Asian biotechnology information and development initiative for biotechnology assessment and policy relevant indicators

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In the recent past several public agencies along with private sector firms have entered into the biotechnology sector. India and several other developing countries in Asia are passing through a phase in which there is a sharp rise in the budgetary allocations and investments in the biotechnology industry. The wide-ranging applications of biotechnology in the spheres of pharmaceuticals, industrial services and agriculture have raised expectations in almost all the developing countries, primarily for addressing certain key development issues like food security and health care. Indian public agencies have also shown great interest in the new technology. In the Eleventh Five-Year Plan, allocation is likely to be doubled with the launching of the Life Science and Biotechnology Commission. The estimation as mentioned in the Strategy Plan of the Department of Biotechnology (DBT), Govt of India is that by 2010 the Indian biotech market turnover would be around US $10 billion.

However, there have been no systematic efforts to put together quantitative details of these advancements for in-depth impact assessment. As a result, different statistics and claims are going around – NGOs projecting a doomsday, and a rosy world for the industry and its proponents. Classification of biotechnology commodities for data collection purposes becomes difficult. This may be largely because industrial production of some of these commodities is a recent phenomenon. Another reason probably is that efforts are yet to be made to conceptually separate them for accounting purposes. As a result, these goods get added in the broad categories for different products. For instance, biofertilizers have not been included in the Indian Trade Classification (ITC) system based on the harmonized system and they are for the purpose of customs duties and other purposes considered under the code 3101.00 along with various chemical fertilizers. Similarly, biopesticides have also not been classified in the ITC harmonized system and are considered along with chemical pesticides under the code 38.08, and the rates of customs duty are identical for both. However, according to the statement on Industrial Policy 1991, bio-insecticides as well as nitrogen fixers (biofertilizers) have been included under Item No. 27 of the list of industries for automatic approval of Foreign Technology Agreement as a special class. Considering the biological nature, both these could be well classified under Chapters 6, 12 or 14. In fact, a special class with titles such as biopesticide and biofertilizers should have been specifically mentioned and classified.

As a result, estimation of the market size for biotechnology products also varies a great deal (Table 1). It seems there might be many other considerations behind these projections. Similarly, problems are being confronted in data management for patent-related details. Technology Information Forecasting and Assessment Council (TIFAC), which manages the database for patents, has yet to separately classify biotechnology patents. Quantification of various initiatives, at an internationally comparable level, could have provided precise estimation of complementarities that exist especially among developing countries for cooperation and also for supplementing national efforts for optimum utilization of available resources. Similarly, there are several issues that deserve the attention of policy makers and researchers for understanding the S&T policy and its impact on society at large.

It is against this background that the Asian Biotechnology Innovation and Development Initiative (ABIDI) was launched during a day-long workshop organized in New Delhi by a Delhi-based 'think-tank', Research and Information System for Developing Countries (RIS), in collaboration with DBT. In this meeting more than 12 representatives from different Asian countries participated. The idea was to bring together the policy community, academics and interested institutions for facilitating greater understanding on policy aspects related to innovation and development of biotechnology. The issues related to ABIDI that were discussed in this meeting included the nature of agencies to be encouraged for collection of biotechnology statistics at the national level and how best methods of collection, authentication and curing of data across countries should be identified.

Definition of biotechnology

In this context, the efforts at the Working Party of National Experts on Science and Technology Indicators (NESTI) of Organisation for Economic Cooperation and Development (OECD), a think-tank of developed countries, assume major importance. (Some non-member countries like India and Israel have also been involved recently.) In its various meetings, NESTI decided to initiate a data collection exercise after finalizing a definition of biotechnology for statistical purposes. An inventory of policy issues and related indicators was prepared. The OECD came out with guidelines for the compilation

Table 1. Differing perspectives on biotechnology in India (2001)

	CII	DBT	*The Economist*[1]
Biotech market	US $ 2.5 billion[2]	US $ 1849 million	US $ 1475 million
Agri/seed market	US $ 500 million[3]	–	US $ 450 million
Bioinformatics market	US $ 2.2 million[4]	–	–
Diagnostic/vaccine market	US $ 420 million	US $ 150 million	US $ 375 million

Source: RIS based on [1]*Economist*, 1 September 2001; [2]*Financial Express*, 10 October 2001; [3]*Business Standard*, 24 December 2000; [4]*Business Line*, 9 July 2001.

of these indicators along with model questionnaires and surveys. The work at this group was also linked with other existing manuals for S&T policy like *Oslo Manual* and *Frescati Manual*. Several of the OECD member countries launched the data-collection exercise. The first report was published in 2006. To maximize comparability of both public and business sector biotechnology statistics, a definition of biotechnology was developed by OECD with the help of an expert group. There are two definitions that the OECD came out with. These were updated after field-based experience in some countries.

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

Although a single definition defines the purpose of biotechnology, a list-based definition is also developed identifying modern biotechnology. In the biotechnology statistics 2006 report of OECD, data for a few countries that used a different definition of biotechnology are included, only if the definition was limited to 'modern' biotechnology. The second list-based definition of biotechnology has the following contents:

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

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

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

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

Gene and RNA vectors: Gene therapy, viral vectors.

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

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

There are several OECD member-countries which have launched this exercise of data collection on the basis of the OECD definition. Canada is one of the major economies following the OECD definition of biotechnology. The Canadian agency, Statistics Canada, is currently running its fourth dedicated survey on biotechnology covering almost 12,000 firms, a revenue of $ 250,000 (Canadian $) and using 22 different categories of biotechnology, according to list-based definition of biotechnology prepared by the OECD. Canada has come out with an exhaustive model survey with almost 30 questions spread over several pages[1]. In France, two surveys have already been conducted for the years 1999 and 2000, while the third survey[2] is all set to be launched in the middle of 2002. This survey will cover 1500 firms engaged in biotechnology. Plans are also being worked out to incorporate results of these surveys in the annual R&D survey of France. There are two major government departments in France, viz. the Bioengineering Department and the Bureau of R&D Statistics, which together have been conducting the biotechnology surveys since 2001. Prior to this, the Bioengineering Department was managing its own database of firms entering incubators, awarded by the annual national contest by the firms' creation and voluntary registrations in the national database, while the Bureau of R&D Statistics relies on its own surveys. The first in the series was launched in 2000.

In the United States, the National Science Foundation of the Department of Commerce has launched a limited data-collection exercise of biotechnology statistics[3]. Since 2001, data about biotechnology were being collected as part of the Survey of Industrial Research and Development, as was being done for other technologies like information technology and materials synthesis. However, realizing the importance of biotechnology in the economic growth, it has been decided to make the Bureau of Industry and Security as the lead agency to collect statistics on biotechnology from 2002 onwards. In order to facilitate this exercise, an inter-agency working group has been constituted. This survey would be mandatory in nature.

Similarly, Japan and Australia have also conducted their first limited surveys in 2000 and 2001 respectively. Australia has developed the Australian FoS classifications that are relevant to biotechnology[4]. Australia will shortly include FoS in their next R&D survey. Results are expected in 12 months time. Australia will also report results of this survey back to the ad hoc group, which will guide the group as to final levels of FoS in the future.

Policy indicators

OECD is facilitating the evolution of a common approach towards biotechnology data collection, so that international comparison becomes easier. At this point, there are significant differences in terms of approach towards data collection, definition of biotechnology and variables being covered among different OECD member countries[5]. However, the central issue concerns financial cost, lack of expertise and regulations and finally, market uncertainty. Canada and New Zealand distinguish four major areas for biotechnology processes, namely DNA-based processes; Biochemistry and immunochemistry; Bioprocessing and Environment. The French survey does not distinguish major categories. Within these major categories, several sub-groupings are distinguished. These are fairly similar for Canada and New Zealand, and differ somewhat with those identified in France. Similarly, these country surveys approach the question of barriers in adoption of biotechnology in different ways. The Canadian survey requests information on barriers to biotechnology use, whereas the New Zealand survey requests information on barriers to R&D in biotechnology, while the French survey does not ask for barriers. It is expected that the statistics would provide clarity about the governance of biotechnology.

In case of developing countries, particularly in Asia, such efforts are important so as to outline a statistical framework that allows the measurement of industrial and developmental activities, so that policy makers may evolve adequate responses. During the launching meeting of ABIDI, it was realized that Asian countries should evolve an analytical framework for policy-makers in the area of biotechnology, which is relevant to the region's requirements. The

idea is to collect policy relevant statistics for analysing trends in investment, public allocations, availability of manpower and activities of private sector. Since in a globalized world innovation is influenced by several interdependent regional systems, it would be useful to launch this initiative at the Asian level. This should be done in the context of overall socio-economic requirements in the region. The presentations of this meeting are available at www.ris.org.in.

1. Rose Anthony, Paper submitted at the Working Party of National Experts on Science and Technology Indicators, Finland, 13–15 May 2002.
2. Francoz, D., Paper submitted at the Working Party of National Experts on Science and Technology Indicators, Finland, 13–15 May 2002.
3. Beuzekom, Brigitte van, Paper submitted at the Working Party of National Experts on Science and Technology Indicators, Finland, 13–15 May 2002.
4. Byars, D., Paper submitted at the Working Party of National Experts on Science and Technology Indicators, Finland, 13–15 May 2002.
5. Pilat, D., Paper submitted at the Working Party of National Experts on Science and Technology Indicators, Finland, 13–15 May 2002.

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OPINION

Need for a comprehensive re-assessment of the conservation status of critically endangered (?) freshwater fishes of Kerala

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As an exceptional hotspot of freshwater biodiversity[1], showing high degree of endemism[2], the streams and rivers of Kerala (8°17′30″–12°27′40″N, 74°51′57″–77°24′47″E) have been receiving global attention. The diversity and distribution of freshwater fishes in Kerala have been documented in detail[2–7]. A comprehensive review on the distribution, endemism and threat status of the 175 freshwater fishes from the fourty-four rivers of Kerala was presented at an international large rivers conference[6]. A recent document on the fish diversity of the streams and rivers of Kerala[7] has accounted for 18 critically endangered species (Table 1).

The 'critically endangered' (CR) species of the region have been categorized on the basis of their (i) restricted distribution to a single location and a single river system, (ii) a range distribution of less than 100 sq. km and (iii) an 80% population reduction during the past decade, based on the classification originally proposed by IUCN[8]. Although population is one of the criteria on which various species have been listed as CR, an extensive literature search revealed lack of scientific data pertaining to aspects of population dynamics and/or wild stock analysis, including information on 'population reduction' or 'population estimates' of any of these species. This therefore suggests that restricted distribution of the species may be the single most important criterion on which these species have been given a CR status. Even if we are led to believe that 'restricted distribution' and 'a limited range of occurrence' are the major factors that have been taken into account to categorize the different species as CR, there still exists a case for much debate and discussion.

The detailed account on the biodiversity status of the freshwater fishes of Kerala[6] reports that among the 18 critically endangered species, seven are confined to only a single locality, while five are found in two locations in the same river, thus supporting the reasoning that restricted distribution of the species is probably the most important criterion, on which the species have been listed as critically endangered. However, our analyses, based on results from detailed literature searches reveal that existing data on several species listed as CR make them unfit to be listed under this threat category. Most species listed as CR are now distributed widely across several river systems located several hundreds or in some cases thousands of miles apart. Here are some examples.

(i) Waynad mahseer, *Barbodes wynaadensis*[9] (Day, 1871) has been listed as CR in view of its restricted distribution to the Kabini river, Wayanad district (11°27′–15°58′N and 75°47′–70°27′E), Kerala[6,7]. However, field surveys have recorded this species from Abby Falls, Madikeri town, Coorg district (14°30′–15°50′N and 75°40′–77°11′E), thereby extending its range distribution to the neighbouring state of Karnataka[10].

(ii) Malabar catfish, *Pterocryptis wynaadensis*[11] (Day, 1873) also deserves mention here, in the way it has been listed as a CR and endemic fish of Kerala. Even the most recent paper[7] mentions that this catfish is known only from the Kattivattom area of Kabini river, Wayanad district, Kerala and draws the attention of global scientists due to its endemism to this locality. However, this species has been recorded from neighbouring Tamil Nadu[12] (13.09°N, 80.27°E) and also from regions as far as Maharashtra[12] (18.96°N, 72.82°E), and a number of collections of this catfish have been made from its new geographical areas. Researchers[13] who studied the life history traits of *P. wynaadensis*, had also suggested that the fish no longer merits a CR category.

(iii) *Dayella malabarica* (Day, 1873) listed as CR[6,7] has been collected from as many as 25 river systems of Kerala[14]. It is highly surprising that a fish species,