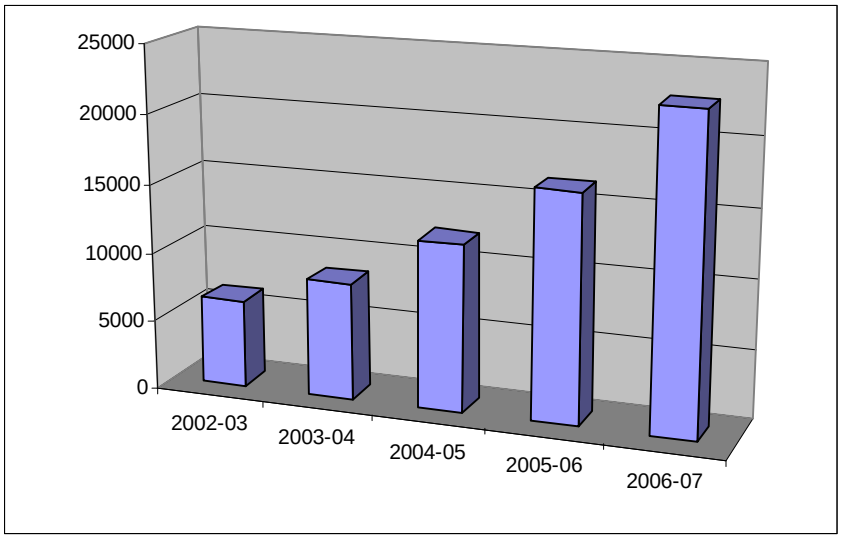


Source: Gupta (2007).

The biotech industry in India relies on exports to get its revenue. In share of export revenue in total industry revenue was 58 percent in 2006-07, compared to 51.5 percent in 2005-06.

The investment in the biotech industry, both in R&D and infrastructure have been on the rise after 2002. In 2006-07, the investment crossed INR 22700 million, up by almost 38 percent compared to the previous year (fig. 7.3). The research intensive biotech industry is concentrated in six major clusters in Bangalore, Hyderabad, Chennai, Pune- Mumbai, Delhi and Ahmedabad- Vadodra and employed about 20000 scientists in 2006-07.

Figure 7.3: Investment in Biotech Industry, 2002-07 (INR million)

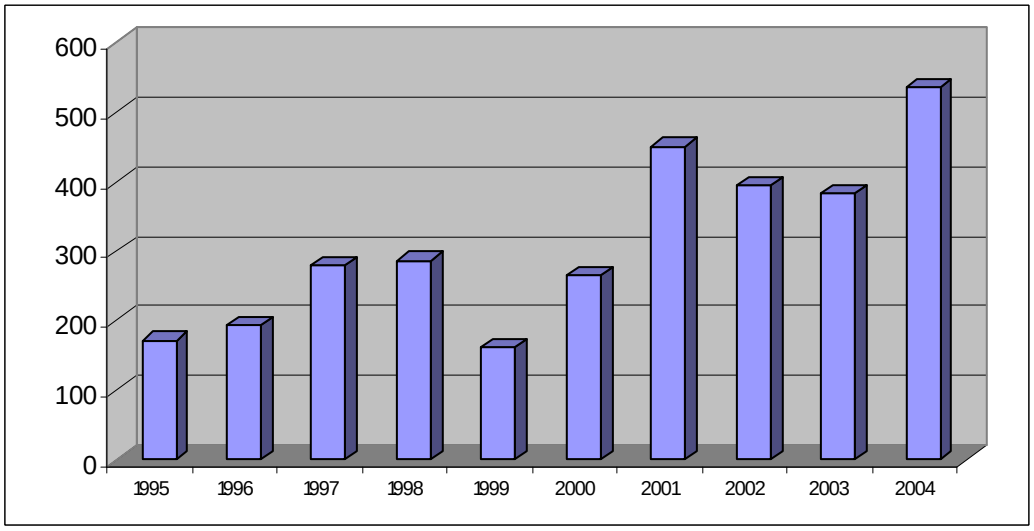


Source: Gupta (2007).

7.4 Innovation and Patents

A total of 3123 patents related to biotechnology have been filed in India from 1995-2004 (fig. 7.4). On analysing these biotech related applications, it was observed that a large number of inventions originated from foreign countries. There was a radical change in the number of patents filed in the year 2001, with 451 patents being filed in that year. This had further increased to 536 patents filed in the year 2004.

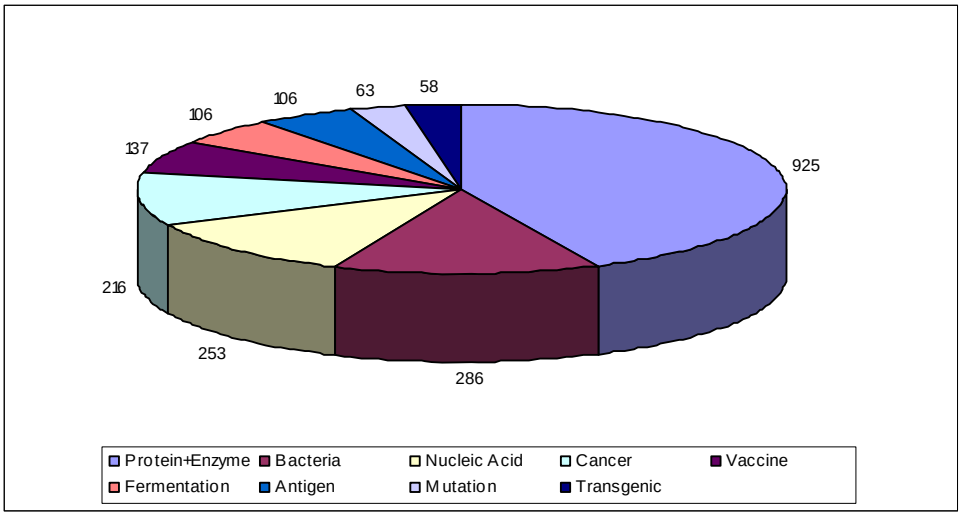
Figure7. 4: Biotechnology Patents in India, 1995-2004



Source: CII (2007).

An analysis of the break-up of biotech patent applications filed till 2004, it can be observed that Protein and Enzymes is the leading field with more than 900 patent applications. Bacteria and Nucleic acids are also important areas of research closely followed by cancer, with 286, 253, 216 applications (fig. 7.5).

Figure 7.5: Major Biotechnology Areas in which Patent Applications filed till 2004



Source: CII (2007).

The number of Biotechnology PCT Patent filed by India was just 7 in 1994-96 which had increased to 213 in 2004-06. Still India's share in total Biotechnology PCT Patents was under 1 percent in 2004-06.[80]

7.5 Biosafety

India is a signatory to the Cartagena Protocol on Biosafety and ratified it on January 23, 2003. The India Biosafety Clearing House (IND-BCH) has been established as per Article 20 of the Cartagena Protocol on Biosafety, in order to facilitate the exchange of scientific, technical environmental and legal information on living modified organisms (LMOs). The following is a list of Acts and Rules governing biotechnology development in the country.

- Rules for the manufacture, use, import, export & storage of hazardous micro organisms, genetically engineered organisms or cells, 1989
- Drugs and Cosmetics Rules - 1988 (eight amendment)
- Schedule–Y of Drugs and Cosmetics Act
- Seeds Policy – 2002
- Protection of Plant Varieties and Farmers' Rights Act, 2001
- DGFT Notification No. 2(RE-2006) / 2004-2009, 2006
- Food Safety and Standards Act 2006
- Plant Quarantine Order, 2003

7.6 Conclusion

India has come a long way since the establishment of the National Biotechnology Board in the early eighties. The biotechnology sector is well diversified. The pharmaceutical sector and chemical industry in India are well developed and are known for their capacity to reverse engineer and develop new and cost effective processes in manufacturing. When combined with strategic advantage that India enjoys in ICT, biotechnology in India can grow faster and can do well in niche areas like biopharmaceuticals. As in many countries of AP, biotechnology policy of the government has resulted in enormous

investment in human resources development and in support of basic research done at universities and research centers. The challenge lies in converting the research and capabilities in developing new products that are commercially viable and globally competitive. India has to compete with countries like Korea, Singapore and China, not to speak of Japan. To what extent the innovation system in India can meet these challenges is the major question that needs to be addressed.

Chapter 8: Indonesia

Introduction

Indonesia is a country that is well endowed with natural resources and is rich in biodiversity. It is rich in terms of marine biodiversity, agricultural biodiversity and forest biodiversity. Hence there is enormous scope for application of biotechnology in these sectors and in using the biodiversity as a resource. In terms of application of biotechnology Indonesia has a long way to go. The private sector in Indonesia is not advanced enough to use or apply biotechnology. The scope for applications in other sectors like health/medical is recognized by the strategy on biotechnology.

8.1 Industry Structure and R&D

The national policy was first formulated in 1990 and biotechnology was identified as a priority sector. Four centers were identified as centers of excellence in biotechnology and Inter-University Centers in Biotechnology on agricultural, industrial and medical biotechnology were established. An Indonesian Biotechnology Consortium with 33 institutions was founded. The consortium drafted the strategy program for biotechnology in Indonesia in 2004. In 2005 the regulation on GM products was passed. The industry is in nascent stages. There are five public sector research institutions engaged in biotechnology R&D. Three private sector firms are engaged in R&D. The activities of these firms (Charoen Pokphand,Thailand; Cargill, United States; and Dupont, United States) are limited to some high value horticultural crops and hybrid corn. East-West seeds are the largest producer of vegetable seeds.[81]

Indonesia's spending on science and technology is not adequate. The financial crisis of 1998 affected Indonesia and as a result the allocations for agricultural research were reduced in the subsequent years. The private sector spends only 19 per cent of the agricultural R&D and in biotechnology R&D it is much less. Through various schemes government is trying to accelerate development of R&D in biotechnology. According to V.V. Krishna,

"The current investment of around 0.2 per cent of GDP on R&D is very inadequate to meet the objectives and challenges outlined in the government's S&T policy, particularly those concerning the new technologies. In a relative sense, much of Indonesian strength in innovation is in the agriculture and related areas of research. In a situation of low levels of R&D investment and efforts during the last three decades, over emphasis on developing high technology and high capital-intensive sectors such as nuclear and aviation industries has further compounded the S&T and R&D problems for Indonesia"[82]

Indonesia imports about $1 billion of transgenic products from USA (alone) and this includes Bt cotton, herbicide tolerant soya and soya meal, Bt corn and food products from transgenic crops.[83]

External funding and assistance is another source of support to biotechnology R&D. Funding through World Bank loans, Rockefeller Foundation, USAID and bilateral projects has been available but mostly in capacity building, infrastructure development

and human resources development than in major research programs per se. Netherlands has supported training of students from Indonesia for PhD in Netherlands. Indonesia is exploring the possibility of co-operation with ASEAN countries, particularly with Korea. Marine biotechnology has been identified as a thrust area. However it is acknowledged that funding is the constraint and biotechnology in Indonesia, particularly R&D is largely driven by government. According to one report in 2003 there were about fifteen projects involving transgenics in Indonesia, in different stages.[84]

The potential of microbial resources for biotechnology utilization in Indonesia is well known. The isolates from microbial resources find wide use in agriculture and veterinary. For example Bt (Bacillus thuringiensis) is used in controlling sugarcane borer, rice stem borer, and cotton bollworm. The appropriate strains have to be identified first and then a bioinsecticide or biofungicide can be developed for application on a large scale. Another application of microbial resources is the development of bio-fertilizers, plant regulators and organic decomposers. Such applications are less controversial than GMOs and are acceptable to all types of farmers. For example Bt is used in organic farming to control bollworm. Using these microbial resources, genetically modified plants and organisms can be developed and the microbial diversity is important to develop appropriate solutions. Indonesia, in view of its rich microbial diversity has used these resources and various biofertilizers, bio-insecticides, and plant regulators have been commercialized in Indonesia. The table below gives the list of the applications that are in use in Indonesia.

Table 8.1 Products Based on Microbial Resources

Biofertilizer *Emas*	The function of this fertilizer is to increase the efficiency of fertilizer application (N, P, and K). The bioactivator of this biofertilizer is bacteria: *Azospirilium lipoferum*, *Azotobacter beijerinckii*, *Aeromonas punctata*, and *Aspergilus niger*. It is used mostly for estate crops.
Biofertilizer *RhiPhosan*	This biofertilizer is used to improve the nitrogen fertilizer from the air and to promote the liquidation of P and C fertilizer in the soil. It can also produce photohormonal Indol Acetate Acid (IAA), which will increase root growth. Its bioactivators are *Brandyrhizobium joponicum* and *Aeromonas punctata*. It is used mostly for secondary crops and cover crops
Organic Decomposer *OrgaDec*	*OrgaDec* is a bioactivator that decomposes the organic materials in a short period of time and is antagonistic to some root diseases. It consists of *Trichoderma pseudokoningii* and *Cytophaga sp.* OrgaDec is used mostly to decompose organic material with a high cellulose content (cocoa and palm tree waste, paddy straw, leaves, bud, and other materials).
Plant Regulator *NoBB*	*NoBB* consists of a plant regulator which can stimulate the function of cambium for cell fission and recovery of latex vessels. It also helps in the recovery of the skin of the rubber tree from Brown Bast. NoBB can be used to increase the productivity of rubber estates.
Biofungicide *Greemi-G*	*Greemi-G* consists of two green microbes (*Trichoderma harzianum* and *Trichoderma pseudokoningii)* which can be used to manage the impact of Ganoderma for palm oil trees, JAP for rubber and Phytophthora for cocoa
Bioinsecticide *BioMeteor*	The bioactivator of this product is *Metharhizium anisopliae*, which can manage plant pests in soil, such as *Dorystheness sp*. (bokor tebu) and *Xystrocera festiva* (bokor sengon).
Bioinsecticide *NirAma*	*NirAma* consists of the bioactivator *Paecilomyces fumosoroseus*. It is

	used mostly to manage plant pests such as *Heliopeltis antonii*, fire worm, *Ectropis bhurmitra*, *Antitrygodes divisaria*, *Hyposidra talaca*, *Metanastria hyrta*, *Homona coffearia*, *Poicilocorys sp*., *Spodoptera litura*, and *Meloidogyne sp*.

Source: Agricultural Biotechnology Development in Indonesia *Iwan Ridwan* from Business Potential for Agricultural Biotechnology Products 2007 Asian Productivity Organization Tokyo.

These can be used as a stepping stone for development of microbial resources in biotechnology. The major limitation in using these resources in the absence of biotechnology is that the desired traits are not transferred to plants and this necessitates repeated application of bio-insecticides. In terms of value addition and large scale production the industry is growing.

But in the long run this alone would not be sufficient. The challenge lies in isolating the relevant genes and transferring them into products or plants. Moreover microbial resources per se are not patentable and are found in many environments. Developing processes that result in purified microbes not found in nature and that can be used in many industries is necessary to maximize the benefits from these resources. Thus at some point or other the policy makers will have to frame a policy framework that encourages innovations based on these resources without sacrificing sustainability.

As Indonesian agriculture is diversified in terms of crops it should give more importance to develop these resources in a big way and try to develop industries where innovation and value addition are given due importance. In this, biotechnology has a crucial role to play. It is suggested that Indonesia should use multilateral initiatives in biotechnology to develop this sector.

To begin with the focus should be to move to the next stage of applying biotechnology in agriculture even when the earlier applications like bio-fertilizers and bio-insecticides should be developed further on a large scale. The commercial cultivation of transgenics should be encouraged and the government should decide on grant of approval for cultivation of Bt cotton and Roundup Ready Soybean as early as possible.

The current research projects in biotechnology should be reviewed and expedited. Wherever financial constraints are holding up projects increased allocations should ensure timely completion of projects. Since the research projects are on traits that are important or can enhance productivity, the transfer of results for commercial application is necessary to gain most from the research.

Indonesia should identify niche areas where it can derive the maximum benefits. Linkages between transgenics research and development and research and development in microbial resources should be developed.

Indonesia embarked upon using biotechnology more than two decades ago but it has not made much headway in using biotechnology. The time has come to move forward from this state and to maximize gain from biotechnology.

As Iwan Ridwan points out

> *"The strategic approach of biotechnology development for industrialization in Indonesia will be addressed from two levels: macro and micro approaches. On the macro level, the first element is positioning biotechnology in terms of technology capacity and the industrial stage of development. Worldwide competition among research institutes and business enterprises in the field of biotechnology is severe. To be significantly competitive, the specific area of biotechnology to be focused on should be determined with care. The second element is national capacity building, including the development of human resources, small- and medium-sized enterprises for the domestic market, and large-sized ones with the possibility of entering the global market under joint ventures, foreign direct investment, or licensing."*
> *Iwan Ridwan (ref as above)*

Commercialization of GM crops is not yet wide spread although transgenic rice, transgenic sugar, transgenic potato have been field tested. The government has decided that more field tests at various locations have to be done. The research projects include development of drought tolerant rice, pest resistant soyabeans, virus resistance for tomatoes. But how soon these will be field tested and commercialized is not clear. The Indonesian experience in biotechnology has been confined to using tissue culture and production of bio-fertilizers and bio-pesticides.

The bio-safety assessment has been completed in cotton, soyabean and corn. The two tables below give an idea about the current status of transgenics in Indonesia.

Table 8.2: Transgenic Crops in Indonesia

Plant	Trait	Gen	Source	Transfer Technique	Event
Cotton	IPR	Cry1 AC	Bacillus thuringensis subsp kurstaki	Agrobacterium tumefaciens	MON531/757 /1076
Cotton	HT glyphosate	CP4 EPSPS	A. tumefaciens strain CP4	Agrobacterium tumafaciens	MON1445/1698
Soybean	HT glyphosate	CP4 EPSPS	A. tumefaciens strain CP4	Particle gun method	GTS 40-3-2
Corn	HT glyphosate	EPSPS	Corn	Particle gun method	GA 21
Corn	IPR	Cry1 Ab	Bacillus thuringensis subsp kurstaki	Particle gun method	MON810

Source: Indonesian Center for Agricultural Biotechnology and Genetic Resources Research and Development (ICABIOGRAD), Ministry of Agriculture: http://biogen.litbang.deptan.go.id/cms/

Table 8.3: Approval Status

No	Transgenic Product	Bio-safety Committee Recommendation	Government Approval Status

1.	Bt Cotton Variety Bt DP 90 B (identical 90 BE 60023) & PM 1560 B (identical 1560 BE 72022) Event MON 531/757/1076 (MON-ØØ531-6, MON-ØØ757-7)	Safe towards environment and biodiversity (1999)	Limited release based on the Decree of Minister of Agriculture Decree in 2001, 2002, and 2003
2.	Roundup Ready Cotton Variety DP 5690 RR (identical 1220 RRA 68022) & DP 90 RR (identical 90 RE 60012) Event MON 1445/1698 (MON-Ø1445-2)	Safe towards environment and biodiversity (1999)	Approval letter by the Chairman of National Bio-safety Committee
3.	Roundup Ready Soybean Variety Cristalina RR & Jatoba RR Event GTS 40-3-2 (MON-Ø4Ø32-6)	Safe towards environment and biodiversity (1999)	Approval letter by the Chairman of National Bio-safety Committee
4.	Roundup Ready Corn Variety RR-1 & RR-2 Event GA 21 (MON-ØØ21-9)	Safe towards environment and biodiversity (1999)	Approval letter by the Chairman of National Bio-safety Committee

Source: Indonesia Biosafety Clearing-House: http://indonesiabch.org

8.2 Biosafety

Indonesia signed and ratified the Cartagena Protocol in 2004. It has biosafety regulations in place. The regulation for Biosafety of Transgenic Products No21/2005 was promulgated but the rules have not been fully implemented. Similarly there are food labeling rules but these have not been fully implemented. In 2008 the National Agency of Food and Drug Control issued the guidelines for food safety assessment for transgenic products. However, it is not clear as to how the overall framework will be harmonized with commitments under the Cartagena Protocol. Although it seems that the labeling norms require that food products containing more than five percent content derived from transgenic processes should be labeled, whether this is enforced is not clear.

The biosafety policy has implications for cultivation of transgenic crops in Indonesia besides trade in transgenics. The policy framework should be implemented as early as possible so that there is certainty. For exporters and importers the certainty will send clear signals. If Indonesia wants to export GM food products to markets like USA it has to implement a comprehensive framework on regulation, approval, labeling and trade in biotechnology particularly in transgenics. Since it imports significant quantities of food products including GM food, development of a vibrant agricultural biotechnology sector can result in less imports and more exports in the biotechnology sector. Since GM food like transgenic soyabeans are used for human consumption, implementation of regulation will avoid controversies. It is essential that while biosafety norms are being followed, they should not become stumbling blocks for utilization of agricultural biotechnology. Indonesia should try to expedite commercialization of agricultural biotechnology even as it implements the biosafety norms.

8.3 Patent

Indonesia has a negligible presence in patenting with PCT or US PTO.

8.4 Conclusion

Indonesia has potential for using biotechnology in various sectors. It is likely that in the coming decade it will achieve a breakthrough in this as more GM plants are approved and the investments in infrastructure and capacity building begin to yield results. But to gain maximum from biotechnology, Indonesia will have to develop and apply a strategic plan for the biotechnology sector.

Chapter 9: Japan

Japan is a leading country in many sectors including electronics with significant share in the global market. For instance in communication devices its share is 53 per cent, in automobiles its share is 31 per cent, in robots it is 40 per cent. In photo masks for liquid crystals and silicon wafers its share is above 70 per cent. [85] It has embarked upon an ambitious plan to promote biotechnology and life sciences and emerge as a world leader in some applications. Although Japan's industrial prowess and capability for innovation are unquestionable in biotechnology it lags behind USA and Europe. In Asia countries like Korea, China and India are fast catching up in developing biotechnology applications and the state in them is also giving importance to biotechnology. But Japan has some advantages over these countries as its capacity to innovate and introduce new products is unparalleled in Asia.

9. 1 Industry Structure

The biotechnology market in Japan is considered as the second largest in the world, next to USA. The market size of the Japanese biotechnology industry in 2007 was $19.5 billion, a 10.9 percent growth rate over the previous year. In 2005 it was estimated that the biotechnology market in Japan is about 1.76 trillion yen. It is expected to grow to 25 trillion yen by 2010.[86]

The number of biotechnology firms is Japan is 1007. In terms of size 320 firms have less than 50 employees, while 309 have employees more than 50 but less than 249 and 364 firms have 250+ employees.[87] In Japan the pharmaceutical companies, huge food companies, chemical industries, heavy engineering giants and IT firms drive biotech research in Japan. The number of start ups is less when compared to USA. In USA since the early 1980s there has been a vibrant biotechnology industry thanks to the start ups and support from venture capital. Many of the start ups struggle to survive but in terms of innovation and commercialistion the US biotech industry is a global leader. In Japan most of the biotech companies are first either incubated as a venture or started as a project by large companies. Once they are ready to do business on their own they are spun out as separate entities. These spin outs often form a network to support the parent company.[88]

For example, companies in the pharmaceutical sector and chemical industry are major players in the biotechnology and life science industry. Companies in the food industry and diagnostic industry are also engaged in biotechnology industry. Some of the major companies that are involved in biotechnology include Astellas Pharma Inc., Eisai Co. Ltd., Daiichi Sankyo Pharmaceutical Co., Ltd., Takeda Pharmaceutical Industries, Ltd., Chugai Pharmaceutical Co., Ltd., Asahi Kasei Corporation, Mitsui Chemicals Inc., Mitsubishi Chemical Corporation, Lion Corporation, Ajinomoto Co., Inc., Kyowa Hakko Kogyo Co., Ltd., and Kirin Brewery Co., Ltd.[89]

Compared to the US drug MNCs or giants like Roche, GSK, Novartis, the Japanese pharmaceutical companies can be considered as middle-sized. The large domestic market was their major market and they did not become specialized or internationalized firms.

But during the last two decades the government policy on drug pricing and the growth and increased presence of foreign firms posed challenges to the pharmaceutical firms. Expenditure on R&D tripled in the last decade and the firms eyed the lucrative global market rather than rely largely on the domestic market. By 2006 about 50 per cent of the sales were abroad, from less than 35 per cent in 2001. The industry also went through a spate of mergers and acquisitions and is undergoing major transition now. The top ten pharmaceutical firms in Japan figure among the 50 largest firms in the world although none of them are in the top 10 league.[90]

The lack of dedicated biotech firms in Japan is well acknowledged. Shortage of venture capital and non-availability of trained scientists and engineers are cited as some of the reasons for this. According to one report,

'*The make up of the Japanese venture capital sector is different from that in western countries: - the number of venture capitals is quite limited; - many of them are subsidiaries of banks or securities companies; - the scale of funds available is comparatively small (than, for instance, that of the U.S.); - money invested in individual companies is also comparatively small; and - there are a limited number of venture companies focused on bio businesses*'.[91]

But the picture is changing now with more venture capital funds flowing into biotechnology.

The market for biopharmaceuticals was 459.4 billion yen in 2005 (Fig. 9.1). Of the approved drug products they account for 5 to 10 per cent which is lower than their share in USA. The market is growing at 10 per cent. Erythropoietin is the largest selling product with 130 billion yen in 2005. In human growth hormone and insulin, the foreign firms dominate the market. The market for therapeutic antibodies is a fast growing market, where Japanese firms are competing with foreign firms. The bioservices market in 2005 was 24.34 billion yen and is increasing at the rate of 10.5 per cent per annum. Basically the market is divided into fabrication and refining, analysis and synthesis sectors (Fig. 9.2).[92]

Figure 9.1: Market Size of Biopharmaceuticals

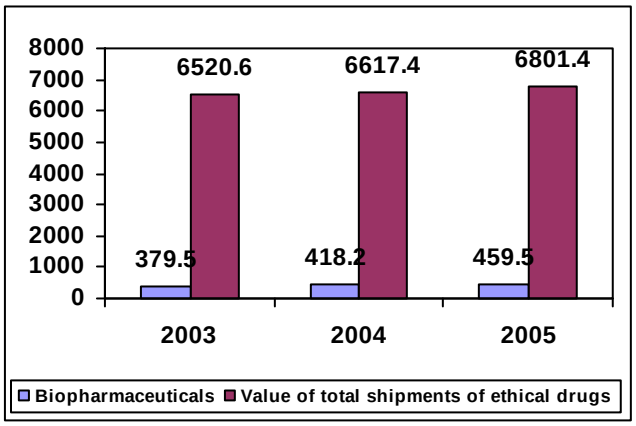
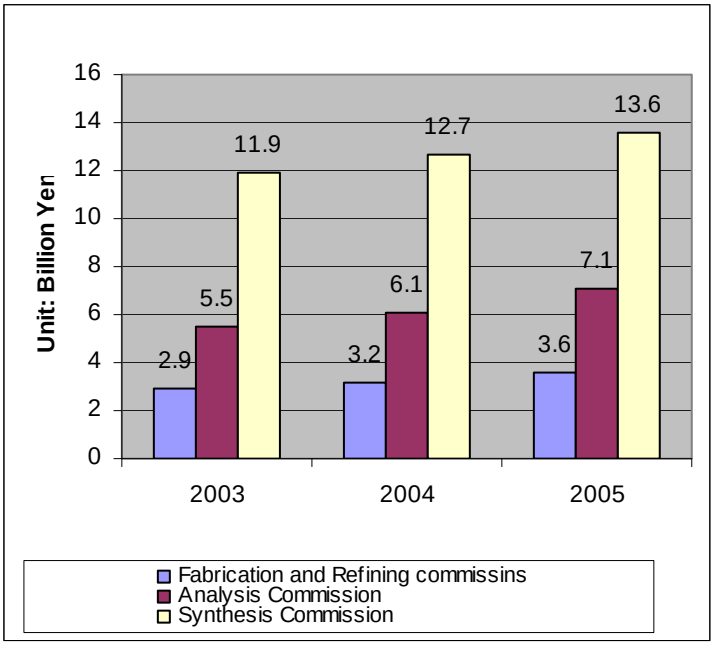
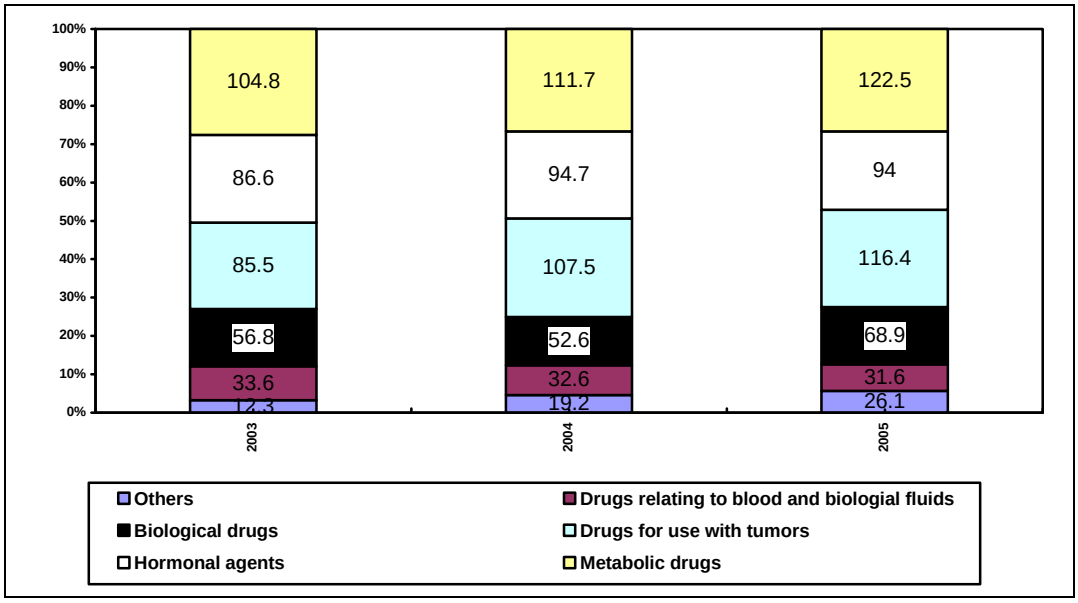


Figure 9.2: Market Size of Bio-Services



Source: JETRO (2007).

Figure 9.3: Structure of the Market by Therapeutic Category

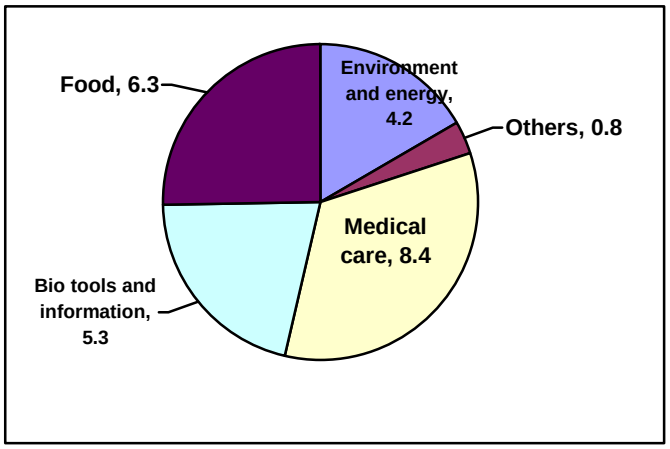


9.2 Initiatives[93]

The Japanese government had set an ambitious target of creating at least 1000 new biotech companies. The biotechnology market will reach 25 trillion Yen. The BioStrategy 2002 focused on four sectors (Bio-Medical, Bio-Agricultural, Bio-Ecological, and Bio-informatics). The Bio-medical industries turnover in 2010 is expected to be 8.4 trillion yen while that of Bio-Agriculture is expected to be 6.3 trillion yen, Bio-Ecological industry 4.2 trillion yen and Bio-informatics/bio-tool industry 5.3 trillion yen (Fig. 9.4).

The policy framework aimed to achieve this by promoting joint ventures, research collaborations, industrial partnerships, and encouraging venture capital, development clusters, and increased collaboration between academic institutions and industries. JETRO identified seven major bio-clusters in Japan. Each cluster consists of research institutes including Centers of Excellence (COEs), universities, and companies in biotechnology and life sciences. Each of the clusters will also specialize in a core technology/application and the synergy between academic and industry in the clusters is expected to make them leading centers of innovation. For example Kinki Bio-Cluster project has Genome-based drug discovery, and regenerative medicine as the core technologies. There are three COEs and the presence of pharmaceutical and chemical industries in the vicinity is considered as an added advantage. The funding from government has increased considerably for research in biotechnology/life sciences.

Figure 9.4: Projected Size for Japan's biotechnology market in 2010, Unit trillion yen



Source: BSC (2002).

The National Bioresource Project envisages systematic collection and preservation of all bioresources including stem cells and genetic materials. The government has also funded the translational research program in a big way. Instead of allocating financial resources in all sectors, the government has identified priority areas and is supporting basic research and developing world-class research facilities. Since 2000, the support for life sciences through government funding has steadily increased.

In this, the approach of the Japanese government is no different from that of governments like Korea and the idea of clusters for biotechnology is not new. The policy can be understood as a response to concerns expressed about lack of growth in biotechnology in Japan and fears about Japan lagging behind USA in life-sciences research and missing the post-genomic revolution in health sciences. Although Japan has world class universities and in terms of publications is doing exceedingly well, concerns have been expressed about the mismatch between scientific capability in basic sciences and developing applications/commercializing the research done in universities. The new policy framework supports new ventures and start-ups are expected to play an important

role. Another significant aspect of the policy is the goal of listing 100 Initial Public Offers, originating from universities/ start-ups based in universities. The government is also supporting development of human resources. The goal is to create an attractive environment for firms, both domestic and foreign, and to attract capital to invest in biotechnology.

The policy framework has been supplemented by changes in the regulatory regime and laws. The changes made in 2005 in Pharmaceutical Affairs Law (PAL) simplified procedures for approval for manufacturing and importing of medicines. Outsourcing of manufacturing to domestic/overseas manufacturers was allowed. The objective behind the changes was to open up new business opportunities and to derive benefits from outsourcing including lowering the cost of production. In 1999 the Japanese version of Bayh-Dole Act that facilitates commercialization of technologies and transfer of technology from universities to industry was passed. Guidelines on clinical research on gene therapy and ethical guidelines on clinical research were issued. Similarly changes were made in intellectual property laws. Thus between 1998 and 2005 major changes in the regulatory regime were brought in to create a liberalized milieu for development of biotechnology and commercialization of research.

Life sciences have been identified as one of the four priority areas and five ministries are playing an important role in this. About 60 per cent of the Millennium projects were allotted to biotechnology before the development of a comprehensive national strategy for biotechnology. The 3rd Basic Plan for S&T identified the following areas in life sciences as strategic priority areas: (i) Research on Complex Biological Systems, (ii) Translational and Clinical Research, (iii) Cancer therapies, (iv) Infectious diseases, (v) Safe foods, (vi) Bio-processing and (vii) Research infrastructure. The third basic plan gives more emphasis to innovation than the previous two.

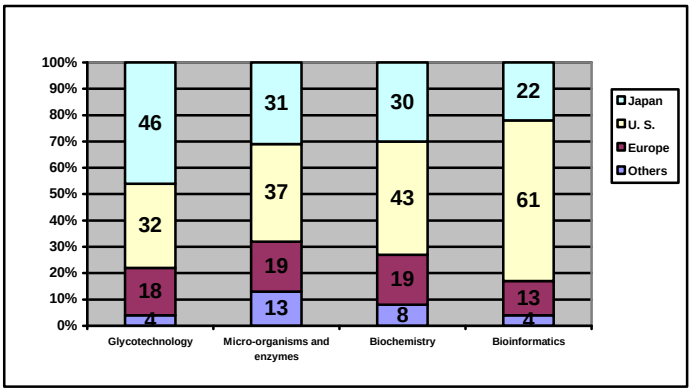
The government's increased funding to biotechnology is evident in the budgetary allocations for 2009. Funding for clinical studies on cancer increased by 90 per cent in 2009. [94]

9.3 Patents and Publications

Japan has a significant presence in biotechnology patents, particularly in patent applications related to microorganisms, enzymes, biochemical and glyco-technology. In glycol-engineering it accounts for 46 per cent of the patents. Japan's share of biotechnology PCT applications in 2006 was 11.9 per cent and it was in the third position. In terms of revealed technological advantage in biotech Japan scored about 75 (fig. 9.5). [95]

In terms of scientific publications many of the Japanese universities/research institutes rank among the top most 50/100 institutions in terms of their citations received. In four categories (Materials Science, Physics, Chemistry and Biology/Biochemistry), there is at least one Japanese institution that figures in the most. [96]

Figure 9.5: Patent Applications on Life Science by Sector/Applicant's Nationality between 1991 to 2000



Source: JETRO (2007).

The scope of patent protection had been extended as the Japanese patent law and practice earlier favored narrow claims over broad claims.

9.4 Biosafety

Japan has signed and ratified the Cartagena Protocol. It has established a regime for regulating import and use of LMO's under the protocol. During 2006-2008 there were 42 trials and of this, herbicide tolerant trait trails accounted for 26. Japan has regulations on labeling of GMO products.[97]

Box 9.1: KINKI BIO CLUSTER

Number of Bio Ventures: 110

1. Presence of distinguished COEs

Kyoto University, Osaka University

Tissue Engineering Research Center, AIST

The Kobe Medical Industry Development Project (Institute of Biomedical Research and Innovation, RIKEN (Centre for Development Biology), etc.

2. Accumulation of related industries

Key industries such as pharmaceutical/chemical, electromechanical/electronic parts, precision machinery, food and textile

Small and medium-size enterprises that have advanced skills (example: SMEs in Higashiosaka City)

Core Technologies

Genome-based drug discovery, regenerative medicine

↓

Promising Industrial Areas/Ideas

Biomedicine (drug discovery, regenerative medicine)

Bio environment (microbial bio, plant bio)

Bio tool/information (advanced analytical equipment)

9.5 Conclusion

Japan's thrust in biotechnology including state support for basic research and promotion of cluster approach and bringing in changes in regulatory regimes indicate that Japan is determined to use biotechnology in a big way. To what extent the ambitious targets will be achieved and whether Japan is as innovative as USA in biotechnology is yet to be seen.[98]

Chapter 10: Biotechnology in Korea

Korea has emerged as a major biotechnology country in the AP region and its biotechnology industry is trying to be globally competitive. From the initial stages in the early 1980s the Korean biotechnology industry has come a long way. The supportive policy framework of the government played a major role in development, diversification of the biotechnology industry and R&D activities in the industry and in academia. The efforts made since the 80s have borne fruit and Rand Corporation identified Korea as one of the countries that could acquire all the sixteen significant technologies including biotechnology by the year 2020. Thus Korea is well prepared for harnessing the technological convergence of nanotechnology, biotechnology and information technology.

In 1983 Korea enacted a Biotechnology Promotion Law and the eighties also witnessed the setting up of various biotechnology departments and research institutes, making it one of the pioneering countries in Asia to identify and develop biotechnology as a promising sector. The nineties saw further consolidation of this and development of biotechnology industry in Korea. This decade also witnessed the proclamation of Bioindustry Vision 2000 and advances in bioprocess technology and commercialization of various products.

Since 2000 Korea has further encouraged Biotechnology as a Key National Strategic Industry. The National Bioindustry Action Plan was launched. Investments by the public sector and private sector in biotechnology went up considerably even as the industry moved up in the value addition chain and brought out new and modified bioproducts. Korea was well equipped to capitalize on the post-human genome mapping developments in biotechnology and the genomics revolution in biosciences did not bypass Korea.

10.1 Programme Framework

As far as funding in biotechnology is concerned, the major fund providers are the Ministry of Knowledge Economy (MKE), Ministry of Education, Science and Technology (MEST), Ministry of Food, Agriculture, Forestry and Fisheries (MAF), Ministry of Environment (ME), Ministry of Health, Welfare and Family Affairs (MW) and public research institutes. Table 10.1 gives the funds provided by the above bodies since 1994 till 2007.

Table 10.1: Public R&D Expenditures and Providers (2007 US $ million)

R&D fund provider	1994-97	1998-2001	2002-06	2007	1994-2007
Ministry of Knowledge Economy(MKE)	18	140	707	193	1058
Ministry of Education, Science and Technology (MEST)	253	564	1335	352	2503
Ministry of Food, Agriculture, Forestry and Fisheries (MAF)	86	111	433	133	764
Ministry of Environment (ME)	10	21	111	140	282
Ministry of Health, Welfare and	48	95	654	29	827

Family Affairs (MW)					
Public research institutes	0	0	76	100	177
Sum	415	932	3317	946	5610

Note: Public R&D includes pure research activities (accounting for around %), infrastructure, human resource development.

Source: Biotech Policy Research Center, 2008; KIET, Annual Biotechnology Industry Survey, 2008.

Ministry of Education provides the largest amount of funds followed by Ministry of Knowledge Economy (MKE), Ministry of Environment (ME), Ministry of Food, Agriculture, Forestry and Fisheries (MAF), Public research institutes and Ministry of Health, Welfare and Family Affairs (MW).

So, as in table 10.1, the public R&D expenditure rose from US $ 415 million in 1994-97 to US $ 946 million in 2007, with the cumulative expenditure of US $ 5610 million during 1994-2007. The MEST was a major funding agency and other ministries also contributed to the funding. In terms of sector wise allocation Life Science was a major beneficiary of pure public R&D expenditure and Life Sciences and health accounted for a major share of this expenditure which amounted to US $ 836 million.

In the financial year 2003, total expenditure on R&D by biotechnology- active firms, million PPP $, was $ 699 million. Biotech R&D as a percent of total business expenditure on R&D was 3.2. Biotechnology R&D expenditures by the public sector (million PPP$), 2003 was 727.4, which accounts for about 58 per cent of the total expenditure on biotechnology.

In the financial year 2006, total biotechnology R&D expenditures in the business sector increased to 709 million PPP$. Total biotechnology R&D expenditure was 2375.1 million PPP$, where public expenditure was 1446.8 million PPP$ (18.7 per cent).

Table 10.2: Biotechnology R&D Firms and R&D Expenditures

Year	**2002**	**2003**	**2004**	**2005**	**2006**
Biotech R&D firms	510	528	596	638	627
Dedicated Biotech R&D firms	503	250	279	312	265
%Dedicated Biotech R&D firms	99	47	47	49	42
Total R&D expenditure (million PPP$)	-	1582.8	2376.0	2714.1	2596.3
Biotech R&D expenditure (million PPP$)	386.6	429.7 (27.1%)	503.7 (21.2%)	601.6 (22.2%)	709.3 (27.3%)
Spent by Dedicated Biotech R&D firms (million PPP$)	386.5	158.7	210.3	258.5	266.5

Source: OECD, biotechnology statistics, January 2009.

Table 10.2 shows the trend of biotechnology R&D expenditure over the years 2002 to 2006. In absolute terms, with the increase in total R&D expenditure, expenditure on biotechnology R&D also increased. In real terms, biotechnology R&D expenditure was maintained around 27.3 per cent in 2006 which is not significantly different from the 27.1 per cent in 2003. Of the 709.3 million PPP$, in 2006 in Biotech R&D expenditure, dedicated biotech R&D firms spent $266.5 million PPP$. Biotech R&D as per cent of total business expenditure in R&D was just 3 per cent in 2006. But share of public biotechnology R&D in total biotechnology R&D expenditure was 60.9 per cent in 2006 (Table 10.2).

Table 10.3: Biotechnology R&D, Million PPP$, 2006

Total public biotech R&D expenditures	Total biotech R&D expenditures	% public biotech R&D in total biotech R&D	Government Intramural Expenditure on R&D + Higher Education Expenditure	% public biotech R&D in total public expenditures on R&D (GOVERD + HERD)
1446.8	**2375.1**	**60.9%**	**7720.3**	**18.7%**

Source: OECD, Biotechnology statistics database; OECD, MSTI 2008/1, January 2009.

As table 10.3 shows, public biotech R&D accounts for almost 61 per cent of the total biotech R&D expenditure. Public sector expenditure on biotechnology R&D was US $ 1446.8 million PPP in 2006. These figures indicate that the biotechnology industry is yet to mature and is still dependent on government support, and the heavy investment in R&D by public sector may be because of the inability of the private sector to invest heavily in R&D. In terms of value addition also per cent of biotech R&D as a per cent of value added is just .093 in 2006 which is much lower than that of countries like France and Sweden.

Table 10.4: Distribution of Pure Public R&D Expenditures (2007 US $ millions)

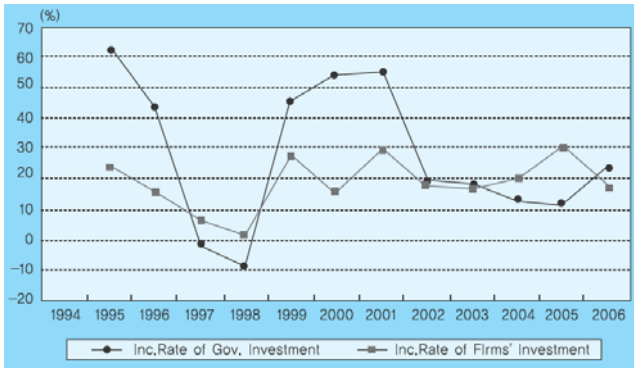
	Life science	Health	Agri. Food	Ind. Process	Bio-fusion	Sum
2007	274	178	101	104	91	748
2008	314 (37.5%)	221 (26.5%)	107 (12.8%)	100 (11.9%)	94 (11.3%)	836
change, %	14.9	24.1	5.7	4.2	2.9	11.7

Note: Pure public R&D includes only research activities.

Source: Biotech Policy Research Center, 2008; KIET, Annual Biotechnology Industry Survey, 2008.

From table 10.4 , we se that life science has the largest share in receiving public R&D which is about 37.5 per cent, followed by health (26.5 per cent), agri-food (11.9 per cent), industrial (11.9 per cent) and bio-fusion with an 11.7 per cent.

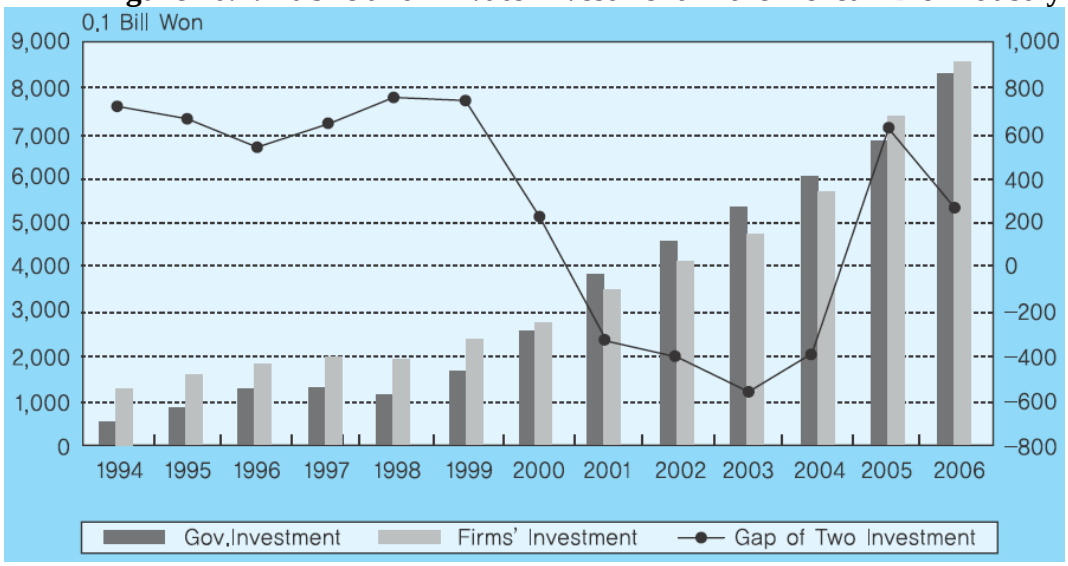
Figure 10.1: Growth Rates of Public and Private Investment



Source: Biotech Policy Research Center, 2008; KIET, Annual Biotechnology Industry Survey, 2008.

Figure 10.2 shows the trend of Public and Private Investment in the Korean bio-industry over the years 1994 to 2006.

Figure 10.2: Public and Private Investment in the Korean Bio-industry



Source: Biotech Policy Research Center, 2008; KIET, Annual Biotechnology Industry Survey, 2008.

The growth rates of public and private investment in biotechnology have fluctuated over the years as shown in Figure 10.1. The national market is not big enough to attract significant amounts in R&D and hence returns on R&D may not be high, unless the industry develops products that have a demand elsewhere also. Venture capital is also a source of investment in biotechnology although the share of life sciences is just 6 per cent of the all venture capital investments.

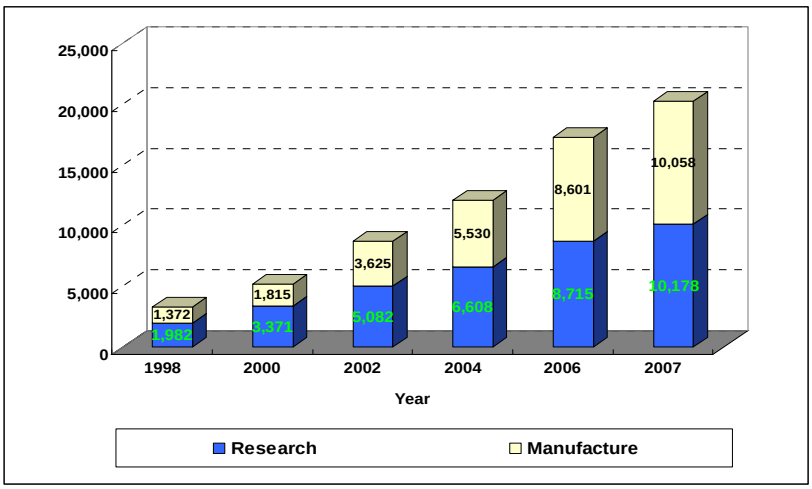
Thus the constraints on commercialization are obvious and Korean firms have to compete with well established MNCs in foreign markets. Thus the biotechnology industry in Korea is in the early stages of R&D when compared with firms in USA or Europe or Japan where they have a long history of R&D and successful commercialization of R&D.

But as Korea has made considerable investment in R&D infrastructure and with an enabling framework the industry may achieve in the next few decades what the automobile and electronics industries have achieved today, i.e. competing in global markets successfully and identifying niches where they have competitive advantage. Yet here Korean firms will have to compete with not just MNCs but also firms from Singapore, India and China which are also growing fast and are gearing up themselves for global markets in bio-drugs and biotechnology products.

10.2 Biotechnology Employment and Firms

In terms of number of employees, most of the firms have less than 50 employees and these firms constitute 63 per cent of the total number of firms. Similarly in terms of biotech R&D firms 60 per cent of the firms have less than 50 employees. Figure 10.3 will give a clearer picture as to how many are employed in different sectors of biotechnology.

Figure 10.3: Biotech Employment by Application Field, (Unit: persons)



The number of biotechnology firms in FY 2003 was 640.[99] In 2006, the number of biotechnology firms with less than 50 employees was 487 and that of biotechnology R&D firms with less than 50 employees was 773 (Table 10.5).

Table 10.5: Biotech Firms by Size Class

Year	2002	2003	2004	2005	2006
Less than 50 employees	290	369	402	437	487
50 to 249 employees	87	114	121	121	179
250+ employees	80	83	97	88	107
Total biotech R&D firms	457	566	620	646	773
% of firms with less than 50 employees.	63	65	65	68	63

Source: OECD, Biotechnology Statistics, January 2009.

In terms of growth rates over the period, 2003-2006, they are 11 per cent for biotech firms, 6 per cent for biotech R&D and 2 per cent for Dedicated Biotech R&D firms.[100]

In terms of export and import, total bio-industry imports amounted to US $ 1099 million in 2007 with biopharmaceutical, biochemical and biofood industries contributing to more than 80 per cent. In terms of export, total exports amounted to US $ 1584 million with biofood industry contributing 1004 US $ million indicating the predominance of biofood industry in exports. The biofood industry imports was just 13 US $ million, indicating that the industry was capitalizing more on resources available within Korea than imports. In contrast the biopharmaceutical industry imported (US $ 853 million) more than what it exported (US $ 452 million) in 2007. This indicates that the biopharmaceutical industry in dependent on imports for value addition. In overall terms, the exports were more than the imports and the surplus was significant i.e. about US $ 500 million which is about 50 per cent of the imports or 33 per cent of the exports.

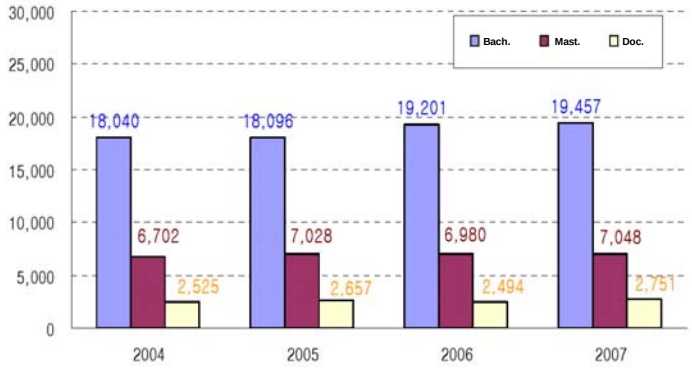
Thus, although the biotechnology industry in Korea is well established and growing, it has a long way to go to reach the level reached by the biotechnology industry in the USA. Without the enormous support from the state the industry would not have come this far, but whether the support from the state alone is sufficient for the industry to attain maturity is a billion dollar question.

10.3 Human Resources

In 2007 employment in the biotechnology industry was about 20,000 of which 50 per cent was in research and the rest in manufacture. The number of graduates in biotechnology has increased considerably over the years. In 2007, bachelor degree holders accounted for 66.5 per cent, masters 24.1 per cent and PhD 9.4 per cent, and the total number of students was about 30,000.

Figure 10.4 shows the number of graduates, post graduates and Ph.Ds in Biotechnology from the years 2003 to 2007.The increase has been significant as shown by the figure.

Figure 10.4: Graduated Students from Biotechnology and Bio-engineering (Unit: persons)

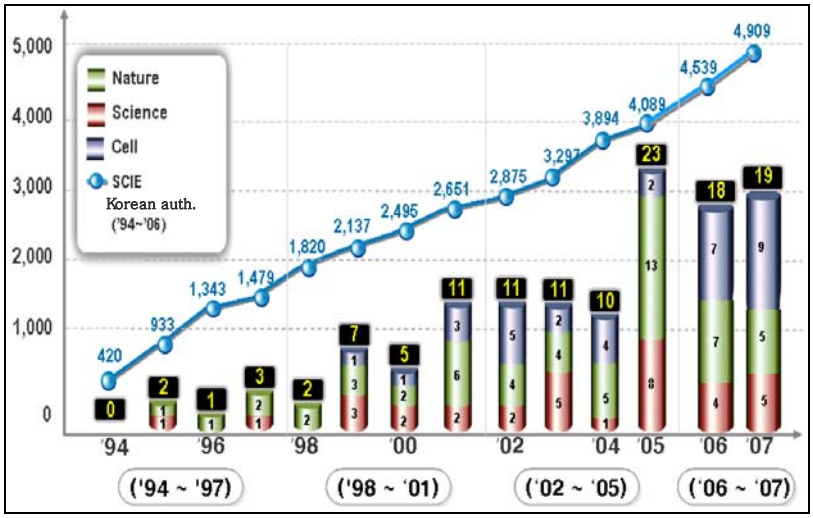


Source: Biotech Policy Research Center, 2008; Annual Education Statistics (www.std.kedi.re.kr), 2008.

10.4 Patents and Publications

In terms of professional publications in biotechnology and bio-engineering the papers have increased from 420 in 1994 to 4909 in 2007 as shown in Figure 10.5. This shows that investment in biotechnology has resulted in knowledge generation and in publications.

Figure 10.5: Professional Papers of Biotechnology and Bio-engineering

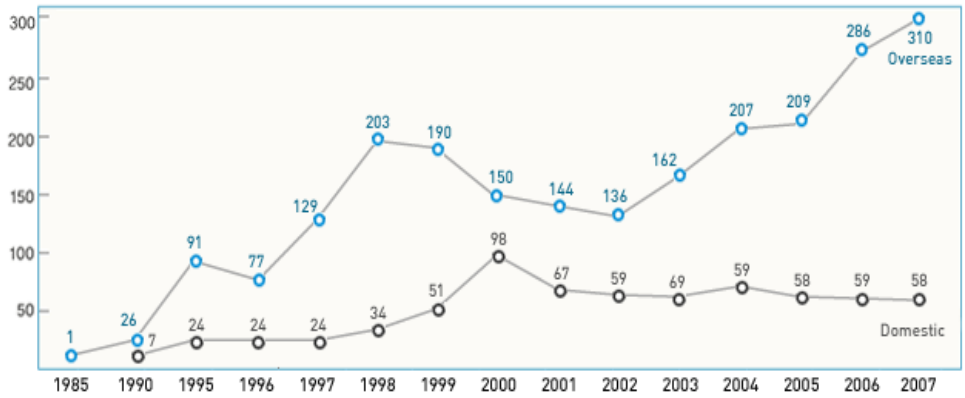


Source: Biotech Policy Research Center, 2008.

In terms of patents,o Korea has done well also. Figure 10.6 shows the trend in biotechnology patents. Despite fluctuations overseas patents have increased from 1 in 1985 to 310 in 2007.

Figure 10.6: Trend of Patents of the Korean Biotechnology

(Unit: items)



Source: Biotech Policy Research Center, 2008

As far as biotechnology patent applications with the PCT and total PCT patent applications are concerned, in financial year 1994-96, there were 59 biotechnology patents out of a total of 643[101] and in the financial year 2004-06, the number of biotechnology patents increased to 653 out of a total of 15,780. It is worth noting that patent counts are based on the priory date, the inventors' country of residence and use fractional counts on PCT filings at international phase (EPO designations).

10.5 Bioindustry Regulatory Framework

Since 1980s, the Korean Government has been constantly involved in coming up with strong fundamentals for developing the biotechnology industry in Korea.[102] The Korean Science and Technology administration system on biotechnology is clearly shown below. The Ministry of Knowledge Economy and the MEST are the two major ministries.[103]

S&T Related Ministries

Ministry of Knowledge Economy (MKE)

* Agency for Technology and standards
* Small & Medium Business Administration
* Industrial Property Office

Ministry of Health & Welfare

* Food and Drug Administration
* National Institute of Health

Ministry of Construction & Transportation

* National Railroad Administration

Ministry of Education, Science and Technology (MEST)

* National Universities and Colleges
* Basic and Leading-edge Technologies

* Promotion of Biotechnology-supporting Systems
* Education
* Assistance of Basic Researchers on Life Sciences

Ministry of National Defense

* Agency for Defense Development
* Military Manpower Administration

Ministry of Environment

* National Institute of Environmental Research

Ministry of Agriculture & Forestry

* Rural Development Administration
Agricultural Research Institute
* Forestry Service
Forestry Research Institute

Ministry of Finance and Economy

* National Tax Service
* Customs Service
* Public Procurement Service
* National Statistical Office

The Korean government has been successful in establishing the required infrastructure and it did introduce biosafety, biosecurity and bioethics laws in an attempt to facilitate compliance of biotechnology and bio industry.[104] But this does not mean that the present infrastructure is sufficient. The Korean government also has a strong stance for protection of IPR.

The Korean government implemented the Biosafety and Bioethics Act in 2004, which bans human cloning experiments.[105] Korea also enacted the Act on Cross-Border Movement of LMOs in 2001 as part of its implementation of the Cartagena Protocol to the Convention on Biological Diversity.[106] Moreover, importation and manufacturing of GMOs requires government approval and biosafety regulations.

10.6 Conclusion

Korea's national biotechnology strategy indicates that the state is playing an important role in deciding the key sectors for growth of biotechnology. Korea is focusing on biomedical technology. Despite the set back in stem cell research on account of fabrication and falsification of data, it is proceeding ahead with full support to research in biomedical technologies. The industry relies on continued support from the state to grow and diversify. In terms of patents and publications, Korea is doing well and has improved its position. But the challenge lies in keeping the pace of growth and catching up with countries like the USA. Whether Korea can repeat in biotechnology the success it had in consumer electronics and automobiles is yet to be seen. Korea's potential in biotechnology is not in doubt, and whether it can reach the high targets it has set for itself is an interesting question.

Chapter 11: Lao PDR

Lao PDR is a landlocked country where modern biotechnology R&D activities are still nascent in its national R&D institutions. For some years to come it has to depend on agencies like IIRI on capacity building.

11.1 Specific Initiatives

Lao PDR completed a joint project by participating in an ADB TA project (No. 6214-REG) entitled "Strengthening Capacity and Regional Cooperation in Advanced Agricultural Science and Technology in the Greater Mekong Sub-region (GMS)" This sub-regional project has brought countries in the sub-region to work more closely in agricultural technology, including biotechnology. The National Science Technology Agency (STEA), the NEA, has established a National Authority for Science and Technology (NAST), as the national coordinating institution at the central level, for the research, development and management on biotechnology, genetic engineering, biosafety and advanced technology. NAST also has a Biotechnology Center to support its work on biosafety.

11.2 Human Resources

Lao PDR is generally dependent international agencies and bodies like IRRI.

11.3 Patents and Publications

There is no significant activity in this on biotechnology.

11.4 Biosafety

The government of Lao PDR acceded to the Convention on Biological Diversity on September 20, 1996 and the Cartagena Protocol on Biosafety on 1 November 2004. In preparation to be able to comply with its obligation as Party of the CPB, Lao PDR participated in a GEF/UNEP funded project to develop National Biosafety Framework (NBF) and successfully completed the project on in December 2004.

This draft NBF was used to prepare a Biosafety Law, which was considered initially at the Lao Government Meeting on 30 August 2005. However, this draft Biosafety Law is yet to be approved. Additionally, biosafety being new to the country, awareness among the policy makers and public is low. More attention has to be directed at enhancing public awareness before they can participate actively and meaningfully in decision-making. The goal of this project is to assist Lao PDR to have a workable and transparent regulatory regime for biosafety by 2010 and to fulfill its National Socio-economic Development Plan to 2020 and obligations as Party to the CPB. At present, there is inadequate capacity in Lao PDR in human resource, institutional and national infrastructure for Lao PDR to fulfill her obligations as Party to the CPB.

Lao PDR is also participating in a GEF-funded project on "Building Capacity for Effective

Participation in the "Biosafety Clearing House". The National Authority for Science and

Technology (NAST) has been the coordinating mechanism between all the above initiatives and will also continue as the National Competent Authority (NCA) for this project.

In addition, the government of Lao PDR will establish a Biosafety Fund to support activities beyond the project life.

Chapter 12: Biotechnology in Malaysia

Malaysia has identified biotechnology to be the new engine of growth. Being endowed with a rich biodiversity, cost-competitive skilled labor markets, good transportation and ICT infrastructure along with a strong support in R&D, Malaysia does present a favorable destination for foreign biotechnology companies. Although biotechnology in Malaysia is still in its infancy, nevertheless, recognizing the immense potential benefits which biotechnology can bring, the country is making every effort to improve its competitiveness in a global setting. This is clearly reflected by the Malaysian government's launching of a 15-year National Biotechnology Policy (NBP) in April 2005.[107]

12.1 Human Resources and Capacity Building

The Malaysian biotechnology industry thrives on more than 65 life science and biotechnology companies that are being supported by 14 academic institutions and another 24 research institutes.[108] More than 50 government ministries and organizations are involved in Malaysian life science activities.[109] Due to its strong economic ties with agriculture, much of the life science research in Malaysia focuses on agriculture. Several major industries are built around agricultural products. In addition to support for local industry, Malaysia has strong life science research programs in nutraceuticals and botanical extracts that are exported to the U.S. and Europe.[110] Several universities in Malaysia have strong teaching and research programs in life sciences and engineering.

Though lack of human capital and skilled workers has been a limiting factor, there are a good number of scientists and support staff to start with unlike many other developing countries. Local research institutes and universities not only offer good facilities but also a number of excellent projects that could be taken to the next level of developmental stage for example into commercialization with the correct collaboration with the industry.[111]

12.2 Specific Initiatives

Malaysia is one of the countries where the government has pledged strong support and commitment to develop this sector. Various incentives and funding mechanisms are in place to encourage local companies as well as to attract foreign players. Under the Ninth Malaysia Plan (2006-2010), US $ 548 million has been allocated for the development of biotechnology industry in Malaysia. Emphasis will be placed on research, development and commercialization, strategic technology acquisition, business and entrepreneurship, development and infrastructure.[112] The Malaysian government has also allocated $3 billion in its budget, 2008 to enhance healthcare, increase the supply of medicine, intensifying research and enforcement activities and strengthen healthcare biotechnology.[113] There are various initiatives on biotechnology.

12.3 The National Biotechnology Policy

The National Biotechnology Policy was launched in 2005 to provide a comprehensive framework for the development of biotechnology in Malaysia. The main objectives are to develop human resources to meet the industry’s skill needs and to nurture

entrepreneurship and the development of niches in agriculture biotechnology, healthcare biotechnology, industrial biotechnology and bioinformatics.[114]

The Ninth Malaysia Plan 2006-2010

The Ninth Malaysian Plan aims to at least double the number of biotechnology and biotechnology-related companies to 400 in 2010. Furthermore, the Ninth Malaysian Plan will focus on implementing the New Biotechnology Policy (BNP) to develop Malaysia's niches in agriculture biotechnology, healthcare-related biotechnology, industrial biotechnology as well as bioinformatics.[115]

The government has allocated RM2 billion under the Ninth Malaysian Plan to cover the development of biotechnology industry within the areas: agriculture, healthcare, industry and bio-informatics. Of the RM2 billion 45.9 per cent will be used to develop the physical infrastructure and the remaining 54.1 per cent will be for R&D and commercialisation as well as business development programmes.[116] Moreover, under the 2006 Budget the Malaysian government has announced the setting up of the Malaysian Life Science Capital Fund which will be launched with RM100 million under the expectation that government-linked companies and private investors, both foreign and local, top up the fund.

New Biotechnology Policy

The New Biotechnology Policy (NBP) was launched in 2005 to promote growth of the biotechnology outlined in the 9 thrusts namely, Agriculture Biotechnology Development, Healthcare Biotechnology Development, Industrial Biotechnology Development, R&D and Technology Acquisition, Human Capital Development, Financial Infrastructure Development, Legislative and Regulatory Framework Development, Strategic Positioning and Government Commitment.[117] The policy constitutes three phases:

Phase 1 (2005-2010) – Capacity Building: the establishment of advisory and implementation councils, education and training of knowledge workers, business development and industry creation in agricultural biotech, healthcare biotech, industrial biotech and bio-informatics.

Phase 2 (2011-2015) – Science to business: involves developing expertise in the discovery and development of new drugs based on natural resources.

Phase 3 (2016-2020) – Global Presence: will focus on taking Malaysian companies globally.

12.4 Malaysian Biotech Corporation

The Malaysian Biotech Corporation (MBC), established in 2005, acts as the implementing agency responsible for furthering Malaysia's biotechnology objectives with the focus on companies that are in the biotech industry or want to get into the industry.[118] The primary tasks are to attract biotech investments, source partnerships opportunities and support local biotech entrepreneurs in setting up their business. The MBC is located under the Ministry of Science, Technology and Innovation (MOSTI).

The Malaysian Biotech Corporation has RM300 million for funding – divided into RM100 million for commercialization, RM100 million for technology acquisition, RM50 million for entrepreneur development and RM50 million for intellectual property framework development.[119]

12.5 BIOTEK

A National Biotechnology Directorate (BIOTEK) was established to replace the National Working Group, when the number of biotechnologists and the number of research activities increased. Under BIOTEK, the National Biotechnology programme was coordinated by 7 Biotechnology Cooperative Centers (BCCs). These BCCs include agricultural, veterinary, medical, food, molecular biology, industrial & environmental and pharmaceutical biotechnology.[120]

Bionexus

Recently, the Government of Malaysia has been moving towards an infrastructure that builds on existing institutions rather than a single one. It has come up with the concept of "BioNexus", which is essentially a network of centers throughout the country, composed of companies (both local and foreign) and institutions that specialize in specific biotech-subsectors.[121] Initially, three centers of excellence will be established as part of the BioNexus. The BioNexus initiative allows the Malaysian government to grant BioNexus status on selected companies, local and foreign, providing benefits including eligibility for financial incentives and assistance, access to shared equipment facilities, and administrative support through BiotechCorp.[122]

BioMalaysia

BioMalaysia is a key event for the Malaysian biotechnology industry. The event is hosted annually and it is organized by the Ministry of Science, Technology and Innovation (MOSTI), BiotechCorp and Protemp Exhibitions Sdn Bhd. [123]The event is further supported by Malaysian Biotechnology Information Centre (MABIC) and Malaysian BioIndustry Organization (MBIO). The event comprises a conference and an exhibition. In BioMalaysia 2008, 60 prominent industry experts from all over the world and more than 1,000 business leaders, scientist, executives, investors and industry leaders were represented.[124] The exhibition featured more than 8,500 visitors and 150 exhibitors from Malaysia and around the world.[125] BioMalaysia offers strategic experiences and resources that could take Malaysia closer to achieving its scientific and business objectives in biotechnology.

Financial Incentives

Malaysia provides competitive financial incentives under existing packages, which are also applicable to biotech proposals. Additional attractive incentives to support biotechnology ventures at all stages of development amongst the incentives are incentive for the holding company, tax exemption for biotechnology companies, 100 per cent income tax exemption for a period of up to 10 years for approved biotech companies, investment tax allowance, etc.[126]

12.6 Biotechnology Industry

Biotechnology in Malaysia is expected to generate US$75 billion (RM270 billion) in revenue for the country by 2020.[127] The biotechnology industry is expected to contribute approximately 2.5 per cent to the GDP of the country by 2010, 4.0 per cent by 2015 and 5.0 per cent by 2020.[128] Furthermore, it is estimated that the industry will create 280,000 new jobs, both directly and indirectly, by 2020. In addition, it is expected that 100 biotechnology companies will be established in Malaysia over the next 15 years.[129] . Kuala Lumpur-based BiotechCorp was established in 2005 to play the leading role in building the biotechnology business in Malaysia by creating a conducive environment and actively promote foreign direct investments in biotechnology.[130]

When compared to Korea or Japan, the biotech industry in Malaysia is still in its infancy but with the strong commitment from the government the industry is poised to grow. The pharmaceutical and healthcare sector has emerged as one of the fastest growing biotech sectors in Malaysia.[131] This sector comprises the development of vaccines and therapeutics, contract research and manufacturing, medical devices, diagnostics and drug delivery technologies. With the skyrocketing rise in the cost of clinical trials, many companies are shifting their activities offshore and Malaysia is seen as an attractive destination. Malaysia also boasts a strong foundation in diagnostics products using homegrown technology. The medical devices sector is another area that has been flourishing, the bulk involved in rubber-based medical supplies and consumables.

BiotechCorp developed 92 BioNexus companies, up 119 per cent from the 42 BioNexus companies in the previous period. Total approved investment in BioNexus increased 18 per cent to RM1.3 billion (USD 375.7 million) from RM1.1 billion (USD 317.9 million).[132] BioNexus companies continue to attract international investments from UK, US, France, Germany, Italy, Belgium, India, China, Japan, Taiwan, Hong Kong, Singapore, Thailand, Australia and New Zealand.

Of the 92 BioNexus companies, 47 generated total unaudited revenue of RM378.6 million (USD 109.4 million) for the reporting period – which represents the first full year of financial reporting for BioNexus companies.[133] BioNexus companies continue to expand competencies in agricultural, healthcare, industrial biotechnology and bioinformatics. As one group, BioNexus companies is a significant contributor in the creation of knowledge workers - recording a substantial 382 per cent increase in knowledge workers to 1,851 from 384 in the previous period.

Table 12.1 shows the segmentation of the 92 BioNexus companies into the different areas of biotechnology. There are 36 companies in Healthcare, 31 in Agriculture, 22 in Industrial and 3 in Bioinformatics.

In funding the biotechnology business, BiotechCorp provides grants for seed funding, research and development matching and international business development. At the end of the review period, RM52.2 million (USD 15.1million) were approved for 25 BioNexus companies, up from RM6.25 million (USD 1.8 million) for four BioNexus companies in

the previous financial year. There is a further 15 grant applications in the pipeline amounting to RM 32 million (USD 9.2 million) pending approval.[134]

Table 12.1: BioNexus Companies by Application Fields

Sectors	Healthcare	Agriculture	Industrial	Bioinformatics	Total
Number of BioNexus companies	36	31	22	3	92

Source: Biotech Corp (2008).

Malaysia's biotech industry is largely driven by the development of oil palm and it is expected to grow 22 per cent annually. The industry is currently valued at RM1.3 billion.[135] In the National Budget 2009, RM13.7 billion is allocated to enhance healthcare, which includes increasing the supply of medicines, intensifying research and enforcement activities, further strengthening the growth of healthcare biotechnology which accounts for RM326 million approved investment up to date. There are many expectations for Malaysian biotechnology industry in 2009. The Pharmaceutical industry in Malaysia is expected to surpass RM1.2 billion in 2009.

Table 12.2: Growth in Number of Biotechnology Companies, Revenue, Investment and Knowledge Workers in Malaysia

Public-listed Biotechnology & Life Sciences Companies	2008	2007	% increase
Number of Companies	13	11	18%
Market Capitalisation	RM1.7 billion	RM2.5 billion	32%
Market Capitalisation versus total Bursa Malaysia Market Capitalisation	0.26%	0.23%	13%
Revenue Generation	RM2.4 billion	RM2.2 billion	9%

Source: BiotechCorp (2008).

From Table 12.2, it is clear that the Malaysian public funded biotech companies have witnessed significant growth in 2008 compared to the previous year in terms of number, market capitalisation and revenue generation. The number of companies increased by 18 per cent while market capitalisation increased by 32 per cent. In terms of revenue, the companies saw an increase of 9 per cent, the corresponding figures being shown above.

Table 12.3: Growth of BioNexus Companies

BioNexus Companies	2008	2007	% increase
Number of Companies	92	42	119%
Public Companies	2	1	100%
Market Capitalisation	RM218.5 million	RM676.5 million	68%
Revenue Generation	RM378.6 million	RM131.8 million	187%
Knowledge Workers	I851	384	382%

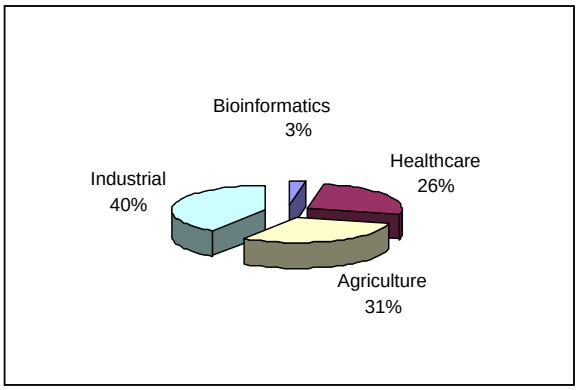
Investment	RM1.3 billion	RM1.1 billion	18%

Source: BiotechCorp (2008).

As table 12.3 shows, the BioNexus companies saw an enormous increase in terms of number, market capitalisation, knowledge workers and revenue generated. Number of companies increased by a huge 119 per cent, from 42 in 2007 to 92 in 2008.Similarly for revenues, market capitalisation and knowledge workers, the increases are magnanimous given by 187 per cent, 68 per cent and 382 per cent respectively, while investment saw a decent increase of 18 per cent.

Figure 12.1 show investment in different sectors, where industrial firms receive the largest share and bioinformatics the smallest. The total investment amounted to RM 1.3 billion in 2008 where investment in Healthcare is RM 346 million, RM 412 million in Agriculture, RM 541 million in Industrial and RM 36.4 million in Bioinformatics.

Figure 12.1: Sector wise investment in BioNexus Companies (2008)



Source: Biotech Corp (2008).

Recent Developments in Private Enterprise

In Malaysia, there are several companies developing novel pharmaceutical products. One of these, Bioven, has established relationships with multiple institutes in Cuba and is actively developing products from those Cuban partners for approval and distribution in Malaysia and elsewhere.[136] Another, Duopharma, manufactures more than 300 items for use in Malaysia and for export, including small-volume injectables and generic pharmaceuticals. GENERTI Biosystems fabricates molecular diagnostics and is focused on blood disorders. Additionally, two companies, Alpha Biologics and Inno Biologics have recently been established to provide contract manufacturing services to the global biopharmaceutical industry.

The industry is also going for international collaboration. BioTech Corp is wooing investors and industries from India to set up units in Malaysia.[137]

12.7 Investment Capital and Funding

The Government remains the largest source of funding for biotechnology projects and companies, offering 17 funds totalling RM4.7 billion for the period under review. Of this, only RM1.6 billion or 34.2 per cent has been utilised as on 31 December 2008, while

RM3.1 billion or 65.8 per cent are available for application. It is expected that the utilisation rate will increase due to the growth in the biotechnology industry.

In the context of supporting private sector initiatives in the biotechnology industry, the Government will continue to provide infrastructure and technological facilities. For this purpose, a sum of RM236 million is provided in the 2008 Budget.[138]

Private funding for biotechnology in Malaysia is largely provided by venture capital funds. As on 31 December 2008, RM 212 million had been utilised from the available venture capital funds for biotechnology and life sciences totaling RM 394 million. Within the sectors of life sciences, the sub-sectors of biofuels, bioinformatics and healthcare (primarily biopharmaceuticals) continue to generate interest of local venture capitalists. A number of Malaysian venture capitalists have invested in BioNexus status companies, namely those in healthcare biotechnology. The role of the Malaysian capital market as a key funding source for the local biotechnology industry, remains underdeveloped, with only two Initial Public Offerings in 2008, namely Sunzen Biotech Berhad (a BioNexus status company) and Asia Bioenergy Technologies Berhad. Nevertheless, a total of RM 20.9 million was raised from the Initial Public Offering exercise of these two companies.

12.8 Patents

Regarding the number of biotechnology patents in Malaysia, WIPO Statistical Database, April, 2009 has the figures for the number of patents filed with the PCT given by 21, 41, 56, 76 in the four quarters of 2008 respectively.[139]

12.9 Biosafety

The Biosafety Act 2007 was passed in August of 2007, although the accompanying regulations, which were envisaged to complement the Act, have yet to be gazetted.[140] As it happens with a large number of countries worldwide, the formulation and adoption of a formal Access & Benefit Sharing (ABS) framework is still under development. Malaysia needs to expedite this effort to enable the preservation of its biodiversity and to prevent bio-piracy.

In Pharmaceutical Regulations, a total of 9 initiatives were completed including participation in the APEC Harmonization of Medial Device Regulations, Review of Drug Development in Clinical Trials and Malaysian Guidelines on Biosimilars. In International Accreditation, a total of 9 initiatives were completed, including participation in the OECD Principles of Good Laboratory Practices with Ministry of Health and Standards Malaysia, Good Clinical Practice Workshops with Clinical Research Centre, Ministry of Health and Good Manufacturing Practice Workshops.[141]

Such initiatives would have surely had a strong impact in building an environment ready for the commercialisation of biotechnology in Malaysia.

12.10 Conclusion

Hence, the Malaysian biotechnology sector, though still young, is expected to experience further growth with the government's strong supportive policies and institutional framework aided by the growing expertise and ongoing research activities. Biotechnology, having come a long way since the late 1980s, is one of the keys to Malaysia's future prosperity with the potential to generate enormous economic, health and environmental benefits and it would certainly help transform Malaysia into a highly developed nation by the year 2020.

Chapter 13: Nepal

Introduction

With the return of normalcy and political stability, Nepal has exhibited improved economic performance and greater commitment for technological improvement. In 2008, economic growth went up to 5.3 per cent which was a great improvement over the 2.7 per cent of 2007. The major push in this growth process has come from the services and agriculture sectors. The share of the service sector in overall GDP is 48 per cent which has now expanded to 70 per cent and contributes around 3.6 per cent points to overall growth. Agriculture with 36 per cent share in overall GDP has shown strong growth with 4.7 per cent rate per annum. This has largely come from increased paddy production. Industry growth however, has slacked at 1.9 per cent.

Nepal has launched several initiatives for upgrading biotechnology infrastructure in Nepal. The Science and Technology Policy, 2004 has adopted a policy of using science and technology to increase production and productivity, and strategies to carryout studies, research and development activities in the field of biotechnology. In 2006, the National Biotechnology Policy was launched by the government. The Nepalese government has undertaken measures for linking Nepal with international R&D establishments. In 2009, Nepal has received membership for the International Centre for Genetic Engineering and Biotechnology (ICGEB). Nepal has also launched joint biotechnology research projects with Asian Institute of Technology (AIT), Bangkok. Nepal's share of world's land is not more than 0.1 per cent while its share of flowering plant species is over 2 per cent. In this relatively small area, more than 700 species of medicinal and aromatic plants have been reported, of which 250 species are endemic to the country. Similarly, Nepal has all topographical regions starting from tropical to alpine regions.[142]

However, Nepal is worried about the research costs which are significant, and with the IPR issues surrounding the most promising biotechnology, multinational companies can obtain profits in relation to their costs.[143] Their primary interests are profit and their focus is primarily on larger and more capital-intensive markets. Therefore, the scope for developing new biotechnology products that involve licensing and hence royalties needs exploring. The Nepal Biodiversity Strategy, 2002 has given priority to conserve and sustainable use of the biodiversity of the nation, which is rich in biodiversity, and equitable sharing of benefits arising from the use of the biological resources. The Nepal Biodiversity Strategy Implementation Plan, 2006–2010 is a plan to implement the Nepal Biodiversity Strategy and thereby achieve the goals of sustainable use of biological resources and of alleviating poverty for conservation of biodiversity. This plan has set priority of the activities to be carried out for implementing the strategy and has also accorded priority to implement the plan through direct participation of all concerned stakeholders and people.

13.1 Institutional Framework and Human Resources

Nepal has also made substantive efforts to improve the institutional framework in the country (see Table 13.1). There are more than 50 biotechnology institutions with 4 universities apart from public sector institutions. The key public sector institutions are

Department of Plant Resources (DPR), Thapathali; Nepal Agricultural Research Council (NARC), Singha Durbar Plaza; Nepal Academy of Science and Technology (NAST), Khumaltar; Fruit Development Directorate (FDD), Kirtipur; Central Veterinary Laboratory (CVL), Department of Livestock, Tripureshwor and Institute of Agriculture and Animal Science (IAAS), Rampur.

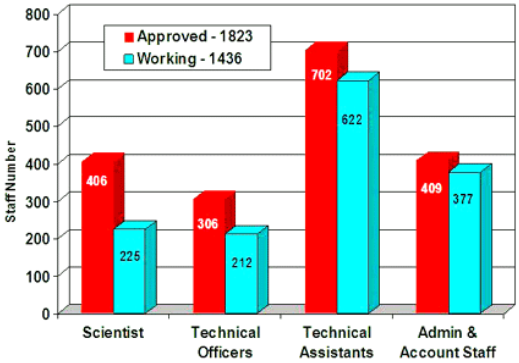
Table 13.1: Academic Institutional Framework in Nepal

University	**Course**
Kathmandu University	B.Sc. (Biotechnology)
Pokhara University	Biochemistry
Purbanchal University	B.Sc. (Biochemistry)
Tribhuvan University	B.SC. & M.Sc
Kathmandu University (Department of Biotechnology)	Post-Graduate: M.S. by Research in Biotechnology (2 years) -Under-Graduate: B.Tech in Biotechnology (4 years)
Himalayan White House College of Science & Engineering	Under-Graduate: B.Tech in Biotechnology (4 years) [affiliated with Purbanchal University, Nepal]
SAAN International College & Research Institute	-Under-Graduate: B.Sc. in Biotechnology (4 years) [affiliated with Purbanchal University, Nepal]
Lord Buddha Education Foundation	Under-Graduate: B.Sc. in Applied-Biotechnology (3 years) [affiliated with Sikkim Manipal University, India] - Post-Graduate: M.Sc. in Bioinformatics (2 years) [affiliated with Sikkim Manipal University, India]
Universal Science College	- Under-Graduate: B.Sc. Biochemistry (4 years)[affiliated with Pokhara University, Nepal]

Source: Biotechnology Society of Nepal (2009).

The Nepal Agricultural Research Council (NARC) established in 1991 leads agricultural research in the country to uplift the economic level of the people. NARC currently has a total of 2008 approved positions that includes scientists, technicians and administrative and finance staff (see Figure 13.1) The Institute of Agriculture and Animal Science (IAAS), Nepal, offers a B.Sc. Agriculture (Bachelor of Science in Agriculture), B.V.Sc. & A.H. (Bachelor of Veterinary Science and Animal Husbandry), M.Sc. Agriculture, M.Sc Animal Science and Doctor of Philosophy (Ph.D.) programs at the central campus at Rampur. The two branch campuses at Lamjung and Paklihawa also offer initial two years of B. Sc. Agriculture course. The funds internally generated by IAAS or the grant money received from internal or external funding agencies on meritorious basis are the only resources being used for the research programs. At present, more than 50 internally, nationally and internationally funded research programs are in operation. [144] Tribhuvan University, Kathmandu University and many private campuses have been delivering B.Sc and M.Sc courses in biotechnology. Tribhuvan University has opened the M/Sc. biotechnology from middle of 2006.

Figure 13.1 Manpower at NARC, Nepal in 2008



Most of the scientists and researchers involved in biotechnology are specialized in agriculture and botany. It is estimated that a total of 57 MS and 32 Ph D level researchers are engaged in biotechnology research and development.[145] Several Universities (Tribhuvan University, Kathmandu University, Purbanchal University and Pokhara University) now have realized the importance of biotechnology and offer undergraduate and graduate degrees in biotechnology.

13.2 Budgetary Allocations

The new government in Nepal has identified science and technology as the key sectors for economic growth of this land-locked country. Within S&T, biotechnology has been identified as the main technology for optimum utilisation of the rich bioresources of Nepal along with reviving the agriculture sector through this technology. By 2008, the budgetary allocation had increased 12 times. The share of biotechnology in 2002-03 was 22 per cent which increased to 52 per cent in 2004-05 and remained around 43 per cent in 2005-06. The budget for biotechnology has again gone up in subsequent years. The budgetary allocation for S&T in 2008 was raised to $125 million with biotechnology research given priority. A National Biotechnology Research and Development Centre is to be established[146]. The 2006 Biotechnology Policy envisaged setting up of this Centre.

Table 13.2: Budgetary Allocation for Biotechnology in Nepal

Fiscal year	Biotechnology budget	Total S & T budget	% Share of Biotechnology in Total Budget
2002/2003	$26,000	$120,000	21.67
2003/2004	$6,000	$31,000	19.35
2004/2005	$23,000	$44,000	52.27
2005/2006	$ 12,000	$28,000	42.86

The Ministry of Environment, Science and Technology (MEST) has initiated construction of a major biotechnology laboratory in Kathmandu which is expected to be ready by the end of 2009. The MEST has also initiated a programme to use biotechnology for addressing continued energy crisis in Nepal. Nepal experiences power and fuel shortages, so the government will also devote a large part of the money to developing clean energy, including the use of a jatropha as a biofuel.[147]

Box 13.1 Cooperation for Fodder Development

Nepal has launched research based initiatives for improving the quality of fodder in Nepal. A memorandum of understanding (MoU) was signed on 9 March 2008 between Nepal Agricultural Research Council (NARC) and Institute for Crop and Food Research Limited (CFR) to implement the project 'Sustainable Animal Fodder System for Improving Household Incomes'. The objective of the project is to build technical capacity and familiarization for on-farm fodder extension packages among established clusters of farmers; to improve the quality of onfarm winter and summer fodder crop production and animal feeding systems; to improve animal health, fertility and milk yields; to reduce the heavy work loads of women farmers; and to sustain long-term improvements for the livelihoods of farmers and their families. Essentially the projects aims, in participatory way, to change farmers from gatherers of low quality fodders into producers of high quality fodder on their current land holdings, utilizing fallow winter fields between summer grain crops.

According to the agreement, NARC, in collaboration with CRF will: identify and organize the formation of appropriate farmer cluster groups, oversee organization of training needs and media materials for training of extension field staff and farmers, coordinate the technology transfer process to farmers, identify and manage potential soil sustainability issues, facilitate ongoing reviews of the technologies in accordance with the agreed project objectives, modify the technologies where and when appropriate, and facilitate the collection and collation of technical and social impact data for the monitoring, evaluation and reporting requirements of NZAID. The duration of the project is for three years from 1 January 2008 to 31 December 2010.

Source NARC News Letter Vol 15 (10 January-March 2008

Nepal has also explored ways for financing of most pressing challenges through external help. A project to improve fodder quality was launched in 2008 with NZAID (See box 13.1). Nepal has also expressed its solidarity and commitment toward several international efforts related to the environment conservation. Consequently it has become a signatory to a number of international legal instruments. Agriculture remains the main sector in which majority of these projects are coming up and invariably have a biotechnology component linked to it. There are several external funding agencies active in Nepal. Some are Rockefeller Foundation, USAID, JICA, IFS, FAO, ODA (UK) and ADB.

13.3 Biosafety

Nepal's biosafety policy is based on the precautionary principle.[148] Realizing the need of biosafety for the conservation of biodiversity it has made a provision for forming a biosafety sub-committee under the National Biodiversity Coordination Committee. Nepal signed the Cartagena Protocol on Biosafety on 2nd March, 2001. The Ministry of Forest and Soil Conservation (MFSC) has enforced Biosafety regulations 2062 BS throughout Nepal since 25th May, 2005. Accordingly, the Government of Nepal gave high priority to Biosafety Policy in its budget policies and programs statement for fiscal year 2006–007. The Government has identified various agencies responsible for different functions in managing the biosafety requirements. As GMOs may be seed, plants animals for the agriculture or forestry purpose, and products of GMOs or products containing GMOs such as food, feed or pharmaceuticals, therefore, depending upon the types of the GMOs and products thereof, respective sectoral line agencies as presented in table 13.3 are designated by the Government as sectoral competent authority, responsible for the

evaluation of the respective proposals and its risk assessment report, monitoring of the implemented proposals, ensure that the GMOs or its products permitted for testing, storage, use are properly labelled with the description of its composition, direction for use, potential risk, and management of the risks arising from implementation of the proposal.

Table13.3: Sectoral Competent Authorities and Responsible GMOs

Name of Institution	GMOs and Products thereof
Department of Agriculture	Plants, Micro-organism and Fish for Agriculture Purpose,
Department of Food Technology and Quality Control	Food and Feed
Department of Livestock and Animal Health	Animal, Birds and Forage
Seed and Quality Control Centre	Seed for Agricultural Purpose
Department of Plant Resources	Seed and Plant for Forestry Purpose
Department of Drug Administration	Pharmaceuticals

The guideline aims to layout safety measures for study and research in laboratories and in the field trials, and in various industries using biotechnology. It also envisages guiding in handling, transport, export import of LMOs and their products. The guideline however doesn't have any legal binding and thus remains voluntary rather than regulatory.

Chapter 14: New Zealand

New Zealand is member of OECD and has a small population of 4 million. It is situated closer to Australia. Biotechnology in New Zealand is growing fast but has a long way to go when compared to Japan or China. As a small country with limited national market, New Zealand has to focus on global markets and develop linkages for the national biotechnology industry to survive and grow. Inevitably it has to focus on industries in which New Zealand has competitive advantage globally and develop innovative products for the global market. New Zealand thus is facing an unusual challenge in using biotechnology. In one sense its position is similar to the city republic Singapore. But the difference lies in the agriculture and dairy sectors, in which New Zealand has competitive advantage. New Zealand is giving importance to health biotechnology also. The state in New Zealand is actively supporting biotechnology industry and is also supporting the research in basic life sciences.

14.1 Industry structure

In 2007, 168 organizations were active in biotechnology compared to 126 in 2005. More than a third of the organizations employed less than 10 persons while the number of organizations employing more than 100 decreased from 60 in 2005 to 45 in 2007 on account of restructuring in industry and variation between reported activities. 85 per cent of the biotech R&D firms have employees less than 50. The number of dedicated biotech firms is estimated to be 120, although OECD considers this an overestimate.[149] The total no. of biotech R&D firms is estimated to be 60 in 2007. Of the 60 dedicated biotech firms only 6 had more than 250 employees. Biotech firms had a compound annual growth rate of 25 per cent during 2005-07.

The total income of core biotechnology organizations was about $ 276 million with exports contributing $ 104 million.[150] Although there is a policy framework that promotes biotechnology the industry relies on their own funds to a very great extent than government funding. For instance in case of funding for core biotechnology organizations own funds amounted to $ 214 million i.e. 86 per cent of the expenditure. Overseas funds were just 2 per cent while government funding was 8 per cent.

In terms of usage of biotechnology 67 per cent were in R&D, 21 per cent was part of the production process while 13 per cent was as part of a product sold.[151] Process biotechnology including fermentation and bioprocessing is a major application of biotechnology. In terms of areas of application the status of biotechnology in 2007 was as below:[152]

Plant based biotechnology	14 per cent
Animal based biotechnology	12 per cent
Biomedical science and drug discovery	25 per cent
Marine biotechnology	3 per cent
Innovative foods and human nutrition	16 per cent
Environmental biotechnology	12 per cent
Bioprocess and biomanufacturing	10 per cent

Others (impacts and integration of biotechnology)	8 per cent

Thus the industry is well diversified and the educational and R&D infrastructure in New Zealand is advantageous to the growth of the industry. In 2007 the Ministry of Research, Science and Technology produced a Biotechnology Research Roadmap. In 2008 the government funding for research was about $250 million.

The public funding is directed through various agencies and bodies including Foundation for Research, Science and Technology (FRST), Health Research Council, and Royal Society of New Zealand. The FRST approved $ 785 million for more than 24 research organizations. Public sector biotech R&D as % of total expenditure on biotech R&D was 61 per cent in 2005. Of the dedicated biotechnology firms by application health and agriculture together constituted 40 per cent.

14.2 Government Strategy

In 2003 the Ministry of Research, Science and Technology came out with a New Zealand Biotechnology Strategy and indicated that the biotechnology policy of the government would be guided by the following principles : (i) Benefit for New Zealand, (ii) Sustainable development, (iii) Responsibility and Ethics, (iv) Innovation, (v) Partnership and Participation (vi) Treaty of Waitangi and (vii) Biosecurity and Biological Diversity.[153]

The Growth and Innovation Framework identified biotechnology, information and communication technology and creative industries as three enabling sectors crucial to the future of New Zealand with applications across the economy. The Biotechnology Taskforce was set up to focus on the commercial application of biotechnology. After consultations on the Strategy Discussion Paper, Biotechnology Taskforce Report, Report of the Royal Commission on Genetic Modification and review of biotechnology strategies of other countries, the Biotechnology Strategy was finalized.

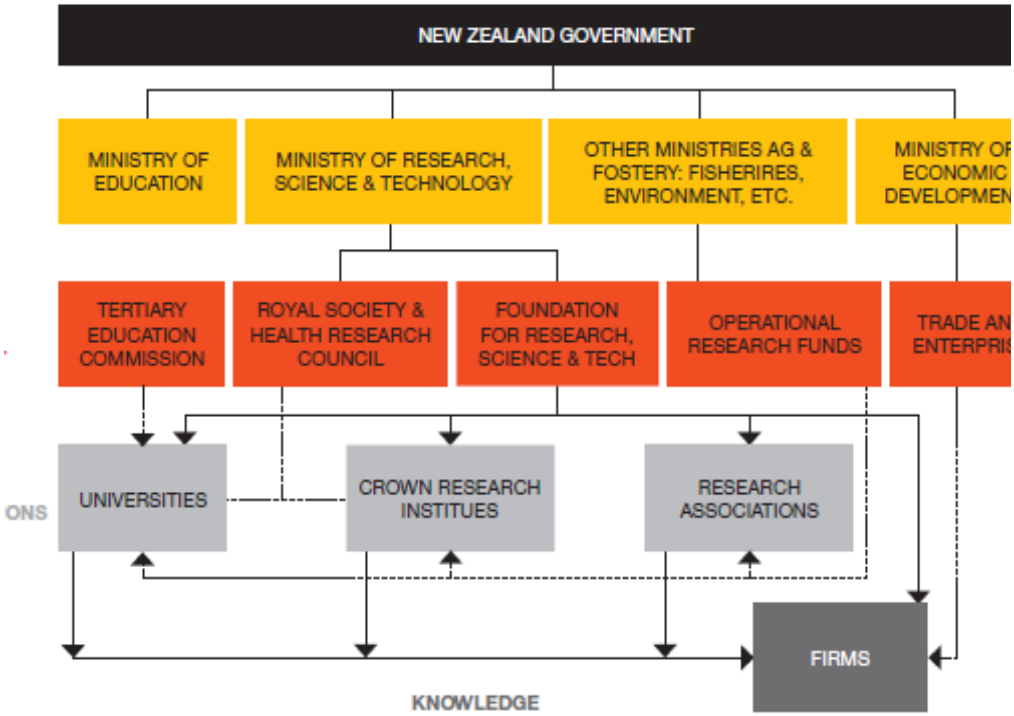
One of the elements of the strategy is to strengthen the capability and the actions on this include enhancing science and technology education, recruit and retain science entrepreneurs, invest in excellence in fundamental research, foster and use the Maori biological knowledge and innovative capacity, and develop commercial skills and experience. The strategy identified both traditional areas like plant based biotechnology and niche areas in biomedical technologies as areas in which New Zealand has existing strength. The strategy indicates that government can support building a critical mass in areas of strength and support clustering and developing alliances and collaboration.

The Biotechnology Taskforce's updated recommendations in 2007 suggested that unified industry body NZBIO could be set up to promote growth. It also suggested more research incentives in tax laws, expanding the NV Venture Investment Fund, and creation of Australia- New Zealand Biotechnology Partnership Fund (ANZBPF) to facilitate collaboration between Australia and New Zealand in biotechnology. New Zealand Trade

and Enterprise was established in 2003 as an agency to boost economic development. NZTE has initiated many initiatives and administers the ANZBPF.

The funding from government for research, science and technology is routed through many ministries and the FRST under Ministry of Research, Science and Technology (MRST) is a major source of funding.

Figure14.1: Biotechnology Research and Funding from Government[154]



Besides the national initiatives under the Biotechnology Strategy, there are many regional initiatives. In the Wellington region Grow Wellington is an initiative that helps firms and enables venture development. There are some public-partnerships in biotechnology. In terms of clusters and regions that are active in biotechnology, New Zealand lags behind. There are no clusters that could be compared with those in other countries. In terms of activity, Auckland is the most active region with 21 per cent of nation's total biotechnology investment.

But lack of experts in biotechnology R&D is considered as a constraint in R&D by the industry. In the surveys conducted in 2005 and 2007 this was cited as a constraint by 24 per cent of the organizations.[155] It is not surprising therefore that the firms recruited staff from overseas with Europe contributing about 40 per cent. Venture capital and private equity investments have increased since 2005. In 2007 it was about $67 million, three times that of 2005. Although there was no public offering the biotechnology companies raised $100 million from secondary offerings in 2006. Access to capital was cited as another major constraint to biotechnology R&D.

14.3 Patents

In 2007, till June 30, 225 biotechnology related patents were granted to New Zealand organizations. Private sector was granted 108 patents while public sector was granted 75 patents and 45 patents were granted to higher education sector. In terms of international patent data New Zealand‘s share is just 0.3 per cent of patents in biotechnology under PCT. But its revealed technological advantage in biotechnology is 1 which is higher than that of even USA. This perhaps indicates that New Zealand is not converting that advantage in terms of patents under PCT or elsewhere. Of the 1057 patents filed in PCT in 2004-2006 104 related to biotechnology.

14.4 Biosafety and Regulation

New Zealand signed the Cartagena Protocol in 2000 and ratified it in 2005. Biosafety regulations are in place in New Zealand. Between 2006 and 2008, field trial for 14 GM crops was approved. Of these herbicide tolerant trait trials were 5. The share of public sector in this was 100 per cent.[156]. In regulating biotechnology the government’s strategy is sensitive to the issues of transparency and preservation of biotechnology. Many agencies are involved in regulating biotechnology (e.g. Environmental Risk Management Authority, the Gene Technology Advisory Committee and Food Standards Australia New Zealand).

14.5 Conclusion

In New Zealand, biotechnology as in many countries in AP is heavily promoted by the government as part of the broader economic strategy. Besides this there is a specific national strategy also. Public sector funding is a major source of funding in basic research. In terms of employment biotechnology’s contribution is small. The presence of a diversified biotechnology industry with many firms engaged in R&D activity is an important aspect of biotechnology in New Zealand. In terms of employment the contribution of biotechnology is small but it has potential to create value addition in other industries and stimulate employment growth in other sectors.

Although some constraints like lack of sufficient funding and non-availability of trained personnel may not be unique to New Zealand they can derail the plans to use biotechnology for economic development. The biotechnology industry in New Zealand has to focus on global markets but in terms of size it is miniscule when compare to the industry in Japan or USA. On the other hand the industry can still be a global player in niche areas and can offer specialized services.

Thus, biotechnology in New Zealand is an emerging industry with much potential to grow and diversify and contribute to economic development.

Chapter 15: Pakistan

The high growth rate achieved in Pakistan during 2003-07 was premised on economic reforms and an expansionary policy framework that aimed to achieve high growth rates, and as evident, Pakistan had around 7 per cent growth in this period. However, later in 2008, it showed major deceleration and is expected to drop to 5.5 per cent by 2009.[157] There are several factors responsible for this like political instability, worsening security situation and impact of high international oil prices. Within agriculture water scarcity and high price of fertilisers brought down growth of major crops. Industrial growth remains subdued. As a result, R&D expenditure within biotechnology have not gone up in recent years.

Pakistan started to work on biotechnology in the early 1980s and since then biotechnology has received continuous support from the government. The government has funded more than $16.7 million through various ministries.[158] Although most of the research is focused on agriculture, there are initiatives in other sectors also. The biotechnology industry in Pakistan is not well developed. The biotechnology in Pakistan to a great extent is government driven with participation of many universities and institutes. The first major initiative was National Institute for Biotechnology and Genetic Engineering (NIBGE) at Faisalabad founded in 1987 by the Pakistan Atomic Energy Commission (PAEC). Since then many centers and universities have been established to do research in biotechnology. The National Commission on Biotechnology was formed in 2001.[159]

15.1 Specific Initiatives

The potential for biotechnology was realized in the early 1980s.[160] After that many research centers were setup and most of them were devoted to agricultural biotechnology, with research focus on crops that are of economic importance to Pakistan. This is understandable given the importance of agriculture's contribution to GDP and in terms of employment.[161] Tissue culture was one of the first applications of biotechnology in Pakistan. The institutes and centers were funded mostly by the various ministries/departments of the government including University Grants Commission and Ministry of Science and Technology (MOST). At present there are 29 departments/institutes/centers involved in biotechnology. Of the 29, 21 are university departments and the rest are R&D organizations. Of these, four are focusing on development of GM crops. In terms of investment, more than US $25 million has been invested during the last five years in biotechnology R&D. The Institute of Agricultural Biotechnology and Genetic Resources, Islamabad, is doing research on transgenic Basmati Rice. Earlier it had developed technology for use of tissue culture in date palm resulting in increase in exports of date palm. Research to tackle the Banana Bunchy Top Virus (BBTV) problem is also undertaken. Most of the crop improvement efforts using biotechnology are on rice and cotton. Virus-resistance and salinity tolerance GM cotton varieties have been developed and are under going trials. Private sector involvement in GM crops is minimal. Monsanto is active in Pakistan and has not released any GM crop for cultivation. In use of tissue culture in agriculture the success is limited to just two or three crops and the activities in this are yet to reach commercial scale in other plants.

Although there have been significant investments in Pakistan in creating centers and institutes, not all of them are capable of taking up advanced biotechnology R&D. Limited financial resources is a constraint. Moreover biotechnology applications in different sectors of the industry are confined to mostly first generation biotechnology. Thus,although the importance of biotechnology was realized in early 1980s, Pakistan has a long way to go in using as well as in benefiting from biotechnology. This should be understood in the larger context of the problem of low-yields in agriculture and the problems in the agriculture innovation system including the lack of trained personnel in agricultural R&D. According to one author the proportion of agricultural scientists with PhD is just 10 per cent of total agricultural scientists in Pakistan. Another factor is the low level of investment in agricultural innovation system. [162]

Although Pakistan has not embarked on commercialization of agricultural biotechnology in a big way, major advances are expected in the coming years as many trials have been approved. GM cotton is expected to be approved soon. Still, issues of unauthorized use of Bt Cotton and regulating the wide scale application of Bt cotton remain. Although there are no authorized Bt cotton varieties, planting of smuggled varieties is rampant. Many farmers are using the seeds obtained from farmers who cultivated the unapproved varieties in the first place. This is likely to create a problem as norms on planting of non-Bt cotton as refuge may not be observed by these farmers.

The importance of biotechnology in Pakistan's agriculture has been recognized by IFPRI which argues that current technologies and current best practices alone will not be sufficient by 2030 when the population is expected to be in the range of 23- 260 million and other problems like declining water resources, and land degradation are likely to intensify further.[163]

15.2 Human Resources

According to one estimate there are 504 scientists involved biotechnological R&D in Pakistan, of which 50 are Post-Doctoral scientists and 188 are PhD holders. Between 1985-1995, MOST supported S&T Fellowship program for 100 PhDs and biotechnology was given 3 per cent of the fellowships. It is expected that among the PhD students and post-doctoral scientists being trained abroad under various bilateral projects and through schemes of the Higher Education Commission of Pakistan, a significant number will return to Pakistan and contribute to its growth in biotechnology. The new initiatives in human resources for S&T include schemes for hiring faculty from abroad, split PhD scheme and more fellowships for pursuing PhD in sciences.[164]

15.3 Biosafety

Pakistan has biosafety rules in place. National Biosafety Guidelines have been issued in 2005. Still the episode of illegal planting of Bt Cotton on a wide scale exposed the flaws in the system. Pakistan is a signatory to Cartagena Protocol.

15.4 Patents

The information on patents is scanty. Pakistan has enacted various laws including plant breeders rights Act. The Patents Act has also been amended.

15.5 Capacity Building and Bilateral Efforts

Pakistan has been a beneficiary of many bilateral efforts including projects supported through bilateral and multilateral initiatives. Among others USAID, Rockefeller Foundation, ADB helped Pakistan since the early 80s in capacity building efforts, particularly in human resources development.

15.6 Conclusion

Although biotechnology is more than two decades old in Pakistan, it is yet to reach the critical stage of being applied on a large scale in any sector or contributing to increased productivity of agriculture. The reasons are many. Pakistan's experience indicates that while investments and policies are necessary, they themselves cannot achieve much when there are other constraints and when the National Innovation System is not equipped to absorb and benefit from a new technology.[165]

Chapter 16: Biotechnology in the Philippines

The Philippines started its biotechnology programs in 1980 with the establishment of the National Institute of Molecular Biology and Biotechnology (BIOTECH) at the University of the Philippines at Los Baños (UPLB).[166] In 1987, the Philippine Council for Advanced Science and Technology Research and Development (PCASTRD) was created under the Department of Science and Technology (DOST) with an aim to develop, integrate and coordinate the advanced S&T sector including biotechnology. DOST also take up some projects related to genetic modification sometime between 1985 to 1989.[167]

In 1990, National Committee on Biosafety of the Philippines (NCBP) was created under Executive Order No. 430,a maiden venture among developing countries of Asia apart from Japan. In 1995, three other biotechnology institutes were established within the University of the Philippines System to focus on three sectors – industrial biotechnology, health biotechnology and marine biotechnology.[168] The biotechnology institute in UP Los Baños (UPLB) was involved in agricultural, forestry, industrial, and environmental biotechnology. In UPLB itself there are other institutes that are involved in biotechnology in one way or other. For example the Institute of Plant Breeding, Institute of Biological Sciences, Institute of Animal Sciences, Institute of Food Science and Technology, and the College of Forestry and Natural Resources. Other institutes and centers such as the Philippine Rice Research Institute, Philippine Coconut Authority, Cotton Research and Development Institute, Bureau of Plant Industry, the Bureau of Animal Industry, and the Industrial Technology and Development Institute are also involved in biotechnology R&D. Thus there are many institutes that are actively involved in biotechnology.

16.1 Human Resources and Capacity Building

Based on a survey conducted by PCASTRD agency in 1998 covering about 10 institutions across the country, there were 346 M.Sc. Degree holders and 301 Ph.D. holders in biological sciences.[169] Table 16.1 provides a rough profile of the Philippines potential.

Table 16.1: Philippines Biotechnology R&D Sector, 2003

Institution	***No. of senior researchers***
Specialised government research institutes	7
State Universities	31
Private Medical Institution	2
Private Agriculture Foundation	4
Total	44

Source: Enriquez- Novenario, Virginia G. (2007a).

Another survey was also conducted by an agency of the DOST covering 7 research institutes, where it was found that 105 experts were involved in modern biotechnology and about 212 in conventional biotechnology.[170] Although Philippines have many institutes in terms of human resources it lags behind. The human resources needed for biotechnology R&D are not available and this imbalance should be rectified.

16.2 Programme Framework

In the Philippines, DOST and the Department of Agriculture are the two departments actively involved in biotechnology management programme. The key R&D funding agencies are the Department of Science and Technology, Department of Agriculture, University of the Philippines/National R&D Networks, Private Sector and Foreign Institutions.

As in many countries in AP, in the Philippines, government funding is substantial. Almost 80 percent of the total annual budget for biotechnology R&D comes from the government. Fifteen percent comes from international development agencies, while the private sector contributes approximately 5 percent.[171] The private sector is expected to provide more funding in the future as they see the potential of biotechnology in agriculture. But this is not likely to happen unless the industry reaches a critical stage where innovation is the key to progress.

In 1997, the Agriculture Fisheries Modernization Act (AFMA) was enacted, with an objective to modernize agriculture, including infrastructure, facilities, and R&D. AFMA recognized biotechnology as a major strategy to increase agricultural productivity. By this law, AFMA will provide a budget of 4 percent of the total R&D budget per year for biotechnology during the next 7 years. This allocation provides an annual budget for biotechnology of almost US$ 20 million.[172] Before AFMA, the annual budget for biotechnology averaged less than US$ 1 million.

Table 16.2: Area of Application: Agriculture, 2002-06

Source of funding	DOST	DA (Department Of Agriculture)	State Universities
Total amount of funding(5 years)	US$ 1,608,950 (33.9%)	US$ 1,639,664 (34.6%)	US$ 1,496,408 (31.5%)
Primary recipients of funding	UP System, DOST-ITDI	PhilRicePCA Research Centre UP system	UP System
Implementing Agencies	Philrice, DOST-ITDI,UP System	PhilRicePCA Research Centre UP System, DOST-PNRI	UP System

Source: Enriquez- Novenario, Virginia G. (2007a).

In agriculture, DOST, DA and the State Universities are the main sources of R&D funds. They provided funds that amounted to almost US$ 4.8 million during 2002 to 2006, of which 33.9 per cent was provided by DOST, 34.6 per cent by DA and the remaining 31.5 per cent by the State Universities (Table 16.2). The primary recipients of funding by DOST are University of the Philippines (UP) System and DOST-Industrial Technology Development Institute (ITDI) while the implementing agencies are Philrice, DOST-ITDI and UP System. For DA, the primary recipients of funds are PhilRicePCA Research Centre UP system and the implementing agencies are PhilRicePCA Research Centre UP System and DOST-Philippine Nuclear Research Institute (PNRI). And for the State

Universities, UP System is both the primary recipient of funds as well as the implementing agency.

Table 16.3: Area of Application: Medical, 2002-06

Source of funding	**DOST**	**State Universities**	**Others (Department of Health)**
Total amount of funding(5 years)	US$ 2,754,053 (97.3%)	US$ 447,187 (1.6%)	US$ 31,000 (1.1%)
Primary recipients of funding	UP Manila, UP Diliman Research Institute for Tropical Medicine (RITM) St. Luke's Medical Center	UP System	Research Institute for Tropical Medicine (RITM)
Implementing Agencies	UP Manila, UP Diliman Research Institute for Tropical Medicine (RITM) St. Luke's Medical Center	UP System	Research Institute for Tropical Medicine (RITM)

Source: Enriquez- Novenario, Virginia G. (2007).

As shown in the table 16.3, for the medical sector, DOST provided 97.3 per cent of the medical biotechnology R&D funds in the period 2002-06. Its primary recipients of funding are UP Manila and UP Diliman Research Institute for Tropical Medicine (RITM) St. Luke's Medical Center. These institutes are also the implementing agencies. The State Universities provided 1.6 per cent of the funds to the UP System. There are other funding bodies too, like the Department of Health, and they provided 1.1 per cent of the medical funds to the Research Institute for Tropical Medicine (RITM).

Table 16.4: Area of Application: Industry, 2002-06

Source of Funding	**DOST**	**State Universities**
Total amount of funding (5 years)	US$ 321,802 (78.81%)	US$ 86,517 (21.19%)
Primary recipients of funding	DOST-ITDI, DOST-FPRDI State Universities	UP Visayas UP Los Baños
Implementing Agencies	DOST-ITDI, DOST-FPRDI State Universities	UP Visayas UP Los Baños

Source: Enriquez- Novenario, Virginia G. (2007).

For industrial biotechnology, DOST and the State Universities provided a total of around US$ 4.1 million, of which DOST provided 78.81 per cent and the State Universities provided 21.19 per cent. DOST-ITDI and DOST-Forest Products Research and Development Institute (FPRDI). State Universities are the major recipients of the funds provided by DOST. They are the implementing agencies too. In the case of funds from

the State Universities, UP Visayas and UP Los Baños are the recipients as well as the implementing agencies.

Table 16.5: Philippines R&D Funding: 2002-06 (Amount in US $)

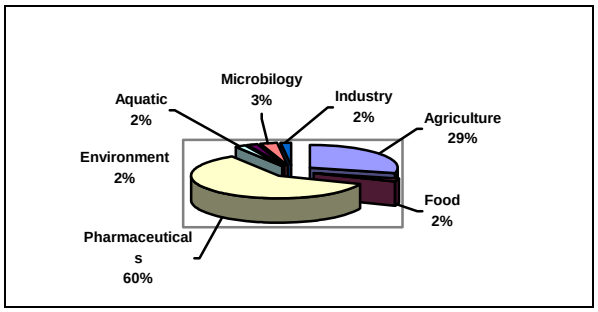
	Agriculture	Medical	Industrial	Environmental	Aquaculture	Total
DOST	1,608,950 (34.1%) (50projects)	2,754,053 (58.3%) (5projects)	321,802 (6.8%) (18projects)	37, 844 (0.8%) (5projects)		4,722,649 (49.9%)
DA	1,639,665 (68projects)					1,639,665 (17.4%)
Philippines Government Soft Loan (Public Law 480)	916,500					916500 (9.6%)
UP System	1,496,408 (139projects)	447,187 (25projects)	86,517 (23projects)	86,517 (23projects)	20,112 (5projects)	2,151,239 (22.8%)
Others(DOH)		31000 (4projects)				31,000 (0.3%)
Total	5,661,523 (59.8%)	323,240 (3.4%)	413,041 (4.4%)	408,320 (4.3%)	20,112 (0.2%)	9,461,053

Source: Enriquez- Novenario, Virginia G. (2007a).

From table 16.5, it is evident, that almost 60 percent, i.e. more than half of the funds go to agriculture, 3.4 percent goes to medical and health related research, while less than 5 percent goes to industrial and environmental each. Aquaculture, being in an infant stage, receives only 0.2 percent. Table 16.5 also shows that DOST provides almost half of the total biotechnology R&D funds in the Philippines. UP System also provides a significant 22.8 percent. The funds released by the Philippines Government Soft Loan under Public Law 480 amounts to almost 10 percent. The Department of Agriculture contributes about 17.4 percent. The other funding bodies like the Department of Health provide only an insignificant amount. There are other sources of funds for biotechnology R&D in the Philippines. They are the Department of Agriculture and the University of the Philippines or the National R&D System. The total funds provided by these institutes amount to P 74.373 M for the period 2002-06.The Department of Agriculture undertook 30 projects, providing funds worth P60.131M while the University of the Philippines undertook 48, providing funds worth P14.242M.[173]

From 2007-2008, the DOST allotted 11 per cent (P267.018 million) of its total R&D budget (P2.282 billion) to biotechnology. Figure 16.1 shows the DOST fund allocation per sector of biotechnology for FY 2007-08.[174]

Figure 16.1: DOST Fund Allocation Per Sector (%), 2007-08



16.3 Foreign Participation in R&D

Foreign Sources of funding are US-PL480 Program (Food for Peace), USAID, Nanosys Int', Pioneer and Croplife and the allocation of foreign funds in agriculture, pharmaceuticals and food amounts to 7, 21 and 8 percent respectively.[175]

Thus biotechnology R&D is heavily dependent on government funding. This is unlikely to change in the future as well.

16.4 Biotechnology Firms and Private Participation

Monsanto, Pioneer Hi-Bred, Syngenta and East-west are the major private sector entities in biotechnology. The Philippines' definition for a biotechnology firm extends to the firm's engagement in biotechnology using at least one biotechnology technique (as per the OECD definition of biotechnology techniques) to produce goods or services or to perform biotechnology R&D. Biotechnology firms are further subdivided into Dedicated and R&D firms, where the former refers to those firms that predominantly involve application of biotechnology techniques and the latter to those that perform R&D. By 2006, the Philippines had 24 biotech R&D firms and 13 dedicated biotechnology firms, amounting to a 62 per cent share of firms with less than 50 employees (Table 16.6).[176]

Table 16.6: Biotechnology Firms by Size Class, 2006

Type of Firms	Less than 50 employees	50 to 249 employees	250+ employees	Total biotech firms	%of firms with less than 50 employees
Biotechnology	16	4	4	24	67
Dedicated	8	4	1	13	62

Source: OECD (2009).

In terms of total employment in biotechnology R&D firms, Philippines have a total of just 663. Of the 663 employees, 126 are biotech employees.[177] Thus in terms of human resources the govt. funded institutions and institutes like IRRI are the major employers.

16.5 Biotechnology Applications

Figure 16.2 gives the data on share of dedicated biotechnology firms by applications in different fields for the year 2006.

Figure 16.2: Share of Dedicated Biotechnology firms by Application, 2006

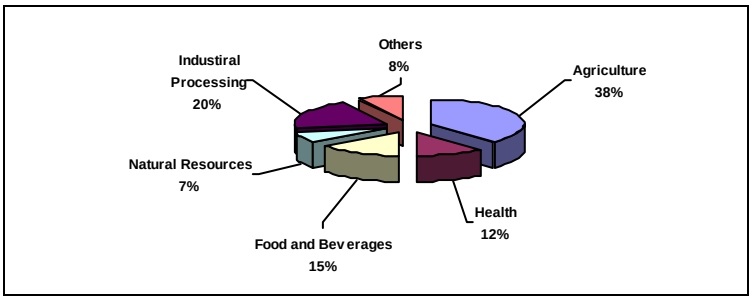


Table 16.3 details the breakdown of the biotech firms with respect to the different application fields of biotechnology in the Philippines.

Table 16.3: Biotechnology Firms by Application

Nature of firm	Health	Agriculture	Food and beverages processing	Natural resources	Environ-ment	Industrial processing	Bioinformatics	Other	Total biotech firms
Biotechnology firms	3	10	4	2	0	5	2	0	13
Dedicated biotechnology firms	4	19	6	6	1	9	2	0	25

Source: OECD (2009).

In 2008, just 7 per cent of all the arable land was planted with GM crops.[178] Data for arable land does not measure the amount of land that is potentially cultivable. Area of land planted to GM crops in 2006, 2007 and 2008 (in million hectares) are 0.2, 0.3 and 0.4 respectively.[179]. Thus the penetration of GM crops is too low in Philippines.

16.6 Biotechnology Patents

Table 16.4 shows that there have been 29 patent applications filed of which 24 came from the RDIs and 5 from the private firms. 2 patents out of 5 have been granted to the private firms. In the case of RDIs, 3 out of 24 have been granted. For patents granted to RDIs in the past 5 years, 2 patents were licensed out while one was already marketed and a start-up company was formed as a result. [180]

Table 16.4: Patent Applications in the Past 5 Years

	Status of patent applications		Total
	Granted	Pending	
Private Firms	2	3	5
RDIs	3	21	24
Total	5	24	29

Source: Enriquez- Novenario, Virginia G. (2007).

Table 16.5: Biotechnology PCT Patent Applications and Total PCT Patent Applications

1994-96		2004-06	
Biotechnology	Total	Biotechnology	Total
1	13	0	108

Note: Patent Counts are based on the priority date, the inventor's country of residents and use fractional counts on PCT filings at international phase (EPO designations).
Source: OECD (2009).

Table 16.5 shows that there was only 1 biotechnology patent application during from 1994 to 1996 and none between 2004 and 2006.However , as per the latest update given in the WIPO Statistical Database, 2009, the numbers of biotechnology patent applications filed with the PCT for the four quarters of 2008 are 1, 5, 1 and 5 respectively.

From this it is clear that biotechnology innovation lags behind in Philippines.

16.7 Biotechnology Regulatory Framework

In October 15, 1990 ,The National Committee on Biosafety of the Philippines (NCBP) was created through Executive Order No. 430.In 2002- the Department of Agriculture issued Administrative Order No. 8 which formed the basis for the commercial release of GM crops. And in March 17, 2006, Executive Order 514 was issued to further strengthen the NCBP and establish the National Biosafety Framework.[181]

16.8 Biosafety

The first guidelines were patterned after those used in the United States, Australia, and Japan in the early 1980s.[182] But they were not liberalized in subsequent years. For Philippines, the challenge lies in updating and better implementation of the current biosafety guidelines, taking advantage of experience gained elsewhere in the world. At present, all regulatory bodies such as the Bureau of Plant Industry (BPI), Bureau of Animal Industry (BAI), Fertilizer and Pesticide Administration (FPA), Bureau of Food and Drugs Administration (BFAD), and the Environment and Management Bureau (EMB) do not have a well developed policy and guidelines to regulate the commercial release of new genetically improved products. In addition, the institutional support system, such as laboratories and infrastructure is inadequate.[183]

16.9 Conclusion

Biotechnology in Philippines has a long way to go although the beginning has been made much earlier. The scope for agricultural biotechnology has not been utilized well and in terms of human resources, the Philippines has to increase the number of trained scientists. Biotechnology thus needs a major push now, to leap forward.

Chapter 17: Singapore

Singapore has focused on biotechnology based on biomedical/life sciences and there is no worthwhile activity in agricultural biotechnology. Singapore is capitalizing on its position as regional hub in trade, finance and services etc to build up a biotechnology industry that is specialized. Singapore places enormous emphasis in attracting investment, infrastructure and capacity building in human resources. The various agencies work in tandem with a total systems approach backed by the political will of the state. In that sense, the city republic has embarked upon an unique biotechnology strategy that leverages on the capacities built earlier in electronics and information technology. The investments are massive and public research institutions in biotechnology are supported to a great extent.[184]

Singapore has firmly established itself as a key global manufacturing site for pharmaceutical leaders. Today, the city-state is host to 11 global pharmaceutical and biotechnology companies that have set up more than 25 commercial manufacturing facilities here. These facilities are validated by American and European regulatory authorities, and produce innovative medicines for the global market. In R&D, Singapore is quickly emerging as one of Asia's fastest growing bio-clusters. The city-state is one of the world's most prolific research locations with 1.41 papers per 1,000 people (Wiley-Blackwell, 2007). Alongside the seven public-sector biomedical sciences research institutes and world-class hospitals, 50 companies from the US, Europe, Japan, Korea and other parts of Asia are carrying out R&D that straddles drug discovery, translational research and medical technology innovation. Today, there are more than 2,000 international researchers in Singapore (EDB Singapore 2009)

17.1 Industry Structure and Initiatives[185]

Biomedical research in Singapore is a coordinated endeavor focusing on finding cures/drugs for five target diseases (cancer, ageing/neurobiology, cardiovascular, liver and infectious diseases). Singapore has identified five platform technologies as key technologies in biotechnology that would spur biotechnology R&D in Singapore and place it firmly in the global R&D map. The five key technologies are – bioinformatics, bioengineering, experimental therapeutics, immunology, and structural biology (including genomics, proteomics). Under Translational and Clinical Research five flagship programs were launched in 2007-2008, each valued at S$25 million. They are Singapore Gastric Cancer Consortium (Cancer); Translational Research Innovations in Ocular Surgery (Eye Disease); Vulnerability, Disease Progression and Treatment in Schizophrenia and Related Psychoses (Neuroscience); Developmental pathways to metabolic diseases (Metabolic Diseases) and Scientific exploration, translational research, operational evaluation of disease prevention and preventive measures through new treatment strategies against Dengue (STOP Dengue).

The establishment of a Biopolis hub in 2003 can be considered as a significant landmark in development of biotechnology and biomedical sciences in Singapore.[186] It is noteworthy that even during the current global economic downturn Singapore has been

able to attract significant FDI in biotechnology R&D. For instance global biomedical companies invested more than US $500 million in Singapore in 2008. Singapore invests heavily in biomedical R&D with investments exceeding US $760 million in 2007. In 2006 Singapore invested S $ 5000 million in R&D which is 2.39 per cent of GDP. The quantum and scale of investment in R&D has gone up from the 0.26 per cent of GDP in 1981 and 1 per cent of GDP in 1991.

Singapore gives importance to private sector investment and joint R&D in public and private sectors. By ensuring that the existing university system is well funded in biomedical and life sciences Singapore is building up a strong R&D infrastructure. The private sector and public sector institutions complement each other. According to one estimate more than 50 global pharmaceutical, biotechnology and medical technology companies are active in Singapore and this includes companies like Bayer, Schering-Plough, GlaxoSmithKline (GSK). There are more than 50 manufacturing facilities, many of which have been accredited by FDA (USA) and European Medicines Agency. The value addition per employee and contribution to the GDP is significant.

For Year 2008*		
BMS Manufacturing Output	S$19.0 billion (US$12.7 billion) (7.6% of Total Manufacturing Output)	
BMS Manufacturing Value-Add	S$10.6 billion (US$ 7.1 billion)(4.1% of GDP)	
Manufacturing Employment	Total	12,450
	Pharmaceutical	4,169
	Medical Technology	8,281
Value-added per worker	S$0.8 million	

About 30 public-sector research/medical institutions are active in Singapore. The combination of huge investments in R&D with synergy between public sector and private sector can be expected to give Singapore an unique advantage. Obviously Singapore is giving emphasis to sectors/areas where it can draw on existing strengths of the National Innovation System even as it aims to attract not only FDI but also a pool of scientists and technocrats from other parts of the world to buttress its strategy. The enormous investment in Biopolis is attracting scientists working in stem-cells to Singapore.[187]

This is evident from A*STAR Investigatorship (A*I) award launched in 2008, to attract bright young researchers from other parts of the world to pursue research in Singapore. Singapore is also paying attention to nurturing and encouraging homegrown talent and expertise through incentives like fellowships. For example in 2001 a scheme was launched with the objective of training 1000 local PhD graduates in the leading universities of the world by 2015.

In terms of human resources Singapore is in an enviable position as 26.3 per cent of research scientists in private sector and 48.5 per cent of research sector in public sector

biomedical sciences hold PhD, as of 2006. In 2006 the private sector R&D expenditure in biomedical sciences, S$ 531 million was almost double of public sector investment which stood at S$277 million. Since Singapore has a long history of investment by foreign pharmaceutical and electronics industry and as has had a liberal policy that encouraged FDI in key sectors, the current policy should be seen as a continuation of the earlier policy regime. According to Paul Teng, "Countries like Singapore and Korea have purposely targeted specific sectors, such as the Life Sciences, for exploitation. The goal has been to broaden the base of the current economies through future diversification beyond current strengths like manufacturing and ICT." [188]

Singapore is also planning to emerge as regional hub for clinical trials. In 2007 the number of approved clinical trials was 253. Lest should it be construed that Singapore is interested in only cutting edge and world-class research without any interest in developing innovations or products that can meet the demands of the global market.

17.2 Patents

Singapore has a proactive policy on IPRS and emphasizes on IP rights and ownership of innovation. It in that sense takes positions that are similar to that of USA and EC on IPRS where the underlying logic is strong IPRS stimulates innovation and hence are a must to attract investment in R&D and to encourage commercialization of innovations.

According to OECD Compendium of Patent Statistics, "Finland, Singapore, China, the Netherlands, Korea and Japan had a large concentration of ICT-related patents compared to all countries, as depicted by the revealed technological advantage index" (p14). The same report points out that Singapore has the world's highest revealed technological advantage in Nanotechnology which is 2.7 (p16 ibid). In biotechnology Singapore's revealed technological advantage is little less than 2, which is lower than Denmark which enjoys the No. 1 position in that in the world (p18).

In terms of patent filings in PCT the higher education sector and the government have a share of 24 per cent. Globally, the Singapore government leads in % of patents owned by the government which is 14 per cent. These indicate that Singapore state has pursued an active patenting policy which is in contrast with the position in most OECD countries where government and government agencies play a minor role in patenting and private sector owns a good majority of the patents.

In terms of commercializing inventions and revenue generation through licensing, firms/research centers in Singapore have entered into deals with foreign firms. For example S*Bio is likely to receive more than US $600 million in payment under two licensing schemes with Onyx and Tragara to develop oncology drugs. The spinning off of units based on innovation is another practice that is being followed by institutions in Singapore. Thus emphasis on IP rights coupled with commercialization/ using innovations to generate revenue indicates that R&D is not viewed as an activity with no commercial objective. Although most of the research in basic science cannot be simply converted into viable products without further R&D the approach in Singapore is to encourage both basic science and applied R&D and focus on specific sectors and within

sectors giving emphasis in selected technologies/platforms/problems. This helps in preventing the tendency to spread the resources too thin and attempting to do what all is possible. In other words the Singapore's agenda is a carefully developed agenda with well-laid out objectives and investments to match with the objectives. In this regard it should be pointed out that Singapore has been pursuing the government-directed economic strategy for long and this has resulted in development of a National Innovation System that has been built assiduously over the years with active participation from the government.

Singapore is not the only country in Asia that is vying for a share in the global biotech market, particularly in bio-medical technologies. Nor that is the only AP country in which government is taking a pro-active approach in promoting biotechnology, investing heavily in basic sciences and R&D, in developing human resources and in adopting FDI friendly policies in selected sectors. Thus Singapore has to compete with nations like Korea, China and India which have their own advantages with well-developed innovation systems. Singapore has crafted a strategy that is much focused and well laid out in terms of targets. It has advantages like the active commitment from state and a bureaucracy that is committed to the plan.[189] Its other advantages include successful implementation of similar strategies in other sectors in the earlier decades.

While the Singapore economy is open and conducive to the promotion of innovative research, there is official consideration that important social, legal and ethical issues are also addressed. Thus a strong regulatory structure is in place to ensure high standards and protection of intellectual property rights (IPR). The other factor in Singapore's favour is the widespread acceptance of quality assurance and quality control (QA/QC) programs, where industrial best practices in industrial standards and processes exist to provide guarantees against inferior or defective products. Additionally, the Singapore government has a good reputation for its integrity, efficiency and political will, which are factors offered as distinct advantages to bio-business investors, against the competition.

17.3 Conclusion

The strategy developed in Singapore cannot be duplicated in other countries, particularly in countries which lack human resources and the economic capacity to invest heavily in infrastructure and promotion of R&D. But some elements of that can be used selectively in developing appropriate policies in other countries. For example the focus on selected niche sectors, with policies that would strengthen the existing capacity and policies that attract talented scientists from elsewhere.

Chapter 18: Sri Lanka

Since 2004, Sri Lanka has exhibited consistently high GDP growth at around 6 per cent which even touched 6.8 per cent in 2007. Agriculture recorded strong growth of 7.5 per cent much higher than other sectors. The Sri Lankan government has focused on agriculture production so as to minimise food imports and contained sharp increase in food prices through intensive paddy cultivation. Another area of focus is on higher tea production with better quality of inputs.

In Sri Lanka agriculture and plantation crops continue to contribute significantly to the nation's GDP and export earnings. In this island country, biotechnology is yet to take firm roots and is in its nascent stage. The scope for biotechnology is at present more or less confined to agricultural sector. As in many developing countries and LDCs biotechnology in Sri Lanka is largely driven by government and most of the research is done by public sector.

18.1 Industry Structure and Initiatives[190]

The private sector in biotechnology is yet to take off in a big way. Biotechnology has been identified as an important area for development in Sri Lanka. Funding comes from international agencies (ADB, SIDA) and national funding agencies (National Science Foundation – NSF, Council for Agricultural Research Policy – CARP, and National Research Council – NRC). NSF and CARP are funding universities and research institutes. The funding for biotechnology by NSF was started in 1992 only. But biotechnology is underfunded in Sri Lanka. In 2003 CARP allotted 3 per cent of the budget distribution to biotechnology.

The number of researchers in the biotechnology sector in Sri Lanka is estimated to be 264 as of 2005. But it lacks the critical mass in human resources to engage in productive R&D in biotechnology[191]. Agricultural biotechnology, medical biotechnology and animal biotechnology are the three sectors that get funded. Research in medical biotechnology is done at, *inter alia*, at University of Colombo, Institute of Biotechnology, Molecular Biology and Biotechnology, University of Kelaniya and University of Sri Jeyawaraenapura. Although some technologies like molecular diagnosis of dengue and PCR for TB have been developed by them, they are not commercialized. The only exception is technology for rapid detection of Salmonella in coconut which has been transferred to Genetech Molecular Diagnostics. Genetech is perhaps the only private sector in medical biotechnology.

The key role of biotechnology in increasing productivity in agriculture has been recognized. Biotechnology has been identified as a thrust area by the government. A National Committee on Biotechnology has been established. The need for a National R&D priorities and strengthening human, institutional and policy capacity has been accepted. With FAO's assistance a project has been established.[192]

The plan is expected, *inter alia*, to prepare an investment plan for 2009-2015, determine National Biotechnology R&D priorities, assess the present status of biotechnology, and

develop plans for human resources development. Surveys were conducted and Workshops were held to determine national R&D priority. Based on these, seven sub-programs were included in the draft R&D program for biotechnology.

Sri Lanka opened up its economy in 1979 and this stimulated investments in export promotion zones, particularly in textiles and garment production. But the phasing out of MFA restricted the expansion of this industry. Only 28 per cent of Sri Lanka's GDP is from industry. Textiles and plantation crops constitute a major portion of the exports. The local pharmaceutical industry is limited to generic producers who lack R&D capacity.

The Gross Expenditure in R&D (GERD) is less than 1 per cent of GDP. This is much less than some countries in Asia. Sri Lanka has not been a favorite destination for FDI in high technology. The lack of trained professionals in R&D, underdevelopment of science and technology in higher education and the lack of indigenous capacity to develop technology are some of the factors that inhibit development of biotechnology. Moreover the lack of a strong and wide industrial sector limits the scope for private sector R&D which prefers imported technology. There is no venture capital activity worth the name.

Regional co-operation with SAARC countries in biotechnology is virtually non-existent. The FAO funded project referred to above can help in formulating the policy but funding and execution are challenging tasks. Mere funding for biotechnology is not sufficient unless forward and backward linkages are established. The need for a longterm plan for S&T is obvious.

18.2 Biosafety

Sri Lanka has signed and ratified the Cartagena Biosafety Protocol. The National Biosafety Framework for Sri Lanka was developed and as a part of that, a Biotechnology regulatory system was developed.[193] But it is yet to be implemented.

GM labeling regulation was published in 2007 and under that non-GMO certification for soybeans and corn imports was required.[194] There is no central authority to regulate or oversee biotechnology regulation or use of biotechnology products. To overcome this lacuna the NBFSL recommended the formation of a national competent authority, to be known as the National Council for Biosafety (NCB).[195]

At present there are many Acts and rules that regulate various aspects of plant protection and environment.[196] But there is no comprehensive framework to integrate and regulate them in the broader context of biosafety. Another issue that has been highlighted is the absence of risk assessment and management of risk in various institutes where biotechnology research is undertaken. [197] As there are no GM plants under commercialization or development, the only route for GM products entering the market is through imports.

18.3 Conclusion

Sri Lanka's biotechnology sector is in nascent stage. Largely government driven, it suffers from many bottle necks and has a long way to go although there is much scope to

grow. But this should be seen in the larger context of absence of a functioning National Innovation System and under-funding for S&T in Sri Lanka.[198] Unless some of these problems are tackled effectively biotechnology in Sri Lanka will continue to suffer from the problems that are affecting its growth.

Chapter 19: Thailand

Thailand is one of the few developing countries that have well articulated a National Biotechnology Policy with specific goals.[199] Agriculture contributes 9 per cent of GDP while manufacturing and services contribute 36 per cent and 55 per cent respectively. Thailand is the worlds 14th largest agricultural and food exporter.[200] Rice, rubber and cassava are the top three crops grown in Thailand. Thailand has a significant generics industry in the pharmaceutical sector. Building on its capabilities, Thailand has ambitious plans to expand its reach in biotechnology into Nano biotechnology, Bioinformatics. Human resources development is also given emphasis in the plans for biotechnology.

19.1 Industry Structure[201]

Of the new companies majority of them are in medical/health, constituting 65 per cent, while agricultural biotech firms constitute 27 per cent and other sectors 8 per cent. In R&D investment 70 per cent of the companies are in agri-biotechnology and the rest are in medical/health. The industry in Thailand is largely an industry that is driven by governments plans and policies. Thailand made a start in agricultural biotechnology in 1983 with founding of National Center for Genetic Engineering and Agricultural Biotechnology (BIOTECH) in 1983. There were many trials and experiments on Genetically Modified Plants in the 80s and 90s including imported transgenic plants. But commercialization was delayed due to resistance from civil society and lack of regulatory framework on biosafety. [202]. Between 1992 and 2000 more than thirty studies on using agricultural biotechnology in various crops were authorized but none of them reached the stage of commercialization or approval for planting. The lack of clear policy framework on trials and commercialization was a stumbling block. [203]

In agricultural biotechnology, Thailand used transgenic technology in economically important crops and in marker assisted selection. Between 1990 and 2003 human resources development was given importance and research grants were provided (See Table 19.1 and 19.2).[204]

Table 19.1: Human Resources and Education Qualification (1990 – 1995)

Degree's Levels	Financial Year						Total
	1990	1991	1992	1993	1994	1995	
B.Sc-M.Sc-Ph.D	4	6	9	8	4	12	43
M. Sc	2	5	-	-	-	1	8
M.Sc-Ph.D	11	15	9	7	5	25	72
Ph. D	12	24	10	11	9	14	80
Total	**23**	**39**	**19**	**18**	**14**	**39**	**203**

Table 19.2: Human Resources and Education Qualification (1996-2003)

Degree's Levels	Financial Year								Total
	1996	1997	1998	1999	2000	2001	2002	2003	
B.Sc-M.Sc-Ph.D	19	6	-	10	2	-	-	-	37
M. Sc	19	24	6	14	20	8	1	7	99
M.Sc-Ph.D	23	24	14	37	15	14	13	33	173
Ph. D	21	29	13	7	12	12	2	30	126
Total	**82**	**83**	**33**	**68**	**49**	**34**	**16**	**70**	**435**

Export of shrimps was a major foreign exchange earner in 1990s with about US $1.5 billion annually and employing 1.3 lakhs people. But the shrimp industry was affected by White Spot Syndrome Virus whose origin was in China. Testing for this virus in batches in shrimps that were to be exported could prevent their rejection later if their presence was detected. Thailand used of DNA technology to screen stocking fry so that WSSV positive batches could be rejected before they were slated for export. When the outbreak of WSSV in South America in late 1990s and first decade of 2000s led to the reduction of exports of shrimps to USA from countries in South America, exports from Thailand increased as by then Thailand had successfully implemented prevention and testing program based on the indigenously developed DNA probe technology. The investment in development of the DNA proble yielded substantial returns on investment. The shrimp fry used to stock the shrimp ponds was identified as the potential source of the virus. The timely detection of the source and development of a DNA prove saved the industry from facing rejections in huge quantities and helped in exporting more to USA. [205]

By the end of 1990s the relative importance of various biotechnology related activities in Thailand was as below.[206]

Table 19.3: Industry and Relative Importance

Industry	Relative importance
Biopharmaceuticals	+++
Specialty chemicals	+
Colorants, food additives, cosmetics	++
Vaccines	+/++
Edible and commodity crops [agri-food industry]	++/+++
Biological clean up [bioremediation]	++
Biomining/ bioleaching	++

- Number of [+] indicates relative importance [more=higher]

Thailand used agricultural biotechnology in biomarker selection and in plant transformation technology to produce transgenics with specific traits and varieties that are resistant, e.g. papaya resistant to ringspot virus and chilli resistant to vein-banding

mottle virus. Transgenic rice research for salt and drought tolerance was undertaken with support from Rockefeller Foundation. Thus by the end of 1990s Thailand proved its capacity to undertake R&D in biotechnology successfully. But this did not result in large scale commercialization of GM crops as the biosafety regulations were not fully developed by then and there was resistance from civil society.

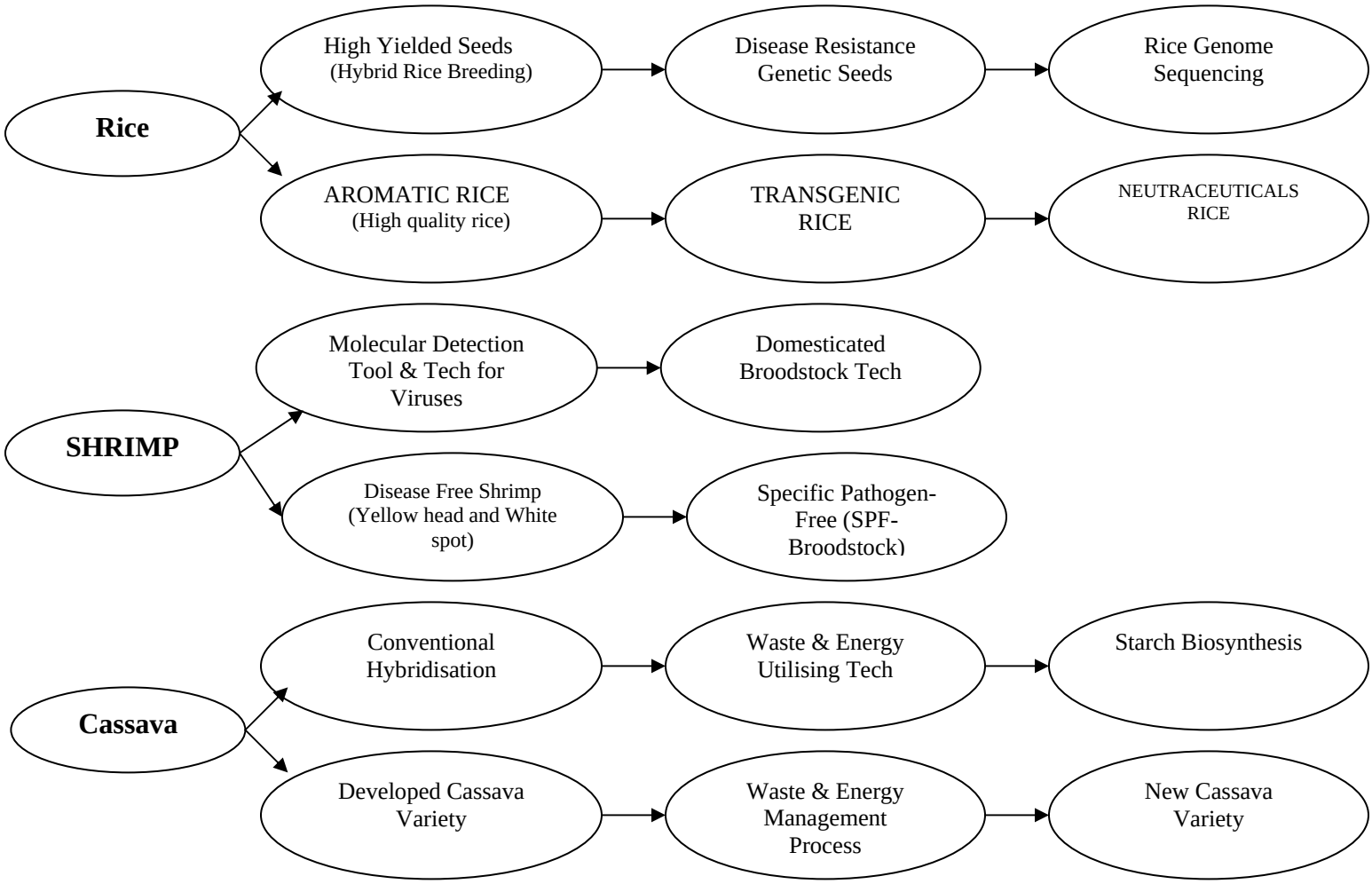
The USA-EU dispute in WTO on trade in GMOs had its impact on commercialization of biotechnology in Thailand as exports of GMOs and GMO based food products to EU faced uncertainty. But Thailand went ahead with its biotechnology plans and saw the potential of using biotechnology in many sectors despite concerns about biosafety and bioethical issues. Thailand is a partner in the International Rice Genome Sequencing project. Teams in Thailand worked on aroma marker and submergence-tolerance marker.

In December 2003 the ambitious National Biotechnology Policy Framework for 2004 – 2009 was unveiled. According to the policy biotechnology will be an important tool in country's overall economic and social development. Emphasis was on new technologies and the value addition was highlighted as one of the objectives. The policy framework envisaged six goals to be achieved by 2009. The policy envisaged that at least 100 companies of modern biotechnology would evolve and annual investment of US $ 125 million will be made in biotechnology. [207]. In agriculture the policy envisages that

'*Biotechnology is to support Thailand to become the .kitchen of the world. by maintaining and enhancing its competitiveness in agriculture and food industries which will increase in export value up to 1.2 trillion Baht (3 times the 2002 export value), and improve the export value of processed agricultural products from 12th in the world ranking, up to the top 5 by the year 2009.'*

Increasing production of all major crops, boosting seed exports, and export of high value added from agricultural commodities was envisaged. An important aspect of the strategy and in general application of biotechnology in agriculture is to increase the value addition through technology and to use technology in such a way that economic benefits could be derived or value addition takes place. This is illustrated in the diagram below. [208]

Figure: 19.1: Innovation Value Chains of Selected Agricultural Biotechnology Products in Thailand



The Board of Investment acts like a catalyst by offering various incentives including no tax incentives. In some activities there is no restriction on foreign equity. In 2007 maximum privileged promotion package was announced for biotechnology. Qualified projects receive 8 year tax holiday. Besides these locating the project in a S&T park would entitle additional 50 per cent income tax holiday for five years after expiry of tax holiday for projects in four areas. It is estimated that more than 20 foreign biotechnology companies have invested in Thailand.

According to a recent news report
"At the end of February 2009, there were more than 80 newly founded biotech companies in Thailand. Thirty one companies have been awarded investment incentives by the Board of Investment, resulting in an estimated investment of more than Bt1.3 billion".[209]

Thailand is a country that benefits from medical tourism. The private hospitals generated US $1 billion in 2003 from medical tourism[210]. Thailand wants to grow as a major country in bio-service sectors also. Companies have invested in stem-cell technologies, medical diagnostics, drug development etc. Similarly companies have invested in industrial biotechnology and also in environmental biotechnology. But Thailand's advantage may not be in medical biotechnology as in terms of human resources, there are more scientists working in agricultural biotechnology than in medical biotechnology.[211]

Although the biotechnology industry in Thailand is thus largely driven by policies of the government its success cannot be taken for granted because Thailand has to compete with countries like Korea in the region. Its pharmaceutical industry is well known more for the generics than for its capacity in new drug R&D.

19.2 Patents and Publications

Thailand had enacted laws on Intellectual Property Rights and the Biotechnology Strategy envisages recognition and protection of these rights. Still Thailand is also considered as a country where piracy is rampant and its use of compulsory licensing has been controversial. Thailand's IPR regime may be a hindrance to biotechnology companies which may prefer countries with better enforcement of IPRS. Although some suggestions in this regard have been made,[212] it is doubtful whether Thailand will opt for such measures.

19.3 Human Resources

Every year the 8 universities award 800-900 bachelors degrees in biotechnology, 300-400 masters degrees and 40 PhDs in biotechnology. The government encourages movement of trained/skilled personnel in biotechnology into Thailand. As a part of the long-term strategy to develop human resources within the country the plan envisages

"No less than 5,000 personnel engaged as professional biotechnology researchers in the public and private sectors.

No less than 500 personnel engaged in biotechnology management.

No less than 10,000 students at the level of bachelor, master and doctoral degree in fields related to biotechnology"

19.4 Biosafety

Thailand has signed and ratified the Cartagena Protocol. Its national biosafety regulations are yet to be enacted and is expected that this will be done before the end of 2009. Although the biosafety law has been debated for many years, it is not enacted. Thailand in the meanwhile has biosafety regulations through rules. The absence of a holistic framework is a major barrier in commercialization of biotechnology.

19.5 Capacity Building

Thailand has been a beneficiary of various capacity building programs and projects supported by UNEP, Rockefeller Foundation, USAID and other agencies.

Box 19.1: Specialise Thy Neighbours

Many AP economies need specially tailored programmes for human resource development in science and technology. There are some major initiatives which need to be further strengthened.

The National Center for Genetic Engineering and Biotechnology (BIOTEC) of Thailand has launched a programme at the state-of-the-art infrastructure at the Thailand Science Park, for Human Resource Development Programme in Biotechnology for Cambodia, Laos, Myanmar and Vietnam (CLMV). This program specifically addresses the underlying causes of the shortage of skilled manpower in the field of biotechnology in CLMV, which are lack of facilities, equipment, technical know-how, limited research and development in biotechnology and inappropriate training facilities and equipment. The program offers short-term training courses to young researchers from CLMV to work/train in BIOTEC laboratories. The training courses consist of teaching of basic and advanced techniques, designing and conducting a mini research project and site visit to factories or project sites. The trainees are provided with living and research/training expenses and are assigned a one-on-one BIOTEC researcher to give the training and guidance. BIOTEC developed a pilot program on HRD for CLMV in 2001 with its own funding. In 2002, the Board of the ASEAN Foundation approved BIOTEC's proposal and agreed to provide the funding of USD 92,070 to co-support this Program, with BIOTEC providing a matching fund equivalent to USD 73,480. Under this ASEAN Foundation – BIOTEC collaboration, a total of 20 fellowships were granted since 2004. From 2007, the Program offered training opportunities to young scientists from the Asia Pacific region, while maintaining funding priority for CLMV. The number of applications grew from 40 in 2003 to 74 in 2008.

***Source*:** BIOTEC Annual Report 2008.

19.6 Conclusion

Thailand has embarked upon an ambitious plan with specific goals and strategies and the policy does not neglect one sector in favor of another. The linking of biotechnology with specific economic, social and health objectives is a step in the right direction. The government is investing heavily in biotechnology and these investments should help it to sustain the biotechnology in the long term.

Chapter 20: Vietnam

The government decree No. 18/CP in 1994 stated that first priority for scientific research is given to biotechnology during 1995-2010. For this 'capacity Development Program in Biotechnology' is initiated and implemented by Ministry of Science, Technology and Environment (MOSTE). A National Commission on Biotechnology was formed in 1997.

The main institute for biotechnological research is the Institute of Biotechnology (IBT) at the National Center of Natural Science and Technology, followed by two research institutions belonging to the Ministry of Agriculture and Rural Development (MARD), namely: Institute of Agricultural Genetics (IAG) and Institute of Agricultural Sciences (IAS). In the universities, new courses specializing in genetic engineering and biotechnology began to be offered. Establishment of genetic engineering research centers within the universities has also been started.

20.1 Specific Initiatives

Agriculture's contribution to GDP is 25 per cent but 70 per cent of the households are involved in it. Over the years Vietnam has moved from a net importer of food to world's third largest rice exporter and is also an important exporter of coffee, rubber, pepper, and cashew. In 2004 the agricultural exports were valued 4billion US dollars.[213] Agricultural biotechnology can enhance the exports besides increasing the productivity of agriculture.

At present, only about one percent of the national budget is spent on agriculture research in all aspects. It hardly covers 30 percent of the total requirement. Also, there has not been adequate international support in this regard, except for purchase of equipment on a small- scale level. The Vietnamese government has a plan to invest $60 million to IBT and United Agricultural Laboratories and to spend $20 million to strengthen eight training centers (H-VNU, HCM-VNU, Hanoi Technology University, HCM Technology University, HAU), $2.5 million for overseas training, 25 billion DVN for R&D programs, and 2 billion DVN for information and libraries. There are 2 national institutes, 16 ministerial institutes involved in biotechnology research.

Even with limited funding, facilities, and biotechnology-experienced scientists, Vietnam has recognized the important role of biotechnology in the development of Agriculture. But so far no significant results have been obtained. The absence of private sector in biotechnology is an important drawback. Since government has limited resources, private sector funding could give a boost to biotechnology. But Vietnam has not fully opened up its economy and agricultural research and biotechnology remain to be the domain of the government. Nor Vietnam has a policy that permits FDI in biotechnology.

20.2 Human Resources

Universities have established biotechnological courses for biology and agriculture students. In recent years, there had been more than 200 scientists involved in R&D biotechnology. However, at present, there are not enough capable scientists with adequate exposure to advanced biotechnology. In addition, they lack of opportunities for interaction with national and international research scientists and organizations. The

approximate figures for the number of students in various courses of biotechnology are as follows: 3500 undergraduates, 400 postgraduates and 520 Ph.Ds.

In terms of fields of application and number of persons involved in biotechnology, the variation among various institutions is indicated in Table 20.1. Biotechnology is a priority activity in some institutions only. Thus, Vietnam has a long way to go in terms of utilization of human resources in biotechnology and application of biotechnology in different sectors, particularly in agricultural biotechnology.

Moreover, research is still scattered and there is no mechanism to ensure that research is not duplicated elsewhere. The agricultural R&D system in Vietnam is not yet mature enough to apply biotechnology and deliver results.

Table 20.1 Institutes and Number of Staff working in biotechnology[214]

Research Institutions involved in Biotechnology R&D	**Field of Application**	**No. of Staff Involved/Total**	**%**
Institute of Biotechnology (NCST)	Animals, plants, microorganisms and basic genetic techniques	200/236	85
Vietnam Agricultural Science Institute (MARD)	Fundamental, R&D and technique transfer	17/212	8
Institute of Agricultural Genetics (MARD)	R&D on crop breeding and breeding science	53/120	44
Cuu Long Delta Rice Research Institute (MARD)	Rice breeding, hybrid rice varieties	15/125	12
Center of Biotechnology-Vietnam National University (MOET)	Basic research and education	15/107	14
Biotechnology Department, University of Agriculture and Forestry (MOET)	Basic research and education	16/?	-
Biotechnology R&D Institute, Can Tho University (MOET)	Agricultural biotechnology, improved plant varieties and animal breeds.	10/16	62

20.3 Patents and Publications

Regarding professional publications in biotechnology and bio-engineering, the number of citations of S&E articles is 307(2001), which amounts to 0.01 per cent of world total. Vietnam's IP regime is TRIPS compliant and the standards of patent protection are at par with global norms. [215]

As per the information given in WIPO Statistics Database, 2009, the number of patent applications filed with the PCT in the first three quarters of 2008 are 1,1 and 2 respectively.

20.4 Biosafety

Vietnam is in the process of establishing biosafety norms including labeling of GM food products.

20.5 Conclusion

Biotechnology in Vietnam is in nascent stages. Vietnam is giving importance to biodiversity conservation and use. Since the agricultural innovation system is weak it cannot be expected to use biotechnology in a big way in R&D or in commercialization.

The policy framework in Vietnam (when seen in the overall context of Vietnam's economic policy and trade policy) will need changes if Vietnam wants to use biotechnology in a big way. More investments in agricultural R&D and in human resources development and capacity building are necessary if Vietnam wants to reap the benefits of biotechnology revolution.

Policy Recommendations

Chapter 21: Policy Recommendations and Way Forward

Our analysis of biotechnology in the AP region shows that biotechnology in AP is doing well and would continue to do well. We have made some suggestions and have recommended some measures to sustain the biotechnology revolution in the region and enhance its relevance and sustainability. In our view the states, various stake holders, international agencies have their tasks cut out in this. The challenge before them is to harness biotechnology for development and use it to enhance their competitiveness and capability for innovation. The coming decades will be crucial for development of biotechnology in Asia and timely measures and positive action can make all the difference.

As is clear from the previous discussions, the AP economies are attempting to enhance their technological options for ensuring food, nutritional and health security in the region through strategic initiatives to biotechnology. Though these responses may place them on a higher trajectory for tapping all the benefits of this frontier technology, however many AP countries still have to make additional efforts for capacity building so as to enable their institutions and enterprises to take maximum advantages offered by this technological revolution. This is amply clear from our survey as indicated in the country reports that most of the AP economies have identified biotechnology as a promising technology and have started developing a policy or national strategy for it. At the same time, AP economies also have to build capacity at the level of policy formulation process especially in terms of analysing policy implications of technology trends and corrective measures required at the global level so that access to biotechnology remains feasible especially for the developing economies. One issue that looms large is the trade dispute on GM foods and countries in AP have to tread carefully in this (See Box 21.1)

As discussed, the OECD statistical definition of biotechnology should also be seriously considered by the AP economies so that they have full clarity on the status of biotechnology in their respective economies. This may help them in adopting evidence-based decision-making. It may also help in identifying regional complementarities for effective and meaningful cooperation among AP economies. This evidence may also be used for economic assessment of the introduction of biotechnology across the sectors especially on agrarian and pharmaceutical sector which should be attempted before huge outlays are made through the budgetary resources. Similar efforts are also needed to identify niche areas for development of a particular economic sector through biotechnology.

It is clear from the earlier discussion that AP economies are at different stages of adoption of biotechnology, for instance, Singapore has developed major areas of research in medical and marine biotechnology with key role in the human genome project.[216] There are several AP economies which are just at the first generation technologies (like Indonesia, Bangladesh, Pakistan, Philippines and Sri Lanka) and in some even they are not well entrenched or widely applied (like Lao PDR, Nepal etc.). In some countries

tissue culture is still a major application and they are yet to adopt GM varieties in a big way like Vietnam, Cambodia etc.

Box 21.1: Biosafety and Trade Conflicts: The US-EU dispute and its relevance for developing countries

The transatlantic divide between EU-USA on GMO food issue shows so signs of resolution. On the contrary, it looks like both parties will continue to live with the stalemate without changing their positions. In Europe, there is no significant development in support of GM food and the resistance continues unabated. While the WTO Dispute Settlement Mechanism is the right forum to resolve trade disputes, the GM food issue has become more than a trade issue. The stakes are too high. There are parallels to another dispute between EU-USA, the dispute over hormone-treated beef. In both cases both parties assert that their regulations are based on science and are their respective policies perfectly justifiable in terms of adherence to science-based decisions and protecting human health.

What are the implications of this dispute for countries in AP and how they should use this dispute to understand the linkage between regulatory regimes and global trade norms under WTO? USA and EU are export markets for agricultural products and both are engaged in capacity-building activities in many countries. By and large, they put emphasis on the merits of their respective regulatory regimes. The absence of coherent and global trade rules in this gives leeway to countries to develop regulatory regimes modeled after, but not necessarily identical to that of, USA or EU or develop their regulatory regimes based on best practices followed elsewhere. For example, in applying the precautionary principle, there is much to learn from both and adapt to suit national needs and contexts. Similarly in deciding over product vs. process distinction in regulation countries can identify which model is more appropriate to them and what are the costs and benefits to them.

Another issue is that of complying with the Cartagena Protocol and its implications for trade in GM foods. A country that opts for a very strict compliance coupled with labeling norms may find that it is too expensive to implement if the volume and value of trade and production of GM foods is too little to warrant such a strict compliance and norms. In such cases countries should decide upon the level of compliance with Protocol and to what extent they want to regulate GM foods. For example, a provision for labeling if the GM food is more than 1% of the quantity is more expensive for producers and processors than a provision that is more liberal. So cost-benefit analysis of regulation and its implications for trade should be taken into account in developing a regulatory regime. One approach is to opt for enforcing a regulating regime for some products first and then based upon the experience extend it or fine tune it for other products. Another option is to strictly regulate GM food for human consumption and not so restrict regulation for use of GM food for purposes other than human consumption, provided the processed food is not used for human consumption directly/indirectly. For example, use of GM soya for industrial purposes may be de-regulated while use of GM soya to derive products like Tofu may be strictly regulated. It is suggested in capacity-building programs in Biosafety these factors are taken into account and countries should not opt for stronger versions of precautionary principle for regulating GM foods and crops, if they find that such options entails more costs and little benefits.

As both USA and EU are promoting Free Trade Agreements with many countries/ regional trading blocs, countries in AP, particularly LDCs should know how best to deal with this issue. If a country that is largely dependent on the EU market for its agricultural markets decides to adopt GM agriculture rapidly, that may affect the export potential. On the other hand if a country has no clear cut policy on GM foods and imports GM and non-GM food from other countries, it has to be careful when it exports food products that has both GM food and non-GM food as even adventitious presence of GM food beyond the acceptable level can create problems in some export markets.

The reality is that the dispute between USA-EU on GM foods is not likely to end soon. At the core of the dispute are the differences in regulatory regimes and perceptions about GM food. Although this is prima facie a trade dispute, it is also dispute about limits of regulatory harmonization at a global level. Based on a detailed analysis on the genesis of this dispute and the implications of the same, two scholars draw five lessons from it.(Mark A. Pollack ,Gregory C. Shaffer 2009)

1) "The transatlantic GMO dispute does not represent a deep civilizational divide, but it is real, and deeply entrenched."
2) "Deliberative decision-making is a hothouse flower, which has seldom bloomed in the intense politicization of GMO regulation. Our expectations for it should be tempered accordingly"
3) "Multilateral regimes can help states cooperate, but they are hampered by the dual challenges of distributive conflicts and regime complexes
4) " International pressures—from markets and multilateral regimes—can have domestic effects, but these effects are limited by the path-dependent nature of domestic regulatory systems, which are unlikely to converge on any common denominator."
5) "The World Trade Organization and its Dispute Settlement Body cannot definitively solve regulatory disputes such as those over GMOs, but they can help to manage conflict, clarify the obligations of all sides, and provide some opportunities and leverage in domestic political and judicial processes".

After analyzing how countries have responded to regulatory commitments and concerns, they argue that a monolithic developing country position is not likely to emerge and LDCs adopt different positions on regulation and the scope of global harmonization of regulation in GM foods and crops is limited. In other words the LDCs should use creatively the policy space available to them without imitating USA or EU and craft policies that are suited to their national contexts and needs.

Translating this into practice is not likely to be easy, particularly when countries face dilemmas over GM foods and crops. Elsewhere in this report we address the issue of organics, standards and biotechnology policy where a similar dilemma is in the offing.

However, as the experience of the Philippines and Thailand show, agriculturalbiotechnology has to come to the center-stage to address some of these challenges. The policy uncertainty regarding biosafety regulation should be reduced. In countries where GM crops are being field tested, it is necessary that a science-based, transparent approval regime is in place. Equally important is the need to educate the public and the farmers about these issues. As many of these economies have a predominant role for agriculture, the efforts in biotechnology have also been confined to this sector only. The governments and public research laboratories have launched agricultural biotechnology research programmes and in some of the AP countries agricultural biotechnology products have reached the stage of commercialisation. Commercialisation signifies another emerging area of cooperation between the public and the private sector. This is unlike what was being envisaged in late eighties that biotechnology would remain with the private sector alone and in a proprietary regime the public sector would lose out. The dynamics of this relationship has added new economic value to this emerging technology.

In many countries there is little scope for medical biotechnology or application of biotechnology in industries including in the pharmaceutical industry. In some countries the pharmaceutical industry is capable of generics production but lacks the R&D capacity to develop new drugs or produce bio-pharmaceuticals.[217] Thus while some countries are slowly evolving and graduating to the next level, others have advanced rapidly and are in a race with USA and Europe. For example in Japan while agricultural biotechnology is important, it has not gone in a big way for widespread use of GM rice. South Korea and Singapore are giving topmost priority to health sector biotechnology and life sciences. Japan and South Korea are leading producers of industrial enzymes.

Trade in GM goods has, however been affected due to the delay in the implementation of the Cartagena Biosafety Protocol, which has caused problems regarding the trade in genetically modified goods. The SPS committee at WTO has received some submissions from the member countries in this regard. It is also relevant to add some caveats necessary for adoption of biotechnology policy at the public level. The diffusion of biotechnology in the goods, import of which is being banned in the European Union in light of the precautionary principle, may decelerate the quantum of exports from developing countries. It is in this context that the developing countries, on the one hand would have to carefully design their requirements and effectively intervene for a meaningful technology policy and on the other would have to actively persuade international standard setting agencies like Codex to come-up with GMO standards. Similarly organic labeling and standards is becoming an important issue. (See Box 21.2)

Some of the key recommendations which may be considered for capacity building in Asia-Pacific are being given below. The same is also summarised in Box 21.3 for easy reference.

21.1 Strengthening Linkages in Innovation Systems

As is clear from the country reports, there is considerable technology gap between various AP economies. There maybe several factors responsible for this. One of the key reasons for this is absence of a functioning national innovation system. The innovation system needs more support in terms of financial resources. Although it would not be fair to expect that countries would give top most priority to this, when there are other sectors that are starved of funds, in our view, the countries can set a target of spending at least 2 per cent of the GDP for improvising the innovation system. It is also important that the productivity of the innovation system is increased and the priorities are identified and the weaknesses are examined.

Box 21.2: Organic Agriculture, Standards and Biotechnology Regulation: Dilemmas in the Offing?

The global organic market is growing and in the organic market there are different players with different capacities to exert influence. Although in terms of total cultivated land, the area under organic production may be small but it is growing. Supportive policies and the premium price for organic products is likely to encourage more farmers to switch over to organic farming, particularly for market. In India the state of Kerala has drawn up an ambitious plan to promote organic culture while some other states have started taking a closer look at organic culture and its potential. The increasing importance of standards in global organic production, distribution and consumption provides an opportunity for countries although it is also a threat as complying with that standards can increase the cost of production and fewer acceptances for organic produce that does not meet these standards. Under the norms in USA, foods labeled " organic " should not contain bio - engineered ingredients or be irradiated to kill bacteria and lengthen shelf life. Similarly meats labeled and sold as organic cannot be produced from animals that have received antibiotics.[218]

But what is proving to be more relevant and challenging for countries in AP is the emergence of MNCs as major buyers of organics and their attempts to bring in standards for organic products. The standards are no longer informal or set by farmers associations but are outcomes of standard setting processes at global level. The state/national governments have an important role to play in this and often realize the need for establishing standards. Although within the organic movement itself there are voices that are not happy with this sort of globalization of organic agriculture and producing primarily for foreign markets, governments cannot remain mute spectators in standard setting. According to a recent study as the export of organic food from three South-East Asian countries (Thailand, Vietnam and Indonesia) grows, the state is increasingly getting involved in standard setting and in this exercise the structural power of the corporate agri-food industry is very much evident.[219] The state and the civil society have to be aware of the issues in organic standard setting and have to make interventions lest should that be determined solely by buyers or supermarket chains.

The challenge before governments that want to encourage such exports is how to reconcile this with the policies for promotion of agricultural biotechnology. Opting for one or another is not possible. Organic agriculture is well suited as an option in crops where there are no transgenics and where the scope for contamination from GM crops does not exist. For many small and marginal farmers organic agriculture is also a cost effective solution if they can get a premium price for their produce. Current standards in organic produce are likely to be harmonized on a global level as bodies like Codex and ISO are involved in the process and a globally uniform standard is in the interest of traders and procurers like supermarkets. Implementing such standards may be expensive but inevitable when it comes to catering to global markets. Here governments and other stakeholders should work together to ensure that standards are not unilaterally set or are unduly difficult to implement.

If there is a global demand for organic rice and if the government is keen on promoting transgenic rice, reconciling between both is necessary and possible. For this the government can enforce norms on cultivating organic rice in some areas while in some areas transgenics can be encouraged. Another option would be to designate some zones as GM free zones where production i.e. cultivation and processing of organic food is encouraged. Some areas can be classified as mixed zones or zones where both GM and non GM crops can be grown. When it comes to conducting field trials also such classifications can be made and it could be ensured that for varieties/crops that are grown organically areas where conservation of germplasm is encouraged, there are no field trials or experiments. One of the recommendations of the Taskforce headed by Dr. Swaminathan on Biosafety Regulation in India was transgenic research should not be done on crops which earn substantial foreign exchange e.g. basmati rice, Darjeeling Tea.

Finally if the governments think it is necessary to opt for a strict liability regime for GM 'pollution' then they should examine the consequences of this option for development of biotechnology.

We suggest that a technology needs assessment of the capability and capacity be done for countries where biotechnology is not well entrenched. For example a country rich in biodiversity can assess the technological and infrastructural needs that are essential to use biodiversity as a resource in biotechnology and examine its capacity and capability in this. In countries where agricultural biotechnology is important such an assessment could be in terms of capacity to take up advanced research, develop GM plants and apply the fruits of research into products and services. UNESCO can help countries in these assessments and also help in identifying measures to overcome the structural constraints.

It would be useful if countries in the Asia Pacific work more closely in technology development and transfer in different sectors of biotechnology, particularly applications in public health. This will succeed only if countries are willing to supplement the technology transfer and application with appropriate investments in public health and strengthening of the health care sector. In order to move in this direction, what may be urgently needed is a mapping of technological trends, needs, possibilities and identifying the barriers in applying appropriate technologies in the Asia Pacific. For instance, it is becoming evident that in medicine the importance of pharamacogenomics, therapies like stem cell, gene therapy, and in food, nutraceuticals, will increase in future.

Any approach to develop products through the innovation system may not succeed, in fact, national social and economic priorities may be hampered by barriers like intellectual property rights and lack of regulatory capacity. But if the current trends in IPR continue it is likely that these needs may not get the priority they deserve, hence national innovation plans are important.

Box 21.3: Key Recommendations

* Take measures including adequate financial support, to enhance the productivity of the National Innovation Systems.

* Perform Technology Assessments taking into account the resources, structural constraints and capacity to innovate and engage in advanced research in biotechnology.

* Promote South-South co-operation for wider diffusion of biotechnology.

* Develop regional networks in biotechnology so that technological gap among countries can be minimized.

* More support from multilateral agencies including UN agencies in identifying needs, strengthening institutional capacity, developing regulatory regimes and enhancing capacity of National Agricultural Research Systems' in biotechnology.

* Encourage growth of Small and Medium Enterprises in biotechnology and promote biotechnology entrepreneurship.

* Regional co-operation in implementation of regulatory regimes to be encouraged.

* Provide a supporting framework through funding for infrastructure, investment in human resources development.

* Promote commercialization of research by universities and research institutes, and, Public-Private Partnerships in biotechnology taking in to account the access to knowledge and the need to balance public and private interests.

21.2 Effective Regional Links for Innovation

AP cooperation in the framework of South-South Cooperation may play an important constituent in wider diffusion of biotechnology among the AP countries. The OECD members from Asia like Korea and Japan may be enthused to play a catalytic role in this process. The direction and destination of ODA should assess the role of biotechnology for meeting major challenges before AP countries. This may include programmes related to poverty alleviation, food and nutritional security in the region. The European Commission has launched several initiatives for its members, in the field of biotechnology, from which lessons may be drawn for technology transfer and capacity building across AP countries. Whether it is South or South East Asian countries the technological gap among countries in biotechnology is thus widening and this trend will affect the growth of biotechnology in this region. In such a scenario, convergence of opinion and response at the international fora is extremely needed.

The response, however, has varied from region to region. The European Community, which was already evolving a strategy for regional cooperation to deal with a perceived threat of economic decline and losing the technological edge over the US and Japan, accelerated the pan-Europe exercise for strengthening the national initiatives in the realm of frontier technologies. And in this way evolved the coordinated European high technology policy and related programmes. The operational aspects of this were very close to the typical Japanese-style, MITI-led, and government-sponsored research and technology development agenda. This pro-active policy has started getting in, its dividends. The EC is now all set to launch the European Research Area where the plans are to have Labs Without Walls.[220]

EC has built expertise in fostering regional co-operation and in encouraging collaboration. In the AP region there is no regional institution that can play the role the EC is playing in Europe. The EC thinks in terms of common vision and objectives for Europe and it benchmarks Europe's performance vis-a-vis. other major technology developers like the USA and Japan. Though in Asia, while it may be premature to imagine a common vision or developing shared objectives for some common funded programme, the regional associations and networks can certainly be expected to initiate a similar job. For example the discussions at South Asian Association for Regional Cooperation - may be expanded to cover specific capacity development efforts may be through specific research plans in biotechnology with precise goals and objectives. In ASEAN there are major initiatives but again there also the focus is on regulatory capacity in the region but not on joint human resource development for specific regional challenge

in, say, medical biotechnology or any other stream. While regional initiatives are necessary, but they may not be effective till sizable resources are available with them. In that context the multilateral efforts may play an important role. Multilateral initiatives under the auspices of or through GEF, UNEP, UNESCO, and FAO have helped the countries in identifying needs, developing national action plans, framing regulatory regime and in strengthening institutional capacity, enhancing NARS's capacity in biotechnology.

21.3 Regional Support for Technology Firms

The economic buoyancy in the AP region should be guided to support technology funds for supporting biotechnology enterprises. In countries like Japan venture capital is becoming an important source of finance. Perhaps the most important lesson is that the biotechnology industry offers immense scope for small and medium enterprises to flourish and biotech entrepreneurship is important for its growth. In USA since the 1980s many start-ups and small and medium enterprises have been an important part of the innovation landscape in biotechnology industry and have been the pioneers in inventions and innovations. Although many of them have been acquired by large firms their role is important. In AP the scope for such SMEs in biotechnology is immense. The national strategies should take this into account and give adequate support for enterprises and promote bioentrepreneurship.

21.4 Exchanges of Experience on Regulatory Regimes

An unambiguous and functioning regulatory regime is a must for biotechnology to flourish. This applies to all sectors of biotechnology. Governments should strive to develop a regulatory framework that is appropriate to the needs of the governments and one that is compatible with the country's commitments under the international agreements/treaties it has ratified.

While all stakeholders should be involved in developing a national strategy including the regulatory framework it is important that once the strategy is framed the rules and regulations are in place. Unfortunately in some countries there is considerable time gap between development of the strategy and its implementation. This is all the more true in case of biosafety regulations and policies on using GMOs in agriculture and labeling of agricultural GM products and foods. The uncertainty in policy formulation and implementation affects the development of industry.

At another level, regional cooperation for implementation of biosafety guidelines may also reduce the cost of capital investment necessary for such an implementation. In this regard, some of the international conventions like Cartagena Biosafety Protocol may also play an important role. As of now, this protocol is far away from the stage of implementation and the non-implementation of this protocol is likely to complicate the international trade rules. It would be in the interest of the AP economies, especially those, which have planned multi-level biotechnology interventions for economic development, to pool their experiences together and work towards the convergence of regulatory regimes.

21.5 Regional Initiatives for Building Infrastructural Support

One of the key lessons from the experiences of the previous decades is that biotechnology cannot flourish alone in a milieu unless the milieu provides a supporting framework particularly funding for infrastructure development and adequate investment in human resource development. Biotechnology innovation cannot be viewed in isolation of the national innovation system. Hence systematic efforts in strengthening the latter would be necessary when a developing country wants to apply biotechnology as a part of its development strategy. Universities and other centers should be encouraged to commercialize research, transfer technology and develop linkages with industry. The Bayh-Dole Act in the USA gave enormous opportunities to the universities to do all these. Although there are valid points in the criticisms of the Act and its impacts we think that lessons from this have to be applied creatively by states in AP while taking into account the need to provide access to knowledge and balance public interests to be served by the universities with their activities related to technology transfer and commercialization.

21.6 Public-Private Interface

The policy framework would also have to make adequate provisions for promotion of the private sector in the area of biotechnology. The technological and financial support would have to come from the Government to tap the entrepreneurial skills for growth of this sector. In this regard, the public-private partnership (PPP) would have to be encouraged. In the case of India, the Indian Institute of Science (IISc), Bangalore has supported entrepreneurial skills of their faculty members by allowing them to launch their own biotechnology start-up firms. This example shows the attitudinal change that is coming in the publicly supported institutions but this would have to be infused as a policythrust to be adopted at a much wider level so as to facilitate a systemic change for diffusion of biotechnology. The fact that the Economic Development Board (EDB) of Singapore has established Singapore Bio Innovations Private Limited (SBI) with the objective of assisting in the commercialization of local and overseas reservation and also for initiating strategic alliances for promoting business development is a great push to public-private collaboration. Similarly, in 1998 Kent Ridge Digital Lab (KRDL) was formed through a merger of the Information Technology Institute (ITI) and the Institute of System Science (ISS). It is mostly funded by NSTB – around 65 per cent – and the rest comes from other sources. aKRDL quickly established itself as one of the most dynamic software labs in Asia. In short span of two and a half years, its 10 spin-offs founded by its staff utilising KRDL technologies is a good example of public-led private sector development in areas which hitherto are overlooked by the private sector due to several challenges particularly related to technology limitations and extraordinary resource demands vis-à-vis returns on such investments.

There is no doubt that by now biotechnology is well entrenched in AP. But taking this further is a challenging task. We have identified some of the areas that merit attention and further action. The countries need to strengthen their innovation systems, develop more coherent frameworks in regional collaboration and do a SWOT analysis of the biotechnology sector. This chapter is intended to suggest some proposals that can be

taken up by the countries, UN agencies and funders for further development and deployment of biotechnology in AP.

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