

Biotechnology and Innovation related Policy Indicators in Asia: An Introduction

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Background

In recent past adoption and diffusion of biotechnology has raised several policy challenges for the governance of biotechnology especially in the developing countries. The clarity about its governance has yet to take a concrete shape. It is therefore, important to outline a statistical framework that allows the measurement of these industrial and developmental activities so that the policy makers may evolve adequate responses. There have been intense discussions on the impact assessment of this technology and its measurement. In several developing countries biotechnology products such as GM crops have confounded the prevailing confusion on the intricate issues related to the measurement of the impact of the technology. These discussions have implications for both developed and developing countries. Several initiatives are taking place in various institutional settings which may influence eventual policy debates in the ambit of trade, international regulatory arrangements like the Cartagena Protocol on biosafety (CPB) and within the multilateral, regional and national

standards and regulation agencies responsible for the release, safety assessment and food use of biotechnology products. This brings forth a need of reliable statistics for sound policy formulation for the biotechnology sector (See Arundel in Section I). Adoption of biotechnology in industrial and other activities is a relatively recent phenomenon in India.

At the UN there have been attempts to capture impact and status of the Information and Communication Technology (ICT). In fact three surveys are already out on ICT which attempt to analyse issues related to digital divide and issues related to the impact of information and communication technology. However, UN has not come out with any initiative to periodically assess impact of biotechnology on a regular basis. There are reports from FAO and other agencies on the impact of biotechnology. UNIDO also had one report on possible impacts but, statistics collection, defining biotechnology and putting the statistics together in a cogent manner is a task that was still left. At the level of developed countries, OECD took that initiative and more and more

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countries are realizing the importance of putting policy-relevant indicators together in this area (See Vanbeuzekom and Arundel for details in Section I).

The Working Party of National Experts on Science and Technology Indicators (NESTI) of Committee for Science and Technology Policy of OECD has initiated an exercise of data collection in biotechnology for member countries¹. In its various meetings NESTI decided to initiate the exercise after finalising the definition of biotechnology for statistical purposes. An inventory of policy issues and related indicators has also been prepared. Different working groups have come out with guidelines for the compilation of these indicators along with model questions and surveys. These working groups are also identifying links with other existing manuals like Oslo manual and Frascati manual. Some of the member countries have already launched data collection exercise, which we discuss briefly herewith.

Policy Formulation Process

Innovation is possible through proper policy perspective and by critical review of existing processes. Any policy to be effective in the area of innovation would require numbers and quantifiable parameters for example, you need not only the qualitative things like 'AIDS is caused by HIV' but, how many people suffer from HIV? Are they carriers? Are there serious expressions of leading to mortality? Which are the companies which are doing vaccine trials? Which are the companies that are engaged in vaccine production? What are the manufacturing capacities? What are the

investment possibilities? Whether India could invest on vaccine development? Whether a country like Uganda should invest on vaccine development? Whether it should be a collaborative effort? What are the levels that are required in terms of mobilizing all the resources, technical, human and financial? Where are the figures? They are all scattered when it comes to Asian countries.

There are very few initiatives in the Asian countries even to that extent but there were some at random, scattered, statistical information available with every agency. The Section II in this volume provides an overview of different countries in this respect (Liu and An for China; Gupta for India; Purwantara for Indonesia; Dha kal and Joshi for Nepal; Enriquez for Philippines; Hong for Singapore; Lim for South Korea; Jayasekera for Sri Lanka and Meerod and Smitamana for Thailand). In the Indian context, some say India has a market of over US\$ 2.6 billion dollars some puts it at US\$ 3.5 billion. The debate on vendors and suppliers in biotech industry is another example although statistics on them is still scanty. One publication in India gave a very bright picture about biosuppliers. In India, mostly biosuppliers, who are supplying goods from western countries? That is what we spend our public sector money on, to get equipment. So, when they were making those statistics on biosuppliers, what they found was that a famous company wrote a letter to that Journal taking exception to it saying, "If somebody supplies a pH meter to a biotechnology industry, do you call him a bio-supplier? What is your definition of a bio-supplier?" Though lot of data is

¹ Some non-member countries like India and Israel have also been involved recently.

available but one does not know whether to rely on that data and from where that data has been obtained, whether somebody has authenticated it? What are the methods of collection, etc? These rudimentary, unauthenticated, uncured statistics are also not expected to be quoted because we do not know who has authenticated it.

Public sector investment is based on plan activities, plan budgets from the Government subject to many socio-economic development determinants. In most of the countries particularly developing countries it is the finance ministries which play a key role in budgetary allocations for various other ministries. It is at this point, the concerned persons at the science technology agencies require numbers.

In the Asian region, especially among the developing countries, India is a big investor after China and other countries. But many times we are going without numbers. Surprisingly, this happens more frequently in the developing countries where resources are scarcer than in the developed countries, for instance, production and promotion of biofuels are going on without much economic or social impact analysis. Therefore, these countries have to be very careful as it is public investment, statistics should be used to promote biotechnology development and to give a correct picture to the policy-makers as to how to put their finances, policies of foreign direct investment and other things, how industrial policy should be motivated, etc. An exaggerated and hyped picture without authentication would be giving undue signals to policy makers.

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 concerning us in Asia, where do we do some value addition and what other parameters Asia should consider. For example, inclusion of biofertilisers and biologicals derived by non-recombinant route into the definition of biotechnology is a major policy dilemma. Whether there is a scope within the OECD definition for that? The only idea is to bring in elements of low end technology products contributing towards a strong bioeconomy. There are many perspectives possible on this. Some effort in this direction come from Gloriani, Reddy and Mareida and Weebadde included in the Section I of this volume.

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.

Statistical Definition of Biotechnology: Bringing in Asian Concerns

In order to collect policy relevant statistics, it is at most important to have a precise definition of biotechnology. OECD over the years to has come out with a broad definition which says, "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 2006) includes data for a few countries that used a different definition of biotechnology, as long as the definition was limited to ‘modern’ biotechnology. This option will still be available in 2008, although we encourage countries to adopt the OECD definition.

In the Asian 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 Asian 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.

Evolving Pan-Asian Approach

With the growing economic integration in the Asian region, it would be important for policy makers to consider various elements of sectoral innovation system for facilitating growth of value chains across various

biotechnology industries (See Chaturvedi in Section I). The East-Asia Summit (EAS) emphatically identified technology cooperation in frontier areas. Given the geographic proximity and similar level of economic development it would be important to develop joint strategies for knowledge creation and innovation for developing useful and commercially viable technologies which can also help address the wider economic challenges confronting the region, as is laid out in the Cebu Declaration adopted during the Second EAS. It is hoped that work on these lines would provide important inputs to the track two studies launched as part of Comprehensive Economic Partnership in East Asia (CEPEA)

In this context, it would be highly relevant to evolve reliable indicators for identifying complementarities that exist in the region for collective and rational promotion of the technology. This would also help in identifying the factors which are inhibiting growth of biotechnology in the developing world of Asia. The definitional part of biotechnology and the idea of going beyond the OECD is a preposition worth exploring. However, it is important to work out modalities for future expansion of this work in the region particularly, when we do not have effective counterpart of OECD for developing countries. This leaves larger responsibility on these independent initiatives like ABIDI for coming up with policy relevant suggestions. After that it is upto the national governments for appreciating and supporting such work for effective policy response.

Indicators identified for capturing inhibitors juxtaposed over development

indicators may help us in evolving modalities for cooperation for instance, one may try to see what are the complementarities that exist in the region in terms of reducing the cost of testing GM products, sharing that data with other countries so as to reduce the cost of development of GM products across, as we have to realize the fact that Asian countries have limited resources. One may want SMEs (small and medium

enterprises) to grow in the region especially in frontier technology for which one would have to identify ways and means for necessary policy support. In this respect, scientists may play a major role in terms of suggesting modalities, which are safe and cost effective. It is important not only in the sense of capturing developments in biotechnology but also in terms of identifying the exchange and sharing of data.

Section I:
Concept, Measurement
and Asian Concerns

Biotechnology Indicators for Public Policy

Anthony Arundel *

The key issue is why one should be interested in biotechnology indicators and why we are interested in collecting them. From the OECD point of view, we are largely interested in them from a policy perspective. There are also two other reasons for collecting indicators. One is because they are very much of interest to academics who can use indicators to develop a long-term or deeper understanding of how economies are structured and how economies can change. Second, indicators are of interest to private investors who can use the information to guide their investment decisions in one particular technology or another. But many of the indicators for investors come too late. This has always been a problem for us because the investment community really wants to know what is happening right now and by the time our indicators are published we are usually several years too late.

From a public policy perspective, we are still really in the world of expectations when we talk about biotechnology, particularly modern biotechnology. I think we are all familiar with these type of expectations, and variations of them show up in many different reports from all around

the world. The problem with biotech is that many of these expectations have not yet been realized except in very small ways.

Challenges in Measuring Biotechnology

Partly because of the slow development of biotechnology applications, policy support for biotech is still very much dependent on high expectations. Governments are investing money in biotech because they still expect enormous benefits to come in the future. We can partly measure these expectations through input data such as business investment in R&D or the number of biotech firms.

The number of biotech firms is the most widely available indicator but it can be very misleading. Even though the OECD publishes such data, we discourage its use. In biotech you are almost in a situation where the more commonly available the indicator, the less useful it is. This is one of them.

A simple example can illustrate why the number of biotech firms is a poor indicator. Think of a country which has a hundred biotech firms with five employees

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each, for a total of 500 employees, and another country which has two firms with 2000 employees active in biotech, with a total of 4000 employees. In many cases biotechnology is likely to be more developed and applied in the latter country with two firms. Consequently, counts of the number of biotech firms does not really tell us much about the economic viability of biotech.

One of the main functions of metrics is to justify long-term targeted policy support for biotechnology. The most useful indicators for this are on the actual economic, environmental and social costs and benefits of biotech. These show high positive expectations for biotech, such as the large private and public sector investments in biotechnology, although they are largely in health applications.

There are three main policy options when faced with biotechnology or any other technology. The first is a positive intervention to support biotechnology. This is the most common policy option today, with large public financial investments to encourage the development, adoption, and diffusion of biotechnology. Many of these programmes are targeted, meaning that biotechnology is actually selected and favoured over other options, with specific programmes that only fund biotechnology. Examples include funding for collaboration, public sector spin-offs of biotech, and policy interventions to improve public acceptance of biotechnology and market conditions for biotechnology. These policies are always based on the assumption that there are large economic or social benefits from biotech.

The second option is to adopt a technology neutral stance, where funding is based on competitive bidding. An example is when there are many other

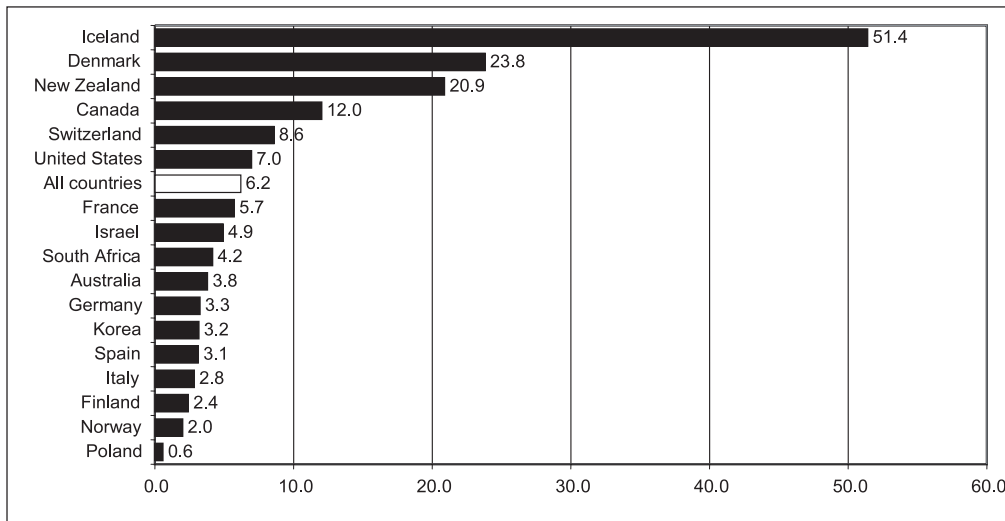
competitive alternative technologies to solve a problem. In this case, one can leave investment decisions either to the market or to the quality of the research funding proposal. As an example, is there a public interest in targeting biotechnology research into nutraceuticals and functional foods? If not, then research in this area should not be targeted. Another example concerns animal feed. Should policy target funding to develop genetically modified crops that include phytase enzymes to reduce water pollution from certain types of animal production? The alternative is to add phytase enzyme supplements to the animal feed. In these cases with clear technological alternatives, it might be better to simply let the market decide.

Of course, the third policy option is negative, in the sense of constraining or putting limits on investments, although the results might be positive. Many things such as regulations can actually be positive in the sense that they push or help guide public investments and private investments into areas that are socially beneficial. But there are certainly areas where regulation is required for technologies with potentially harmful effects. Gene therapy is a current example.

Biotechnology in OECD countries

Figure 1 gives biotechnology R&D by businesses as a share of total business sector expenditures on R&D. On average, approximately 6 per cent of OECD private R&D spending is in biotech, with enormous variations from almost half of all business expenditures on R&D in Iceland to two per cent in Norway and 2.4 per cent in Finland. Of course, a lot of the differences in the intensity of business

Figure 1: Biotechnology R&D by businesses as a share of total business



investment in biotechnology are based on differences in the underlying industrial structure. You can see that Denmark is way up there with about 24 per cent of business sector R&D going into biotechnology and this is because the structure of the Danish economy is based on pharmaceuticals and agriculture.

Figure 2 gives the distribution of business R&D in biotechnology by

application. Almost all R&D in the business sector in OECD countries is for health. Aside from all of the fuss over Monsanto and herbicide tolerant crops, very little goes into agricultural biotechnology and even less is invested in industrial and environmental applications.

Results from 12 countries: Australia, Canada, China, France, Germany, Iceland, Israel, Norway, Switzerland, UK, and US.

Figure 2: Percent distribution of total business R&D in biotechnology by application

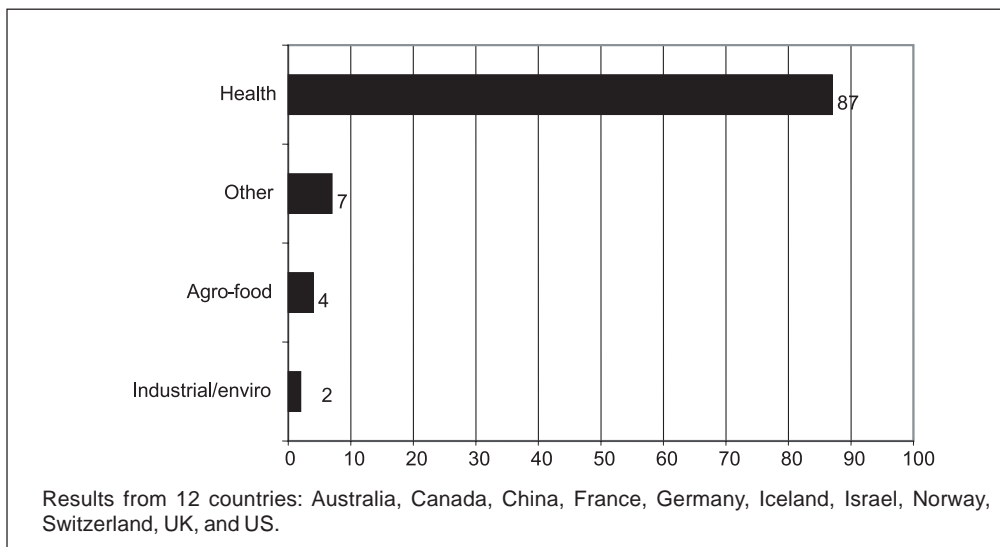


Figure 3: Public R&D expenditures on biotechnology as a percentage of total public expenditures on R&D, 2003 or nearest year

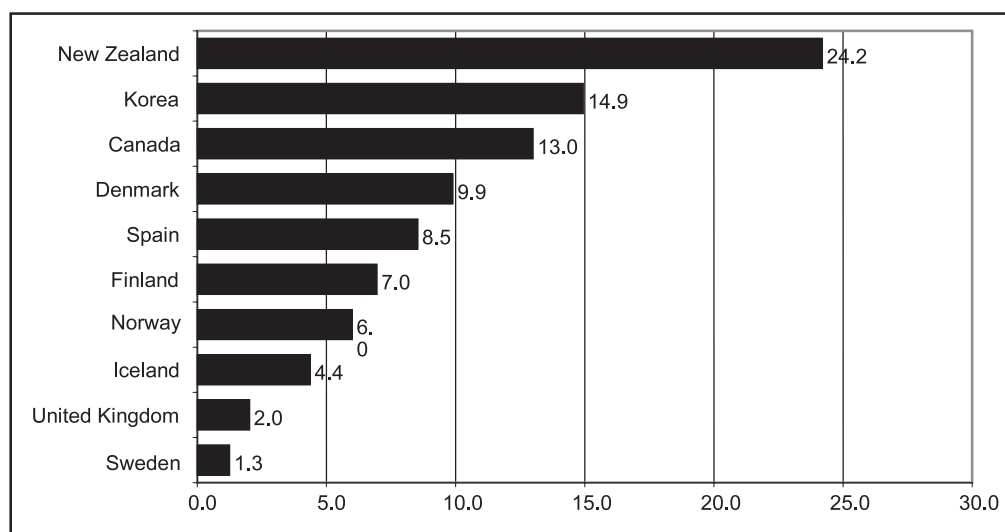


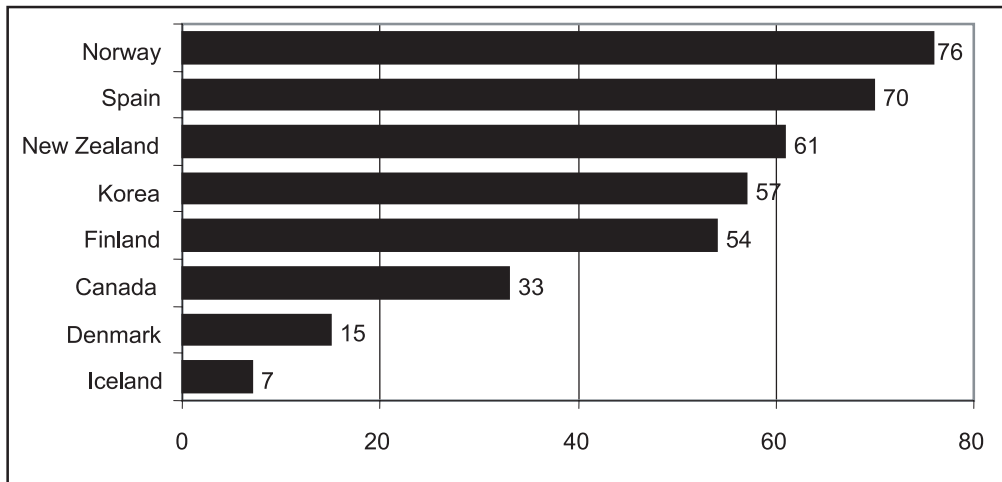
Figure 3 gives public R&D expenditures in biotech as a percentage of total public expenditures on R&D, which gives us an idea of how much targeting might be going on. In New Zealand almost one quarter of all public investment on R&D is flowing into biotech. Again this is due to the structure of the New Zealand economy, which is essentially based on resources. There is a lot of potential there for biotech applications in forestry, animal husbandry and in crops. In Korea the high public expenditure share for biotechnology is partly due to a strategic decision by the Korean Government to invest in biotech.

Figure 4 gives the percentage of all biotech R&D that is due to the public sector, which accounts for over 70 per cent of all R&D in Norway and Spain. This share is suggestive of policy targeting, particularly when public investment is greater than private investment. In Norway and Spain there is actually very little interest in biotech on the part of the business sector. Denmark is not a case of targeting because the Danish public share is less than the

private share. But from Canada up you could say there are signs of policy targeting to favour biotech.

Output indicators measure the actual use or economic impact of biotechnology and are consequently very useful for assessing the results of investment in biotechnology R&D. There has been a tremendous amount of focus in the last twenty years on publications and patents as output indicators. However, publications and patents are not output indicators, even though they are widely discussed as such. They are actually intermediate outputs at best. They measure research, but you could easily imagine that you can have thousands of patents and thousands of publications but nothing on the market. From the policy perspective, it is not the publications you are interested in, but the actual use of biotechnology. We would be happier having one patent and a firm with a billion dollars of sales based on that patent than 500 patents and not a single product on the market. I think you can even go so far as to say that patents and publications can

Figure 4: Public biotech R&D as a share of all biotech R&D (public and private combined), 2003



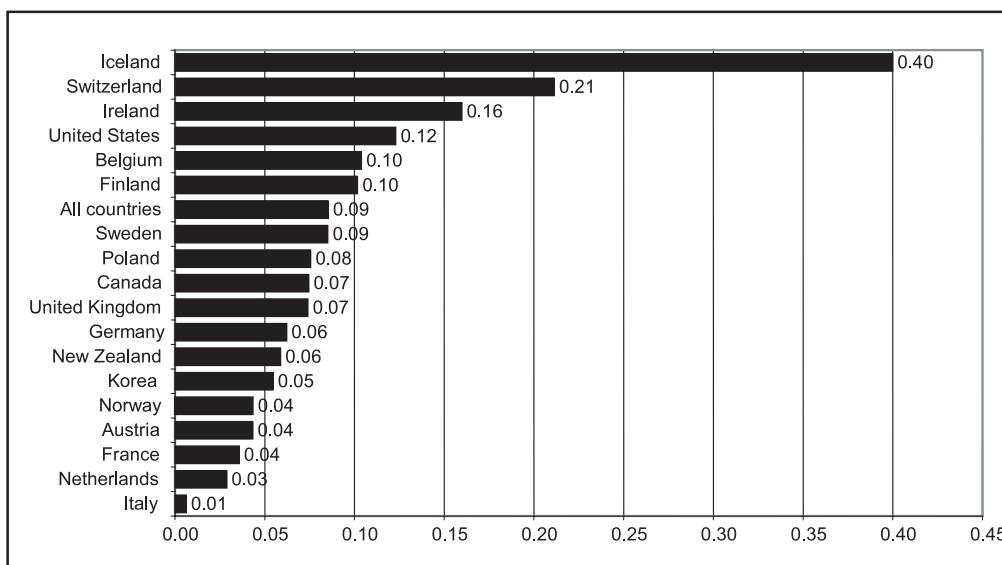
become a fetish. They can disorient and distract us from what really matters.

To give an example of what we have currently available as an output indicator, Figure 5 gives total bioactive employment as a percentage of total employment. By bioactive, we mean employees whose job description involves biotechnology in some way. You can see that in total over all of these countries, about 0.1 per cent of all

employees are active in biotech. This is a very small percentage of total employment. I put this in perspective below.

We can supplement the sparse availability of post-commercialization output indicators that we have to date, which is employment and sales, with forecasting and developing leading indicators to improve predictions. This is possible using things such as field trial data

Figure 5: Total bio-active employment as a percentage of total employment, 2003



of GM crops, which are similar to patents except that they are much closer to the market. Another option is to analyze trends in clinical trials. Recent OECD work under *the Bioeconomy to 2030* project has been using both of these types of data to predict the types of biotechnology products that should reach the market by 2015.

Comparison with ICT

An interesting comparison of relevance to the assessment of the economic and social impacts of biotechnology is to compare the growth of biotechnology with ICT. Manufacturing ICT employment reached a peak in 2002 when it accounted for three per cent of total employment in OECD countries. Of course, this rate of three percent employment has had an enormous social and economic impact, such that most people are surprised when they hear that ICT accounted for only 3% of employment. In comparison, biotech only accounted for 0.1 per cent of total employment in 2001. This can appear to be negligible. Yet, if

biotech reaches even one per cent of total employment, its effect will be enormous, although not as large as the effect of ICT.

When we look at ICT, we also see that in 2002 ICT accounted for 40 per cent of total business R&D in the OECD, whereas biotech accounted for six per cent. So, we can still see that as far as business investment goes, ICT has attracted far more investment than biotech. This is partly because we are still in the early days of biotech. We have now had 33 years of biotech since the crucial Cohen and Boyer patent in 1974. If you think about 33 years after the start of the ICT age, which is commonly taken as the ENIAC computer in 1946, we reach 1979. ICT was widely diffused in 1979 as mainframes, but the real explosion did not come until later. This shows how long the lead times can be for major new technologies like ICT or biotech.

In OECD countries, positive policies that target biotechnology are actually difficult to justify based on our current economic outputs, say 0.1 per cent of

Table 1. Therapeutic value of biopharmaceuticals and all other drugs (Jan 1986 – April 2007)

	Biopharmaceuticals		All other pharmaceuticals	
	N	%	N	%
Major advance	0	0.0%	7	0.4%
Important advance	8	6.6%	56	3.1%
Some advance	21	17.4%	185	10.3%
Minimal advance	39	32.2%	425	23.8%
No advance (me too)	28	23.1%	898	50.2%
Not acceptable	12	9.9%	107	6.0%
Judgment reserved	13	10.7%	111	6.2%
<i>Total</i>	<i>121</i>	<i>100%</i>	<i>1,789</i>	<i>100%</i>

Source: Based on data from *Prescrire* issues between January 1986 and April 2007. All other drugs: 1986–2000 data on page 59, *Prescrire* Jan 2001, 2000–2006 data on page 142, *Prescrire*, Feb 2007; data for 2007 from individual *Prescrire* issues. The evaluations for biopharmaceuticals were subtracted from the totals for all drugs.

employment. However, the main impacts of biotechnology are not likely to be economic in strict terms, but environmental and social. Of course, as there are many economists who are capable of turning everything into dollars and cents, we could get economic indicators for these effects. But I think for general policy and public purposes we would actually be perfectly happy to have indicators of environmental and social impacts without any attempt to try and transfer these into economic terms.

Table 1 gives an example of a very powerful indicator of some of the benefits of biotechnology. This is the additional therapeutic value of pharmaceuticals that entered the market between 1986 and April 2007. Additional therapeutic value is the extra benefit compared to drugs that were already on the market to treat a certain condition – such as psoriasis or cancer. In total about 24 per cent of the biopharmaceuticals made ‘some’ or higher advance over existing therapies compared to only about 14.4 per cent of all other pharmaceuticals coming on to the market. Only 23% of biopharmaceuticals made no advance (me too drugs) compared to 50% of all other drugs.

Concluding Remarks

Biotechnology has global applications, but these will differ substantially across countries. As mentioned above, in some of the OECD countries investment in biotechnology is strongly related to the underlying industrial structure. Countries that heavily invest in agriculture or pharmaceuticals have a much bigger investment in biotech.

As a first step, we need consistent and internationally comparable metrics across

countries for biotechnology inputs, which are often the easiest thing to measure. We are increasingly trying to encourage countries to take the second step, which is to measure outputs, such as employment and sales. We very much need data for Asia. We suspect that Asia is probably the biggest growth area for biotech in the future, with more potential applications than Europe or the United States. This is because of the number of potential agricultural and health applications of relevance to Asian countries and the size of the future Asian market.

The next point is that we need biotechnology metrics by application. Comparisons about biotechnology in general can muddy the picture because many of the benefits are application-specific. The benefits from agricultural biotech are very different from the benefits of health biotechnology.

Another requirement is for better information on social and environmental impacts in a global context. These include both metrics and indicators, leading indicators, and metrics that can help predict the future, such as analyzing clinical trials and developing long-term forecasts. Long-term here can mean anywhere from eight years to twenty years. Again, these forecasts are needed by application.

At the OECD, we are trying to meet the needs of policy analysts by first improving national coverage within the member countries for basic indicators on biotechnology inputs. We very much would like to have more such data from non-OECD countries.

Second, we want to develop current and leading impact indicators by application. Much of the OECD work on

indicators occurs at the national level - we have national R&D expenditures etc. - but many of these impact indicators are not needed at the national level. For example, we can estimate them using international data for clinical trials or for therapeutic value.

Finally, the OECD *Bioeconomy to 2030* project is using scenarios to look

farther into the future. The project contains two parts. The first part uses a range of data to estimate trends in applications up to 2015, while the second part develops 'plausible' scenarios for up to 2030 in each of the three main applications areas for biotechnology. Both sets of results can help assist long term policy development.

Contours of Asian Biotechnology, Innovation and Development Initiative (ABIDI)

Sachin Chaturvedi*

Introduction

Asia has seen a sharp rise in the biotechnology industry in the last decade. The wide-ranging applications of biotechnology in the spheres of pharmaceuticals and agriculture have made not only an instrument for addressing certain key development issues like food security and health care but it also has emerged as a catalyst for economic growth. This has prompted several developing countries in the region for launching measures for promoting new technologies along with the industries based on biotechnology.

However, there have been no systematic efforts to put together quantitative details of these advancements. The quantification of various initiatives, at an internationally comparable level is possible only through a precise estimation of complementarities that exist in Asia for promoting regional cooperation and also for supplementing national efforts for optimum utilisation of available resources. Similarly, there are several issues that deserve the attention of policy-makers, researchers and other stakeholders for understanding

direction of S&T policy and its impact on society at large. Since adoption of biotechnology in industrial and other activities many developed countries also launched specific measures to capture statistics, which would provide clarity about the governance of biotechnology. It is therefore, important to outline a statistical framework that allows the measurement of these industrial and developmental activities so that the policy makers may evolve adequate responses.

In context of developing countries the development indicators of biotechnology are as important as the indicators for factors which work as inhibitors so that necessary initiatives may be launched. Compendium of these details may help in identifying the complementarities that exist in the region in terms of reducing the cost of testing GM products, sharing that data with other countries so as to reduce the cost of development of GM products across as most of the Asian countries have limited resources. If we want our SMEs (the small and medium enterprises) to grow in the region especially in the frontier technology, we would have to identify ways and means. Key stakeholders would play a major role

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in terms of suggesting modalities which are safe and that are why this session on definition is extremely important. It is important not only in the sense of capturing developments in biotech but also in terms of identifying the exchange and sharing of data which is safe so that safety considerations are taken care of. The second important fact is that biotechnology capacity is definitely varying among Asian countries. In case of some countries, it is just seeded, somewhere like India, China, Thailand and Indonesia, there are some statistics emerging, Philippines for example. This also gets reflected in the statistics.

The ABIDI Initiative

During the Third Asian Conference on Biotechnology and Development at Manila on November 9-10, 2006, many participants felt that Asian countries should launch an initiative to evolve an analytical framework for policy makers in the area of biotechnology. The idea is to collect policy relevant statistics for analyzing trends in investment, public allocation, skilled and semi-skilled manpower supply and activities of private sector. This should be done in the context of overall socio-economic requirements of the region. Since in a globalised world innovation is influenced by several interdependent regional systems hence, it would be useful to launch this initiative at the Asian level.

The idea is to bring together policy community, academics and interested institutions for facilitating greater understanding on policy aspects related to innovation and development of biotechnology. The issues related to ABIDI that were discussed in the meeting are summarized as follows:

- (a) Organisational structure or nature of agencies to be encouraged for collection of biotechnology statistics at the national level,
- (b) How convergence would be achieved in the methods of collection, authentication and curing of data across countries,
- (c) The publication of comparable results at the Asia level would require some resources and an international institutional support not only for financial resources but also for analytical inputs. It is also to be seen whether ABIDI would remain web based or would publish this statistics,
- (d) Another important issue is to see the focus of the survey, that is, to see which all indicators would be incorporated and what would be the frequency of these surveys, and
- (e) Set of modalities for the initiative for its smooth working.

Definition of Biotechnology and International Initiatives for Collection of Biotechnology Statistics

To maximize comparability of both public and business sector biotechnology statistics definition of biotechnology was developed by OECD with the help of an expert group. There are two definitions the OECD came out with. These were updates after the field based experience in some countries.

The first defines biotechnology as “*the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.*”

OECD list-based definition of biotechnology techniques

DNA/RNA: Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, and use of antisense technology.

Proteins and other molecules: Sequencing/synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signaling, identification of cell receptors.

Cell and tissue culture and engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation.

Process biotechnology techniques: Fermentation using bioreactors, bio-processing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biofiltration and phytoremediation.

Gene and RNA vectors: Gene therapy, viral vectors.

Bioinformatics: Construction of databases on genomes, protein sequences; modelling complex biological processes, including systems biology.

Nanobiotechnology: Applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics etc.

Although the single definition defines the purpose of biotechnology, the list based definition is essential for identifying modern biotechnology. In the *Biotechnology Statistics 2006* report, the OECD includes data for a few countries that used a different definition of biotechnology, as long as the definition was limited to 'modern' biotechnology. This option will still be available in 2008, although we encourage countries to adopt the OECD definition.

The Working Party of National Experts on Science and Technology Indicators (NESTI) of Committee for Science and Technology Policy of OECD has initiated an exercise of data collection in biotechnology for member countries.¹ In its various meetings NESTI decided to initiate the exercise after finalising the definition of biotechnology for statistical

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Canada is one of the major economies following the OECD definition of biotechnology. Statistics Canada is currently running its fourth dedicated survey on biotechnology covering almost 12,000 firms, a revenue of \$ 250,000 (Can \$) and using 22 different categories of biotechnology, as per the list based definition of biotechnology prepared by

¹ Some non-member countries like India and Israel have also been involved recently.

² Rose (2002).

OECD. Canada has come out with an exhaustive model survey with almost 30 questions spread over several pages.²

In France, two surveys have already been conducted for the years 1999 and 2000, while the third survey is all set to be launched in the middle of 2002.³ This survey is to cover 1500 firms engaged in biotechnology. Plans are also being worked out to incorporate results of these surveys in the annual R & D survey of France. There are two major government departments in France viz. the Bioengineering Department and the Bureau of R & D Statistics, which together conduct the biotechnology surveys, since 2001. Before this, the Bioengineering Department was managing its own database of firms entering incubators, awarded by the annual national contest by the firms' creation and voluntary registrations in the national database, while the Bureau of R & D statistics relies on their own surveys. The first in the series was launched in 2000.

In the United States, the National Science Foundation (NSF) of Department of Commerce has launched a limited data collection exercise of biotechnology statistics.⁴ Since 2001, data about biotechnology was being collected as part of the Survey of Industrial Research and Development, as was being done for other technologies like information technology and material synthesis. However, realizing the importance of biotechnology in the economic growth, it has been decided to make Bureau of Industry and Security (BIS) as the lead agency to collect statistics on

biotechnology from 2002 onwards. In order to facilitate this exercise, an inter-agency working group has been constituted. This survey would be mandatory in nature.

Similarly, Japan and Australia have also conducted their first limited surveys in the years 2000 and 2001 respectively. Australia has developed the Australian Field of Science (FoS) classifications that are relevant to biotechnology.⁵ Australia will shortly include FoS in their next R&D survey. Results are expected in twelve months time. Australia will report results of this survey back to the Ad Hoc group in 2003, which will serve to guide the group as to final levels of FoS in the future.

Actually, OECD is facilitating the evolution of a common approach towards biotechnology data collection so that international comparison becomes easier. At this point, there are significant differences in terms of approach towards data collection, definition of biotechnology and variables being covered among different OECD member countries.⁶ However, the central issue remains around the financial cost, lack of expertise and regulations and finally, the market uncertainty. Canada and New Zealand distinguish four major areas for biotechnology processes namely (i) DNA-based processes; (ii) Biochemistry and immunochemistry; (iii) Bio-processing, and (iv) Environment. The French survey does not distinguish major categories. Within these major categories, several sub groupings are distinguished. These are fairly similar for Canada and New Zealand, and differ somewhat with those identified in

³ Francoz, Dominique (2002).

⁴ Beuzekom, Brigitte van (2002).

⁵ Byars, Derek (2002).

⁶ Pilat, Dirk (2002).

France. Similarly, these country surveys approach the question of barriers in adoption of biotechnology in different ways. The Canadian survey requests information on barriers to biotechnology use, whereas the New Zealand survey requests information on barriers to R & D in biotechnology while the French survey does not ask for barriers.

In the *Biotechnology Statistics 2006* report, the OECD includes data for a few countries that used a different definition of biotechnology, as long as the definition was limited to ‘modern’ biotechnology. This option will still be available in 2008, although we encourage countries to adopt the OECD definition.

Proposed Plan for Asia

In case of Asia, we are beginning the biotechnology statistics collection exercise with the following template.

1. Please list the publicly funded biotechnology R&D programmes that exist in your country in the table below. For each programme, please
2. Provide as much of the information below as possible. Please use another sheet if you have more than three biotechnology R&D programmes.
3. Please provide available official statistics on biotechnology R&D performed or funded by the government. Where possible, please break out funding by type of performer (government, business, higher education, other), by type of application (e.g. health, agriculture, environmental, industry) and by type of instrument used (e.g., institutional funding, contracts or grants).
4. Please provide available official statistics on the estimated number of researchers (or science and technology personnel) in the biotechnology sector. If possible, please distinguish among researchers in the business, higher education and government sectors.
5. Please provide number of private sector companies (if possible sectorswise distribution and their turnover).

1. Name of the key funding agency (ies) dealing with biotechnology			
2. Year of launching of first biotech initiative (both research and commercial)			
3. Generic areas of funding (e.g. Agriculture, Medical, Animal, etc.)			
4. Implementing Agencies			
5. Amount of funding total and approximate funding (US \$) during last 5 years			
6. Primary recipients of funding (e.g. private sector, higher education, government research organizations)			
7. Cost-sharing between funding agencies and R&D performers (if any)			
8. Web address (URL) of key government agency dealing with biotechnology.			

RIS and Its Biotechnology Programme

The Research and Information System for Developing Countries (RIS) is an autonomous research institution established with the financial support of the Government of India. RIS is India's contribution to the fulfilment of the long-felt need of the developing world for creating a 'Think Tank' on global issues in the field of international economic relations and development cooperation. RIS has also been envisioned as a forum for fostering effective intellectual dialogue among developing countries.

RIS launched its biotechnology programme way back in 1987 after several rounds of discussions at RIS especially with Mr. N. Krishnan, formerly India's Permanent Representative to United Nations Headquarters, New York and Dr. S. Varadarajan, Chief Consultant, Planning Commission and formerly Director-General CSIR. The then DBT Secretary Shri S. Ramachandran; and, the former Chairman, National Biotechnology Development Board, Government of India, Dr. M. S. Swaminathan encouraged RIS to bring out a volume on Biotechnology Revolution in the Third World that was published in 1988, on the eve of the Inter-Governmental Consultative Conference of Experts on New and High Technology Areas for Non-Aligned and Other Developing Countries that took place in New Delhi on October, 1988. It had contributions from among other experts from UNESCO, United Nations University, International Labour Organisation and RAFI.

In 1991 RIS became part of the network of international agencies bringing out the Biotechnology and Development Monitor, published by the University of Amsterdam.

RIS launched a newsletter, Biotechnology Development Review (BDR) in 1992 with Biotech Consortium India Limited. In 1997 RIS launched, the *RIS Biotechnology and Development Review*, as a journal targeted exclusively for Asian and other developing countries. This publication was relaunched as *Asian Biotechnology and Development Review* (ABDR) in 2002 with support from Department of Biotechnology, Government of India and UNESCO, Paris.

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Providing Biotechnology Statistics and Indicators to the OECD Biotechnology Statistics 2008

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Introduction

The OECD has been collecting and publishing data on biotechnology from its member and several non-member countries since the 2001 Biotechnology Compendium. The most recent publication is the *OECD Biotechnology Statistics 2006*¹, which includes more internationally comparable indicators than the 2001 Compendium. The OECD is planning to produce its next collection of biotechnology statistics in 2008 and hopes to further improve international comparability. This involves increasing the number of countries that provide comparable data for specific indicators and the absolute number of comparable indicators.

The *Biotechnology Statistics 2006* report includes data for three non OECD countries: Israel, South Africa and the Shanghai province of China. For the 2008 edition, the OECD would like to include comparable data on biotechnology statistics for a larger number of non OECD countries, or, if necessary, for regions or provinces within large countries such as China, India, or Brazil.

This brief report explains the approach of the OECD to producing internationally comparable biotechnology statistics. This information should be helpful for countries that would like to provide indicators for inclusion in the 2008 edition of *Biotechnology Statistics*.

Relevant Data

The *Biotechnology Statistics* reports include three types of data:

1. Biotechnology activities of the public sector, particularly investment in biotechnology R&D.
2. Biotechnology activities of the business sector.
3. Methodology of data collection (metadata).

The information needed by the OECD for each type of data is given below in sections 2 through 4. A country only needs to provide a few internationally comparable indicators and the supporting metadata to be included in the 2008 *Biotechnology Statistics*.

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¹ The report can be downloaded for free from <http://www.oecd.org/dataoecd/51/59/36760212.pdf>

Definition of Biotechnology used by the OECD

International comparability is strongly dependent on how biotechnology is defined. The OECD limits biotechnology indicators to modern biotechnologies. This excludes traditional fermentation of soy, dairy and alcohol products. Conventional plant and animal breeding are also excluded, unless biotechnologies such as marker assisted selection (MAS) are used as part of the conventional breeding programme.

To maximize comparability of both public and business sector biotechnology statistics, countries should use the OECD single definition of biotechnology and the list based definition (see Box 1 below) of different types of biotechnology. Both definitions were developed by an OECD expert group. The first defines biotechnology as “*the application of science and technology to living organisms, as well*

as parts, products and 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 *Biotechnology Statistics 2006* report, the OECD includes data for a few countries that used a different definition of biotechnology, as long as the definition was limited to ‘modern’ biotechnology. This option will still be available in 2008, although we encourage countries to adopt the OECD definition.

Reference Year

The OECD prefers to have data for the most recent available year, which is 2006 or 2007 for the 2008 report. However, the report will include data for 2004 or 2005, if no data are available for 2006 or 2007.

BOX 1: OECD list-based definition of biotechnology techniques

DNA/RNA: Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, and use of antisense technology.

Proteins and other molecules: Sequencing/synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signaling, identification of cell receptors.

Cell and tissue culture and engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation.

Process biotechnology techniques: Fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biofiltration and phytoremediation.

Gene and RNA vectors: Gene therapy, viral vectors.

Bioinformatics: Construction of databases on genomes, protein sequences; modelling complex biological processes, including systems biology.

Nanobiotechnology: Applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics etc.

Application Field

Where possible, the OECD provides biotechnology statistics for up to four major applications of biotechnology: health, agriculture (including food processing and marine uses such as aquaculture), industrial, and environmental. Data by application has many advantages in terms of predicting the future direction of biotechnology, improving the comparability of output indicators², and estimating social and economic impacts, which are strongly dependent on the application.

Public Sector Investment in Biotechnology R&D

Optimally, the OECD would like to publish data on total government expenditures on biotechnology R&D, plus expenditure data broken down by application field and by the recipient of the funding. The template for 'Public Biotechnology R&D' is provided as an example of how to obtain the basic data from Government ministries.³ The following indicators for a specific year can be produced using the information collected in the template:

1. Total public expenditures on biotechnology R&D.
2. Total public expenditures on biotechnology R&D by field of application.
3. *Alternative if a breakdown by application is not available:* Share of all Government

programmes for biotechnology R&D by application field.

4. Total public expenditures on biotechnology R&D by type of recipient.
5. *Alternative if a breakdown by recipient is not available:* Share of all Government programmes for biotechnology R&D by recipient.

Section 4 below lists four metadata items that are required for public R&D data.

Public Biotechnology R&D Template

Please list **publicly** funded biotechnology R&D programmes that exist in your country in the table below. For each programme, please provide as much of the information below as possible. Please use a separate template for each programme that funds biotechnology R&D.

Biotechnology Activities of the Business Sector

The OECD *Biotechnology Statistics* publishes indicators on the number of biotechnology firms and R&D, employment and sales within these firms. Ideally, data on R&D, employment and sales are obtained for both biotechnology-related activities and for all activities of biotechnology firms. For example, many firms that perform biotechnology R&D also conduct R&D in

² As an example, Biotechnology Statistics includes an output indicator for the total sales of biotechnology goods and services as a proxy measure of the economic effects of biotechnology. However, market sales data combine non-biotechnology inputs into the production of the good or service plus biotechnology inputs. The share of biotechnology inputs in the sales price is likely to vary substantially across applications, but less within applications.

³ An earlier version of this template was produced in 2003 and circulated to OECD experts. Based on experience with the 2003 version, the complexity of the current template was reduced in order to focus on collecting useable data.

1. Basic information		
Name of programme		
Responsible Government ministry		
Is this programme dedicated to funding biotech R&D?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Or, other programme that also funds biotech R&D?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Duration of programme (number of years)	_____ Start year	_____ End year
Total amount of funding for biotech R&D (<i>exclude non biotech R&D</i>) over the lifetime of the programme	_____ (National currency)	
2. Distribution of programme funding for biotechnology R&D by application field		
Type of biotech R&D funded:	Check all that received funding:	Estimated share of total funding of biotech R&D (<i>Exclude non biotech R&D from total</i>)
Health (human and animal)	<input type="checkbox"/>	_____
Agriculture-marine-food processing	<input type="checkbox"/>	_____
Industrial	<input type="checkbox"/>	_____
Environmental	<input type="checkbox"/>	_____
Other (please describe):	<input type="checkbox"/>	_____
		100%
3. Distribution of programme funding for biotechnology R&D by sector of recipient		
Recipients of biotech R&D funds:	Check all that received funding:	Estimated share of total funding of biotech R&D (<i>Exclude non biotech R&D from total</i>)
Business	<input type="checkbox"/>	_____
Higher education	<input type="checkbox"/>	_____
Government research organizations	<input type="checkbox"/>	_____
Private non-profit	<input type="checkbox"/>	_____
		100%

other fields, or some sales could be due to non biotechnology goods and services. However, depending on the survey design, some studies are not able to provide results that are limited to biotechnology. Consequently, the OECD publishes data on all activities of biotechnology firms plus results that are limited to biotechnology. The only requirement is that each country includes metadata that clearly defines R&D, sales and employment data plus the

survey design or other information on how the data are obtained.

The template given below obtains the required metadata for the business sector, plus additional details are requested in the data collection template. The variables in column 1 are defined in section 4. The data collection template (available as an Excel file) defines six main indicators (if data are unavailable, the relevant cell should be left blank). Of note,

Metadata Template for Business Surveys

Variable	Result	Comments
Reference year	_____	
Definition of biotechnology	<input type="checkbox"/> OECD definition <input type="checkbox"/> Other 'modern' <input type="checkbox"/> Other	<i>If 'other modern' or 'other', give details</i>
Definition of a biotechnology firm	<input type="checkbox"/> Core <input type="checkbox"/> Bio-active <input type="checkbox"/> Other	<i>If 'other', give details</i>
Must perform biotech R&D?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Sample frame	<input type="checkbox"/> Large scale survey <input type="checkbox"/> R&D survey <input type="checkbox"/> Secondary sources <input type="checkbox"/> Other	<i>Give details</i>
Number of firms surveyed	_____	
Survey response rate	_____ %	
Results weighted?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not relevant	<i>If not relevant, give details</i>
Results extrapolated?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not relevant	<i>If not relevant, give details</i>
Coverage area	<i>Describe if limited to a specific province, region, etc</i>	

wherever possible the OECD would like to have data on firm numbers disaggregated by the firm's main area of application for biotechnology. Five application areas are given, such as health (which includes both human and animal health), agriculture/ marine/ forestry, food and beverage processing, industrial, and environmental. If data are not available at this level, applications can be combined. For example, the application 'industrial' could be combined with 'environmental'. The 'other' category can be used for different applications or for different ways of combining applications.

Methodology of Data Collection (metadata)

Due to the complexity of biotechnology, there are many different ways of defining biotechnology, a biotechnology firm, and

of measuring biotechnology activities. For these reasons, *Biotechnology Statistics* includes information on the definitions used to collect biotechnology data as well as information on the methodology. Page 11 of *OECD Biotechnology Statistics 2006* summarizes the necessary metadata for each country in a single table.

Business Sector

The following metadata are needed to support indicators of business sector biotechnology activities:

Year: Reference year for the biotechnology statistics.

Definition of Biotechnology: How biotechnology was defined, for instance in questionnaires sent to firms. Possible options include the OECD list based definition or other definitions of modern biotechnology.

Data Collection Template for the Biotechnology Activities of the Business Sector

Biotech firms Country: _____ Reference year: _____		Source (name of survey, secondary sources etc.)
Notes (Please indicate whether the reference period differs; whether the indicator's comparability could be affected by you country's question wording or the population asked the question; detail any reliability issues associated with the indicator etc.)		
Firms		
1. Total number of biotechnology firms		
2. Biotech firms by application field: Health <input type="checkbox"/> Agro/Marine/Forestry <input type="checkbox"/> Food & beverages processing <input type="checkbox"/> Industrial <input type="checkbox"/> Environmental <input type="checkbox"/> Other: please specify <input type="checkbox"/> Other: please specify <input type="checkbox"/>	If not available please give approximate distribution by industrial sector.	
3. Total biotech firms by size-class: <50 employees <input type="checkbox"/> 50-249 employees <input type="checkbox"/> 250+ employees <input type="checkbox"/>		
R&D	4. Expenditures on R&D by biotech firms (millions national currency) Total <input type="checkbox"/> Of which: <input type="checkbox"/> Biotech R&D <input type="checkbox"/>	
Employment	5. Employment in biotech firms Of which <input type="checkbox"/> Total employees <input type="checkbox"/> <input type="checkbox"/> Biotech employees <input type="checkbox"/> Of which <input type="checkbox"/> Total R&D employees <input type="checkbox"/> <input type="checkbox"/> Biotech R&D employees <input type="checkbox"/>	Please check if these data are for: Full-time equivalent (FTE) _____ Headcount _____
Sales firms	6. Total sales of biotech firms (million national currency) Total sales <input type="checkbox"/> Of which <input type="checkbox"/> Sales of biotech goods & services <input type="checkbox"/>	

Definition of a Biotechnology Firm:

How a biotechnology firm is defined. For guidance, three defining characteristics are in common use:

Core biotechnology firm: The firm's main activity is biotechnology. Most of these firms are likely to be small, with less than 500 employees. Most consulting reports, such as by Ernst and Young, are limited to core biotechnology firms.

Bio-active firm: Includes all firms with some activities in biotechnology. Some of these firms will be very large, with only a small share of total economic activities due to biotechnology.

R&D status of the firm: Both the definition of a core and a bio-active firm can vary depending on whether or not the firm performs biotechnology R&D. For example, R&D surveys capture all bio-active firms with some biotechnology R&D.

Definition of a Biotechnology Employee: All employees that have biotechnology-related responsibilities in R&D, production, administration, and management.

Sample Frame: Describe the basic structure of the sample frame. It is often difficult to construct a sampling frame for surveys of biotechnology firms because firms with some biotechnology activities can be difficult to identify. Three methods of constructing the frame are in common use:

Large Scale Survey: All firms are randomly sampled and asked if they have biotech activities. To save costs, these surveys are usually limited to sectors where biotechnology is thought to have applications.

R&D Survey: All respondents to the business R&D survey are asked if they have expenditures for biotechnology R&D.

Secondary Sources: A list of biotech firms is constructed from a diverse set of sources, such as biotechnology industry associations, searching patent data to identify firms that have applied for a biotechnology patent, results of previous R&D surveys, applicants to government support programmes for biotechnology R&D, etc.

Survey Response Rate: Give the percentage of the sampling frame that responded to the survey. In some cases this is not relevant, as when biotechnology data are extracted from the annual reports of firms.

Weighting and Extrapolation: Give details on weighting and extrapolation methods, if used. When the survey response rate is less than 100%, the results for non respondents can be extrapolated or imputed. When the survey is a random sample of a much larger population, the results should be weighted to reflect the full population. In both cases weighting and extrapolation techniques estimate indicators for the complete population of biotechnology firms.

Region: Give details if the survey is limited to a region or province of a country.

Public Biotechnology R&D Expenditures

The main challenge for indicators of public sector biotechnology activities is to determine if all government support is adequately covered, or only a part of such support. The necessary metadata for

government support of biotechnology R&D include the following:

Year: Reference year for the biotechnology statistics.

Definition of Biotechnology: How is biotechnology defined in support programmes for biotechnology R&D, etc.

Level of Government: Government R&D data can be limited to specific levels of government, such as federal expenditures only. Some information on this is necessary,

particularly when different levels of government (federal, provincial/state, municipal) can fund biotechnology R&D.

Coverage: How was government R&D expenditures for biotechnology obtained? This can be based on surveying the location of the expenditures (for instance universities and government research institutes) or on the source of the funding (different government ministries). The template on public biotechnology R&D uses the latter method.

Statistical Definition of Biotechnology: Identifying Philippine Concerns - Asian Perspective

Nina G. Gloriani*

Introduction

The Philippines recognizes the importance of using clear standard definitions of biotechnology and biotechnology-related activities to improve the comparability of biotechnology statistics across institutions at the local or national levels, and across countries within the region and around the world. In particular, comparability of biotechnology indicators between countries based on such standard definitions for different areas and aspects of biotechnological activities will provide guidance on domestic and international policies for adoption and prioritization on directions for the Biotechnology industry globally. These should provide the framework for all stakeholders to analyze trends in Biotechnology investment, make decisions on allocation of funds for public R & D, address gaps in manpower capability and understand activities and priorities of both public and private industry sectors. For Asia, this regional initiative (ABIDI) should identify common practices as well as problems in gathering such biotechnology statistics, and in the process, come to a consensus to use a

standard, possibly modified statistical framework for data collection in the region.

OECD Definition of Biotechnology- Single vs List based Definition

The OECD single definition defines biotechnology as “the application of Science and Technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services. “This single definition is certainly viewed as a broad definition that covers traditional, borderline and modern biotechnology”.

An OECD list-based definition has been proposed which is currently being used based on a definition of biotechnology techniques. This list-based definition approximates more the modern or “third generation” biotechnologies.

The Philippine Definition of Biotechnology

The Philippines has been engaging in various forms of biotechnology activities

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covered in the OECD single definition since the late 1970s, when the first national Institute of Biotechnology and Molecular Biology was established at the University of the Philippines in Los Banos. The activities included traditional as well as borderline and modern biotechnologies. However, the Philippines came up with an official definition of Biotechnology back in 2000 when we had to put in place, the regulatory framework for the importation and commercialization of genetically modified crops in our country. Understandably, the definition covered “modern biotechnology”. Thus, the Philippine Administrative Order # 8 (AO # 8, series approved in 2002) includes the following in its definition of modern biotechnology:

- i. Recombinant nucleic acid techniques involving formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur, but in which they are capable of continued propagation.
- ii. Techniques involving direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation
- iii. Cell fusion, including protoplast fusion or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means

of methods that do not occur naturally.

Additionally, Philippine Executive Order # 514 (EO # 514, approved in 2006) for the National Biosafety Framework, defines modern biotechnology as the application of in vitro nucleic acid techniques including recombinant deoxyribonucleic acid (DNA) or direct injection of nucleic acid into cells or organelles and the fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding or selection.

Both AO # 8 and EO # 514 definitions are covered in the OECD list-based definition of biotechnology techniques.

Philippine Biotechnology Statistics – Issues on Definition

This 2007 report on how the Philippine biotechnology sector defines biotechnology or biotechnology-related activities included submissions from 2001 to 2006 (to the Department of Science and Technology or DOST) on all kinds of biotechnology, the majority from public academic institutions and government-run research bodies and a small number from private research institutes some of which are also tied up with the universities or private hospitals, and one from an international research institute, the International Rice Research Institute in UP Los Banos. This report does not include privately-run companies (Filipino-owned or multinational) engaged in biotechnology industry.

OECD List-based definition	Listed as being Used in the Philippines	Not listed as being used in the Philippines
DNA/RNA: genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling and use of antisense technology	All except *	* pharmacogenomics
Proteins and other molecules : sequencing/synthesis/engineering of proteins and peptides (Including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signaling, identification of cell receptors	All except *	* proteomics, signaling, identification of cell receptors
Cell and tissue engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation	All except *	* tissue scaffolds and biomedical engineering
Process biotechnology techniques: fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biofiltration and phytoremediation	All	
Gene and RNA vectors: Gene therapy, viral vectors	Viral vectors	Gene therapy
Bioinformatics: Construction of databases on genomes, protein sequences, modeling complex biological processes, including systems biology	All except *	* Modeling complex biological processes
Nanobiotechnology: applies tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics, etc.	Listed but some problems in “official definition of nano - biotechnology	Based on strict operational definition of “nano”, this technology is not being used

Some of DOST submissions used different categories of applications not consistent with OECD main application fields and listed a variety of biotechniques used which they considered under “biotechnology”. In general, based on the titles of projects reported by most agencies on biotech, we were able to easily classify the techniques they use under the OECD list-based definition.

A number of other techniques used in agricultural applications were also listed

as “biotech”, but cover traditional, borderline and modern biotechnology activities as well.

Examples are the following:

1. Reproductive biotechniques for cattle or carabao
2. Cloning through somatic cell nuclear transfer for improvement in water buffaloes
3. Identifying mutations in genes of antibiotic resistant organisms

4. Biofortification (not genetic modification)
5. T3 generation of transgenic IR 72 with Xa-21 gene
6. Traditional cross breeding of 2 transgenic parents; stack hybrid seeds
7. Introgression of cucumber mosaic virus coat protein resistance to tomato varieties
8. Small ruminant genetic improvement
9. Gene discovery in coconut/ promoter analysis
10. In vitro propagation of dwarf bananas genetically modified for delayed fruit ripening

We are thus proposing an expansion of the list-based definition to possibly include the following: Environmental biotechnologies: biosensing, biological control, any other process biotechnology techniques; metabolomics/ metabonomics and biodiscovery, as well as others that may capture the above techniques.

Biotechnology Applications in the Philippines

The OECD broadly classifies biotechnology applications into three main fields that are deemed to be generally comparable across countries. These are Health, agro-food and industry-environmental applications. Under the OECD definition of applications, health includes both human and animal health, agro-food includes all agricultural applications plus fishing, silviculture and food processing, and industry environmental includes industrial processing, natural resources and

environmental applications. An “other” category includes Bioinformatics.

Biotechnology Applications in the Philippines differ somewhat from the OECD three main application fields. These are reflected in the DOST statistical reports classified as “areas of application” and include the following: agricultural biotechnology applications in plants and animals, medical, industrial, environmental and aquaculture. Thus, we see that health applications per OECD classification include humans & animals, whereas in the Philippines, we separate humans from animal biotechnology; Food-Agriculture in Philippines includes plants and animals and as the country embarks on developing Plant Made Pharmaceuticals, we will have a merging of agricultural and medical biotechnology. Aquaculture application is also considered to be separate from agricultural applications. The Industrial Biotechnology application in the Philippines is also separated from environmental application. Considering the OECD general biotechnological applications as well as our own system in the country (based on governmental organizational structural mandates for policy and regulation), we would propose the classification of Biotech applications to be the following:

1. Agriculture – plants, animals and animal health and aqua culture
2. Biomedicine / human health
3. Environment – includes Forestry and biocontrol agents
4. Natural resource extraction – mining, petroleum, energy extraction, biofuels, biolubricants
5. Industrial processing- bioproducts, bioplastics, biodetergents

There is also an issue as to whether there is a need for another classification that will cover other biotechnology related activities. These include development of medical devices and gadgets, nutraceuticals and functional foods.

We understand that the OECD definitions are by no means exhaustive and are in fact evolving. The proposed modifications to the standardization of the statistical definitions of biotechnology in our country as outlined in this report will require further consultation and discussion among the many stakeholders in the biotechnology industry. A National Biotechnology Survey on both public and private research institutions (involved in R & D as well as in commercialization) in the Philippines has been ongoing since

January 2007. This survey uses the OECD definition / list based techniques and was initiated by the Biotechnology Coalition of the Philippines. The results of this survey hopefully, will be available in mid 2007.

Conclusion

The Philippines recognizes the need for standardizing the statistical definition of biotechnology, as well as its applications. Our participation in the Asian Biotechnology Innovation and Development Initiative (ABIDI) will help us develop an Asian regional statistical framework that will allow commonalities and cooperation for harnessing the potentials of the biotechnological revolution not only in our respective countries, but in the region as well.

Biotechnology Definition: An Indian Perspective

V. S. Reddy*

To maximize comparability of both public and business sector biotechnology statistics, definition of biotechnology was developed by OECD with the help of an expert group. There are two definitions that the OECD came out with. These were updated after the field based experience in some countries.

The first defines biotechnology as “*the application of science and technology to living organisms, as well as parts, products and 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 second list based definition is essential for identifying modern biotechnology.

The OECD list-based definition of Biotechnology techniques in its present form in my opinion is not sufficient to cover the activities that are covered under biotechnology in India. Therefore, India may consider “OECD plus” for defining biotechnology techniques. For example, our recent understanding of gene expression has

changed radically after the discovery of RNA interference (RNAi) technology and is the most common technology for gene expression and gene function studies that need be included. Similarly, transcription factors that are regarded as master switches in controlling gene expression need be included. Molecular markers are another set of tools used in molecular breeding and molecular medicine. Besides this biopesticides and biofungicides need to be included as they are covered under Department of Biotechnology (DBT), Govt. of India activities. Immunotherapy, *In silico* techniques for gene identification/expression/splicing are also important to be included in the list based definition. Therefore, India may include additional technologies that are currently covered under biotechnology to the OECD list-based definition.

“OECD PLUS” list-based definition of biotechnology techniques

DNA/RNA: Genomics, pharmacogenomics, gene probes, genetic engineering,

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DNA/RNA sequencing/synthesis/amplification, gene expression profiling, and use of antisense technology, RNA interference (RNAi) technology.

Proteins and other molecules: Sequencing/synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein expression, isolation and purification, signalling, identification of cell receptors, transcription factors, nanotechnology.

Cell and tissue culture and engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation.

Process biotechnology techniques: Fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biofiltration and phytoremediation, biopesticides, biofungicides.

Gene and RNA vectors: Gene therapy, immunotherapy, viral vectors.

Bioinformatics: Construction of databases on genomes, protein sequences; modelling complex biological processes, including systems biology. *In silico* techniques for gene identification/expression/splicing.

Nanobiotechnology: Applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics etc.

Molecular markers: Molecular markers based on specific DNA sequence are useful tools in crop improvement programs. Restriction Fragment Length Polymorphism (RFLP), Amplified Fragment Length Polymorphism (AFLP), simple sequence repeats (SSRs) are used in molecular breeding programs. Also the Biomarker, a biochemical feature or facet that can be used to measure the progress of disease or the effects of treatment (the presence of an antibody may indicate an infection).

Agricultural Biotechnology and Emerging Global Linkages: Perspectives from Michigan State University

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Founded in 1855, Michigan State University (MSU) is a premier land-grant university in the United States of America. MSU has a three fold mission – research, teaching, and public service through extension and outreach. As a global public university, the outreach mission of the university is extended to all over the world. MSU is recognized worldwide as a center of excellence in international agricultural development, and is actively involved in international agricultural biotechnology collaborative research, training and capacity building.

Michigan State University scientific community have embraced and integrated the new tools of biotechnology in their agricultural research and development programs. The research scientists at MSU view biotechnology as one of the many tools in an integrated approach to enhance agricultural productivity. MSU has more than 25 research laboratories dedicated

towards biotechnology research in a wide range of areas to address issues such as biotic and abiotic stresses, nutritional enhancement, phytoremediation, biofuels etc. Prominent among these laboratories are the core genomics, proteomics and bioinformatics research facilities as well as the newly established biotechnology resources and outreach center. The biotechnology research and development work at MSU ranges from simple biotechnology applications such as tissue culture to molecular breeding to more sophisticated applications such as genetic engineering and genomics. MSU thus view biotechnology applications as more than just GMOs. The plant biotechnology research is well integrated into already existing plant breeding and crop improvement programs. The plant breeders in the College of Agriculture and Natural Resources (CANR) for example are using biotechnology tools to not only discover and introduce new genes and traits into crop

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plants but also to breed new varieties faster. More than 10 Million dollars are invested each year in biotechnology research and development activities by the MSU-CANR through various grants and other support.

The biotechnology research at MSU is regulated by an Institutional Biosafety Committee (IBC), and through the Biosafety regulations, guidelines and procedures developed by the state and federal government agencies (MDA, USDA-APHIS, EPA, FDA). MSU has an institutional intellectual property (IP) policy and a well established IP office (OIP). The biotechnology researchers at MSU routinely exchange research tools and materials using material transfer agreements (MTAs) developed through the OIP. MSU has a multidisciplinary group (NNF) that fosters open discussion forums on various scientific, legal, ethical and socio-economic issues related to biotechnology thus providing a platform for an open and honest dialogue among various stakeholders. The biotechnology applications at MSU are thus handled in a safe, legal and an ethical manner.

MSU scientific community very carefully considers both, potential risks and benefits of using the new tools of modern biotechnology. The potential risks and benefits are considered within a broad framework of overall environmental safety and food safety issues/aspects. While most of the genetically modified (GM) Biotech crops grown in Michigan are commercialized by the private sector, MSU plays a unique role of conducting basic research, gathering regulatory data through field and laboratory trials, and in providing education to farmers and other stakeholders through a well established extension system.

The farmer educational programs address the issues related to use, management and stewardship of biotechnology products thus promoting the responsible use of these new technologies. The Biotech crops such as herbicide tolerant round-up ready soybean and insect resistant B.t. maize have become an integral part of the Michigan agroecosystems. Where appropriate, MSU protects and licenses new inventions related to biotechnology to private sector to benefit the society. The additional royalty income and revenue generated through licensing also help support research and educational programs and further advancement of science.

MSU has well established working links with the state and federal government agencies, private industry, and Michigan farmers. MSU takes active input from various stakeholders in the design and implementation of biotechnology educational programs. Through the World Technology Access Program (WorldTAP) of the Institute of International Agriculture (IIA), MSU is very active in providing education and training to international biotechnology community. Considering that biotechnology is more than science, while designing educational programs, MSU takes an integrated approach to include research, policy, technology transfer and communication issues. These programs are offered through international short courses, workshops and seminars conducted both in the US and in international settings. In addition, as the biotechnology capacity in the developing countries evolve, MSU is also offering more in-depth long term training programs through internships, certificate and sandwich degree programs. These training programs are designed and

implemented in collaboration with the faculty members of MSU Plant Breeding and Genetics program, National Food Safety and Toxicology Center and MSU College of Law while taking into consideration the emerging needs of developing countries and active input/feed back from the participants.

The portfolio of international training programs in agricultural biotechnology at MSU includes environmental biosafety, food safety, integrated pest management (IPM), intellectual property (IP) management and technology transfer and a general course on agricultural biotechnology. MSU also provide training in research areas of biotechnology including molecular breeding, plant transformation, genomics, etc. through Plant Breeding and Genetics program (PBG) and the Biotechnology Resources and Outreach Center. Interactive group discussions and hands-on experience are integral parts of all of these training programs. As an example, MSU has established a Transgenic Teaching Garden (TTG) that serves as a demonstration of

various biotech crops commercially available in the US. This provides an opportunity for trainees to get a feel of the technology and prepares them well for the farmer field visits.

The international cooperation and collaboration is a hallmark of MSU. Through the MSU biotechnology training programs, more than 500 research scientists, policy makers, academic, media and NGO personnel, industry representatives etc from more than 60 countries have been trained. The IIA-WorldTAP maintains an active database of the trained personnel for future networking and follow-up programs. MSU routinely collaborates with these trained personnel in organizing in-country and regional programs promoting regional and international linkages. MSU programs thus not only help in building capacity but also in building a global network in biotechnology to foster exchange of information, technologies and experiences promoting true global inter-dependence broadening the mission of MSU from a land grant to a global grant university.

Section II:

Status of Biotechnology
Across Asia: Country Papers

Biotechnology Statistics: Publicly Funded Biotechnology R&D Programs in China

Xielin Liu*
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Introduction

In China, Ministry of Science and Technology (MOST)¹ has been supporting biotechnology R&D programs for more than two decades. Almost in every important program it launched, biotechnology projects are listed on the top and take up essential share in the total budget. In the following part, we identified two predominant programs to show how MOST financed biotechnology R&D programs in China. Programs launched by MOST are very diverse and complicated, our choice of discussed programs are not only based on importance of the programs, but also the availability of data. Some other programs such as 973 Program (a basic research program launched in March, 1997) are influential to biotechnology R&D activities in China, too. But as we could get very little statistics till now, we have to satisfy with the current limited pictures.

Hi-tech Research and Development Program of China (863 program)

The Hi-tech Research and Development Program of China is an ambitious program

launched in March, 1986. So it is also named as the 863 Program. Biotechnology was listed as the most important category of program funding (Table 1). There are 7 to 8 categories of program funding in the 863 program in which biotechnology takes up a second biggest share of the total fund (the biggest is information technology).

During the past two decades, the funding policy of 863 Program has been fluctuating. Initially, recipients of the public fund of 863 Program were mostly from higher education and government research organizations. Firms from private sector only took up 5 per cent of the total fund during the first decade. But later, the 863 Program became more and more concerned on commercial projects. Private firms are encouraged to apply for public fund, joint applications by private firms and academic units are specially advocated. In 2005, higher education and government research organization totally shared 54 per cent of annual budget, firms in private sector took up 37.1 per cent of the budget (annual report of 863 Program, 2006).

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¹ www.most.gov.cn

Table 1: Budget of 863 Program and the share of biotechnology programs

Year	Total Budget (million\$)	Share of BT Program
1987-2000	712.5	26 per cent
1998	87.5	22 per cent
1999	100	25 per cent
2000	112.5	25 per cent
2001	206.25	27 per cent
2002	537.5	33 per cent
2003*	384.4	26.8 per cent
2004*	468.75	22.6 per cent
2005*	511.9	18.5 per cent

Source: Annual Reports on 863 Program, www.863.org.cn, *www.most.gov.cn

Innovation Fund for Technology-Based Firms (Innofund)

Different from the 863 Program swaying between academic and commercial orientation, the Innovation Fund for Technology-Based Firms was definitely designed and established to offer public fund to small-medium sized private firms in the year 1998. Biotechnology is listed as a prior area, too. But the Innofund for Technology-Based Firms only has a very tiny budget less than \$125 million per year (Table 2).

The funding instrument is contract. According to formalized contract text, recipients of Innofund usually have to invest one to several times of the fund received to

conduct the R&D projects funded. Public fund could not be taken as the only financial source of their research proposal.

R&D Programs Funded by National Natural Foundation of China (NSFC)

National Natural Foundation of China was established in 1986 and has been aiming at supporting basic research. It has always been spending one third of its total budget on life science and biotechnology very steadily since its establishment (see Table 3). As the projects financed by NSFC are focused on basic research, recipients of NSFC grant are primarily higher education and government research organizations.

Table 2: Budget of Innofund and the share of biotechnology programs (\$million)

Year	Total Budget	Share of BT Programs	Budget of BT Programs
1999	102.04	19.7 per cent	20.1
2000	82.46	23.2 per cent	19.1
2001	97.9	15.8 per cent	15.425
2002	67.5	15.1 per cent	10.2
2003	83	19.0 per cent	15.73
2004	82719	17.5 per cent	18.13
2005	98848	17 per cent	21

Source: Liu and An (2007).

Grant is the funding instrument used by NSFC.

Table 3: Budget of NSFC and expenditure on life science and biotechnology

Year	(\$million)	
	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: Annual Reports of NSFC from www.nsf.gov.cn

Financial Supports on Biotechnology Programs from National Development and Reformation Commission (NDRC)²

National Development and Reformation Commission is a much more powerful agency than MOST in the central governmental system of China. But it is more concerned on economic activities other than R&D programs. So it never pays as much attention to R&D programs as MOST has done. But NDRC does finance the commercialization of biotechnology R&D projects and could afford more expensive projects than MOST could do. During the year 1999 to 2002, NDRC had spent \$250 million in total on more than 140 commercial biotechnology projects. Though we do not have systematic statistics on the financing activities of NDRC, we could only report that NDRC spends much more than MOST on every single project, the average amount is about \$1million, as

the fund from MOST for a single project could range from several thousand dollars to \$1million.

MOST, NDRC and NSFC all have their branches in every regional government. These regional branches in developed area such as Beijing, Shanghai and Shenzhen have very sufficient financial income and could offer essential fund to local biotechnology R&D performers, too. For R&D performers in developed areas, they could get much more fund from very diverse governmental agencies, from central government to local government than their counterparts in less developed area. The Science and Technology Committee and Development and Reformation Commission of Beijing could spend half million dollars on one single biotechnology R&D project, which is no less than what MOST could afford.

Biotechnology Researchers and Private Sectors Companies in China

Up till now, there has been no official survey on how many biotechnology companies exist in private sectors in China. How many companies are active in medical, agricultural and environmental industry, how about their turnover, these are still open questions to be answered. A well recognized estimation of company number is about 2000, but no definite proofs could be found. According to our review on the 1200 Chinese publicly-offer firms, there are about 200 of these firms have daughter firms or projects related to biotechnology. Medical firms that have been officially approved to produce biotechnology drugs are

² www.sdpc.gov.cn

Table 4: Publicly Funded Biotechnology R&D Programs in China

Name of the Programs	Hi-tech Research and Development Program of China (i.e. 863 program)	Committee of National Natural Foundation	Innovation Fund for Technology-Based Firms
1. Name of the key funding agency (ies) dealing with biotechnology	Ministry of Science and Technology (MOST)	Committee of National Natural Foundation of China(NSFC)	Ministry of Science and Technology (MOST)
2. Year of launching of first biotech initiative (both research and commercial)	1987	1987	1999
3. Generic areas of funding (e.g. Agriculture, Medical, Animal, etc.)	Agriculture, Medical, Animal, environmental;	Agriculture, Medical, Animal, environmental;	Agriculture, Medical, Animal, environmental;
4. Implementing Agencies	United Office of Hi-Tech Program, MOST	Committee of National Natural Foundation of China	Administrative Center of Innovation Fund for Technology-Based Firms, MOST
5. Amount of funding total and approximate funding (US \$) during last 5 years	2001: \$55.7 million; 2002: \$177.3 million; 2003: \$103 million; 2004: \$105.9 million; 2005: \$94.7 million; 2006: data not available	2001: \$66.6 million; 2002: \$82 million; 2003: \$85.4 million; 2004: \$ 93.7 million; 2005: \$ 112.6million; 2006: data not available	2001: \$15.4million 2002: \$10.2 million 2003: \$15.73 million 2004: \$18.13 million 2005: \$21 million 2006: data not available
6. Primary recipients of funding (e.g. private sector, higher education, government research organizations)	private sector higher education, government research organizations	higher education, government research organizations	private sector
7. Cost-sharing between funding agencies and R&D performers (if any)			Usually, R&D performers are required to invest at least no less than the fund received to double the total R&D budget
8. Web address (URL) of key government agency dealing with biotechnology.	www.863.org.cn www.most.gov.cn	www.nsfc.gov.cn	www.innofund.gov.cn

about 70.³ But firms active in medical industry should be far more than that number (Table 4).

How many biotechnology researchers or science and technology staffs are there in China? Here we only have another estimated number without supporting data, about 40000. Every year, there are about 4000 graduates trained in colleges and universities, one third of them go overseas to

get further professional training on biotechnology. Obviously, the biotechnology industry offered very limited jobs for graduate students with biotechnology degrees.

References

- Liu, Xielin and Jinhui An (2007). 'Biotechnology Statistics: Publicly Funded Biotechnology R&D Programs in China' based on presentation at the Asian Biotechnology, Innovation and Development Initiative (ABIDI), January 25, 2007 at New Delhi.

³ www.ccd.org.cn/Data on firms approved to manufacture drugs and medical equipments can be searched very exactly.

Indian Biotechnology Industry: An Overview

Shalini Gupta*

The Indian Biotechnology Industry is on a growth curve. Clearly the industry has attained critical momentum and is on the roll. This is further evident from the fact that about 7-8 years back there was no biotech industry to speak of in India. Biotechnology was confined mostly to a few dozen national research laboratories and universities along with a few enterprising entrepreneurs. But the 21st century ushered in major developments and the entire scenario changed. The first wave of biotech entrepreneurship started in 1999-2000. At that point of time there were about 75 companies with not much of revenues to speak of, where as, by 2005 the number of companies climbed up to 200 generating revenues to the tune of \$1 Billion.

In 2003, both BioSpectrum magazine, a CyberMedia Group Publication, and ABLE (Association of Biotechnology Led Enterprises) were born and together and both the institutions decided to map the biotech industry. In September 2003, the first ever biotech industry sizing was unveiled—about 150 companies and \$400 million (Rs 1,8400 million) in revenues. In 2006-07 industry

crossed the \$2-billion mark. This has mainly been possible due to the Indian government's support to the biotech industry through streamlined regulatory framework and policies and fiscal benefits. The approval path of biogenerics has been smoothened; the national biotech strategy is awaiting final approval and other regulatory hurdles are being cleared. Although challenges still remain like the industry is still awaiting clear guidelines on transgenic food products and there is still just one transgenic bioagri product (Bt Cotton) in the market.

The year 2006-2007

The industry in 2006-07 has witnessed a lot of action. Globalization, alliances, investments, and product launches happened during the year. Fiscal 2006-07 can easily be termed as the year of GMP-Globalization, Maturity, and Products. These three elements have been the pillars on which the biotech industry continues to make progress. Each and every action of the industry demonstrated these three characteristics. Be it sales, human resource, expansion, diversification, products, or services.

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Table 1: Biotech Industry Revenue 2002-06

	2002-03	2003-04	2004-05	2005-06	2006-07
Biopharma	1790	2752	3570	4708	5973
BioServices	135	275	425	720	1102
BioAgri	110	130	330	598	926
BioIndustrial	235	238	320	375	395
Bioinformatics	75	80	100	120	145
Total	2345	3475	4745	6521	8541

Source: Biospectrum, Issue June 2007.

The industry in 2006-07 clocked \$2.08 billion (Rs 85410 million) in revenues, registering 30.98 percent growth, over the previous year's figure of Rs 65210 million (\$1.45 billion). Sustaining a 30 percent growth for five continuous years, and that too on a figure of Rs 65210 million, means the industry is maturing. The biopharma segment still accounts for over two-thirds of the industry. During 2006-07, it has recorded sales in excess of \$1.45 billion (Rs 59730 million) and accounted for 71 percent of the total industry revenues (Table 1). The biopharma sector registered 26.87 percent growth. The biotech industry in India, mainly consisting of five distinct segments—biopharma, bioagriculture, bioinformatics, bioindustrial and bioservices—had over 325 companies contributing to the growth of the sector in 2006. Nearly 40 percent of the companies operate in the biopharma sector, followed by the bioservices (21 percent), bioagri (19

percent), bioinformatics (14 percent) and lastly the bioindustrial sector (5 percent).

The biotech industry relies on exports to get its revenue. The share of exports has increased to 58 percent in the passing fiscal from 51.5 percent in 2005-06, generating Rs 49370 million in revenues. Biopharma's exports accounted for over 61 percent of the market share (36730 millions) while bioservices contributed to a fifth of the exports (Rs 10520 million) (Table 2 and Figure 1). The bioservices sector registered 53 percent growth. The bioagri sector grew by 54.85 percent to Rs 9260 million. Rasi Seeds and Nuziveedu Seeds accounted for 60 percent share of this market. The bioindustrial sector recorded a marginal growth of 5.33 percent to grow to Rs 3950 million in sales. Novozymes and Biocon accounted for 50 percent of the total bioindustrial market (Table 3 and Figure 2).

Table 2: Biotech Industry Exports vs Domestic Sales

Sector	Biotech Related Revenues in Rs. Million		
	Exports	Domestic	2006-07
BioPharma	36730	23000	59730
BioServices	10520	500	11020
BioAgri	470	8790	9260
BioIndustrial	450	3500	3950
Bioinformatics	1200	250	1450
Total	49370	36040	85410

Source: Biospectrum, Issue June 2007.

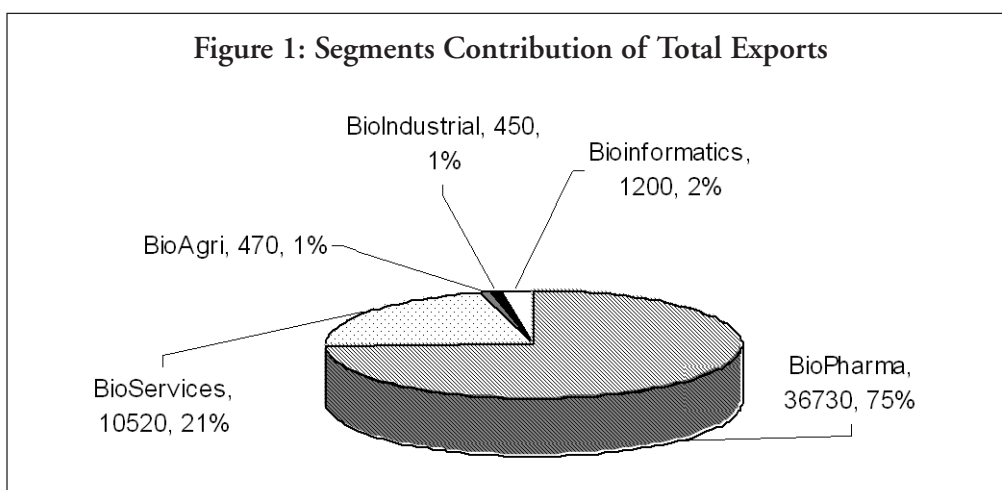
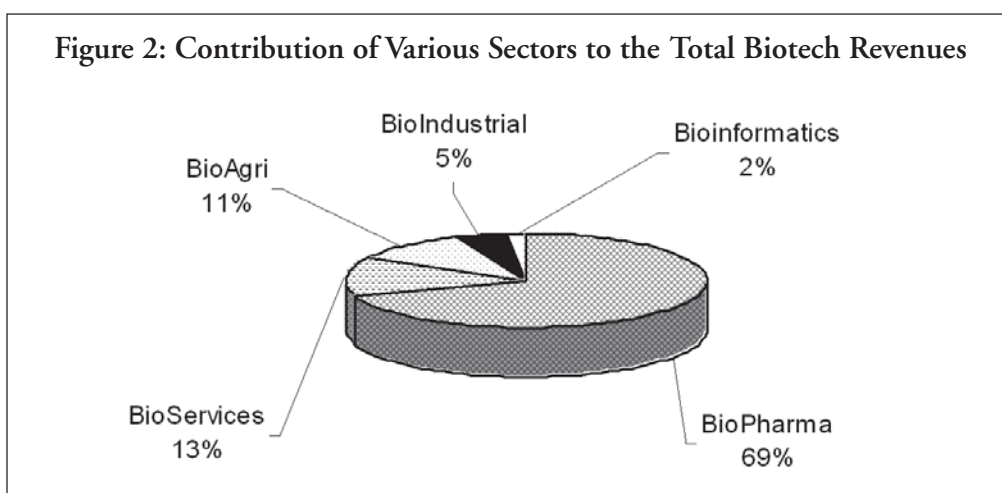


Table 3: Biotech Industry in 2006-07

Sector	Biotech Related Revenues in Rs. Million		
	2006-07	2005-06	% Change
BioPharma	59730	47080	26.87
BioServices	11020	7200	53.06
BioAgri	9260	5980	54.85
BioIndustrial	3950	3750	5.33
Bioinformatics	1450	1200	20.83
Total	85410	65210	30.98

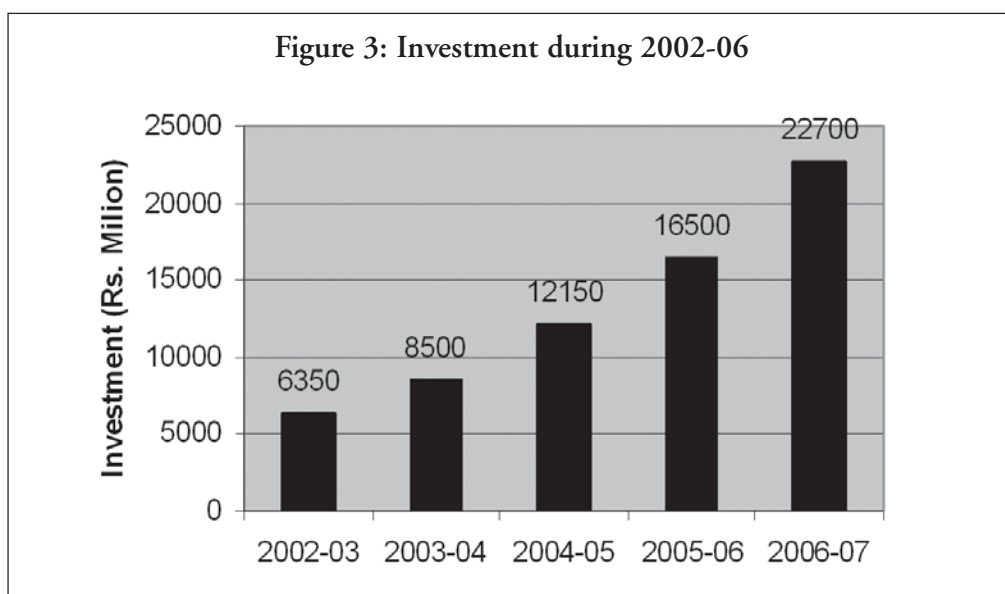
Source: Biospectrum, Issue June 2007.



Investments

The investments (both in R&D and infrastructure) in the biotech industry have been on the rise over the past five years. In 2006-07, the investments crossed Rs 22700 million, up by almost 38 percent compared

to the previous fiscal. The research intensive biotech industry currently employs about 20,000 scientists and is concentrated in six major clusters in Bangalore, Hyderabad, Chennai, Pune-Mumbai, Delhi and Ahmedabad-Vadodara (Figure 3).



Mergers and Coalitions

Further, global alliances and merger and acquisition efforts have taken center stage. For example, Merieux Alliance has strengthened its presence in Asia by acquiring a majority stake in Shantha Biotechnics Ltd, which is focused on vaccines, therapeutic proteins and monoclonal antibodies.

Panacea Biotec, the second largest vaccine producer of India, signed an agreement with PT Bio Farma, Indonesia, to manufacture and market the measles vaccine. As per the terms of agreement, Panacea Biotec will procure the bulk vaccine from PT Bio Farma and formulate it into a finished product. This collaboration will help boost Panacea Biotec's revenues and profits besides widening the product range.

Reliance Life Sciences Pvt Ltd (RLS), a flagship company of Mukesh Ambani's Reliance Group, will invest to the tune of Rs 2790 million in GeneMedix, a UK-based biopharmaceutical company, to take the latter's biosimilars through to launch in the EU and the US.

Serum Institute Ltd, the largest manufacturer of vaccines in India, has picked up a 14 percent stake in the UK-based Lipoxen, a biopharmaceutical company specializing in the development of differentiated biologicals, vaccines and oncology drugs. Lipoxen has raised £2.6 million in new funds from the Serum Institute of India through a subscription agreement and associated warrant agreement.

Serum Institute also entered into another agreement with Akorn of the US for definitive development and exclusive distribution rights for rabies monoclonal antibody. As part of the agreement, Serum has agreed to appoint Akorn as the exclusive distributor for rabies monoclonal antibody. In exchange for Akorn receiving the exclusive marketing and distribution rights to North, Central, and South America, Akorn has agreed to help fund product development through milestone payments.

Biocon's Syngene entered into a research partnership with Bristol-Myers Squibb to provide R&D services for discovery and early drug development.

Bristol-Myers Squibb will also increase the scope of its existing relationship with Syngene to further develop integrated capabilities in India in medicinal chemistry, biology, drug metabolism, and pharmaceutical development.

Wockhardt has signed an in-licensing agreement with Advanced Biotechnologies of USA to market Kelocote, a patent protected product to treat scars. Wockhardt plans to launch Kelocote in India in the third quarter of 2007. This gives Wockhardt an entry into the anti scar market, a high potential market. Wockhardt has also entered into a marketing agreement with Bharat Biotech.

Alembic Ltd, a pharmaceutical major in India, has entered into a licensing agreement with Brussels-based UCB for its novel drug delivery platform, Keppra XR (Levetiracetam Extended Release Tablets). UCB is a leading global biopharmaceutical company in the area of central nervous system (CNS) disorders, respiratory diseases, immune and inflammatory disorders and oncology.

Strides Arcolab announced the acquisition of Diaspa's USFDA approved fermentation facility in Italy. The acquisition will spearhead its foray into the niche fermentation business and also facilitate backward integration for significant part of Strides' dosage form business.

Intas Biopharmaceuticals has entered into a strategic R&D agreement with the US-based Virionics Corporation for development of Human Papilloma Virus (HPV-16 & HPV-18) therapeutic vaccine, useful for treatment of cervical cancer. It has also signed an MoU with Viropro Inc. to jointly explore the possibilities of

production of an undisclosed molecule. Intas Biopharmaceuticals has also entered into a joint venture with Progenetics LLC, a US based company that has created transgenic animals producing Factor-IX (a drug used for treatment of Hemophilia-B), in milk. As per the agreement, Intas Biopharmaceuticals would develop drugs from such transgenic animals, carry out clinical trials and launch the drugs in India and in overseas markets.

Nicholas Piramal India Ltd (NPIL) and Eli Lilly and Company have signed a landmark new drug development agreement to develop and, in certain regions, commercialize a select group of Lilly's clinical drug candidates that span multiple therapeutic areas. The NPIL-Lilly alliance seeks to increase productivity in drug development by synergizing the unique strengths of both companies and equitably sharing risk and reward.

GSK India has tied up with TCS, for a data management deal, where GSK's worldwide clinical trial data would be managed by TCS. Avestha Biotherapeutic and Research Pvt Ltd (ABRPL), a joint venture between Avesthagen and Meditab Specialities Ltd of Cipla group, signed an MoU with Malaysian Biotechnology Corporation to enhance the infrastructure needs with an objective to accelerate its 11 biosimilar product development programs.

Products Galore

Today there are close to 17 recombinant products approved for marketing in India, according to Indian GMO Research Information System (IGMORIS), compared to 12 in 2005-06. Several new and innovative products have been launched. In fact, all the top Indian and

global companies have launched one new product.

Serum Institute of India Ltd has launched its indigenously developed HIB vaccine. It has a capacity to produce over 100 million doses of the vaccine. Serum Institute will supply this new age HIB vaccine to GAVI (Global Alliance for Vaccines and Immunization), PAHO (Pan American Health Organization) and UNICEF.

Biocon launched BIOMAb-EGFR, a therapeutic monoclonal antibody-based drug for treating solid tumors of epithelial origin, such as head and neck cancers in September 2006. This is an indigenously developed product. "This drug is the first of its kind to be clinically tested in India and is the first anti-EGFR humanized monoclonal antibody for cancer to be made available anywhere in the world," said Kiran Mazumdar-Shaw, CMD, Biocon Ltd.

Panacea Biotec launched Siropan for renal disease management, Lower A for dyslipidaemia, Myelogen Forte and Inrica for neuropathy, TOFF Expectorant and Toff DC for cough and cold, Upright SP for pain management, Trepro for cardio vascular disease and a total range for diabetes management.

In January 2007, Dabur Pharma launched Nanoxel, a new version of an existing anti-cancer drug Paclitaxel, which is a nanoparticle-based formulation. The new drug can be delivered in higher doses while reducing side effects associated with chemotherapy. The generic anti-cancer drug paclitaxel is not usually soluble in water or blood, and so must be administered to patients in a castor oil-based solvent called cremophor that itself can cause dangerous side effects.

Hyderabad-based Bharat Biotech International has launched an anti-rabies vaccine, Rabirix, for both prophylactic and therapeutic treatments. The company is also in the process of developing vaccines against rotavirus and malaria. It invested Rs 270 million for developing vero cell-based anti-rabies vaccine and got the rabies strain from US-based Centre for Disease Control and Prevention (CDC). Rabirix is chromatographically purified to reduce cellular DNA content and foreign protein content. Dr Reddy's Laboratories announced the launch of Redituxa, the Dr Reddy's brand of rituximab, a monoclonal antibody (MAb) used in the treatment of Non-Hodgkin's Lymphoma.

The Future

Based on the current trends, the forecast for 2010 is that the Indian biotech industry would boast of over 400 companies, of which nearly 10 biotech companies will go public and another 50 companies will be on a high growth curve. The size of the biotech industry would be about \$5 billion revenue, with about 100 biotech (domestic and imported) products in the market and there will be about 50,000 technologists working in the biotech labs.

The figures and data above has been taken from a survey conducted by Biospectrum in May 2007, published in June 2007. BioSpectrum conducted this survey in association with the Association of Biotechnology Led Enterprises (ABLE). BioSpectrum and ABLE have jointly been doing this exercise since 2003. A detailed questionnaire (survey form) is sent to over 450 companies to capture the needed information for the analysis.

Biotechnology in Indonesia: An Overview

Bambang Purwantara*

Indonesia is in the preliminary stage to deal with the biotechnology statistics. In year 2006, its population reached about 240 million people. With the growing population, Indonesia had been facing several constraints like increasing agricultural production, etc. As shown in Table 1, Indonesian estimate of area needed based on the need for food. As the population is increasing there should be an increase of food availability.

In Indonesia, agriculture biotechnology is fast growing in terms of research in comparison to application and

trade. Table 2 provides data on which institutions are involved in biotechnology research including the University Research Centre for Agriculture, Indonesian Institute of Science and so on. So, for rice, for instance, several traits have been done in the research part and then also corn, soybean, sweet potato and potato. This is just to have an overview. Also, we have food crops and vegetables like kasava for industry. This is not mainly for agriculture but for industry in terms of food industry. Peanut and cabbage are also a part of the study. Also we have papaya under the network of ADSP too. And then we have citrus research activity in Bali.

Table 1: The Estimate of Land Area Extension needed based on the Need of Food in Indonesia (2005-2010)

Commodity	Production 2005 (mill. tons)	Additional Need 2005 – 2010 (mill. tons)	The Need of land area extension (000 ha)
Rice	32	2.4	1,000
Corn	12.4	1	400
Soybean	0.8	2	2,000
Peanut	0.8	1	1,000
Sugarcane	2.2	1.6	400
Fruits	15.1	3	200
Vegetables	9.2	0.5	20
Biopharmaca	*	0.1	5
Livestock	*	0,40 cattle head	<u>50</u>
Total need of land area extension 2005 - 2010			5,070,000

Source: Sumarno, 2005.

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Table 2: Indonesian Biotechnology Information Centre

Food crops and vegetables			
Rice	Resistance to rice brown plant hopper	ISI	Pending
	Resistance to rice stem borer	ISI	Transgenic lines in the contained trial
		IAARD	Transgenic lines in the contained trial
	Resistance to rice tungro diseases	University (UNS)	gene Sequent encoded "coat protein" of tungro
	Resistance to rice Blast Diseases	ISI	T3 transgenic lines in the contained trial
	Resistance to stress water	ISI, IAARD	genes constructs
	Antigen for human diseases	ISI	Planning
Corn	Resistance to Asian Corn Borer	IAARD	Pending
Soybean	Resistance to pod borer	IAARD	T3 transgenic lines in the contained trial
	Increase albumin content	University (UNUD)	Transgenic lines in the contained trial
	Increase yield	University (UNUD)	Transgenic lines in the contained trial
Sweet potato	Resistance to sweet potato weevil	IAARD	Pending
	Ketahanan terhadap penyakit virus	IAARD	Pending
Potato	Resistance to potato tuber moth	IAARD	Pending
	Resistance to PVY virus	University (BAU)	Pending
	Resistance to fungal diseases and	University (BAU)	Plantlets
	nematodes Resistance to bacterial diseases	University (BAU)	Plantlets
Cassava	Amy lose free	ISI, IAARD	Contained trial
Peanut	Resistance to PStV	IAARD, University (BAU)	Transgenic lines in the contained trial
Cabbage	Resistance to leaf diseases	University (GMU, UNAIR)	Transgenic lines in the contained trial
Fruit crops			
Papaya	<i>Delay ripening</i>	IAARD	Transgenic lines in the contained trial
Citrus	Resistance to CVPD	University (UNUD)	Transgenic lines in the contained trial
Forest or estate trees			
Teakwood	Levy plant stay green	University (ITB)	Plantlets
	Resistance to insects	Private	Pending
Cacao	Resistance to fruit borer	IAARD	Genes construct
Coffee	Resistance to rust	IAARD	Plantlets
Sugarcane	Sugar content	Private	Transgenic lines in the contained trial
	Resistance to stress water	Private UNES	Confined field trial Genes construct

Microbe			
Fungi	Genetic diversity of plant fungal diseases	IAARD	Genetic distance of <i>Phytophthora palmivora</i>
	Genes encoded chitinase	IAARD	Clone of chitinase gene
Bacteria	Over expression of thermophilic enzyme	University (ITB)	Mutant over expression
	Cloning genes encoded insecticidal toxin from <i>Photobhabdus</i> sp.	IAARD	On going
Livestock Biotechnology			
Chicken	Quantitative Traits Loci mapping Bird Flu Vaccine	University (UNDIP) University (IPB)	QTL map of local chicken
Cattle	Mapping of genes related to meet production	University (UNS)	RAPD polymorphisme
	Mapping and cloning genes for improving local cow	University (UNIBRAW)	
	Selection on local cow produce high meet using molecular marker	ISI	Target genes identified
Sheep	Resistance to pathogenic nematodes	IAARD, ISI	Segregate analysis for back cross using informative primers

Note: ISI: Indonesian Science Institute

IAARD: Indonesian Agency for Agricultural and Research Development

University: (UNS=University of Sebelas Maret, BAU=Bogor Agricultural University,

ITB=Institut Teknologi Bandung, UNUD=Universitas Udayana,

UNIBRAW=Universitas Brawijaya, UNDIP=Universitas Diponegoro,

GMU=Gadjah Mada University,

UNAIR=Universitas Airlangga)

In Indonesia, we have also the forest and estate trees biotechnology research and development and also estate crops like cocoa, coffee, sugarcane and so on. Microbes are used mainly for enzyme production and fungi. This is also for industrial purposes. Livestock is quite okay with some of the genetic or molecular biology research activities over there. Some of them are related with animal diseases, in sheep for instance.

Bhagyavati et al. 2006 provides the estimated cost of research and development

and showed that small funding is available from the government and different sources internally and externally (Table 3).

The four commodities which are very much in line with the food stability or food security – potato, citrus, sugarcane and rice – which have four different institutions, two universities, two other Department of Agriculture Research Centres and government owned company attached to the Ministry of Agriculture (Table 4).

Table 3: Estimate costs of selected transgenic plants R&D

Crop	Target traits	Thousand USD
Potato	Fungi /nematode resistance	650.8
Citrus	CVPD resistance	641.4
Sugarcane	Drought tolerance	255.1
Rice	Stemborer resistance	1466.1

Source: Bahagiawati et al., 2006.

Table 4: Cost of R&D of transgenic crops by institution

Crop	Institution	Period	Cost (\$ US)
Potato	Bogor Agricultural University	1994-2004	650.8
Citrus	Udayana University	1997-2004	641.4
Sugarcane	PTPN XI (Government owned Company)	1999-2002	255.1
Rice	Indonesian Institute of Science	1996-2002	1466.1

Source: Bahagiawati et al., 2006.

Table 5: Cost of R&D of biotech by private sector (very limited information – also confidential)

Company	Location	Investment (in thousand \$ US)
X	Crop, food and feed	5000
Nugen	Crop and food/feed	8-10000
IPB-Shigenta	Bird flu vaccine	2000

The bird flu vaccine has started to be developed in collaboration with ITBC-Junta. It is non-cigenda crop industrially by the Japanese supported animal health company combined with the university to invest on bird flu vaccine in chicken (Table 5).

The development of industry, especially biotechnology industry in Indonesia depends on how the regulation takes place. Few years ago, due to the Monsanto scandal the government is hesitant to support any regulation takes

Table 6: Legal status on assessment and use of bioengineered products in Indonesia

Commodity	Desired traits	Applicants	Contained Facility	Confined Field Facility	Multi location trials	Recommendation of BSFSC
Corn	Insect resistance	DuPont/Pioneer	On going	–	-	–
	Insect resistance	Monsanto	Done	Done	Done	Safe to environment
	Herbicide tolerance	Monsanto	Done	Done	Done	Safe to environment
Cotton	Insect resistance	Monsanto	Done	Done	Done	Commercial release
	Herbicide tolerance	Monsanto	Done	Done	Done	Safe to environment
Soybean	Herbicide tolerance	Monsanto	Done	Done	Done	Safe to environment
Cotton	Insect and Herbicide resistance	Monsanto	Done	Done	-	-
Ronozyme	Feed additive	Rondo	-	-	-	Safe to environment
Phytase	Feed additive	Bhen Mayer	-	-	-	Safe to environment

Source: Mulya et al., 2003

Table 7: Estimate Costs to Comply Biosafety Regulation (direct costs)

Crop	Proponent	Cost (\$ US)*
Rice (stemborer resistance)	IIS/ICABIOGRAD	29.2
Sugarcane (drought tolerance)	PTPN XI	24.1
Bt cotton	Monsanto	99.9
RR-corn	Monsanto	14.1

* Not include food/feed safety tests/trials

Source: Bahagiawati et al., 2006.

place in the country. So, it has a snowballing affect to the industry and also to the research community.

Table 7 provides the estimated cost to comply with biosafety regulation which is only for direct cost and do not include the indirect costs like salary, electricity, water and so on which is sometimes belong to the government. Indonesia is still lagging behind in terms of capacity–building in research and development including the support of the government as well as the industry.

From last five to ten years good research has been done in Indonesia and graduates, Masters and Ph.Ds from abroad came back but the environment of research and development is not conducive to use their expertise and resource to be done maximally. There is a need to establish the statistics studies. We are working with different bodies and organizations to collect the data from different institutes and organizations but still we are at a very initial stage in terms of producing the statistics. Probably it is fortunate when we have defined the framework of collecting the

statistics we will just follow the consensus from here.

For cotton, we can see from the table 7, it is because BT cotton biosafety tests and trials have been done outside of Java. So, it is mostly in Sulawesi which is very costly in terms of transportation. The difference in cost is because the trait has to be analyzed or to be tested. Secondly the area, how wide and how far from the centre of the government because sometimes people just try to move people from one place to another. About 31 activities which have a long history of achievement, there are just three left. So, as you may understand, the economic crisis that still hits our country sometime puts the research and development in this area is also neglected. I mean people try to move to activities MORE acceptable to more wider group of people. I think it is as a matter of fact of lobby and how to make government understand about that. But some of them still continue close to the commercialize, near at least to test the product. But most of them aborted in some way at some step of the development.

Research and Development of Agricultural Biotechnology in Nepal: A Review

Durga D. Dhakal*
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Introduction

Research and development in agricultural biotechnology in particular is very new initiative in Nepal. There are few research and development efforts scattered in different private and public sector institutions. However, there is limited published data on the investment in researches from different donors. Scientists and researchers involved in agricultural biotechnology have expressed the need for an organised initiative in agricultural biotechnology in Nepal. Some of the research works carried out by public and private sector institutions are reviewed in this paper.

Biotechnology holds the potential for sustainable and environment friendly agricultural, industrial and economic development through adequate exploitation of abundant genetic resources and biological diversity found in Nepal. Since agriculture is the mainstay of Nepalese economy, research and development works on agricultural

biotechnology would accelerates economic growth in Nepal.

Traditional biotechnology of Nepal includes use of local yeasts to produce brewery products, fermentation of vegetable and vegetable products for producing pickles, production of dairy products and making of rope from Sun hemp etc.

Modern biotechnology in Nepal is comparatively in a state of infancy.¹ It includes tissue culture application for horticultural, medicinal, aromatic and ornamental plants, development of bio-fertilizers and production of mushrooms and livestock vaccines.² Some of the research works in this area are being carried out at molecular level as well. There are several ministries that are concerned with agricultural biotechnology; Ministry of Agriculture and Cooperative, Ministry of Forest and Soil Conservation, and Ministry of Environment, Science, and Technology. Following are the public institutions where research is carried out in one or the other aspects of agricultural biotechnology:

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¹ Tuladhar (2006).

² Rajbhandary and Ranjit (2001).

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

There is no definite Government authority, which looks after exclusively for biotechnology Research & Development (R&D).

Status of Biotechnology Research and Development

A. Plant Tissue Culture

Plant tissue culture activities have been carried out both in public as well as private sectors. Protocols for in vitro propagation of different plant species have been mostly developed by public laboratories whereas elite plants have been commercially produced by private laboratories using these protocols. Among the public sector laboratories, the prominent ones are:

1. Tissue culture laboratories of Department of Plant Resources (DPR)

DPR has developed protocols for tissue culture propagation of more than 100 plant species so far and run pilot project of producing 100,000 in vitro plantlets of

disease-free banana and citrus for distribution.

2. Nepal Agriculture Research Council (NARC)

For past several years, Potato Research Program (PRP) under NARC has been producing 200,000 virus-free pre-basic seeds of potato per year at its tissue culture laboratories and green house facilities at Khumaltar. Currently, PRP facilities are suffering from lack of qualified manpower to run the program efficiently. The Agriculture Botany Division of NARC has initiated some work on anther culture of rice and wheat and is planning to establish germplasm conservation and diagnostic facilities using PCR (Polymerase Chain Reaction) technology.

3. Horticulture Development Project of Department of Agriculture at Kirtipur

This department has once produced in vitro plantlets of apple rootstocks but the facilities remain unused at present.

4. Institute of Agriculture and Animal Sciences, Rampur

With the grant assistance from Rockefeller Foundation this institute has established moderate facilities for doing tissue culture work but it is limited for graduate thesis work.

Following tissue culture laboratories have been established so far in the private sector in Nepal:

1. **Botanical Enterprises Pvt. Ltd., Godawari** has undertaken in vitro propagation on many plant species such as orchid, potato, fodder,

- Chrysanthemum, Gerbera, African violet, Lily etc. At present, it is engaged in micro-propagation of aquatic plants and Phalanopsis which are shipped directly to the Netherlands.
2. **Nepal Biotech Nursery, Bhainsepati** has been producing banana, orchid and ornamental plants by tissue culture and non-sterile sand rooting technique.
 3. **Research Laboratory for agriculture biotechnology and biochemistry (RLABB) Maitidevi:** RLABB has once developed tissue culture propagation techniques for pine, *Artocarpus*, *Brassica* and anther culture of cold-tolerant rice. It also has good facilities for DNA work by PCR technology and enzyme analysis. At present, the facilities are used both for research and teaching purposes.
 4. **Microplants, Kamal Pokhari** specialises in commercial propagation of many plant species such as banana, orchid, lily, mums etc.
 5. **Green Research and Technology (GREAT, NEPAL) , Baneshwor** is developing virus testing and elimination facilities on horticultural crops such as potato, citrus, banana, cardamom, strawberry and some ornamental crops using tissue culture technologies. It also provides training on virus testing using DAS-ELISA and biological indicator plants for the diagnosis of Asian citrus greening disease or Huanglongbing. Recently, it has helped nurserymen develop CTV and CGD-free plants of mandarin orange grafted on tissue cultured rootstocks of trifoliolate orange (*Poncirus trifoliata*) under screen. Grafted mandarin plants thus produced were found to be free from citrus Tristeza virus (CTV) by DAS-ELISA and from Asian CGD by PCR. It has recently cleaned two potato cultivars from Bangladesh namely Petronese and Multa from potato viruses such as PVX and PVY. It has also cleaned three leading cultivars of large cardamom (*Amomum subulatum*) namely Ramshahi, Golshahi and Dambarshahi from Chhirke and Furke viruses.
 6. **Himalayan Botanical Research Centre (HIMBORCE), Machhegoan:** This centre has been recently established to micro-propagate medicinal and ornamental plants indigenous to Nepal. It is embarking upon micro-propagation of *Gladiolus*.

B. Biofertilizers

Nepal Academy of Science and Technology (NAST) has developed *Rhizobium* Inoculant Technology for pulses, as well as Microbial Inoculant Technology for composting. It has also initiated works on molecular studies on genetic variation of rhizobia. NAST is also engaged in the use of ecto and endo-mycorrhiza in conservation of forest soils. With the widespread popularity of organic farming and with the growing demand of organic food including tea in Nepal and abroad, the academy has recently been engaged in quality production of organic fertilizers. In this respect, it is doing research on microbial inoculation to expedite composting, select best substrates for vermicomposting and study microflora of gut of red earthworm for vermicomposting and vermicasting.

Division of Soil Science, NARC has been producing and distributing legume inoculant packets for more than a decade. In 2004 alone, it has distributed 2,627 *Rhizobium* inoculant packets to the farmers for important pulse and pasture crops.

Research Centre for Applied Science and Technology (RECAST) has been engaged in improvement of traditional composting technology and improvement of Biogas production by using weeds such as *Eupatorium adenophorum* and Water Hyacinth.

Plant Pathology Division of NARC and Agriculture Technology Centre, Gwarko have been engaged in spawn production technology for mushroom culture using two genera namely *Agaricus* and *Pleurotus*. The latter institute is also involved in the production of Shitake mushroom and *Ganoderma*.

C. Biopesticides

At NAST, eight strains of *Bacillus thuriensis* have been isolated and identified from soils of different agro-climatic zones of Nepal. Out of these, three strains were found to be very effective in controlling a lepidopteran pest (*Pieris brassicae nepalensis*) of cruciferous vegetables. The academy also has been doing field trials of bio-pesticides in collaboration with Department of Agriculture, Ministry of Agriculture by using different indigenous pesticidal plants such as *Eupatorium adenophorum*, *Lantana*, *Azadirachta indica* etc.

D. Diseases diagnostics

Institute of Agriculture and Animal Science (IAAS), Rampur has been engaged in

molecular work on diagnosis of viral and bacterial diseases in rice. NAST has been engaged in diagnosis of Citrus Greening Diseases or Huanglongbing of citrus using Polymerase Chain Reaction (PCR) based diagnostic technique, and diagnosis of *Citrus tristeza* virus disease using Double Antibody Sandwich Enzyme Linked Immunosorbent Essay (DAS – ELISA) technique for the study of distribution of *Citrus tristeza* virus in Nepal.

E. Animal Biotechnology

In animal biotechnology, in the livestock sector, initiation of Vaccine production against P.P.R. (Pestes des petites Ruminant) and rabies using tissue culture has just started at Central Veterinary Laboratories at Tripureshwor. NARC has been doing embryo transfer and artificial insemination in cattle.

F. Molecular characterization of plants and micro-organisms

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. The genetic diversity of all living organisms also must be very interesting to study. With the entry of Nepal in WTO, it has become compulsory to identify living organisms including plants at genetic level. NAST has initiated research work on molecular characterization of medicinal plants such as *Swertia chirata*, *Camellia sinensis*, etc and some important micro-organisms such as *Bacillus thuriensis*.

NARC has been engaged in genetic diversity analysis of *Fagopyrum spp*s (wild, sweet and bitter buckwheat) using randomly amplified polymorphic DNA (RAPD), genetic diversity analysis of isozymes in eight indigenous crops such as rice, finger millet, barley, pigeon pea, buckwheat, Taro, cucumber, sponge gourd, citrus and *Swertia spp*.

The IAAS has been working on molecular characterization of 200 local landraces of rice and MAS for blast, bacterial blight and Tungo virus resistance, and MAS for leaf blight of wheat.

Biotechnology and Biosafety Policy

- Ministry of Environment, Science & Technology submitted a Biotechnology Policy in 2002 and it was approved by the government in 2006.
- The Ministry of Forest & Soil Conservation is developing the Biosafety Policy, legal and administrative framework to safeguard the biological diversity, human health and environment from the adverse effects of GMOs & their products in accord with the CBD CPB.

Human Resources and Capacity Building

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.³ 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.

Conclusion

Research and development in agricultural biotechnology is very new initiative in Nepal. However, it lacks organised and continued efforts in both public and private sectors. The pace of development is very slow. The main achievements in agricultural biotechnology in Nepal are in tissue culture/ micro propagation and bio-fertilizers. Lack of funds for research, institutional infrastructure including human resource, and lack of interest by the industries towards collaborating with research institutions are the key factors hindering the R & D in agricultural biotechnology in Nepal. It is high time that the state realizes the importance of this field and allocate adequate budget for research and development. Because of the lack of adequate infrastructure and lack of adequate funding, there is an increasing trend of brain drain especially in this field.

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³ Tuladhar (2006).

Status of Biotechnology in the Philippines

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The Philippine Council for Advanced Science and Technology Research and Development (PCASTRD) is under the Department of Science and Technology (DOST) and was created in 1987 by the Executive Order with the mandate to develop, integrate and coordinate the advanced science and technology sector which includes biotechnology.

The Philippines is one of the mega-diversity countries of the world. It is one of the early starters in biotechnology among developing countries in Asia. In 1979, BIOTECH was established as a dedicated R&D organization at the University of the Philippines Los Baños to be able to exploit the various prospects and applications of biotechnology in agriculture, industrial, environmental and forestry. Sometime in 1985 to 1989, DOST undertook some preliminary projects relating to genetic modification. So, there were attempts to do gene cloning and other molecular biology projects. In the early 1990s biotechnology was already identified as a priority of the Philippine government.

In 1990, National Committee on Biosafety of the Philippines (NCBP) was created through Executive Order No. 430 and appeared first among the developing countries in Asia apart from Japan. NCBP acted as the regulatory body for biotechnology research. In 1991, the first genetic engineering project was started at the International Rice Research Institute (IRRI), the Philippines and in 1992-1997, the first locally-funded genetic engineering project was conducted at the BIOTECH and Institute of Plant Breeding. In 1995, it was decided that to really benefit from the potential of biotechnology National Network for biotechnology R&D was set up at four campuses of the University of the Philippines through Presidential Proclamation 529, which would be channeling the efforts along specific areas. For example, the UP Los Baños would be focusing on agribiotech and also some on industrial. UP Diliman would be doing more of the industrial biotech, while UP Manila, would be focusing on medical biotechnology and UP Visayas which is in the central part of the Philippines would be for aquatic biotechnology.

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In the 1997, again another policy directive came. This was with the enactment of the Agriculture and Fisheries Modernization Act. By this law, four per cent of the R&D budget of the Department of Agriculture was supposed to be allocated to biotechnology. In 2002, commercialization guidelines was issued by the Development of Agriculture through Administrative Order No. 8.

In December 2002, first GMO product (Bt corn) was commercialised. This was the product from private company Monsanto.

In 2006, National Biosafety Framework came which aimed to really harmonise and synchronise the regulatory tasks that are actually earlier distributed between the Department of Science and Technology and the Department of Agriculture into a more synchronous setup, with the NCBP now really being on top of the whole regulatory system as an oversight body. The NCBP actually is an attached unit of the Department of Science and Technology.

As far as human resources are concerned, in 1998, because of the recognition of the good potential of biotechnology, PCASTRD agency conducted a survey of about 10 institutions spread across the country. According to

their count, there were 346 M.Sc. Degree holders biological sciences and 301 Ph.D. holders in the biological sciences. Of course, as mentioned earlier, this does not really directly correlate in terms of capacity to do research or to develop biotechnology products (See Table 1). But this is an easy way to more or less have a profile of the Philippines potential.

Another agency of the Department of Science and Technology (DOST) conducted a survey on agricultural biotechnology experts and according to their count there were something like 105 experts who are involved in modern biotechnology and about 212 experts in conventional biotechnology. The survey was actually limited only to seven research institutes.

As far as having biotechnology research leaders, in 2003 another survey was conducted and it counted that there were a total of 44 senior researchers involved in the Philippines biotechnology R&D sector in different institution. That would mean about 44 ongoing projects in biotechnology at that time.

In the Philippines, there are two key institutes involved in biotechnology management programme, viz. the DOST, created through the Executive Order 128 and the Department of Agriculture which

Table 1: Highlights of the Philippines Biotechnology R&D Sector, 2003

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

Source: Halos, 2003.

gets its mandate through the Agriculture and Fisheries Modernization Act which work with different research techniques (Annex 1). DOST manages the biotechnology sector through its five Sectoral Planning Councils that plan, fund, and coordinate the research agenda. These includes:

1. Philippine Council for Aquatic and Marine Research and Development (PCAMRD);
2. Philippine Council for Agriculture, Forestry and Natural Research and Development (PCARRD);
3. Philippine Council for Advanced Science and Technology Research and Development (PCASTRD);
4. Philippine Council for Health Research and Development (PCHRD); and
5. Philippine Council for Industry and Energy Research and Development (PCIERD)

Apart from these agencies, we have the DOST Central Office which administers a grant-in-aid (GIA) programme. The DOST-GIA is also very significant funding actually.

In Philippines, the data on biotechnology are really spread out across the government. Government is the main funding agency and actually also the higher institutes of education, with the U.P. System as the primary R&D hub and some other State Universities located in the provinces which may be doing more traditional biotechnology or a little of the mid level biotechnology. The first of our data as far as this summary is concerned actually involved something like eight funding units or agencies and about ten of our R&D institutes. From here you can see that actually regardless of funding source, and regardless of implementing agency, all the application areas are actually covered. So, agriculture, health, industrial, environment, aquaculture and then we can go down to the molecular level with a lot of activities in genetic sequencing and determination of molecular markers at different institutes (Table 2). During the period 2002-2006, DOST, spent something like US \$ 4.7 million. The Department of Agriculture with its mandate for funding research had allocated US \$ 1.6 million. The State universities themselves actually have their own programme funds for research. Cumulatively just for the UP System alone, there is already something like 2.1 million

Table 2: Area of Application: Agriculture

Source of Funding	DOST	DA	State Universities
Total Amount of Funding (5 years)	US \$ 1608950	US\$ 1639664	US\$ 1496408
Primary Recipients of Funding	UP System, DOST-ITDI	PhilRicePCA ResearchCentre UP system	UP System
Implementing Agencies	PhilRice, DOST-ITDI, UP System	PhilRicePCA Research Centre UP system, DOST-PNRI	UP System

Table 3: Philippines R&D Funding: 2002-2006 (Amount in US\$)

	Agriculture	Medical	Industrial	Environmental	Aquaculture	Total
DOST	1608950 (50 projects)	2754053 (5 projects)	321802 (18 projects)	37844 (5 projects)		4722649
DA	1639665 (68 projects)					
Philippines Government Soft Loan	916500					
UP System	1496408 (139 projects)	447187 (25 projects)	86517 (23 projects)	86517 (23 projects)	20112 (5 projects)	2151239
Others (DOH)		31000 (4 projects)				
Total	5661523	323240	413041	408320	20112	9461053

dollars (Table 3). We have identified some organizations, some entities which have provided cost-sharing or collaborative funds. But in reality, the extent of funding of these agencies is very minimal compared to the totals. The data also covers private units in the area of agriculture and environment. The number mentioned are the minimum number of firms present in the Philippines (Table 4).

Apart from the Department of Agriculture's appropriations for R&D, the Philippine government through the Department of Agriculture actually also is able to allocate funds for R&D through the so called soft loans programme of the US.

This is covered by the Public Law 480 wherein some of the surplus commodities of the US government are supplied to the Philippines. When these commodities become cash, the cash that is generated from the sale of these commodities can now be channeled to R&D activities. There is a repayment programme. So, this is actually a soft loan. That channel of funding actually has generated something like US \$ 0.916 million.

One can see that of the total US \$ 9.4 million more than half actually goes to agriculture, while about one-third goes to medical and health-related research. For industrial, it is less than five percent and

Table 4: Number of Firms in the Philippines in Biotechnology Business

Sector	Area	Conv. Biotechnology	Modern Biotechnology
Agriculture	Seeds	Undetermined	5 (All TNCs)
	Biofertilizers	3	
	Tissue culture	4	1
	Probiotics	2	
	Animal Vaccines	1	
Environment	Water treatment	2	

Note: Numbers given in the table are the minimum number of firms present in the Philippines.

for the environmental also less than five per cent. Aquaculture is something very new. Below the numbers you can actually see how many projects are actually ongoing in terms of research.

There are some papers that have been studied on the environmental impact and also economic impact. As far as economic impact, as of now the coverage of Bt corn has moved from the initial 20,000 hectares to over 40,000,000 hectares. So, there is already a big increase in coverage from 2002 to 2007. As far as farmer benefits are concerned, there is a report here from an ex-ante analysis (Gonzales, 2002) prior to commercial release showing a yield advantage of as much as 41 per cent from Bt corn over non-Bt varieties with profitability gains of 15 to 86 per cent.

This was a study done in 2002. So, as far as the acreage, in 2003 when it was first really brought to the farmers fields there were 20,000 hectares which went up to 55,000 hectares in 2004 and presently increasing. As for the yield, yield increases have been noted by as much as 37 per cent which translates into an additional profit of about 10,000 pesos per hectare. Reduction of pesticide use has been estimated at about 60 per cent. This was based on a study by Yorobe and Quicoy in 2006.

References

- Gonzales, L. A. 2002. Harnessing the Benefits of Biotechnology: The Case of Bt Corn in the Philippines. SIKAP/STRIVE. Los Baños, Laguna, Philippines. 27 p.
- Yorobe, J. M. and Quicoy, C. B. September 2006. "Economic impact of Bt corn in the Philippines." *The Philippine Agricultural Scientist*. 89 (3); 258-267.

Annex 1: Yearly Agricultural Funding*
Per Biotechnology Technique: 2002-2006

Year	Biofertiliser			Biocontrol			Cell and Tissue		
	Plants	Animals	Aquaculture	Plants	Animals	Aquaculture	Plants	Animals	Aquaculture
2002	37809	-	-	697	-	-	67176	6270	-
2003	14719	-	-	14719	-	-	65565	3873	-
2004	18966	-	-	178	-	-	62535	-	-
2005	9873	-	-	488	-	-	172002	-	-
2006	6821	-	-	-	-	-	111605	-	-
Year	Protein and Other Molecules			Nanobiotechnology			DNA/RNA		
	Plants	Animals	Aquaculture	Plants	Animals	Aquaculture	Plants	Animals	Aquaculture
2002	20665	-	-	99192	16904	22761	366947	32943	19002
2003	-	-	-	29487	-	21764	286663	9224	18284
2004	-	-	-	-	-	21051	105820	20818	-
2005	-	-	-	-	-	-	267997	21179	-
2006	-	-	-	-	-	-	224055	-	-

Note: * Data from DA-BAR, PhilRice, BIOTECH-UPLB, DOST-PCARRD.

Biotechnology in Singapore

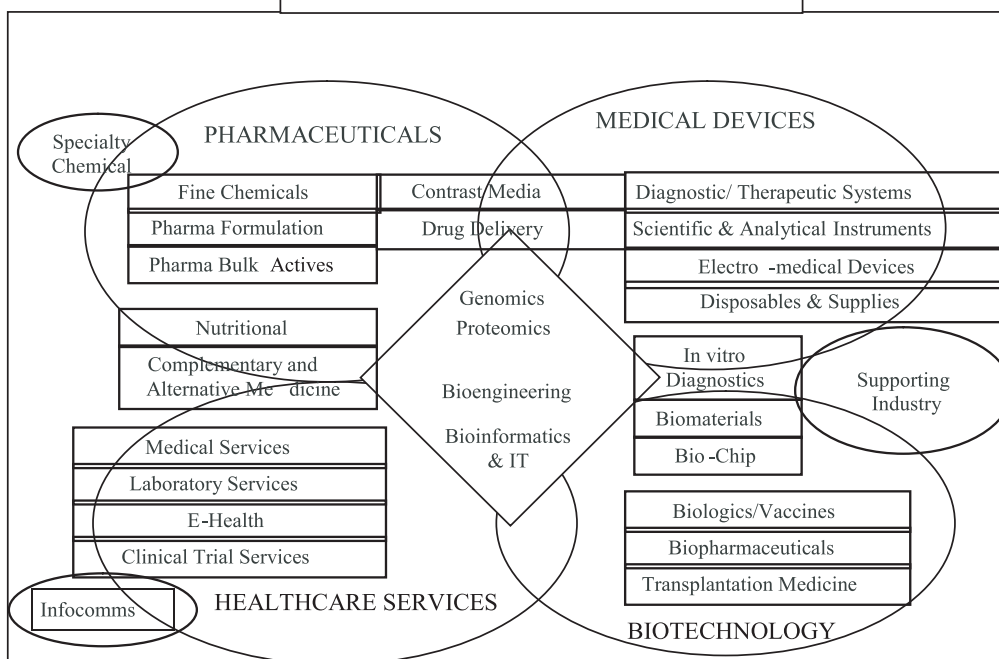
Phua Kai Hong*

In Singapore, there is virtually no agriculture sector. The life sciences is featured in the government's strategy as one of the pillars of the new economy, and going into the new millennium, the biomedical industry is targeted to be an engine of growth. Singapore has always emphasized its role as a financial hub, where there has been a lot of focus on business, but it has

recently positioned itself as the hub for medical care in the region.

Many innovative policies are driven top-down by government in Singapore, unlike the context that is presented in many other countries where government may become a hindrance. Here is a progressive government that is very pro-active, which seeks all those innovative programmes by

Figure 1 : Biomedical Sciences Cluster



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providing generous support and even subsidies, which attracts talent from the region and pays world-class salaries, and by hook or crook, makes things work. There is a strong political will to establish or restructure the major agencies that were responsible for driving economic development along with the life sciences and the biotech industry, as part of this strategy to develop Singapore into a global hub, building upon its position as a regional medical hub.

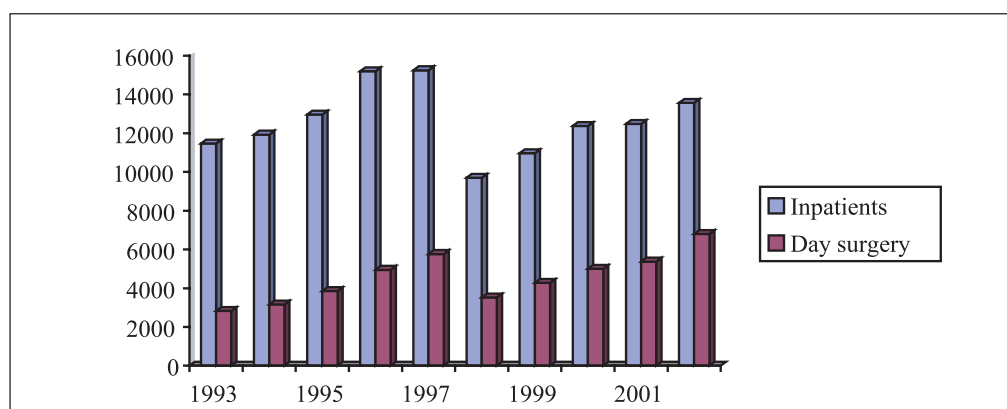
From this perspective, Singapore’s definition of biotechnology may be quite different from usual definitions of biotechnology or the OECD’s definition. Biotechnology is one of four areas that are categorized under the biomedical sciences cluster by the Economic Development Board (EDB) of Singapore. The other three areas are pharmaceuticals, medical devices and healthcare services. Essentially, the economic development policy is related to

strengthening the value chain of the healthcare industry. By developing Singapore into a regional hub for healthcare through aggressive marketing, the strategy is also to link the value chain backwards to production and manufacturing of medical technologies and more into basic value creation. In the recent past, the EDB launched a massive promotion to attract all the big pharmas and managed to do that quite successfully. Six of the largest pharmaceutical companies have located their plants in Singapore and invested hundreds of millions of dollars within the last five to ten years.

The current initiative by the Singapore government and the Singapore Tourism Board (STB) is really another marketing exercise to promote the “SingaporeMedicine” brand. This arose from the recommendations of the Economic Review Committee’s Health Services Working Group in 2003. Based on

Table 1: Foreign Patients in Singapore

Year	1992	1994	1996	1998	2000
Number of foreign patients 13291 (public & private hospitals)	12801	15844	10698	12746	
Total no. of hospital admissions	214657	235650	272186	270048	306880
% of foreign to total hospital admissions	6%	5%	6%	4%	4%



largely economic projections, the aim is to attract one million foreign patients with 1,000 daily admissions by 2012, generating \$3 billion in health expenditure or \$2.6 billion value-added to the economy, creating 13,000 new jobs and growing the market share from 1 per cent to 3 per cent of GNP (Table 1 and Figure 2). These ambitious targets for healthcare services have also spilled over to the biotechnology sphere, with the expected creation of new employment and value-added growth. The economic imperative is driven by the prospects of developing Singapore into a hub for medical tourism.

As can be seen from the data of top health care companies in Asia, a couple of Singapore-based companies are way up there in value creation (Table 2). They may not have higher turnover, in terms of the number of patients, as their competitors in neighbouring countries. For example, one hospital in Thailand (sBumrungrad) sees more foreign patients than the total in Singapore. But Singapore is competing on the basis of quality and value-added services, and not so much on the volume. This is a different business model, which is

of course, related to EDB's vision to develop Singapore into a global hub, providing a comprehensive range of world class value-added medical services.

In 2002, pharmaceuticals contributed \$8 million or 82% of the total manufacturing output in Singapore, while generating employment growth of 31%. Pharmaceuticals have actually monopolized the new investments in the biomedical industry. There is some success in attracting the big pharmas to integrate the production process backwards into doing clinical trials with the whole supporting infrastructure present. The intention is to promote basic R&D to be done locally so that pharmaceuticals can be developed for the region to tackle endemic diseases, and to tap the raw materials and talent pool from the region as well. The targets for the biomedical industry are now \$25 billion in manufacturing output with total value-added of \$12.5 billion, and employment of 15,000 workers by 2010 (Table 3).

If one look at the share of the biomedical industry in manufacturing, most of the data is basically secondary.

Table 2: Top Healthcare Groups in Asia

Company	Country	Sales (US\$m)	Market Capitalization (US\$ million)
Nichii Gakkan	Japan	535.1	3,768.1
Parkway Holdings	Singapore	228.3	1,003.6
Prasit Patana	Thailand	51.5	0.6
Bumrungrad	Thailand	42.6	5.7
Bangkok Dusit Medical	Thailand	36.3	15.1
Raffles Medical	Singapore	31.4	279.3
Pantai Holdings Bhd	Malaysia	30.1	186.3
KPJ Healthcare Bhd	Malaysia	28.3	40.8
Samitivej Public	Thailand	26.3	5.2

Source: Economic Intelligent Unit, Healthcare Asia Report - 2000.

Table 3: Growth of the Biomedical Industry in Singapore

	2004	2005	2010 Target
Employment (No)	9200	>10,000	15,000
Manufacturing Output(\$\$ billion)	15.8	18	25
Fixed Asset Investment (\$\$ billion)	849	860	
Total Value Added(\$\$ billion)	1.49	2.57	12.5

Source: Economic Development Board, Singapore.

Available statistics shows relatively successful growth targets, whether in employment or in manufacturing outputs, with much emphasis on the total value added. The bottom line is focused on the profitability of the industry and how biotechnology products can be commercialized in translational research. Thus, investment in R&D is not for its own sake, but to realize the value of the products that eventually enter the market. So, there is a lot of pressure on people doing empirical and basic research to show value creation. For example, it is not just enough to have a patent but to follow up a patent that goes on to be developed into a commercial product. Ultimately, the final test is to look at outcomes and not just intermediate outputs in biotechnology.

The government has been very instrumental in putting up venture capital for investments in the biomedical industry. More than \$10 billion dollars have been raised over the last twenty years along with the creation of many funds for joint ventures. Just recently, there was the launch of another \$7 billion for the next five years, after spending \$5 billion over the last five years. Singapore has also been very successful in attracting all the big names to invest in biotechnology. A few years ago, a huge science park for R&D, the Biopolis, was opened with all the latest state-of-the-art technology and infrastructure. Here again, Singapore has been very successful

in attracting whole research teams from the developed countries, including Nobel laureates, one of the two partners from the Dolly cloning experiment, as well as another Japanese team doing world-class research work. From the small trickle in the 1970s, investments in the biomedical industry did not grow much until the 1990s when major investments in pharmaceuticals began flowing in. In the last ten years or so, biomedical development has really taken off. Many pharmaceutical companies have relocated their manufacturing plants to Singapore and are starting to do clinical trials and basic R&D activities in the region.

Expenditure on R&D has suddenly taken off in the past decade (Table 4). As a

Table 4: Expenditure on R&D in Singapore

Year	EXP (\$\$ million)	GDP (\$\$ million)	EXP/ GDP (%)
1981	81.00	31004.7	0.26
1990	571.70	67878.9	0.84
1991	756.80	75320.9	1.00
1992	949.50	80997.50	1.17
1993	998.20	94258.70	1.06
1994	1174.98	108224.0	1.09
1995	1366.55	120628.8	1.13
1996	1792.14	132629.3	1.35
1997	2104.00	141216.9	1.49
1998	2492.30	141216.2	1.76
1999	2656.40	143814.4	1.84

Source: National Science & Technology Board

percentage, this has gone up to about two per cent of the GNP, and the policy is to push it up even higher. This is also reflected in the growing number of research and training institutes within the recent decade. Many of these, including the key ones, are all set up by government with very strong links to industry. A lot of these initiatives are public-private partnerships.

In the university, attention is given to the life sciences and the focus is on endemic diseases and the relevant platform technologies, linking education and research with training as well. Besides dishing out a lot of scholarships for PhDs, the government has sent many of the top scholars to all the major R&D centres throughout the world. Singapore has been attracting a lot of talent from the region - India, China and so on. Recently, even philanthropy and the private sector have donated huge endowments to go into medical research and education, both for the National University of Singapore (NUS) medical school as well as the joint Duke-NUS Graduate Medical School. Development of the biomedical industry and education, training and research are all coordinated to ensure that there is allocative efficiency and policy integration. Main initiatives in the biomedical sector at NUS are captured in box 1.

Singapore has developed knowledge technologies in many areas of cutting-edge research. For example, there is a research team that is doing world-class work on stem cells. The Singapore environment is kept conducive and open for innovative research but on the other hand, the authorities have to make sure that some of the social, legal and ethical issues are also addressed. There is a strong regulatory structure in place. Good governance is really the secret of Singapore's success. Transparency and accountability are present with the checks and balances and everything is seen to be well-regulated. Otherwise, no investors would come to risk their products being copied and intellectual property rights being lost. So, this is one area that the Singapore government does quite well, that is to protect intellectual property rights (IPR). The other factor in Singapore's favour is quality assurance, where high standards are guaranteed to guard against inferior or defective products, and to prevent corrupt practices or scandals from taking place.

In conclusion, the way the Singapore government or at least the EDB has classified biotechnology, seems to be very much a part of biomedical sciences and not the broader term as generally accepted. However, there is a lot that can be learnt from the Singapore experience in

Box 1: Biomedical/Life Sciences at the National University of Singapore

- \$30 million Office of Life Sciences
- Main biomedical thrust on basic mechanisms of human diseases prevention and treatment
- Main activities – 1) education, 2) research 3) training & recruitment
- New life sciences curriculum jointly launched by faculties of science and medicine in 2002
- Linkages with other institutes and centres
- \$100 million re-development of medical school
 - renamed the Yong Loo Lin School of Medicine

developing biotechnology as part of the biomedical industry. But the official statistics are quite dispersed and these are spread out in a few major government agencies. We will have to persuade the key people from these agencies to join in our initiative and perhaps with technical support from OECD, we may have a credible template to involve them. There are some databases in the public domain;

for example, the government has launched a biomedical researcher's database. Besides providing a reference directory on R&D activities, the basic data is available to be mined. They have also got a directory of company profiles that are listed along with some of their websites. So potentially, all these resources could provide a starting point for further collaborative studies on biotechnology in Singapore.

Biotechnology Statistics in South Korea: Methodology and Implications

Dongsoon Lim*
Youn-Hee Choi**

Introduction

Scientific discoveries in biotechnology are changing our world with new products and medical treatments, improved methods to provide existing goods and services, and, more importantly, shaping current industries into entirely new ones. Biotechnology and the bio-industry are new spheres filled with great potential to induce significant direct and indirect effects to the national economy by improving human health, enhancing industrial applications and their efficiency, food safety and production, and protecting the environment. In Korea, biotechnology and bio-industries are expected to become an important driving force in the future economy. Accordingly, there have been enormous expectations concerning the economic potential of biotechnology.

There have been some fundamental and applied researches done on estimating the size of the bio-industry and economic impact of biotechnology. Most researches are based on industry surveys with R&D surveys of the public and private sectors.

Some work has utilized data on companies listed on the stock exchange. Others have implemented sampling surveys to construct systematic and structural analysis of the bio-industry.

The results of the OECD Workshop on the Economic Impacts of Biotechnology, held in May 2004 in France, provided insightful methodological approaches to estimate the impacts and introduced some pioneering researches to expand the application of analytical tools and outcomes. One of the implications of the workshop was that there is a range of approaches using different definitions of biotechnology and the bio-industry, especially in the range of bio-industries, which possibly underestimate the range of bio-industries in advanced countries and overestimate the range in developing countries. The other implication includes that the economic impact would vary depending on the choice of modeling scheme.

This article introduces discussion on current Korean bio-industry statistics and

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measuring the economic impact of biotechnology and the bio-industry. We also present a brief discussion of non-economic and social impacts of the bio-industry in Korea. In addition, we attempt to estimate the economic impact of the bio-industry within the Korean economy by constructing a bio-industry augmented input output table (I-O) and to present the government's strategic plan for the future of bio-industry and expert opinions. Finally as concluding remarks, we present some findings and implications for future research.

Brief History of Bio-Industry in Korea: A Statistical View of Survey

Classification of Biotechnology Statistics in Korea

Choi, et al (2004) suggested more comprehensive and consistent classification systems for the Korean bio-industry statistics. They proposed a biotechnology classification system of thirteen key categories and a bio-

industry classification system of eight categories (Annex 2). The scope of the biotechnology classification system reflected the status of the domestic bio-industry. The bio-industry classification system, by which each firm's activity is classified into a specific sub-group, was designed to facilitate analysis of the bio-industry and the economic impact of biotechnology on the various industrial sectors.

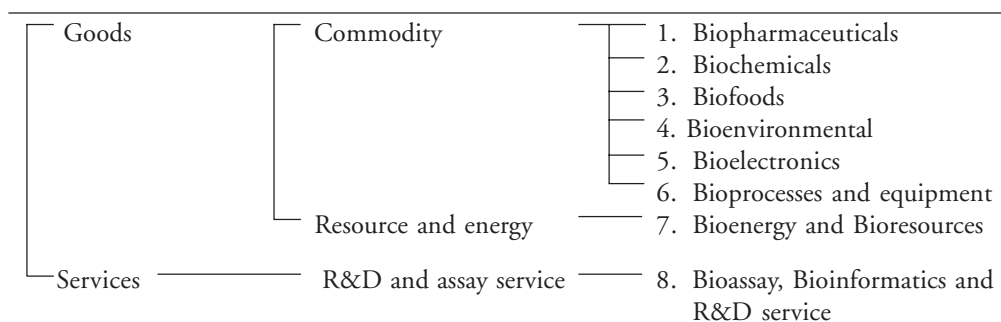
Those classification systems have been improved to create more stable structures of the bio-industry in Korea (Table 1). The biotechnologies are classified by the following criteria: the main value-chains used, and the object of the technology. The bio-industries are primarily classified into goods and services (Table 2).

Brief History of the Korean Bio-industry

According to the historical data on the bio-industry in Korea, obtained from the annual biotechnology firms survey, the

Table 1: Structure of the Biotechnology Classification System in Korea

Value chains	Purpose of the technologies	Key Biotechnologies
R&D	Biological Material and Cell	A. Genetic engineering B. Protein engineering C. Other macromolecular engineering D. Cell and tissue engineering
	Bioinformation analysis and application	E. Systems biology and bioinformatics F. Metabolic engineering
Production and Applications	Production	G. Bioprocess
	Biosecurity and sustainable development	H. Bioresource production and utilization I. Environmental and bioenergy J. Nanobiotechnology K. Bioelectronics
	Fusion	
Evaluation	Safety and efficiency	L. Biosafety and bioefficiency
Others		M. Other biotechnology

Table 2: Structure of the bio-industry classification system in Korea


Korean bio-industry has been growing rapidly (Table 3, Annex 3). The CAGR during the last 5 years is around 22 per cent. The major driving force behind the Korean bio-industry seems to be the synergy effect between enthusiastic governmental policies and the entrepreneurship of research-oriented companies.

Artuso (2002) classified Korea, Taiwan and Singapore by the following common features; (a) political support, (b) government-led funding opportunities for R&D to commercialize inventions and applications, (c) collaboration among federal and/or local governments, the public, universities, and the private sector, and (d) financial and business support for

new biotechnology companies, including venture capital financing and establishment of national centers.

In 2004, a total of 640 companies were active in the Korean bio-industry. According to the survey results (See Annex 1 for the format), a large majority of biotechnology firms in Korea are located in the Seoul Metropolitan Area, including Seoul and Gyeonggi Province, approximately 55 per cent of total firms. The locations of the domestic biotech firms, by headquarters, are as follows: Seoul, 22 per cent; Gyeonggi Province, 33 per cent; and Daejeon, 10 per cent. Some existing firms in different industrial sectors, including pharmaceuticals, chemicals, and

Table 3: Growth Rate of the Korean Bio-industry

Year	1999	2000	2001	2002	2003	2004	CAGR (99-04)
Biopharmaceuticals	30.02	4.94	28.47	-8.92	33.94	13.15	13.23
Biochemicals	-3.81	50.78	47.69	50.19	-11.18	42.51	33.46
Biofoods	-7.07	65.99	-10.72	91.03	3.40	14.91	27.46
Bioenvironmental	-33.44	41.62	138.88	45.56	-5.39	22.51	41.67
Bioelectronics	N/A	N/A	198.16	-10.80	-15.39	120.59	ii
Bioprocesses and equipment	41.12	10.02	66.17	79.36	-37.61	5.79	16.70
Bioenergy and bioresources	N/A	N/A	N/A	N/A	-68.43	-33.85	N/A
Bioassay, bioinformatics and R&D service	N/A	180.05	707.85	-7.61	37.53	47.01	111.44
Total	11.37	29.19	18.27	35.73	9.81	16.39	21.52

food and beverage industries, utilized biotechnology, thus are advancing into the bio-industry. An estimated 12,150 employees were involved in the bio-industry in Korea. An estimated 55 percent of them were in research; 45 percent, in production.

Based on these survey results, we estimate that an average of US\$ 2,580,000 per firm was spent on R&D, and an average of US\$ 550,000 per firm was spent on biotechnology R&D in 2004. The capital investment of the responding firms was an estimated average of US\$ 740,000 per firm; the capital investment for the bio-industry, an average of US\$ 230,000 per firm.

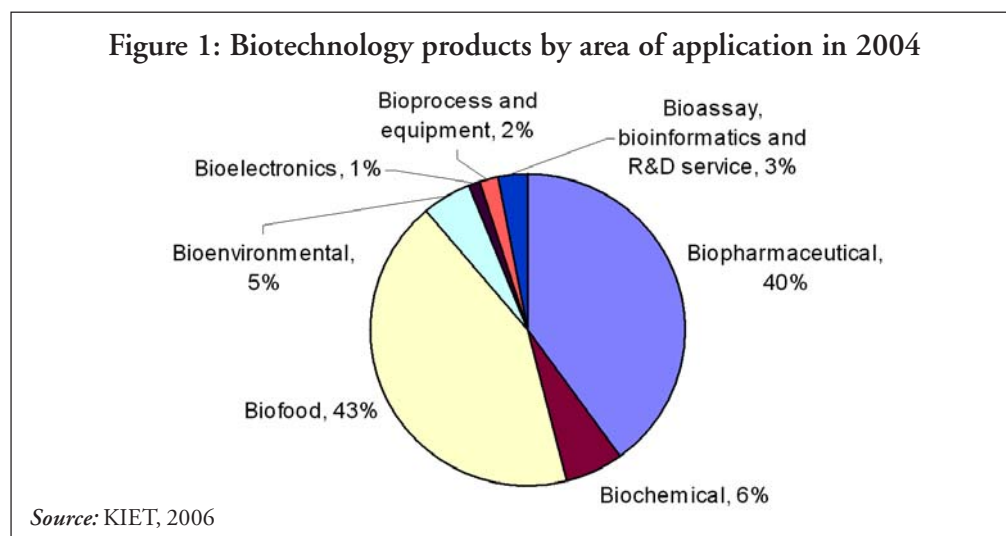
In identifying biotechnology firms, each firm was classified according to their main area of application. Figure 1 shows the percentage for each bio-industrial sector based on the bio-industry classification as of 2004. By far the largest share is for the Bio-food sector, accounting for 43 percent of total bio-industry production. After Bio-foods, the bio-pharmaceutical sector is the next largest, accounting for 40 percent. The remaining 17 per cent are comprised of small shares of bio-industrial activities range from bio-chemicals to bio-electronics.

Economic Impact of Bio-industries in Korea

How to capture the Bio-industry in the Perspective Industrial Structure

As in defining the scope of biotechnology and the bio-industry, the economic impacts of biotechnology may be different according to measurement methods. In principle, the approach should measure the impacts involve productivity gains, or growth effects, at the firm or industrial level, and new creation of business opportunities including employment. This fundamental approach also includes direct, indirect, and induced effects on the economy, since the introduction and growth of the bio-industry affects structural changes in the economy.

Industries are increasingly using biotechnology to produce industrial substitutes for natural agricultural products manufactured in large quantities (and mainly exported by developing countries). Many new substances are competing as viable substitutes for several products (foodstuffs, flavors, additives, fragrances), a trend very similar to the one we see in



new materials. The demand for new foodstuffs and pharmaceutical products (e.g. vaccines) is becoming increasingly diversified, and biotechnology is providing industry with the opportunity to abandon commodity chemicals and move into more lucrative specialty and agricultural chemicals. Older biotechnological techniques (e.g. fermentation) are themselves benefiting from additional inputs from genetic engineering and new enzymatic processes.

From the perspective of economic agencies, the impacts may become more significant if firms use these technologies in their production processes. For example, industrial firms may be able to reduce expenses on capital or running costs, pharmaceutical firms may produce more cost-effective products, health providers may be able to improve overall health and so increase value-added in their sector, and agricultural firms using biotechnology may benefit from higher yields or lower input costs. As summing up the firm level changes in other industries derived from the bio-industry, this could be regarded as the emergence of substitutes as production of intermediate inputs.

The other economic impact stemming from bio-industries is the so-called fabrication effect, referring to the altered proportion of value-added items of a sector's total purchases. For example, over time, a product of bio-relevant sectors such as Chemicals, Pharmaceuticals, Energy, and Foods will depend more on bio-technology capital equipment and/or skilled labors. Thus, a KRW (Korean Won)'s worth of the product embodies proportionately less conventional, industrial inputs and proportionally more value-added inputs.

Considering the above premises, an input-output analysis would be a useful tool in capturing the overall impacts of the biotechnology industry by studying their relationship with the economy, industrial sectors, and technology. Instead of investigating technological change in a series of input-output tables, I-O analysis enables the study of the impacts of new technologies on economy by adjusting input-coefficients. Duchin and Lange (1994) investigated the potential of technological measures to fulfill economic objectives (in terms of GDP per capita). Generally, a static input-output model is sufficient to determine the impact of new technologies on economy. In order to also investigate the penetration of new technologies, a dynamic approach is required. Contrary to static input-output models, in which investments are part of the final deliveries, dynamic input-output models include the stocks and flow of capital goods explicitly.

An optimal aggregation to include bio-industry as a separate sector should also be taken into account. The major question is how many aggregate or disaggregate industrial sectors, by adding bio-industries, are optimal in a practical sense. Aggregation of detailed bio-industries, especially in an I-O framework, has to be done within the scope of microeconomic foundations of macroeconomic analysis. This point is controversial and there are no convincing arguments that allow us to keep a "golden rule." The usual way to carry out aggregation is to simply consolidate industries by appropriate sector size. There are several reasons to support this kind of aggregation which are based on the manageability of the data. The only justification, however, is the necessity of

working with empirical data, not theoretical interest or justification.

Related to the optimal detailed classification of bio-industries in an analytical sense, we may miss important information from over-aggregation within the bio-industry. On the other hand, if the degree is quite low, we may be violating the homogeneity hypothesis. In an I-O model, it is assumed the existence of production functions with constant returns is defined to an undetermined number of goods. These two characteristics are known as the homogeneity and stability hypothesis and are not completely compatible. This is due to the aggregation degree: in a model. The stability hypothesis is related to the fixed coefficients of the production functions of the industries. In order to maintain the stability hypothesis, we must aggregate industries into an adequate number of sectors (not being too large).

If we have a modeling framework with many sub-sectors in a bio-industry group, where each sub-sector produces only one homogeneous good, it is not easy to assume that all cross-elasticities will be zero. With such a large number of goods, it has to be easy to find substitutes among them. In order to maintain the stability hypothesis (i.e. fixed coefficients) we must aggregate industries, and this is the opposite effect required by the homogeneity hypothesis. Since the higher the degree of aggregation, the greater is the set of heterogeneous goods encompassed in a sector. Hence, it is almost impossible for both hypotheses to be proved simultaneously.

For analytical purposes in grouping bio-industry sub-sectors, the above categories suggested by Choi, et al (2004) should be carefully reviewed. Though the

degree of aggregation is a matter of empirical estimation, we may decide on an optimal aggregation somewhere between Category I and Category II.

With a manageable survey scheme and an appropriate aggregation of the bio-industry, we may be able to apply various analytical tools in order to estimate the economic impacts of the biotechnology industry on the Korean economy. A simple framework for analysis would be as follows: looking at the main actors in the biotechnology area, namely the production dedicated biotechnology firms and diversified firms engaged in biotechnology production; evidence on the possible impacts of biotechnology in sectors using the technology, e.g. agriculture, health, environment and industrial processing; and innovative and scientific efforts that underpin biotechnology.

It is also important to examine the interaction between them, for example, the interaction between scientific progress and commercial application of biotechnology. Even more important is the analysis of the impact of biotechnology use on outcomes in sectors using the technology, such as health, agriculture and the environment. This is currently a difficult step to take, but one that is crucial in addressing the question of biotechnology's impacts on economic activity as well as its social and environmental outcomes.

The Economic Impacts of Bio-industry in Korea

To estimate the economic impact of the bio-industry on the Korean economy, we construct an I-O framework with augmentation of separate bio-industries. Since the bio-industries are not specifically

classified, we conducted the bio-industries as new sectors, based on the above survey results. That is, within the existing I-O of n sectors, we create bio-industry sectors as an $n+1^{\text{st}}$ to $n+m$ sector. To do so, we separate the total amount of the surveyed results from the relevant sectors as in equation (1).

$$A_1 = A_{1a} + A_{1b}, Y_1 = Y_{1a} + Y_{1b}, VA_1 = VA_{1a} + VA_{1b}$$

where,

A : intermediate transactions,

Y : final demand,

VA : Value-added

1 : conventional sectors such as Chemicals, Pharmaceuticals, Energy, and Foods,

$1a$: conventional sectors – relevant bio-subsectors,

$1b$: relevant bio-subsectors

To resolve the previous two questions, substitution and fabrication effects, the

study utilizes a survey of existing bio-firms in Korea and applies RAS to establish the Korea Bio-augmented I-O (KB I-O). The RAS technique is a useful “updating” procedure which makes uniform changes along any row or column as reflecting the substitution and fabrication effects after introducing bio-industry as a new sector.¹

As shown in Table 4, the ratio of value-added (VA) in bio sectors are generally much higher than those of conventional manufacturing and related industries, almost double the manufacturing total. This means that bio sectors, as new technology-oriented sectors, are in a superior position in the value chain. Since services are by nature value-added oriented, these sectors have a higher value-added ratio than the bio-industries.

There is a wide variation in value structures within the bio-industry group.

Table 4: Input Structure of the Bio-industry (per cent)

Bio subsectors	Inter-mediate	Value-added					
		Sum	Wages	Operating revenue	Depreciation	Indirect tax (-subsidy)	Gross output
Bio-pharmaceuticals	39.5	60.5	20.9	16.6	26.2	17.6	0.0
Biochemicals	62.0	38.0	11.3	17.8	16.7	3.5	0.0
Biodfoods	66.9	33.1	14.6	13.0	18.8	1.3	100.0
Bio-environment	66.2	33.8	16.9	8.1	20.5	5.2	100.0
Bio-electronics	49.2	50.8	7.9	37.9	11.7	1.2	100.0
Bioprocess and equipment	59.0	41.0	22.4	12.5	28.1	0.4	100.0
bio-energy and bio-resource	66.9	33.1	19.3	8.4	23.4	1.3	100.0
Bioassay, bioinformatics and R&D service	32.9	67.1	49.2	11.2	55.7	0.2	100.0
Bio-industry Total	54.4	45.6	18.1	14.6	22.9	8.1	100.0
Manufacturing Total	75.5	24.5	11.2	8.1	11.9	4.4	100.0
Service Total	41.6	58.4	23.3	24.8	26.7	6.9	100.0
Economy Total	59.7	40.3	17.1	15.7	18.9	5.7	100.0

Note: Extracted bio-industry from updated 2004 Korea Bio-industry augmented I-O table.

Source: KIET, 2006.

¹ Miller and Blair, 1985. Input-Output Analysis: Foundations and Extensions.

Table 5: Major Multipliers and Economic Impact Coefficients in Selected Industries

Industry	Output multiplier	Impact coefficients	Sensitivity coefficients
Agriculture	2.0577	0.8000	0.9660
Foods	2.8405	1.1043	0.8056
Chemicals	3.2683	1.2706	2.9404
Machinery	3.2596	1.2672	1.5236
Electric, Electronics	3.2363	1.2582	1.8706
Precision machinery	3.0872	1.2002	0.6325
Education and Health	1.5960	0.6205	0.7835
Bio-pharmaceuticals	1.8863	0.7333	0.4034
Biochemicals	2.6107	1.0149	0.3927
Bio-foods	2.3478	0.9127	0.3919
Bio-environment	2.7649	1.0749	0.3901
Bio-electronics	1.8308	0.7117	0.3898
Bioprocess and equipment	2.7134	1.0549	0.3890
Bio-energy and bio-resources	3.0213	1.1745	0.3902
Bioassay, bioinformatics and R&D services	1.7287	0.6720	0.3896

Source: KIET, 2006.

In Korea, bio-pharmaceuticals, as technology-oriented has the highest VA ratio. Biochemicals and bio-foods are currently similar in value structure to manufacturing industries.

The output multiplier indicates how one unit of money, in this case, Korean won, spent by an industry, impacts other industries in the economy. For example, in this bio-technology industry analysis, one KRW spent on a product in the bio-industry increases activity in other industries, the impact on the entire economy. As shown in Table 5, the output multipliers for the bio-sectors are ranged from 1.72 to 3.02, and are slightly lower compared to other manufacturing industries. The impact coefficients representing the backward linkage effect used to indicate demand-side interconnection of a particular sector to those sectors from which it purchases inputs. The impact coefficients for bio sub-sectors are around 1, which means that those sectors in

the Korean economy likely have average demand-side effects. The sensitivity coefficient shows supply-side interconnection. Since the bio sectors in Korea are in a developing stage, their coefficients are not as high as those of other industries. More importantly, there might be an optimal aggregation question, since a higher degree of disaggregation in a sector usually induces a lower sensitivity coefficient.

A multiplier determines by how much the economy will increase or decrease with a change in final demand. Multipliers are simply the sum of direct effects, indirect effects and induced effects.² In general, the multiplier impact of the bio-industry is not as large as manufacturing sectors, though higher than those of Agriculture and other service sectors. This reflects the fact that Bio-industries are usually more technology-oriented and have less input requirements from other sectors and, in Korea, bio sectors are still in the middle of growing and integrating.

² Industry matrix by Choi, et al. does not include households and therefore the multipliers in Table 5 does not account for induced effects.

Table 6 summarizes the estimates provided by the assumption that the final demand for Korean bio-industries has increased at a rate of 20 percent, for an easier understanding of the components of economic impact analysis applied in this study.³ The economic activity of this 20 percent increase, or the 230 millions of US\$ increase in final demand of bio products and services is expected to generate close to

Table 6: Summary of Economic Impacts of the Korean Bio-industry

(Unit: KRW, persons)

Industries	Total Sales	Value-added	Employment (persons)	wages	taxes	operational profits
Agriculture	20	12	8	1	2	9
Mining	670	420	315	117	63	224
Food	13	3	4	1	0	1
Textiles	33	8	28	5	1	1
Wood, Paper	127	33	56	23	6	3
Printing	95	26	76	17	4	3
Oil and Coal	429	103	8	36	21	41
Chemicals	215	51	58	18	10	21
Non-ferrous	25	8	9	4	2	2
Primary metals	188	43	23	16	8	17
Metal Products	71	17	40	6	3	7
Machinery	119	33	57	14	5	13
Electric, Electronics	93	25	28	11	4	10
Precision machinery	16	4	12	2	1	2
Transportation machine	59	12	18	8	3	1
Other Manufacturing	52	16	35	10	2	3
Electric utilities	90	38	16	8	15	15
Construction	67	29	80	19	2	7
Wholesale, Retail	122	34	447	53	7	41
Restaurant, Lodging	12	4	37	5	1	6
Transportation	116	87	127	19	3	21
Communications	102	79	33	17	3	18
Finance, Insurance	272	179	238	45	5	13
Real estate	181	85	163	33	18	18
Public administration	71	50	77	22	3	39
Education, health	35	28	78	2	5	12
Social services	49	26	158	23	4	10
Bio-pharmaceuticals	521	315	233	109	92	86
Biochemicals	1	0	1	0	0	0
Bio-foods	1901	629	625	278	24	248
Bio-environment	95	32	83	16	5	8
Bio-electronics	6	3	5	0	0	2
Bioprocesses and equipment	74	31	107	17	0	9
bio-energy and bio-resource	2	1	10	0	0	0
Bioassay, bioinformatics and R&D	48	32	40	24	0	5
Sum (100 millions of KR won)	5992	2495	3335	981	324	918
Sum (billions of US\$)	5.24	2.78	3335	0.86	0.28	0.80

Note: 1. As of 2004, 1 KR won/US \$ is 1143.74; 2. a 15 percent increase of bio final demand, approx. 263.8 billion won or \$US2.3 billion.

Source: Authors' estimation, 2006.

³ Annual growth rate of bio industries at 20 per cent is a medium range of government target.

Table 7: Summary of Economic Impacts of the Korean Bio-industry

	Total sales	Value-added	Employment	Wages	Taxes	Operational profits
Direct	232	91	1,104	39	11	31
Indirect and induced	292	127	2,231	47	18	49
Total	524	218	3,335	86	29	80

Note: unit; millions of US dollars

524 millions of US\$ in the Korean economy. This amount includes an estimated 86 millions of US\$ in wages and 290 millions of US\$ in tax revenues. The total employment impact was approximately 3,335 jobs to the national economy.

Table 7 summarizes the break-down of the bio-industries' direct, indirect and induced economic impacts on the Korean economy as a result of ongoing operations. The total impact on employment was 3,335 jobs, with 1104 direct jobs, and 2,231 indirect and induced jobs. Other economic variables can be summarized as the same way.

Non-economic Impacts of Bio-industries in Korea

In addition to economic impacts, the biotechnology and the bio-industry have a broader impact in that they dramatically affect human health and welfare and promote the innovation in the other technologies and industries through the convergence and linkage processes. All of the above influence change in society through ethical, legal, and social implications (ELSI).

First, biotechnology and bio-industry influence health-care strategies and

behaviors, eventually affecting health-care related factors. Secondly, the impact of intellectual property access to and use of biotechnology, as one of the ELSI issues, is strengthened. Accordingly, national competitiveness differences are derived from Intellectual property of biotechnologies and bio-industries, which are closely related to the quality of life. Also, cutting edge biotechnology R&D and applications that specifically involve human information and participation need acceptance of society. Biotechnology and the bio-industry co-evolve with the society while appreciating how different individuals, cultures and religious traditions correspond to this biotechnology. Finally, biotechnology-related-environmental issues such as bio-safety and bio-security are a significant part of the non-economic impacts.

The Korean government has established infrastructure⁴ and laws related to bio-safety, bio-security, and bioethics, in order to facilitate the non-economic impacts of biotechnology and the bio-industry. However, there are still more infrastructure and societal "software" needed for the ELSI of biotechnology and bio-industry.

Concluding Remarks

This study has provided a preliminary review of biotechnology and the bio-

⁴ One example is the Korea Bio-safety Clearing House established in 2001 according to the Cartagena Protocol on Bio-safety to the Convention on the Biological Diversity.

industry's role in the Korean economy. It also explains fundamental methodologies and implications of estimating the economic impacts of the biotechnology industry. The main findings of the work thus far are as follows: the biotechnology industry in Korea is made up of dedicated firms of both narrow and general definition that have diversified lines of production using both biotechnology and conventional technologies.

According to the historical data set on the bio-industry in Korea obtained from the annual biotechnology firm survey, the Korean bio-industry has been experiencing rapid growth. The CAGR over the last 5 years has been 22 per cent. The major force behind the Korean bio-industry is the synergy created by enthusiastic governmental policy and the entrepreneurship of the research-oriented companies.

There are wide variations in value structures within the bio-industry. In Korea, Bio-pharmaceuticals, as a highly technology-oriented industry, has the highest VA ratio. Bio-chemicals and bio-foods are very similar in value structure to that of manufacturing. In terms of inter-industrial position, the output multipliers for the bio-industry sub-sectors ranged from 1.72 to 3.02, and slightly lower compared to other manufacturing industries. The impact coefficients for bio sub-sectors are around 1, which means that those sectors in the Korean economy seem to have average demand-side effects. Since the bio sectors in Korea are at the developing stage, the sensitivity coefficients of supply-side interconnection are not as high as those of other industries. This may stem from the higher degree of disaggregation in the bio-sectors.

A final demand of \$US2.3 billion associated with bio products and services is expected to generate close to \$US5.24 billion for the Korean economy. This amount includes an estimated \$0.86 billion in wages and \$0.28 billion in tax revenue. The total job impact is close to 3,335 jobs for the national economy. While the bio-industry is still in its early stages in Korea, it is expected to play a major role in future economic growth as well as in national innovation through both public and private R&D.

In addition to economic impacts, the biotechnology and bio-industry induce a broader impact, by dramatically affecting human health and welfare and promoting innovation in other technologies and industries. For the non-economic impacts of biotechnology and the bio-industry, Korea needs to develop further infrastructure and societal "software" to prepare the "bioeconomy" for the future.

In the methodology of estimating economic impact, the two cases raise some interesting points regarding further researches. As this study employed fixed input-output coefficients originating from the survey data, the model could have benefited from the use of more dynamic procedures. For instance, many researches estimate the change of input coefficients over time with the help of R&D intensities of particular industrial branches. Mori, et al. (1992) formulated an input-output table for science and technology development to estimate their economic impacts. The inclusion of these procedures and changes in estimating the coefficients of the input-output models with newly emerging industrial branches could provide rather realistic growth paths for future bio industry.

Annex 1: 2005 Survey for the Korean Biotechnology and Bio-industry

Certification
No. 11515

Purpose, Objective, Scope of survey etc. Corresponding			
Name of company		Address	
Ind. Registration No.			
Name of mother company			
CEO		Establishment	YY/MM/DD
Homepage			
KSIC			
Respondent		Department	
Tel/Fax		e-mail	

- Scope of biotechnologies and bio-industries
 - As of the end of the year 2005
 - 2005. 1. 1.-12. 31..
- A. General Information**
- A1-1. No. of employee
 - A1-2. Main location (headquarter)
 - A1-3. Status of companies (venture, INNO-BIZ KOSDAQ, KOSPI, etc)
 - A1-4. Factory and/or research centers at other locations
 - A2. *Shareholders*
 - A3. *Implementing organization of biotechnology and bio-products*
- B. Employment**
- B1. No. of employees by sector and degrees
 - B2. Job turn-over rates
- C. Financial Status**
- C1. *Capital*
 - C2. *Own capital ratio*
 - C3. *Financial support from other sources*
 - C3-1. Major financial sources
 - C4. *Gross sales*
 - C5. Operating profits, wages, depreciations, current expenditures, etc (PL)
 - C5-1.
 - C5-2.
 - C5-3.
 - C6. *R&D*
 - C6-1. Bio R&D by sub sectors
 - C6-2. Bio R&D by agent
 - C6-3. Bio R&D by financial sources
- D. Status of Bio-industry**
- D1. *Stage of bio-industry*
 - D2. *Bio-products and/or services*
 - D2-1. Specific bio-products and/or services
 - D2-2. Own vs. assigned
 - D2-3. Bio-products and/or services codes

D2-4. Characteristics of bio-products and/
or services

D2-5. Sales

D2-6. Domestic sales

D2-7. Exports by countries and products

D2-8. Major clients

D3. Imports of bio-products

D3-1 Major clients

D4. Motive of participating bio-industry

D4-1. Beginning

D4-2. Contribution of bio-industry

D5. Innovation, R&D, etc

D5-1. No. of innovation, R&D, etc

D5-2. Sales (per cent)

D5-3. Duration for commercialization

D5-4. Changes

E. Cooperation

***E1. Cooperation with biotechnology
firms and/or bio-industries***

E1-1. Types of cooperation

E1-2. Matrix of cooperation by agents and
by subjects

E2. Government supports

E2-1. Participating government projects

F. Status of Intellectual Properties

F1. Type of protecting information

F2. Bio-related patent, etc.

F2-1. Bio-related patent by countries, etc

F3. Bio-related intellectual properties

F3-1. Bio-related intellectual properties by
countries, etc.

Annex 2: Biotechnology Classification System (summarized version)

- | | |
|--|---|
| A Genetic engineering | F0 Metabolic engineering, n.e.s. |
| A1 Gene manipulation | G Bioprocess |
| A2 Gene expression and regulation | G1. Fermentation engineering |
| A3 Gene application | G2. Cell culture engineering |
| A4 Gene therapy | G3. Biotransformation |
| A0 Genetic engineering, n.e.s. | G4. Bioseparation engineering |
| B Protein engineering | G5. Industrialization |
| B1 Protein structure analysis | G0. Bioprocess, n.e.s. |
| B2 Protein function analysis | H Bioresource production and utilization |
| B3 Complex protein engineering | H1 Plant resource technology |
| B4 Peptide engineering | H2 Animal resource technology |
| B5 Protein application | H3 Microbial resource technology |
| B0 Protein engineering, n.e.s. | H4 Insect resource technology |
| C Other macromolecule engineering | H5 Marine/fresh water organism technology |
| C1 Lipid engineering | H6 Food engineering |
| C2 Carbohydrate engineering | H7 Biomaterial technology |
| C0 Other macromolecule engineering, n.e.s. | H8 Biodiversity conservation |
| D Cell and tissue engineering | H0 Bioresource production and utilization, n.e.s. |
| D1 Stem cell therapy | I Environmental biotechnology and bioenergy technology |
| D2 Bioenvironment regeneration | I1 Clean technology |
| D3 Functional biomaterial development | I2 Environmental pollution control and management technology |
| D4 Cell engineering | I3 Bioenergy technology |
| D5 Tissue engineering | I0 Environmental biotechnology, n.e.s. |
| D0 Cell and tissue engineering, n.e.s. | J Nanobiotechnology |
| E Systems biology and bioinformatics | J1 Nano-biodevice fabrication |
| E1 Genome sequence analysis | J2 Nanoscale biomaterial |
| E2 Functional genomics | J3 Nano drug delivery system |
| E3 Proteomics | J4 BioNEMS, nano-LOC(lab-on-a-chip) |
| E4 Bioinformatics | J0 Nanobiotechnology, n.e.s. |
| E0 Systems biology and bioinformatics, n.e.s. | K Bioelectronics |
| F Metabolic engineering | K1 Biosensor fabrication |
| F1 Metabolite production | K2 Bioelectronic device fabrication |
| F2 Applications of metabolic engineering | |
| F3 Understanding the metabolism and metabolic pathways | |

K3 Biochip fabrication

K4 Microfluidics

K0 Bioelectronics, n.e.s.

L Biosafety and bioefficiency

L1 Safety evaluation

L2 Safety management

L3 Environmental assessment

L4 Biohazard management

L5 Bioefficacy

L0 Biosafety and bioefficiency, n.e.s.

M Other Biotechnology

M1 Combinatorial biology

M2 Drug delivery

M3 Immunotechnology

M0 Other Biotechnology, n.e.s.

Annex 3: Bio-industry Classification System (summarized version)

1. Biopharmaceutical industry	4000 Other bioenvironmental productions and services
1010 Antibiotics	
1020 Anticancer medications	5. Bioelectronics industry
1030 Vaccines	5010 DNA chips
1040 Hormones	5020 Protein chips
1050 Immunotherapeutics	5030 Cell chips
1060 Hemotherapeutics	5040 Biosensors
1070 Inhibitors	5050 BioMEMS
1080 Growth factors	5000 Other bioelectronics
1090 New therapeutics(ex. gene therapeutics, cell therapy, cloned organs, etc.)	6. Bioprocess and equipment industry
1100 Diagnostic kits	6010 Bioreactors
1110 Animal medications	6020 Biomedical and diagnostic apparatuses
1000 Other biopharmaceuticals	6030 Bioprocess and analysis equipments'ex. equipments for separation and purification; synthesizers and amplifiers; sequence analyzers; analysis instruments; etc.)
2. Biochemical industry	6040 Plant and process design
2010 Biopolymers	6000 Other bioprocesses and equipments
2020 Industrial enzymes and reagents	7. Bioenergy and bioresource industry
2030 Enzymes and reagents for research	7010 Biofuel
2040 Bio-cosmetics and home & personal care chemicals	7020 Artificial seeds and seedlings
2050 Biological agrochemicals and fertilizers	7030 Experimental animals
2000 Other biochemicals	7040 Transgenic animals and plants
3. Biofood industry	7000 Other bioenergy and bioresources
3010 Health\$functional foods	8. Bioassay, bioinformatics and R&D service industry
3020 Amino acids	8010 Bioinformatics services
3030 Food ingredients	8020 Gene analysis services
3040 Fermented foods	8030 Proteome analysis services
3050 Feed ingredients	8040 R&D services(ex. drug development services, etc.)
3000 Other biofoods	8050 Biosafety and efficacy assessment services
4. Bioenvironmental industry	8060 Diagnosis and preservation services
4010 Microbial treatment agents	8000 Other bioassays, bioinformatics services
4020 Microbe-immobilized materials and equipments	
4030 Bioenvironmental agents and systems	
4040 Measuring apparatus for environmental pollution (service for pollution assessment)	

Status of Biotechnology Research and Development in Sri Lanka

G.A.U.Jayasekera*

Introduction

Research and development in biotechnology in Sri Lanka is still at a nascent stage. Activities have been slow, partly based on the interests of individual researchers on an ad hoc basis. Currently biotechnology related programs are related to disease diagnosis, biological control, biofertilizers, tissue culture of plants, embryo-rescue, micropropagation, vaccine production, conservation of plant genetic resources, molecular characterization of pests and pathogens, identification of useful genes, Marker Assisted Selection (MAS), genetic transformation of plants and development of recombinant vaccines. However, field testing of transgenic plants has not been initiated so far.

All biotechnology related activities are dealt by the Ministry of Science and Technology. Biotechnology research is being carried out by research institutions of the Department of Agriculture and Universities, which do not have adequate infrastructure for biotechnology research. Some private institutions are also engaged in biotechnology related activity.

Sri Lanka is a party to the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety (CPB), member of Trade Related Aspects of Intellectual Property Rights (TRIPS), but not of International Treaty on Plant Genetic Resources (ITPGR). Sri Lanka is also a signatory of SPS Agreement of WTO, but does not have adequate expertise in the Quarantine department to test for GMOs. Patent Laws are also being prepared, and draft regulations for plant variety protection have been prepared. The plant species requiring protection have been documented, but apparently there is no documentation of hazardous organisms. However, mechanism for trademark protection is available.

The country has legislations on Intellectual Property Rights and Biodiversity and Community Knowledge Protections Act. Seeds are regulated through Plant Protection Act, Plant Quarantine Act and Seed Act. Food safety is regulated by Food & Drug Administration.

Biotechnology research and development in the public sector are being

Table 1: Local Funding Agencies

Funding agency	Year of 1st Biotech initiative	Generic areas	Amount of funding(US \$)	Recipients of funding	Web address(URL)
NSF	1992	Agriculture, Medical, food, animal, industrial	220932 (last 5 years)	Universities Research institutes	www.nsf.ac.lk
CARP	—	Agriculture	168600	Universities Research institutes	www.slcarp.lk

funded by few national and international organizations. International organizations include ADB and SIDA, whereas local funding agencies include National Science Foundation (NSF), Council for Agriculture Research Policy (CARP) and the National Research Council (NRC). Research and development efforts are scattered in different public and private sector institutions. However there is limited involvement of the private sector.

Main generic areas for biotechnology research and development in Sri Lanka are agricultural, medical and animal biotechnology. Since agriculture is the mainstay of Sri Lankan economy, research and development in agricultural biotechnology will lead to economic growth in Sri Lanka. Some of the research work carried out by the public and private sector institutions are reviewed here.

Status of Biotechnology Research and Development

Medical Biotechnology

Health research in Sri Lanka has expanded considerably during the last few years however till now medical biotechnology work is only limited to molecular biology work done by a few medical research

groups. Institutions and organizations involved include the National Institute of Health Sciences, the Medical Research Institute, the Faculties of Medicine of a few Universities and operational units of the Ministry of Health such as the Family Health Bureau and Epidemiology Unit.

The Department of Clinical Medicine, Faculty of Medicine, University of Colombo

Major research projects/activities of the institutes includes OX-COL project (with the Nuffield Department of Clinical Medicine, Oxford and University of Liverpool), developing a species specific anti venom against Sri Lankan snakes, a search for effective therapy for Kaneru (Yellow Oleander) poisonin and malaria project in collaboration with the Malaria Research Unit, Faculty of Medicine, Colombo.

Medical Research Institute (MRI), Colombo

The MRI is the premier biomedical research institute in the country and provides services to all hospitals in Sri Lanka with special diagnostic laboratory tests. It functions as a laboratory diagnostic centre and as a reference laboratory for poliomyelitis diagnosis.

Institute of Biochemistry, Molecular Biology and Biotechnology (IBMBB)

IBMBB conducts research and training in Biomedical Sciences, Plant Molecular Sciences and Molecular Entomology.

Genetech

Among the private sector firms Genetech is one of the leading and probably only firms in Sri Lanka engaged in Molecular disease diagnostics and DNA fingerprinting for forensics. Currently, over 70 molecular diagnostics assays which have been developed in house are performed. These include diagnostic tests for infectious diseases including Dengue, genetic disorders, and cancer genetics.

Some biotechnology research activities in Medical biotechnology field carried out by local universities are summarized in the following Table 2.

Agriculture Biotechnology

Sri Lanka has made use of the potential of biotechnology as early as 1970s, by initiating commercial production of orchids by tissue culture. Since then Universities, the Department of Agriculture, some Research Institutes, and a few companies have been using tissue culture techniques for mass production of ornamental plants,

flower crops, fruit crops and a few medicinal plants. However, such mass production of planting material has not been developed to a satisfactory level and has had little or no impact on the economy of the country. Similarly, research is being carried on advance tissue culture and biotechnology based on molecular tools but the information available to interested commercial organizations is very limited.

Given below is an overview of the institutions involved in agriculture biotechnology (plant tissue culture and transgenic crops) in Sri Lanka.

Department of Agriculture, Government of Sri Lanka

Established in 1912, the Department of Agriculture (DOA) was the main agency involved in non-plantation crop research. Its research mandate covered more than 100 crops, dispersed over three main research institutes and six agricultural research and development centers.

In 1994, DOA was restructured and various commodity research centers were established: the Rice Research and Development Institute (RRDI, formerly the Rice Research Station), the Horticultural Crop Research and

Table 2: Research in Medical Biotechnology

Institute/ University	Web address	Area of activities
Faculty of Medicine, University of Colombo	www.cmb.ac.lk	Species specific anti venom against Sri Lankan snakes Effective therapy for Kaneru (Yellow Oleandre) poisoning
University of Kelaniya	www.kln.ac.lk	Rapid detection of Salmonella in coconut
University of Sri Jayawardenepura	www.sjp.ac.lk	Molecular diagnostics for dengue and typhoid
University of Colombo	www.cmb.ac.lk	Immunodiagnostic assay for malaria Herbal anti-malaria

Development Institute (HORDI, formerly the Central Agricultural Research Institute), and the Field Crops Research and Development Institute (FCRDI, formerly the Mahailuppallama Research Station) in collaboration with the Regional Agricultural Research and Development Centers (RARDC), Agricultural Research Stations (ARS) and Adaptive Research Units (ARU).

The mandated crops for each Institute are:

- HORDI** Fruits, vegetables, root and tuber crops and ornamental plants
- RRDI** Rice
- FCRDI** Grain legumes, coarse grains, oil seeds and condiments

Council for Agricultural Research Policy (CARP), Sri Lanka

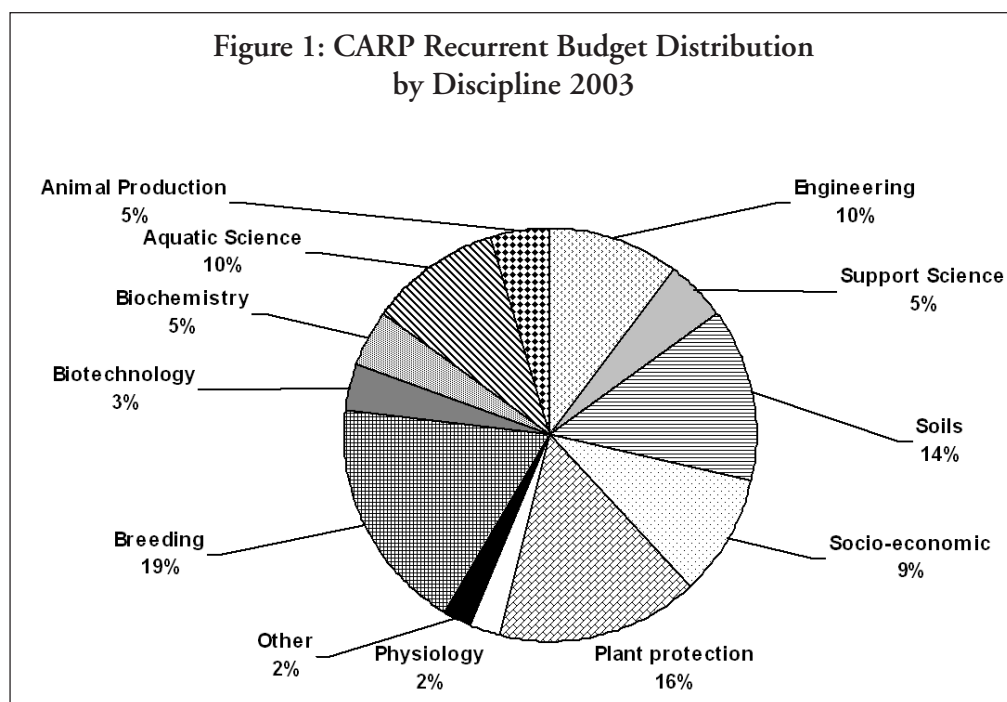
CARP has the mandate to formulate a National Agricultural Research Policy,

organize and execute agriculture research, Allocate/generate funds for contract research, monitoring and evaluation, technology dissemination, and to develop human resources (scientific & technical) in the agricultural sector (Figure 1).

Agricultural Biotechnology Centre, Faculty of Agriculture, University of Peradeniya

The agriculture Biotechnology Centre provides research facilities in biotechnology at undergraduate and postgraduate levels, promotes basic and applied research of high quality and builds capacity for innovative research. Some of the ongoing research projects involve characterization of Sri Lankan medicinal plants by RAPDs and Microsatellite technique, GMO/GMF testing in Sri Lanka, disease diagnostic through molecular technique and genetic transformation of plants.

Following are the private sector industries involved in various agriculture



biotechnology work in Sri Lanka.

Ceylinco Foliage (Pvt) Ltd

100 per cent Export-Oriented Unit (EOU), engaging exporting cut flowers, foliage, rooted plants, and accessories. The company has established a strong buyer network in Europe, the Middle East, and Japan.

Chemical Industries (Colombo) Ltd., (CIC) Seeds/ Agribiotech

CIC Seeds (Pvt) Ltd. is the market leader of the private sector seed companies in Sri Lanka and the only seed company in Sri Lanka to receive ISO 9001 quality management system certification. The company manages three major seed farms leased out by the government on a long term basis. An out grower seed production program is carried out to supplement the production coming out from farms.

Mike Flora Pvt. Ltd

Mike Flora Ltd. was formed in 1980 and today is one of the leading exporters of foliage plants and cut flowers from Sri Lanka. The company's product list includes rooted plants, un-rooted cuttings, anthurium flowers, seedlings, tissue culture plants and cut foliage (leaves and un-rooted cuttings). The company's subsidiary Mike Biotech Asia (Pvt.) Ltd., is engaged in tissue of the above mentioned plants and has a laboratory capable of producing 1.2 million plants per annum.

Serendib Horticulture Technologies (Pvt.) Ltd

The company is involved primarily in the

commercial aspects of floriculture production, through conventional means and by tissue culture. The company also carries out research and development activities in collaboration with premier public institutes. With a sizable investment being made in R&D, the company is focused on getting Sri Lanka into the global map of horticulture production and research in partnership with the universities and the Department of Agriculture.

Research Institutes and Universities

In addition to the above given public and private sector organizations, there are several research institutes and universities that carry out agricultural biotechnology research including micropropagation & pathogen elimination, *In vitro* techniques for conservation of germplasm & cryopreservation, and wide hybridization. These research institutes and universities include the following:

- CRI – Coconut research Institute
- RRI – Rubber Research Institute
- TRI – Tea Research Institute
- UC – University of Colombo Centre at Weligatta
- UP – University of Peradeniya
- IFS – Institute of Fundamental Studies
- BMARI – Bandaranayake Memorial Ayurveda Research Institute
- SRI – Sugarcane Research Institute
- ITI – Industrial Technology Institute
- University of Ruhuna – Faculty of Agriculture
- University of Colombo – Faculty of Science
- University of Kelaniya – Faculty of Science

Table 3: Research in Agricultural Biotechnology

Institute	Activities	Web address
Department of Agriculture	Research, Extension, Seed and planting material production, Regulatory Services	www.agridept.gov.lk
Council for Agricultural Research Policy (carp)	Funding R&D, Technology dissemination, Formulation of a National Agriculture Research Policy	www.slcarp.lk
Forest Department	MAS, Micropropagation (selected trees for breeding programs)	www.dwlc.lk
Coconut Research Institute (CRI)	Somatic embryogenesis, Micropropagation	www.cri.lk
Rubber Research Institute (RRI)	DNA fingerprinting for clonal identification, Micropropagation, MAS	www.rri.lk
Sugarcane Research Institute (SRI)	Micropropagation, MAS	www.sugarres.gov.lk
Tea Research Institute (TRI)	Micropropagation, Mutation breeding, DNA fingerprinting for clone characterization	www.tri.lk
Veterinary Research Institute	Development of -PCR-based techniques for viral disease diagnosis, Production of vaccines, Use of biotechnology for improvement of vaccines	www.vri.lk
Industrial Technology Institute (ITI)	Micropropagation, Genetic transformation studies	www.iti.lk
Agricultural Biotechnology Center, University of Peradeniya	Research and Development, undergraduate and postgraduate teaching / training in Biotechnology	www.pdn.ac.lk
Faculty of Agriculture, University of Peradeniya	Development of transgenic plants for disease resistance, Mutagenesis, Tissue culture	www.pdn.ac.lk
Faculty of Agriculture, University of Ruhuna	Tissue culture, Molecular markers, Gene transformation studies (Rice, Cinnamon, lemon)	www.ruh.ac.lk
Faculty of Science, University of Kelaniya	Tissue culture and micropropagation	www.kln.ac.lk
Faculty of Science, University of Colombo	DNA probes for identification of fungal pathogens, Tissue culture, Gene transformation studies	www.cmb.ac.lk

R&D activities in some of the institutes related to Agricultural Biotechnology are given in the Table 3.

Animal Biotechnology

Activities related to animal biotechnology are mostly at teaching and research levels. However, a few closely related areas can be seen in the livestock industry (Table 4).

Development of the livestock

industry in Sri Lanka falls within the purview of the Department of Animal Production and Health, which comes under the Ministry of Agriculture and Livestock. It is directly responsible for the control of livestock diseases, livestock research, animal training, training of trainers in animal husbandry, preparation of project proposals for developing the industry and implementing special developmental programs covering the whole island.

Table 4: Proposed Research in Animal Biotechnology

Proposed Industry/ Research	Opportunities Offered by Biotechnology	Proposed participating Authorities/Organisations/ Individuals
Disease diagnostics	Already established technology is available locally and globally	Universities Veterinary Research institute (VRI) Private sector
Vaccines	Already established technology is available	Private sector

Biotechnology Policy

The Ministry of Environment and Natural Resources (MENR) has constituted the National Biosafety Framework for Sri Lanka (NBFSL) to regulate the import of bioengineered food and the application of biotechnology in domestic agriculture. The NBFSL drafted a National Policy for Biosafety (www.biosafety.lk/pub/policy/policy.doc), which is currently open for public comments. The NBFSL website, www.biosafety.lk, contains various draft proposals pertaining to biotechnology such as the Legal Report on Biotechnology and Biosafety; Technical and Technology Aspects of Biosafety; and Institutional Aspects of a National Biosafety Framework.

Currently, there is no single regulatory authority that handles biotechnology products. The MENR was designated to establish the NBFSL and to liaise with the Cartagena Protocol (CP) Secretariat. The NBFSL has recommended the formation of a National Council for

Biosafety (NCB) as the apex body on biotechnology. The NCB, comprised of representatives of various concerned Ministries and civil society, will be tasked with a wide range of responsibilities, such as developing research & development-industry linkages to promote biotech industries, and establishing legislation, protocols, and guidelines.

Conclusion

Biotechnology research and development in Sri Lanka is still at a nascent stage. Biotechnology policy and regulations are still evolving. There is a lack of adequate financial resources for biotechnology R&D in universities and research institutes. Private sector investment needs to be strengthened. Fast access to rapid advances in techniques is needed for improvement of local research efforts.

Biotechnology holds the key to agricultural sustainability, environmental protection and economic growth in Sri Lanka. With the adequate utilization of this technology a vast range of benefits can be reaped.

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Thailand's Biotechnology Status

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Introduction

Biotechnology has been applied in Thailand for a long time ago, based on local wisdom, without noticed; many products have been developed using biotechnology means. Thai people are familiar with the fermented vegetables, fish, meat and other ingredients like rice, soybean, mungbean or the combination of meat, rice flour and spices. Soy- and fish sauces are also the products in many areas through out the country. Composts used in the farm lands and recently the biocontrol agents as well as the plant and animal growth promoting microbes are widely accepted and practiced among the farmers in order to minimize the chemical application following the food safety policy promoted by the government. Anyhow, these could be counted as the conventional biotechnology which the uncomplicated techniques were applied.

Next era of biotechnology started with the plant tissue culture mostly applied for the mass-propagation of orchids which led to the increasing of the Thai orchids. Furthermore, the tissue culture techniques could also enhancing the orchid improvement through the application of

embryo rescue. Consequently, the disease-free plant material production using the combination of thermotherapy and meristem culture was widely applied. Though these techniques are counted as the basic ones but they are the strong piling stone for the modern biotechnology especially the plant genetic engineering in the present period.

At present, Thailand has expanded to the modern biotechnology dealing with the DNA and RNA technology, the proteomics and the genome technology which involve not only the bioinformatics but also the applications of gene therapies and then we come across to the agriculture biotechnology which includes the cell, tissue, organ culture, cell fusions, and genetic engineering. Besides that we start working on the animal biotechnology as well for the cloning of animals and manipulating the gene in animals to get certain characteristics which are desirable for the fast-growing fish industry. However, these are limited only in the laboratory scale.

For the medical biotechnology, vaccine technology and also stem cell technology are now the focal points which

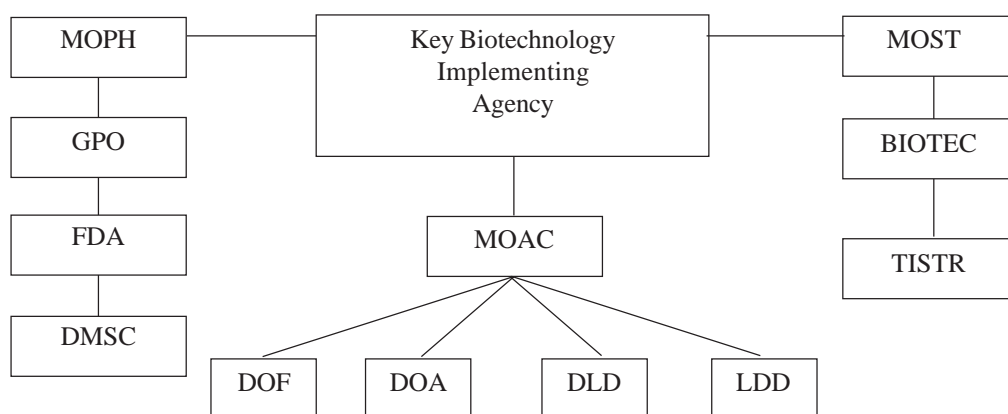
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will lead to the gene therapy in the near future. Based on the cell and the stem cell technology, many projects on animal cloning are successfully accomplished. Genetic markers in plants, animals and human being are other areas that biotechnology has been applied in the past ten years which facilitated the diagnosis of the genetic disorders, diseases in plant animal and human being as well as the plant and animal improvement.

Development of Biotechnology in Thailand

New era of biotechnology started after the establishment of the National Center for Genetic Engineering and Biotechnology (NCGEB at that moment and now changed to BIOTEC) in 1983. BIOTEC is one of the NSTDA (National Science and Technology Development Agency) centers, operating outside the normal framework of civil service and state enterprises. This

enabled the Center to operate more effectively to support and transfer technology for the development of industry, agriculture, natural resources, environment and consequently the social and economic well-being of Thai people. The main objectives of BIOTEC are to induce dynamics in research, development and application of biotechnology in order to support technology development and adoption in both public and private institutions. This is achieved through establishing research programs, which include funding, and program management, as well as establishing research laboratories in collaboration with universities and government agencies. BIOTEC is both a major granting agency as well as having its own research laboratories. The Center also engages in human resources development, management and technical services, technology investment, public awareness, information services and international cooperation.



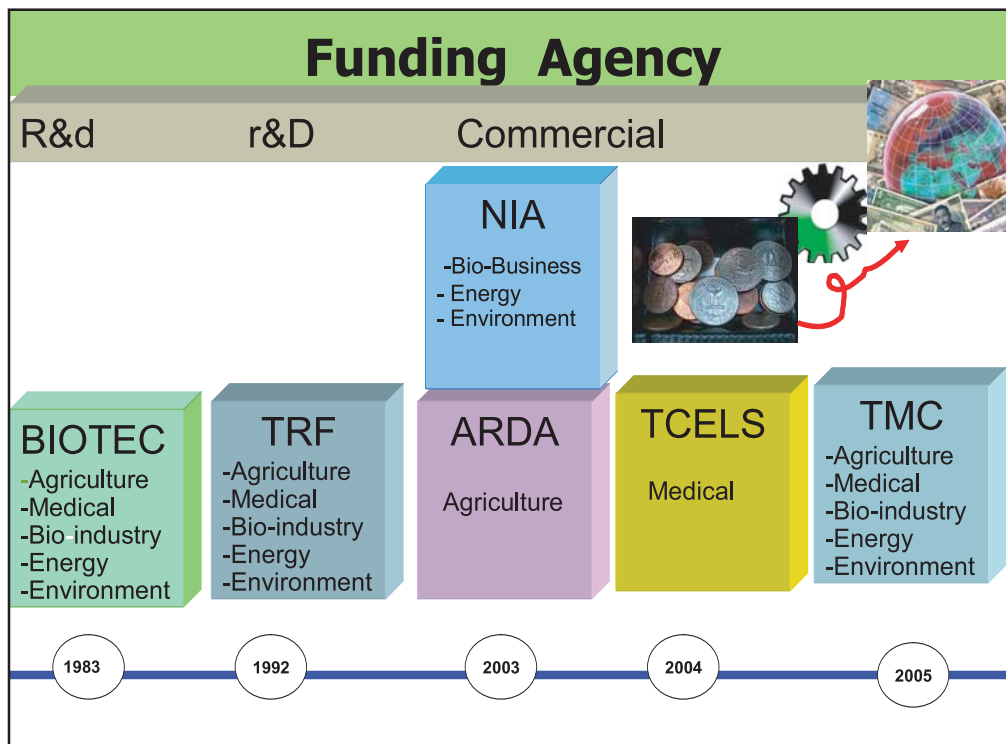
MOPH:
 DMSC: Medical Biotechnology Center
 GPO: The Government Pharmaceutical Organisation
 FDA: Food and Drug Administration
 BIOTEC: National Center for Genetic Engineering and Biotechnology
 TISTR: Thailand Institute of Scientific and Technological Research
 DOF: Department of Fisheries
 DOA: Biotechnology Research and Development Office
 DLD: Department of Livestock Department
 LDD: Land Development Department

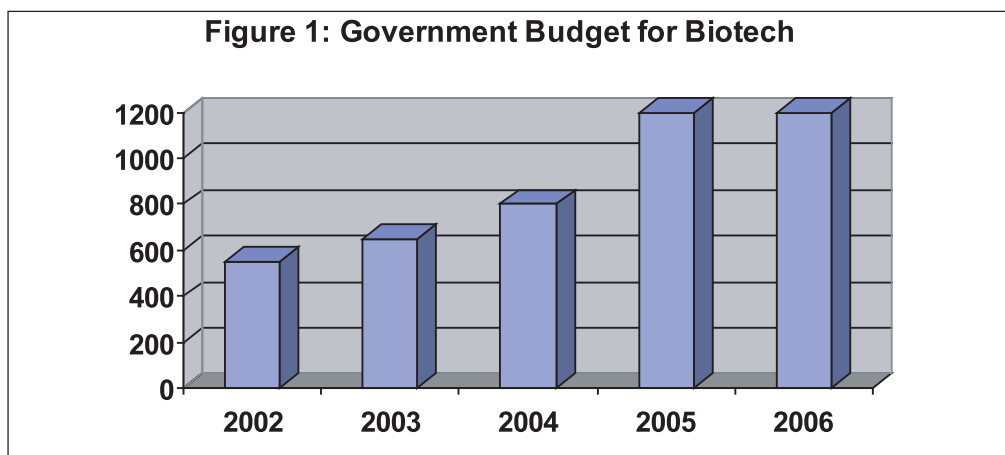
Biotechnology policies have been commenced in 2003, which concentrated on strengthening Thailand's research and development emphasized on the infrastructure and capability building. There are six goals for biotechnology developments in Thailand are:

1. Emergence and Development of New Bio-Business
2. Biotechnology Promotes Thailand as Kitchen of the World
3. Thailand Represents Healthy Community and Healthcare Center of Asia
4. Utilization of Biotechnology to Conserve the Environment and to produce Clean Energy
5. Biotechnology as the Key Factor for Self-Sufficient Economy
6. Development of Qualified Human Resource System

Key Funding Agency for Biotechnology

BIOTEC is known as the major funding agency for biotechnology research and development since 1983. Later on the Thailand Research Fund (TRF) was established in 1992 with the aims on supporting research both basic and applied ones significantly to national development. Two decade later, many specialized funding agencies are established, namely Agriculture Research Development Agency (ARDA), National Innovation Agency (NIA), Thailand Center of Excellence for life science (TCELS). ARDA was initiative to support research development, promote the commercialization in agricultural including agricultural biotechnology area. NIA was founded for a technically and financially support a project after research and development, or bring the research or creation into the commercial market. While TCELS be aimed for life sciences sector.





Government Budget for Biotechnology Sectors

By 2006, Thailand Government invested more than 1,200 million Baht (ca. 40 Baht = 1 U.S. \$) in projects that strengthening biotechnology sectors, including building leading-edge science infrastructure, developing dedicated biotechnology precincts and supporting the commercialization of biotechnology research.

Government expenditure on R&D was mainly on development of agriculture, environment and energy, medical/health and bio-industry sectors. Over the period 2003 – 2009, the government plans to increase R &D funding to \$ 412.5 Million. The private sector, through various incentives and collaborative schemes, will allocate up to \$125 Million in R&D investment.

Key Biotechnology Implementation Agency

The universities mostly public ones also play very important role in both conduction research and implementation of biotechnology by obtaining the research grants from the funding agencies locally and internationally which BIOTEC, TRF and NRCT are the major supporting agencies. More over, the Commission of the Higher Education, Ministry of Education has the strong policies in developing the center of excellent in the public universities and the biotechnology is counted as the important one.

Besides the mentioned organizations or agencies, within the major science and technology based ministries; Ministry of Agriculture and cooperative, Ministry of Public Health and Ministry of Natural

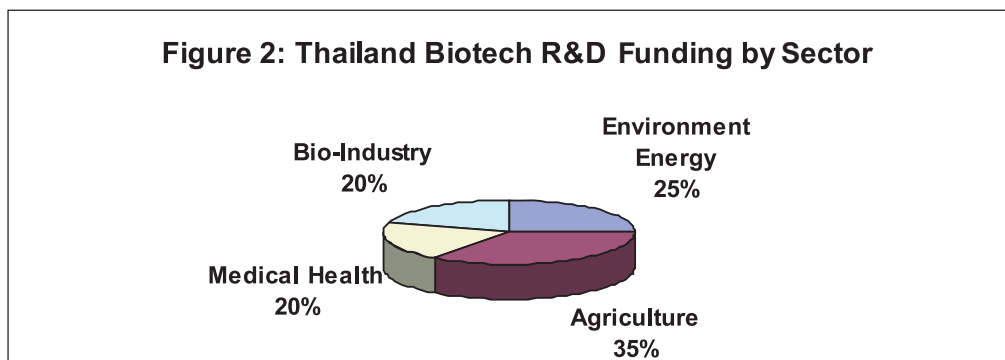
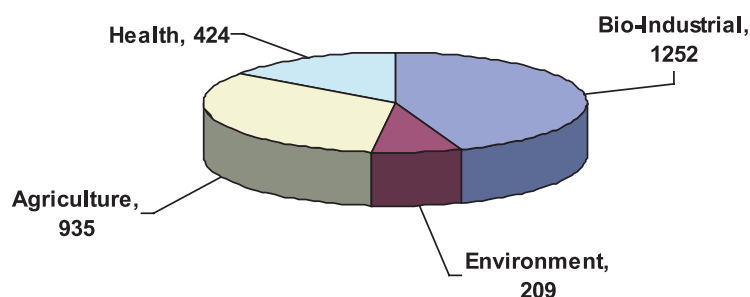


Figure 3: R&D Personnel in Biotechnology Sector in Thailand



Resources also conducting the research in biotechnology fields. Moreover, as the regulatory agencies, Departments of Agriculture; Fisheries; Livestock Development; Food and Drug Administration; Medical Sciences; National Park Wild life and Plant Conservation, are conducting research in biotechnology aspects, mostly for the biosafety purposes.

R&D Personnel in Biotechnology Sector

In 2006, approximately 2,000 scientists work in biotechnology areas; mainly on agricultural and bio-industrial research (See Figure 3). At present, approximately 900 B.S., 350 M.S, and 100 Ph.D. are graduated from biotechnology programs offered in twenty four universities annually.

Biotechnology Business

Commercial bio-industry products in Thailand has been recently developed and emphasized mainly on limited products such as amino acid production for feed industries, cassava starch modification, commercial plant propagation and improvement using tissue culture, antibiotics and animal vaccines production. By the end of 2006, there are 70 companies

operating the biotechnology business. Under the strong support form the government, more industries will be established and ready for the operation within the next development plan.

The limitation of the biotechnology development in Thailand based on the public acceptance of the biotechnology products or goods, so all of the works are now still in the laboratory scale or in the control containments. With the strong biosafety policy, risk assessment and communication in order to create the better understanding of the biotechnology application would lead to the acceptance of the modern biotechnology among the Thai population and hopefully the field releasing of the "biotech products" will be possible in the near future. Then, the real application of modern biotechnology in Thailand could be on the right track.

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