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# DYNAMICS OF BIOTECHNOLOGY RESEARCH AND INDUSTRY IN INDIA: STATISTICS, PERSPECTIVES AND KEY POLICY ISSUES

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**Sachin Chaturvedi**

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# DYNAMICS OF BIOTECHNOLOGY RESEARCH AND INDUSTRY IN INDIA: STATISTICS, PERSPECTIVES AND KEY POLICY ISSUES

Sachin Chaturvedi*

## ABSTRACT

The purpose of this paper is twofold. First, an inventory is made of biotechnology data collection in India. This will include an assessment of how the need for biotechnology related statistics is being addressed, mainly in terms of patent data, commercialisation of genetically modified organisms, R&D allocations for biotechnology and industry statistics. In general, limited efforts have been made by different Indian agencies to collect statistics on biotechnology. One of the reasons for this scarcity of statistics is a missing consensus in India on a definition of biotechnology. However, initiatives are underway to address this and to establish a measurement framework.

A second objective of this document is to present a broad overview of the status of biotechnology in India, with a focus on the agricultural and the health sector. First the funding and research programmes of various institutions are discussed, followed by an overview of human resources development and training possibilities in the country. A third section discusses capital venture funding and the role of financial institutions, while the last two sections look at initiatives by state governments and the policy regulations in place.

The paper concludes with a number of conclusions and policy specific recommendations, which can be summarised as follows.

- To address the current lack of focus, India needs to establish a mechanism that will help to set priorities in the R&D work programme of various public laboratories and departments. India also needs to adjust the human resource policy according to these research priorities.

- There is a large number of agencies dealing with biotechnology, which has led to duplication of research funding and a lack of co-ordination. This needs to be addressed urgently.

- Once core areas of competencies have been identified, efforts need to be undertaken to attract star scientists back to the country.

- Small and medium-sized enterprises need more support to face the intense competition from multinationals.

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- Policies need to be developed or articulated better to deal with various technology inherent and technology transcending risks.

- The Department of Biotechnology (or another relevant agency) should urgently initiate an data collection exercise, especially concerning data on biotechnology related allocations at the individual institute/laboratory level and on patent data using International Patent Classification details. It is also important to evolve a consensus among agencies on the definition of biotechnology. Lessons can be learned from the experience of OECD countries. However, while doing so, specific policy thrusts in India need to be kept in mind, such as nutritional security and indigenous technological efforts.

- India should tap the complementarities that exist both at the regional and sub-regional level in Asia for the collective advancement both in terms of establishing a physical infrastructure and in terms of an evolving common approach to policy issues. A forum like the Asian Co-operation Dialogue may help in achieving this.

- In light of these conclusions, it is important that India comes out with a comprehensive national policy to balance national socio-economic priorities with adequate technological expertise. Such a policy may also provide an overarching framework for regulatory issues, which may help in strengthening not only the process of inter-ministerial co-ordination but also in accommodating expectations of various state governments.

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# DYNAMIQUE DE LA RECHERCHE ET DE L'INDUSTRIE BIOTECHNOLOGIQUES EN INDE: STATISTIQUES, PERSPECTIVES ET PRINCIPAUX ENJEUX

Sachin Chaturvedi*

## Résumé

Cet ouvrage répond à un double objectif. Il vise tout d'abord à faire le point sur la collecte des données relatives aux biotechnologies en Inde, notamment à travers une évaluation des solutions apportées aux besoins de statistiques dans les domaines suivants : brevets, commercialisation d'organismes génétiquement modifiés, crédits de R-D consacrés aux statistiques des biotechnologies et de l'industrie. Les différentes instances indiennes concernées ont en général relativement peu investi dans la collecte de statistiques, entre autres parce qu'il n'existe en Inde aucun consensus sur la définition des biotechnologies. Des initiatives ont toutefois été engagées dans le but d'y remédier et d'établir un cadre d'analyse.

Cette publication a par ailleurs pour ambition de présenter un vaste panorama des biotechnologies en Inde, en privilégiant plus particulièrement les secteurs de l'agriculture et de la santé. Sont tout d'abord décrits les dispositifs de financement et les programmes de recherche de diverses institutions, puis est présenté un tour d'horizon des perspectives de développement des ressources humaines et de formation. Une troisième section est consacrée à l'analyse du financement du capital-risque et du rôle des institutions financières, tandis que les deux dernières sections passent en revue les actions engagées par les autorités publiques des Etats et les réglementations en place.

La publication s'achève par la présentation de conclusions et recommandations pour l'action publique qui peuvent se résumer comme suit :

- Pour pallier l'absence de grandes orientations en la matière, l'Inde doit instaurer un mécanisme facilitant la fixation des priorités du programme de R-D de divers laboratoires et services relevant du secteur public. La politique indienne relative aux ressources humaines doit par ailleurs être adaptée à ces priorités de recherche.

- Il existe en Inde une multiplicité d'instances intervenant dans le domaine des biotechnologies, d'où des chevauchements dans le financement de la recherche et un déficit de coordination qu'il est impératif d'éradiquer dans les plus brefs délais.

- Une fois recensés les grands domaines de compétence, il faudra s'employer à inciter les scientifiques indiens de renom à revenir travailler dans leur pays.

- Les petites et moyennes entreprises doivent bénéficier d'un soutien plus conséquent afin de leur permettre d'affronter la concurrence des multinationales.

- Il convient d'affiner ou de mieux articuler les politiques en vue de faire face aux divers risques inhérents ou extérieurs à la technologie.

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- Le ministère des Biotechnologies (ou toute autre instance compétente) devrait entreprendre sans délai une vaste opération de collecte de données, en particulier concernant les crédits alloués à chaque institut ou laboratoire au titre des biotechnologies, ainsi que les brevets - en s'appuyant sur la Classification internationale des brevets. Il faudrait par ailleurs que les différentes instances impliquées parviennent à un consensus sur la définition des biotechnologies. Des enseignements peuvent être tirés de l'expérience acquise par les pays de l'OCDE dans ce domaine, mais ce faisant, il convient de garder à l'esprit les spécificités de l'action publique indienne, notamment la sécurité nutritionnelle et les initiatives technologiques locales.

- L'Inde devrait mettre à profit les complémentarités existant en Asie aux niveaux régional et infra-régional pour susciter une mobilisation collective non seulement en faveur de la mise en place d'infrastructures physiques, mais aussi de l'élaboration d'une stratégie d'action commune. Une enceinte telle que le Asian Co-operation Dialogue pourrait faciliter cette démarche.

- Il ressort de ces conclusions que l'Inde doit impérativement définir une approche nationale globale lui permettant de trouver un juste équilibre entre les priorités socioéconomiques nationales et un niveau approprié de compétence technologique. Cette approche pourrait également fournir un cadre général permettant d'aborder les aspects réglementaires et, partant, de renforcer non seulement le processus de coordination interministériel, mais également de prendre en compte les attentes des différents Etats.

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## 1. Introduction

In developing countries, the emergence of frontier technologies, particularly biotechnology, is accompanied by an intense debate on techno-protectionism vis-à-vis the role of the nation-state in technological development. In this context, several issues pertaining to the role of government and the space for public sector supported R&D have been raised.[1] The rapid economic development in many developing countries, especially in South East Asia, has demonstrated that national technological capability remains a key factor in competitiveness (Lall, 1992). Some papers in the recent past have underscored the importance of a country specific institutional context as a determinant of technological capability (Dosi, Pavitt and Soete, 1990; and Nelson, 1993). In the context of developing countries, thus, one idea has been that public funded R&D institutions should develop more competence in the realm of core technologies.[2] In this context, the Indian case becomes very interesting to look at.

In India, government is playing an increasingly important role in bringing dynamism to the very functioning of the national innovation system. At the policy level, there has been a strong emphasis on an advanced physical infrastructure to provide critical support to the various endeavours in different streams of technology. They include information and communication technologies (ICTs), intelligent materials and new production processes, nanotechnology and biotechnology, apart from various other emerging areas. Furthermore, a change in the production profile of the manufacturing sector with new molecules and enzymes, along with a strong knowledge-intensive services sector is being observed.

This new policy thrust has exposed the Indian economy, especially agriculture and the health sector, to an entirely new set of technologies. The developments in the area of biotechnology are of particularly great interest. This frontier technology becomes important in a developing country like India, where agriculture, with stagnating productivity and crops confronting many biotic and abiotic stresses, looks for growth avenues. Similarly, in the health sector, a new set of government policies and regulations and new alignments among firms are leading to a major structural transformation. The associated changes are being implemented through a stronger regulatory regime, both in the spheres of intellectual property rights (IPRs) and biosafety. In fact, with the advancements in this technology, stronger instruments, such as utility patents are being proposed for its protection.[3] In the case of biosafety, efforts are being made to bridge the gap between the Cartegena Biosafety Protocol and national legislation.

However, the need for a reliable data set for accurate assessment of its adoption is widely felt. This need has become more pressing over the last few years, as a formal system for regulation of biotechnology, it seems, is trailing behind the informal channel for infusion of this technology, especially in the agricultural sector. In this paper, an effort is being made to briefly take stock of the collection of data in India relating to biotechnology (Section 2). This includes an assessment of how the need for biotechnology related statistics is being addressed, mainly in terms of commercialisation of genetically modified organisms (GMOs), R&D allocations and industry statistics. Section 3 presents a broad overview of the status of biotechnology in India in the various sectors, namely agriculture and health. Section 4 concludes by enlisting several policy specific suggestions for advancing the biotechnology innovation frontier in India.

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1. Archibugi and Machie (1997).
2. Kumar (1998).
3. Chaturvedi (2002).

## 2. Measurement framework for biotechnology

It is often observed that most studies on biotechnology are descriptive and essentially qualitative in nature and thus do not provide firm specific data and analysis.[4] These studies do help in exploring further the contours of this enabling technology, but do not give a full picture of its dynamics. While industry specific policy measures are evolving this emerges as a major constraint, as no indicators are available to capture the nature and complexity of innovation being imbibed by biotechnology firms. In the recent past though, several sets of economic evidence have been placed before us, to assess the impacts of the most widely adopted transgenic crops and other biotechnology products. However, some of these studies have triggered an intense debate questioning the validity and reliability of data and thus of observations made.[5] It is in this context, that a need is being felt to evolve statistical concepts and measures to capture economic activities in the biotechnology sector which may help in setting the right policy tones.

In the case of the OECD, an effort has been made to harmonise data collection initiatives by its member countries. Some of its members have launched national surveys to assess the status of biotechnology and its contribution to their economies. These surveys are based on the OECD definition of biotechnology, which has been revised and updated through various approaches after successive rounds of data collection in the respective member countries. The biotechnology data collection exercise has actually evolved around a conceptual framework for collecting statistical data involving various indicators including a model survey, which incorporates social responses to biotechnology, R&D allocations, export-import of biotechnology goods, the number of biotechnology patents, total employment in biotechnology related industries and other such indicators chosen for this purpose.

In the case of countries like India and other developing countries there may be certain additional issues that policy makers and others may like to incorporate while evolving such a framework. Since the peak of the Green Revolution years[6], agriculture continues to face serious challenges on account of input resource imbalance and stagnating yield levels. The excessive usage of chemicals and pesticides has adversely affected the soil fertility. The varieties used during the Green Revolution have also attained the maximum yield potential, so despite the continuous rise in inputs there is no productivity gain. In this context, the biotechnology statistics should help in setting the right direction for the R&D support. Similarly, biotechnology indicators should also help in identifying the needs of the poorest of the poor for instance through the addressing of ‘orphan crops’ like cowpea, millet, sorghum, etc. These crops may play a crucial role in ensuring food security in several rural areas. Another important dimension in the agricultural sector could be to generate indicators which may reflect on non-farm rural income such as tissue culture, biofertilisers, biopesticides, etc.

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 of developing countries. For instance, the Hepatitis B vaccine was developed in 1989 and since that year more than 300 biopharmaceutical products have been put on the world market. These have reduced the cost of adoption and diffusion of these products. Biotechnology statistics in the health sector may address the cost

4. Rose (2004).

5. For instance, see the debate on yield gains from Bt Cotton in India (Jishnu and Radhakrishna, 2003; Krishnakumar, 2003; Sahai, 2003; Arunachalam and Bala Ravi, 2003; and APCID, 2003).

6 . The Green Revolution was the introduction of high yielding varieties in several developing countries which happened towards the end of 1960s. This made several developing countries, including India, almost self-reliant in food production.

advantage of the technology and may also help in identifying the right research priorities. 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 desirable attributes developing economies may expect biotechnology products to be equipped with. Some of these policy issues may be captured in the statistical work.

Furthermore, the illegal introduction of biotechnology products is also a great menace in India as it is in several other developing countries as well. The claims for economic gains are valid under specific situation of biosafety management, but if these situations are not maintained, expected gains might be reduced drastically. In neighbouring countries that lack biosafety protocol and capacity to implement biosafety guidelines, introduction of unauthorised varieties may lead to harmful environmental consequences, high pesticide cost and eventually pest resistance.[7] Statistics on these should help policy makers identify the great opportunity cost of biosafety management mechanisms.

In light of these issues, we may assess how the statistics collection system is working in India. At the outset we may look into the general framework of statistics collection.

### *2.1 Statistics collection and the biotechnology sector*

In India, the Central Statistical Organisation (CSO) is the key agency for data collection on industries. It brings out the Annual Survey of Industries (ASI), which is the principal source of industrial statistics and provides statistical information to assess growth, composition and structure of the organised manufacturing sector. CSO has yet to include the biotechnology industry as a separate category. However, the CSO has paid increasing attention to developing a database on emerging issues such as the environment. It has published data on various aspects of environment, in the “Compendium of Environment Statistics”, for the first time in 1997. Subsequently, this has been published on an annual basis. The current issue pertaining to the year 2002 is the fifth in the series. This issue covers biodiversity-related indicators as well. This series has indicators covering various accessions in the gene banks across India.

Another agency engaged in data collection in a major way is the National Science and Technology Management Information System (NSTMIS) of the Department of Science and Technology (DST). It has been entrusted the task of building an information base 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 financing at a broad macro level, but biotechnology related specific issues are still not included in its surveys.

The Department of Biotechnology of the Government of India provides some specific biotechnology data. The DBT has taken a very broad definition of biotechnology. According to this definition, “biotechnology is an application of recombinant and non-recombinant technologies in biological resource utilisation for product and process development aimed for commercialisation.”[8] The definition is so wide that the classification of biotechnology commodities for data collection purposes becomes very difficult. Furthermore, industrial production of some of these commodities is a rather recent phenomenon. As these goods are included in broad product categories, efforts are yet to be made to conceptually separate these commodities for accounting purposes. Accordingly, the estimation of the size of the market for biotechnology products by various agencies also varies a great deal (see Table 1). There may be other considerations behind these projections as well, depending on various perceptions and interests.

7. FAO (2003).

8. Sharma (2002).

**Table 1. Differing perspectives on biotechnology in India, 2001 (millions of USD, PPP adjusted)**

| | CII (Confederation of Indian Industry) | DBT | The Economist[iv] |
|---|---|---|---|
| Biotech market | 13 642[i] | 10 090 | 8 049 |
| Agri/seed market | 2 728[ii] | | 2 456 |
| Diagnostic/vaccine market | 2 292 | 819 | 2 046 |
| Bio-informatics market | 12[iii] | | |

*Sources*: RIS based on: (i) Financial Express, October 10th, 2001; (ii) Business Standard, December 24th, 2000; (iii) Hindu Business Line, July 9th, 2001 and (iv) The Economist, September 1st, 2001.

In the remainder of this section we will see the status of data collection in areas like patents, GMO releases, trade and government R&D funding. The private sector has also made some efforts in data collection, which are also being looked into. At the end, we contextualise data collection in India in light of OECD initiatives.

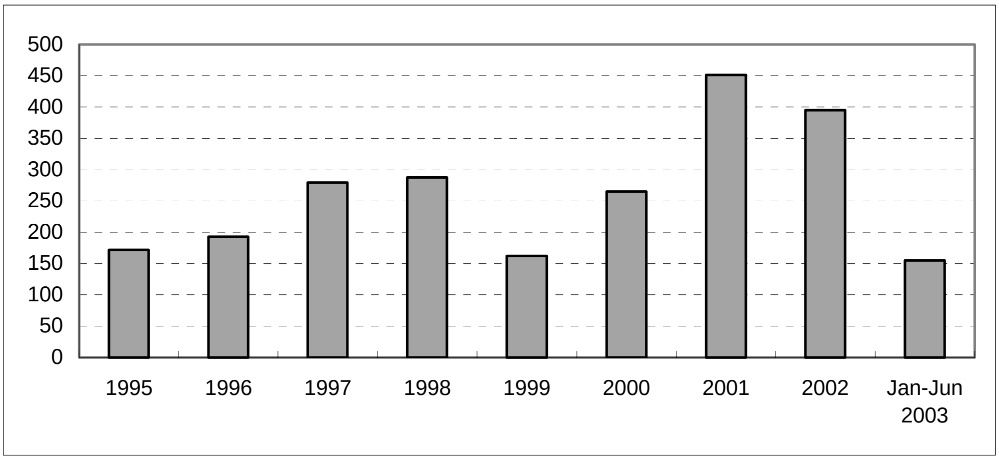
### *2.1.1 Patent data*

Despite two revisions of the Indian Patents Act, 1970 and accession to the Budapest Treaty in 2001, there is a lack of clarity on the patentability of biotechnology inventions.[9] The Budapest Treaty and TRIPs do not define 'micro-organisms' and India has yet to adopt such a definition. In a further amendment of the Act (Third Amendment Bill, 2003) the issues being addressed include the definition of inventions and pre-grant opposition of patents. The earlier amendments included creation of 'mail-box' provision and arranging for the 'exclusive marketing rights' (EMRs) as an interim protection for pharmaceutical products, which would eventually lead to the provision of product patent protection for pharmaceuticals and others by 2005.

Problems are found in the data management for patent related indicators. The Technology Information Forecasting and Assessment Council (TIFAC) and the National Research Development Corporation (NRDC) manage the database for patents in electronic form, but have yet to separately classify biotechnology patents as per an international classification, as they do not collect International Patent Classification (IPC) details. Adopting IPC may help in identifying biotechnology patents. Notwithstanding, this data limitation, recently TIFAC (2004) estimates show that from 1995 to 2003, 2 378 biotechnology patent applications were filed in India. Out of these applications 716 were convention applications while 774 were PCT applications. The highest number of patents was filed in 2001 (see Figure 1).

9. The Budapest Treaty accords international recognition of the deposits of micro-organisms for the purpose of patent protection at the sites located within the member countries. India recognised its first International Depository Authority (IDA) at the Microbial Type Culture Collection Centre at the Institute of Microbial Technology (IMTECH), Chandigarh in 2002.

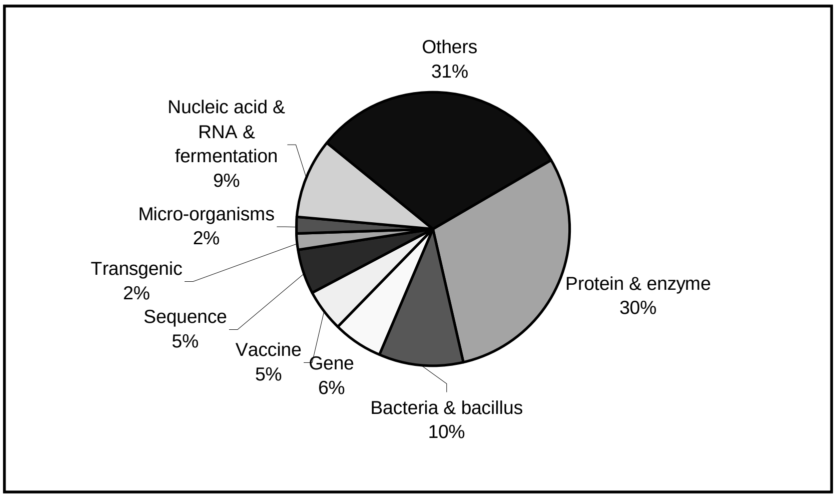
**Figure 1. Number of biotechnology patents filed in India, 1995-2003**




*Source*: RIS based on TIFAC (2004)

Among the areas within biotechnology, the largest number of patents was related to protection in research areas like proteins (30%) and enzymes and bacteria (10%) (see Figure 2). The other categories include RNA and fermentation (9%), gene specific patents (6%) and vaccines (5%), while sequences and transgenics accounted for 5% and 3% of patents filed respectively. Providing patent data as per the IPC classification may facilitate access to rich, plentiful and internationally comparable data.

**Figure 2. Biotechnology patents in India by area of filing, 1995-2003**




*Source*: RIS based on TIFAC (2004)

### *2.1.2 GMO field releases*

In last seven to eight years transgenic related activities in the agriculture sector have increased significantly in India. In this context, the GMO field releases may be a rich source for data on biotechnology. The regulatory authority for transgenic crops in India, the Genetic Engineering Approval Committee (GEAC) has permitted a seed company, Mahyco, to commercially release genetically modified hybrid cotton varieties. The area under cotton cultivation is little more than 9 million hectares, out of which little more than half a million hectare is under Bt cotton. Thus the coverage is very low. [10]

GEAC has approved 12 varieties of Bt cotton hybrids developed by Rasi Seeds, Ankur Seeds and the Maharashtra Hybrid Seeds Company (Mahyco).[11] These Bt cotton hybrids contain Bt cry 1 ac gene developed by US seed multinational Monsanto. While Mahyco is Monsanto's partner in India, Rasi Seeds and Ankur Seeds are the sub-licensees of Bt seed technology. The GEAC has allowed Rasi Seeds to conduct large-scale field trials and seed production in central India and south India. GEAC has allowed Ankur Seeds to conduct large-scale field trials in north India and central India. Mahyco has been allowed large-scale field trials and seed production of MRC 6301 Bt and MRC 6160 Bt in central India and of MRC 6301 Bt and MRC 6322 Bt in south India.

Monsanto-Mahyco had asked for the approval of a Bt cotton variety for commercial cultivation in north India in 2003, but the proposal was turned down by GEAC as the variety was susceptible to the deadly leaf curl virus. GEAC has now approved seed production of the above hybrids in an area of maximum 100 hectare for each variety on a trial basis. However, at present there is no approved Bt cotton variety for commercial cultivation in north India.

The next genetically modified crop hopefully to be cleared for commercialisation may be mustard. Table 2 gives a broad idea about GM plants being tested under the approval process. It also gives details about the companies which propose to commercialise these plants along with the characteristics being inserted. As is clear, four companies and seven public research institutes are attempting eleven crops for transgenic manipulation. The interesting point about this table is that though this data is widely available at various seminars and in different papers, there is no regular mechanism in the government to disseminate these details even periodically.

10. India has emerged as the third largest producer of cotton in the world, contributing 9.4% of global production in the year 2003.

11. Financial Express, April 16, 2004.

**Table 2. Current profile of GMOs under research in India**

| Crop | Source | Gene | Developer | Trait |
|---|---|---|---|---|
| Cotton | Monsanto | *Cry2Ab2* | Mahyco, Mumbai | Insect resistance against lepidopteran pests |
| | | Bt | Mahyco, Mumbai | To evaluate the incidence of the leaf curl virus disease and its insect vector on transgenic Bt cotton |
| | | *Cry1Ac* | Rasi Seeds Company Ltd. Attur | Insect resistance |
| | | *Cry2Ab2* | Rasi Seeds Company Ltd. Attur | Insect resistance |
| | Syngenta | *Vip-3* | Syngenta India Ltd. Pune | Insect resistance |
| | University of Ottawa, Canada | Synthetic *cry1Ac* | Central Cotton Research Institute, Nagpur | Insect resistance |
| | Monsanto | *Cry1Ac* | Mahyco, Mumbai | Insect resistance |
| | | *Cry2Ab2* | Ankur Seeds Limited, Nagpur | Insect resistance |
| | | *Cry1Ac* | Ankur Seeds Limited, Nagpur | Insect resistance |
| | | *Cry2Ab2* | Krishidhan Seeds Ltd. Jaina | Insect resistance |
| | | *Cry1Ac* | Ajeet Seeds Ltd. Aurangabad | Insect resistance |
| | Dow | *Cry1F/cry1Ac* Stacked genes | De-NOcil, Mumbai | Insect resistance |
| | Biocentury Transgene Company (China) | GFM *cry1A* | Nath Seeds Ltd. Aurangabad | Insect resistance |
| | ICGEB, New Delhi | *Cry1Ac* | Maharashtra State Seeds Corporation Ltd. Akola | Insect resistance |
| | NBRI/Monsanto | Bt gene | Nuziveedu Seeds Company Ltd. Hyderabad | Insect resistance |
| | BREF-Biotek, IIT, Kharagpur & University of Delhi, South Campus, New Delhi | *Cry1Ac* | JK Seeds, Secunderabad | Insect resistance |
| Rice | | Snowdrop Lectin (gna) gene | Centre for Plant Molecular Biology, Osmania University, Hyderabad | To develop plants resistant to sap-sucking insect pests |
| | IRRI | Chitinase, Bt gene Bacterial Blight resistant gene, Xa-21,Cry 1A(b), Sheath Blight resistant gene (imported seeds) | Directorate of Rice Research (DRRI), Hyderabad | To generate transgenic rice line resistant to sheath blight and stems borer (lepidopteran pests, bacterial and fungal diseases) |
| Mustard | | *Arapidopsis annexin gene* | Indian Agricultural Research Institute, New Delhi | Stress tolerance |
| | | *Choline dehydrogenase gene* | Indian Agricultural Research Institute, New Delhi | Stress tolerance |
| | | *Coda gene* | Indian Agricultural Research Institute, New Delhi | Salt stress tolerance |
| Tomato | Koo Shimamoto, Plantech Research Institute, Yokohoma, Japan | Bt Gene | Indian Agricultural Research Institute, New Delhi | Lepidopteran pest resistance |
| Potato | ICAR from Bose Institute and IRRI | Bt toxin gene *Cry1Ab* | Central Potato Research Institute, Simla | Insect resistance |
| | | *Ama1* | National Centre for Plant Genome (NCPGR), New Delhi | High protein content |
| Groundnut | | *Replicase* gene of IBCV | ICRISAT, Hyderabad | Viral resistance |

*Source*: RIS based on Mayee (2004).

### 2.1.3 Trade data

Though efforts have been made to analyse the possible impact of biotechnology on exports (Panchamukhi and Kumar, 1998), no separate classification is being followed in India for biotechnology commodities. As a result, it is difficult to assess their position in trade. 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 at this point.

### 2.1.4 Public R&D funding

There are several public agencies, such as the Department of Scientific and Industrial Research (DSIR), the Department of Science and Technology (DST), the Department of Biotechnology (DBT), the Indian Council of Agricultural Research (ICAR) and the Indian Council of Medical Research (ICMR) that have programmes supporting biotechnology, and each of them has growing allocations for biotechnology (see Table 3). However, except for DBT, no agency separately announces the budget allocations for biotechnology, as the allocations are integrated into broader headings, for accounting purposes, which makes it difficult to precisely estimate allocations for biotechnology for these agencies. The annual report of both ICAR and ICMR show an increasing engagement with genomics. In DST several new initiatives in the realm of biotechnology are launched.

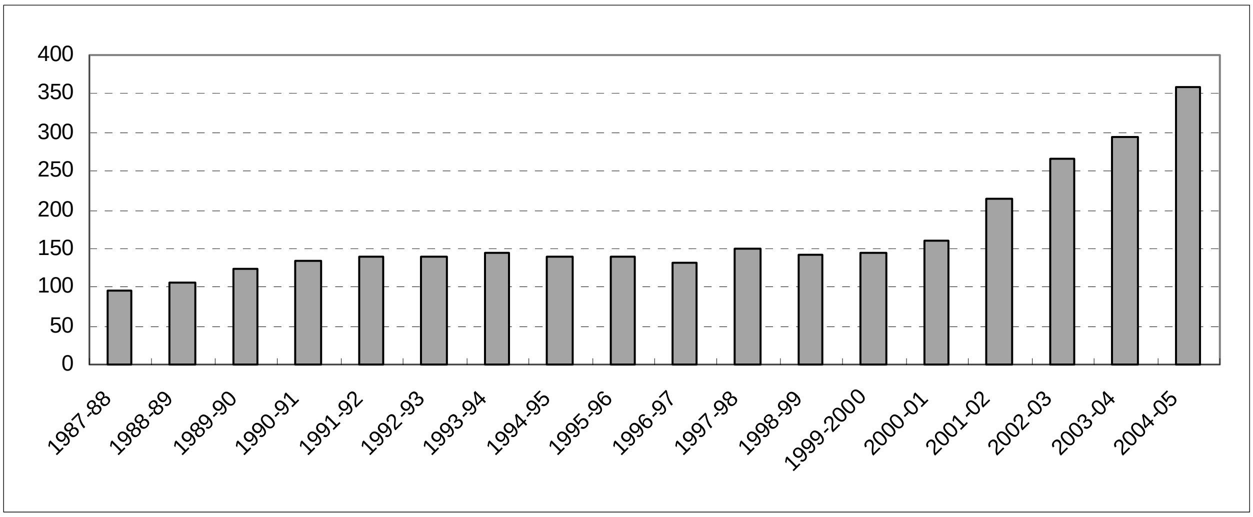
**Table 3. Budget allocations of major biotechnology funding agencies in India (millions of USD PPP)**

| | 1990/91 | 2000/01 | 2002/03 | 2003/04 | 2004/05 |
|---|---|---|---|---|---|
| Indian Council of Agriculture Research (ICAR) | 667 | 1 647 | 1 667 | 1 615 | 1 934 |
| University Grants Commission (UGC) | 720 | 1 656 | 1 774 | 1 749 | 1 832 |
| Department of Scientific and Industrial Research (DSIR) | 511 | 1 142 | 1 180 | 1 219 | 1 439 |
| Department of Science and Technology (DST) | 533 | 918 | 1 150 | 1 262 | 1 420 |
| Council of Scientific and Industrial Research (CSIR) | 484 | 1 073 | 1 145 | 1 184 | 1 399 |
| Department of Biotechnology (DBT) | 135 | 160 | 267 | 293 | 358 |
| Indian Council of Medical Research (ICMR) | 82 | 173 | 185 | 179 | 197 |
| **Total** | **3 133** | **6 768** | **7 368** | **7 501** | **8 579** |

*Source:* RIS based on budgetary papers of relevant years, Ministry of Finance, Government of India and International Financial Statistics Yearbook (IMF) for exchange rates.

The data available from DBT concerning budget allocations during 1987-88 to 2004-05 are presented in Figure 3. The sectoral allocations of DBT are summarised in the Table 13. As is clear, there has been a continued emphasis, in terms of allocations, on basic and applied R&D. Basic R&D was initially given almost 35% of total allocation, which now has become 31.5% after touching a peak of 58% in 1994-95. DBT initially extended grants in terms of institutional allocations. Since the late 1990s this trend has changed and grants are now focused more in terms of research areas. As a result, in recent years new areas are being added to the list, for example plant agriculture and bioinformatics. It is not that these areas were not receiving allocations earlier, but with the changed approach these areas now are listed separately, with genomics and bio-nanotechnology being rather recent additions to this list of allocations.

**Figure 3. Budgetary allocations to the Department of Biotechnology (millions of USD PPP)**




*Source*: RIS, based on budgetary papers of relevant years, Ministry of Finance, Government of India.

Some recent analytical papers, published by individual co-ordinators of different government programmes at DBT, also give details of data related to the programmes they deal with (Ghosh, 1997; Wahab, 1998; Ramanaiah, 2002). These papers are full with insights and sometimes provide time series data as well. However, it is difficult to get a full account of biotechnology statistics in one place. Harmonisation of concepts about biotechnology across these agencies may help in resolving this difficulty to some extent.

### *2.1.5 Biotechnology industry statistics*

There are a few major private sector and other organisations, which have been collecting and disseminating biotechnology statistics. However, leaving one or two aside, these are largely confined to sectoral interests. For instance, the All India Biotech Association (AIBA) regularly publishes details about adoption and production of biofertilisers and biopesticides, while PharmaBiz (a private website) is providing details about medical biotechnology. The Confederation of Indian Industries (CII) and Ernst and Young are agencies that may provide a macro picture of the biotechnology industry at different points in time. However, a comprehensive survey is yet to be launched for a regular industry data collection in India.

The Fertiliser Association of India (FAI) regularly brings out production and composition statistics about biofertilisers in India. Since 1996 three issues in this series are published by FAI, namely in the years 1998, 2001 and 2003. Table 4 gives details about the total quantum of biofertiliser produced in India and the number of units engaged in its production. The production level has gone up from 2.5 thousand tonnes in 1992-93 to almost 13 thousand tonnes in 2003-04. Biofertilisers are now being adopted across the country as part of the integrated pest management (IPM) strategy, but also otherwise. The number of producing units has also gone up from 35 in 1992-93 to 95 in 2001-02. The latest Biofertilizer Statistics (FAI, 2003) reports about 71 firms engaged in biofertiliser production in the country. The trend shows a growing gulf between the capacity and actual production. The apparent reason being given is the lower growth rate in demand.[12]

12. Rao (1999).

**Table 4. Indian production of biofertilisers**

| | Production(1000 tonnes) | Capacity (1000 tonnes) | Number of producing firms |
|---|---|---|---|
| 1992-93 | 2.5 | 5.4 | 35 |
| 1993-94 | 3.1 | 6.1 | |
| 1994-95 | 5.8 | 8.1 | 72 |
| 1995-96 | 6.7 | 10.7 | |
| 1996-97 | 7.4 | 12.6 | |
| 1997-98 | 7.1 | n.a. | 80 |
| 1998-99 | 6.0 | 16.4 | |
| 2001-02 | 7.4 | 15.4 | 95 |
| 2003-04 (estimated) | 12.6 | 18.6 | |

*Source*: RIS based on Biofertiliser Statistics, various issues, FAI, New Delhi

Similarly, individual initiatives in putting data together have facilitated the evolution of a macro level perception of various agricultural input industries. Sadananda (2002) has made an effort to analyse the Indian seed industry (see Table 5). The turning point in India's history of seed industry development was the announcement of the Seed Policy (1988). This policy statement and related institutional reforms have given a boost to private sector participation in the growth of the industry. Private companies have increased their share in the organised industry from 35% in 1994-95 to 60% in 1998-99[13] and 67% in 2003. There are nearly 150 registered seed companies. As Table 5 shows, the market size for seeds has grown from 1 500 million USD PPP in 1994-95 to more than 5 300 million USD PPP in 2003-04. The interesting point to note is that the concentration in favour of the organised private sector has grown manifold. The share of the public sector seed supply has declined from 40% to almost 22%, while the share of the unorganised sector has declined from 25% to 11% in the same time period. The share of the organised seed sector has grown from 35% to 68%.

**Table 5. Indian seed market**

| Sector | 1994-95 | | 1998-99 | | 2003-04 | |
|---|---|---|---|---|---|---|
| | Market size (millions of USD PPP) | % | Market size (millions of USD PPP) | % | Market size (millions of USD PPP) | % |
| Public sector | 612 | 40 | 672 | 25 | 1 162 | 22 |
| Private sector organised | 540 | 35 | 1 617 | 60 | 3 593 | 67 |
| Private sector unorganised | 386 | 25 | 404 | 15 | 581 | 11 |
| **Total** | **1 538** | **100** | **2 694** | **100** | **5 336** | **100** |

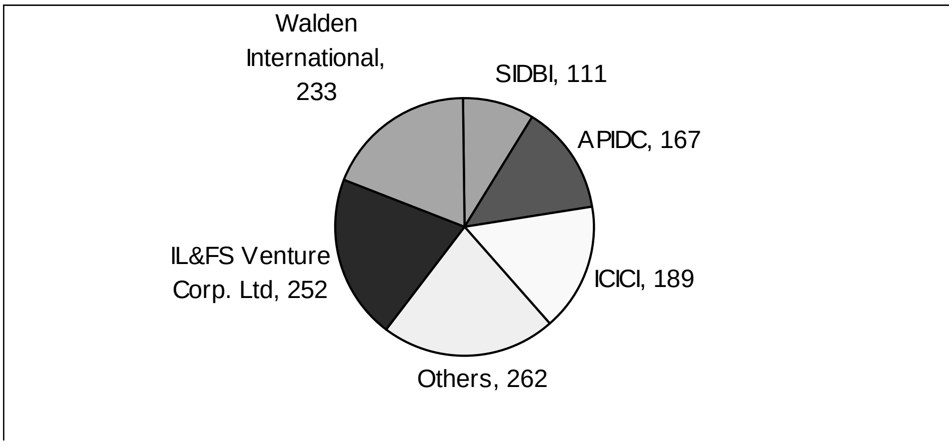
*Source*: RIS based on Sadananda (2002) and personal communication with A.S. Kataria of the Seed Association of India.

On the front of biotechnology financing, venture capital is emerging as an important source of funding. Biotechnology has attracted a large number of commitments by different agencies. A broad picture of these allocations in the specific context of biotechnology is presented in Figure 4, on the basis of press reports and other sources. At the broader funding level, there are almost 70 venture capital funds (VCFs) operating in India, which have 5.6 billion USD (29 billion in USD PPP) in assets under management. The biotechnology commitments by different VCFs include leading public sector banks and private venture capital firms apart from agencies like the Technology Development Board (TDB). There is a major data constraint when one tries to aggregate the figures available for venture capital investment in biotechnology in India. Some of these agencies have dedicated biotechnology funds, while others have identified biotechnology as one of their priority areas for investment. Together, they amount to almost 1.1 billion USD PPP by the end of 2003 (see Figure 4). Of this amount, the Indian Credit and Investment

13. Asian Seed and Planting Material (1999) and personal communication with A.S. Kataria of the Seed Association of India.

Corporation of India (ICICI) and the Andhra Pradesh Industrial Development Corporation – Venture Capital Ltd. (APIDC - VCL) are the leading dedicated biotechnology funds with a share of 16% and 14% respectively. Another dedicated biotechnology fund is the Small Industries Development Bank of India (SIDBI), which has a share of 9%. Among the other leading venture capital funds are IL&FS Venture Corporation Ltd. and Walden International, which have identified biotechnology as a key area for investment with a share of 21% and 19% respectively. There are several other financial agencies with limited funds marked for biotechnology sector. These include the Kerela Venture Capital Fund (KVCF), the Karnataka State Industrial Infrastructure Development Corporation (KSIIDC), the Canbank Venture Capital Fund Ltd., Chrys Capital Fund II, LIC, ICF Ventures, IFCI Venture Capital Funds Ltd. and IndAsia Fund Advisors Pvt. Ltd. Two of the leading biotechnology VCFs in India along with their specific initiatives are discussed in section 3.3.3.

**Figure 4. Biotechnology commitments of venture capital funds in India, 2003 (millions of USD PPP adjusted)**




*Source:* RIS data based on several press clippings

*Industry composition*

Biotech Consortium India Limited (BCIL), a public limited company promoted by the Department of Biotechnology of the government and the Industrial Bank of India (IDBI) have pioneered in the biotechnology firm level data collection. It has come out with a sizeable list of biotechnology institutions and industries in the years 2001 and 2003 in form of an industry directory. The survey for 2001 lists some 176 firms, while the 2003 survey gives a total number of biotechnology firms of 401.[14]

According to the BCIL survey, out of a total of 176 biotechnology firms in 2001 almost 48% were agriculture based companies, 24% had an interest in health related medical activities and 28% had varied interests, including environmental biotechnology (see Table 6). In 2003, the number of biotechnology firms was 401, with healthcare firms showing the largest increase, overtaking the number of agricultural biotechnology companies. The share of healthcare sector firms increased from 24% to 35% while that of agriculture based firms declined from 48% to 33%. However, as mentioned, the absolute number of total entities in the agricultural sector increased significantly, from 85 in 2001 to 132 in 2003. Similarly, in the health care sector the number of firms increased from 43 to 142 in the same period. In the year 2003, data on some new areas such as industrial biotechnology was also collected. In this category the number of

14. Though BCIL must have taken care in collecting and presenting the firm data, still one would have to be extremely careful when interpreting industrial trends from the data based on the directories. A close look at this data shows that only 23% of the firms are common to both surveys, which means a large number of new firms have responded to the data questionnaire. However, there is no note on the missing firms.

firms reported was 42, equal to 10% of the total number of firms. In this time period the number of firms engaged in environmental biotechnology also went up from 4 to 16, which is almost 4% of the total number of firms in 2003. These are basically firms engaged in extraction related activities.

**Table 6. Sectoral breakdown of biotechnology firms in India**

| | 2001 | | 2003 | |
|---|---|---|---|---|
| | **Number** | **Share in total (%)** | **Number** | **Share in total (%)** |
| Agriculture | 85 | 48.3 | 132 | 32.9 |
| Healthcare | 43 | 24.4 | 142 | 35.4 |
| Environment | 4 | 2.3 | 16 | 4.0 |
| Industrial biotechnology | -- | -- | 42 | 10.5 |
| Others | 44 | 25.0 | 69 | 17.2 |
| **Total** | **176** | **100** | **401** | **100** |

*Source:* RIS based on BCIL 2001 and 2003

*Firm size*

As regards size and sector of biotechnology firms, BCIL again provides some interesting evidence. As is clear from Table 7, the biotechnology sector in India has a pre-dominant presence of small firms. In 2001 and 2003, the share of small firms in the total number of firms has remained around 60%. Similarly, in the same time period, the share of large firms has also remained the same, around 25%. However, it is the share of medium firms which has gone up from 13% to almost 20%. The absolute number of firms in this category has gone up from 24 to 78.

It is interesting to see that the number of small firms has gone up much more quickly in the healthcare sector where several start-up firms have emerged. The small firms in this sector are largely Contract Research Organisations (CROs)[15]. In both agriculture and the healthcare sector, medium-sized firms have grown almost at the same pace. The healthcare sector is also the one in which the number of large firms has also grown by 88%, which signifies a rapid entry of transnational corporations in the sector. In the agriculture sector, there are very few firms in the business of transgenics. They are largely firms dealing with biofertilisers, biopesticides and tissue culture. There is also sizeable growth in firms dealing with sectors like environment and industrial biotechnology. In the environment sector, firms are dealing with waste management and business related to biosensors and are generally smaller firms. In the year 2003 their number has gone up from 4 to 9, while 6 large firms were reported in this sector. The data on industrial biotechnology firms is a new addition in the 2003 directory. These firms have undertaken various activities including areas like enzyme production, herbal extraction, genomics and proteomics tools, etc. In this sector also small firms dominate the scene, as the BCIL directory reports 39 small firms and 15 each in the medium-sized and large firm category.

15. Contract Research Organisations (CROs) are small technology led firms, which are engaged by medium-sized and large firms for outsourcing part of their larger research plans. CROs undertake research assignments on a contract basis for developing a molecule to a certain stage. They at times also undertake assignments related to clinical research and trials.

**Table 7. Number of biotechnology firms by size and sector (2001 and 2003)**

| | Total | | Agriculture | | Environment | | Healthcare | | Industrial Biotech | | Others | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 2001 | 2003 | 2001 | 2003 | 2001 | 2003 | 2001 | 2003 | 2001 | 2003 | 2001 | 2003 |
| Small firms (<51 employees) | 107 | 248 | 63 | 87 | 4 | 9 | 10 | 74 | -- | 39 | 30 | 39 |
| Medium firms (51-150 employees) | 24 | 78 | 10 | 26 | -- | 1 | 8 | 21 | -- | 15 | 6 | 15 |
| Large firms(>150 employees) | 45 | 102 | 12 | 19 | -- | 6 | 25 | 47 | -- | 15 | 8 | 15 |
| **Total no. of firms** | **176** | **401** | **85** | **132** | **4** | **16** | **43** | **142** | **--** | **42** | **44** | **69** |

*Source*: RIS based on BCIL 2001 and 2003

*Employment*

With respect to employment data, again BCIL sources have provided some interesting figures. In 2001, the healthcare sector enterprises provided employment to about 47% of total jobs created by biotechnology (Table 8), which increased to 53% of the total by 2003. This sharp rise in the health sector over-shadowed the increase in employment in other sectors. For instance, in agriculture the number of employees more than doubled, while the number of employees in the environmental sector went up from 66 in 2001 to 6 136 in 2003. The concentration of technical manpower in the health sector has increased in a major way from 2001 to 2003. Similarly, in the agriculture sector the number of technical people have gone up from 5 217 to 12 206. The industrial biotechnology sector created 3 335 posts, accounting for almost 9% of total technical jobs in 2003.

**Table 8. Number of employees in the biotechnology industry in India**

| | 2001 | | | | 2003 | | | |
|---|---|---|---|---|---|---|---|---|
| | Total | % | Technical | % | Total | % | Technical | % |
| Agriculture | 15 029 | 24.8 | 5 217 | 30.8 | 32 623 | 20.3 | 12 206 | 31.3 |
| Healthcare | 28 520 | 47.1 | 3 066 | 18.1 | 85 600 | 53.2 | 11 948 | 30.6 |
| Environment | 66 | 0.1 | 30 | 0.2 | 6 136 | 3.8 | 3 295 | 8.5 |
| Industrial Biotechnology | -- | -- | -- | -- | 14 514 | 9.0 | 3 335 | 8.6 |
| Others | 16 905 | 27.9 | 8 619 | 50.9 | 22 026 | 13.7 | 8 228 | 21.1 |
| Total | 60 520 | 100 | 16 932 | 100 | 160 899 | 100 | 39 012 | 100 |

*Source*: RIS based on BCIL 2001 and 2003.

*Turnover*

Turnover is an important indicator of analysis for any industry. BCIL provides time series data on turnover for firms across segments. The share of the health sector in total turnover has consistently gone up (see Table 9). It was 53% in 1997, 64% in 1998 and 68% in 1999. The amount of turnover generated by the agricultural sector remained stable between 1997 and 1999

**Table 9. Turnover of the biotechnology industry in India (millions of USD PPP adjusted)**

| | 1997 | 1998 | 1999 |
|---|---|---|---|
| Agriculture | 1 365 | 1 410 | 1 375 |
| Environment | 5 | 5 | 5 |
| Others | 1 081 | 1 041 | 1 298 |
| Industrial biotechnology | -- | -- | -- |
| Health | 2 759 | 4 346 | 5 617 |
| **Total** | **5 210** | **6 803** | **8 295** |

*Source*: RIS based on BCIL 2001

*Investment*

As regards investment in the sector, there was a total investment of 10.6 billion USD PPP in 2002. Investment in this case means the total sum of investments made by companies in the sector. This excludes investment by public sector companies and institutions. Agriculture accounted for 32%, while the health related medical sector received 47% of total investment made in the biotechnology sector (see Table 10).

**Table 10. Investment of the biotechnology industry in India (millions of USD PPP adjusted)**

| | 1999 | 2002 |
|---|---|---|
| Health | 2 118 | 5 024 |
| Agriculture | 900 | 3 350 |
| Industrial biotechnology | -- | 635 |
| Environment | 3 | 253 |
| Others | 101 | 1 354 |
| **Total** | **3 122** | **10 616** |

*Source*: RIS based on BCIL 2001 and 2003

*External orientation*

The biotechnology industry in India has grown more as an outward looking industry with a growing number of external alliances. The number of alliances grew from 47 in 2001 to 129 in 2003. As Table 11 shows, out of 129 firms with foreign alliances, 70 are in the health sector. Thus, firms in the health sector have shown a greater external orientation as the number of foreign alliances is much higher in this sector.

**Table 11. Foreign alliances with Indian biotechnology firms**

| | 2001 | | 2003 | |
|---|---|---|---|---|
| | Number | % | Number | % |
| Agriculture | 17 | 36.2 | 35 | 27.1 |
| Healthcare | 17 | 36.2 | 70 | 54.3 |
| Environment | 1 | 2.1 | 1 | 0.8 |
| Industrial Biotechnology | -- | | 11 | 8.5 |
| Others | 12 | 25.5 | 12 | 9.3 |
| Total | 47 | | 129 | |

*Source*: RIS based on BCIL 2001 and 2003.

### *2.2 Challenges for data collection in India*

As is clear from Table 12, limited efforts have been made by different agencies to collect statistics on biotechnology. There are several reasons for this lack of statistics. First, a consensus on a definition of biotechnology *per se* is yet to be attempted. Therefore, the nature of the technology being supported under the heading of biotechnology is probably interpreted in many different ways. Second, the data collection exercise is not complete. For instance, even though the DBT Annual Report gives a detailed account of budgetary allocations, including for R&D, Section 3 of this paper elucidate that the data collection exercise is not complete, in the sense that there are many other agencies allocating budgets for biotechnology related projects.

Thirdly, the data being collected by organisations such as BCIL, FAI and AIBA, largely depend upon feedback from questionnaires being sent to different companies. These agencies furthermore make efforts to supplement information through secondary sources, such as reference books, internet websites, company profiles and reports. However, the general sensitivity about the precise definition of biotechnology and its various sub-components during the data collection 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 a few of these agencies to adopt a common definition and clearly defined methodology for data collection.

**Table 12. Biotechnology statistics collection in India**

| Agency | Indicators | Frequency |
|---|---|---|
| Department of Biotechnology (DBT) | R&D allocations by DBT | Annual |
| Biotech Consortium India Limited (BCIL) | Industry directories; sectoral details about biotech companies, area of research, budget allocation, no. of patents and foreign collaboration | Occasional; three editions have been published, in 1992, 1994 and 2001 |
| Fertiliser Association of India (FAI) | Production and composition details of bio-fertilisers; companies engaged and their quantum of production | Occasional; three reports have been published |
| All India Biotech Association (AIBA) | Production levels of bio-fertilisers and bio-pesticides | Occasional. Until now, three surveys are out |
| Department of Science and Technology (DST) | R&D expenditure and manpower; biotechnology products, projects, services and patents | Limited data collected, a structured survey is yet to be launched |
| Technology Information, Forecasting & Assessment Council (TIFAC) | Biotechnology Patents | Limited data collected, a structured survey is yet to be launched |

*Source*: RIS based on reports from respective agencies.

### 2.3 Initiatives for the collection of biotechnology statistics

The National Science and Technology Management Information System (NSTMIS) at the Department of Science and Technology (DST) is planning to initiate an exercise in the collection of biotechnology statistics. They have approached the Research and Information System for the Non-Aligned and Other Developing Countries (RIS) to help in formalising the methodology for a biotechnology data collection in India. 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 product development, projects in vogue, services provided, patents granted, research, testing and production infrastructure. This study will cover major biotech firms, research institutions, consultancy services as well as biotechnology research at major universities.

On the initiative of RIS, a meeting of experts was organised in Delhi with support from the Department of Biotechnology (DBT), Government of India.[16] The meeting recommended DBT to constitute two Working Groups: a Working Group on the Definition of Biotechnology (in the context of the OECD definition) and a Working Group on the Selection of Statistical Indicators as may be identified by DBT and other agencies in light of ongoing international efforts in this direction. During the ACD meeting, India has tabled a proposal for adoption of a definition of biotechnology and identification of statistical indicators as recommended at the Second Asian Conference on Biotechnology and Development, organised by RIS and DBT.

#### *2.3.1 Asian co-operation*

As part of the Asia Co-operation Dialogue (ACD) launched in June 2002 in Thailand, India has been identified as co-ordinating country for initiating regional co-operation among ACD countries in biotechnology. In India, the Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India (GOI) is identified as nodal agency. Out of 22 ACD countries, 13 countries responded, including officials from the Embassies of Japan and Cambodia as observers for joint collaboration programmes. It is proposed that ACD would attempt harmonisation of procedures/protocols for conducting biosafety experiments on LMOs/GMOs and products thereof among its countries. It would also identify indicators for generation of minimum acceptable data on risk assessment and risk management on LMOs/GMOs for the generation of biosafety data, jointly and severally by member ACD countries. Wherever agro-climatic conditions are similar and the data acceptable there would be a possibility of undertaking joint initiatives. It is also proposed that ACD countries would evolve a programme whereby access to infrastructure facilities among the ACD countries for generation of biosafety data would be established. It is also proposed that ACD countries would establish a Biotechnology Consortium (ACDBC) for quick implementation of joint programmes. Information on the status of patents and procedures would be made available on the ACDBC website to facilitate filing of patent application information. As part of this a mechanism to facilitate screening of patent applications in the countries of this region and also to advise other relevant protection measures to safeguard the inventions, biodiversity, etc. would also be attempted.

16. February 18, 2003. Refer to www.ris.org.in for details.

## 3. Status of biotechnology in India

There seems to be a great effort in India to tap the synergies between ICT and biotechnology. The Indian strategy for biotechnology is broadly in line with the strategy for information technology, often described as 'path dependency model'. There is a growing emphasis on bioinformatics in this strategy. The government has recently proposed to enhance the equity by foreign companies and institutions in government funded research centres to 51%.[17] In order to support the bioinformatics sector, a network of 57 research centres has been established. This is linked by a high speed computer network, called the Biotechnology Information System Network (BTISnet). In addition, bio-nanotechnology and plant genomics are other areas in which lots of activities are being planned at the federal level, while the state governments are planning at various levels to supplement national efforts in capacity building. The growing interest of financial markets and initiatives for the strengthening of IPR regimes are some of the key areas which may give fillip to the whole range of activities within biotechnology.

In this section, we are going to discuss some of these issues in the context of the role of central government institutions in terms of an evolving policy regime for the management and promotion of biotechnology, human resource development related programmes and participation of the private sector. This section also briefly discusses initiatives by various state governments.

### *3.1 Institutional framework and public sector research support*

India is one of the first among the developing countries to have recognised the importance of biotechnology as a tool to advance growth of agricultural and health sectors as early as in the 1980s. India's Sixth Five Year Plan (1980-85) was the first policy document to cover biotechnology development in the country.[18] The plan document proposed to strengthen and develop capabilities in areas such as immunology, genetics, communicable diseases, etc. In this context, the Council of Scientific and Industrial Research (CSIR), was expected to ensure co-ordination on an inter-institutional, inter-agency and multi-disciplinary basis, with full utilisation of existing facilities and infrastructures in biotechnology. Programmes in the area of biotechnology included tissue culture application for medicinal and economic plants; fermentation technology and enzyme engineering for chemicals, antibiotics and other medical product development; agricultural and forest residues and slaughterhouse wastes utilisation; and emerging areas like genetic engineering and molecular biology.[19]

The existing national laboratories under the S&T agencies, such as the Indian Council of Medical Research (ICMR) and the Council for Scientific and Industrial Research (CSIR), had initiated several research programmes to fulfil the above plan objectives. At the top, an apex official agency, namely the National Biotechnology Board (NBTB) was set up in 1982, to spearhead the development of biotechnology. The NBTB was chaired by a Science Member of the Indian Planning Commission with representations from almost all the S&T agencies in the country, namely the Department of Science and Technology (DST), the Council for Scientific and Industrial Research (CSIR), the Indian Council of Agricultural Research (ICAR), the Indian Council for Medical Research (ICMR), the Department of Atomic Energy (DAE) and the University Grants Commission (UGC).

NBTB was formed with the specific purpose of the identification of priority areas and for evolving a long-term plan for the country in biotechnology. It was also to initiate and promote conducive activities for further development of various areas in biotechnology. The NBTB, through the "*Long Term Plan in*

17. Suresh (2003).

18. Bhargava (1995); Chaturvedi and Rao (2004).

19. Planning Commission (1981).

*Biotechnology for India"* in April 1983, spelt out priorities for biotechnology in India in view of national objectives such as self sufficiency in food, clothing and housing, adequate health and hygiene, provision of adequate energy and transportation, protection of the environment, gainful employment, industrial growth and balance in international trade. Later, in 1986, NBTB graduated to the Department of Biotechnology.

At present, there are seven major agencies in India responsible for financing and supporting research in the realm of biotechnology apart from other sciences. They are the Department of Science and Technology (DST), the Department of Biotechnology (DBT), the Council of Scientific and Industrial Research (CSIR), the Indian Council of Medical Research (ICMR), the Indian Council of Agriculture Research (ICAR), the University Grants Commission (UGC) and the Department of Scientific and Industrial Research (DSIR). DST, DBT and DSIR are part of the Ministry of Science and Technology, while ICMR is with the Ministry of Health, ICAR with the Ministry of Agriculture and UGC with the Ministry of Human Resource Development. DSIR is the funding agency for CSIR and both of them independently fund biotechnology related research programmes. On biosafety regulatory aspects, the Department of Biotechnology and the Ministry of Environment and Forest (MoEF) are involved in managing the various committees. However, since transgenics in the agriculture sector raised several concerns, the agricultural ministry appointed a Task Force to review the regulatory structure in India (see Box 1).

**Box 1. M.S. Swaminathan Task Force**

The recently submitted report of the 'Task Force on Application of Biotechnology in Agriculture' to the Ministry of Agriculture has again evoked wide reactions on the intricacies of biosafety management. The Task Force was set up in 2003 under the Chairmanship of Dr. M.S. Swaminathan. The current debate has brought the regulatory system in sharp focus. Since the submission of the report of the M.S. Swaminathan Task Force on agricultural biotechnology (July 2004) the biosafety regulatory mechanism has come up at the centre stage of the policy debate. It has recommended the setting up of an autonomous National Biotechnology Regulatory Authority (NBRA) with chapters at the state and district level.

The Task Force has suggested a work plan for the creation of infrastructure for development, monitoring, evaluation and promotion of biotechnology and genetically engineered products. The report has suggested the setting up of agricultural biotechnology parks in every state and agri-biodiversity sanctuaries in areas considered to be the habitat centres of genetic diversity of different crops to conserve this germplasm for posterity.

The NBRA recommended by the panel will have two wings. One will handle agricultural and food biotechnology, and the other medical and pharmaceutical biotechnology. The biosafety and agronomic evaluation can be done concurrently to save on time taken for approval of genetically modified (GM) products. While advocating high priority using transgenic technology for imparting resistance to crops against pests, diseases and other stresses, the panel has categorically barred transgenic research in crops where India's international trade interests might be jeopardised. These include crops like basmati rice, soybean and Darjeeling tea. The Swaminathan panel has recommended the allocation of INR 120 million (13.3 million USD PPP using 2003 conversion rates) of additional funds in the remaining 3 years of the current plan for capacity building and creation of necessary infrastructure for development, evaluation and application of biotechnology. This includes INR 20 million (2.2 million USD PPP) suggested to be set apart for providing venture capital to entrepreneurs. The setting up of the NBRA and strengthening of the regulatory and surveillance mechanisms will require INR 15 million (1.7 million USD PPP). About INR 40 million (4.4 million USD PPP) has been proposed for upgrading the research infrastructure and developing trained human resources for the biotechnology sector. INR 15 million (1.7 million USD PPP) has been recommended for the setting up of agri-biotech parks along the lines of the one developed at Hyderabad by the International Crops Research Institute for Semi-Agrid Tropics (Icrisat).

*Source:* Chaturvedi (2004) and Business Standard, June 3, 2004.

As Table 3 shows, the allocations for all of these agencies have gone up in the last decade. Out of this, DBT is the only agency with a committed allocation for biotechnology. It is very difficult to estimate the total allocation for this sector *per se* from other aforementioned agencies, as in some cases the allocations are not separately marked for biotechnology. One faces this kind of constraint especially with those organisations, which are focusing on technological solutions and are not committed to a specific type of technology. Separate accounting for biotechnology thus becomes difficult. It would probably become possible only if a detailed survey at the institutional level would be undertaken. Table 3 also gives a broad idea about total allocations by major Indian funding agencies to science and technology related projects, not necessarily to biotechnology alone. The data mentioned for UGC include data not only about S&T related projects but also about other research streams. The various programmes supported by UGC will be discussed in Section 3.2, while the rest of the agencies are discussed below.

### *3.1.1 Department of Biotechnology (DBT)*

There has been a significant increase in the Government of India's outlays for biotechnology over the past decade. Since the time of establishment, in 1986, the allocation for the Department of Biotechnology has increased manifold (see Figure 3), from 96 million USD PPP in 1987-88 to 358 million USD PPP in 2004-05. In India, the developmental allocations are generally made for five years under the National Five Year Plans. The Government has recently completed the mid-term review of the Tenth Five Year Plan (2002-2007). The Planning Commission has enhanced the original outlay of INR 20 750 million (2 350 million USD PPP using 2002 conversion rates) for the period 2002 to 2007 (see Table 13), to INR 22 250 (2 520 million USD PPP using 2002 conversion rates) as part of the additional gross budgetary support.[20] This marks a sharp increase from the budgetary provisions made during the Ninth Plan period (1997-2002) which totalled at 6 215 million INR only (810 million USD PPP using the PPP conversion rate for 1997). The Vision Statement for the Tenth Five Year Plan emphasises more work on human genome sequences, proteomics, structural biology and bioinformatics.

20. The Hindustan Times, September 10, 2004.

**Table 13. Allocations for biotechnology under the Ninth and Tenth Five Year Plans (millions of USD PPP)**

| Name of the scheme | Ninth Plan (1997-2002) | Tenth Plan (2002-2007) | of which 2002-03 | of which 2003-04 | of which 2004-05 |
|---|---|---|---|---|---|
| **Biotech facilities, centres of excellence & programme support** | 71.6 | 110.2 | 22.6 | 22.6 | 25.2 |
| **Research and development** | 112.7 | 214.3 | | | |
| Agricultural biotechnology | 49.7 | 61.2 | 10.6 | 16.9 | 25.2 |
| Medical biotechnology | 48.9 | 122.4 | 14.3 | 14.7 | 22.4 |
| Environmental biotechnology | 14.1 | 30.6 | 4.5 | 5.6 | 5.6 |
| **Biotechnology for societal development** | 4.0 | 30.6 | 4.0 | 7.9 | 11.2 |
| **Bio-process and product development** | 51.1 | 61.2 | | | |
| Food biotechnology | 0 | 24.5 | 4.0 | 3.9 | 4.5 |
| Microbial and industrial biotechnology | 0 | 24.5 | 4.4 | 3.4 | 7.8 |
| IPR & biosafety | 0.9 | 12.2 | 0.6 | 0.6 | 1.1 |
| Programmes merged with other heads | 50.2 | 0 | 0 | 0 | 0 |
| **International co-operation** | 12.5 | 49.0 | 6.6 | 9.1 | 11.2 |
| **Human resource development** | 48.9 | 110.2 | 10.6 | 14.7 | 20.1 |
| **Bioinformatics** | 27.5 | 85.7 | 8.8 | 11.3 | 20.1 |
| **Autonomous institutes** | 162.3 | 520.3 | | | |
| National Institute of Immunology | 67.7 | 183.7 | 26.8 | 28.2 | 39.1 |
| National Care for Cell Science | 36.5 | 73.5 | 11.3 | 10.1 | 16.8 |
| Centre for DNA Finger Printing and Diagnostics | 33.0 | 91.8 | 10.0 | 9.1 | 13.4 |
| National Brain Research Centre | 13.7 | 91.8 | 12.6 | 12.4 | 23.5 |
| National Centre for Plant Genome Research | 11.2 | 61.2 | 8.8 | 7.9 | 13.4 |
| Institute of Bioresources and Sustainable Development | 0.2 | 18.4 | 1.5 | 2.3 | 3.9 |
| **I & M sector** | 0 | 24.5 | 0.1 | 16.9 | 0 |
| **Secretariat** | 4.5 | 0 | 0 | 0 | 0 |
| **Total** | **495.1** | **1206.0** | **162.0** | **197.7** | **264.4** |

*Source:* RIS based on DBT Reports (various years)

The Ninth Five Year Plan put a special emphasis on developing technology for the agricultural sector. Accordingly, agricultural and allied biotechnology was given 26% of the total allocation, while medical biotechnology was given 13%. It is with the growing opportunities with the human genome project and other advances that the focus in the Tenth Five Year plan has shifted to medical biotechnology. In the Tenth Five Year Plan, agricultural biotechnology has been given only 27% of total allocation, while medical biotechnology has been given almost 36%. This includes 14% on human genetics and genomics and 7% on vaccine research and other medical science related developments. In the agriculture sector, the Tenth Plan Approach Paper assigns a higher priority on developing transgenic crops particularly for cotton, rice and wheat. It also emphasises the need for commercialisation of the tissue culture programme. The document also mentions biocontrol agents for pesticides and biogenic fertilisers, bio-integrators and biosensors for pollution control. In immunologicals and vaccines, research will be related to the applications. There is a marginal increase in the allocations for IPR and biosafety implementations. Now that bioinformatics centres have been established all over the country, the allocations for them have been squeezed and more is being given to newer centres in other areas, like the National Centre for Plant Genomic Research.

The DBT has established a huge infrastructure for bioinformatics. There are almost 58 bioinformatics centres working as a strong information network in the country, linked with databases and networks around the world for easy access by a large number of scientists. Similarly, the DBT has supported 51 courses at different academic institutions all over the country to meet the growing demand of skilled manpower in the country, as will be discussed later. Eleven of these centres are connected to Biogrid India, a virtual private network of DBT for data and resource sharing. The supercomputing facility of IIT Delhi is to be put on Biogrid India shortly to provide a computational backbone to this network.[21] In this regard, DBT has come out with a Draft National Bioinformatics Policy 2003, which is under discussion.

The DBT has 17 task forces in different areas of importance, each comprising several experts who help the DBT Secretariat in recommending and monitoring R&D projects.[22] The DBT has launched an innovative scheme of developing institutional clusters to exploit the institutional and academic synergies and economise on resources. Recently, micro propagation technology parks have been established at the Tata Energy Research Institute (TERI)[23], New Delhi and the National Chemical Laboratory, Pune. They are serving as an important interface not only between industry and the developers of technology in the areas of plant tissue culture, but also among the academic institutions. Technologies for eucalyptus, teak and bamboo have been transferred to Cadila Pharmaceuticals Limited. On similar lines, three turn-key projects have been developed by these centres for three different federal states in collaboration with respective academic institutions.[24]

The DBT has also worked to achieve a balance between different sections of society as far as technology absorption is concerned, apart from promoting industrial development. It is supporting low-cost biotechnology adoption programmes for socially backward communities. The programmes include vermi-composting, use of organic manure, silk-worm rearing, mushroom cultivation, etc. Some training cum demonstration programmes are also being supported by them. Efforts are also being made for gender mainstreaming. The DBT has launched 11 projects for women in the areas of waste management, bio pesticides, bio fertilisers, floriculture and fish farming for poor women in rural areas. At the Golden Jubilee Biotechnology Park for Women at Siruseri, near Chennai, the capital of Tamil Nadu, many of these activities have been launched. This park has central facilities for the entrepreneurs for technology resourcing, training and marketing. In this park, industrial modules have been allotted to women entrepreneurs for setting up units in the above-mentioned areas. This is a first and unique project of a joint effort by the central and state government in the realm of biotechnology.

In the recent future, two more Central-State joint projects would become operational, one of them a biotechnology park at Lucknow, focusing on medicinal and aromatic plants, and the other a biotech incubator at Genome valley, Hyderabad.[25]

### *3.1.2 Council of Scientific and Industrial Research (CSIR)*

The Council of Scientific and Industrial Research was established in 1942. It is India's leading research and development organisation with 40 laboratories and 80 field stations/extension centres spread all over the country. The total allocation for CSIR in the year 2000-01 was 9 120 million INR, equal to 1 073 million USD PPP, which is 13% higher than in 1999-00 (7 940 million INR or 950 million USD

21. Chowdhary (2004).

22. This unfocused approach has been discussed at length in Dhar and Chaturvedi (1998).

23. The new name for TERI is The Energy and Resource Institute.

24. DBT Annual Report 2000-01.

25. Financial Express, September 10, 2004.

PPP). CSIR's Centre for Cellular and Molecular Biology (CCMB) incubated India's first recombinant protein product from a private company, Shantha Biotech, a hepatitis B vaccine, and it has numerous industrial relationships, including a joint venture with Biological E and Amersham Pharmacia to build DNA micro-arrays.

CSIR proposes to continue programmes in the area of agro-biotechnology, industrial biotechnology and toxicant identification control, with a strategy for controlled change in a direction as dictated by market needs. Strategic alliances would thus be sought for programmes for understanding the processes, molecular genetics and control of gene expression, genetic manipulation of microbes, recombinant DNA products, engineering new protein molecules/new chemical entities, development of immuno-diagnostics and biotechnology of prospective medicinal and aromatic plants. Some of the other CSIR led initiatives are listed in Annex 1.

### *3.1.3 Indian Council of Medical Research (ICMR)*

Another major institution working in the area of biotechnology is the Indian Council for Medical Research (ICMR), which falls under the Ministry of Health. It is the apex body in the country to promote, co-ordinate and formulate biomedical and health research. This organisation carries out research in communicable diseases, contraception, maternity and child health, nutrition, non-communicable diseases and basic research.

The total allocation for ICMR from the Central Government (Ministry of Health) was 1 470 million INR in 2000-01 (equal to 173 million USD PPP), which was 21% higher than the allocation of the previous year, which stood at 1 160 million INR (139 million USD PPP). The Council is also engaged in research on tribal health, traditional medicine and publication and dissemination of information. In the year 2001, ICMR has launched a major programme in the field of genomics (vector, microbial, human) with an initial allocation of 510 million INR (58 million USD PPP). One of the major areas of focus is disease susceptibility gene identification, especially for communicable diseases like leprosy and tuberculosis, non-communicable diseases as rheumatic fever, or genetic diseases as thalissimia.[26] ICMR has established four centres for developing molecular medicine at the All India Institute of Medical Sciences (AIIMS), New Delhi, the Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Lucknow, the Jawaharlal Nehru University (JNU), New Delhi and the Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh. ICMR has also established six biomedical informatics units in different parts of the country. The Tenth Five Year Plan has proposed an allocation of 1 000 million INR, or 113 million USD PPP, for ICMR.

### *3.1.4 Indian Council for Agriculture Research (ICAR)*

Agricultural research in India is being spearheaded by the Indian Council for Agricultural Research (ICAR), under the Ministry of Agriculture. The Council is engaged in conducting research in the field of agriculture, soil and water conservation, animal husbandry, fisheries, dairying, forestry and also in agricultural education. The allocation for ICAR from the Ministry of Agriculture was 13 990 million INR in 2000-01 (1 646 million USD PPP), up from 12 060 million INR in the previous year (1 442 million USD PPP). It has several research laboratories all over the country conducting research in biotechnology, besides using traditional breeding techniques for different research projects.

ICAR has established a National Research Centre on Plant Biotechnology (NRCPB) at the Indian Agricultural Research Institute (IARI), Pusa, New Delhi, which is fully dedicated to work on plant biotechnology. The annual expenditure for 2002 on the projects at NRCPB was 150 million INR (17

26. Personal communication with ICMR officials in New Delhi.

million USD PPP). ICAR also supports a research network, combining ICAR research laboratories to work on 14 crops like rice, cotton, brasica and brinzal. ICAR is implementing a World Bank supported programme called the National Agriculture Technology Programme (NATP), through which huge allocations have been made to different research laboratories for strengthening infrastructure for biotechnology and other research facilities.[27] The project is entering in its second phase.

ICAR has collaborated with DBT and the Rockefeller Foundation to jointly launch a National Rice Biotechnology Network (NRBN) in 1988.[28] This project helped in evolving a culture of collaboration among different institutions, which has led to the publication of several international papers in established journals. This network could put together plant breeders and molecular biologists and also provoked interests of the private sector in R&D. For instance, Mahyco and the Rockefeller Foundation worked together on identifying the relevant genes for saving Indian rice from brown plant hoppers. In this collaborative effort, interaction was not limited to private entities only, it was between private and public sector organisations as well. Several universities also have links with private sector organisations. For instance, the Tamil Nadu Agricultural University (TNAU) attempted joint trials with Monsanto on weed resistance in soil.[29] TNAU was also partner in monitoring the Bt Cotton field trials of the Mahyco-Monsanto alliance. TNAU is also holding exploratory talks with Rasi seeds (also in alliance with Monsanto) to conduct and monitor field trials of Bt crops. Similarly, rice research work at the National Research Centre for Plant Biotechnology has attracted business interest of companies like Nath Seeds Ltd. and JK Agri-genetics.

### *3.1.5 Department of Science and Technology (DST)*

The Department of Science and Technology has enhanced its allocations for life sciences in the last few years. In 2003-04 the share of the life sciences project has increased from 19% to 32% in the total budgetary allocation of DST.30 These projects range from drug development, drug discovery to the development of new molecular entities (NMEs) from plant sources of medicinal importance and characterisation of active principles. DST has also supported research on problems like Parkinson’s disease, neuronal control and hypertension. There are networks of institutions funded and supported by DST for development and evaluation of diagnostics for malaria, filarial, kala-azar and PKDL.

Under DST, the National Science & Technology Management Information System (NSTMIS) has been set up, which is entrusted with the task of collection, collation, analysis and dissemination of vital S&T information at the national level. With a view to build a reasonable database and carry out analyses on S&T investment, S&T manpower availability/development/gap and S&T indicators, a number of studies were sponsored during the year. The national survey for bringing out the report entitled ‘Research and Development Statistics 2002-2003’ was completed recently and the data is being analysed now. NSTMIS is planning to launch a biotechnology statistics survey from 2005.[31]

27. Personal communication with IARI scientists.

28. McGaw (2001).

29. *Ibid.*

30. DST, Annual Report 2003-2004.

31. Personal communication with NSTMIS officials.

### *3.2 Human resources development and training*

The National Biotechnology Board launched an integrated short-term training programme long ago in 1984, to cope with a growing demand for highly trained manpower in biotechnology. In the first phase (1984-85), five universities were selected for initiating an M.Sc./M.Tech programme in this multi-disciplinary area. Subsequently, in 1985-86 and 1986-87, the DBT added eight universities/institutions for M.Sc./M.Tech/Post-doctoral teaching programmes. Subsequently, DBT was entrusted with the responsibility of evolving the curriculum for biotechnology courses and meet the demand for human resources in the field of biotechnology. In 1986-87 a model system of post-graduate/post-doctoral teaching in biotechnology in seven universities/institutions was launched.[32] Some of the specialised M.Sc. courses in marine and agricultural biotechnology were launched in 1988-89, initially at three universities. In 1992-93, DBT supported a five year Integrated Programme in biochemical engineering and biotechnology in the Indian Institute of Technology, Delhi and a post-doctoral programme at the Indian Agricultural Research Institute, New Delhi.[33] Table 14 provides a summary of the latest status in this regard. Apart from the institutions mentioned, there are some 68 more such institutes set up by the private sector for various degrees and diplomas in biotechnology. There are no statistics available on them in one place.

As Table 14 and Annex 2 show, currently DBT is supporting 30 M.Sc. courses in general biotechnology, 7 in agricultural biotechnology, 1 each in medical and marine biotechnology and some diploma courses in molecular and biochemical technology.[34] The total intake of students in the various post-graduate courses supported by the DBT in the country is around 729 per year. As a part of the restructuring of the post doctoral research and training programme, DBT has cancelled the ongoing programme with different institutions and has given this responsibility to the Indian Institute of Science (IISc), Bangalore. This is to ensure a competitive attitude and quality output in the life sciences. It is being proposed that IISc would award up to 75 fellowships of two-year duration in different streams of biotechnology.

**Table 14. Technical manpower turnout in biotechnology in India, 2003-04**

| Courses | No. of institutions | Six months/ one year | Two/ three years | Five years (integrated PhD program) |
|---|---|---|---|---|
| M. Sc. (General Biotechnology) | 30 | | 413 | |
| M. Sc. (Agriculture) | 7 | | 80 | |
| Master in Medical Biotechnology | 1 | | 10 | |
| M. Sc. (Marine) | 2 | | 30 | |
| M. Sc. (Neurosciences) | 3 | | 25 | |
| M. Sc. (Industrial Biotechnology) | 1 | | 10 | |
| M. Tech (Biochemical Engineering & Biotechnology) | 6 | | | 110 |
| M. Tech (Pharma) | 1 | | 10 | |
| Post M.D./M.Sc. Certificate in Medical Biotechnology | 2 | 9 | | |
| PG Diploma in Genetic Engineering & Bioprocess Development | 1 | 12 | | |
| PG Diploma Courses in Molecular Biotechnology | 1 | 20 | | |
| Post Doctoral Course from DBT | 3 | | | |

*Source:* Annual Report of Department of Biotechnology (2004).

32. DBT, Annual Report 1987-88.

33. DBT, Annual Report 1993-94.

34. DBT (2004).

DBT is also supporting overseas associateships and short-term training courses for at least 22-25 scientists in a particular year for exposing Indian scientists to newer trends in R&D. This helps working researchers and scientists to upgrade their knowledge and research areas of interest. In this context, the services of the Biotech Consortium India Limited (BCIL), New Delhi, a DBT floated organisation, are also being used to bridge the scientific knowledge of DBT supported associates and industry requirements. The State Governments are also exploring various options to finance higher education in these advanced technologies. Recently, the Karnataka government has established an Institute of Bioinformatics and Applied Biotechnology (IBAB), in collaboration with ICICI Ventures, to offer a postgraduate course in bioinformatics on its International Technology Park campus (see Box 2).[35]

As part of a wider effort for capacity building in institutes of higher learning, full-fledged departments of biotechnology are being set up. The Indian Institute of Science, Bangalore, the Indian Institute of Information Technology and Management, Gwalior and selected Regional Engineering Colleges are setting up departments of biotechnology. The All India Council for Technical Education (AICTE) has already approved B.Tech. programmes in biotechnology in eight engineering colleges and has since been advised to develop a model curriculum for undergraduate programmes. All the new departments will have undergraduate, post-graduate and doctoral programmes. Special funding will be provided for this purpose in the Tenth Five Year Plan. Apart from expanding teaching of biotechnology at higher educational institutions, a separate module on biotechnology would also be integrated with the school curriculum. The Department of Biotechnology of the Government of India will provide the necessary outline of this module so that the National Council of Education Research and Training (NCERT) and the Boards of School Education would be accordingly advised.[36]

The Indian University Grants Commission has come out with a scheme to promote higher centres of learning at one place and assist them as much as possible. In this regard, the Delhi based Jawaharlal Nehru University (JNU) has been identified by the UGC as centre for excellence in the areas of genomics, genetics and biotechnology.[37] The University has received funds to the tune of 300 million INR (33.3 million USD PPP) in the year 2003 and is planning to start a new integrated M.Sc./Ph.D programme in life sciences and biotechnology. It is setting up a modern animal house for experiments. Efforts are also being made to upgrade equipment and library facilities. JNU is aiming at ten seats for the integrated course and another 20-25 seats in the School of Life Sciences. The University has so far received 40 proposals for possible projects, which can be pursued in these fields. Out of the funds that JNU has finally managed to get from the University Grants Commission on its selection as the University with potential for excellence, 100 million INR (11.1 million USD PPP) have been set aside for upgrading facilities and equipment. The remaining 200 million INR (22.2 million USD PPP) would help the University to subscribe to some 8 000 online journals, both in the field of science and in the field of social sciences. JNU also announced the recruitment of more researchers. The links with industry are also likely to grow. For instance, researchers at the Center for Biotechnology (CBT) at Jawaharlal Nehru University in New Delhi have been working for four years on a recombinant anthrax vaccine and soon will start Phase I clinical trials in collaboration with Panacea Biotech Ltd. (New Delhi).

In order to tap the CRO opportunity, several Indian firms are hiring a large number of scientists. In fact, there is a growing trend now among the pharmaceutical companies to get Indian scientists back from abroad (read the United States). Several Indian firms are trying to make available a similar kind of working and research environment apart from similar pay packages. As a result, a large number of firms may boast of their growing profile with star scientists. The leading firms have got almost a hundred such scientists

35. www.ibab.ac.in.

36. The Hindustan Times, December 8, 2001.

37. Indian Express, January 9, 2002.

back in the last six months or so.[38] At the firm level, Ranbaxy has 22 star scientists while Wockhardt has 10, NPIL has 25, DRL has 20 and Lupin has 4.[39] Apart from this, companies are also planning domestic recruitments at a huge level. Ranbaxy is intending to increase the number of scientists from 700 to 900 while SunPharma is proposing to go from the current level of 150 to 300 over the next two years. Similarly, Nicholas Piramal is planning to double the number of scientists from 100 to 200.[40]

However, in India serious discussions are needed to ensure higher standards of research and learning. Attempts are needed to evolve necessary guidelines and curriculum contents. The ongoing GATS negotiations at the WTO may facilitate foreign universities to come up in this area in a major way in India. The ongoing exercise to project India as a centre for contract research may get adversely affected if this dimension is not taken care of. Biotechnology personnel would play a key role once healthcare services are also opened up as part of GATS commitment. In such a scenario, manpower planning would have to account for semi-trained biotechnologists. This should largely be in response to the emerging demand from industry for which more academic innovations would be needed to facilitate university and collegiate autonomy. Therefore, manpower planning should be looking for two parallel tracks, one for highly specialised scientists and the other to create specialised skills for specific assignments.

Another dimension of the situation is the fact that the student community has very well realised the advent of the age of biotechnology. The large number of advertisements is a clear reflection of that, but the real question is whether lucrative and challenging jobs will be waiting for them when they enter the labour market. This again calls for a constant monitoring of the biotechnology industry in India, which should provide inputs for manpower planning through constantly improved and detailed surveys. In this regard it is important that industry sector-wise projections are made which address at least the medium-term, say up to 5 years for the planning of the national technical education system. In the context of India, the manpower planning model must consider, in addition to the employment scenario, other factors which reflect the state-wide requirements, such as for example population, state domestic product, number of school leavers, sector-wise development plans, etc. Inclusion of these factors may only improve the predictive abilities of the model.

### *3.3 Private sector participation and the role of financing institutions*

In India, the biotechnology industry has grown at a very rapid pace over the past few years to reach a sizeable scale in terms of turnover. According to the available estimates, the size of India's market for biotechnology products in 2001 could be between 8 and 14 billion USD PPP as shown in Table 1, depending upon, among other factors, how a biotechnology product is defined. Of this, the agriculture sector market is valued between 2.5 and 2.7 billion USD PPP and the diagnostic/vaccines market at between 800 and 2 300 million USD PPP.

As discussed earlier, according to BCIL (2001) there are a total of 176 biotechnology based companies in India. Table 7 presents a sectoral break-up of these companies. As many as 49% of the companies are agriculture-based companies having interests ranging from tissue culture to bio pesticides. Almost 25% of the companies are active in health related activities and are in medical sciences, while 26% have varied interests, including environmental biotechnology. Although in absolute numbers there are less health biotechnology companies than those active in the agriculture sectors, they account for a much higher proportion of foreign alliances. Table 8 shows the composition of these foreign alliances entered into by Indian biotechnology companies. The changing profile of the health biotechnology scenario in India is

38. The Economic Times, September 6, 2004.

39. *Ibid.*

40. The Economic Times, November 28, 2003.

quite evident from its growing external orientation. In the next section, this is examined in greater detail. Actually, a large number of generic pharmaceutical companies are diversifying into molecule research and stem cell research. A number of Indian companies have achieved notable success. For instance, Bangalore based Biocon claims a quarter of the world market for pectinase, an enzyme that breaks down the pectin in fruit juice. In the fiscal year 2000-01, it reported net profits of about 8 million USD (42.3 million USD PPP) on sales of 52 million USD (275 million USD PPP).[41]

### *3.3.1 Agricultural biotechnology*

Some important private institutions in the non-profit sphere have linked biotechnology with sustainable development. For example, the M.S. Swaminathan Research Foundation (MSSRF) of Chennai has taken up important initiatives in terms of bridging the gap between technology development, its commercialisation and ultimately its diffusion.[42] One of the leading projects MSSRF launched in early 1990s was the establishment of Biovillages in India and China. The Biovillage approach aims at covering principles of ecological sustainability and economic profitability with equity. This project actively promoted interaction between society, industry and R&D institutions. Some of the firms such as the Indo-American Hybrid Seeds Company, Bangalore and R&D institutions such as the Tamil Nadu Agricultural University were prominent partners. This project boosted the demand for biofertilisers in southern Indian villages.

Similarly, other institutions and NGOs, like the Foundation for Biotechnology Education and Awareness, Bangalore, Gene Campaign, New Delhi and Navdanya, New Delhi are also actively working in the area of biotechnology apart from many others.

#### 3.3.1.a Seed industry

In the agricultural sector, a large number of companies have taken up activities related to biotechnology. Leaving aside subsidiaries of transnational corporations (TNCs) in India, the agribiotech companies can be classified into three broad groups. The first group consists of larger integrated seed companies such as Mahyco, Indo-American Hybrid Seed, etc., which are expanding their R&D to cover biotechnology in order to develop their own transgenics. The second group is that of smaller companies, which have not been active in research or product development, but have started employing techniques such as tissue culture for their breeding programmes, *e.g.* companies like Kastur Rangan and Adikeshevalu. The third group covers highly specialised technology companies that undertake services for specified research, such as contract research organisations (CROs). This is a relatively new concept in agriculture R&D in India. Companies like Avesthagen qualify in this group.

At this moment, indigenous firms are under heavy pressure to technologically improve their seeds. This pressure emanates not only from consumers but also because of the growing market penetration by multinational seed corporations, which have high technology seeds. As a result, these firms are now exploring the possibilities to embark on biotechnology related research programmes. For instance, a large-sized seed company, JK Agri-Genetics, has set up a separate division for biotechnology research in those crops in which it has a larger share of the hybrid seed market. However, on the other side of the spectrum one finds old hands in the field of biotechnology, like Indo-American Hybrid Seeds, Bangalore. This was one of the premier companies, which entered the scene way back in 1992-93, but is still struggling with the identification of relevant gene sequences, high capital cost of R&D leading to resource crunch for research and, on top of that, shortage of skilled manpower. The company officials point out that despite the large amount of institutes and universities they are not getting relevant manpower for absorption in R&D units.

41. The Economist, September 1, 2001.

42. Prakash (1997).

They are continuing with this urge simply because a breakthrough in biotechnology may help them in retaining their market share in vegetable hybrid seeds, as their competitors are gradually tying up with TNCs for accessing their vast pool of gene sequences for crop improvement.[43] Their problems become further confounded by a growing number of relevant genes or gene sequences coming under patent ownership of TNCs.

However, some of the larger companies, which have readily gone for alliances with TNCs, are engaged in low-end technology research only.[44] For example, Maharashtra based Mahyco Seeds, which has a tie-up with Monsanto, has developed transgenic cotton seeds through back-crossing with the genes borrowed from Monsanto for pest resistance. Some relatively smaller companies, like Ankur and Rasi and a few others, have also alliances with Monsanto for similar endeavours. However, these alliances, as Scoones (2002) suggests, are much different from the Mahyco-Monsanto alliance, where Monsanto has a 26% stake in Mahyco and may guide its policies, while other alliances are loosely held for marketing of Bt cotton and Monsanto charges a technology license fee to these partners. The combined market share of Monsanto through these three tie-ups (in cotton) comes close to 20%, which is second only to the 45% share of the public sector giant National Seeds Corporation (NSC). In fact, NSC is also concerned about its declining share over the years. In India, almost 9 million-hectare of land area are under cotton cultivation with 2.86 million tonnes of cotton lint a year. Since Indian independence (1947), nearly 150 hybrid varieties of cotton have been released and hybrids account for 60% of cotton cultivation.[45] Similarly, small companies such as Bangalore based Kastur Rangan and Adikeshevalu have entered in up-scale tissue culture research and related plant development.

The third group of firms are the upcoming companies with a strong science base. This category has companies such as Meta Helix and Avesthagen. They have entered in the area of contract research for DNA finger printing and data mining. They are also providing identification facilities for viral diseases in plants and animals.

Recently, Chinese companies have started entering the Indian market. One Indian company, Nath Seeds has forged a strategic alliance with the Biocentury Transgene Company, a Chinese biotechnology company, to introduce transgenic technology in cotton crop.[46] The partnership aims at significantly reducing the cost of cotton production by reducing the consumption of pesticides and improving cotton yields. Biocentury has patented a technology for Bt and Bt+ genes developed by the Biotechnology Research Institute (BRI) of the Chinese Academy of Agricultural Sciences. Nath Seeds has the license for the exclusive use of Chinese Bt+ genes in India. The gene will be incorporated into the parent lines of cotton hybrids bred by Nath Seeds for the Indian market. Nath Seeds, with this alliance, hopes to compete in the area of transgenic technology for seeds, which is currently a monopoly of multinational firms such as Monsanto, Novartis and Dupont. The company plans to boost the top and bottom line of Nath Seeds as it has the right to sub-license Bt to other seed companies, besides using Bt gene in its own hybrids.

#### 3.3.1.b Biofertilisers and biopesticides

In the recent past, private sector participation in the production of biofertilisers has grown at a very rapid pace. As Table 4 shows, the production has gone up from 2.5 tonnes in 1992-93 to almost 13 tonnes in 2003-04. Accordingly, the number of firms engaged in biofertilisers has also gone up from 35 in 1992-

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43. Personal communication with company officials.

44. This is not an isolated case, as a similar experience of another company, Rallis, is traced in Scoones (2002).

45. Economic Survey, Ministry of Finance, 2001.

46. The Economic Times, December 25, 2001.

93 to 95 in 2001-02. The biofertiliser statistics that are being regularly provided by the Fertiliser Association of India show that the production of fertilisers is concentrated in western Indian states (37). These are Gujarat (3 units), Madhya Pradesh (7 units), Maharashtra (24 units) and Rajasthan (3 units). However, some of the Southern states like Tamil Nadu have also encouraged private industry to set up biofertiliser units. In three years time, more than 13 units have come up in this state.

There are several types of biofertilisers being marketed in India. Some of the prominent ones are *Rhizobium, Azatobacter* and *Azospirillum.* The Indian Council for Agriculture Research has actively encouraged application of rDNA technology for better quality Rhizobium and Azatobacter. In order to help the industry, DBT has established certain repositories to keep micro organisms.[47] In the case of biofertilisers, the established repository for microbes is the "National Facility for Rhizobium Culture Collections", Division of Microbiology, IARI, New Delhi. The others are the National Centre for Conservation and Utilisation of Blue-Green Algae, IARI, New Delhi, the Microbial Type Culture Collections, Institute of Microbial Technology, Chandigarh, the National Facility for Marine Cyanobacteria, Bharatidasan University, Tiruchurapalli and the Facility for Mycorrhizal Culture Collections, The Energy and Resources Institute, New Delhi.

However, it is important to mention here that the demand for biofertilisers suffers from three major factors: poor and uneven quality, short shelf life and small contribution to crop yield.[48] A new technology on mycorrhiza biofertiliser is developed by TERI under support received from DBT. The unique feature of this product and technology is the assured quality and long shelf life (2 to 5 years) at room temperature and broad-spectrum host range. The technology is now being transferred to two industries in India and the production from these industries is being expected at 100, 250 and 400 tonnes respectively. There is still a need of bringing many strains of potential organism in to this process to draw large-scale benefits in plant production.[49] The DBT has established a Biocontrol Network Programme to emphasise better formulations and cost effective commercially viable biopesticides, including microbial pesticides, parasitoids and bacteria for use under IPM. In 2003, the project had 80 R&D units and total allocations of INR 1.8 million (0.2 million USD PPP).

### *3.3.2 Medical biotechnology*

In the recent past, allocations by different government agencies for medical biotechnology have expanded manifold. In the Tenth Five Year Plan, allocations have gone up (see Table 13). In medical biotechnology, government emphasis has been on research and product development in the areas of infectious and non-infectious diseases, oral cancer and clinical application of stem cells. There was also an emphasis on the development of reagents/kits for disease diagnostics. Many public laboratories, in collaboration with the private sector, have commercialised the molecular diagnostic kits developed indigenously. Among the commercialised diagnostic kits are kits for detection of HIV/AIDS, hepatitis C, cysticercosis, malaria and typhoid through the ELISA technique. The kits for tuberculosis and leishmania are being developed through the PCR technique.

The recombinant Hepatitis B vaccine was the first biotech product to be commercialised in India in the health sector. The introduction of this product has reduced the prices of the Hepatitis B vaccine several times and it is likely to go down further. Earlier, India was completely import dependent for this vaccine. This has given new confidence to both academic research institutes led by government agencies and private sector firms. Later, a *Jai Vigyan Mission* of the Prime Minister was launched in 2003 to work

47. See Rao (1999).

48. Alam (1994).

49. *Ibid.*

further on modern vaccine development on diseases like cholera, rabies, malaria, HIV and Japanese encephalitis virus. Table 15 gives a brief account of this. Out of this, the discovery of a first new medicine to treat tuberculosis (also called the white plague) is a noteworthy example of public-private partnership for drug discovery. The project was launched in the year 2000 by 12 public sector laboratories, led by the Council for Scientific and Industrial Research (CSIR) and a private sector firm, Lupin Laboratories of Mumbai, with a budget of 1.9 million USD (10 million USD PPP). This breakthrough in combating this disease may help in saving millions of lives. According to statistics, 3 million people die every year worldwide due to tuberculosis.[50]

**Table 15. Indigenous modern vaccine development plans in India**

| Disease | Vaccine Type | Status | Firms/Institutions |
|---|---|---|---|
| Hepatitis B | Recombinant | Commercial | Shantha Biotech & Bharat Biotech |
| Cholera | Recombinant | Phase III Trial | IMTECH & NICED |
| Rabies | DNA Vaccine | To be launched in mid-2004 (brand name Dinrab) | IISc and Indian Immunologic, Hyderabad |
| Japanese Encephalitis Virus (JEV) | Live Vaccine/DNA Vaccine | Pre Clinical Trials | NII and Panacea Biotech Ltd. |
| Malaria | Recombinant | Pre Clinical Trials | ICGEB, MRC & Bharat Biotech Ltd. |
| Tuberculosis | Recombinant/DNA Vaccine | Clinical Trials | 12 Government Research Centres & Lupin Pharmaceuticals |
| HIV/AIDS | Recombinant/DNA Vaccine | Under Development | AIIMS and an undisclosed industrial partner |
| Anthrax | Recombinant | Commercialised | JNU and Panacea Biotech |

*Source:* RIS based on DBT Annual Reports (various years)

Companies in medical biotechnology in India can be divided into three broad categories. One is that of small start-up companies that have indigenously developed biotech products, *e.g.* Shantha Biotech and Bharat Biotech. Then there are large established companies, which have started responding to biotechnology by incorporating it in their work plans. For instance, Dr. Reddy's Laboratory (DRL), Ranbaxy Laboratories and Wockhardt Ltd. have major plans in this area. These companies are continuously enhancing their R&D allocations. Average R&D expenses as a percentage of sales stood at 4.6% in 2003 as compared to 3.8% in 2002 (Table 16). The aggregate R&D expenditure of the top 7 leading pharmaceutical companies increased by INR 4.3 million in 2003 (0.5 million USD PPP).[51] It is estimated that average R&D expenditure as percentage of sales may jump to 12% by 2005-06. The growing competition in key growth areas like drug discovery, branded generics, bulk activities, formulations and chemical synthesis has made R&D a prime focus area for most drug makers.[52] In the third group are companies that are all set to emerge as contract research organisations (CROs). Their work comes largely from TNCs.

50. Financial Times, September 7, 2004.

51. The Economic Times, June 9, 2003.

52. The Business Standard, April 6, 2004.

**Table 16. R&D expenditures of selected pharmaceutical firms (as a % of sales)**

| Company | 2001-2002 | 2002-2003 |
|---|---|---|
| Ranbaxy | 3.0 | 4.3 |
| DRL | 5.9 | 7.6 |
| Wockhardt | 5.2 | 5.5 |
| Sun | 3.1 | 3.8 |
| Torrent | 5.6 | 6.8 |
| Lupin | 2.6 | 2.5 |
| Nicholas | 1.6 | 1.7 |

*Source:* RIS based on Economic Times, June 9, 2003 and Business Standard, March 7, 2004.

Then there are companies such as Biocon India, which do not fit well in this kind of classification, as they have an established presence in industrial biotechnology (the fermentation sector) and a growing presence in the pharmaceutical sector, so eventually encompass the first and second category. There are also reports of Biocon having plans of being a CRO as well – so also covering the third group of our classification. Biocon has set its sights on biopharmaceuticals and has been using its capabilities in a wide range of fermentation technologies since 1995. Two years later, Biocon established Helix – a wholly owned subsidiary – to develop its biopharma operations, which began with a range of anti-cholesterol statin drugs. Another subsidiary of this company, Clinigene International, was set up to initiate longitudinal clinical studies in selected disease segments. With a synergy-based expansion, Biocon is now recognised as the country's leading biotech conglomerate.[53] What follows are case studies of some of these firms.

### *3.3.3 Private firm strategies*

*Start-up SMEs*

Shantha and Bharat Biotech are the leading examples of the first category of firms – small start-ups with their own biotechnology niche. Both these firms take credit for developing India's first world class hepatitis-B vaccine and making it available at a much lower price than the prevailing market price of imported vaccines.

Shantha Biotech has an active biotechnology programme since 1994. Pfizer Ltd., the major pharma TNC, has obtained the first refusal rights from the Hyderabad based Shantha Biotechnics Pvt. Ltd. for exclusively marketing the products to be developed by the latter in the future. Earlier, Pfizer had entered into a co-marketing agreement with Shantha Biotech for marketing the latter's recombinant DNA vaccine for hepatitis-B. Shantha Biotech is currently in an advanced stage of discussion with one European pharma major and about three US based pharma companies for its research projects. The company plans to carry out research on protein purification, molecular cloning and expression of native and synthetic genes. Shantha Biotech will also be offering polyclonal and monoclonal antibody development and formulation of certain types of vaccines. Shantha Biotech has developed in-house expertise in recombinant DNA technology and is very strong in development of cell lines for development of recombinant products. The company has invested 100 million Rs (11.1 million USD PPP) in the biotech facility with external funding (from the Bank of Oman) in the year 2003.

Bharat Biotech International Ltd. (BBIL) is developing 3 new vaccines for the first time in the world.[54] These are the vaccines for malaria, rotavirus and rabies. While the rabies vaccine is being developed by BBIL on its own, the one for malaria is coming up in collaboration with the International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi. The rotavirus vaccine project is

53. The Economic Times, July 29, 2001.

54. The Hindustan Times, April 8, 2003.

being taken up in collaboration with the DBT. BBIL is in Phase III clinical trials of r-human insulin as well.

*Forays of established firms in biotechnology*

Some of the companies like DRL have grown in the recent past. DRL is India's second largest drug manufacturer with sales of 380 million USD (almost 2 billion USD PPP) in the year 2003. It was established in 1984. DRL is now setting up biotechnology production facilities as per the US FDA specifications. This includes the setting up of three 10 000 bulk recombinant protein production suites and a new formulation facility. The company has also identified biogenerics as a significant market area which is estimated at 14 billion USD (72.5 billion USD PPP) in 2003. This would add to ease its dependence on generics. The biotechnology business covers therapeutics, vaccines and diagnostics. DRL has a research alliance with the Centre for Cellular and Molecular Biology (CCMB), Hyderabad. DRL has established a research subsidiary in Atlanta called Reddy US Therapeutics Inc., which works as a contract research subsidiary, largely to undertake work related to genomics.

Similarly, Ranbaxy, India's largest pharma company with sales of more than 1 billion USD in the year 2003 (5.2 billion USD PPP), also views innovation in biotechnology as key to its future.[55] It is one of the oldest pharmaceutical firms, founded in 1968. The company has branched out from creating new formulations of existing drugs and has half a dozen molecules under development. Ranbaxy has collaborations with several US and European companies to develop new formulations and technologies. For example, Ranbaxy and Vectura Ltd. (Bath, UK) announced in 2001 that the Indian company's Ranbaxy B.V. subsidiary (based on the Netherlands Antilles) will develop oral formulations using Vectura's controlled release drug delivery technology, with Ranbaxy providing clinical development, scale-up, manufacturing and marketing expertise. Ranbaxy is also aligning with leading biotechnology firms like Avesthagen for accelerating the new drug discovery research. The tie-up is for carrying out project activity relating to the construction of recombinant cell lines required for screening Ranbaxy's drug candidates.[56] Similarly, it has also established a research alliance with GlaxoSmithKline (GSK). As part of this alliance, Ranbaxy would enter in drug development, as GSK may not be keen for undertaking this because of the high cost involved.

Another major company in this category is Wockhardt Ltd., established nearly four decades ago and is the fifth largest pharmaceutical company of India. Wockhardt has grown at over 20% annually for the last 5 years.[57] In the year 2000, it acquired Merind from Tata's and Wallis Laboratories, a UK company, apart from entering into a marketing alliance with American Sidmak Labs. The company is formulating its biotechnology strategy around these initiatives. It has decided to split its business into two separate entities. Wockhardt Ltd. will remain a pharmaceutical company, while the new entity will focus on life sciences only. The new company will have all the other businesses, namely hospitals, nutrients, IV fluid and agrovet (crop protection). The R&D activity is also being categorised into three divisions. The first division concentrates on developing new bulk drugs (novel drug delivery system (NDDS)) and generics. As part of its strategy Wockhardt recently acquired the German pharma company Esparma GmbH and a UK based company CP Pharma for 11 million USD.[58] The second division concentrates on recombinant biotechnology. At present, the second division is focusing on technology absorption with the assistance of scientists from abroad. The third division is dedicated to the discovery of new molecules. Wockhardt is expected to come out with its first investigational new drug (IND) in the anti-infective therapeutic

55. The Financial Times, July 8, 2004.

56. The Economic Times, September 7, 2004.

57. IndiaInfoline.Com, July 14, 1999.

58. The Business Standard, New Delhi, May 7, 2004.

segment. Wockhardt has already launched some of its biotechnology products like Biovac-B (hepatitis B vaccine) and Wepox (erythropoietin) in Asian and South American markets.[59]

*Firms with contract research*

It is estimated that the turnover of CROs was 100 million USD (518 million USD PPP) in the year 2003.[60] The number of CROs has grown from 5 in 1998 to 25 in 2003. Out of these 25, almost 21 companies undertake only bio-equivalence studies and 2 or 3 companies undertake clinical research. The major companies in this category are Quintile India, Lambda, Welbech, Lotus and SIRO Clinpharm Ltd. Indian scientists from leading institutions are also enthused for floating their own companies. For instance, two scientists from the Indian Institute of Science (IISc), Bangalore have floated a company called Metahelix Life Sciences with 1.5 million USD venture capital funding. The company will focus on providing contract research services in genomics, molecular markers and bioinformatics, to begin with and eventually develop new molecules on its own.[61] One of the leading CRO is Reliance Clinical Research Services (RCRS), the clinical research organisation set up by the Reliance group of companies. It focuses on project management, clinical operations and bio-matrices.[62]

### *3.3.4 Role of financial institutions*

In recent times, liberalisation has unleashed competition for garnering capital in the Indian market, in particular for technology companies. Three sources of support – offshore funds, Indian venture funds and the Technology Development Board (TDB), have been active in supporting and financing biotechnology.[63] Some of the major firms in the IT and pharmaceutical sector have already achieved a listing at Nasdaq. In this regard, the TDB has played a pivotal role in promoting many start-ups in the biotechnology sector, such as ABL Biotech, Ajay Biotech India Ltd., Bharat Biotech, Javeri Agro Industrial & Investment Co., Mark Medicines, Prathista Industries, Shantha Biotechnics, Shantha Marine Biotechnologies, SPIC Ltd. and Venketeshware Bioproducts Ltd.[64] In its sixth year of operation, the TDB, has demonstrated that even within the government conscious efforts and proper management can keep the flip side at bay.[65] The TDB has (by 2003) handled 103 projects valued at a total of INR 15 billion (1.7 billion USD PPP) in areas such as medicine and health, agriculture, engineering, transport, chemicals, waste utilisation, information technology, food processing and biotechnology.

The venture capital (VC) industry in India is also emerging as a vibrant sector to support information technology, biotechnology, telecommunication and food processing related industries**.** There are at least 70 different funds operating in India. A majority of the venture funds are located in four major clusters – Bangalore, Hyderabad, Pune and Mumbai and Chennai – where growth in the biotech industry is very fast. While the biotechnology industry needs substantial venture funds, the venture companies feel they are not getting attractive projects with high growth potential in the Indian context. The venture capital industry in India has emerged after the government, in 1988, announced guidelines for setting up venture capital funds (VCFs). These guidelines restricted the setting up of VCFs by banks or financial institutions only. Later, in September 1995, the Government of India issued guidelines for overseas venture capital investment in

59. Deccan Herald, August 30, 2004.
60. Personal communication with Chairperson, CII, Task Force on Biotechnology.
61. The Economic Times, July 18, 2001.
62. The Economic Times, May 11, 2004.
63. Business Line, December 27, 2003.
64. BioSpectrum, June 10, 2004.
65. Frontline, Vol. 19, Issue 12, June 8-21, 2002.

India, whereas the Central Board of Direct Taxes (CBDT) issued guidelines for tax exemption purposes.[66] As part of its mandate to regulate and to develop the Indian capital markets, the Securities and Exchange Board of India (SEBI) framed the SEBI (Venture Capital Funds) Regulations in 1996. While only eight domestic VCFs were registered with SEBI during 1996-98, more than 70 additional funds have already been registered in 2003-04.[67] The figures from the Indian Venture Capital Association (IVCA) reveal that until 2000 around INR 22 billion (2.6 billion USD PPP) had been committed by domestic VCFs and offshore funds which are members of IVCA in several activities including biotechnology. Here it may be interesting to see the priorities at the two leading public sector VCFs.

#### 3.3.4.a ICICI

ICICI Venture currently manages and advises eleven funds, aggregating about 2.2 billion USD PPP, making it one of the largest private equity investors in the country in the year 2002.[68] Consistent with its strategy of focusing on sectors where Indian companies have a global competitive advantage, all of ICICI Venture's funds make investments only in companies belonging to IT, life sciences and services sectors. These industries have demonstrated a capability to leverage the intellectual capital in India to effectively address the global markets.

ICICI Venture is currently in the process of constituting a dedicated incubator fund for supporting start-ups in the area of biotechnology and life sciences. As in information technology, the ICICI Venture Incubator team would be extending support services to its incubated companies, including basic research infrastructure in a partnership with ICICI-Knowledge Park Limited. The targeted fund size is 1 billion INR (113 million USD PPP). In the year 2002, ICICI Venture and the Global Trust Bank have invested 1.5 million USD (8.3 million USD PPP) in Avestha Gengraine Technologies Pvt. Ltd. (Avesthagen), a fully-integrated biotechnology and bioinformatics company based in the International Tech Park Ltd (ITPL), Whitefield.[69] It is focused on genomics and bioinformatics, with expertise in marker-aided selection, genome sequencing, gene discovery, plant transformation, database management and 3D structure-function analysis.

#### 3.3.4.b SIDBI

The Small Industries Development Bank of India (SIDBI) and the Department of Biotechnology (DBT) decided to set up a 1 billion INR (122 million USD PPP) Biotechnology Development Fund in 1998, to encourage private-public partnerships in the small-scale sector, as well as to promote entrepreneurship in biotechnology. However, somehow it did not take off. The current proposal is that DBT will put in 200 million INR (24 million USD PPP), while SIDBI would contribute the remaining 800 million INR (98 million USD PPP) for the fund. Earlier, the proposal of DBT-SIDBI was a 500 million INR (61 million USD PPP, 30.5 million USD PPP each) National Biotech Venture Fund, but the Planning Commission of India did not agree with that proposal on the pretext that it would be better to leave it to the financial intermediaries, as it would entail nurturing and monitoring apart from financial management, which financial intermediaries can do much better.[70] At this stage, finer details of the proposal, such as whether to give assistance as soft loans or set in place a programme with an exit clause that would help the fund sustain itself through royalties and so on, are being worked out. The proposal is part of a larger

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66. The Reserve Bank of India governs the investment and flow of foreign currency in and out of India.

67. Sethi (2001).

68. Based on the ICICI web page.

69. The Business Standard, January 9, 2002.

70. The Economic Times, October 27, 2001.

industry orientation proposed by the DBT in its Tenth Plan Approach Paper. In collaboration with the Agriculture Ministry, a large number of decentralised production units (at least 1 000 for biofertilisers and biopesticides) in the small scale sector are proposed to be established with new technology packages all over the country by the end of the Tenth Plan.

### *3.3.5 Emerging areas*

Apart from agricultural and medical biotechnology, several private sector firms are entering into completely new areas of research and product development. Some of them are being taken up herewith. In these areas various models of public-private partnership are emerging.

#### 3.3.5.a Bioinformatics and genomics

Recently, bioinformatics and genomics are the two areas in which investment has expanded very rapidly. The public sector has come forward for R&D and other support, while the private sector has enhanced investment and has explored various alignments. As discussed earlier, the Tenth Five Year Plan has special emphasis on the bioinformatics sector. In India, the sector is currently valued at 15 million USD and is expected to touch 120 million USD by 2006.[71]

The key companies in this sector are Strand Genomics, Ocimum Biosolutions, SysArris, SciNova India, Cyto Genomics, Mascon and Molecular Connections. It is being suggested that with the entry of software firms in the area of life sciences, the cost of drug development may go down by at least 40%.[72] Some of the subsidiaries of major software multinational companies, such as IBM, are planning to start with consultancy on biotechnology, followed by bulk drug research and clinical trials. Another initiative is the setting up of a Bio-Informatics Institute at the Bangalore Software Technology Park by the Karnataka government in association with ICICI and the IISc, Bangalore, with a funding of INR 100 million in 2003 (11.1 million USD PPP). Some niche software companies, such as Genotypic, Bangalore, will possibly access the facilities (see Box 2 for details).

In the area of genomics, DBT and ICMR are working on two independent initiatives. DBT has launched an Indian Genome Initiative (IGI). This project would be for a period of five years with a budget of 20 million USD (104 million USD PPP using 2003 conversion rates). As part of the project, DBT would strengthen the facilities available at the Plant Genomics Centre, New Delhi and also at the Centre for Human Genetics, Bangalore. Part of the project under the Indian Statistical Institute (ISI), Calcutta, is to improve database design, software for database access and manipulation, and data-entry procedures that are compatible with the diverse computational platforms.

The ICMR initiative is aiming to acquire and analyse DNA sequence data of human and other organisms (including bacteria, viruses and plants) and to generate value-added knowledge for the national development of health, medicine and agriculture. The Institute of Genomics and Integrative Biology (IGIB), formerly the Centre for Biochemical Technology (CBT), has also been established to work on various aspects of biotechnology research, for instance isolation of fine biochemicals from natural resources. As biochemical technology enters the genomics era, the IGIB is in the process of transforming from a singular laboratory working in the area of biochemical research to a network laboratory, leading to the formation of a virtual institute of new biology.[73]

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71. The Economic Times, April 6, 2004.

72. The Financial Express, March 29, 2004.

73. http://www.igib.res.in.

There are certain interesting public-private alliances emerging in this area. For instance, CCMB, Hyderabad, in collaboration with the company Biological Evans, which has earmarked a budget of INR 10 million (1.2 million USD PPP using 2000 conversion rates), has launched a facility for 'gene chip' technology.[74] This is basically a rapid scanning technique for creating clinical genotypic databases and for the diagnosis of diseases. There are some major Indian IT firms which are all set for partnerships for various purposes. These firms include Satyam Online, NIIT and Reliance Industries. Out of these, NIIT is also in touch with CBT for a possible alliance.

3.3.5.b Bionanotechnology

The Department of Biotechnology has launched almost ten projects of more than INR 10 million in 2003 (1.1 million USD PPP), focusing on nanoparticles for therapeutic use, biosynthesis of nanoparticles, bionano composites and imaging of nanoparticles.[75] The Indian Institute of Chemical Technology (IICT) has been nominated as a nodal agency for nano science studies, research and development.[76] IICT has developed synthetic nanotubes, which can be used for delivering the DNA material for gene therapy besides making bio census.

3.3.5.c Bioenergy and biofuel

The Department of Biotechnology has launched a major project for the efficient production of alternate fuels such as ethanol and biodiesel in the year 2001-02. Study projects are being conducted at the Indian Institute of Technology (IIT), New Delhi, The Energy and Resource Institute (TERI), New Delhi and the Institute of Microbial Technology (IMTECH), Chandigarh, to develop bioethanol from alternate feed stocks like fruit and vegetable waste, sugarcane/sorghum and bagasse material, including forest and coir waste. India has initiated joint co-operation programmes with some private laboratories in the United States to develop bioethanol. There are proposals before the government to provide tax incentives to the firms engaged in R&D and production of bio fuels. The incentives may be in terms of concessional prices of land for biofuel plantations, such as Jatropha curcas. This aspect is likely to be further addressed in the proposal for a National Energy Policy.[77] There are private research institutes working on various options for bio fuel. The Nimbkar Agricultural Research Institute (NARI) has pioneered work on sweet-stem sorghum as a possible source for bio fuel. Similarly, ethanol offers an ideal opportunity for the sugar and distillery industry in India. The annual sugarcane output in India is about 300 million tonnes and the availability of surplus molasses is about 700 million litres, which is available for the purpose of fuel. Exploring various such options is becoming very important, as – according to the Indian Economic Survey (2003-04) – at 20 billion USD (104 billion USD PPP), petroleum products constitute more than 30% of India's import bill.

### *3.4 Initiatives by State Governments*

In the recent past, several State Governments in India have launched different initiatives to attract a biotechnology industry to their respective States. An attempt to summarise some of these initiatives has been made in Annex 3. However, key features of some of the leading states are covered here for a detailed discussion. Andhra Pradesh is seeking to leverage its strengths in pharmaceuticals, agriculture and IT services to put it at the forefront of biotechnology among the various state governments and announced a policy in May 2001. Around this time, Karnataka also came out with a Biotechnology Millennium Policy.

74. Ramachandran (2000).

75. DBT Annual Report, 2003-04.

76. The Financial Express, August 4, 2004.

77. The Hindu Business Line, September 4, 2004.

Tamil Nadu which has announced its biotechnology policy in September 2003, is the only one with a women biotechnology park. Not surprisingly, the States have extended similar attractions and concessions, already available to the IT sector.

As Annex 3 shows, most of the States have identical strategies to attract the industry, such as offering tax concessions, cheap credit, subsidised industrial infrastructure and state support to technology incubators. However, it is being observed that most of the biotechnology firms are based in select metropolitan cities, where biotechnology clusters are rapidly emerging (see Box 2).

### *3.4.1 Andhra Pradesh (AP)*

As part of the Andhra Pradesh (AP) biotechnology policy, among other things, the companies would enjoy a lower sales tax of just 1%, down from the present 8% to 16%, on all high-end biotechnology products produced within the State. They would also be able to book space at concessional rates at the proposed 600 square kilometre Genome Valley. The policy proposes setting up an exclusive INR 1.5 billion (167 million USD PPP) venture capital fund in 2003.[78] The policy also speaks of funding biotechnology start-ups through the existing Andhra Pradesh Industrial Development Corporation (APIDC) Venture Capital Ltd. The aim of the policy is to leverage on the existing strengths of the state for rapid commercialisation of biotechnology, so that innovative biotechnology products and services could be produced in the State. AP has already numerous centres of excellence in healthcare, agriculture and biotechnology. The government is also trying to use its strength in IT for the growth of bioinformatics in the State for the rapid growth of this sector. The government has identified field diagnostics, therapeutics, pharmacogenomics, bioinformatics, agriculture, marine, industrial biotechnology and contract research as some of the thrust areas. The government has roped in ICICI, which has planned a Knowledge Park at Turkapally near Hyderabad in an area of 200 acres, for promotion of life sciences. It was announced in 2001 that the Knowledge Park would have an investment of INR 310 million (36 million USD PPP).[79] It is a joint initiative of ICICI and the Andhra Pradesh Government. The ICICI Knowledge Park and the Biotechnology Park together form part of a larger blueprint of the Genome Valley project.[80] In the state, public-private partnerships are emerging as a major instrument for the advancement of biotechnology. It has taken the shape of a unique network.

ICICI has signed an MoU with the Indian Institute of Chemical Technology (IICT), the Centre for Cellular and Molecular Biology (CCMB) and the University of Hyderabad, in a new “knowledge network initiative”. This project has also been assisted by the Department of Scientific and Industrial Research (DSIR), to the tune of 15 million INR (1.7 million USD PPP) to set up a Virtual Information Project, taken up by the Knowledge Park in 2001. The Park has been licensed under Section 25 of the Companies Act, 1956, and is thus approved by the DSIR for the benefits of customs duty exemption and excise duty waiver. Under the initiative, partners in the Knowledge Park will get on-line access to library-based information expertise from national laboratories and the university system. It would also encourage undertaking collaborative research between corporate and research companies based in the park. The park has identified another 20 premier research organisations and universities during the first phase of the programme. At this point, only two start-ups – Medicorp Technologies and Pulsar Electro-Optics Ltd – have moved into the park with their projects. Two more companies are actively considering to move in. They are Bijam Biosciences Ltd., a Nagarjuna Group company which wants to set up a research centre in

78. The Hindu Business Line, December 27, 2003.

79. The Hindu, February 4, 2001.

80. The Hindu Business Line, April 30, 2001.

agri-biotech and MedGene Biotech, which plans to start a research centre for new drug discovery and genomics research.[81]

### *3.4.2 Tamil Nadu (TN)*

The Tamil Nadu Industrial Development Corporation (TIDCO) has made a technical service agreement with Cornell University, USA for setting up a biotechnology park in Chennai, christened TICEL (Tidco Centre for Life Sciences), which proposed to attract fresh investment of INR 10 billion in 2001 (1.2 billion USD PPP) from 50 new companies, to be set up in the park and fuel bio-entrepreneurship. Among the states, Tamil Nadu is the only state with such kind of foreign collaboration. This initiative will put Chennai in the global network of Cornell, which has technical collaboration in 36 countries.[82]

TICEL is modelled on the TIDEL Park, the information technology park set up by TIDCO. As per the MoU, valid for five years renewable for another five years, Cornell University will help from the conceptual stage to the commissioning stage of the park. The state-of-the-art park will provide complete technical and other allied services under one umbrella, including technology transfer, monitoring, networking, contract and collaborative research work, product validation, documentation, commercialisation, training and a separate intellectual property rights (IPR) cell, which will support in the areas of patents, licensing, royalty sharing and copyrights. The total cost is pegged at 625 million INR (72.3 million USD PPP). TIDCO will be investing 90 million INR (10.4 million USD PPP) as equity. The Tamil Nadu government would bring in 200 million INR (23.1 million USD PPP), while the remaining 330 million INR (38.2 million USD PPP) would be raised from various banks and financial institutions. It is stated that the State Bank of India, the Industrial Development Finance Corporation and Exim Bank have also shown interest in picking up equity.

In addition to the above, Cornell University will also be setting up a special project cell at its premises in the United States to provide advanced training, apart from offering access to its electronic library. It will also facilitate relationships between the tenants of similar parks abroad and in the Chennai park, besides an exchange of faculty for conducting specific and advanced training programmes. TICEL would be set up in a five acre area consisting of two major facilities – a bio-resource centre of 18 000 square feet and customised laboratories of 12 000 square feet. It will explore the Indian genetic pool and exploit the germplasm base available and leverage on the existing pool of Indian biotechnology scientists and low cost software skills.

### *3.4.3 Himachal Pradesh (HP)*

Himachal Pradesh is probably the only Northern Indian state which has prepared a detailed plan for promotion of biotechnology industries in the State. This would include setting up a biotechnology park at Solan, conservation and exploitation of bioresources, intensification of R&D and promoting biotechnology entrepreneurship through tax concessions and relaxed labour laws. At Solan, land has been earmarked at New Solan to set up the biotech industries. The idea is to tap the huge potential of bio-resources and commercially exploit the state's rare herbal medicines, the annual global trade flow of which is close to 20 billion USD in 2002 (110 billion USD PPP). HP could help enhance the country's share in this sector, as more than 3000 varieties are present in the state.[83] It is also proposed to provide research based support to the private companies in form of providing, for instance, access to a database of bio resources which is

81. The Hindu Business Line, October 20, 2001.

82. Pharmabiz.com, August 28, 2001.

83. The Economic Times, April 6, 2001.

being developed along with separate entries of endangered medicinal plants. Apart from this, a germ plasm collection and culture facilities and bioinformatics network is also being established.

In order to tap these strengths, a series of concessions and incentives have been chalked out. The industry has been given priority sector status and assured uninterrupted power supply at industrial rates. Labour laws have been relaxed, arrangements made for single window clearance of projects, with mega project status for ones with over INR 500 million (56.7 million USD PPP) investment in 2002. This would encourage diversification of farming through companies, which are already into micro-propagation units in other states for plants and crops like ginger, saffron, potato, strawberry and bamboo.

**Box 2. Emerging biotechnology clusters in India: Bangalore**

The emergence of biotechnology clusters in India is a unique link in the wider effort for a knowledge-based economy. Among the important elements of a cluster one finds specialisation, proximity as well as spill-over and synergy as the essential characteristics. Out of 401 firms in India, almost 83% of the firms are based in the major five metropolitan cities (Table 2.1). They include Hyderabad, Bangalore, Delhi, Mumbai/Pune and Chennai. In the context of key elements of a cluster mentioned above, it would be interesting to study Bangalore, in the southern Indian state of Karnataka in more detail, as it has an amazing mix of large numbers of bioinformatics, genomics and healthcare firms. In light of IT achievements, Bangalore is also seen as a major window towards the global knowledge economy. Among other cities, Mumbai and Pune provide another such wide sectoral coverage in terms of firms active across various sectors of biotechnology. In the case of Hyderabad, the focus is on the healthcare sector, while in Chennai the number of agricultural biotechnology firms is very high. In Delhi firms in healthcare lead the biotechnology sector.

**Table 2.1 Proportion of biotechnology companies in different areas in India, 2003**

| City | Number of companies | Proportion of companies (%) |
|---|---|---|
| Hyderabad | 81 | 20 |
| Bangalore | 69* | 17 |
| Mumbai/Pune | 105 | 26 |
| Delhi | 44 | 11 |
| Chennai | 33 | 8 |
| Others | 69 | 18 |
| **Total** | **401** | **100** |

Note: * Some sources, such as Bangalore Bio, claim the number of firms in Bangalore is 111.

*Source:* RIS based on BCIL 2003.

**Definition**

Bangalore is the capital city of Karnataka, which is probably the only state that has adopted a definition of biotechnology to define biotechnology firms. It says that ‘a biotechnology company means and includes inter-alia a company engaged in any of the following activities: [a] Research and development and/or manufacture of products or processes, which use or are derived by using specific living systems, and or enzymes/biocatalysts derived therefrom; [b] Genetic engineering or cell culture or microbiology or biochemistry, [c] Bio-informatics’. It further explains that the “Living system” would include plants, animals and microbes. “Biocatalyst” would mean proteins or proteinaceous molecules naturally occurring in or derived from living systems whose primary function is to assist in biochemical reactions.

**Policy initiatives**

Karnataka is one of the first states to have announced a Biotechnology Policy in February 2001. This envisaged spurring the growth of the biotechnology industry in the State and encouraging extensive research and development networks. Bangalore occupies a key position in the state in terms of biotech companies and quality research institutions.

The Government has drawn up plans to provide incubation for new projects and promotion of the sector in the State. Karnataka has planned to launch a biotechnology venture capital fund with an initial seed capital of 100 million INR in 2003 (11.1 million USD PPP), to be operated through the Karnataka State Industrial Investment and

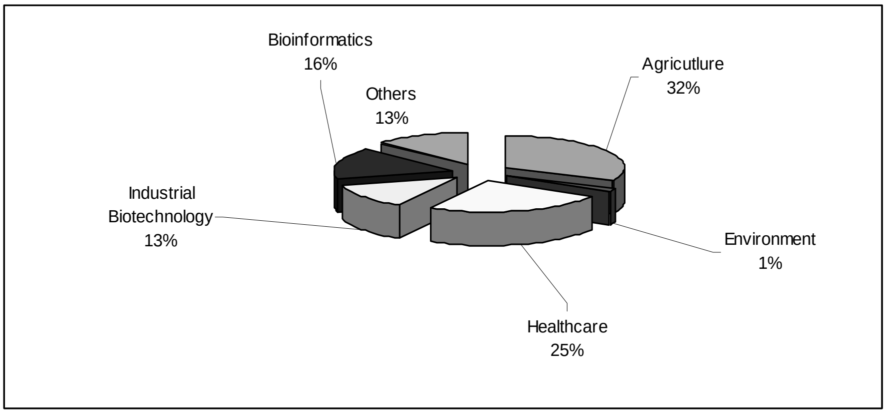
Development Corporation (KSIIDC) and the Karnataka State Finance Corporation (KSFC). Karnataka was also the frontrunner in setting up the first state financed IT VC fund. To supplement the modest initial contribution, the state has plans to mobilise additional funds for the biotechnology corpus from other domestic and global financial intermediaries and multilateral agencies. Recently, Karnataka's IT and commerce-industries team tried to pitch for a share in the 1.2 billion USD incubation fund of Singapore's National Science and Technology Board (NSTB). The synergy between information technology and biotechnology is also being placed before the firms.

**Research institutes and industry**

The government is aiming for joint R&D between the Institute of Bioinformatics in Bangalore and the Centre for Cellular and Molecular Biology, Hyderabad, and two top Singapore agencies, namely the Institute of Molecular & Cellular Biology (IMCB) and the Institute of Agri Biology (IAB). The Karnataka government is setting up an ultra-modern Centre for Human Genetics at the Agriculture University campus in Bangalore on a 20-acre plot. The Government allocated 50 million INR (5.7 million USD PPP) and an equal amount by ICICI to develop the Institute of Bioinformatics and Applied Biotechnology in Bangalore in 2002 (Srinivas, 2001). Star scientists are roped in to look after the institute. The institute will have four primary objectives: conducting research in biotechnology, providing education and training in similar areas, providing incubation facilities for start-up projects with common facilities and creating a platform for teachers, scientists, industry, venture funds and Government, to interact with each other for the development of the sector in India. Among the research centres of transnational companies, Monsanto in the agricultural sector and Astra-Zeneca in the pharmaceutical sector have a strong presence in Bangalore. In fact, their India based research centres find a prominent place in the global R&D plans of these companies. Reliance, a leading Indian firm, has set up a huge R&D base with a focus on stem cell research.

According to the BCIL Biotechnology Industry Survey, BCIL (2003), there are 69 biotechnology firms in Bangalore. Out of these a large number of firms (32%) are active in the agricultural sector. They include firms active in biofertilisers and biopesticides, while healthcare accounts for 25% of the firms and 16% of the firms are from the bioinformatics sector. Several of these firms have close linkages with other major firms in their respective sectors or with the leading institutes in Bangalore. The close linkage between the various actors is being ensured through various initiatives of the government, like the sectoral committees, etc.

**Figure 2.1 Sub-segments in the biotechnology industry in Bangalore, 2003**




*Source:* RIS based on BCIL 2003.

### *3.5 Policy environment and regulatory approach*

In the context of biotechnology there are two important areas, namely biosafety and bioethics, where the Indian government has come out with guidelines and regulatory structures. The policies related to the intellectual property regime, especially patents, come out of international commitments at TRIPs, while the plant variety protection is an attempt to avail the *sui generis* option. In this section, we briefly discuss some of these policy and regulatory instruments.

### *3.5.1 Biosafety guidelines*

Though India established the biosafety guidelines way back in 1989, until now only one commercial trial of GM crops has been allowed (Bt Cotton in March 2002). At present, in India, almost 22 genetically modified plants are being tested by different organisations for different purposes (see Table 2). This also includes endeavours by the private sector. Pro Agro-PGS, for instance, is conducting tests of brassica, brinjal, cabbage, cauliflower and tomato for developing resistance to various pests and extending the shelf life value of some of these. Among the other private companies, Rallis India and Mahyco are the prominent ones working on vegetable crops and cotton respectively. Among the public sector institutions, a network on rice, sorghum and vegetables, led by the South Campus Delhi University, is working very actively with several other institutions. IARI, Pusa is working on brinjal, mustard, rice and tomato, while Bose Institute, Calcutta and Tamil Nadu Agricultural University (TNAU) are also working on rice. JNU, New Delhi is working on different varieties of transgenic potatoes along with the Central Potato Research Institute, Shimla.

India's Biosafety and Recombinant DNA Guidelines (1990) fall under the Environment (Protection) Act of 1986. In 1994, after India signed the Convention on Biodiversity, the DBT revised its earlier guidelines to accommodate the safe handling of GMOs in research, application and technology transfer. This includes the large-scale production and deliberate release of GM plants, animals and products into the environment. The guidelines are also provided for the shipment and import of GMOs for laboratory research. In India, there is no permanent secretariat to monitor GMO trials. Instead, the regulations are implemented by various ad-hoc committees. The most important committees are the *Institutional Biosafety Committees* (IBSC), responsible for the local implementation of guidelines, the *Review Committee on Genetic Manipulations* (RCGM), responsible for issuing permits, and the *Genetic Engineering Approval Committee* (GEAC), responsible for monitoring the large scale and commercial use of transgenic materials. These committees have statutory authority. Most of the committee members are from the scientific community and representatives from the Department of Biotechnology (DBT) and the Ministry of Environment and Forests. DBT appoints the members to the committees. The GEAC is supposed to be assisted by the *State Biotechnology Co-ordination Committees* (SBCC) and *District Level Committees* (DLC). However, very few states have established SBCC and DLC committees.

Recently in India, the debate on biosafety guidelines has come a full circle as the Indian Ministry of Environment and Forests (MOEF) reported sowing of unapproved genetically modified (GM) cotton seeds in several hundred hectares of land. The report has stirred the ongoing debate on GM crops in India, as happened in 1997 when, unapproved, GM eggplant was located in a public agricultural research institute without sufficient safeguards.[84] This has once again brought the implementation-related aspects of biosafety protocol at the centre-stage and has raised several issues concerning the very ability in many developing countries to handle sensitive technologies in such vital sectors as agriculture (refer to Box 1 for details).

Similarly, the unauthorised introduction of Bt cotton in the western Indian state of Gujarat led to a major policy challenge. The whole controversy started when the Genetic Engineering Approval Committee (GEAC), visited the village Mehsana in the agriculturally prosperous western Indian state Gujarat and found cotton crop flowering on a land area of 12 000 hectares. A local seed company, Navbharat Seeds, supplied the seeds. The cotton seeds used were genetically modified, carrying the *Cry 1 Ac gene*, for which Monsanto has a patent. At present, Monsanto has a collaboration with an Indian company, Mahyco, for conducting field trials for Bt cotton in some other states. The results of the first round of trials were submitted to the DBT almost two years back, but the government did not grant permission for

84. Chaturvedi (1997).

commercialisation of these seeds, as the Ministry of Agriculture had objections about it.[85] Ultimately, in the seventh year of its application, Monsanto-Mahyco got official clearance for Bt cotton commercialisation.

In context of these constraints, the Ministry of Agriculture appointed a task force to look into the various aspects of biosafety management. The Task Force was set up in 2003 under the Chairmanship of Dr. M.S. Swaminathan. Though details are discussed in Box 1, it is relevant here to mention that the Task Force Report has suggested certain institutional modifications and a re-orientation of policy thrusts, apart from several other measures to make the system more responsive and faster for diffusion of biotechnology products. The Task Force has recommended the setting up of an autonomous statutory National Biotechnology Regulatory Authority (NBRA). This report is under discussion among various agencies of the government.

### *3.5.2 Stem cell research and bioethics guidelines*

The Department of Biotechnology has written to all the major biotechnology companies to make it clear that any transfer of biological material would be subject to clearance by the Ministry of Health and Family Welfare and the Indian Council of Medical Research (ICMR). This precautionary move has come in the wake of a global debate on the existence of stem cell lines in India, after the Bush Administration identified India on its list of sources of stem cell lines, among other institutions (see Table 17). A National Bioethics Committee has been formed to grant such permissions and to monitor research endeavours.[86] It has since been established that human stem cell lines do exist in the country, with Reliance Life Science (RLS) making it public that it had filed a "provisional patent" in the field of embryonic stem cells in the United States. While much of the debate centers around possible US-funding for such research, the Indian government is now getting concerned about the possibility of a Singapore and Australia like scenario where stem cells from aborted foetuses and frozen embryos in IVF clinics are reportedly being sold in the United States.

**Table 17. Prominent labs developing stem cells**

| Lines | University/institute | Place/country |
|---|---|---|
| 19 Lines | Goteborg University | Goteborg, Sweden |
| 9 Lines | Cythera Inc. | San Diego, US |
| 7 Lines | Reliance Life Sciences | Mumbai, India |
| 5 Lines | Karolinska Institute | Stockholm, Sweden |
| 5 Lines | Wisconsin Alumni Research Foundation | Madison, Wisconsin, US |
| 3 Lines | National Centre for Biological Sciences | Bangalore, India |

*Source*: RIS based on *The Times of India,* September 5, 2001

The guidelines for biomedical research in India were framed in 1992, but finalised only after several rounds of discussions in the year 2000. It defines human material with the potential for use in biomedical research as organs and parts of organs, cells and tissue, sub-cellular structures and cell products, blood, gametes (sperm and oval), embryos and foetal issues and wastes (urine, faeces, sweat, hair, epithelial scales, nail clippings, placenta and cell lines from human tissues). The Bioethics Committee, set up by the DBT two years ago, is yet to announce a Bioethics Policy in the near future. This would not allow human cloning in the country, but would promote embryonic stem cell research, provided a consent form is part of each study.

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85. See Sharma (2002) for details.

86. The Times of India, September 9, 2001.

There seems to be only one private company, Reliance Life Sciences (RLS), which is set to come out with its product in this field by early 2005. The product, *Christened Relicord,* contains cord blood stem cells.[87] Cord stem cells are obtained from the umbilical cord of human babies. The stem cells – undifferentiated cells with the ability to regenerate and grow into different tissue – can be used to treat patients with disorders like thalessimia or leukaemia. It can also be used as a back-up for patients who have to undergo chemotherapy, which results in depression of the bone marrow. *Relicord* will be the first product of its kind in the country. The procedure is performed at a few hospitals across the country, although hospitals have to depend on donors for the cells. RLS plans to have as many as 50 000 samples, almost making it an off-the-shelf product. Earlier this year, RLS filed a provisional US patent for *Relicord.* The company is now awaiting the approval by the Drug Controller General of India, following which it will launch the product. The first *Relicord* transplant was recently performed at Kothari Hospital in Kolkata.

### *3.5.3 Patent regime*

In 1972, India replaced the Patent Act of 1911 with the Patent Act 1970, and adopted a patent regime that provides only process patents for foods, chemicals and pharmaceutical products, with a patent term of seven years. All other patents had a term of 14 years.

The Patent Act, 1970, is widely believed to have helped the Indian pharmaceutical industry to develop its process innovation capabilities that is now recognised worldwide. In 1999, India amended the Patents Act 1970 to provide for exclusive marketing rights (EMRs), as per obligations under the provisions of the WTO/TRIPS agreement.[88] EMR allows pharmaceutical companies to exclusively market their products for which they have obtained patents in any WTO member country. The TRIPs agreement requires a form of "pipeline protection" for pharmaceutical inventions in those member countries that do not provide pharmaceutical product patents. This "pipeline protection" includes establishments of the 'mail box' for receiving the chemical/pharmaceutical product patent applications[89], which shall be opened for examination by the Indian Patent Office on or after the 1st of January 2005. EMRs can only be granted until the 1st of January 2005, and that too only in cases where the corresponding patent application has been submitted in or after 1995. Ranbaxy Laboratories has filed an EMR application for Cipro-OD, its once-per-day form of antibiotic ciprofloxation.

In keeping with other TRIPs commitments, the Indian Parliament has recently passed the Protection of Plant Varieties and Farmers' Rights Act, (PVFR) 2001.

#### Patenting of life forms

The proposed Third Amendment may facilitate the granting of patent rights over micro-organisms, microbiological and non-biological processes for the production of plants and animals.[90] Though India opted for a *sui generis* system for protection of varieties and enacted a law for the purpose, it is likely that the transgenic seeds developed through human intervention may be covered under the new patent regime. In absence of a clear definition of a micro-organism and micro-biological processes in the TRIPs

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87. The Economic Times, December 18, 2001 and personal communication.

88. Kumar (1998).

89. Chaturvedi (1999).

90. The Financial Express, November 8, 2004.

agreement, the Indian legislation need to draw a distinctive line between the product of human intervention leading to novelty and those freely occurring in nature.

### *3.5.4 Plant variety protection*

As part of India's TRIPs commitments, the Government introduced the Plant Variety and Farmers's Bill 1999 (PVFR) in the Parliament which was later referred to a Joint Parliamentary Committee (JPC), to ensure that the Bill considers protection of farmers' interests. On the basis of the recommendations of the JPC, the Government passed the Plant Varieties and the Farmers' Rights Act, 2001.

In the present form, the PVFR attempts to ensure the delicate balance between the interests of plant breeders and farmers. The farmers now can raise crops of a protected variety every year from their saved seeds. Under this legislation the plant breeders can make profits from the first time sale of self-perpetuating plant species. The Act has taken care of farmers' interests (Section 18 (c)), requiring an applicant to provide an affidavit that the newly bred variety does not contain the terminator gene.[91] The Act has a strong provision for compulsory licensing to undertake production, distribution and sale of the seed/planting material of a particular variety, if the same is not available for a reasonable price or in adequate amount. The act also distinguishes between new varieties and the extant varieties. In the case of new varieties, they are expected to be new and distinctive with uniformity and stability, while in the case of extant varieties the novelty criterion is relaxed, but they still need to be distinctive with uniformity and stability. Similar due weightage is given to the farmer's variety as well. Farmers who have bred or developed a new variety would be entitled for protection as a breeder of a variety. Farmers' variety as part of the extant variety will be entitled for registration/protection.

However, the interests of breeders are proposed to be duly taken care of while settling the terms and conditions of granting a license. Similarly, there is a provision for revocation of the compulsory license, if the compulsory licensee fails to provide seeds/planting material at a reasonable rate to the farmers.

### *3.5.5 Seeds Act*

After the clearance of Bt cotton by the Genetic Engineering Approval Committee (GEAC) for commercial production, the draft Seeds Act of 2001 would have to include more stringent provisions for genetically modified seeds.[92] The objective of the new legislation, which is to replace the existing Seeds Act of 1966 and the Seed (control) Order of 1986, is to provide an effective system for stimulating investment for research and development. The draft Act aims at encouraging development of new plant varieties by ensuring appropriate returns on all such investment by domestic players. However, at this point a revamp exercise is on to address the sale of Bt cotton seeds, which are also likely to be governed by the same provisions controlling other varieties under the legislation, such as specific labelling.

There is still no domestic policy on genetically modified crops and all proposals would receive their approval from the GEAC on a "case to case" basis. However, any exercise to pointedly address the lapse in the draft legislation regarding the sale and stringent labelling of genetically modified seeds would also lay the ground rules for other seeds in the future. The draft legislation now pending with the law ministry refers to transgenic seeds, in fact, primarily as imports. It holds that the importer of seeds or planting material will be required to declare whether such material is a product of transgenic manipulation or involves genetic use restriction technology. The draft law also proposes the compulsory registration of all such seeds, seed producers and seed processing plants and the regulation of import and export of seeds through the National Seed Board.

91. Mehra (2000).

92. The Economic Times, April 25, 2002.

## 4. Conclusions and policy implications

Over the years, India has developed strengths in biotechnology in public sector institutions. The graduation from the Biotechnology Board to the Department of Biotechnology in the late eighties was a decisive step to address a wider canvass in the sector. In these years DBT has emerged as a major force to spearhead biotechnology development in India. In this section, we would like to flag some of the key concerns which may be relevant from the perspective of policy formulation. Apart from these, there are some broad concerns, like an equitable distribution of gains from biotechnology – hence a pro-poor focus – along with an effective IPR regime, which would be of significance in a knowledge-based economy. In the case of biotechnology, the challenge would be the effectiveness of the *sui generis* system, which India is attempting to build.

### *4.1 Prioritising public sector research*

India needs to set a mechanism which may facilitate priority setting in the R&D work programme of various public laboratories and departments. At this point, the Tenth Five Year Plan proposes to include every conceivable sector in the priority list. Thus, there is a lack of focus. As mentioned earlier, the list includes biodiversity conservation, environmental protection, agricultural biotechnology, medical biotechnology, bioinformatics, etc. Like this, there are enumerable sub-themes in the broad category of 17 priority areas.

There is an urgent need to identify socio-economic needs of the country for which biotechnology may be applied. Even within a particular sector, like for instance within the crop improvement programme, the nature of crops being addressed would have to be done keeping the public and private sector niche in perspective. At this point, India also needs to set the human resource policy according to the research priorities. Efforts are to be made to link up human resource development programmes according to industry requirements. The academic institutions are also to be encouraged to work in close collaboration with industry for research purposes. Currently, more than 90 universities and institutions are engaged in biotechnology training and education related programmes. In the context of the industrial application of biotechnology, a narrow approach to promote national competitiveness needs to be at the centre-stage, while research priorities are being worked out, as transnational companies may not go for tailor made products to suit Indian socio-economic priorities.

### *4.2 Co-ordination between agencies*

Over the years, several Ministries other than DBT have entered the scene both for the development of the technology and for its regulation, depending on their role in the system. The multiplicity of agencies dealing with this technology has helped in developing indigenous technology capacity at various levels. As a result, on the one hand there are several institutions engaged in the products of the first generation of agricultural biotechnology, like biofertilisers and tissue culture, while on the other hand there are several other institutions working on upcoming business areas such as bioinformatics and stem cell line research. The National Centre for Plant Genome Research and the National Brain Research Centre are some of the recent additions. On the downside, there is a risk of multiplicity. In some cases it has led to duplication of research funding and a lack of co-ordination has further confounded research priorities. This needs to be addressed with priority.

### *4.3 Innovation and star scientists*

India has a strong public sector in the realm of science and technology in general, which has contributed a great deal to the economic growth in the manufacturing sector. When supporting priority areas for R&D in biotechnology, one needs to identify core areas of competencies, something that has often been described as the ‘path dependency model’ for effectively promoting innovation. There are several key challenges facing the sector, for instance there is no substantive rise in the budgetary allocations vis-à-vis other major economies. Moreover, entering in several activities by different institutions itself thins down the quantum of resources available. It is important to provide early stage and assured funding for star scientists (who have a proven track record), so that indigenous capabilities are developed for technology generations. As noted earlier, there is a strong trend emerging where biopharma firms are getting star scientists back. This trend may require a more intense policy response for being firmed up further.

### *4.4 Innovation system for SMEs*

In India, the sharp growth of SMEs in frontier areas is a result of the initiatives for industrial promotion efforts to ensure participation in the technology evolution exercise. However, small and medium-sized enterprises (SMEs) need more support for facing the intense competition from a whole range of transnational corporations. The ongoing alliances, a number which has increased manifold in the recent past, may end up only at ‘low-end technology’ co-operation. The pressure is immensely acute in the agricultural sector, where small and medium-sized firms are finding it difficult to access relevant gene sequences given the emerging trend of broad patenting, including that of research tools. In the pharmaceutical sector, where advanced forms of biotechnology are being used, firms are facing severe liquidity constraints for investment. The biosafety and other regulations work as a major barrier for entry and survival of SMEs. In fact, the high cost of regulation can only be absorbed by large firms with higher absorptive capacities.

In this regard, there is a need to explore various elements of a technology business incubation system to encourage technopreneurship at the SME level. The incubation system for SMEs in biotechnology may require setting up an R&D fund to ensure sustained support. In this regard, the proposed arrangement between SIDBI and DBT should be made functional at the earliest opportunity. This may help in overcoming the usual strategy of venture capital funds to focus on late stage funding, which adversely affects entrepreneurship. Another feature of an incubation system could be to promote an industry cluster approach in collaboration with leading research institutes. In this paper, the case of Bangalore has been discussed, but more conscious efforts are needed to develop effective clusters. In this regard, the floating of firms by star scientists at leading institutes like IISc is a novel experience for supporting the development of clusters. Research has shown that clustering has helped SMEs in becoming more competitive by improving ‘collective efficiency’, that is tapping the gains from local external economies. This would also encourage entrepreneurs to attempt product development at the high-end of technology.

### *4.5 Technology inherent and transcending problems*

In a country like India, the introduction of biotechnology places at the centre stage problems and technological risks related issues, so called ‘technology inherent’ risks, and ethical, social and economic risks, so called ‘technology transcending’ risks. At the level of addressing the technology inherent risks, a lot more leaves to be desired at the regulatory level. The biosafety policy was announced in India right in the beginning when this technological revolution was being unfurled. A three-tier structure was put in place to monitor biosafety regulations back in 1987. However, the excessive time consuming regulatory mechanism at the top and near absence of bottom level agencies has created immense challenges. The proposed NBRA may help to streamline, provided there is clarity in the policy itself. For instance, India has yet to announce a policy related to trade in GMOs. It is through continuous efforts that India has developed indigenous strengths in developing GMOs, but imports of GM products have been banned for several commodities. This dichotomy is leading to confusion at several levels of governance of this technology. Moreover, the wide gap between promoting agencies like DBT and the regulatory agencies like MoEF needs to be bridged.

The issues related to technology transcending risks need to be very actively considered in India. The bioethics debate is in its nascent stage and so is the state of incorporation of ethical concerns in the regulatory framework. Another important issue related to transcending problems is that of the IPR regime. In the case of IPRs there are still grey areas which need to be addressed with priority. Though a debate on Article 27(3) b of TRIPS still continues in India, an amendment is being brought in the Patents Bill (1970) so as to facilitate research and development in biotechnology. However, the absence of the definition of micro-organisms and a conflicting stand on Article 27(3) b needs to be resolved, as has been attempted while promulgating the Plant Variety Protection Act, which has brought in a rare balance between the interests of farmers and industry. Still, statistics are needed to see in what direction these policy responses are taking the nation to.

### *4.6 Evolving statistical framework*

As noted earlier, it is difficult to estimate precise R&D allocations as all the major funding agencies like CSIR/ICMR and ICAR give only an aggregate picture of their allocations. Therefore, there is an urgent need to consolidate the efforts being made by different agencies for establishing the national edge in selected niche areas.

Another major challenge related to data management is the case of patent data. TIFAC and NRDC are the agencies providing patent statistics in electronic form, but they do not collect International Patent Classification (IPC) details, which would help in identifying biotechnology patents. Thus one can not precisely work out even a broad trend in technology development. Since the number of patents being granted is increasing every year, the situation may become more complicated. At the policy research level, there is a need to launch a detailed survey to collect specific biotechnology related allocations at the individual institute/laboratory level for collecting specific sectoral policy insights.

Apart from this, DBT or some other agency should urgently initiate an exercise for data collection either on its own or through specialised agencies. It is also important to evolve a consensus among agencies on the definition of biotechnology. Inferences may be drawn from the experience of some of the OECD countries in conducting industrial surveys based on the OECD definition of biotechnology. However, while doing so, specific policy thrusts in India need to be kept upfront while statistical indicators are being shortlisted, like, for instance, nutritional security would be a priority in India to which OECD may not attach much importance, but at the same time collecting data on internationally comparable indicators is equally important. For example, indigenous technological effort (using firm R&D as a proxy) is one of the most relevant factors for improving industrial performance in both industrial and developing countries.

### *4.7 Regional complementarities and integration*

India should tap the complementarities that exist both at the regional and sub-regional level in Asia for the collective advancement both in terms of establishing a physical infrastructure and in terms of an evolving common approach to policy issues. As mentioned earlier, forums like the Asian Co-operation Dialogue (ACD) may help in launching policy frameworks related to harmonised biosafety guidelines, an approach towards TRIPs plus a regime and framework for a liability redress mechanism. Some of the ESCAP reports have observed that the regional economies in Asia are undergoing momentous changes with increased prospects for integration through industrial investments and technology transfer. Biotechnology may provide immense opportunities. Tapping regional complementarities for a joint R&D agenda and building of selective joint facilities should be explored.

### *4.8 Integrated policy development*

In light of the above mentioned issues it is important that India comes out with a comprehensive national policy to balance national socio-economic priorities with adequate technological expertise. This policy may also provide an overarching framework for regulatory issues, which may help in strengthening not only the process of inter-ministerial co-ordination but may also accommodate expectations of various state governments.

The growing competition among the various state governments to provide incentives to the biotechnology industry in terms of tax exemptions and concessional infrastructural facilities may adequately be assessed to avoid a race to the bottom. The policy component related to human resource development may also address the growing concern about the quality of scientists, engineers and managers to sustain the industrial growth in this sector. It should realise the fact that at this stage neither at the union government level nor at the state government level, trained manpower is available to look into the technical details of GM crops. Apart from this, neither the quarantine agency nor any other agency has the necessary gadgets to locate transgenic material. The suggested policy at the national level must take these constraints into account while evolving any recommendation related to traceability, labelling, etc. In this regard, the idea of a 'single window regulatory system' vis-à-vis a 'single regulatory body' may also be carefully analysed as part of this policy framework. There is an urgent necessity to initiate a mechanism to check the illegal introduction of genetically modified crops in Indian agriculture as happened with Bt Cotton. A related issue is to check the multiplication of spurious seeds.

The participation of the private sector is critical to ensure the delivery of new products for which an enabling environment to encourage public private partnership, in its various facets, is important. Biotechnology parks and biotechnology clusters are being explored as policy instruments for encouraging the biotechnology sector, which is also important to facilitate synergies with other sectors like information and communication technology. This may eventually be targeted to provide an enabling and dedicated infrastructure and conducive environment for financing the technology. The potential for intra firm co-operation in biotechnology may also be further explored in the high-end technology as it has also taken several forms like joint ventures, joint research and development, technology exchange agreements, co-production, direct minority investment, etc. In Bt Cotton itself, the Monsanto-Mahyco alliance has issued production/field trial licences to 11 firms. In the public-private partnership mode, universities and other academic institutions should also be encouraged to be part of this exercise.

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## ANNEX 1: BIOTECHNOLOGY PROGRAMMES AT MAJOR INSTITUTIONS OF CSIR

| Area | Institution |
|---|---|
| Allergy & immunology | Centre for Biotechnology (CBT) |
| Diagnostics | CBT, Indian Institute of Chemical Biology (IICB), Central Drug Research Institute (CDRI), National Chemical Laboratory (NCL) |
| Development of antibody based diagnostics and site specific drug delivery systems in infectious diseases such as malaria, leishmaniasis and tuberculosis. | Institute of Microbial Technology (IMTECH) |
| Studies on the mechanisms of multi-drug resistance; new in yeast | IMTECH |
| Development of an in vitro endocrine disorders model system for screening due to mutation in steroid receptor gene and possibility of its repair by gene targeting. | IMTECH |
| Membrane structure, function and to study possible applications in site-specific drug/antigen delivery. | IMTECH |
| Microbial Genetics. | Centre for Cellular and Molecular Biology (CCMB) |
| Cell Biology & Development. | CCMB |
| Biomedicine & Biotechnology. | CCMB |
| Molecular Biology. | CCMB |
| Biochemistry & Biophysics. | CCMB |
| Genetic manipulation of essential oil bearing plants for high yield and value addition for the international market. | Central Institute of Medicinal and Aromatic Plants (CIMAP) |
| Morphine deficient and hyper morphine-codeine yielding genotypes for alternate methods of opiate alkaloid production. | CIMAP |
| Improvement in productivity and Quality of Hill Area Tea. | Institute of Himalayan Bioresource Technology (IHBT) |
| Plant Molecular Biology. | National Botanical Research Institute (NBRI) |
| Tissue Culture of Economic Plants. | NBRI |
| Biodiversity and conservation of lower group of plants (Lichens, Bryophytes and Pteridophytes) | NBRI |

*Source:* CSIR Annual Report (various years)

## ANNEX 2: MANPOWER DEVELOPMENT AND TRAINING OPPORTUNITIES IN INDIA

| |
|---|
| **M.Sc. General Biotechnology (2 year courses)** |
| Jawaharlal Nehru University, New Delhi |
| Madurai Kamaraj University, Madurai |
| MS University, Baroda |
| University of Poona, Pune |
| Guru Nanak Dev University, Amritsar |
| Devi Ahalya Viswavidyalaya, Indore |
| University of Hyderabad |
| Himachal Pradesh University, Shimla |
| University of Calicut, Kerala |
| Tezpur University, Tezpur (Assam) |
| Gulbarga University, Gulbarga (Karnataka) |
| Jammu University, Jammu |
| Gujarat University, Ahemadabad |
| Guru Jambheshwar University, Hissar |
| Kumaon University, Nainital |
| Banaras Hindu University, Varanasi |
| Indian Institute of Technology, Mumbai Entrance Exam by IIT, Mumbai |
| Roorke University Entrance Exam by University of Roorke |
| Aligarh Muslim University, Aligarh Entrance Exam by AMU |
| Banasthali Vidyapeeth, Banastha Rajasthan (for girls only) Entrance Exam by Banasthali Vidyapeeth |
| Mysore University, Mysore. M.Sc. Agricultural Biotechnology (2 years) |
| Assam Agricultural University, Jorhat Exam by AAU Jorhat |
| Tamil Nadu Agricultural University, Coimbatore, Combined Entrance Exam by JNU |
| G.B. Pant University of Agricultural and Technology, Pantnagar, Combine Entrance Exam by JNU. |
| Birsa Agricultural University, Ranchi. Combined Entrance Exam by JNU |
| Himachal Pradesh Krishi Vishvavidyalaya. Palampur (H.P.) Combined Entrance by JNU |
| Indira Gandhi Agricultural University. Raipur Combined Entrance Exam by JNU |
| **Master in Medical Biotechnology (2 years)** |
| All India Institute of Medical Sciences New Delhi, Exam by AIIMS |
| **M.Sc. Marine Biotechnology (2 years)** |
| Goa University, Goa Combined Entrance Exam by JNU |
| **M.Tech/M.Sc (Tech) Biochemical Engineering & Biotechnology (5 years integrated/3 semesters/1.5 years course)** |
| Indian Institute of Technology, Kharagpur, through GATE |
| Indian Institute of Technology, New Delhi (5 years integrated) JEE |
| Anna University, Chennai. Combined Entrance Exam by UDCT, Mumbai |
| **Post MD/MS Certificate Course in Medical Biotechnology (1 year)** |
| All India Institute of Medical Sciences, New Delhi Exam by AIIMS |
| Post Graduate Institute of Medical Education & Research, Chandigarh. Exam by PGI |
| Sanjay Gandhi Post Graduate Institute of Medical Education & Research, Chandigarh. Exam by SGPGI |
| **PG Diploma Course in Clinical Biochemistry & Biotechnology (1 year)** |
| Utkal University, Bhubneshwar. Exam by Utkal University |
| **PG Diploma Courses in Molecular & Biochemical Technology (1 year)** |
| Sri Venkateshwara College, University of Delhi, New Delhi. Exam by Sri Venkateshwara College. |

*Source*: Annual Reports DBT (various years).

## ANNEX 3: KEY FEATURES OF INITIATIVES BY SELECTED STATE GOVERNMENTS

| Name of the State | Policy Announcement | Special Measures |
|---|---|---|
| 1. Andhra Pradesh | May 2001 | • Establishment of ICICI knowledge park and biotechnology park to prove bioentrepreneurship<br>• 'Single window clearances' on all state related matters<br>• Sales tax at 1% for 7 years for high-end biotechnology products and land at concessional prices.<br>• APICDVCL fund of INR 1 500 million (8.2 billion USD PPP)<br>• Simplified labour laws |
| 2. Karnataka | February 2001 | • 'Millennium Biotechnology Policy'<br>• Exemption of entry tax on inputs and capital goods along with exemption on electricity tax<br>• Simplified labour laws<br>• Relaxation of floor area ration regulation, rebate on registration charges<br>• KSIDC seed money |
| 3. Maharashtra | October 2001 | • Setting up of Biotechnology Commission under Dr. R.A. Mashelkar<br>• Biotech development fund of INR 500 million (2.7 billion USD PPP)<br>• Biotechnology parks at 'Jalna', Pune and Aurangabad<br>• Concessional electricity tariff |
| 4. Kerala | November 2003 | • Setting up of Biotechnology Commission<br>• Predominant focus on agricultural crops |
| 5. Punjab | March 2003 | • Vision Document (2001)<br>• Strengthening infrastructure for biotech parks<br>• Promotion of cluster approach |
| 6. Tamil Nadu | September 2003 | • INR 300 million venture fund (1.6 billion USD PPP)<br>• Emerging technology fund of INR 300 million (1.6 billion USD PPP)<br>• Special gender focus: women's biotechnology park at Kelambakkam<br>• Focus on marine board biotechnology |
| 7. Madhya Pradesh | October 2003 | • Integrated biotechnology parks<br>• Special emphasis on medicinal and aromatic plant and industrial development |
| 8. Himachal Pradesh | June 2001 | • State Government announced 100% tax exemption for all biotechnology units until 2012.<br>• Focus on bioresource based drug development |

*Source:* RIS database compiled from various sources