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Measuring Developments in Biotechnology: International Initiatives, Status in India and Agenda before Developing Countries

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I Introduction

In last couple of years, biotechnology has emerged as a complex and cumulative set of technologies covering almost all the major sectors affecting economic growth. In the agriculture and the pharmaceutical sector biotechnological inputs have strongly influenced the production pattern and the final output. Efforts have been made by different agencies at national and international level to enhance intrinsic capacity for adoption and diffusion of biotechnology.

The Organization for Economic Cooperation and Development (OECD) has made an effort to harmonize initiatives by some member countries like Canada, New Zealand, France, Germany and Australia. They have launched national surveys to assess status of biotechnology and its contribution in their economies. OECD is evolving a consensus on the very definition of biotechnology along with identifying a set of issues for developing a conceptual framework for collecting statistical data. This involves, largely, putting together various indicators including a model survey, which incorporates social responses to biotechnology. R & D allocations, export-import of biotechnology goods, number of biotechnology patents, total employment in biotechnology related industry, are some of the other indicators chosen for this purpose.

In order, to effectively analyze the various linkages between biotechnology and other sectors, in light of their plan priorities, it is important to build a data set for informed policy making in these countries. The biotechnology programs in developing countries are to be evolved in such a way so that potential benefits of this technology remain rooted in the national development strategy. In the context of developing countries, one would have to be extremely careful while selecting the indicators, which can address their needs and requirements.

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The indicators should reflect capability of this technology in terms of dealing with the challenges in different sectors. In the agricultural sector, for instance, managing food security, nutritional security and working for reducing input demand for crops, are some of the important targets to be statistically captured. In China genetically modified rice offers 15 per cent higher yields without the need for increases in other farm inputs and modified cotton (Bt cotton) allows pesticide spraying to be reduced from 30 to 3 times[1]. Similarly in the health sector providing access to lifesaving drugs and cost effective vaccine production are some of the other major challenges. Scientific achievements in this field have been very encouraging and of direct relevance for dealing with specific challenges before developing countries. For instance, the Hepatitis B vaccine was developed in 1989 and down these years more than 300 biopharmaceutical products are in the world market. They have reduced the cost of adoption and diffusion of these products.

The widespread use of high-throughput experimental approaches and completion of the human genome project have enhanced the number of therapeutic targets available to the pharmaceutical industry. There may be several more desired attributes, developing economies may expect biotechnology products to be equipped with, such as, longer shelf life value of products and reducing environmental pollution etc. However, it is equally important to emphasize provisions for biosafety policies and adequate regulatory mechanisms to enforce it, when the issue of diffusion of biotechnology comes up. Accordingly, in the broader biotechnology assessment strategy, biosafety related indicator especially trained manpower should also be incorporated. The central issue is, to what extent developing countries are prepared to evolve appropriate strategies to assess the direction of their biotechnology R&D expenditure and subsequent returns on them.

In this regard, developing countries face several policy challenges. The policy makers, here, have to grapple with several sets of issues, which are to be addressed at different levels and needs to be responded to, in a much different way. In fact, the spectrum of issues is very large for them. Such as how best developing countries are enhancing their capabilities to absorb this technology? How the potential dangers of biotechnology are minimized to protect the indigenous biodiversity? What are those sectors in which biotechnology is urgently needed and in what ways current budgetary allocations can be channeled towards these ends?

It may be difficult to respond to all these questions, as a large number of developing countries, do not have a conceptual classification for positioning biotechnology, in the overall developmental framework. In this paper, an effort is being made to look into some of these issues. Section II analyzes the evolving statistical framework in OECD and some non-member countries. Among the developing countries, India has been chosen here for a case study in data collection in biotechnology. A detailed account of statistics collection in India is reported in section III of this paper. The section IV outlines an agenda for developing countries while last section draws the conclusions from the paper.

II International Initiatives

In recent past, a number of initiatives have been launched to statistically analyse developments in biotechnology and growth of biotechnology industry. Several annual reports from Ernst & Young for the United States and the Europe gave detailed account of corporate data related to biotechnology while publications like, 'International Service for the Acquisition of Agri-Biotech Applications (ISAAA) Briefs', provided insights on adoption of agriculture biotechnology across the world. However, OECD has initiated a systematic exercise for bringing different perspectives together on various aspects of data collection for biotechnology. Similarly, European Commission and Intermediary Biotechnology Service (IBS) of ISNAR have also initiated a limited exercise for data collection, which we discuss herewith.

II.1 European Commission

The Policy Unit of the European Commission's Life Sciences Program has conceived two studies for collecting biotechnology-related statistics for its member and non-member countries. The first study would cover number of students, researchers, trainees, and employees in both private and public sector as well as their mobility. While the second study would cover all the aspects of biotechnology industry such as number of companies and their employees, investment, R & D spending, patent and other data. The results of these studies are expected to be out by end of 2003. The studies would be launched soon[2].

The Commission has also established, on pilot basis, BIOSTAT, a database intended to collect biotechnology related economic data. At present, it largely draws its information from European Commission's Life Science programme supported documentation unit, called BIODOC. It has more than 1000 entries. The focus of this is very wide and it covers political, economic, social, legal, and ethical aspects. It contains information on scientific development and breakthroughs, however rarely in form of original articles. Meanwhile, the commission has launched two studies to look into the manpower profile of biotechnology sector and current status of biotechnology industry in Europe.

II.2 Intermediary Biotechnology Service

International Service for National Agricultural Research (ISNAR) established in 1979, is one of the 16 Future Harvest Centers supported by the Consultative Group on International Agricultural Research (CGIAR). ISNAR established Intermediary Biotechnology Service (IBS), as a project in 1993, for an initial five-year period (1993–1997) and later extended it to more years. IBS has launched a limited exercise of conducting surveys to collect data related to agricultural biotechnology across different countries. In 1998, surveys were conducted for four countries viz. Mexico, Kenya, Indonesia and Zimbabwe[3]. The data was reported for 1997. They largely cover public sector allocations only. At the end of the summary, a list and number of institutions engaged in agricultural biotechnology in each country along with nature and quantum of human resources involved is given.

IBS has attached a greater emphasis on collection of data on resource indicators in terms of investments made through public sector allocations. Additionally, these surveys also collect information about size, structure, and content of public research along with some details on international collaborations of public sector organizations. The most important expected output of this initiative is to collect new information for the country reports and the synthesis research reports. These outputs in agricultural biotechnology provide a new set of information that may enrich the decision-making capability of the policy makers.

II.3 OECD

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[4]. 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 Frescati manual. Some of the member countries have already launched data collection exercise, which we discuss briefly herewith.

Canada is one of the major economics 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 OECD. Canada has come out with an exhaustive model survey with almost 30 questions spread over several pages[5].

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[6]. 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[7]. 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 FoS classifications that are relevant to biotechnology[8]. 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[9]. 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: 1. DNA-based processes; 2. Biochemistry and immunochemistry; 3. Bioprocessing and 4. 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 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.

III Case Study of Bio-Statistics in India

Adoption of biotechnology in industrial and other activities is a relatively recent phenomenon in India. The clarity about its governance has yet to take a concrete shape. However, need for a reliable data set for accurate assessment of its adoption is being widely felt[10]. This has become a pressing need in last one year or so, as formal system for regulation of biotechnology is found to be trailing behind the other informal channels for infusion of this technology, especially, in the agricultural sector. In this section, a brief account of general data collection system in India is given. Then we try to see how need for biotechnology related statistics is being addressed mainly in terms of commercialization of GMOs, R&D allocations and industry statistics. It also provides an outline of a possible plan for adoption of statistical indicators for data collection, as is being done in other parts of the world.

III.1 General Framework of Statistics Collection

The Central Statistical Organisation (CSO), under the Ministry of Statistics and Programme Implementation, is the key agency for data collection on industry. It brings out the Annual Survey of Industries (ASI), which is the principal source of industrial statistics in India. It provides statistical information to assess the changes in the growth, composition and structure of organised manufacturing sector. Industrial sector occupies an important position in the Indian economy and has a pivotal role to play in the rapid and balanced economic development. CSO also comes out with Index of Industrial Production (IIP) which is widely used as a short-term indicator, measuring industrial growth, till the actual result of detailed industrial survey becomes available. Actually, IIP is an abstract number, the magnitude of which represents the status of production in the industrial sector for a given period of time. The CSO being the nodal agency for the development of the statistical system in India, it has paid increasing attention at the emerging issues for data collection, such as collection of environment related data. CSO came out with the first publication containing data on various aspects of environment entitled “Compendium of Environment Statistics” in 1997[11]. Subsequently, it has been decided to bring out this publication on an annual basis. The current issue pertaining to the year 2000 is the fourth in the series. This issue has covered biodiversity-related indicators also. It provides detailed account of germplasm collections in India along with the number of inventorisations for *ex-situ* collections.

In India, collection of trade data and its compatibility with production data has emerged as a major challenge before economists. Authors like Debroy and Santhanam (1993) have made efforts to address these issues. However, extent and coverage of different categories of commodities under two major systems of classification viz. National Industrial Classification (NIC) and Indian Trade Classification Harmonized System (HS Code) has remained limited. The challenge for data compilation has gone up several times as Indian economy has been liberalized over the years. In the erstwhile policy regime of licensing and regulations, there was some sort of compulsion for filing up of some data returns. There is thus a fear of a large “data vacuum” emerging in the country unless some corrective measures are taken and new mechanisms are established[12].

The Department of Science and Technology (DST) has been conducting since 1973-74 surveys at the national level to collect data on resources devoted to scientific and technological activities[13]. UNESCO recommendations regarding international standardisation of statistics on science and technology are adopted in the collection of the data. Their report “Research and Development Statistics 1994-95”, twelfth in the series, presents data and analyses with supporting graphical presentations on the input and output parameters covering R&D resources by objectives, fields of science, industry groups, manpower, gender and other related issues. An estimate of the likely Research and Development (R&D) expenditure for the year 1995-96 was also been projected, using an improved time-series regression model. Another major agency engaged in data collection is the National Science and Technology Management Information System (NSTMIS). It is a division, under the Department of Science and Technology (DST), and has been entrusted with the task of building an information base on a continuous basis, on resources devoted to scientific and technological activities for policy planning in the country. Through its various reports it provides data on R&D/manpower and finance related details, at broad macro level but has yet to launch any specific effort to collect biotechnology related statistics.

III.2 Biotechnology Statistics in India

Department of Biotechnology (DBT), under Government of India, has taken a very broad definition of biotechnology. According to the several documents of DBT one gets an impression that, "biotechnology is an application of recombinant and non-recombinant technologies in biological resource utilisation for product and process development aimed for commercialization." Thus, classification of biotechnology commodities for data collection purposes becomes very difficult. This is largely because industrial production of some of these commodities is a recent phenomenon. Another reason probably is that efforts are yet to be made to conceptually separate them for accounting purposes. As a result, these goods get added in the broad categories for different products. For instance, the biofertilisers have not been included in the Indian Trade Classification System (ITC) based on harmonized system and they are for the purposes of custom duties and other purposes considered under the code 3101.00 along with the various chemical fertilizers[14]. Similarly the biopesticides have also not been classified in ITC harmonized system and are considered along with chemical pesticides under 38.08 and the rates of custom duties are identical for both. However, as per the Statement on Industrial Policy, 1991 Bio-Insecticides as well as Nitrogen Fixers (Biofertilizers) have been included under Item No. 27 of the list of Industries for automatic approval of Foreign Technology Agreement as a special class. Considering the biological nature, both these could be very well classified under Chapters 6, 12 or 14. In fact, a special class with titles such as biopesticides and biofertilizers should have been specifically mentioned and classified.

As a result, the estimation of the size of market for biotechnology products also varies a great deal (Table 1). It seems there might be many other considerations behind these projections. Similarly, problems are being confronted in the data management for patent related details. Technology Information Forecasting and Assessment Council (TIFAC), which is managing the data base for patents has yet to separately classify the biotechnology patents.

Table 1: Differing Perspective on Biotech in India (2001)

	CII	DBT	the Economist[iiii]
Biotech Market	$ 2.5 billion[i]	$ 1,849 million	$ 1,475 Million
Agri/Seed Market	$ 500 million[ii]	---	$ 450 million
Bio Informatics Market	$ 2.2 million[iii]	---	----
Diagnostic/Vaccine Market	$. 420 million	$ 150 million	$ 375 million

Source: RIS based on i *Financial Express*, 10th October 2001, ii *Business Standard*, December 24th 2000, iii *Business Line*, July 9th 2001, iiii *Economist*, September 1st 2001.

III.2.1 Patent Data

At, this point, there is a limited provision in India for granting patents on microorganisms[15]. The prevailing perception is that, as of now, India is not obliged to introduce laws for patenting micro-organisms till 31.12.2004. In India, TIFAC is the only agency giving patent statistics in electronic form but they do not collect International Patent Classification (IPC) details. Using IPC may help in identifying biotechnology patents. Indian Parliament has recently adopted a Plant Variety Protection Act 2001. This is the introduction of *sui-generis* system for the protection of new plant variety and new seeds including seeds produced through the transgenic route. Despite of the fact that microorganisms and genes do not have any protection through patents in India, these will get an indirect protection through the new seeds and plants. In the proposed plant variety Act, a stipulation may be considered so that the genes used in such varieties may also get adequate protection.

III.2.2 GMO Field Releases

Indian agriculture has formally entered the transgenic era in March 2002, with the approval of cultivation of Bt cotton. The Genetic Engineering Approval Committee (GEAC) has permitted seed company, Mahyco, to commercially release three genetically modified hybrid cotton varieties. At present India plants nearly 9 million hectares of land under cotton and produces 3 million tonnes of cotton lint annually. India is the third largest producer of cotton in the world contributing 5.2 per cent of the global production.

The next genetically modified crop to be cleared for commercialization is likely to be mustard. Table 2 gives a broad idea about GM plants being tested at different stages of approval process. It also gives details about the companies, which proposes to commercialise these plants along with the characters being inserted in. According to this table, 4 companies and 7 public research institutes are attempting

11 crops for transgenic manipulation. Apart from the UNIDO source being quoted for Table 2, this data has also been presented by DBT in an international conference recently.[16]

Table 2: Current Profile of GMOs in India

	Organisation	Crop/ Gene/Purpose
(1)	M/s Rallis India Ltd. Bangalore	**Bell pepper, Chilli** and **Tomato (**Snowdrop (Galanthus nivalis) Lectin gene): Resistance against pest;
(2)	M/s Proagro PGS (India) Ltd.	**Brassica / Mustard (**Barstar, Barnase, Bar) and **Cauliflower (**Barnase, Barstar and Bar): To develop better hybrid cultivars; **Brinjal and Tomato (**Cry1A(b)): To develop plants resistant to pests; **Cauliflower and Cabbage (**Cry1H/Cry9C): To develop resistance to pests.
(3)	Indian Agricultural Research Institute, New Delhi	**Brinjal, Cauliflower and Tomato** (Bt gene): To impart lepidopteran pest resistance; **Mustard/ rapeseed (**Arabidopsis annexin gene): Transformation completed, Green house trial completed, ready for field-trials for moisture resistance stress;
(4)	M/s MAHYCO, Mumbai	**Cotton** (Cry1A(c)): To develop resistance against lepidopteran pests;
(5)	Delhi University, South Campus, New Delhi	**Mustard / rape seed (**Bar, Barnase, Barstar): Plant transformations completed and ready for green house experiments; **Rice** (Selectable marker genes): Gene regulation studies. Transformations completed;
(6)	Jawaharlal Nehru Univ., New Delhi	**Potato (**Gene expressing for seed protein containing lysine obtained from seeds of Amaranthus plants (Ama-1 gene): Transformation completed and transgenic potato under evaluation;
(7)	Central Potato Research Institute, Shimla	**Potato** (Bt toxin Gene): To generate plants resistant to lepidopteran pests. Ready to undertake Green House trials;
(8)	Bose Institute, Calcutta	**Rice** (Bt toxin genes): To generate plants resistant to lepidopteran pests;
(9)	Tamilnadu Agricultural Univ. Coimbatore	**Rice** (Reporter genes like hph or gus A): To study extent of transformation;
(10)	Indian Agricultural Research Institute sub station at Shillong	**Rice** (Bt toxin gene): To impart lepidopteran resistance;
(11)	Central Tobacco Research Institute, Rajahmundri	**Tobacco (**Bt toxin gene Cry1A(b) and Cry1C): To generate plants resistant to H.armigera and S.litura.

Source: Biosafety Information Network and Advisory Service (BINAS), UNI DO, various years.

III.2.3 Trade Data

Though efforts have been made to analyse the possible impact of biotechnology on exports (Panchamukhi and Kumar 1988) no separate classification is being followed in India for biotechnology commodities. As a result, it is difficult to assess their position in trade. In fact, even otherwise, in India, the coverage of trade and production data systems often does not match at the disagrregate level. The matching is neither easy nor automatic[17]. In the report of the National Statistical Commission (2001), it has been suggested to adopt national classification code to overcome this problem. The 8-digit coding system being adopted by the Task Force constituted by Central Board of Excise and Customs (CBEC) needs to be finalized urgently. There is also a need to adopt national classification code based on Harmonized Commodity Description and Coding System (HS) by all the producer and user organisations engaged in product-level data. The use of national classification would eliminate the multiplicity of the product-level coding system and would also enable a study of the flow of output through various economic systems apart from cross-classification of activity and product data. Though several non-government organisations have suggested that a large number of GM food and feed is being exported to India but there is hardly any account of it. However, recently Ministry of Agriculture has imposed restrictions on imports of GM soybean oil.

III.3 Government R&D Statistics

There are several public agencies such as Department of Scientific and Industrial Research (DSIR), Department of Science and Technology (DST), Department of Biotechnology (DBT), Indian Council of Agricultural Research (ICAR) and Indian Council of Medical Research (ICMR), etc. that have several programmes supporting biotechnology. Their total budgets have gone up in the last decade (Table 3). Each of them has growing allocations for this particular technology. However, except DBT, no agency separately announces budget allocation for biotechnology, as the allocations are included into the broader heads for accounting purposes. Therefore, it is difficult to precisely estimate allocations for biotechnology. Nevertheless, an attempt may be made to collect this statistics, as one may go unto the level of laboratories and research institutes to find out nature and composition of biotechnology programmes at that level and this would certainly give a definite indication about the allocations.

In recent past, a couple of analytical papers have been published by individual coordinators of different government programmes, giving details of data related to the programmes they are dealing with (Ghosh 1997, Wahab 1998, Ramanaiah 2002). These papers are full with insights and at places give time series data. Otherwise, at one place, it is difficult to get full account of biotechnology statistics. However, harmonization of concepts about biotechnology across these agencies may help in resolving this difficulty to some extent.

The details available from DBT about the allocations is being presented in Figure 1. This gives data in absolute numbers and thus, does not take into account monetary devaluation due to inflation, etc. However, Figure 2 presents a more realistic picture as it presents a bar graph showing the shares allocated to various sectors over the years. As is clear, there has been a continued emphasis, in terms of allocations, on infrastructure and basic R & D. In the initial years of DBT, the allocation of infrastructure development was 13 per cent, which now has grown to almost 18 per cent. Basic R & D was initially given 35 per cent of total allocation which now has become 46 per cent after touching peak at 58 per cent in 1994-95. DBT initially extended grants in terms of institutional allocations, which right from 1988-89 constituted to be more than 20 per cent of the allocation. However, since late 90s this trend has changed and grants are now being focussed in terms of areas of research. As a result, in recent years, such as 2000-2001, one finds new areas are being added in the list for example, plant agriculture and bioinformatics. It is not that they were not getting allocations earlier but now with this changed approach these areas have come upfront when allocation are being discussed.

Table 3: Budgetary Allocations of Major Funding Agencies in India **($ Million)**

	1990/91	2000/01
Department of Scientific and Industrial Research (DSIR)	7.50	12.99
Department of Science and Technology (DST)	147.90	173.51
Department of Biotechnology (DBT)	37.42	30.28
Indian Council of Agriculture Research (ICAR)	184.87	311.29
Indian Council of Medical Research (ICMR)	22.62	32.71
Council of Scientific and Industrial Research (CSIR)	134.31	202.93
University Grants Commission (UGC)	199.67	313.07

Source: RIS based on budgetary papers of relevant years, Ministry of Finance, Government of India.
Note: The figures have been converted in dollars through the IMF exchange values for concerned years.

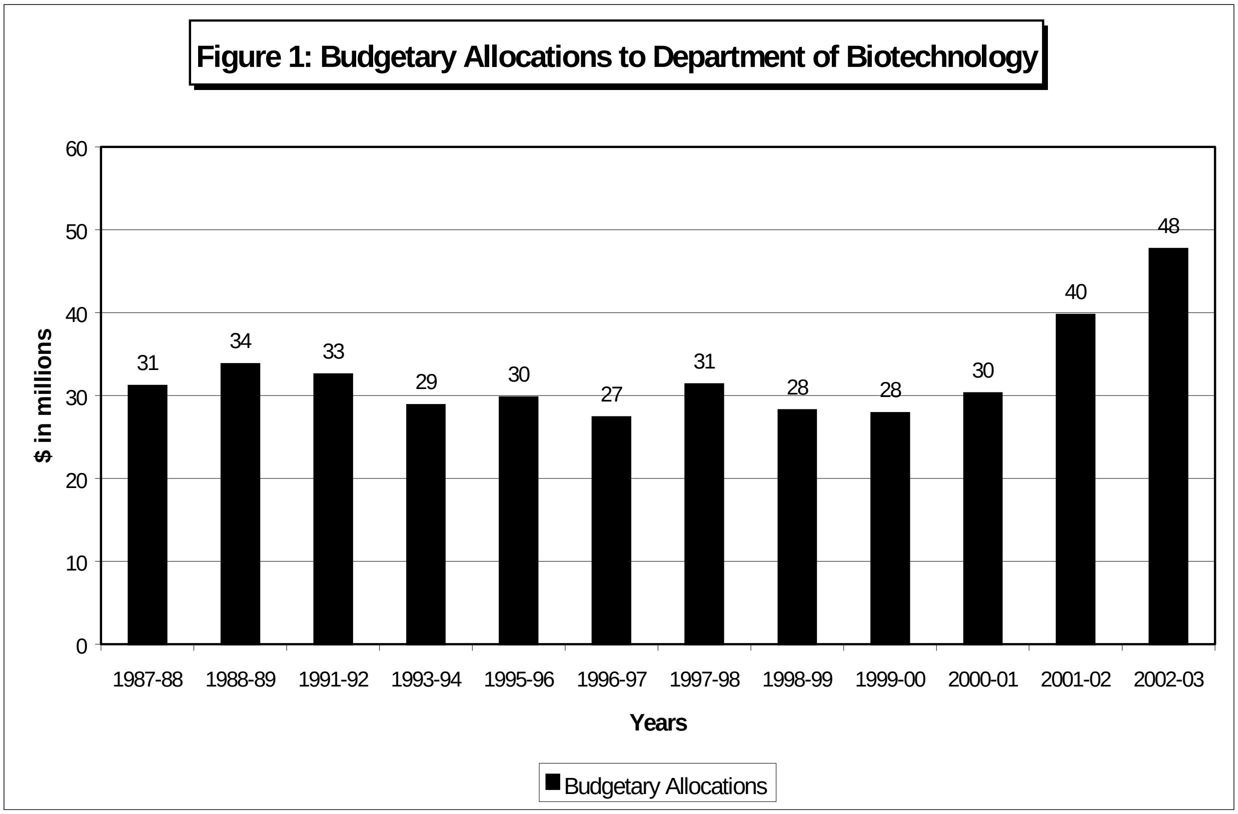
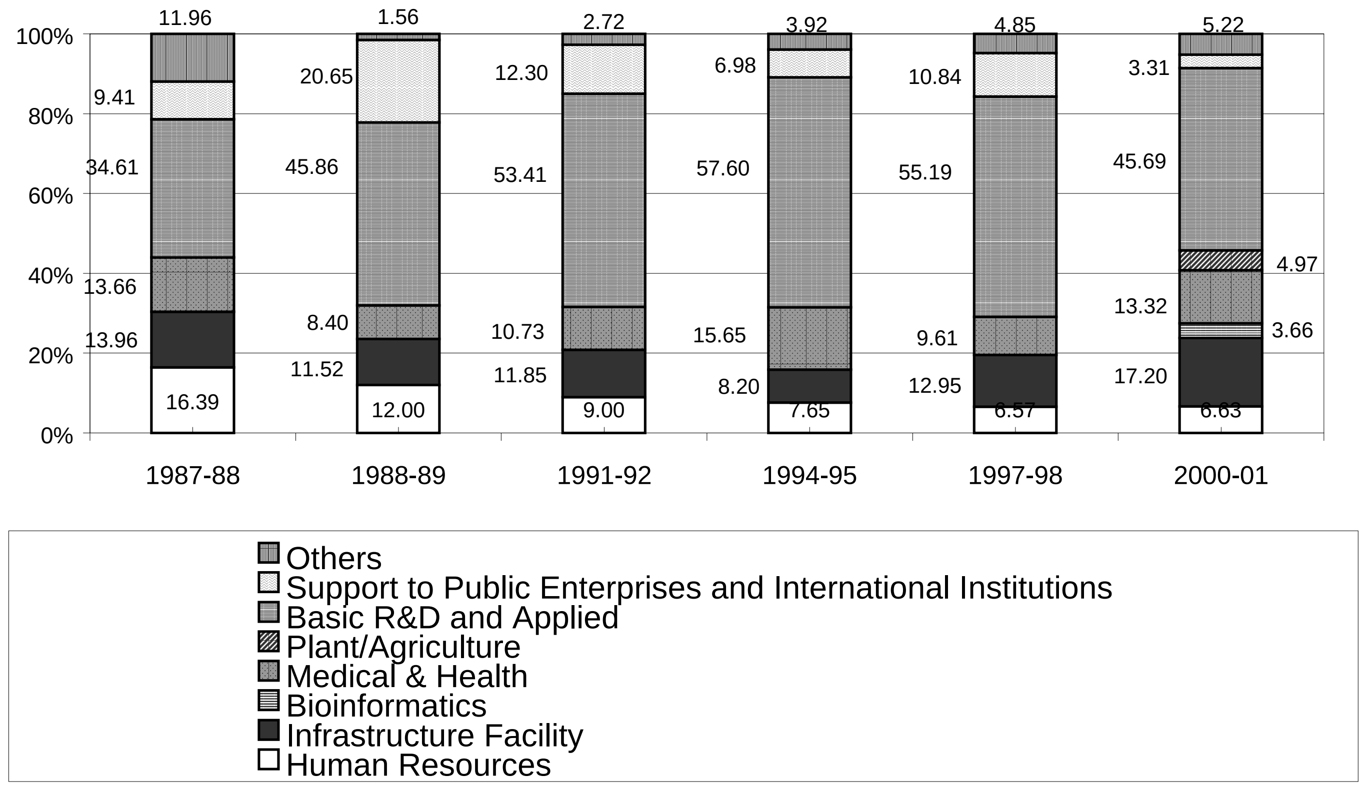


Figure 1: Budgetary Allocations to Department of Biotechnology
60
50
40
30
20
10
0
$ in millions
31
34
33
29
30
27
31
28
28
30
40
48
1987-88
1988-89
1991-92
1993-94
1995-96
1996-97
1997-98
1998-99
1999-00
2000-01
2001-02
2002-03
Years
Budgetary Allocations

Figure 2: Secotwise Allocations of DBT



Source: RIS based on DBT Reports (several years).

III.4 Statistics collected by Private Organisations

There are couple of major private sector organisations, which have been coming out with biotechnology statistics for India. However, leaving one or two aside they are largely focussed to a particular sector only. For instance, All India Biotech Association (AIBA) has been regularly coming out with details about adoption and production of biofertilizers and biopesticides while PharmaBiz (a private web site) has been providing details about medical biotechnology only. Confederation of Indian Industries (CII) and Ernst and Young are the agencies, which may provide a macro picture of biotechnology industry. However, they also have yet to launch an exercise for regular data collection.

The Fertiliser Association of India (FAI) regularly brings out production and composition statistics about biofertilisers in India. Table 4 gives some details about total quantum of biofertiliser being produced in India since 1992-93 and the number of units engaged in its production. The production level has gone up from 2.5 thousand tonnes in 1992-93 to 10 thousand tonnes in 1999-2000. The biofertilisers are now being adopted across the country in a major way. Accordingly, number of producing units have also gone up from 35 in 1992-93 to 95 in 2000. Similarly, individual initiatives in putting data together has facilitated evolution of macro level perception of various agricultural input industries. Sadananda (2002) has made an effort to analyse Indian seed industry (Table 5).

Table 4: All India Production of Biofertilisers

Year	Biofertiliser ('000 tonnes)	No. of Producing firms
1992-93	2.5	35
1994-95	5.8	72
1997-98	8.5	80
1999-00	10.38	95

Source: Biofertiliser Statistics, various issues, FAI, New Delhi

Table 5: Indian Seed Market

Sector	1994-95		1998-99	
	Market size ($ Million)	**Per cent**	**Market size ($ Million)**	**Per cent**
Public Sector	127.49	40	133.30	25
Private Sector				
Organized	111.56	35	319.93	60
Unorganized	79.68	25	79.98	15
Total	**318.74**		**533.22**	

Source: (Sadananda 2002)

Note: The figures have been converted in dollars through the IMF exchange values for concerned years.

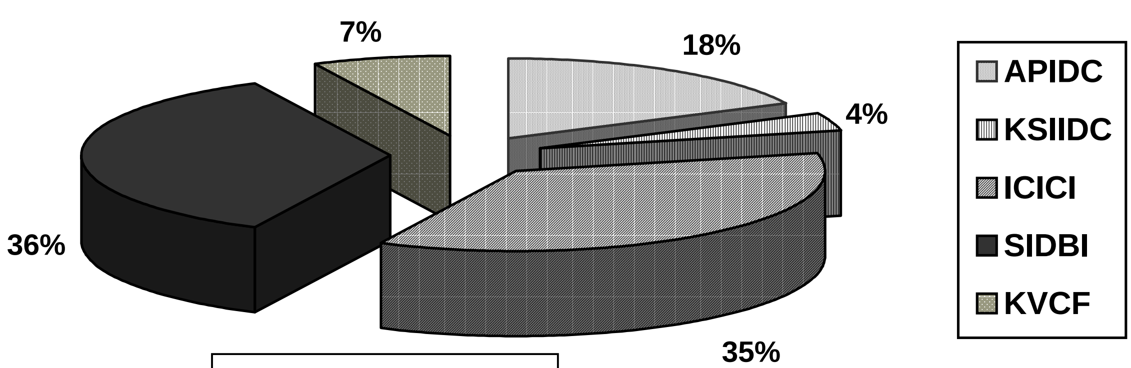
The venture capital has emerged as a major source of funding frontier technologies across the world. Biotechnology has attracted a large number of commitments by different agencies. This report has presented a broad picture of these allocations on the basis of press clipping and other sources. This is being presented in Figure 3. However, some agencies like National Association of Software and Services Companies (NASSCOM) also occasionally come out with some statistics on venture capital disbursement in India. One of the recent report from NASSCOM gives detailed information about the number of companies which received venture capital across major Asian economies. This has been briefly presented in Table 6.

Table 6: Venture Capital Disbursements in India (2001) **($ Million)**

Country	**Investment**	**No. of Recipient Companies**
Japan	1,858	39
India	1,105	91
South Korea	1,054	19
Singapore	965	26
Australia	548	81
China	393	11
Hong Kong	263	23

Source: Nasscom (2001)

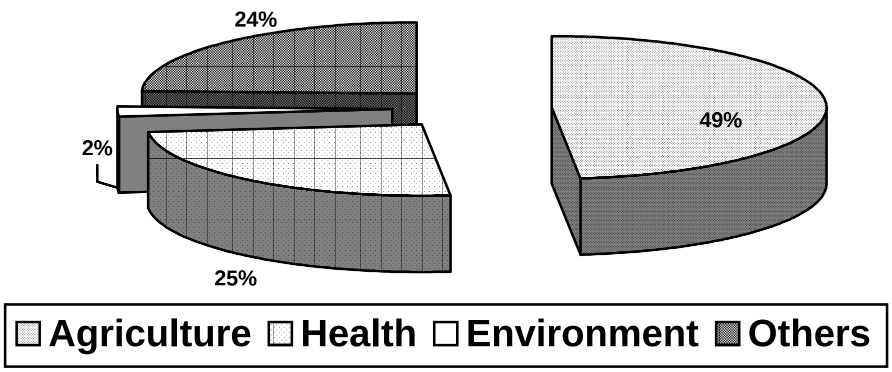
Figure 3 :Biotechnology Commitments of VCFs in India



Source: Chaturvedi (2002b)

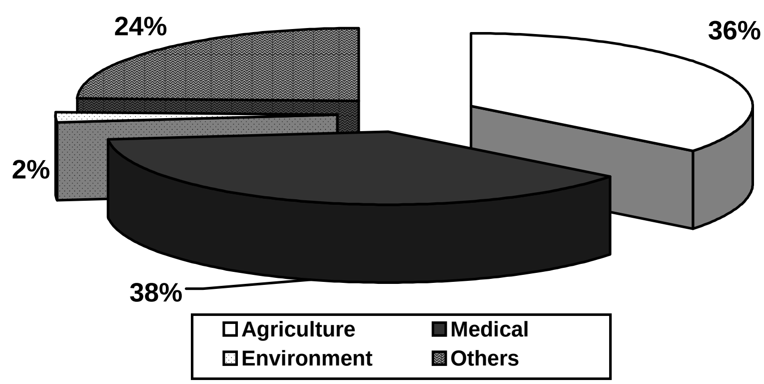
The Biotech Consortium India Limited (BCIL), a public limited company promoted by Department of Biotechnology (DBT), Government of India, has come out with its recent (2001) directory on biotechnology institutions and industries. According to the BCIL survey, there are in total 176 biotechnology firms present in India out of which 49 per cent are agriculture based companies while 25 per cent companies have interest in the health related medical activities and 26 per cent companies have varied interests including in environmental biotechnology (Figure 4). Though, total number of firms in health sector is lesser but more of them have external alliances. As Figure 5, shows 38 per cent of health related companies have external alliances while only 36 per cent agriculture firms have such alliances. Table 7, has made an effort to capture total investment in biotechnology industry in India along with its sectoral break up. It also provides details about total and technical manpower employed and growth in turnover at the sectoral level.

Figure 4:Sectoral Breakup of Biotechnology Firms in India



Source: RIS based on BCIL 2001

Figure 5: Foreign Alliances of Indian Biotechnology Firms



Source: RIS based on BCIL 2001

Table 7: Investment, Total Employees and Turnover of Biotechnology Industry India						
Field	**Investment in $ Million**	**Total Employees**	**Technical Employees**	**Turnover 1997 in $ Million**	**Turnover 1998 in $ Million**	**Turnover 1999 in $ Million**
Agriculture	207.21	15029	5217	287.80	279.27	266.86
	0.79	24.83	30.81	0.72	0.50	0.38
Environment	0.55	66	30	0.89	0.69	0.56
	0.00	0.11	0.18	0.00	0.00	0.00
Health	487.83	28520	3066	581.86	859.79	1090.97
	1.87	47.12	18.11	1.46	1.55	1.57
Others	23.37	16905	8619	228.21	205.78	252.31
	0.09	27.93	50.90	0.57	0.37	0.36
Total	**718.96**	**60520**	**16932**	**1098.75**	**1345.53**	**1610.70**

Source: RIS based on BCIL 2001.

Biotechnology industry in India has attracted total investment of Rs. 26,108 million, out of this, agriculture could get 29 per cent while health related medical sector got 68 per cent share. Accordingly, enterprises engaged in health sector provided employment for a large number of people (28, 520). This is 47 per cent of the total jobs created by biotechnology in India. While, enterprises in agriculture sector generated almost 25 per cent jobs. The number of technical people employed in agricultural sector is very high. This sector shares 31 per cent of technical manpower employed in biotechnology while health sector’s share is 18 per cent only. Accordingly, the agricultural sector has 35 per cent of its employees as technical manpower while similar number for the health sector is 11 per cent only. The share of health sector in total turnover has consistently gone up. It was 53 per cent in 1997, 64 per cent in 1998 and then 68 per cent in 1999. While the agricultural sector, which has higher number of technical manpower has seen a decline in its share in total turnover of biotechnology industry in India. It has come down from 26 per cent in 1997 to 16 per cent in 1999.

III.5 OECD Methodology and Current Data Collection Exercise in India

As is clear from Table 8 limited efforts have been made by different agencies to collect statistics on biotechnology. The DBT Annual Report gives detailed account of budgetary allocations including for R&D and other heads. The data collection exercise is to be further strengthened in the sense that there are many other agencies allocating budgets for biotechnology related projects. Moreover, a consensus on the definition of biotechnology *per se* is yet to be attempted. Therefore, nature of technology being supported under the head of biotechnology probably may lead to different sets of conclusions altogether. According to OECD, following approach has been adopted to define biotechnology.

The Single definition

The single definition agreed to, by the OECD ad hoc committee meeting was as follows:

"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."

The List based defintion

The list based definition agreed to by the ad hoc meeting contains the following five categories:

1. DNA (the coding)

genetics, pharmaco-genetics, gene probes, DNA sequencing/synthesis/simplification, genetics engineering.

2. Proteins and molecules (the functional blocks):

Protein/peptide, sequencing/synthesis, lipid/protein engineering, proteonics, hormones, and growth factors, cell receptors/signalling/pheromonics.

3. Cell and tissue culture and engineering:

Cell/tissue culture, tissue engineering, hybridisation, cellular fusion, vaccine/immune stimulants, embroyo manipulation.

4. Process biotechnologies:

Bioreactors, fermention, bioprocessing, bioleaching, bio-pulping, bio-bleaching, biodesulphurization, bioremediation and biofiltration.

5. Sub-cellular organisms:

Gene therapy, viral vectors.

The data being collected in India by organisations such as BCIL, FAI and AIBA largely depend upon feed back from questionnaire being sent to different companies. However, they make efforts to supplement information through secondary sources such as reference books, internet, company profiles and reports. The general sensitivity about precise definition of biotechnology and about its various other sub-components, while data is being collected seems to be very low. Moreover, the frequency is not very regular. Therefore, strong efforts have to be made to initiate a dialogue among at least few of these agencies to adopt a common definition and clearly define methodology for data collection.

National Science and Technology Management Information System (NSTMIS) at Department of Science and Technology (DST) is planning to initiate some exercise in this regard. NSTMIS has already initiated a project to map biotechnology capability in its entirety through an assessment of various types of competence, embodied knowledge and research infrastructure. This will be achieved through the use of direct questionnaires, interviews and assessment of projects and patents. This will involve mapping the technology capability in terms of R&D expenditure and manpower in the various segments such as research, manufacturing, consulting and biotechnology products developed, projects in vogue, services provided, patents granted, research, testing and production infrastructure. This study will cover major biotechnology firms, research institutions, consultancy services as well as biotechnology research at major universities.

Table 8: Biotechnology Statistics Collection in India

S.N.	Agency	Indicators	Frequency
1.	Department of Biotechnology (DBT)	R&D allocations by DBT	Annual
2.	Biotech Consortium India Limited (BCIL)	Industry directories. Sectoral details about biotech companies/their area of Research/budget allocation/ No. Of patents/foreign Collaboration.	Occasional. Till now, three editions are out 1992; 1994 & 2001
3.	Fertiliser Association Of India (FAI)	Production & composition details of bio-fertilisers; companies engaged & their quantum of production	Occasional. Till now, three reports are out.
4.	All India Biotech Association (AIBA)	Production levels of bio-fertilisers and bio-pesticides	Occasional. Till now, three surveys are out.
5.	Department of Science And Technology (DST)	R&D expenditure and manpower; biotechnology Products, projects, services And patents.	Limited data collected but a structured survey is yet to be launched.
6.	Technology Information, Forecasting & Assessment Council (TIFAC)	Biotechnology Patents	Limited data collected but a structured survey is yet to be launched.

Source: Chaturvedi, Sachin (2002b).

IV Agenda before Developing Countries

At the international level, there is an over dominating emphasis on data collection on biotechnology process and product development along with statistics collection on social attitudes towards biotechnology. In the context of developing countries, the concerns and perceptions about biotechnology and its diffusion are much different than say in the developed countries. The basic policy concerns in developing countries are much wider and deeper. As has been mentioned earlier, they range from resource substitution for R&D among different technologies to sustenance of food security, ensuring availability of low cost but effective vaccines etc. They also have country specific challenges in terms of human resource development and also in terms of establishing right kind of linkages among different constituents of a national innovation system. Accordingly, the formulation of indicators should be such that they capture contribution of biotechnology towards these ends.

Since in developing countries, share of public allocation for R&D is many times more than the private sector allocation in biotechnology, it is important for the policy planners to correlate R&D priorities in new technologies with the technological constraints emerging from conventional methods. At this point, biotechnology is being attempted in many developing countries in isolation of their established R&D systems[18]. As a result, its infusion and absorption has largely remained at the periphery only. The technological frontier for developing countries has to be an outcome of accumulation of both new and conventional techniques rather then an outright replacement of the conventional techniques with new techniques[19]. For instance, most of the green revolution varieties of different crops have reached their peaks in terms of their productivity[20]. Similarly, in the health sector tropical diseases still get very little attention of international agencies. Therefore this aspect should be addressed on priority basis in the health sector research agenda. Therefore expenditure on biotechnology R&D would be justified if budgetary allocations move research agenda in the direction which can solve these problems.

Apart from influencing R&D planning towards these objectives it is also important to ensure that adequate infrastructure comes up to support indigenous research endeavors. This includes both physical infrastructures like high-grade instruments and advanced laboratories, adequate germ-plasm collection, etc. and human resources. There again, the human resource development is to be encouraged at various levels and in different magnitudes. Since biotechnology program objectives needs to be very clear, the developing countries might even have to plan for manpower with super-specialization to attend the high priority areas defined by the relevant public policy. An attempt is being made in Table 9 to capture these different attributes in one matrix to determine the position and direction of biotechnology policy in different countries. This is specifically attempted for agricultural sector but may be extended to others with change in biotechnology attributes and policy targets[21]. The factors determining economic cost would largely remain the same. The matrix consists of the major crops in a given developing country on the vertical axis, while the aggregate cost values for R&D, IPR protection, biosafety enforcement, infrastructure, distribution cost and cost for human resource development all on the horizontal axis. These costs may be involved in introducing any of the biotechnological traits such as pest resistance, drought resistance and productivity improvement etc. in the ordinary varieties of different crops listed on the vertical axis. These crops are generally important for food and nutritional securities or exports of developing countries.

Table 9: Biotechnology in Developing Countries: Matrix for assessing Technology Direction and Cost of Adoption

	Biotechnology Traits (Economic Cost)	Productivity Improvement (RPBIDH)	Pest Resistance (RPBIDH)	Drought Resistance (RPBIDH)	Enhancing Shelf Life Value (RPBIDH)	Reducing Post Harvest Losses (RPBIDH)	Nutritional Improvement (RPBIDH)
Food Grains							
Cereals							
Rice							
Wheat							
Coarse cereals							
Pulses							
Gram							
Non-Foodgrains							
Oilseeds							
Groundnut							
Rapeseed							
Fibers							
Cotton							
Jute							
Mesta							
Plantation crops							
Tea							
Coffee							
Rubber							
Others							
Sugarcane							
Tobacco							
Potato							

Note: Economic Cost constitutes RPBIDH.
R: R & D Allocation; P: Patent (IPR) Protection; B: Biosafety Enforcement; I: Infrastructure; D: Distribution Cost; H: Human Resource Development
Source: RIS 2002.

In some of the developing countries biotechnology industry has already made a niche for itself. In countries like Indonesia and Thailand firms are largely engaged in agricultural biotechnology while in India and Singapore a large number of firms are involved in contract research for health and pharmaceutical industry[22]. This is largely happening because of the fact that a large number of non residents of these countries and other scientists are coming back to get affiliated to any of the major research institutes and are floating their own companies. This would certainly enhance domestic capability of private sector in developing advanced indigenous products in pharmaceutical sectors. Since both these countries have rich racial diversity, they are much better placed, to conduct pre-clinical trials for tropical drugs and vaccines[23].

This brings the very role of private sector upfront in this frontier technology and the various ways and means available to the developing countries for supporting domestic entrepreneurship. They may be financial mechanisms like tax incentives, venture capital funds and even R&D grants. Some of the governments have encouraged private sector to supplement the government efforts in tapping biotechnology while others have marked different trajectories for growth of private sector. Some of these countries have now also encouraged institutional arrangements between the private sector and the other actors of innovation system, such as, public sector research laboratories, universities etc. like Singapore has established several companies attached with public institutions for commercializing the products developed at these institutions[24].

The developing countries also have a major challenge in terms of balancing the regulatory regime for biotechnology viz. a viz. the returns to society from this technology. Here the bio-safety guidelines, intellectual property laws, trade regulations and bio-ethical guidelines become extremely relevant and important. Each of them have their own role in terms of affecting the growth of biotechnology and all most all the developing countries are committed to similar nature of international treaties and governing regimes in these fields. This commonality should be used by developing countries for evolving policy responses in their respective national biotechnology policies.

At the Doha Ministerial Meeting of WTO, the labelling of GMOs has emerged as a key point for future work agenda. Even otherwise, this issues span several WTO agreements, including SPS, Agriculture, Intellectual Property (TRIPS) and Technical Barriers to Trade (TBT). It has also been discussed in the Trade and Environment Committee. Although member governments have notified a large number of regulations related to GMOs to the SPS Committee, most of the discussion on the subject has been in the TBT Committee with the focus on labelling regulations. However, since quarantine agencies in developing countries are not well equipped to identify biotechnology goods, it is important to ensure a separate category for biotechnology goods under HS and SITC trade classifications. This would have to be addressed on a priority basis as far as international biotechnology statistics is concerned. While at the domestic level indicators related to national innovation system are important and relevant for policy formulations.

V Concluding Remarks

As is clear, biotechnology has reached at a stage of development and diffusion where developing countries should take stock of its direction and related cost of its adoption. This exercise would also help in identifying major policy concerns related to biotechnology. In light of those concerns statistical indicators may be identified to equip policy makers with relevant information and data. In this regard, OECD led initiatives become important and relevant. The various stages of developing national statistical framework for this kind of data collection require harmonization of approaches not just among different national agencies dealing with biotechnology but also among various international agencies working with data on trade, investment, technology, etc.

The efforts to evolve a common approach for defining nature and coverage of biotechnology itself should be urgently initiated in the developing countries. At this point, such efforts are completely missing in many developing countries. This may create confusion in enlisting various industries eligible for classification in the biotechnology category. This emerging stumbling block should be cleared much before data collection exercise is launched across the countries. Though OECD methodology and list of short listed indicators may be a good starting point for the developing countries but they should give precedence to their policy concerns while evolving their statistical framework for analysing impact of biotechnology on their economies. As has been mentioned earlier, the public sector in most of the developing countries still share a large portion of biotechnology expenditure. Ideally the data should reflect on the ‘public-good’ biotechnologies have created and their diffusion by commercial companies. Thus the developing countries would have to choose indicators, which give them a robust account of economic requirement of biotechnology in their respective economies along with placing biotechnology in their national innovation systems. Since resources are scarce with these economies, data collection may even help in avoiding research duplication and help in addressing the specific challenges in a focussed manner.

In case of India, though there is no common definition of biotechnology being followed by different agencies and organisations an effort has been made in this paper to present the existing biotechnology statistics available from different sources. The Department of Biotechnology (DBT) or any other concerned agency should urgently address to this need of having a common definition of biotechnology in place in India. Subsequently, an initiative to collect national biotechnology statistics on lines of Tenth Five-Year Plan priorities should be launched. This would have to be an inter-agency exercise, possibly involving, Department of Science and Technology, Ministry of Commerce, Central Statistical Organiation, industry chambers, academics and think tanks.

The prioritization within this exercise is of equally great importance. For instance, after the Doha Ministerial of WTO, the trade related biotechnology issues have come up at the centre stage of international debates. Efforts would have to be launched to adequately classify biotechnology goods and services under the current system of trade classification. This would enable the policy makers, across the countries, to address the social concerns and attitudes towards this technology. Biotechnology, especially in the agricultural sector at WTO, is facing a major challenge in terms of intellectual property rights regime. This is a new instrument in the agricultural sector. The data being collected on patents and their classification has yet to reflect on some of the concerns mentioned earlier. The patenting of research tools in biotechnology has generated a wide debate. A database on biotechnology patents would help in bringing out these trends in a comprehensive manner. WIPO has made an effort to address to these concerns through some of its projects but as is clear more has to be done.

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