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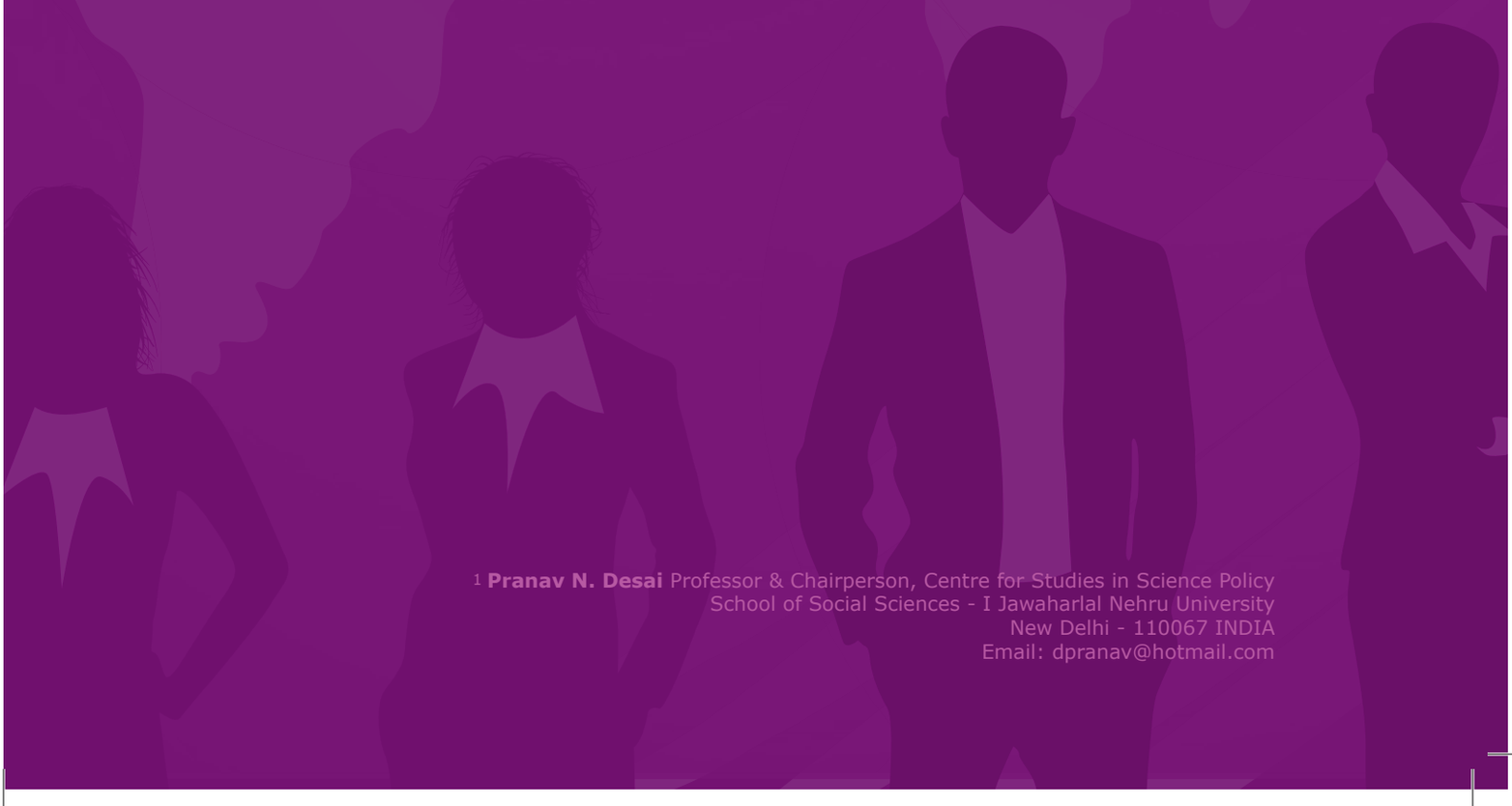
Technology foresight in the Indian biotechnology innovation system



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Abstract

Purpose Technology foresight or technology futures analysis is increasingly being recognised as a tool for planning sustainable development. Similarly, as argued by many, biotechnology could be harnessed for sustainable development. Hence, the present paper aims to map out foresight activities in the Indian biotechnology innovation system.

Methodology The present paper has adopted a systemic approach to analyse the foresight activities in the Indian biotechnology sector. An online Delphi survey, including interviews, was conducted for 750 biotech units.

Findings The greatest need of foresight is felt in the biopharma sector, especially in the small- and medium-sized firms. The methodologies used are only pre-foresight in nature and for short-term time horizons. The output preferred is "setting the R&D planning and priorities". "Assessing socioeconomic and environment impact" is not accorded a high priority. Most of the regulatory agencies do not carry out foresight exercises.

Originality/value The research holds significance for evolving sustainable development policy.

Keywords Agribiotechnology, Biopharmaceuticals, India, Innovation System, Sustainable Development, Technology Foresight

Introduction

The present paper aims to map out foresight activities in the Indian biotechnology innovation system. The Indian biotechnology sector has reached a cross-road at this juncture. Hence, it will be crucial to analyse the innovation environment, as well as the status of foresight activities in this sector. Some of the foresight issues confronting the sector today are varied for different sub-sectors. Agribiotechnology has reached saturation in investment and growth. New paths need to be charted out for further growth. Biopharma is the most dominant segment and will continue to grow. However, the vaccine industry and export market is fuelling the growth, and this requires high standards of maintenance, quality of testing infrastructure and strict regulatory norms. Secondly, most of the biotech-based drugs are expected to be out of the patent system by 2015. This phenomenon is likely to encourage resource shift towards improvement in generic drugs and biosimilar compounds rather than focusing on new molecules or radical innovation. The sector of industrial biotech promises discoveries in biofuel, water purification and enzymes. However, it has failed to attract greater FDI and public awareness. In the recent period, the sequencer has witnessed a drastic cost reduction. India has yet to take advantage of its human resource potential and to reduce the costs of the sequencer. Bioinformatics is yet to achieve a significant share in the industry. The nanotechnology mission has placed adequate emphasis on the health and agricultural sector, however, the nanotech-based industry is still in a nascent stage for innovative activity.

In the preceding context, the paper aims to analyse the foresight activities of the Indian biotechnology sector with a systemic perspective.

Analytical framework

In the last two decades (2010–1990), the approaches to thinking regarding technology futures have undergone significant transformation. This period has not only witnessed the increasing influence of emergence and convergence technologies such as bio-, nano- and information/communication-technologies, but international environmental movements in addition. This has led to an acceleration of the unfolding globalisation process often punctuated by the global economic crisis. Emerging technologies have promised many solutions to issues relating to food, health, environment and industrial productivity, and at the same time posed many challenges of a socioeconomic, political, environmental, ethical and legal nature. These challenges have partly resulted in growing public distrust of modern science (public or private). Hence, those who are involved in science and technology (S&T) policy and technology futures decision-making need to respond to such challenges. These factors have not only changed the policy-making context, but have also facilitated an alteration of the focus of foresight studies from positivist and technology-focused approaches towards a wider perspective of the entire innovation system.

Not only is there a need for the identification of the drivers and barriers emanating from the ‘uncertain quest’ of modern S&T, but in the

socioeconomic, cultural, political and environmental domain as well. Thus, the task of shaping the technology futures that lie ahead is more daunting. This fact is reflected in the evolution of several generations of technology futures studies stimulating foresight of many national and international actors and occupying various national governments, business and other stakeholders. Starting from technology forecasting in the 1950s, these generations of foresight studies include efforts to integrate technology and markets, then social and economic dimensions, and finally, in the 1990s and onwards, the efforts are to integrate innovation system perspective with a broader policy framework. In order to respond to new challenges, it has become imperative to resort to interactive learning, networking and fore sighting. This requires focus not only on one actor or agency but the interactions involving different actors, agencies and institutions in the biotechnology system of innovation.

Methodology

The present work has covered all the biotechnology firms and institutions in India comprising different sub-sectors. It has included a target population and sample size of 750 biotechnology firms with an online questionnaire survey. Several structured interviews in Delhi-NCR, Mumbai, Pune and Bangalore were carried out along with a literature survey. Using a -10year reference period (2010–2001), the study has covered databases from the Directory of Biotechnology Industries and Institutions in India (BCIL) and the Biotechnology Industry Research Assistance Council (BIRAC).

The study has identified the status of foresight activities in Indian biotechnology firms, regulatory authorities and venture capital firms. The present work attempts to explore the current uses, practices and impacts of technology foresight applied in both public and private sector firms in all the major sub-sectors of biotechnology, especially in research- and manufacturing-based firms. This study has correlated the nature and size of biotechnology firms with the type of foresight methodologies; time horizons used; geographic scope and approaches adopted across different sectors. It also provides a particular view to the possible contributions to innovation that foresight activities might bring to the Indian biotechnology sector. It is also pertinent to discuss the role of the institutional framework, as this has played a dominant role in shaping the biotechnology innovation system.

Institutional development of biotechnology in India

In the year 1982, the Government of India constituted an agency viz. the National Biotechnology Board (NBTB) in order to promote biotechnology. This was an apex coordinating body under the Ministry of Science and Technology. Some of the major functions of this body were to identify priorities, coordinate, oversee and plan for required manpower, promote integrated industrial development and large scale use of biotechnology products and processes. A unique feature of this board was that all the existing S&T organisations and allied agencies participated in formulating the objectives and organisation of the structure of the board as well as making a financial contribution to the core funding of the board. In terms of the identification of needs and priorities in biotechnology, in India, the board had a unique international interaction through the formation of the Scientific Advisory Committee (North America) (SAC [N]) in 1983. Accordingly, various

programmes for integrated manpower development and the establishment of essential infrastructural facilities were initiated, thus meeting the need for capacity building through strengthening of existing laboratories, training of young scientists abroad and introducing a course curriculum in biotechnology.

Coinciding with the production of the first transgenic farm animal and the first approval of controlled experimental release of genetically engineered organisms into the environment in the year 1986, the NBTB was upgraded into a fully fledged separate department under the Ministry of Science and Technology, viz. Department of Biotechnology (DBT). This was undertaken in recognition of the need for a focal point in the administrative structure of the Government of India for the purpose of planning, promoting and coordinating biotechnological programmes. Thus, setting up the separate Department of Biotechnology gave new impetus to developments in the fields of modern biology and biotechnology in India, and has paid rich dividends (DBT, 1985).

Moreover, DBT has so far worked to achieve a balance between different sections of society as far as technology absorption is concerned, in addition to promoting industrial development. It supports low-cost biotechnology adoption programmes for socially backward communities. The programmes include vermicomposting, the use of organic manure, silk-worm rearing and mushroom cultivation. Some training-cum-demonstration programmes are also supported, and efforts are being made for gender mainstreaming. The DBT has launched several projects for women in the areas of waste management, biopesticides, biofertilisers, floriculture and fish farming for poor women in rural areas.

Biotech infrastructure

After the establishment of the Department of Biotechnology, concerted efforts have been made by the Government of India towards capacity building, both in terms of human resources and sophisticated infrastructure for R&D. As a result, India has world-class facilities for DNA sequencing, protein engineering, bioprocessing, crystallography, molecular graphics and modelling, PL3 and PL4 level containment for work on dangerous pathogens, prescribed glass/animal houses for transgenic animal/plant research, repositories of microorganisms important in agriculture, healthcare and industry, ex-situ and in-situ gene banks for crops and endangered medicinal and aromatic plants, medium and high throughput screening facilities for drugs and pharmaceuticals, biosensors, nuclear magnetic resonance machines, different mass spectrometers for various purposes, GM testing laboratories and recently, microarrays, automated DNA sequencing as well as robotic plasmid isolation equipment. Most of the facilities can be shared by both the public and private research laboratories at a cost comparable to that of developed countries. There are about 200 laboratories with state-of-the-art equipment and facilities for recombinant DNA research. Many private sector R&D facilities also have sophisticated equipment in most of these areas, and some of them are paid-up service facilities for researchers. The biotechnology equipment market in India is about Rs.1500 million and is growing at the rate of two to three per cent, and the demand is shifting from public research laboratories to the private sector (Rao, 2005).

The Government of India has also formulated a regulatory framework

for recombinant biotech products for biosafety mechanisms.

Regulatory mechanisms for rDNA products

The Indian rules and regulations and procedures for handling the genetically modified organisms (GMOs) and rDNA products have been formulated under the Environment (Protection) Act (EPA) 1986. The rules enforced since 1993 cover manufacture, use/import/export and storage of hazardous microorganisms, genetically engineered organisms or cells. However, a set of rDNA guidelines were issued in 1990 covering genetically engineered organisms, genetic transformation of plants and animals, mechanism of implementation of biosafety guidelines and containment facilities at laboratory level under three risk groups. The guidelines have been reworked and issued as Revised Guidelines for Safety in Biotechnology in order to comply with the newer aspects of technology. In order to provide special thrust to genetically engineered plants, the "Revised Guidelines for Research in Transgenic Plants and guidelines for Toxicity and Allergenicity for Evaluation of Transgenic Seeds, Plants and Plant Parts" came into force in 1998. Since these regulatory mechanisms came into force, ten rDNA drugs have been approved for marketing, four industrial units are manufacturing recombinant hepatitis vaccine, and locally and indigenously produced erythroprotein and G-csf are also available in the market. Several novel processes to produce rDNA vaccines and drugs are in the advance stages of development. Under the plants category, cotton with insect-resistant Bt gene was given approval and was commercially released in March 2002. Following the regulatory procedures, at least 165 institutions are working in r-DNA research in India, which include 55 organisations engaged in transgenic plant research, both in the public sector (42) and private sector (13). A large number of private organisations are engaged in r-DNA therapeutics: about 25 out of 85 are doing basic research (Biospectrum, 2005).

Implementing agencies

For the implementation of the government's rules and regulations in the biotechnology area, different bodies exist, including the Ministry of Environment and Forests, and the Department of Biotechnology and State Governments. There are also six competent authorities under the government's regulatory mechanism which are as follows:

i. Recombinant DNA Advisory Committee (RDAC)
ii. Institutional Biosafety Committees (IBSC)

iii. Review Committee on Genetic Manipulation (RCGM)

iv. Genetic Engineering Approval Committee (GEAC)

v. State Biosafety Coordination Committees (SBCC)

vi. District Level Committees (DLC).

While the RDAC is advisory in function, the IBSC, RCGM and GEAC have a regulatory function. The SBCC and DLC are for monitoring purposes. Furthermore, regulatory policies in general are compliance-friendly. However, it may be argued that at present, there are too many agencies involved in giving regulatory clearances. To address the concern of both the public and private sectors, efforts are underway to establish a single window regulatory mechanism or

to put in place a structure which could promote speedy commercialisation of recombinant products and processes. For this purpose, the Biotechnology Regulatory Authority of India (BRAI) has been formed and is waiting to be passed by Parliament. Further, after discussing the emergence and regulatory structure of the biotech industry in India, its current status is discussed as follows:

Growth and composition of the Indian biotechnology industry

The Indian biotechnology sector has evolved from a nascent stage over the last three decades into a matured stage. It has grown at a compounded growth rate of 22–20 per cent over the last decade. In 12–2011, the overall biotech industry registered 18.5 per cent growth rate (Biospectrum-ABLE survey, 2012).

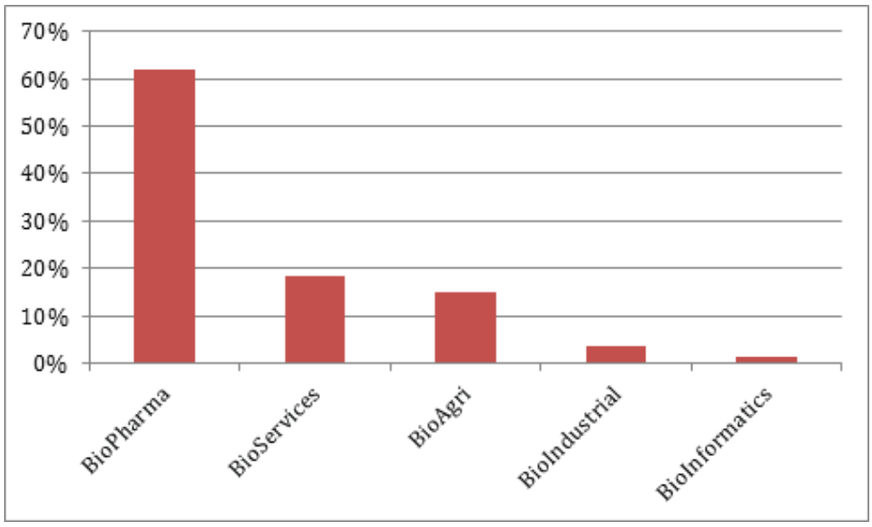
The preceding figure shows that the Indian biotechnology sector has grown at a steady rate in the past decade. It grew to around 21 per cent in 11–2010 but dipped to 18.5 per cent growth in 12–2011; this may be because of the financial slowdown in the market of biotechnology products and services.

The revenue of the biotech sector has grown to over US 4$ billion dollars in 2011 from a mere US 530$ million dollars in 2003 (ABLE Report, 2012). Out of the total revenue, the biotech industry has received Rs. 9842 crore from exports and Rs. 10599 crore from domestic revenue (Biospectrum-ABLE survey, 2012). The sector consists of firms from all aspects of Indian biotechnology viz. biopharmaceuticals (vaccines, biosimilars, medical device, stem cells), BioServices (CROs and clinical trial management firms), bio-agri and bioinformatics, including systems biology firms. This sector consists of more than 700 firms spread across the country, especially in the southern and western region (BCIL Directory, 2007). The sector consists of both multinational (such as Astra Zeneca, Novozymes, Monsanto) and indigenous firms (such as Serum Institute, Biocon, Bharat Biotech, EcronAcunova, Metahelix and Strand Lifesciences to name a few). There are a few large firms; however, there is a long tail of small- and medium-sized enterprises (SMEs). India is now recognised as a global destination for vaccines, bio-services and increasingly for contract manufacturing, especially in biosimilars. Many firms are exploring exciting areas of stem cell biology, synthetic biology, agribiotechnology systems biology and exploring evidence based traditional medicine (ABLE Report, 2012).

Sectoral composition of the biotech industry

The biotech industry has undergone structural change in the last three decades. In the early 1980s, BioAgri was the most dominant segment. Currently, BioPharma has emerged as the most dominant segment and entirely new segments like BioServices and bioinformatics have emerged. According to the Biospectrum-ABLE survey 2012, the revenue for the total biotechnology industry has reached Rs. 441 ,20 crore. Out of the total share of the biotech industry, BioPharma consists of 62 per cent (Rs. 679 ,12 crore) and remains the most dominant segment. BioServices is an emerging segment with an 18 per cent (Rs. 3,749 crore) share. BioAgri is the third biggest segment with a 15 per cent share (Rs. 3,050 crore). The BioIndustrial segment accounts for three per cent (Rs. 696 crore) and bioinformatics one per cent (Rs. 266 crore). Another interesting feature is that although the share of the BioAgri segment has slipped down to third

position, growth is currently saturated, following growth at almost 50 per cent CAGR during the last decade (10–2001). Furthermore, in the last decade, the biotech industry remained export- and urban-oriented. In 2012, for the first time, revenues from the domestic sources (Rs. 10599 crores) surpassed that of the export sources (Rs. 9842 crores) in rupee terms. The percentage-wise share of different sectors is shown in Figure 1.



Source: Biospectrum-ABLE survey, 2012

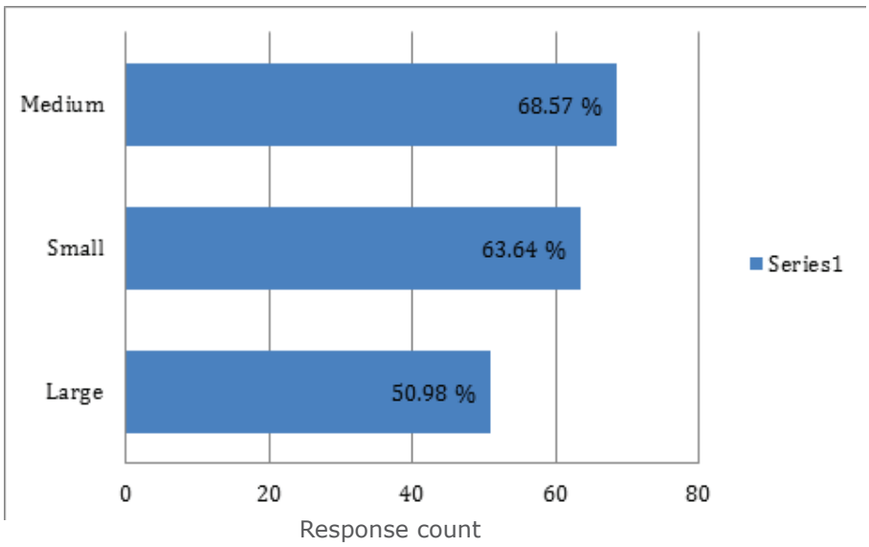
Figure 1. *Segments of Indian biotech industry*

In the year 2012, the BioAgri sector recorded a growth of 23 per cent and BioServices sector 16 per cent. While the BioPharma sector is currently growing at a CAGR of 13 per cent, BioIndustrial sector has been growing at a CAGR of 11 per cent and bioinformatics has grown at a growth rate of 10 per cent (Biospectrum-ABLE survey, 2012). It is interesting to observe that although the share of the BioAgri sector is low, it has recorded the highest growth rate in comparison to other sectors of biotechnology. While the BioPharma sector comprises the highest share, it has witnessed a slowdown in its growth.

Status of technology foresight

It is necessary to map out the foresight activities in this sector in order to gauge the foresight needs across sub-sectors, the nature and size of the firms and the methodologies they use. Moreover, this exercise has an integrated innovation framework. Hence, not only are the biotechnology firms covered, but the regulatory authorities and venture capital firms are also included. A summary of the analysis of 43 questions sent to firms/ organisations, 27 questions to venture capital firms and 23 questions sent to regulatory authorities is as follows.

Out of the total 750 biotech organisations/firms contacted, 133 biotechnology firms and institutions have responded and 66.9 per cent of them have reported regular or periodic foresight exercises. Private-sector firms of small and medium sizes, mostly involved in research and manufacturing conduct foresight activities more often compared to larger firms (Fig. 2).



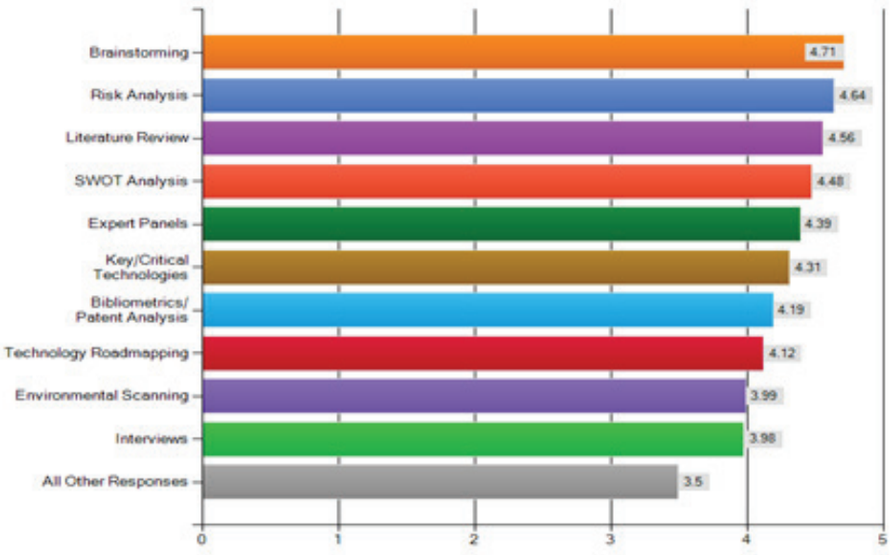
Source: Compiled from the results of the primary survey

Figure 2. *Percentage of firms doing foresight according to their size (133 firms responded)*

The majority of the pharmaceutical biotech firms carry out foresight exercises, mostly annually and for short-term horizons. These firms mainly carry out pre-foresight exercises and are at a nascent stage. They mostly use preliminary methods of foresight.

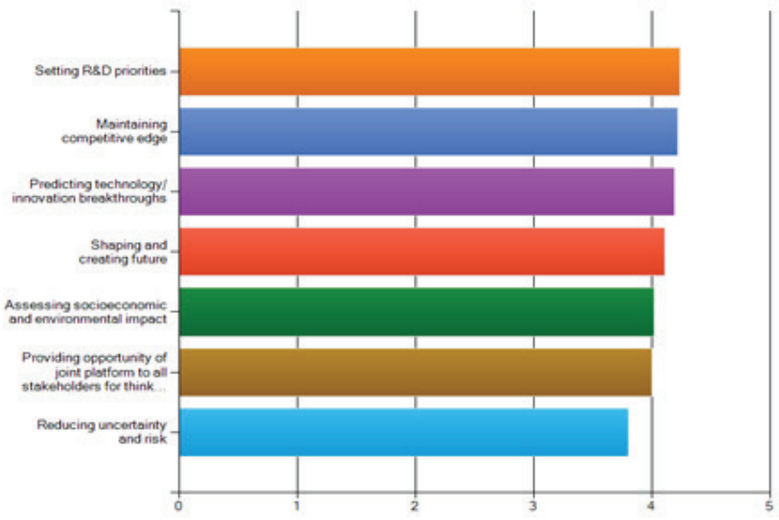
The sub-sectors in manufacturing firms such as Agribiotech, Biopharmaceuticals and Industrial Biotech have conducted a maximum number of foresight exercises. However, other sectors including bioinformatics and environmental biotech also engage in foresight activities.

Ninety per cent (65 companies) of the companies surveyed from the biotechnology manufacturing sector are domestic in nature, while the MNCs constitute only 10 per cent (7 companies) of these companies. Most of the manufacturing firms use some of the preliminary methods, such as Brainstorming, Risk Analysis, Literature Review, SWOT Analysis and Expert Panel, rather than more sophisticated formal methods. Figure 3 reveals reported usefulness on a five-point scale with weighted average. The usefulness of the foresight appears to be quite diverse, ranging from maintaining a competitive edge, predicting technologies, setting R&D priorities and shaping futures (Fig. 4). On the other hand, issues like profit maximization, marketing, cost reduction and enhancing the functional capability of the products appears to be the foremost expected output from the foresight exercise (Fig. 5).



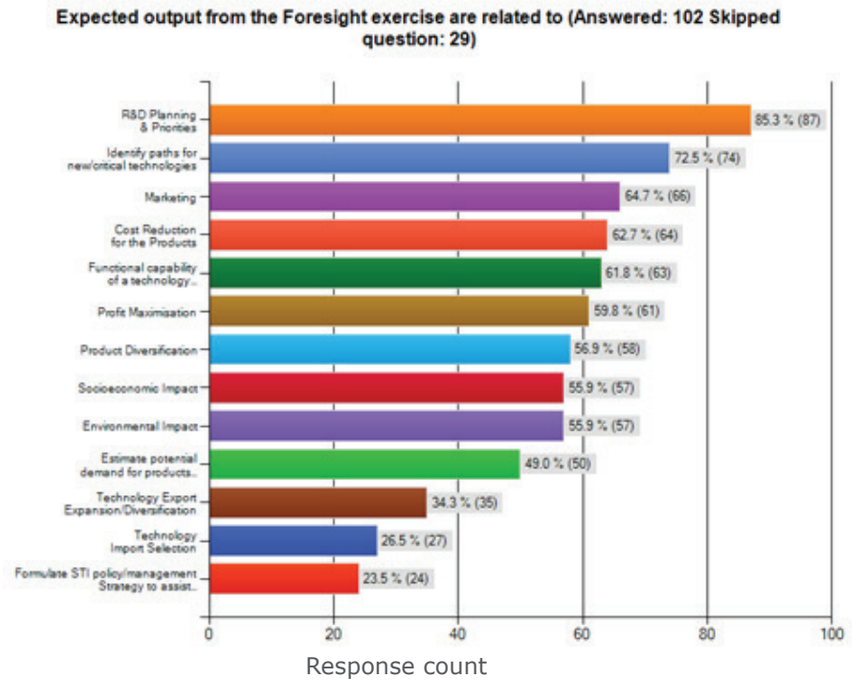
Source: Compiled from the results of the primary survey

Figure 3. *Tools/methods for technology foresight (Answered questions: 102 Skipped questions: 31)*



Source: Compiled from the results of the primary survey

Figure 4. *Usefulness of technology foresight exercise (Answered questions: 117 Skipped questions: 16)*



Source: Compiled from the results of the primary survey

Figure 5. *Expected output from foresight exercise*

Most of the biotechnology firms collaborate for technology and R&D and the main output for conducting foresight exercises is setting the R&D planning and priorities. Regulation of biotechnology in India is more inclined towards health, genetic engineering and environmental issues. Convergence is seen amongst the different stages of regulation at 'release of biotechnology product/services, monitoring, evaluation, testing' stages, and is highly regulated.

Safety and efficacy are the most decisive criteria of regulation for all the regulatory agencies. Health and environmental concerns are also essential criteria. They also follow safety, efficacy and health concerns as significant regulatory criteria for biotech exports and imports. All the regulatory agencies in biotechnology consider technology foresight as a necessary step for the regulatory process of biotechnology. However, most of them do not conduct foresight exercises. They are using preliminary methods and are still in the process of exploring the formal methods of technology foresight. Most of the regulatory bodies conduct foresight annually and on a short-term basis.

The majority of the regulatory bodies perceive technology foresight as an instrument of shaping the regulation of biotechnology in India by 'assessing public perception and acceptance of biotech products and services'. Amongst venture capital firms, only 17 per cent of the firms conduct foresight exercises and all belong to the private sector; while preferring national-level foresight and sub-sectors like pharmaceutical biotech (83 %), industrial biotech (67 %) and agriculture biotech (42 %) also attract their attention. VC firms use both their own research and also the market report prepared by an outside agency before funding any biotechnology or any other new project. These firms also use syndication as a tool to cross-check their investment plans.

Concluding observations

Out of the 133 responses received, 67 per cent reported some kind of foresight activity. Most of the firms belonged to the private sector, while the preference was absolutely visible for national-level foresight compared to regional or international levels. Sub-sectors such as pharmaceutical biotech (83.3 %) pay more attention to foresight compared to industrial biotech (66.7 %) and agriculture biotech (41.7 %). Brainstorming, Risk Analysis, Literature Review, SWOT Analysis and Expert Panel, were chosen as the important methods of foresight rather than more sophisticated formal methods such as Scenario Planning, Growth Curves and Analytical Models. Issues like profit maximization, marketing, cost reduction and enhancing the functional capability of the products appear to be the major expected output from the foresight exercise. On the other hand, the utility of the foresight appears to be quite diverse, ranging from maintaining a competitive edge to predicting technologies, setting R&D priorities and shaping futures. VC Firms use both their own research and the market report prepared by an outside agency before funding any biotechnology or any other new project. VC firms also use syndication as a tool to cross-check their investment plans.

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