Report of the Working Group for the Eleventh Five Year Plan (2007-2012)

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Department of Biotechnology
Ministry of Science & Technology
Government of India

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3.13 Expansion and Remodeling of Existing Autonomous Institutions

PREFACE

The Department of Biotechnology established in 1986, has completed two decades of existence. Human resource development, establishment of biotechnology facilities and capacity building for R&D in priority areas has been given thrust. The Economic liberalization in 1991 provided much needed impetus for FDI flows, foreign collaborations, incentives and tax exemptions for industrial growth and the department had facilitated these developments for biotech industrial growth. During the last five years, Biotechnology industry in India has been growing at an average annual rate of 40 % and its turnover during 2005-06 exceeded US$ 1.5 billion. Biotechnology business segment has the potential of generating revenues to the tune of US$ 10 Billion and creating one million jobs by 2010 through bio-products and services. Indian Biotech sector is acquiring global visibility and is being seen as a major investment opportunity. These resources need to be effectively marshaled, championed and synergized to create a productive enterprise. For this purpose, at mid term of 10th plan, the department had embarked on preparing a "National Biotechnology Development Strategy". The document in its final form was a result of marathon two year long nation wide consultations and comments from all stakeholders including students, experts, scientists, industry and other ministries and departments.

Coinciding with preparation of final version of above strategy document, the Working Group Under the Steering Committee on S&T has been constituted the 10th Plan objectives versus achievements and to make suitable recommendations for the 11th plan approach in policy and programmes of the department. Several subject specific sub groups were constituted by the Working Group to have a detailed assessment and suggestions. The Working Group met twice and made several recommendations keeping in view of the directives of the Steering committee on S&T of Planning Commission as well as observations of the various sub sectoral groups. The Working Group appreciated the efforts of the department in preparing a

National Biotechnology Development strategy and recommended suitable integration of the same in the final report of the group on the 11th plan activities.

The overall strategy embodied in this report is based on constraints and lesson learnt in 10th plan as well as potential for biotechnology development and bioindustrial growth in the country. For India to be a sustainable knowledge economy in the life science sector, there are many real challenges ahead. Fewer students are developing interest in science education including in life sciences and biotechnology. An ecosystem for innovation is still underdeveloped; while we continue to do well through reverse engineering, discovery and innovation in the life science and biotechnology sector is low. There is an increasingly widening gap in research productivity as compared with other emerging and competing economies that are investing substantially more in the life science sector and are providing a more enabling environment. Finally, the translation of science knowledge and technology into implementable solutions for societal problems is currently inefficient and has low impact.

The main strategy for 11th plan is to create such tools and technologies that address the problems of the largest section of the society, provide products and services at affordable prices and make India globally competitive in the emerging bio-economy. Developing a strong biotechnology industry and technology diffusion capacity is critical to fulfill this vision. The advancement of biotech as a successful industry confronts many challenges related to research and development, creation of investment capital, technology transfer and technology absorption, patentability and intellectual property, affordability in pricing, regulatory issues and public confidence and tailor made human resource related to all these aspects. Central to societal impact are two key factors: affordability and accessibility to the products of biotechnology. Policies that foster a balance between sustaining innovation and facilitating technology diffusion need to be put in place.

Thus, the report takes stock of what has been accomplished so far and provides a framework for the future within which strategies and specific actions to promote biotechnology can be taken. It focuses on cross-cutting issues such as human

resource development, smarter re-entry for our scientists abroad, new and varied models of creating innovation-friendly micro-environment, R&D in small and medium size companies, newer ways of collaborating with large companies, establishing centre of excellence, remodeling life science departments in universities/institutions, establishment of technology management centres, promoting dynamic biotech regional clusters, interdisciplinary networks, academic and industry interface, infrastructure development, lab and manufacturing, promotion of industry and trade, expansion of autonomous institutions and establishment new institutions, biotechnology parks and incubators, regulatory mechanisms, public communication and participation. This report also aims to chalk out the path of progress in sectors such as agriculture and food biotechnology, industrial biotechnology, medical biotechnology, bio-engineering, nano-biotechnology, bio-informatics and IT enabled biotechnology, bio-resources, environment, intellectual property & patent law, international cooperation and, of course, in meeting the basic needs of the society. The time for investment in biotechnology is now. A wait and watch approach may result in missed opportunities. It is envisaged that clearly thought-out strategies will provide direction and enable action by various stakeholders to achieve the full potential of this exciting field for the social and economic well being of the nation.

(M.K.Bhan)
Secretary, DBT &
Chairman, Working Group

Vision and Challenge

Biotechnology is a set of rapidly emerging and far reaching new technologies with great promise in areas of sustainable food production, nutrition security, health care and environmental sustainability. Our vision is to use powerful tools of biotechnology to help convert the country's diverse biological resources to useful products and processes that are accessible to its masses for economic development and employment generation.

The Indian Biotech sector is acquiring global visibility and is being seen as a major investment opportunity. For India to be a sustainable knowledge economy in the life science sector, there are many real challenges ahead. Fewer students are developing interest in science education including in life sciences and biotechnology. An ecosystem for innovation is still underdeveloped; while we continue to do well through reverse engineering, discovery and innovation in the life science and biotechnology sector is low. There is an increasingly widening gap in research productivity as compared with other emerging and competing economies that are investing substantially more in the life science sector and are providing a more enabling environment. Finally, the translation of science knowledge and technology into implementable solutions for societal problems is currently inefficient and has low impact.

The success of this strategy over the next decade will be reflected through (i) greater enrolment of students in life sciences; (ii) increase in the number of persons with higher levels of education and skill in life sciences and biotechnology; (iii) greater contribution of research to economic and social development (iv) increased contribution of university system to basic life science as well as translational biotechnology research (v) strong international partnerships linked to national goals. (vi) increased number of new companies and increase in SME's engaged in R&D, and finally, (vii) the Indian biotech industry generating revenue to the tune of at least US $ 10 billion annually and creating substantially more jobs by 2010.

INTRODUCTION

Biotechnology, a collection of techniques and processes that employ organisms or their units to develop useful products and services, has the potential to become a powerful tool in meeting the challenges posed by food insecurity, industrial underdevelopment, disease and environmental degradation.

Biotechnology is globally recognized as a rapidly emerging, complex and far reaching new technology. Biotechnology can, over the next two decades, deliver the next wave of technological change that can be as radical and pervasive as that brought about by IT. The recent and continuing advances in life sciences clearly unfold a scenario energised and driven by the new tools of biotechnology. The convergence of advances in biology – genomics, proteomics, bioinformatics and information technologies is driving the emergence of a new bioeconomy.

Evidence of the shape of things to come is already emerging. There are a large number of therapeutic biotech drugs and vaccines that are currently being marketed, accounting for a US$ 40 billion market and benefiting over a hundred million people worldwide. Hundreds more are in clinical development. In addition to these, there are a large number of agri-biotech and industrial biotech products that have enormously helped people. The global biotech industry recorded a turnover of US$ 64 billion during 2003. Employment generation, intellectual wealth creation, expanding entrepreneurial opportunities, augmenting industrial growth are a few of the compelling factors that warrant a focused approach for this sector.

Biotechnology is Important to India

Biotechnology industry in India has been growing at an average annual rate of 40 %during the last five years and its turnover during 2004-05 exceeded US$ 1 billion. Biotechnology as a business segment for India has the potential of generating revenues to the tune of US$ 10 Billion and creating one million jobs by 2010 through products and services. This can propel India into a significant position in the global biotech sweepstakes. Biopharmaceuticals alone have the potential to be a US$ 2 billion market opportunity largely driven by vaccines and bio-generics. Clinical development services can generate in excess of US$1.5 billion whilst bioservices or outsourced research services can garner a market of US$1 billion over this time scale. The balance US$500 million is attributable to agricultural and industrial biotechnology.

India has many assets in its strong pool of scientists and engineers, vast institutional network, and cost effective manufacturing. There are over a hundred national research laboratories employing thousands of scientists. There are more than 300 college level educational and training institutes across the country offering degrees and diplomas in biotechnology, bio-informatics and the biological sciences, producing nearly 500,000 students on an annual basis. More than 100 medical colleges add ~17,000 medical practitioners per year. About 300,000 postgraduates and 1500 PhDs qualify in biosciences and engineering each year. These resources need to be effectively marshaled, championed and synergized to create a productive enterprise.

India is reorganized as a mega bio-diversity country and biotechnology offers opportunities to convert our biological resources into economic wealth and employment opportunities. Innovative products and services that draw on renewable resources bring greater efficiency into industrial processes, check environmental degradation and deliver a more bio-based economy.

Indian agriculture faces the formidable challenge of having to produce more farm commodities for our growing human and livestock population from diminishing per capita arable land and water resources. Biotechnology has the potential to overcome this challenge, to ensure the livelihood security of 110 million farming families in our country.

Vision & Mission

Our vision is to create such tools and technologies that address the problems of the largest section of the society, provide products and services at affordable prices and make India globally competitive in the emerging bio-economy. Developing a strong biotechnology industry and technology diffusion capacity is critical to fulfill this vision. The advancement of biotech as a successful industry confronts many challenges related to research and development, creation of investment capital, technology transfer and technology absorption, patentability and intellectual property, affordability in pricing, regulatory issues and public confidence and tailor made human resource related to all these

aspects. Central to societal impact are two key factors: affordability and accessibility to the products of biotechnology. Policies that foster a balance between sustaining innovation and facilitating technology diffusion need to be put in place.

Several social concerns such as conserving bioresources and ensuring safety of products and processes need to be addressed. Government and industry have to play a dual role to advance the benefits of modern biotechnology, and educate and protect the interests of the public. Wide utilization of new technologies would require clear demonstration of the added value, to all stakeholders.

The efforts in the last two decades have directed notable interventions in the public and private sectors to foster life sciences and biotechnology. There has been substantial progress in terms of support for R&D, human resource generation and infrastructure development. With the introduction of the product patent regime it is imperative to achieve higher levels of innovation in order to be globally competitive. The challenge now is to join the global biotech league.

This will require larger investments and an effective functioning of the innovation pathways. Capturing new opportunities and the potential economic, environmental, health and social benefits will challenge government policy, public awareness as well as the educational, scientific, technological, legal and institutional framework. In all these areas, we aim to introduce global best practices and the highest ethical standards.

The issue of access to products arising from biotechnology research in both medicine and agriculture is of paramount importance. Therefore, there should be adequate support for public good research designed to reach the unreached in terms of technology empowerment. Both “public good” and “for profit” research should become mutually reinforcing. Public institutions and industry both have an important role in the process.

The Indian biotechnology sector has, over the last two decades, taken shape through a number of scattered and sporadic academic and industrial initiatives. The time is now ripe to integrate these efforts through a pragmatic National Biotechnology Development Strategy.

The National Biotechnology Development Strategy takes stock of what has been accomplished and provides a framework for the future within which strategies and specific actions to promote biotechnology can be taken. The policy framework is a result of wide consultation with stakeholders – scientists, educationists, regulators, representatives of society and others and reflects their consensus. It focuses on cross-cutting issues such as human resource development, academic and industry interface, infrastructure development, lab and manufacturing, promotion of industry and trade, biotechnology parks and incubators, regulatory mechanisms, public communication and participation. This policy also aims to chalk out the path of progress in sectors such as agriculture and food biotechnology, industrial biotechnology, medical biotechnology, bio-engineering, nano-biotechnology, bio-informatics and IT enabled biotechnology, bio-resources, environment, intellectual property & patent law, international cooperation and, of course, in meeting the basic needs of the society.

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interface, infrastructure development, lab and manufacturing, promotion of industry and trade, biotechnology parks and incubators, regulatory mechanisms, public communication and participation. This policy also aims to chalk out the path of progress in sectors such as agriculture and food biotechnology, industrial biotechnology, medical biotechnology, bio-engineering, nano-biotechnology, bio-informatics and IT enabled biotechnology, bio-resources, environment, intellectual property & patent law, international cooperation and, of course, in meeting the basic needs of the society.

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1. EXECUTIVE SUMMARY

The Working Group under the steering committee on S&T constituted by the Planning Commission have reviewed and assessed the 10th plan activities & achievements of the Department of Biotechnology and recommended the approach and activities for 11th Plan **(Annexure-I)**. The group also examined in detail the National Biotech Strategy prepared by the department as a result of two year long consultations and comments from several stakeholders. The final recommendations of the working group therefore not only integrate appropriately the salient features of the strategy document but also the valuable inputs of its sub-committees, major directives given by the Steering Group on Science and Technology for the formulation of the 11th plan (2007-2012) and that of DBT Scientific Advisory Committee (Overseas).

Review and Assessment of 10th plan

The 10th plan had objectives of enhancing the knowledge base and generating highly skilled human resource; nurturing research leads of potential utility through adequate facilities and infrastructure; and bringing bio-products to the marketplace through innovative policies and partnerships. Accordingly, the department focused on post graduate education, introduction of fellowships schemes for Post doctoral and PhD for junior research fellows and awards; establishment of a Board for bioresource conservation and utilization, basic research R&D projects in sectoral areas; with special thrust in emerging areas of stem cell biology, nanotechnology, new generation vaccines and RNAi technology; capacity participation in international genome sequencing consortia of rice, silkworm, and tomato; and introduction of public private-partnership schemes such as Small Business Innovative Research Initiative(SBIRI) and Biotechnology Parks in collaboration with State Governments; patent facilitation, streamlining of regulations, besides strengthening linkages with other S&T agencies/industries.

A detailed assessment of the first four years of the plan (2002-2006) has been undertaken for measuring the indicators of performance. About 1225 projects have been implemented under various schemes costing about Rs.1161.57 crores. Among

the areas 39% (481) of the projects were in the area of agriculture and allied areas followed by 20% in medical biotechnology covering vaccines, diagnostics, human genetics and programmes relevant to society (12%). Basic research and industrial biotechnology received equal thrust of 10% each. Bioresources and bioprospecting as well as capacity building programmes (biotech facilities and human resource development) recorded 5% and 4% share respectively.

The assessment on a reasonable sample of 43% (519) of projects funded at the cost of Rs.222.26 crores involving 254 scientists revealed 979 publications, 234 technologies developed, 94 technologies transferred with 24 products in pipeline for marketing and 17 projects commercialized. Out of 158 patents filed 52 were granted. The funding has been very productive in the sense that cost versus total pooled output is about 1:7 and productivity per scientist funded versus total pooled output is about 1:6 which is very spectacular.

Constraints and lessons learnt from the programmes of 10th plan have also formed the basis for 11th plan recommendations. In general, the scale of operation required; lack of networks/institutional mechanisms of translation and innovation; inadequate mechanisms of monitoring and management of projects; weak linkages with industries; limited and authentic statistical information on biotechnology in India; and framework of public-private partnerships have been noted.

Therefore, to promote innovation several steps have been suggested and approach for 11th plan formulated as given below:

Approach to 11th Plan

The approach towards the 11th plan should be to create such tools and technologies that address the problems of the largest section of the society, provide products and services at affordable prices and make India globally competitive in the emerging bio-economy. Developing a strong biotechnology industry and technology diffusion capacity is critical to fulfill this vision. The success of this vision over the next decade will be reflected through (i) greater enrolment of students in life sciences; (ii) increase

in the number of persons with higher levels of education and skill in life sciences and biotechnology; (iii) greater contribution of research to economic and social development (iv) increased contribution of university system to basic life science as well as translational biotechnology research (v) strong international partnerships linked to national goals. (vi) increased number of new companies and increase in SME's engaged in R&D, and finally, (vii) the Indian biotech industry generating revenue to the tune of at least US $ 10 billion annually and creating substantially more jobs by 2010.

Recommendations for the 11th Plan:

Promotion of innovation*:*

The main components of an innovation system would be availability of required numbers of world class scientists and professionals relevant to R&D; a well trained, skilled work force for industry; adequate infrastructure and providing a fiscal, regulatory and legal framework that encourages risk taking by investors. Following policy interventions and schemes has been suggested:

Establishment of Technology Management – National and Local Centres **:** A technology management network that is locally linked to stronger central resources is an essential and currently, the missing link.

Centres of Excellence**:** Expansion to establish more centres of excellence (CoEs) within existing universities and medical, agriculture and allied colleges, around innovative leaders. A Centre of Excellence may be focused on basic biology emphasizing new opportunities and emerging fields; centers for science, engineering and technology and translation centers directed towards innovation in scale-up and manufacturing processes for biopharma, and bio-based industrial products in health, animal, agriculture, food and environment sectors. Special features would include availability of a world class leader, special rules for ensuring minimal bureaucratization, effective scientific oversight and benchmarks for assessing performance. At each of the CoEs space will be available for small and medium private companies to work in close collaboration with the public institution. It is

necessary to create a central pool of high caliber scientists which can be effectively deployed in to meet the requirement of the CoEs through innovative and competitive modalities of recruitment.

Creating Regional Biotech Innovation Clusters**:** Development of regional innovation clusters has been a critical factor in the success of countries that have achieved the highest level of innovativeness and discovery potential beyond their apparent strengths. The Biotech Cluster concept should be promoted. Existing clusters may be examined for gaps which can then be strengthened. Based on an analysis of opportunities and feasibility, new clusters could be considered - potential new sites are Punjab, Delhi, Haryana, West Bengal, Gujarat and Orissa.

Upgradation / reengineering of existing life science departments: World class quality, life science departments doing both education and research will be created through upgradation of existing promising but small departments by supporting infrastructure and faculty, and creating new research agenda. These will focus on some critical areas, which these departments are currently lacking altogether or are of poor quality. The focus will be on university departments and medical colleges.

Human Resource Development

The policy goal is to ensure a steady flow of young scientists and technologists in life science sector. Interest in science must be stimulated at an early stage and throughout the educational process.

- ✓ National Council on Biotechnology Education & Training: A National Biotechnology Council will be created to formulate model undergraduate and postgraduate curricula in life sciences and in translational science keeping in view, future needs.
- ✓ Creation of leaders in Biotechnology**:** Emphasis is required to be given to interdisciplinary education and training and creation of leaders in biotechnology through substantial expansion of Ph.D and Post Doctoral Fellowship programmes.
- ✓ Quality Teachers**:** At the master's level, emphasis will be on improving the quality of teachers through establishment of a Biotechnology staff college and regional training centres for mid career training programmes.

- ✓ Improve infrastructure in colleges and creating at least one or two 'Star' colleges in each state.
- ✓ At the secondary level to improve the interest in life sciences and biotechnology, it is suggested to (i) increase availability of scholarships on merit cum means basis (ii) summer schools to give exposure to experimentation and (iii) teachers training programs.

Industry promotion

The key mechanisms shall be ensuring participation of SME's while developing technology strategies nationally, increased public contribution for early stage, high risk research for SME's, increase access of SME scientists to public institute facilities and vice–versa, new models of partnership with large industry to pursue path breaking technology initiatives and building greater flexibility in public institutes to be able to work with industry. Specific initiatives are.

- Small Business Innovation Research Initiative (SBIRI): Major expansion of the SBIRI scheme widely acclaimed in the country by SME's. A Special Purpose Vehicle (SPV) may be created for managing this scheme professionally.
- Biotechnology Industry Research Assistance Programme (BIRAP) may be put in place for monitoring, supporting and nurturing R&D in small and medium biotechnology companies.
- Enabling Public Institutions to work with Industry: Public funded successful R&D institutes may be allowed and supported to establish not for profit companies to facilitate collaborative work with industry. In these facilities, industry scientists can pursue innovative projects for defined periods on user charge basis providing access to centralized equipments and scientific consultation.
- Public Partnership with Large Industries**:** Public partnership with large scale companies may be encouraged and supported in areas that are vital to the national development from a scientific, economic or social perspective and focused on technology and product development. The company would then have preferential access to the intellectual property generated in such jointly funded projects.

Infrastructure, Major Equipment and Facilities

Cutting edge research in biotechnology requires creation of state of the art infrastructure. Creation of large animal house facilities with GMP for testing candidate vaccines and biotherapeutics, DNA and stem cell banking facilities, depositories of biological materials, testing facilities for GMO/ LMO and validated laboratory facilities to support major clinical trials may be taken up.

Strengthening bioinformatics R&D and infrastructure in terms of more super computing facilities, expansion of biogrid, human resource development, linkages with industry, institutional mechanisms for software development and validation, development of an Indian portal site and bioinformatics parks and clusters through public private partnerships.

Biotech Parks and Incubators

Biotechnology parks provide a viable mechanism for promoting upcoming biotech companies to start new ventures and achieve early stage value enhancement of technology. Promote establishment of Biotech parks and incubators as a part of biotech clusters, essentially through public private partnerships to be supported. Establishment of incubators by consortia of small and medium enterprises shall be encouraged and supported.

World class Regulatory Mechanism

A scientific, rigorous, efficient, predictable and consistent regulatory regime for biosafety evaluation and release of protocols is essential. A National Biotechnology Regulatory Authority is proposed to be created to provide effective single window clearance mechanism for all biotechnology products.

Social sector priorities

Adequate support should be ensured for “public good” research designed to reach the unreached in terms of technology empowerment. Both “public good” and “for profit” research should become mutually re-enforcing. Public institutions and industry all have an important role in the process.

Mission mode programmes

Interdisciplinary mission mode projects are suggested in the areas of national importance where biotechnology interventions can bring about significant value addition, cost effectiveness and competitiveness in product and process diversity. Mission mode projects could be of three types such as knowledge creation (research and development), knowledge diffusion (education and training), and knowledge application (product development, validation, and commercialization). They should be implemented through special management, administrative and organization streamlined for time bound results. The areas are:

- ✓ Food and nutrition security
- ✓ Molecular breeding of agricultural crops
- ✓ Molecular breeding of silk worm
- ✓ Microbial prospecting for industrial, agricultural, environmental, medical and therapeutic purposes.
- ✓ New generation vaccines and delivery systems
- ✓ Diagnostics for health care
- ✓ Integrated Tuberculosis
- ✓ Stem cell biology regenerative medicine
- ✓ Bioengineering

International collaboration

Biotechnology is a global enterprise and strong international partnerships both at public institution and private enterprise front are essential. International collaborations and networks should be harmonized with National S&T programmes and development goals for leveraging external strength in national objectives.

Prioritization of sectoral R&D

The allocations to different sectors in biotechnology are recommended on the basis of their social relevance, potential to contribute to the economy in the short and long term and the ability to generate employment. Employing these criteria priorities identified are

- ***Agriculture and Food Biotechnology*** – disease and pest resistant, drought and salinity tolerant seeds and plants; nutrition enhancement,
- ***Health care***, particularly mass public health - Vaccines, diagnostics and therapeutics; biomedical devices, implants and instruments; advanced materials for biological and medical use; clinical trial and contract research; nanobiotechnology; regenerative medicine and stem cell technology.
- ***Bioresource development and utilization*** – characterization and inventorization; bioprospecting of plants, microbes, marine organisms for novel products, improved processes for bioresource based product development.
- ***Forest Biotechnology*** – improved biomass productivity, new bioprocesses for paper and pulp, timber and other value added minor forest products.
- ***Animal biotechnology*** - with focus on vaccines, diagnostics and animal feed,
- ***Marine biotechnology*** – increased productivity and disease management
- ***Environment friendly*** technologies and schemes – bioremediation, pollution abatement; biofertilizer and biopesticides.
- ***Industrial biotechnology*** – biotransformation to make bioproducts cost effective; advanced manufacturing technologies for production of vaccines and other medical products; bioseparation technologies for recombinant DNA products; reactor engineering; and development of bioprocesses for high quality textiles, silk and paper industry.

- ***Biofuel –*** New processes for cost effective bioethanol production from agro and cellulosic waste, improved biodiesel production.
- ***Advanced computational biology*** – bioinformatics, genomics, proteomics, pharmacogenomics, in-silico drug design.

New Institutions

The overall policy is to strengthen the existing university system and research institutes. However a critical review has revealed that new Institutional structures are urgently required to be built up, especially in the areas which have marginal strength and a critical mass of expertise. These include institutes for:

- ✓ Stem cell research
- ✓ Animal biotechnology
- ✓ Seri biotechnology Center at Bangalore to be taken over as requested by Silk Board.
- ✓ Translational centers especially designed for technology development in Health, Agriculture and Food sectors and strategically located within or in the vicinity of a University Campus with effective industry linkages.
- ✓ Molecular Medicine Centers in atleast two medical colleges.
- ✓ Agri-food institute and central bioprocessing unit in Punjab
- ✓ Institute of plant health
- ✓ Plant Health Research Institute
- ✓ UNESCO centre for education and research

Expansion and remodeling of autonomous institutions

The Group recommended to remodel the activities of existing autonomous institutions with that of translational and innovation activities in collaboration with public and private sector agencies. In doing so, it was also recommended to expand the scope of the institutions by building centers of translation, innovations, and services along with focused networking.

National Institute Immunology, New Delhi to establish four vertical translational research progrmmes in design of novel inhibitors for decimating pathogens, development of anti-HIV microbicides, anti-viral vaccines and Cancer diagnostics and therapeutics. An innovation foundation through public private partnerships for public goods may be supported for genetically defined MACAQUE primate animal strain facility.

National Centre for Cell Science, Pune to initiate focused programmes on diabetes by use of human fetal pancreatic islet-derived progenitor/stem-cells for diabetes cure and identification of anti-viral compounds with potential for development of microbicides to prevent HIV infection and transmission. Systems Biology of Global Regulatory Networks, unraveling Sequence Features in Promoters that Dictate Tissue-Specificity of Gene Expression, Inter-institutional Network program on HIV and Tuberculosis are to be initiated apart from establishing centres for cell and tissue engineering and immuno-thereupatics.

Centre for DNA Fingerprinting and Diagnostics, Hyderabad to enhance the volume and scope of its existing activities as well as to undertake new activities such as National Facility for Training in DNA Profiling (NFTDP), Disaster Victim Identification Cell (DVIC), Secretariat for DNA Profiling Advisory Board and Creation of National DNA Database, Quality control and accreditation, and Other DNA profiling services.

National Brain Research Centre, Manesar to take up Neural Stem Cell Research - Application of insights from basic research to animal models, Clinical Research Centre for Brain Disorders and Brain Machine Interface, network programme on genetics and pathogenesis of neurological and psychiatric disorders and Development of neural prosthetics in addition to centralized facilities of Brain bank for neural tissue, CSF and DNA samples, Primate Facility and Biological containment facility.

Institute of Bioresource and Sustainable Development, Imphal to establish a Genome Club for regular interaction between bio-entrepreneurs, graduate students and researchers on biodiversity conservation and bioresources management.

*Institute of Life Sciences***,** *Bhuneshwar* to undertake vertical translational activities such as Development of DNA chip based diagnostics, nanomedicine alongwith establishment of National Repository of C.elegans, a model genome for all fundamental biological studies.

To sum up, recognizing the development of product and processes of social and economic value in biotechnology require long gestation periods involving various elements of innovation from R&D to commercialization, the working group has observed that early major initiatives are necessary for reaping the benefits in the years to come. Comparing investments by the leading countries and domestic /transnational companies in biotechnology in the world, the enormous potential that India can offer in this sphere, and for making India a "Biotechnology Hub" of potential investment destination, self reliant in technology with export promotion possibilities in Asia and the rest of the world, the working group strongly recommended an investment of Rs.12000 crores **(Annexure-V & VI)** during the 11th plan (2007-2012).

2. HIGHLIGHTS OF TENTH FIVE YEAR PLAN (2002-2007)

The working group and its subject- specific sub groups reviewed and assessed the achievements of 10th plan in terms of knowledge generated, patents filed/ granted publication and their impact, technologies developed / transferred / commercialized. Along with the achievements shortfalls, constraints and lessons learnt in implementation of the various projects and schemes were taken into account.

The major thrust enunciated in the 10th plan:

- *Enhancing the knowledge base and generating highly skilled human resource:* The national bioscience research endeavour in elucidating the molecular basis of plant, animal and microbial life processes will be honed to the cutting-edge by applying global standards. Necessary informational resources will be systematically developed through data banks, inventories, and germ plasm repositories. Human resource development in biosciences and biotechnology will be enhanced to achieve widespread excellence in both teaching quality and support resources.
- *Nurturing leads of potential utility:* Life technology development leads emerging from the bioscience enterprises will be vigilantly identified and fostered in three major areas; agriculture, health care and the environment. Widely available information resources will be developed for this interface via regulated and comprehensive repositories, systematic biological standardization, and patent support mechanisms. Industrial transitions will be facilitated with large-scale demonstrations and seed partnerships. Pro-active steps will be taken to address societal concerns by establishing transparent mechanisms of systematic public dissemination of bio-information, and by putting into place comprehensive stringent frameworks for both bioethics and biosafety.
- *Bringing bio-products to the marketplace:* Innovative policies will be developed and implemented, in conjunction with other government

departments and agencies, to enhance the biotechnological landscape for investment, to champion Indian biotechnology in the global marketplace, and to design innovative as well as defensive strategies for global intellectual property rights

The following major activities were proposed as part of the biotechnology development during the 10th Five Year Plan:

Core Activities

The ongoing activities of the Department namely, the human resource development, support for new centres of excellence, facilities, repositories and services, basic and product oriented R&D, biotech product and process development, bioinformatics, international cooperation in biotechnology, biotechnology based projects for societal development and support to the autonomous institutions, and the activities of the secretariat in DBT would be consolidated further and continued. New activities for starting courses at engineering colleges and in the areas of genetic counseling, genomics, brain research, IPR related issues, etc. will be taken up.

Special thrust on the following core activities would be given:

- Genomics of human, animals, plants and microbes
- Genetic counseling, human genome diversity studies, molecular epidemiology, etc. to continue.
- Network facilities in at least 4-5 centres in the country for high through put screening, functional genomics, microarray and structural genomics would be set up with major funding coming from industries.
- Pilot production facility for large-scale validation and testing of important diagnostic kits.
- The basic and product oriented supported to the core areas including plant biotechnology, medical, environment and marine biotechnology.
- Bioinformatics and international cooperation modern biology including transgenics, computational biology, pharmacogenomics, neurosciences, etc.

- Biotechnology based programmes for Societal Development: With focus on SC/ST population, rural development and women to utilize proven biotechnological tools for generating employment opportunities. The thrust areas would be agriculture, environment and health related problems. Biovillages, biotechnology parks for rural areas would be an integral part of the societal development programme.

Autonomous Institutions

Support to existing autonomous institutions with clear prioritization. Each institution would be implementing one or more mission mode projects. The new institutions namely, Centre for DNA Fingerprinting & Diagnostics, Hyderabad; National Centre for Plant Genome Research, New Delhi; National Brain Research Centre, Gurgaon; and Institute of Bioresource and Sustainable Development in North-east would receive major thrust for making them fully operational including completion of their buildings, infrastructural facilities, etc.

Significant Achievements

The area-wise achievements during 10th plan period are:

Human Resource Development:

The Department is implementing an Integrated Programme of Human Resource Development in Biotechnology to generate adequate and appropriately trained manpower required for overall development of Biotechnology in the country. Some noteworthy achievements are:

Education & Teaching: Sustained support at M.Sc./M.Tech level

The Department has continued support to a number of M.Sc./M.Tech. teaching programmes in biotechnology. The universities / institutions have been selected on the basis of existing expertise and infrastructure, strong ongoing R&D programmes and nearby institutions engaged in R&D in biotechnology. Collaboration with agencies like University Grants Commission, Ministry of Human Resource Development and respective state governments ensured that

the faculty positions are taken over after the plan period. The department has provided critical inputs like infrastructure, equipment and grants for consumables, visiting faculty, studentship and faculty salaries.

The programme which was started in 1985-86 in five universities and have been gradually increased to 63 courses at the end of 10th Plan by increasing the number of general biotechnology courses as well as starting new courses in marine, agriculture, veterinary, medical, pharma, biochemical engineering, etc.

The programme has an inbuilt component of visiting faculty to encourage interaction and to fill the gap areas in in-house expertise and provision of studentship and summer training for students.

Interactive sessions are organized to consider the curriculum offered by different universities and to evolve model curriculum to be adopted by all participating universities. To keep pace with rapid advancements, this exercise is repeated once every five years.

The total intake of students in the postgraduate courses is around 1000 per annum. Of the total 63 courses, 22 have been started in 10th Plan. Till date 17 universities/R&D institutions have been provided one time financial support under non-recurring grant for strengthening their ongoing PG teaching courses, of which 7 have been supported during 10th Plan.

Hands on exposure to M.Sc. biotechnology students has been enhanced through an extended industry internship as well as through short term placements at appropriate national Institutes.

Realizing the need to upgrade the skills of mid career scientists engaged in research in biotechnology, the department has evolved a scheme for conducting short term training courses for 12-16 participants for duration of 2 – 4 weeks. Every year 10-12 such courses are conducted.

New JRF scheme launched: To fill the gap between PG teaching courses and post doctoral fellowship (PDF) programme of the Department, JRF programme has been started from the year 2004. Under this programme 100 JRFs can be selected through Biotechnology Eligibility Test (BET) conducted by University of Pune, Pune.

Biotech Facilities

The department has established about 35 facilities during 10th plan for production and supply of biologicals, reagents, culture collections and experimental animals have been set up, which are available to scientists, industries and students at nominal costs. The facilities also conduct regular training progrmmes for capacity building in areas of instrumentation, handling of small animal houses, bio-processing, microbial taxonomy and molecular biology.

For the first time, International Depository Authority was established at IMTECH, Chandigarh for patent deposits. It is the first such facility in India, 7th in Asia and 34th in the World.

Centres of Excellence

The Department has initiated this programme during 2005-06 to augment and strengthen institutional research capacity in areas of biotechnology through support for establishment of Centres of Excellence.

During 2005-06, five proposals were proposals were supported in 'Programme Support' mode in areas such as Cancer Biology and Therapeutics, industrially important non-conventional yeasts; Development of drought tolerant crop varieties and Characterization and validation of the mangrove genes in transgenic rice systems for abiotic stress tolerance. Two Centres of Excellence i.e. (a) "Centre of Excellence in genetics and genomics of silkmoths" at CDFD, Hyderabad and (b) "A Virtual Centre of Excellence (COE) for Coordinated Research on Tuberculosis: Development of Alternate Strategies" at ICGEB, New Delhi, UDSC, New Delhi and Central Jalma Institute for Leprosy and other Mycobacterial Diseases, Agra have been supported. During 2006-07, four proposals have been found to be supported as Centre of Excellence and five proposals have been recommended for support in 'Programme Support' mode.

Bioinformatics

India was the first country in the world to establish National Bioinformatics Program.

BTIS is the first network which established virtual private network of broad band connectivity among various Bioinformatics Centres in the country and also high performance national computing facility.

An extensive Bioinformatics Network, covering 65 institutions, spread geographically all over the country, has been established. This network consists of Centre of Excellence (CoE), Distributed Information Centres (DICs), Sub-DICs depending upon their activities and the financial support.

The network has also helped directly as well as indirectly several Bioinformatics companies in India. The scientists from the network have participated in major national millennium technology initiative projects of CSIR such as Biosuite of Tata Consultancy Services (TCS) or software packages for visualization of bioinformatics data by Strand Genomics.

The Bioinformatics resources both hardware & software products are helping to drive the biotech research bioinformatics industry and developmental activities very effectively.

Scientists of this network have published more than 1200 bioinformatics research papers in peer reviewed journals in last five years and helped in publishing more than 3500 research papers in biology/ biotechnology.

Dedicated High Speed Network for the BTISnet – VPN and a Super Computer Facilities for Bioinformatics has been established. With the minimum speed of 512 Kbps for the Sub-DICs and 2 Mbps for the DICs and COEs. 12 major institutions has been inter-connected through high speed Network in the form of VPN (Biogrid India).

Courses such as M.Sc. /M.Tech/ Ph.D. in Bioinformatics has been introduced. Trainees of these programs have been absorbed by various organizations including industries and many of them have started their own companies in Bioinformatics.

Around 400 short term training courses has been organized in different areas of Bioinformatics, training more than 4000 researchers & scientists.

30 New R&D projects have been supported during the plan period in the area of Bioinformatics.

200 software packages for addressing the biological problems has been developed by the Centers. 26 copyrights have been received for the products developed.

Research & Development

Agriculture & Allied Areas

Crops Biotechnology:

During the Plan period, besides Plant Molecular Biology programmes, the Department supported important programmes on rice genome sequencing, rice functional genomics, development of rice tolerant to drought and salinity, cotton resistant to bollworm, rice resistant to tungro virus, brinjal resistant to fruit and shoot borer, field trials of mustard lines with barnase/ barstar genes, gene pyramiding for leaf and strip rust resistance in wheat, development of markers for wheat quality improvement, biotechnological interventions for improving important millet crops. Recently, projects on Crop biofortification have been initiated for enhanced Iron and Zinc contents and reduced phytates, in wheat, rice and maize through marker assisted breeding/ transgenic approaches.

Under Indo-US collaborative programme, two network projects have also been taken up – one on development and evaluation of salt and drought tolerant transgenic rice, and the other on fruit and shoot borer resistant eggplant. Some of the salient achievements are:

Plant genome sequencing capacity built-up: India has successfully decoded the genome information of the rice chromosome number 11. The rice genome has been shown to have 37,544 genes, of which 1443 genes are identified in the region sequenced by Indian Scientists.

Transformation technologies for rice developed: The Indian initiative on Rice Genome Sequencing provided a good opportunity to learn and train large number of our scientists, research fellows and technical personnel. High level competence and infrastructure in Plant Genomics developed and utilized for

genome-wide research on other important crops like tomato, sugarcane and wheat.

Under Salinity and dehydration stress tolerance network project in rice – the glyoxalase 1 and II genes have been transferred in the Pusa Basmati 1 and recently in IR 64, and also sodium proton antiporter gene has been cloned under the constitutive promoter as well as ABA inducible promoter and both the genes constructs have been transformed into Pusa Basmati 1 at ICGEB. Partnership is being developed with certain ICAR institutes for advancing generations and their field evaluation.

Transgenic Rice plants have been generated making use of RNAi approach against Rice Tungro Bacilliform Virus (RTBV), in which the RTBV DNA accumulation is significantly slowed down. Now efforts are continuing to diversify this transgenic resistance to popular rice varieties grown in tungro disease prone areas.

Molecular marker for wheat quality traits develoed: A novel promoter based on Rice Tungro Bacilliform virus has been developed which is active in both monocot and dicot plants having wider application.

In wheat quality network project, markers linked to three quality traits viz. grain protein content; pre-harvest sprouting tolerance, grain weight have been developed for actual breeding work after necessary validation.

Novel public sector Bt cotton technology perfected: In transgenic cotton project, a robust protocol for regeneration and transformation has been developed for Coker 310, and developed four different constructs wherein the *Cry 1Ac* gene was driven by different promoters. Recently 87 new transgenic lines have been developed and 12 of them were found to be single copy number events. The analysis of the expression of Cry 1Ac and Cry1C proteins in the advance generation of selected transgenic lines is being done, along with the development of more transgenics with 35Sde Cry1Ac gene for high expression.

Transgenic virus resistant tomato ready for regulatory tests: In tomato for developing leaf curl resistant transgenic line, a high level of resistance has been observed with single gene insertion. The progeny analysis of these plants showed mendelian pattern of inheritance. The work is being pursued further to develop more transgenic lines and determine the spectrum of resistance under field conditions.

GM mustard with higher yields in field testing: The contained open field trials of transgenic mustard hybrid (DMH-11) conducted at Delhi during 2004-05 & 2005-06 showed 45% & 28% yield advantages respectively over the national check Varuna. The multi-location field trials to be repeated.

A reproducible method ensuring very high frequency of direct shoot regeneration from various explants of sugarcane established for three varieties. Further, the transformation procedure developed is used for developing red-rot disease resistance.

Technology for double haploids in cereals: A new system (wheat x *Imperata cylindrica*) of chromosome elimination technique has been developed for making double haploids. The new system has certain advantages over wheat x maize system.

Molecular diagnostics for bacterial disease of cotton developed: A sensitive molecular diagnostic tools for rapid detection and differentiation of races *Xanthomonas campestris* pv. Malvacearum, causing bacterial blight of cotton has been developed at CICR, Nagpur.

Plant Biotechnology

Major programmes have been supported on Forest trees, horticulture and plantation crops. The thrust is on application of tissue culture for regeneration of high quality economically important plant species, demonstration of large-scale plantation and validation of proven technology; germplasm characterization, improvement of crops through molecular biology tools, basic research, genomics

initiative; host pathogen interaction, resolving of taxonomic problems by molecular interventions etc. Some of the achievements are:

Micropropagation ad transformation protocols developed: Studies has been carried out for developing/standardization of micropropagation protocols of important tree species. Under the horticulture crops, post harvest studies for improved shelf life of Tomato, Grapes and Banana has been supported. Transformation systems have been established. Transgenics of tomato are undergoing field trial. Improvement of selected spices (black pepper, cardamom, ginger, vanilla) through biotechnological tools has been supported concentrating on germplasm characterization and conservation and screening for disease resistance, developing improved varieties through transformation and mutation breeding.

Large scale successful field demonstration:

- Large scale production and demonstration of tissue culture raised black pepper was also taken up. 100 ha in 5 states have been covered so far.
- A Mission programme on field Demonstration of quality planting material of Bamboo was initiated with a target of covering 1000 ha in 12 states.
- Field demonstrations of bamboo plantations supported in Uttranchal, Northeastern India and Southern India have covered around 200 hectares

Micropropagation Technology Parks (MTP's)/ field demonstrations: Two MTP's and 6 Regional hardening facilitates has been supported. More than 15 million plant of important species has been produced and field planted. Protocol of Apple and citrus root stocks multiplications have been perfected and are currently being demonstrated. Nearly 15000 plants each have been field planted. To ensure quality of planting material in terms of virus indexing and true-to-type a National Facility for virus diagnosis and quality control has been set up with 6 satellite centers.

A National Certification system has been developed for the first time. DBT has been authorized as the Certification Agency for Tissue Culture plants. Accreditation guidelines are being developed, alongwith standard for Tissue Culture plants production. Guidelines for potato have been notified.

Solanaceae Genome Initiative launched: An International Solanaceae Genome Initiative (SOI) has been launched with the aim of creating a coordinated network of knowledge regarding the Solanaceae family and address various key issues. The long-term goal of the SOL programme is to create a network of map based resources and information and address key questions in plant adaptation and diversification through this International effort. India joined the International 'SOL' programme and has taken up sequencing of chromosome 5 (12 Mb). Functional Genomics has been supported for three traits of importance – Nutritional Quality, Disease Resistance, Fruit Ripening.

New Capacities in Molecular Taxonomy built: Molecular Taxonomic studies has been supported on important plant species to resolve taxonomic confusions. Fingerprinting studies helped in segregating populations of plant sps. like *Acacia catechu*, *M. latifolia*, *Solanum melongena* species in *Cassia*, *Trigonella*, *Cajanus species*.

Biological agents

Technologies transferred and products marketed: At least four mass production technologies biocontrol agents/biopesticides have been developed and standardized. Mass production technology of *Trichoderma viride* (fermentation based) has been transferred to M/s Prathista Industries Ltd. Nalgonda, Andhra Pradesh and M/s Haryana Biotech, Gurgaon.
Patents: Six patents have been filed for the mass production technologies of various biocontrol agents.

Biopesticides based IPM demonstration: A major programme on IPM as a component of INM for increasing agricultural productivity in cropping ecosystems of various agro-climatic zones has been supported at 14 centres in 12 states. Effective modules/ packages of practices, which are cost effective, sustainable and eco-friendly in different ecosystems were developed. The cost-benefit ratio of IPM/ INM modules worked out at large scale trials showed significant tilt in favour of adopting the technology by farmers for different crops.

Integrated parthenium management: A multicentric programme on the management of *Parthenium* through integrated approach has been initiated for its economic utilization, effect on human health and to observe its distribution through remote sensing.

Website on biopesticides launched: A comprehensive website on biopesticides compiling the achievements made in the major programmes supported by DBT on Biological control of plant pests, diseases and weeds. Salient achievements have been extracted from 120 completed projects for the benefit of scientists, entrepreneurs and other users community including progressive farmers. This website has got a resource directory and linkages with national and international websites.

Network for toxicological tests established: In order to facilitate the commercialization of biopesticides, the Department has taken a proactive step for the generation of toxicological data of potential biopesticides. In the first phase, ten biopesticides have been taken up for the generation of toxicological data both for primary cultures as well as for their formulations. Data have been generated for almost all the biopesticides by the two identified centres viz., ITRC, Lucknow and RRL, Jammu.

Biofertilizers

The essence of biofertilizers use in agriculture lies in attempting to increase their population in quantity and quality around the roots and in soil to allow them to function in time and space. Important Achievement are:

Integrated Nutrient Managements Packages developed: Role of microorganisms in Integrated Nutrient Management (INM) is very critical, since, they provide key inputs in terms of Nitrogen and Phosphorus besides addition of organic matter to soil. It becomes imperative to understand the role played by microorganisms in the diverse plant-soil microbe interactions, to analyze their effectiveness and provide remedial measures for improving their efficiency. Various basic and

applied issues have been targeted to have integrated approach to manage nutrient supply to major cropping systems.

Molecular Biology of biofertiliser strains: Information for transgenic biofertilisers generated with the objective of developing better nitrogen fixing microorganisms, a network programme involving 12 centres has been supported.

Cyanobacteria - A suicide vector capable of integrating cloned genes in *Anabaena*/*Nostoc* genome has been developed. The gene and the operon have been cloned from cyanobacterial genome and successfully transferred into *Anabaena* strain and *Nostoc muscorum* strain.

Rhizobium - The gene responsible for production of bacteriocin facilitating but more nodule occupancy have been cloned

Azotobacter: Elite *Azotobacter* strains developed tested under contained conditions. The genetically modified strains excreted large amounts of Ammonia is indicating that these nitrogen fixing and strains are efficient execrators of ammonia.

Phosphate-solubilizing bacteria- Isolated several gram-negative bacteria from diverse locations and cloned mineral phosphate solublizing.

Animal Biotechnology

Productivity of livestock sector in our country needs to be substantially increased in order to satisfy increasing consumer demand, to more efficiently utilize scarce resources and to generate income for a growing population. Biotechnology has long being a source of innovation in production and processing, profoundly impacting the sector.

Technologies transferred: Technology for the production of recombinant protective antigen (recombinant anthrax vaccine) has been developed and transferred to M/s Panacea Biotech Ltd., New Delhi. Phase I and Phase II, open

labelled, randomized, placebo controlled, ascending dose trial to evaluate the safety and immunogenicity of recombinant anthrax vaccine has been carried out at four centers with more than 100 volunteers.

Animal Nutrition: Leads in bioconversion of crop residues to animal feed and enhanced digestibility obtained: A hyper lignolytic mutant of C*yathus bulleri* with six fold laccase activity has been developed using mutagenesis. Various rumen microbes with enhanced digestibility were identified. For large scale bioconversion of lignocellulosic residues to animal feed using white rot fungus, a reactor of 1200 litre capacity has been designed and fabricated indigenously. Trials showed that system could degrade up to 30% of the crop residues.

Animal Reproduction: Embryo transfer techniques perfected: Embryos of superior animals are being continuously used to preserve and improve indigenous breeds of cattle and buffalo. 40 embryos of Sahiwal, 10 embryos of Jaffrabadi and 6 embryos of Red Sindhi has been preserved for future use.
Inhibin based synthetic peptides has been found to be effective in increasing the ovulation rate in Indian breeds of sheep manifolds over long periods of time.
A non-surgical uterine flushing procedure of embryos has been successfully established in bonnet monkeys.
Ovum pick up technology for the production of large number of embryos in cattle and buffalo has been standardized by producing embryos and calves. This will help to reduce the cost of Embryo Transfer.

Capacity for Genomics of livestock built: Molecular characterization studies of various livestock breeds has been carried out. Three breeds of indigenous of cattle and buffalo each, represented by 46 animals has been analyzed by micro satellite typing, employing 15 different micro satellites for their characterization.
Multicentric Buffalo genomics programme has been initiated and in phase I, genes of economic importance like fertility and milk protein are being identified.

Trasnsgenic Mice produced as model for livestock: Eighteen lines of transgenic mice has been developed as a model system for various diseases. Embryonic development of transgenic mouse and its transgene expression pattern has been studied which would be valuable for studies related to embryonic development and somatic stem cell biology. Based on the clues expression of green fluorescence protein gene has also been established in micro injected rabbit and goat embryos.

Animal Health

Development and technology transfer of vaccines: A recombinant anthrax vaccine developed and its technology transferred to the industry. Phase I and phase II human clinical trials of vaccine has been conducted at three centers. Efforts continued to develop another new generation anthrax vaccine using non-toxic mutants of anthrax toxin proteins for better efficacy in animals/ humans.
A DNA/recombinant vaccine against *Brucella abortus* has been developed and the potency of vaccine is being augmented by using suitable adjuvant and additional dominant antigens.

Technology for diagnostics kits viral and bacterial diseases: A diagnostics kit for Peste des petits ruminants (PPR) virus, based on antigen competition ELISA has been developed and found to be more sensitive than PCR based kit.
A novel PCR based diagnostic kit for rapid diagnosis of Buffalopox virus (BPV) has been standardized.
ELISA based kit has been developed for monitoring the levels of antibodies in serum samples of *Haemorrhagic septicaemia* (HS) vaccinated cattle and buffalo.
Class specific monoclonal antibodies have been produced against chicken for use in simultaneously monitory the immune status/ diagnosis of recent infections in birds for any viral diseases affecting poultry.

Livestock Products Technology development including leather: Bovine collagen has been chemically modified converted into ophthalmic inserts collagen diskette

for using on patients during and post cataract surgery. Collagen ophthalmic inserts were clinically evaluated.

A process for preparation of serum based protein binder has been developed and several batches have been successfully produced at pilot scale at 100 lit batch production.

Aquaculture and Marine Biotechnology

The initiatives undertaken in the area helped in development of marine natural products, novel enzymes, pharmaceuticals, brood-stock improvement, disease diagnostics and prophylactics etc. Some noteworthy achievements are:

- Virus diagnostic diagnostics delivered.
- New source of insulin has been explored from fish adipocytes.
- Measures taken on development of vaccines and prophylactics here helped the sector in aquaculture health management to control the disease outbreak.
- 50 publications on Diagnostics, Prophylactics and Fish Spawning Agents in Aquaculture
- Six technologies transfer to industry

Virus diagnostics: A simple monoclonal antibody (MAb)-based Immunodot kit for detection of WSV of shrimp at the farmers level has been developed as an effective alternative for expensive and complex DNA based tests. Diagnostics developed for WSSV has been commercialized. The kits developed are benefiting aquaculture industry, research and diagnostic labs, hatcheries, shrimp farmers and other academic institutions working on WSSV.

Scientific inputs for development of freshwater pond system: Freshwater pond system has found useful in aquaculture system as a prediction model for pond productivity depending upon certain meteorological and other input variables.

Microsatellite DNA markers and screening of brood stock population from coastal area of West Bengal and Orissa has been carried out along with the prevalence of the disease and viral pathogens in the population studied. The DNA markers

disease resistance found useful in identification of disease free aquaculture stock.

Research on shrimp genomics initiated: A Marine Biotechnology Laboratory has been established at CUSAT. Two projects have been supported as multi-agency network programmes on shrimp genomics. With the objectives to study differential gene expression with respect of infection with viral and bacterial pathogens and salinity in larval and adult stages of development and development of recombinant hormones and their antagonists, development of RNAi technique for silencing regulation of maturation.

Seri-biotechnology

Publication with high impact: High quality research publications emanated from the projects supported in the area of silkworm genetics and genomics in Journals such as Nucleic Acids Research, Genetics, Heredity, Proceedings of National Academy of Science of USA, BMC Genomics, Journal of Biological Chemistry etc. whose impact factor ranges from 3 to 10.

Silkworm hybrids with higher yield to farmers: Three high yielding productive hybrids namely – *Swarnandhra, Hemavathy* and *Kalpatharavu* of silkworm have been developed and released to farmers; these have superior quality of silk by adopting a combination of conventional breeding techniques and DNA marker technology. These hybrids are now being used by farmers of Andhra Pradesh, Karnataka and Tamil Nadu.

Similarly, microsatellite markers for tasar silkworm and muga silkworms have been developed which are being used to study population structure, gene flow and genetic polymorphisms.

Joined international lepidopteron Genomics: India joined "International Consortium on Lepidopteron Genomics" and fulfilled the Indian commitments viz (a) Construction of high-density linkage map of silkworm (*Bombyx mori)* (b) Isolation and characterization of ESTs from non-mulberry silkworms.

Technology for transgenic silkworm: RNA-interference based baculovirus resistant transgenic silkworm lines has been developed. These lines are undergoing laboratory trials.

Web based information on mulberry: A Web-enabled DNA database on mulberry has been developed for the first time in the world encompassing DNA fingerprinting studies carried out on more than 250 genotypes including 50 selected elite genotypes.

Technology for GM mulberry developed: Genetic manipulation of *Morus indica* cv. K-2 via *Agrobacterium* mediated transformation using HVA-⊥ gene for abiotic tolerance has been achieved. Evaluation of putative transgenics in mulberry (with HVA-1gene) under transgenic green house condition is in progress.
A Multi-institutional Network project has been launched on identification of DNA markers associated with disease and pest resistance in mulberry (*Morus* spp.)

Bioresources Development and Utilisation

National Bioresource Development Board (NBDB)

National Bioresource Development Board has been established in 1999 with an overall aim to decide the broad policy framework for effective application of biotechnological and related scientific approaches for R&D and sustainable utilization of bioresources, specially for new products and processes; and to develop a scientific plan of action for contributing to the economic prosperity of the nation through accelerated R&D using the most modern tools of biosciences. The programme performance is reflected in the following indicators.

i.	Number of publications	29
ii.	Patents filed	13
iii.	Patents Granted	4
iv.	Technologies Developed	13
v.	Technologies transferred	3

vi.	Products marketed	7
vii.	Extent of biodiversity assessment.	80% of forest cover
viii.	Number of research leads.	11
ix.	Number of students benefited.	1200
x.	Number of rural people benefited	3974

Bioresource Characterization, Digitized Inventorization and Conservation: National Bioresource Development Board has identified the digitization of data on bioresources from various sources as a priority. Five inventories has been commissioned on medicinal plant resources; other economically important plant resources; animal resources; microbial resources; and marine resources. Nine CDs have been so far prepared under this program and one of them *Sasya Sampada* (Digitized Inventory of Economically Important and Medicinal Plants) is already released for public use. These inventories have now been augmented with primary data.

Major projects on mapping and quantitative assessment of bioresources of Eastern and Western Ghats have been initiated. The major output of the projects would be a detailed resource map of the Eastern and Western Ghats, perhaps first ever of this scale on any of the global hotspots.

Biodiversity characterization studies through remote sensing have been completed for North eastern Himalayas, Western Ghats, Western Himalayas and are being carried out in Central India, Eastern Ghats, and Mangrove region.

An Indian Bio-resource Information Network (IBIN) – a service and network system for all the digital databases on Bio-resources, has been developed under the NBDB. The IBIN is to facilitate the integration of the existing databases with a provision for inclusion of data from similar activities to be taken up later. This is a web-enabled, user friendly single portal providing access to users-researchers, students, field workers, policy planners on the Biodiversity characterization.

Prospecting of genes and molecules for product development: Prospecting for new genes, molecules has been taken up and potential lead molecules which

could be converted to a product have been identified especially for producing biofertilizers and biopesticide formulations.

96 genes for stress resistance have been isolated from plants of fragile ecosystem. Genes responsible for imparting salinity tolerance has been identified from mangrove plants and transferred to other crop plants including rice. Limited field trials are being held after RCGM clearance. Studies for its stable integration are going on.

In prospecting for natural dyes, more than 400 plant species collected from high altitude ranges of North Western Himalayas (6000-12000 ft above m.s.l.) and tropical areas of Northern Western Ghats (~1200 ft above m.s.l.) screened for presence or absence of colouring matter. Information on distribution, habit and natural colouring matter present for 600 dye-yielding plant species from India has also been documented. Large-scale production of the algae *Dunaliella salina* and *D. bardawil* have been developed and methods have been standardized for isolation of stable and high quality β-carotene.

Prospecting for botanical pesticides has yielded good results, so far ~ 575 extracts/fractions have been prepared in different solvent systems, from 29 plants collected by different laboratories.

The first butterfly park of the country has been established, which serves as an integrated centre for research, education and rural livelihood has been established in association with the Zoo Authority of Karnataka (ZAK), University of Agricultural Sciences (UAS), Bangalore and Ashoka Trust for Research in Education and the Environment (ATREE), Bangalore.

Rural Bioresource Complexes: Five Rural Bioresource Complexes have been set up at Bangalore; Hisar; Pant Nagar; Parbhani and Orissa for social empowerment and economic upliftment of the rural population. The complexes provide improved interventions for value addition to the existing technologies, with clear market linkages and buy-back arrangement. These would benefit approximately 10000 families.

Resource Specific Programmes:

Coffee: The Coffee network programme has successfully concluded with substantial achievements in the area of germplasm characterization, molecular marker development and transformation for disease resistance and improved quality. Coffee N-Methyl transferase (NMT) gene, involved in the caffeine biosynthesis was cloned and sequenced. Regeneration system has been developed.

Tea: Procedures of DNA fingerprinting have been evolved for facilitating the work on a common platform. Database for 150 clones in terms of descriptor quality traits and DNA fingerprinting have been established which laid the basis for expanding the database to all clones available in the country. Three important genes have been isolated in relation to regulation of dormancy. Micropropagation protocols and hardening procedures developed have been successfully implemented. More than 2000 accessions are now being characterized.

Jute: Under the Jute Biotechnology Programme the microbial retting protocol was standardized and tested in the farmer's field at different location. Different microbial consortia have been developed the improved retting process showed decrease in number of days required for retting and increase in fibre quality

Sugarcane: PCR based diagnostic kits for red rot and smut diseases have been developed and their validation is underway. A major initiative has been launched for functional genomics studies of sugarcane with special emphasis on biotic and abiotic stress. About 25,384 EST sequences have been submitted to Gene Bank. A total of 432 microsatellite containing genomic clones, 480 microsatellite enriched genomic clones and 240 cDNA clones were sequenced.

Other resources such as Lac, gums & resins, neera etc are also being supported: A project on the development and optimization of processes for value added products from lac has been initiated with emphasis on development of eco-friendly high yield processes for currently marketed products. Programme has been supported for developing novel chemo-enzymatic technology for the food fibre from Guar/Cassia tora gums.

Technology transfer: 2 botanical pesticides and 3 natural dyes are currently under testing for product formulation. Biofertilizer formulation has been transferred to the industry. 96 stress genes have been isolated and 4 genes have been transferred to rice, which is under limited field trials. Capacity building programmes have helped in creating awareness and more than 1100 school children are benefitted. About 4000 people have been trained in various rural technology packages.

Medicinal and Aromatic Plants

High quality research publications emanated from the projects supported in the area of isolation and characterization of novel bioactive molecules from medicinal plants in journals such as in "British Journal of Cancer" which has good citation index.

Four technology transfer agreements: Anna University with Ranbaxy, Gurgaon for further screening of compounds (as potential anti-diabetic and immunomodulaotry agents) and also to take up already identified molecules for further investigations.

Anna University with Nicholas Piramal, Mumbai for further investigations on lead molecules / extracts having anti-cancer properties.

National Institute of Immunology (NII), New Delhi and Nicholas Piramal, Mumbai for further investigations of an anti-inflammatory compound isolated from *Alpinia galanga* .

NII, New Delhi and Reliance Life Sciences, Mumbai for further investigations of an immunomodulation agent (NII-70) isolated from *Tinospora cordifolia*

Conservation and characterization: A Network of four national gene banks on medicinal and aromatic plants at TBGRI, Thiruvananthapuram; CIMAP, Lucknow; NBPGR, New Delhi and RRL, Jammu have been further strengthened. A total of about 8500 accessions of prioritized species are conserved in different forms such as in field bank, seed bank, *in vitro* repository, cryobank and DNA bank.

A germplasm bank for medicinal plants used in Ayurveda has been set up at Arya Vaidya Sala, Kottakkal, Kerala.

Micropropagation and multilocation field trials: Multi-locational field trials to evaluate the performance of tissue culture derived *Pogostemon cablin* (Patchauli) carried out over an area of 32 acres involving five centres.

Field evaluation of the performance of tissue-culture raised elite varieties of large cardamom (*Amomum subulatum*) over a total area of 50 acres in Uttaranchal initiated in association with the Spices Board.

Cell-culture production of therapeutic agents: Efforts have been initiated towards protocol development of production of important therapeutic agents through cell culture methods such podophyllotoxin from *Podophyllum hexandrum,* hyoscyamine from *Hyoscyamus muticus*, guggulsterones Z and E from *Commiphora wightii* and comptothecin from *Ophiorrhyza* spp.

Under multi-institutional project, after bio-activity based *in vitro* screening of 60 medicinal plants (used in Indian traditional system of medicine), a total of 35 lead molecules have been identified so far: Anti-cancer (15); Anti-diabetic (5); and Immunomodulatory (15).

Two anti-cancer lead molecules (from *Aegle marmelos* and *Phyllanthus urinaria*) have been patented

A lead medicinal plant extract exhibiting promising osteogenic (bone forming activity) using several *in vitro* and *in vivo* test systems have been identified. The patent for the above is being filed.

A multi-institutional network project has been recently initiated for developing a standardized herbal product for bovine mastitis.

The capsaicin synthase enzyme (key regulatory enzyme for capsaicin biosynthesis) and its gene (*csy 1)* have been characterized from placental tissues of *Capsicum* sp. Patent has been filed for csy 1 gene.

Basic Research and Nano-biotechnology

Several projects have been initiated in the area of protein engineering. In the projects on production of Streptokinase (SK) and development of technology for expression of Streptokinase in E.coli., a novel mechanism of protein-protein interaction between SK and its 'target' protein, namely human blood plasminogen

has been revealed. First time a new substrate specific binding sites in the SK molecule have been demonstrated.

Specificity of peanut agglutinin has been modified so that it recognizes the T-tumor.

A novel series of phenomenally simple and yet highly efficient non-glycerol based cationic transfection lipids has been designed and synthesized for use in non-viral gene therapy.

Aggregation properties of McrA, a restriction endonuclease has been found to have strong aggregation properties, which are predominantly charge based. This suggests the possibility of using McrA as a candidate fusion protein for selective precipitation of the target protein.

A set of modified CaMV 35S promoters has been developed whose strength was compared with the CaMV 35S promoter per se, using ß-glucoronidase as the reporter gene. The modified promoters has been found to function at par with the 35S and shall be useful for plant transgenics.

Molecular studies initiated on the efflux pumps of both pathogenic and non-pathogenic mycobacterium lead to the identification of the contribution of these pumps in the intrinsic as well as acquired drug resistance in mycobacterium.

Considering the importance of a thermostable anthrax vaccine, a study for the production of a thermostable protective antigen of *Bacillus anthacis* by computational and genetic engineering approach was initiated which resulted in mutants more stable than native PA and could be better candidates for anthrax vaccine.

Publications: Around 300 research articles were published in National/International journals. Around 50 papers appeared in journals having impact factor above 5.

Technologies transferred: Technology for production of natural Streptokinase to M/s Cadila Pharma Ltd., Ahmedabad

Technology for production of recombinant streptokinase to M/s Shasun Drugs and Chemicals Ltd., Chennai.

Technology for virosome based gene delivery system transferred to M/s Panacia Biotech., New Delhi.

Medical Biotechnology

Vaccine and Diagnostics

Development of newer technologies for affordable vaccines for Malaria, Tuberculosis, Cholera, HIV, Rabies and Japanese Encephalities, Helicobactor, Filariasis etc. have been undertaken.

Vi conjugate vaccine for Typhoid has given good leads and technology transfer negotiations has resulted into identification of an industrial partner

Development of vaccine candidates for Human Papiloma Virus vaccine has been initiated.

Effort to develop a tetravalent dengue vaccine candidate are in progress.

Clinical trials for some of the leads such as Zinc as a supplement to children in fighting diarrhea. The role of zinc as an immunomodulator in the treatment of possible serious bacterial infections among infants more than 7 days upto 4 month of age has been supported.

Development of new drugs through combinational chemistry and high screening throughput by molecular tools has been initiated. Drug development using modern biological techniques has been identified as a thrust area for tuberculosis.

Rabies: A DNA rabies vaccine has been developed which provides boost to inoculated animals at Indian Immunologicals, Hyderabad. The formulated vaccine is undergoing trials in Kerala, Chennai, Mumbai, Bhubaneswar and Hyderabad

Cholera: Phase II: A studies on the oral cholera candidate vaccine has been completed. 48% had a 4-fold rise or more and 40% had 8 fold rise or more in Kolkata. The rise as marker of protection is comparable to the level raised with other oral recombinant commercial vaccine. Assay validation showed good concordance. A field site for Phase III trial is being prepared Efforts are being made to transfer the technology as well as to get the clinical grade material to be prepared by conducting Phase III trials.

Malaria: Production of recombinant protein based vaccine candidates for Plasmodium falciparum and P. vivax under GLP and GMP conditions has been fulfilled. A trial site has been prepared at Sundergarh District of Orissa by MRC, Rourkela a Pre-clinical studies would be initiate soon.

HIV/AIDS: Studies on immunogenicity of HIV-1 DNA vaccine expressing the envelope and capsid antigens of Indian Clade C virus in *Macaca radiata* has showed enormous augmentation of CTL immune response in mice. Monkeys immunized against HIV-1 vaccine constructs responded to immunization.

Japanese Encephalitis: An Indian strain of Japanese Encephalitis Virus (JEV) has been grown in Vero Cells to high titers and formalin-inactivated it. Inactivated virus produced high titers of JEV neutralizing antibodies and protected the immunized mice against lethal JEV challenge. Technologies for high-density culture of Vero cells using microcarriers has been standardized and transferred to M/s Panacea Biotech Limited, Delhi. Parallely, native mice immunized IM with recombinant adeno virus with secretary E proteins has showed complete protection against lethal dose of JEV given intra-cerebral. Adeno-based approach is being negotiated as a platform technology with companies

Tuberculosis: Several antigens of *M.tuberculosis* using different vectors in *E.coli* expression system has been cloned. Genes coding for these antigens tailored into DNA vaccine vactors. Antibodies raised using these recombinant proteins and DNA in prime boost approach in rabbits. Challenge experiments are on.

Mycobacterium w: RCT clinical trials adopting ICH-GCP guidelines initiated for testing efficacy of Mw in Category II pulmonary tuberculosis are proceeding well. Modalities for interim analysis being worked out

Rotaviral Diarrhoea: Two candidate vaccines on rotavirus developed under INDO-US Vaccine Action Programme have been incorporated under core mission activities. Both have found to be safe in clinical settings. M/s Bharat Biotech International Ltd. is producing the clinical grade material. Vaccines would be tested for efficacy in larger groups

Human genetics

Functional Genomics: The considerable progress has been made to carry out genetic research in SCA, schizophrenia & bipolar disorder and asthma. Developed high-throughput capabilities and highly skilled manpower in the field of genomics and computational biology.

Novel mutations and SNP in B-thalassemia patients have been identified.

A susceptibility on locus on chromosome 22 for schizophrenia and biopolar disorder in the Indian population has been identified. Identified a nonsense mutation in the synaptogyin 2 gene in schizophrenia. A US patent was filed for a method to detect human spinocerebellar ataxia 2 gene variants.

Human Genome Diversity: India is one of the first country to take up the project on Human Genome Diversity. A major consortium project has been implemented at Kolkata in a network manner with other 14 institutions.

Studies on genetic variation among 53 ethnic population groups (tribal, cast and religious communities) revealed that there is an underlying unity of female lineages in India, indicating that the initial number of female settlers may have been small; the tribal and the caste populations are highly differentiated and that the Austro-Asiatic tribals are the earliest settlers in India. The study also provided evidence of human migration from India to South-East Asia. It was revealed that the expansion of the ethnic population took place about 50,000 years ago.

Post Genome Era Research: Supported projects on microbial functional structural, comparative and computational genomics, clinical proteomics and RNAi, a DNA Micro-array facilities at NBRC, Manesar and CDFD, Hyderabad to carry out studies on neurological and infectious diseases.

The whole genome sequencing of *Mycobacterium wigtii* at 5X sequence has been completed with a sequencing efficiency of 83.93% and total sequence coverage of 5.71 Mb.

A major effort in the area of pharmacogenomics is being undertaken to develop baseline data for genetic response to important drugs for treatment of rheumatoid arthritis, bipolar cardio-vascular and other diseases by involving major research organizations and hospitals.

Stem cell research

Stem cell research is being promoted for basic and translational research. To achieve the goal; "*Human Studies committee*" for evaluation and guidance for clinical research particularly for development of clinical research protocols; "*National Bioethics Committee*" to ascertain rigid ethical guidelines being followed while conducting research on human beings; "*Task Force on Stem Cells*" to evaluate basic research and also recommend funding for clinical research based on the evaluation of the above committees; and "*Programme Advisory Committee"* to consider the proposals of Centre of Excellence and infrastructure have been constituted.

So far, more than 45 programmes have been supported on various aspects of stem cell research.

At LVPEI, Hyderabad, limbal stem cells are being used to repair cornea surface disorders caused by limbal stem cell deficiencies. So far, more than 220 patients have been treated at this Institute.

"*CMC-DBT Centre for Stem Cell Research":* A technology has been established at CMC, Vellore for collection, isolation and purification of HSC for haploidentical HSC transplantation.

Banana lectins have been isolated and purified that have stem cell preservation activities. A patent has been filed through DBT.

Phase I multi-centric clinical trials have been supported for acute myocardial infarction and acute ischaemic stroke.

Stem cell research facilities including clean rooms to handle stem cells have been created at SGPGIMS, Lucknow, PGIMER, Chandigarh, KEM Mumbai and LVPEI, Hyderabad.

A training centre for embryonic and adult stem cells has been supported jointly at National Centre for Biological Sciences & Jawahar Lal Nehru Centre for Scientific & Advanced Research, Bangalore.

City cluster programmes have been implemented at Pune and Vellore by involving basic researchers and clinicians. This includes sharing of information, explore collaboration with clinicians and discuss emerging policy issues in this area.

New initiatives include public-private partnership for large scale production of mesenchymal stem cells under cGMP conditions; national and International training programmes; focused, targeted disease specific basic and applied programmes in this area etc.

National guidelines for stem cell research are being formulated jointly by Department of Biotechnology and Indian Council of Medical Research.

Bioengineering

The key areas identified are: tissue engineering, biomaterials for therapeutics, medical devices, bioinstrumentation and biosensors.

Eight projects have been supported so far on development of biosensors for the measurement of cysteine *in vivo*; biomaterials using Indian tassar silk; reconstruction of epidermal and dermal cells of skin in three dimensional collagen scaffold; development of electrochemical sensor for cholesterol; bioengineered cell sheet for corneal tissue engineering; DNA sequence detection for medical diagnostics; novel biodegradable polymeric materials as functionally active cardiac implant; strip based non-invasive rapid test for diagnosis of new born & childhood sepsis; indigenous production of low cost medical devices of international standard for new born and child health care; biodegradable scaffolds for tissue engineering of blood vessels; silk based hydrogel wound

dressings; biomaterials using Indian tasar silk proteins for biomedical applications; biodegradable hydrogel for controlled drug delivery systems etc.

Environmental Biotechnology

Laboratory for conservation of Endangered Animals has been set up.

DBT-NTPC joint initiative on carbon sequestration has been launched.

Technologies are ready for commercialization:

- Bioremediation of mine spoil dumps through integrated bitechnologies approach
- Ecological restoration of degraded ecosystems and wastelands
- Technology for mangrove aforestation through application of classical and biotechnological tools
- Biosensors ('Enzcol' and Enzstrip') for detection of organophosphorus pesticides
- Biotechnology of bioscrubber for removal of obnoxious odours from industrial emissions
- Oilzapper technology for bioremediation of crude oil spills and treatment of oily sludge
- Microbial treatment of cassava starch factory wastewater
- Chemo-biochemcial process for desulphurization of gaseous fuels and emissions
- Eco-technology for treatment textile dye wastewater
- Process for removal of acid dyes, direct dyes and reactive dyes from the spent dye bath

In addition few more technologies are in the final stage of development like paper and pulp waste treatment, tannery waster treatment eco-restoration, etc.

Food and Nutrition

The main emphasis was to develop novel food products and processes. Efforts focused on: a) Biotechnology research on food safety ; b) Development of rapid diagnostic kits for detection of various food born pathogens ; c) Development of analytical methods for detection of Genetically Modified foods and products

derived there from ; d) Utilization of agricultural residues for obtaining value added products and for developing low cost nutrient food supplements; e) Development of nutraceuticals/ health food supplements/ functional foods ; f) Development of bio additives (food colorants, flavours and preservatives); and g)Development of nutrient foods/food supplements.

Technology Packages developed: Technologies for Manufacture of Nutrient Supplements with products named as Soft Chikki, Suruchi Meetha, and Nutro-Crispo.

Technologies for Health Foods: Low Cholesterol Egg Powder, Rota Virus, Immune Colostrum for use as Baby Food Supplement, Large-Scale Production and Processing of Oyster Mushrooms, and Spirulina production (50kg/day).

Technologies for Fruit Juice Processing: Production and Application of Naringinase for Debittering of Citrus Juices, Enzymatic Application for Peeling, Deseeding and Fruit Juice Extraction, and Membrane Filtration Technology for Clarified Fruit Juices.

Technologies for Production of Natural Food Additives: Betalain (Colorant) Production from Cell Cultures of Beta vulgaris, and Production of Xanthan Gum by Fermentation.

Technologies on Oil and Fat Modification: Reduced Calorie Fat and Lyso Lecithin.

Technologies for Ensuring Food Quality/Safety: (a) Diagnostic Kits for rapid Detection of Food Borne Pathogens like E. coli 0157:H7, Listeria monocytogenes, Bacillus cereus, Staphylococcus aureus, Yersinia enterocolitica, Shigella, Salmonella, Clostridium botulinum, Norwalk and Norwalk like Viruses x) Rota Virus, Aspergillus flavus and Entamoeba histolytica and E. dispar. (b) Technologies for Rapid Detection of Aflatoxin B-1 and Rapid Detection of Pesticide Residues.

Technology for Biodegradable Food Packaging

Production of Chitosan Based Packaging Films

Other achievements:

- Various nutrient supplements has been developed utilizing indigenous agri-resources.
- Generated R&D leads in molecular probes for Quercetin, the common food toxicant; microbial bioassay method for detection of toxic metals in foods – estimation of chloride and mercury; technology for degradation of organochlorine pesticides by microbial culture; biosensor for detection of organophosphorus pesticides, ELISA detection kits for pesticides; and ELISA Kits for rapid detection of aflatoxin in foods.
- Towards detection of transgenic traits in food and food products, PCR assays have been developed to detect transgenic traits in Genetically Modified Foods with insect resistance Bt genes. These detection methods will also be addressing quarantine issues. In short an important step towards capacity building was undertaken.
- Out of 19 technologies developed- 8 technologies transferred and 3 technologies commercialized.
- Basic research activities resulted in 125 publications in reputed journals
- The programme has come up with protocols which will help ‘quarantine‘ and boost the export potential of quality processed foods from India.

Human resource development: An initiative was undertaken for strengthening of food biotechnology research & training in the country so as the students involved in research at B.Tech/M.Tech/M.Sc./M.Phil/Ph.D courses be benefited through advanced techniques/instruments/Curricula. Six institutions engaged in research and training in the area of food sciences/technology across the country have been strengthened.

Industrial Biotechnology

Emphasis has been given to support projects on development of product/process having industrial importance and by using environment friendly techniques. Research leads and technologies developed include:

Optimization of the production and application of industrially important enzymes:

- Development of keratinase, pullulanase, cellulase, laccase, solvent tolerant protease and salt tolerant alkaline protease.
- Preparation of endoglucanase, glucosidase and xylanase mixture for biological drinking of the mixed office paper-waste
- Development of a clone having α-amylase, glucoamylase and pullulanase genes for direct fermentation of starch to ethanol
- Technology optimization for production of urokinase having medical application.
- Development of cross-linked crystals of lipases
- Bioconversion by lipases
- Development of an improved protocol for crystallization of lipase from *Pseudomonas, Candida* and *Hemicola*.
- Optimization of the Two phase separation protocol for the easy purification of the serine protease from the detergent preparation 'Savinase'
- GA_3 (plant growth harmone) production at a rate of 10 mg/l/h from a selected mutant at NCL, Pune in 10 L fermenter between 48 and 72 h of fermentation time.
- Demonstration of the effectiveness of cellulase treatment in bio-finishing of denim at a pilot scale by NCL, Pune in collaboration with ATIRA.
- Production of extracellular protease and lipase by a solvent tolerant strain of *Pseudomonas aeruginosa* isolated at IIT, New Delhi

In the health sector focus was given on:

- Preparation of polymeric particles for the development of single dose vaccine formulation
- Complete sequencing of rifamycin gene cluster

- Generation of recombinant antibodies against HBsAg
- Development of nutritionally modified egg
- Development of a process for mass production of targeted delivery of antigens through nanoparticles using Sendai virus system.
- Development of a new molecule to detect antibodies to HIV-O subtype 'C'. Performance is comparable to other USFDA approved rapid test kits.
- Purification of the novel lipoxygenase inhibitor from *Penicillium frequentans.*
- Purification of the recombinant asparginase directly from the culture medium using a rapid two-step purification strategy, which resulted in a recovery of ~70% and a specific activity of ~80% of that of the native enzyme.
- Standardization of the entrapment of ovalbumin in hydrogel nanoparticles made up of cross-linked polyvinyl pyrrolidone.

Wastewater treatment: Designing and fabrication a pilot scale reactor for a novel high cell density process and its installation.

Biosafety & IPR

In order to enhance knowledge of IPR,12 seminars and conferences have been organized in various parts of the country for Indian scientists.
IPR awareness programme at National Law School of Indian University (NLSIU) has been supported.
DBT patent facilititations services resulted in filing of 144 patents, and 17 patents granted so far.

Biosafety: The Department had re-constituted the Review Committee on Genetic Manipulation (RCGM) to monitor the safety related aspects in respect of ongoing r-DNA projects & activities involving Genetically Engineered Organisms/ Hazardous organisms and controlled field experiments of transgenic crops, in compliance with the Rules-1989 of Environment (Protection) Act, 1986 (EPA-1986).

New policy decisions taken by RCGM in agriculture sector include:

- Standardization of protocol for conduct of multi-location field trials, data collection parameters, uniformity in the trial layout & data generation on Bt. cotton.
- A new monitoring mechanism to evaluate the Bt. cotton field trials and other transgenic crops by local Monitoring Teams headed & consist of Scientists from State Agricultural Universities and State Agricultural Departments.
- The Department in association with M/s. Biotech Consortium India Ltd. (BCIL), New Delhi had convened National Consultancy Seminars for Institutional Biosafety Committee (IBSC) members at 6 different places of the country.
- The preparations are underway to launch the "Biosafety" and "Indian GMO Research Information System (IGMORIS)" websites.

International Cooperation

So far about 70 joint projects have been implemented with following priorities.

Plant, Animal, Human and Microbial Genomics **:** The specific areas of collaboration include comparative genomics of pathogenic microbes, mapping of buffalo and silk worm genome, identification of genomics factors responsible for genetics disorders and functional genomics involving high throughput facilities such as microarrays and proteomics.

Basic Research in New Biology **:** Medium term collaboration in basic research for understanding molecular and genetic phenomena of pathogenesis in plants, animals and human, plant molecular biology, biosensor development, metabolic and tissue engineering are important through joint research and establishment of centres of excellence.

Product and Process Oriented Research: Collaboration in terms of scale up / field trials and validations through technology transfer involving both techniques and materials would also be taken up. Appropriate policy decisions for sharing of IPR and commercial gains would be worked out.

Indo-Denmark: The Indo-Danish joint Biotech Steering committee has been constituted. The major areas of collaborations include thematic workshops, one in each country every year co-ordinator on both sides. The first workshop on Stem Cell was held on 20-21 February 2006 at NCBS, Bangalore. Four proposals have been recommended for funding from both sides and another four are under consideration.

Indo-Finland: A Memorandum of Understanding (MOU) in the area of biotechnology has been signed between Finland and India. Five have been recommended for funding from both sides in the areas of vaccines: science related to vaccine development, delivery system, products and processes; diagnostics: development of new innovative diagnostics, using different technologies like e.g. FRET-technologies; drug development: computational biology related to drug development

Indo-France: Under the bilateral cooperation in biotechnology CNRS, France has agreed to support five Indian scientists for 3 months training in laboratories in France in the areas of pharmacogenomics, bioinformatics, nanobiotechnology, neurosciences and immunology.

Indo-FRG: Under the ongoing joint collaboration, six projects have been funded. A joint workshop on 'Recent advances in global research on Infectious Diseases' has been organized in Braunschweig, Germany on June 16-18, 2005, under the bilateral agreement.

Indo-UK: A MOU was signed in 1998 with the Biotechnology and Biological Sciences Research Council (BBSRC), Government of United Kingdom on co-operation in the field of biotechnology and biological sciences to facilitate broad opportunities for co-operation between the two countries thereby promoting the areas of research of mutual benefit to both countries. Five projects are being processed for funding from both sides.

*Indo-US:*A new agreement in Vision Research has been signed with Department of Health and Human Services, USA.

Contraceptive and Reproductive Health Research (CRHR) Programme: In the seventh meeting of the Indo-US CRHR Joint Working Group was held in Washington from August 22-23, 2005, two joint projects were recommended for funding.

CONRAD: An amendment to the agreement between the Department of Biotechnology and the Contraceptive Research & Development Programme (CONRAD) on co-operation in reproductive immunology has been signed between the two agencies and proposals are being requested under this programme.

SAARC: MEA has sanctioned project entitled "Study on available technologies and mechanisms of transfer in SAARC region in the areas of vaccines, diagnostics and plant materials" to be conducted by Biotech Consortium India Limited (BCIL) under SAARC.

Indo-Swiss: New Phase of Indo –Swiss cooperation began in 1999 with agriculture and environmentsla biotechnology as focus with eight collaborative projects and two large networks involving a total of 47 research groups and more than 120 researchers. In the field of environmental biotechnology, prototypes of biosensors for the simple and inexpensive detection of pesticides has been developed. New resistance genes against sucking pests (e.g. aphids and white flies) were identified and characterized. In addition, a synthetic gene encoding for an insecticidal toxin originally derived from *Bacillus thuringiensis* (*Bt*) has been developed. Two genes expected to enhance drought and cold tolerance of plants were introduced in chickpea and a number of putative transgenic lines became available at the end of the first programme phase. Already available transgenic lines are currently being multiplied to produce sufficient material for extensive biochemical, biosafety and physiological tests, such as dry-down experiments to assess drought tolerance. Bioremediation techniques has been developed for the restoration of pesticide-contaminated soils. Bacterial strains degrading hexachlorcyclohexane (HCH) and para-nitrophenol (PNP), the most important degradation product of the insecticide parathion, were identified. significant

insights were gained into the function of mycorrhizal fungi, free-living and plant-associated micro-organisms, with regard to soil quality and productivity. A large number of fungal and bacterial strains were screened in functional tests. The beneficial effects of individual strains and combinations were investigated up to the level of field trials. With regard to the improvement of fungal disease resistance in wheat, new sources of resistance genes against different fungal diseases has been successfully identified in wild relatives of wheat. The introduction of these genes in cultivated wheat through classical breeding methods was initiated. Molecular markers were developed for the resistance genes derived from the new sources and for other important genes from cultivated wheat.

Between 1999 and 2005, 60 scientists were involved in scientific long-term exchanges in Switzerland (total 182 months) and 16 scientific trainings took place in India (total 26 months).

The scientific productivity of the projects is underscored by numerous publications in international journals, including high-ranking periodicals such as “Nature Biotechnology”.

A total of 56 Ph. D theses were supported with about 11 patents granted.

Indo-Netherlands: An MoU for collaboration with institutes of higher studies in Netherlands has been signed by the Sepember 2005 including sandwich Ph.D programme. 3 projects are being funded.

Biotechnology for Societal Development

The main objectives of the programme has been to promote the use of biotechnological processes and tools for the benefit of entrepreneurs and create platform for employment generation among the target population, and diffusion of proven and field-tested technologies through demonstration, training and extension activities.

- Through pro-active role towards implementation of new programmes, the programme could extend the benefit to around 1,20,000 beneficiaries through the programmes on various income and employment generation activities.

- Low cost poly house construction for raising nursery-planting material has been developed for cultivation of medicinal and aromatic plants.
- Biovillage project implemented could benefit the farmers in biofertiliser production
- Preparation of liquid seaweed fertilizer and in raising Salvadora persica plants in the wasteland.
- Special programme has been implemented for earthquake victims in Gujarat covering activities viz. vermicompost, organic farming, livestock improvement, tissue culture and spirulina production.
- Awareness and training programmes on vermi-biotechnology implemented in ten states benefited more than 15000 farmers.
- These programmes could lead to entrepreneurship development in the village areas and job creation for the benefit of SC/ST target population.

Autonomous Institutions

National Institute of Immunology

The National Institute of Immunology (NII) was established in with the mandate of research in the defence mechanisms of the body to facilitate the development of innovative futuristic modalities of potential use in health care. During the plan period, a wide range of crucial issues in biological sciences have been addressed imaginatively and successfully by the Institute's scientists in major papers in high-impact journals.

Technological leads

The Institute has continued with the concept of 'end-to-end' research in the biosciences, linking the outcome of cutting-edge biological science at the bench with pursuit of the leads of potential utility thrown up by this research.

Four international patents and ten Indian patents based on such institutional research leads have been granted.

Technology transfer

A technology relating to novel molecules which inhibit tuberculosis, bacteria with the potential to be developed as anti-mycobacterial drugs is being explored under a memorandum of understanding with Astra Zeneca India, Bangalore, and Cadila, Ahmedabad (2006).

A technology developed for the high density culture of Vero cells using microcarriers in spinner flasks for high titer culture of an Indian strain of Japanese encephalitis virus (JEV) in such Vero cells, and for subsequent formalin inactivation of this JEV as a JEV vaccine has been transferred under a memorandum of agreement to International Panacea, New Delhi (2004).

International patents obtained

A recombinant birth-control vaccine designed from the subunit gonadotropin and recombinant luteinizing hormone has been developed. (Patent 3301488, Japan [2002]).

A vaccine delivery modality characterized by an antigen, a scavenger receptor ligand and a pharmaceutically acceptable adjuvant in order to increase and modify immune responses ahs been developed. (Patent 783892 B1, EPO [2002]).

A modality related to the use of peptides, individually or in combination, for treating and/or preventing angiogenesis has been developed as potential anticancer therapy, particularly for preventing metastasis (Patent 6492330 B1, USA [2002]).

A modality has been developed using combination of peptide analogs of somatostatin, VIP, bombesin, and Substance P to block the uncontrolled multiplication of cancer cells of the colon, rectum, lung, breast and kidney. (Patent 2197139, Canada [2003]).

Training and teaching: Doctoral program

NII conducts a residential research programme for undergraduates culminating in a doctoral degree. The Institute is academically affiliated to the Jawaharlal Nehru University for this programme. Every year 20-35 students are selected for this programme.

National Centre for Cell Science

The repository at the NCCS is the only repository that houses human and animal cells in India. The repository serves to receive, identify, maintain, store, cultivate and supply animal and human cell lines and hybridomas. During 10th plan, the repository has procured 34 new cell lines, which raised the total culture collection to 1161, of which about 334 are available for distribution to registered users. At present, approximately 510 researchers from 275 institutes have registered with NCCS

- The number of research fellows has increased from 46 to 102.

Technologies Developed & Transferred

- Bone marrow & cord blood haematopoietic stem cells cryopreservation: The centre has developed methodologies for cryopreservation and revival of bone marrow and cord blood cells. The technology has been transferred to Armed Forces Medical College, Pune. The diseases treated using this technology include Acute lymphocytic leukemia, Chronic myelogenous leukemia, Hodgkin's disease, Germ cell tumor etc. Thus far 4 umbilical cord blood, 2 bone marrow, 8 peripheral blood leukocyte (Autologous) and 2 peripheral blood leukocyte (allogenic) samples have been used with good success rate.
- Anti-malarials: a technology on “Use of selected amino acid – zinc complexes as anti-malarials” has been transferred to Shreya Life Sciences, Mumbai.

Technologies Under Negotiation

- A novel cassette for expression and purification of recombinant proteins” with Shanta Biotech, Hyderabad.
- A protocol for preparation aqueous extract of fenugreek seeds which induces hypoglycemic activity in diabetic mice, activates glucokinase in vivo, enhances insulin secretion and activates insulin signaling pathway in vitro” with Indus Biotech, Pune

Research highlights

- Isolation and characterization of human ovarian tumor stem cells. Further, nuclear-mitochondrial genomic profiling revealed a pattern of evolution in ovarian tumor stem cells
- A new conceptual framework for maintaining immune homeostasis
- HIV-1 Tat disrupts SATB1-HDAC1 complex to induce IL-2 and its receptor in T cells.
- SMAR1 mediates Cyclin D1 repression by recruitment of SIN3/HDAC1 complex.
- Impairment of mitochondrial complex I activity in HIV-1 induced T cell apoptosis.
- HIV-1 Tat protein interacts with NFkB enhancer sequence to modulate TAR independent viral gene expression
- Role of CD40 signaling in pathogenesis of leishmania
- IL-3 and GM-CSF blocks TNF-a-induced osteoclast differentiation by down-regulation of expression of TNF- receptor 1 and 2.
- Co-stimulation/danger signals mediating T cell responses.
- New conceptual advancement of neutrophil's role in initiating T-dependent immune response.
- Tumor suppressor SMAR1 activates p53.
- Control of V(D)J recombination through transcription and chromatin remodeling.
- The first report on identification of complement regulatory protein in Kaposi's sarcoma-associated herpesvirus and its mechanism of complement inactivation.
- A new principle of defining drug targets
- The centre has obtained 7 international projects from the international agencies such as the Wellcome Trust, UK and other collaborative programmes like British council, Indo-UK, Indo-French and NIH, USA AIDS International Training & Research programme.

Publications

Year	No. of publications
2000-2001	39
2001-2002	40
2002-2003	42
2003-2004	37
2004-2005	43
2005-2006	33

Patents

- Commercialized patent on “Use of selected amino acid-zinc complexes as anti-malarials 0409NF2003, US, 21/10/2003, 60/512,778 (#20050090480) ” to Shreya Life Science, Mumbai. The following 5 patents have been sealed.
- An Indian patent # AA No.453 "Improved nutrient composition useful for effective maintenance of hybridoma cell lines".
- A US patent # 6905710 “Pharmaceutical composition useful for inhibition of osteoclast formation and a process for the extraction of mussel hydrolysate from Indian green mussel (*Perna viridis*)".
- A US patent #10/747,671 “Novel molecules to develop drug for the treatment of osteoporosis.
- A US patent # 20050037434 “Monoclonal antibody against costimulatory molecule M150 and the process for preparation thereof”.
- A US patent #20050090480 “Use of selected amino acid-zinc complexes as anti-malarials”.

In addition, twelve patents have been filed recently (Six US and six Indian), while four others are under preparation.

Support services

The support services at NCCS continue to expand in order to meet the increasing demands from researchers of the centre. The experimental animal facility (EAF) supplies standardized laboratory animals such as rabbits, inbred mice and rats of high quality. In addition, the EAF also imparts training to freshers on animal handling and ethics of usage of animals for experimental

purposes. All the protocols employed for animal experimentation at the centre have been approved by the IACUC under the guidelines provided by the CPCSEA. The facility will continue to evolve and adapt to the constantly changing requirements of the Institute and its scientists, encourage active collaborations between its staff and the various research groups in the Institute for the successful conduct of experiments in laboratory animals.

Centre for DNA Fingerprinting and Diagnostics

Increase in the number of labs/groups in CDFD, so that there are at present 14 research groups, and one service group each for DNA fingerprinting and for Diagnostics

- Approximately 900 referred cases of DNA fingerprinting undertaken
- Diagnostic and genetic counseling services provided to 12,800 patients and families
- 18,300 newborn babies screened for inherited disorders of metabolism
- Publications in international peer-reviewed journals approximately 200, with an average impact factor of 3.79

Nine international patent applications filed, including those of

- Development of basmati rice-specific DNA markers
- Process and strains for arginine overproduction
- Process and strains for overproduction of plasmid DNA
- Novel markers for diagnosis of tuberculosis
- Release to farmers of three silkworm hybrids stocks
- Establishment of SUN Centre of Excellence in Medical Informatics
- Preparation of the draft DNA Profiling Bill-2006
- Amongst the institutions of its kind that are working in the various areas of molecular biology, the CDFD is unique in that it has been successfully involved both (i) in providing services, based on modern high-technology DNA-based methods, of direct benefit to the public, as well as (ii) in performing fundamental research of international standards in frontier areas of biological science.

National Brain Research Centre

The centre has networked 45 centres across the country and has initiated several multi-institutional, inter-disciplinary projects to further understanding of human brain. A digital library, which is made available to the scientists all over the country through electronic networks has been created.

The centre has established close collaboration with several institutions abroad, which is shared with the scientists at its networked centers.

The centre has received research grants from international agencies such as The Welcome Trust, UK, National Institutes of Health (NIH) and the Third World Academy of Science.

Trained manpower development in the field of neurosciences is fulfilled through initiation of M.Sc. programme in neurosciences and Ph. D. programme.

National Centre for Plant Genome Resource

The research programme aims to contribute to the understanding of the structure, expression and function of genes along with arrangement of genes on plant genomes and manipulation of plant genes / genomes to breed improved varieties of food and industrial crops for high yields and better quality products.

Ongoing transgenics construction for crop improvement:

Character	Crop(s)
(1) Enrichment of protein essential amino acid content in produce	(1) Potato, Cassava, Sweet Potato, Rice
(2) Reduction in toxin content in produce	(2) Tomato, Lathyrus, Spinach, Groundnut, Soybean
(3) Control of fruit ripening	(3) Tomato
(4) Higher root yield	(4) Carrot, Sweet Potato
(5) Drought tolerance	(5) Brassica, Chickpea, Rice
(6) Improved photosynthesis and thermal tolerance	(6) Rice
(7) Viral resistance	(7) Soybean, Tomato
(8) Hyper ... alkaloid producing cell lines	(8) Catharanthus

Technology transfer: The Centre has transferred two technologies to industry, and filed three applications for patents.

Currently about forty-five students are accommodated in the Ph. D. programme with an average input of ten per year of the centre.

Institute of Bioresource and Sustainable Development

Medicinal and Horticulture Plant Bioresources programme:

The main research focus continued to be on plant collection, taxonomical identification, *in vitro* propagation protocol development, prospecting of bioactive compounds for therapeutic uses and essential oils from the important medicinal and horticultural plant bioresources of Indo-Burma region.

From the studies of collection and evaluation of the plant wealth of the Indian region of Indo-Burma biodiversity Hotspot with special reference to Manipur, 100 indigenous medicinal and horticultural plant bioresources has been identified.

Bioresources database development programme:

A digitized database has been developed from secondary sources and categorized based on kingdom, phylum and common names. Currently 4085 records are available on the database and further data addition from primary and secondary sources is in progress.

Separate bioresources database development of family Zingiberaceae from primary sources with special reference to Manipur giving emphasis on morphological picturization, molecular characterization, bioactive compounds, traditional knowledge on economic and therapeutic uses is in progress. At present, 41 records have been added.

Microbial database of N.E.Region with special reference to Manipur compatible to “Inventory of Microbial Resources of India (MTCC)” has been designed for microbial data collected and identified by the institute and database development is in progress. At present, 80 cyanobacterial records have been added.

Technologies to rural entreprenours

Micropropagation protocol of medicinal Zingiberales viz., *Curcuma longa Cv. Lakadong*, Hedychium coronarium, Kaempferia galanga, K. rotunda, Zingiber *cassumunar, Z. officinale* and *Z. zerumbet*

Protocols for micropropogation and *in vitro* flowering of *Dendrobium transparens*.

Breeding and seed production technology of *Osteobrama belangeri* (local: *Pengba*)

Formulation of low cost concentrate fish feed from locally available biowastes/materials for *Osteobrama belangeri* (local: *Pengba*)

"Spirogel" – a cyanobacterial bioproduct of IBSD, Imphal for piles.

Rural technologies in the pipeline: Value added compost/vermicompost production from "*Phumdi*" (biowaste mostly available from Loktak and other lakes of Manipur) utilizing low cost locally available bamboo bins.

Standardized "*Hawaiza*r" (fermented soyabean product) production with value addition.

Micropropagation protocol for commercial production of disease free quality planting material of *Citrus* sp – *C.macroptera cv.Kwatha, C.aurantifolia cv. Kachai and C.reticulata cv. Khasi*

Novel nitrogen fixing bacteria from *Neptunia* sp. for wetland rice culture

Bacterial biofungicide for control of soil borne *Rhizoctonia solani* in tomato and *Macrophomina phaseolina* in french bean.

Publications:

30 Indian and 4 International publications

Bioresource Education and Training:

Genome Club : 200 (two hundred) students enrolled

Practical training to 8 (eight) fish bioentreprenuers/farmers for breeding and seed production of "*Pengba*" has been imparted.

Technology in production:

in vitro micropropagation for *Kaempferia/galanga* for large scale production of planting material for medicinal and aromatic plant growers of Manipur.

Institute of Life Sciences

The main areas of research concentrate are

(i) Molecular Biology of Aging

- Molecular Analysis of Age-dependent Alterations in the Activity of Transcription Factor NFkB and Androgen Receptor:
- Cloning, Sequencing and Characterization of Senescence Marker Protein (SMP 30)
- Identification, Cloning and Characterization of Age- Dependent Genes

(ii) Infectious Diseases (Cholera, Malaria and Filariasis)

(iii) Molecular Aspects of Cancer

(iv) Environmental Biotechnology

(v) Stress Biology

(vi) Molecular Microbiology (Plant Microbe Interaction)

Important scientific achievement includes characterization of promoters of iPPase, PSTI-II, 3'-non-translated β-F1 ATPase mRNA binding protein gene, cloning of the promoter of iPPase gene and establishing the location of its transcription start site. In kidney, an age dependent increase in cathepsin L expression was observed and so far a CREB transcription factor-binding site (-129 to –116 nt) has been identified. Up to -3 kb of SMP30 promoter and the promoter sequence has been analyzed on transcription factor data base TRANSFAC and identified a total of 11 nuclear factor binding sites within 1.7 kb upstream of transcription start site including five novel transcription binding sites have been identified.

It has been shown that non-toxigenic strains of *V. cholerae* O1 devoid of the core CTX genetic element and isolated from Brazil, Guam and Florida belong to multiple clones, and were clonally related to the non-toxigenic strains isolated from India. For the first time, the presence of the NAG-specific *stn* gene in *V. cholera*e O139 strains isolated from Alleppey, Kerala, Southern India was reported. A tetraplex PCR was developed for rapid detection of antibiotic resistance genes in *V. cholerae* SXT constins. Moreover, a point mutation at codon position 76 of *Pfcrt* gene, one of the factors responsible for chloroquine

resistance in malarial parasite, was reported in a number of blood samples by SSCP-PCR.

- The Plant Biotechnology group has shown that the submerged leaves of *Potamogeton nodosus* are basically endowed with a major function to generate H_2O_2, transport it to the upper leaf to act as a component in signaling cassette of gene expression; a phenomenon comparable to the development of systemic resistance by expression of PR genes in plants under pathogen attack. A significant light dependent expression of CAT-C gene in rice discernible in full-grown plant was suggested to be associated with photo-respiratory activity of the plant. It was also reported that there is no relationship between intracellular water status and proline accumulation in metal stressed plants.
- It has been demonstrated in *Mesorhizobium ciceri* that the gene encoding for an enzyme 3-phosphoglycerate dehydrogenase is the first enzyme which converts 3-phosphoglycerate to 3-phosphohydroxy pyruvate in the pathways for the synthesis of serine.
- Several thermophilic bacteria isolated from the hot springs situated in Orissa and Uttaranchal were identified as the new species of the genus *Bacillus, Thiomonas, Comamonas, Brevibacillus, Aneurinibacillus*.
- Institute is initiating work on leukemia to study effect of post translational modification on the proto oncogene EVI1, novel drug delivery systems and nanobiotecnology with an emphasis on their therapeutic applications in the field of cancer, and finer deletion analysis of Mirabilis Mosaic Virus full length transcript (MMV-Flt) promoter and completion of MMV-Flt promoter DNA shuffled library construction in suitable expression vector.
- Expansion of research buildings, construction of a modern animal house, green house and student hostel has also been initiated.

I & M Sector – Assistance for Technology Incubators, Pilot Projects and Biotechnology Parks

Biotechnology parks:

The department has supported Biotechnology Park, Lucknow, and five Biotechnology Incubation Centres one each at Hyderabad; Bangalore; Kochi; Chandigarh; and Solan.

Hyderabad: In centre provide common instrumentation facilities and bio-reactors, bio-processing instrumentation, down-stream processing & analytical instruments.

Bangalore: In centre would provide common instrumentation facilities.

Trivandrum: in centre would provide bio-processing & scale up facility, micro-propagation facility, plant extraction facility, analytical laboratory facility and utility support & design engineering and project supervision.

Chandigarh centre would provide extraction facility for medicinal and aromatic plants and agro/food testing and certification facility.

Solan centre would provide tissue culture hardening facilities, cultivation of temperate aromatic plants using biotechnological interventions, pilot cultivation of selected high value medicinal plants and post-harvest management of bio-fresh project and technology aided food processing.

The Biotechnology Park, Lucknow is set up on 8 acres of land provided by the Department of Science & Technology, Government of Uttar Pradesh. The thrust areas identified in the initial stage are Health Care, Agriculture, Environment, Industrial Application and Energy.

Industrial units like M/s. Shantha Biotechnics Ltd., Hyderabad; M/s. Green Park Bioherbs Industries, Delhi; STPI, Lucknow and M/s. M.S. Biological Pvt. Ltd., Lucknow has been allotted space and plots on lease agreement. Letters of Intent for plots on lease are received from M/s. Magna Marketing, Kanpur; M/s. Press India, Lucknow; M/s. Kanha Biotech, Lucknow; M/s. Rako Biotech, Lucknow and M/s. Kanjaria Associate, Lucknow.

Small Business Innovation Research Initiative (SBIRI)

The Department has launched “Small Business Innovation Research Initiative (SBIRI)” to boost public-private-partnership effort in the country. The SBIRI aims to strengthen those existing private industrial units whose product development is based on in-house innovative R&D; create opportunities for starting new technology-based or knowledge-based businesses by science entrepreneurs; stimulate technological innovation; use private industries as a source of innovation and enhancing greater public-private partnerships, and increase product commercialization in public-private sector derived from Government funded R&D. The SBIRI scheme operates in two phases viz. SBIRI Phase – I : The funding in this stage is being provided for highly innovative, early stage, pre-proof-of-concept research. Preference is given to proposals that address important national needs and SBIRI Phase – II: The funding in this stage is being provided for late development and commercialization of innovative research leads. Projects wherein proof-of-concept is already established and available with R&D institution or R&D unit of the industry are also eligible for direct phase-II support. The key objectives of the scheme are to provide support for early stage, pre-proof-of-concept research in biotechnology by industry, to support late stage development and commercialisation of new indigenous technologies particularly those related to societal needs in the healthcare, food and nutrition, agriculture and other sectors, to nurture and mentor innovative and emerging technologies/entrepreneurs, to assist new enterprises to forge appropriate linkages with academia and government.

The Agreement has been executed by the department with Biotech Consortia India Ltd., New Delhi who is acting as the Special Purpose Vehicle (SPV) / Fund Managers for smooth running of the scheme.

So far, 10 proposals has been recommended for the support and the process of execution of Agreement with these companies is on.

Summary of assessment of 10th Plan:

Reviewing the subject specific achievements in the aforesaid areas in detailed, the working group made the following observations and assessment.

- During the 10th plan 2002-2007, it appears that the total number of projects would exceed about 1500. Thus, a detailed assessment of the first four years of the plan i.e. 2002-2006 was considered for some trends and thrust assessment. So far, about 1225 projects have been implemented under various schemes costing about Rs.1161.57 crores. Most of the projects were below Rs.1.00 crore and majority of them are in the range of Rs.10-50 lakhs (**Annex-II&III**).
- Among the areas 39% (481) of the projects were in the area of agriculture and allied areas of biotechnology followed by 20% in medical biotechnology covering vaccines, diagnostics, human genetics and basic research; and programmes relevant to society (12% or 146 projects). Basic research and industrial biotechnology received equal thrust of 10% each. Bioresources and bioprospecting as well as capacity building programmes (biotech facilities and human resource development) recorded 5% and 4% share respectively **(Annexure-IV)**.
- In order to assess the performance of extramural research projects, the department was directed to make a representative and meaningful sample study.
- Such study conducted on 43% (519) of projects funded at the cost of Rs.222.26 crores involving 254 scientists reveal that 979 publications, 234 technologies developed, 94 technologies transferred with 24 products in pipeline for marketing and 17 projects commercialized. About 158 patents were filed and so far, 52 of them were granted. In other words, the funding has been very productive in the sense that cost versus total pooled output is about 1:7 and productivity per scientist funded versus total pooled output is about 1:6 (**annex-V&VI**). Therefore, the department was directed by the working group to develop a systematic assessment on these lines on a continuous basis to monitor the productivity of the programmes funded based on statistics of measurable indicators from time to time.

- Comparing the outcome versus the goals set for 10th plan elaborated in the beginning of this chapter (item 3.1), the group noted that:
  - Human resource development programmes would have been expanded beyond post -graduate teaching and training to meet the quality and numbers of Ph.Ds. The initiatives taken such as JRF programme, Ph.D and other national and overseas fellowships should be scaled-up. To ensure teaching and skilled development professional structures have to be put in place for graduate education, faculty upgradation and teachers /technicians training programmes.
  - The centre of excellence programme started by the department would definitely accelerate the pace of basic and translational research and therefore, it should be in a focused manner. However, to build a new capacity in life science research, schemes for departmental reengineering in universities/institutions should be taken up in a large scale.
  - There is an increasing trend to fund individual scientists-based programmes in the sectoral areas. While this trend is useful in promoting basic research, the goal of contributing to agriculture, medical, and industrial biotechnologies through research leads, prototypes and potential products would be hampered. Therefore, a balance has to be exercised. It is appropriate to promote competitive grant involving more than one scientist or implement programmes in network mode linking basic research with translational and innovative steps of biotechnology product development. Similarly, in areas of national importance, mission mode programmes should be taken up.
  - The Small Business Innovative Research Initiative (SBIRI) is an excellent step towards addressing the need for enhanced domestic industrial R&D capacity through public-private partnerships. While the same need to be expanded selectively, similar innovative programmes with large industries and R&D oriented national and international non-governmental and developmental agencies should be also implemented for public good product development through joint ventures or contract research. Further,

the DBT should setup translational research centres and world class facilities for research and services for bringing synergy.

- Biotechnology programmes for societal development tend to be similar that of R&D programmes except for certain demonstrations in traditional biotechnology. A key to success for this programme is to examine how latest knowledge based cost effective and affordable technologies reach the poor in rural areas especially the women. Innovative policy research for developing tailor-made biotechnologies and their out reach through rural development missionary of the government should be taken up as a strategy.
- The autonomous institutions of DBT have been carrying out excellent basic research, and human resource development. However, their contribution in product development is to be enhanced. Therefore, careful expansion of these institutions through translational research facilities needs to be taken up.
- The scientific management resources (personnel and physical) in the departmental headquarters since its inceptions are inadequate compared to the tasks and challenges to be addressed biotechnology in India. The same need to augmented through innovative outsourcing mechanisms for programme implementation and monitoring.

To sum up, Biotechnology caters tools, techniques, methods, products and processes across various developmental areas such as agriculture, health care, industry, and rural development. The establishment of Department of Biotechnology in 1986 as provided needed importance and today, a reasonably strong infrastructure, research base, expertise, regulatory systems, and industry structure is available. Time is ripe now for major investments through innovative programmes, partnerships, networks, institutional arrangement and mission mode projects to make India competitive globally meeting both domestic and export requirements.

3. RECOMMENDATIONS FOR 11TH PLAN (2007-2012)

3.1 Approach

The working group reviewed and assessed the investments, achievements, constraints and lessons learnt in the 10th plan. The group also examined in detail the national biotech strategy prepared by the department. Since the final version of the biotech strategy is a result of year long consultations and comments from several stakeholders including scientists, educationists, regulators, representatives of society, industry and others and reflects their consensus, it has been observed that it may be integrated appropriately in the 11th plan recommendations of this report with additional inputs of the working group and its sub-committees appointed. The major directives given by the steering group on Science and Technology, Planning Commission and that of DBT Scientific Advisory Committee (overseas) were also adequately reflected.

The vision should be to create such tools and technologies that address the problems of the largest section of the society, provide products and services at affordable prices and make India globally competitive in the emerging bio-economy. Developing a strong biotechnology industry and technology diffusion capacity is critical to fulfill this vision. The advancement of biotech as a successful industry confronts many challenges related to research and development, creation of investment capital, technology transfer and technology absorption, patentability and intellectual property, affordability in pricing, regulatory issues and public confidence and tailor made human resource related to all these aspects. Central to societal impact are two key factors: affordability and accessibility to the products of biotechnology. Policies that foster a balance between sustaining innovation and facilitating technology diffusion need to be put in place.

Several social concerns such as conserving bioresources and ensuring safety of products and processes need to be addressed. Government and industry have to

play a dual role to advance the benefits of modern biotechnology, and educate and protect the interests of the public. Wide utilization of new technologies would require clear demonstration of the added value, to all stakeholders.

The efforts in the last two decades have directed notable interventions in the public and private sectors to foster life sciences and biotechnology. There has been substantial progress in terms of support for R&D, human resource reflected in the form of outstanding contributions through high impact publications, and potential research leads and infrastructure development. Now that critical mass of highly qualified scientists and expertise is fully in place, it is feasible to focus on innovation. Further, with the introduction of the product patent regime it is imperative to achieve higher levels of innovation in order to be globally competitive. The challenge now is to join the global biotech league.

This will require larger investments and an effective functioning of the innovation pathways. Capturing new opportunities and the potential economic, environmental, health and social benefits will challenge government policy, public awareness as well as the educational, scientific, technological, legal and institutional framework. In all these areas, we aim to introduce global best practices and the highest ethical standards.

The issue of access to products arising from biotechnology research in both medicine and agriculture is of paramount importance. Therefore, there should be adequate support for public good research designed to reach the unreached in terms of technology empowerment. Both “public good” and “for profit” research should become mutually reinforcing. Public institutions and industry both have an important role in the process.

The success of this strategy over the next decade will be reflected through (i) greater enrolment of students in life sciences; (ii) increase in the number of persons with higher levels of education and skill in life sciences and biotechnology; (iii) greater contribution of research to economic and social

development (iv) increased contribution of university system to basic life science as well as translational biotechnology research (v) strong international partnerships linked to national goals. (vi) increased number of new companies and increase in SME's engaged in R&D, and finally, (vii) the Indian biotech industry generating revenue to the tune of at least US $ 10 billion annually and creating substantially more jobs by 2010.

The recommendations are made on cross cutting issues such as human resource development, academic and industry interface, infrastructure development, lab and manufacturing, promotion of industry and trade, biotechnology parks and incubators, regulatory mechanisms, public communication and participation. This policy also aims to chalk out the path of progress in sectors such as agriculture and food biotechnology, industrial biotechnology, medical biotechnology, bio-engineering, nano-biotechnology, bio-informatics and IT enabled biotechnology, bio-resources, environment, intellectual property & patent law, international cooperation and, of course, in meeting the basic needs of the society.

Recommendations

3.2 Promotion of Innovation

The basic goal of the Biotechnology in future should be to facilitate emergence of an ecosystem that promotes and sustains innovation. The main components of an innovation system would be availability of required numbers of world class scientists and professionals relevant to R&D; a well trained, skilled work force for industry; adequate infrastructure and providing a fiscal, regulatory and legal framework that encourages risk taking by investors.

Innovative capacity determines the ability of a system to create a continuing pipeline of new products and processes. Innovation covers knowledge creation (research and development), knowledge diffusion (education and training), and knowledge application (commercialization).

Innovation is measured in terms of external/ domestic patent application; human capital devoted to R&D; government expenditure on R&D proportionate to country's GDP; business-funded expenditure on R&D; indigenous technologies standardized, demonstrated, and transferred to industry for commercialization; and the number of spin off companies created.

Clear government policies for promotion of innovation and commercialization of knowledge would propel the growth of biotech sector. Considering the proposals in biotechnology strategy of the department, the working group endorsed the following:

Establishment of Technology Management System for Biotechnologies

A key component of an innovation system is smooth and seamless transfer of knowledge and people between universities, institutes and industries. A technology management network that is locally linked to stronger central resources is an essential and currently, the missing link. The proposed Biotech Strategy makes an attempt to address this issue.

It is recommended to create ten national / regional technology transfer cells (TTC) over the next five years to provide high-caliber, specialized and comprehensive technology transfer services; evaluating technology and identifying potential commercial uses; developing and executing commercialization and intellectual property protection strategies identifying appropriate potential licensees; negotiating a wide variety of licenses; and monitoring the licensing arrangements. Each TTC would service a cluster of institutions in a region or a large city. The best practices for effective technology transfer shall be bench marked.

Continuation of setting up of Centers of Excellence for creation of innovative technologies in specific thematic areas

Innovation in Biotechnology requires teams working on defined thematic areas coordinated by outstanding leaders. The scheme for establishment of Centres of Excellence (CoEs) within existing universities and medical, agriculture and allied colleges, around innovative leaders should be continue. The CoEs could be in the form of technology development centers, clinical academic centers or basic research centers in life sciences. COEs are expected to be goal oriented, use a mix of product relevant discovery science and aim at product and process development and promote emerging technologies. Interdisciplinary cross talk would be promoted and collaborations with industry encouraged. The COEs would be established in existing institutes but preferably outside the existing department structures to facilitate translational focus and relationship with multiple departments. The research programmes would be linked with Ph.D programmes. Critical mass of young scientists around a leader is expected to be developed through involvement of the existing scientists and infusion of fresh young faculty.

Key characteristics of Centers of Excellence are acknowledged leadership; administrative independence; financial flexibility and performance assessment. Performance of the COEs will be judged by the following criteria. While considering further support:

Publications: The major criteria will be the quality of publications. A journal impact factor of at least 5 or above would be an essential minimum

Patents **-** The major consideration will be (a) patents (both Indian and abroad) (b) technologies transferred to the industries, (c) publications, (d) progress towards possible product or process development, and (e) innovation support to industry.

The major criteria in order of preference may be (a) quality publications (b) knowledge that has major impact on assessment of application potential (c) patents (both Indian and aboard) (d) proof of principle or otherwise to facilitate development of interventions, products or processes (e) technologies transferred to the industries

Upto 50 centers of excellence may be set up during the next 5-years and each should be provided with 3-5 new research faculty; Physical infrastructure; Equipments; Minimum consumables and contingency expenses for the research programmes; Ph.D, Post-doc fellowships; and Support for road map building meetings.

Creation of a pool of contract jobs for Scientists in CoEs

Each CoE requires a critical mass of high quality interdisciplinary researchers to succeed in translation of knowledge into solutions for major problems. The critical expertise is often either lacking in some specific areas or available too far away. The present experience is that the University departments and research institutes do not have the adequate number of faculties working in focused thematic areas. The Universities are not in a position to create new jobs. There is a need to induct 3-5 new scientists each in those CoEs so that an interdisciplinary team can be created. This requires creation of a central pool of high caliber scientists which can be effectively deployed in to meet the requirement of the CoEs. These scientists will be selected through a set of rigid selection criteria by a national committee and appointed on five yearly contracts. They will be subjected to continuous review and the contract would be extended beyond the five year term for only those who deliver outstanding results. This will also help in preventing brain drain and attracting overseas scientists of Indian origin.

Creating Regional Biotech Clusters

Effective communication among science agencies, state governments, research institutions, Universities and industries will be promoted through regional research driven clusters for sharing expertise, resources and infrastructure.

Biotech cluster concept may be promoted. Existing clusters may be examined with respect to gaps for strengthening. Potential sites for new biotech clusters in Punjab, Delhi, Haryana, West Bengal and Gujarat.

The working group endorsed the proposal of DBT to establish the agri-food biotechnology cluster in Punjab to begin with which would have linkages between Bioprocessing Unit and Biotechnology Park as well as the Punjab Agriculture University, Ludhiana.

3.3 Industrial promotion and development

Programmes which are likely to culminate to a **"lead**" or a "**product**" should essentially have industry involvement from day 0 itself.

The industrial R&D units (irrespective of company being small, medium or large) should also be permitted to compete for the **R&D grants** on the research priorities/merits. However, a partner from a national Institute should be a must.

Criteria should be laid on the quality and competence in the number of employees in a specific R&D unit rather than the total strength of the company.

DBT needs to strengthen the IPR and technology transfer mechanisms with the involvement of appropriate experts to address the relevant issues.

Innovation in biotechnology occurs largely in small and medium companies. There is a need to synergize public sector creativity with private sector management excellence to create world class technologies through a variety of public-private partnership models. Improved availability of funding for early, pre-proof of concept research, including public support is critical and currently lacking.

A major policy goal is to promote R&D in SME's and provide an enabling mechanism to build in-company technology capabilities. The key mechanisms will be ensuring participation of SME's scientists while developing technology strategies nationally, increased public contribution for early stage, high risk research for SME's, increase access of SME scientists to public institute facilities and vice–versa, new models of partnership with large industry to pursue path

breaking technology initiatives and building greater flexibility in public institutes to be able to work with industry.

Three specific recommendations to achieve above goals are .

Continuation and Expansion of Small Business Innovation Research Initiative: There shall be major expansion in the Small Business Innovation Resource Initiative (SBIRI) scheme currently operated by DBT and widely acclaimed in the country by SME's. A Special Purpose Vehicle (SPV) may be created for managing this scheme professionally.

BIRAP: A Biotechnology Industry Research Assistance Programme (BIRAP) may be put in place for monitoring, supporting and nurturing R&D in small and medium biotechnology companies.

Enabling Public Institutions to Work with Industry: Public funded successful R&D institutes may be allowed and supported to establish not for profit companies to facilitate collaborative work with industry. In these facilities, industry scientists can pursue innovative projects for defined periods on user charge basis providing access to centralized equipments and scientific consultations.

Public Partnership with Large Industries: Public partnership with large scale companies may be encouraged and supported in areas that are vital to the national development from a scientific, economic or social perspective and focused on development of technologies and products. The company would then have preferential access to the intellectual property generated in such jointly funded projects.

Access to Infrastructure, Major Equipment and Facilities: Cutting edge research in biotechnology requires creation of state of the art infrastructure. Creation of large animal house facilities with GMP for testing candidate vaccines and biotherapeutics, DNA and stem cell banking facilities, depositories of biological

materials, testing facilities for GMO/ LMO and validated laboratory facilities to support major clinical trials will be taken up on priority.

The public investment in major equipments required for research and development in biotechnology may be so directed as to maximize access not only within the institution but also for other institutions and industry, both in public and private sectors for optimum utilization of resources.

Biotech Parks and Incubators: Biotechnology parks provide a viable mechanism for promoting upcoming biotech companies to start new ventures and achieve early stage value enhancement of technology. The Department of Biotechnology may promote establishment of Biotech parks and incubators as a part of biotech clusters, essentially through public private partnerships.

Establishment of incubators by consortia of small and medium enterprises shall be encouraged and supported.

3.4 Regulation and Biosafety

It is important that biotechnology is used for the social benefit and economic development of India. The policy goal is to ensure that research and application in biotechnology is guided by a process of decision-making that safeguards environmental, human, animal and plant health. A scientific, rigorous, transparent, efficient, predictable, and consistent regulatory mechanism for biosafety evaluation and release system/protocol is an essential for achieving this objective. The regulatory mechanisms need to be rationalized, streamlined, simplified and made transparent. The specific recommendations are:

Establishment of National Biotech Regulatory Authority: A competent single National Biotechnology Regulatory Authority may be established with separate divisions for agricultural products / transgenic crops, pharmaceuticals / drugs and industrial products; and transgenic food / feed and transgenic animal / aqua culture. The authority is to be governed by an independent administrative structure under the chairman**.**

The Authority will have adequate scientific and financial resources to execute its responsibilities in a professional manner.
This step is critical to achieve trust and confidence of public, professionals and industry on biotechnology products and will send a positive signal globally.

Strengthening existing regulatory procedures: The recommendations of the Swaminathan Committee (2004) on regulation of agri-biotech products and of the Mashelkar Committee (2004) on recombinant pharma products should be implemented, as and when these reports are accepted by the concerned ministries/departments.
All existing guidelines may be updated and made consistent with the recommendations of the Swaminathan and Mashelkar committees. New guidelines on transgenic research and product/process development in crop, animal, aqua culture, food, phyto-pharma and environmental application may be put in place by the concerned ministries/departments.
A mechanism for in-service training of all professionals, engaged in the regulatory process may be established/ strengthened by the Department of Biotechnology in close collaboration with other concerned departments and institutions. Regulatory policies and procedures may be evolved for stem cell research and medical devices through inter agency consultation.

Build professionalism and competence: The Department of Biotechnology and other concerned funding agencies may take steps to strengthen capacity in the country for scientific risk assessment & risk management of transgenic crops, foster international linkages; support biosafety research; obtain and review feedback from different stakeholders; and provide support to industry and R&D institutions.
Measures may be taken to build professionalism and competence in all agencies involved with regulation of biotechnology products.

Vigorous efforts may be made to promote acceptance of the Indian regulatory decisions by other trading countries.

Biosafety Research: Proactive *ex-ante* and *post-ante* biosafety research studies may be undertaken for understanding the food and environmental safety of GM crops and foods derived thereof for generating scientific information required for the regulatory authorities for informed decision making.

The GM crops and the foods derived thereof have significant socio-economic impact on the consumers and farmers. Therefore, research on network mode in socio-economic impact of gene technologies in agriculture need to be undertaken.

3.5 New Institutions and Major Centres

It is recommended to setup the following new autonomous institutes under DBT in areas where currently there is no existing appropriate structure.

Agriculture and Food Technology Cluster would be promoted in Punjab, which would have an Institute of Agrifood Biotechnology, a centre for bioprocessing as a commercial entity and a Biotech Park.

Institute of stem cell research: No existing Institute in the country has sufficient scientific expertise in Stem Cell Research. An Institute of stem cell research, with strengths in developmental biology as well as translational research, with the ability to produce and market cell lines and development of therapeutic is an urgent need

Institute of Animal Biotechnology: This has been recommended by SAC – PM meeting as a priority, given the economic and employment potential of the sector

Institute of Seribiotechnology: DBT may take over the existing Seri biotech Research Laboratory of Central Silk Board, as proposed by them. This will be developed as a world class technology centre for work on silkworm and allied insects, host plants and silk processing.

Translational centers especially designed for technology development in Health, Agriculture and Food sectors. These must be strategically located within or in the vicinity of a University Campus with effective industry linkages.

Molecular medicine units focused on chronic diseases biology may be supported as independent centers in existing institutions

Upgradation / reengineering of existing Departments in the universities etc.

Plant Health Research Institute to work on basic and translational research in the area of plant disease /pest resistance, molecular breeding, transgenics, commodity health management, natural products and agro-ecosystem research.

UNESCO centre for education and research.

Departments of world class quality, doing both education and research may be created through upgradation of existing promising but small departments by supporting infrastructure and faculty, and creating new research agenda. These will focus on some critical areas, which these departments are currently lacking altogether or are of poor quality. These would be in the areas of: i) Integrated Chemical Engineering and Biology; ii) Industrial Microbiology; (iii) Infectious disease biology; (iv) Regulatory Science; (v) Chronic Disease Biology linked to heart and neurological diseases and diabetes; (vi) Environment Biotechnology; (vii) Marine Biotechnology; (viii) Integrated Food Science and Nutrition; (ix) Clinical research and Clinical informatics.

The focus will be on university departments and medical schools. Programme support will be given to 25 university Life Science Departments.

3.6 Human Resource Development

The policy goal for the next decade is to facilitate the availability of high quality scientific and technical human resource in all disciplines relevant to the life science and biotechnology sector. Large talent pools are required in multiple scientific disciplines such as molecular and cell biology, physiology, genetics, chemistry, biochemistry, physics, engineering, biomechanics, bioprocessing, bioinformatics, clinical science, agriculture, microbiology, technology transfer & commercialization, bioentreprise & biofinancing and intellectual property rights management. Product and process development are inter-disciplinary in nature and deficiencies in specific areas may weaken the whole sector. An important challenge then is to create an effective interface across disciplines.

Taking note of the Human resource development programmes of DBT since its establishment in 1986, the working group is of the view that there is an urgent need to scale-up the programme as well as improve the quality of course curriculum, teaching, skilled development and industrial involvement at all levels. Three types of interventions could be augmenting number of Ph.D in Life Sciences, promotion of translational research capacity in agriculture and health care, and redesigning the fellowships and awards programmes.

Towards these goals, the following specific recommendations were made besides endorsing certain proposals envisaged in the biotechnology strategy document. These recommendations in the order of priority are as follows:

Establishment of National Council on Biotechnology education & training: A National Biotechnology Council may be created to formulate model undergraduate and postgraduate curricula in life sciences and in translational science keeping in view, future needs. The said curricula must address the underlying need for inter-disciplinary education and the appropriate stage for

introducing experimental work. The school life science curriculum also needs to be improved to make it more engaging and relevant.

Human Resource Need assessment: Reliable estimates of human resource availability for the next 10 years are required. Expert consensus indicates that there is adequate enrollment currently at the post-graduate and under-graduate levels, however the quality is inconsistent. Therefore, a systematic need assessment study for the next ten years may be carried out including annual monitoring and moderation of the data. Since, it involves collection, compilation and statistical analysis of many variables such as number of institutions, companies, areas of activity and so on, it is recommended that special efforts may made to collaborate with organizations doing similar task at international level such as OECD, UNESCO and other national organizations so that the data is comparable and harmonized.

Curriculum development: Course curricula should be reviewed and improved in consultation with educational, industry and research establishments and standard e-learning training modules and kits may be developed for specific skill areas such as IPR, regulations, bioenterprise management, etc. The model curriculum may be reviewed and adopted every three years.

Hands on exposure to M.Sc. biotechnology students will be enhanced through an extended industry internship as well as through short-term placements at CSIR and other appropriate national Institutes.

Dual degree programs in biotechnology that include regulatory matters, IPR and bio-enterprise management should be encouraged and supported.

Technician training programmes: Training of high quality technicians and technologists in skills required by the industry may be major emphasis by establishing regional training centers. While the diploma programme should provide general technician skills in biotechnology, the postgraduate diploma programmes should address specific skills, such as, biomanufacturing

techniques, life science laboratory instrumentation, micro propagation technology, medical technologies, etc.

An accreditation mechanism Quality improvement: An accreditation mechanism may be put in place with the help of Accreditation Agency such as NAAC, NBA etc. for ensuring minimum standard of education and training at the post graduate and. B.Tech programme. Baseline requirements for teaching and laboratory infrastructure may be specified and enforced.

Creating and sustaining the interest in Biotechnology at secondary level: The goal is to help teachers renew their interest in life sciences and biotechnology as researchers, connect them with the life science faculty in universities, IITs and other national institutions, and enhance the quality of teaching across the country

Teacher's training: Mid-career teachers' training programs may be taken up by creating regional teachers' training centers and Biotechnology staff college. These courses may be recognized as refresher courses for the purpose of career enhancement.

College Teachers' Vacation Research (COTVAR) Programme: 100 Fellowships per year should be provided to college teachers teaching life sciences and biotechnology to conduct research alongside a DBT-funded researcher or research team during summer / winter vacations for up to four weeks. This scheme may be operated through science academies such as The Indian Academy of Sciences, Bangalore and the National Academy of Sciences, Allahabad with 50 fellowships each.

Attracting talent to life science and biotechnology: Fewer students are developing interest in science education including in life sciences and biotechnology. Further, the existing educational system at graduate level in private and public sector does not meet the quality and skill requirements for employment in

industry, public sector organizations etc. The under-graduates are the future for all tasks required for promoting biotechnology in the country.

Therefore, it is endorsed by the working group that DBT may support twenty colleges in as many cities to emerge as 'Star Colleges' teaching modern biology at the undergraduate level. Expertise of the local university, institutions and industry may be pooled to enrich these courses. This may increase appeal of life sciences to students.

Bright students may be attracted to take up careers in biology and biotechnology through special scholarships. Summer assignments at academic institutions, Industry and research laboratories may be introduced at the school level to create interest in life sciences.

1000 scholarships on merit -*cum means,* may be given annually to undergraduate students pursuing Life Sciences and Biotechnology.

At present, twenty-five biology scholarships are awarded to top students in Biology/Biotechnology at the CBSE 10 +2 level examination. This programme may be extended to select 2 candidates from each state board and number of fellowships may be increased to 75 per year.

Women scientists may be encouraged to take up careers in biotechnology. Service conditions may be liberalized for women to be able to return to research/academics after maternity breaks.

Strengthening teaching at tertiary level (university) by stronger linkage with R&D:

Strengthening R&D in life sciences and biotechnology in the universities and other teaching institutes may be accorded high priority. This is considered important for improving the quality of education and providing exposure to new technologies for students at various levels. Specific mechanisms to achieve the goal may include:

Creation of inter-disciplinary centres of excellence in R&D linked to Ph. D programs with world class infrastructure in key areas. In this scheme relevant scientists and institutes should form a network around a defined thematic area and admit a specified number of Ph.D. students to choose their research topics

within the defined area. The network would receive core support as an incentive. This may improve quality of Ph.D's, and build expertise in niche areas.

In service personnel may be encouraged to go in for PhD through provision of special incentives

Program support mode of funding may be given to encourage inter-departmental networking

Visiting professorship and creation of industry sponsored chairs in partnership with the Department of Biotechnology to supported.

Teaching in IITs and medical colleges: IITs, the leaders in the country in engineering education, have now started B.Tech. and M.Tech. courses in biotechnology. However, institutional capacity in teaching faculty and laboratories in biology and capability in product conceptualization and development need to be strengthened to add value to these courses and make research more innovative. DBT may work with the Ministry of Human Resource Development to create the additional capacity in IIT's and others leading engineering institutes. Creation of health technology centers at IITs with focus on product development may be encouraged. Medical biotechnology may be introduced as a subject in MBBS curriculum to provide a research flavour to encourage clinicians into active research.

Support MD./ Ph.D Programmes for Human Resource in Medical Research: MBBS and MD's may be encouraged to do M.Sc./ Ph.D. in clinical sciences oriented towards industry and Ph.D. medical biology focused on disease biology. Translation of science into workable interventions and technologies in the heath sector requires a large pool of MBBS/MD- Ph.D's. Medical colleges by themselves and as networks with basic science institutes, may be assisted in terms of restructuring their research programmes, build translational research centres, and run appropriately designed Ph.D programmes for medical graduates. Career paths for physician scientists will be improved by creating a critical pool of full time research jobs. The MBBS/MD/MS programmes could also

be integrated with PhD in medical biology so that the overall duration does not go up very much.

Creating science & technology leaders for the industry: The number of Ph.D fellowships offered by the Department of Biotechnology need to be increased in phases to 500 per annum. This will supply the needed human resource for CoEs.
Public-private partnerships may be encouraged in Ph.D programs through creation of 'Bio-edu-Grid'- a network of universities, institutes and industries facilitating pooling of resources.
In service personnel may be encouraged to go in for Ph.D through provision of special incentives.
Masters degree level professionals in industry may be encouraged to undertake Ph.D. programs while retaining their jobs through industry-university tie-ups.
Existing DBT overseas fellowship programme may be expanded. In addition to the general scheme at present, overseas training in niche areas of great opportunity and where expertise is deficient within the country may be promoted.

Arresting and reversing brain drain: The number of postdoctoral fellowships offered by the Department of Biotechnology may be increased incrementally to 300 per annum. The amount of fellowship may be enhanced to be close to the entry level remuneration of the scientists and faculty members of the host institute.
Outstanding young investigator grants' in biotechnology may be introduced. This will provide a package including salary support, research grant, equipment and opportunities to attend national and international conferences. The salary support under the scheme may be at par with that of entry-level faculty positions.
Information on availability of positions in education/research establishments and industries may be provided on a website to facilitate employment of scientists with specific skills at appropriate positions.
A database of Indian scientists working in different areas of biotechnology within and outside the country may be created to utilize the expertise appropriately.

Enabling working conditions for scientists to undertake industry oriented research: Lateral mobility of scientific personnel: Scientists working at universities and research institutions may be allowed to work in industries for commercialization of their research efforts. This could be in the form of secondment or consultancy with industry or by a sabbatical for three years during the working life of scientists.

Dual/adjunct faculty positions: Researchers working in university/research institutions may be allowed to hold positions in the industry and vice-versa

Joint salary support: Faculty employed in academic institutions may be allowed to hold positions for a period of time in which their salary is contributed both by the industry and the academic institution on a mutually agreed basis. (Such an arrangement may work well only if the teaching requirements of the academic institutions are made obligatory).

Rapid travel grants: Rapid travel grants scheme for approval within two weeks for young scientists to interact with mentors and industry collaborators would be initiated. Travel support for attending national and international conferences shall be liberalized.

Institute Innovation grants: such grants to academic researchers to develop their concepts into patentable and more importantly licensable technologies may be provided. These grants may be utilized for the purpose of providing additional infrastructure and manpower, patenting costs as well as costs related to proof of concept studies. This scheme will be introduced in institutions with a critical mass of scientists.

Strengthening teaching programes in emerging areas: Start a few need based teaching programmes in biosafety, IPR and regulatory measures, food biotechnology, pharmaceutical biotechnology, bioenterprise management, industrial microbiology.

The specialized training courses in upcoming areas like RNAi, stem cell, nanobiotechnology may be supported.

Biotechnology overseas associateship programme may be extended for advanced training of young scientists in niche areas in biotechnology**.** Suggestive areas are (i) medical genetics (ii) stem cell research (iii) nanobiotechnology (iv) transgenic animal models (v) agriculture biotechnology.

New Award

It is recommend to institute a few new awards such as Ramalingaswamy fellowship, emeritus scientist fellowship, national fellowship to encourage Indian Scientists from all over the world to take up scientific positions in India and recognize outstanding contributions of Indian scientists.

3.7 Biotech Infrastructure Development and Manufacturing

Biotech Facilities

The strength of a biotechnology company lies in upscaling a number of proven technologies - diagnostics, vaccines, products, and processes - for fine-tuning and large-scale production. While Indian industry is strong in product development and marketing for commercial benefits, biotechnology in India still lacks the infrastructure for R&D in molecular modeling, protein engineering, drug designing, immunological studies, pre-clinical studies, clinical trials, etc.

The concept of contract research organizations (CROs), contract manufacturing organizations (CMOs), contract packagers, lab services providers etc., is steadily taking shape in India and must be strongly encouraged as it is impractical for companies to do it all by themselves. Endorsing certain proposals in the biotechnology strategy, the working group recommended the following:

Private participation in infrastructure development like roads, water supply and effluent treatment may be encouraged when building biotech clusters, service

facilities like genome sequencing, large animal facility for clinical trial, agricultural biotechnology translational centre etc.

Large Facility Interagency Capital Fund: Access to cutting edge research facilities is critical to the success of product development programmes. This requires large investments. Model best suited for this is the setting up of an Interagency Capital Fund with involvement of all stake holders including private sector.

Depositories of biological materials may be created in partnership with industry on IDA model for agriculturally and medically important organisms, plasmids, cosmids and constructs of special nature.

State-of-the-art large animal house facilities with GLP may be created for testing candidate vaccines and biotherapeutics.

Testing facilities may be created for GMOs/LMOs. Facilities for testing GM crops and GM foods may also be set-up. This may help regulatory studies to establish biosafety of transgenic plants.

DNA & stem banking facilities, validation laboratories facilities to support major clinical trials, and clinical informatics centers may be supported.

Access may be improved to major equipment in public sector to private sector scientists and the human resource required for this purpose may be provided.

Joint sector activities may also be encouraged in the following areas:

- Establishment of clinical trial centers for the potential candidate vaccines (eg.- HIV/AIDS, Typhoid, Influenza, Dengue, JE etc.).
- Provide basic infrastructure facilities to Medical Colleges to conduct health research relevant to the country. One-time grant for strengthening infrastructure in biomedical research in certain medical colleges.
- Infrastructural facilities for stem cell research and linkage with translational research centres for its applications.
- Establishment of Virus Research Centres with appropriate facilities (P3/P4) for addressing various issues related to important viral diseases – basic

biology, molecular characterization, diagnostics, vaccine, drug development etc.

- Creation of state-of-the-art facilities for development of *in vitro* assay systems for microbicides and other anti-microbials.
- Establishing centers for testing herbal products (other compounds) for antiviral activity.
- High energy photon sources for structural biology work with emphasis on new inhibitor design/ drug development.
- Few transgenic knockout animal facilities on sharing model around the biotech clusters and major institutions may be setup to facilitate basic health research and drug discovery.
- National Facilities for genomic and proteomic analyses- strictly on the efficient service basis.
- Establishing facilities in collaboration with Biotech industries to produce simple, easy to use diagnostic assays/reagents for common viral infections like congenital infections (rubella and cytomegaloviruses), upper respiratory tract infections, meningitis and encephalitis, rotavirus, chickenpox etc.
- Augment DNA finger printing facilities in linkage with CDFD and forensic laboratories both for humans and plants.
- Facilities for biomaterials, tissue engineering, medical devices, implants, bio-instrumentation, testing facilities for devices, implants and instruments.
- A National Repository or Library of Natural Products may be created. The same will accelerate the drug discovery research from natural sources.
- An open-access Sepbox Facility may be created for fast processing of large reservoir of natural products in separation and fractionation of samples. It will help in exploring the medicinal plants diversity for drug discovery research.
- A DNA Micro-array and biomarker Facility for Medicinal Plants and Herbal Preparations may be set up to help in drug development research. This will be useful in screening medicinal plants and herbal preparation and in evaluation of seasonal and locational variations.

3.8 Bioinformatics

Having established a robust platform and reliable network for bioinformatics activities in India, it is important to take stock of the situation and delineate the tasks ahead. To start with the platform and the network need to be further strengthened in terms of their reach, infrastructure and competence. While our efforts in the creation of data bases and methodologies, including software development, are laudable, they still do not compare with the very best in the world. In the next few years, we should Endeavour to reach the highest international standards. To achieve the above, the following steps and programs are recommended.

Strengthening the bioinformatics infrastructure

The support for continuation of bioinformatics programme during the 11th plan period is required to make India a major player in biology and biotechnology. The following new activities are recommended:

Setting up of super computing facilities with 10 teraflops computing capacity on biogrid to promote protein folding and drug design activities.

Expanding biogrid with the National Grids which are promoted by the Govt. agencies for the promotion of Bioinformatics research and manpower development.

Expanding bioinformatics infrastructure facilities promoted at universities and other educational institutions to support biotechnology and Bioinformatics teaching, research and information sharing activities.

Setting up of bioinformatics incubator facilities may be explored for strengthening the academia industry tie ups.

Setting up of National Bioinformatics Institute under section 25 company acts may be explored to promote over all growth of Bioinformatics in India in line with USA, Europe and other developed countries.

Establish a high speed network with national grid among institutions for promotion of sharing of resources and collaborative activities.

Human Resource Development

- Continuous talent pipeline to be ensured by producing 100 PhDs, 1000 Post graduate holders in bioinformatics.
- Set up national testing program for accreditation of students at different levels.
- Introduce various fellowship schemes to attract students to undertake Ph.D. and other Post graduate courses in Bioinformatics.
- Introduce industrial training for students pursuing courses in bioinformatics.
- Establish virtual class rooms in identified institutions; teaching material in electronic form may be developed and made available at a reasonable cost. Involve Industry, senior professors/ scientists in developing course content and materials. Organize over 500 short term training programme in bioinformatics.
- DBT may formulate a scheme to encourage educational institutions to start elective course in bioinformatics as part of the Bioinformatics and Biotechnology courses.

Institutional mechanism for software development and validation

Institutional mechanism may be put in place for testing public domain databases and software and making them available to the users from the academia and the industry. After such testing, these databases and algorithms may be graded so that scientists can use them with higher confidence.

Commercial databases and software may be tested before the industry invests in the products. Such service will help the industry to reduce their costs and use only certified products.

There are many government departments and agencies, which are supporting bioinformatics activities. These include CSIR, ICMR, ICAR, DST and MIT. An inter departmental agency may be established to coordinate these activities among these departments and agencies.

Promotion of Research

The CoEs, DICs, sub DICs and super computing facility of BTISnet may be strengthened for hardcore research in bioinformatics as well as high-end human resource development.

Promote establishment of formation of an Indian Bioinformatics Society for the benefit of researchers through exchange of information and other knowledge resources.

Increased Access Information Resources

Develop an Indian portal site on Bioinformatics to provide single window access to information and services offered by various institutions in the country.

Develop a National Bioinformatics Consortium for access to online e-journals in Biotechnology and its allied areas.

Promote establishment of formation of an Indian Bioinformatics Society for the benefit of researchers through exchange of information and other knowledge resources

Promotion of Industry

The Department in association with the Ministry of IT may set up bio IT parks for the promotion of the bioinformatics industry.

High-risk projects in bioinformatics may be promoted through special support mechanism including public-private partnership.

Network projects:

Indian bioinformatics, sustained substantially by the DBT, is now strong enough to embark on specific sectoral efforts. An obvious section in this respect is agriculture. Effective effort in this area calls for collaboration between bioinformatics, agricultural scientists and plant molecular biologists. Special emphasis may be laid on adaptation to environmental stress. Another sector which merits attention is the documentation of the microbial wealth of the country

and its possible utilization. Here again extensive collaboration with microbiologists is important.

International Co -operations in Bioinformatics:

International co-operations to offer trainings for the less developed countries and bring experts from developed countries to train Indian researchers may be explored. Exchange of information resources and expertise with other countries may be explored in line with the present cooperation with Malaysia.

3.9 Mission Mode Programmes

The working group recommended launching few mission mode projects in the areas of national importance where biotechnology interventions can bring about significant value addition, cost effectiveness and competitiveness in product and process diversity. Unlike, the mission projects in developmental areas, biotech product/process development involves an elaborate pathway of innovation value chain over a period of years (7-10 years) with defined elements of basic research, translational research, development, verification and validation, prototype development, field trials, production/manufacturing and marketing. These major elements of the value chain have sub-activity or sub-task to cater for unique differences between biotechnology products for public/private good requirements. In addition, increasing demands of regulation, intellectual property rights and public acceptance have made biotech R&D and innovation more complex.

Innovative capacity determines the ability of a system to create a continuing pipeline of new products and processes. Innovation covers knowledge creation (research and development), knowledge diffusion (education and training), and knowledge application (commercialization).

Therefore, mission mode project in biotechnology could be of three types such as knowledge creation (research and development), knowledge diffusion (education and training), and knowledge application (product development, validation, and

commercialization). These types of mission due to interdisciplinary nature of biotechnology require special management, administrative and organization requirements for time bound results.

Keeping in this view, the working group suggested the following:

- DBT may establish a special office outside the premises of its head office deputing one of its senior officials to coordinate the mission programme alongwith a technical leader of proven track record and the secretariat.
- The mission should have clear goals, interdisciplinary, and of national priority having socio-economic relevance bringing about a difference in the way problem solving at grass root level.
- The mission should develop tools, methods, technologies, products and processes or generate knowledge with verifiable results.
- The mission should be implemented in collaboration with small and medium enterprises through public-private partnerships, government agencies working in the developmental areas related to the mission, national and international non-government agencies, public sector institutions and universities.
- The programme of each of the mission in terms of objectives achievable targets and milestones, implementation modalities, selection of partners and measurable indicators of success should be done through elaborate planning process involving all stake-holders and a techno-economic feasibility report.
- Out of several proposals made by the DBT, the following mission mode progarmmes are recommended:

Mission on biotechnology in food and nutrition security

Food and Nutrition technology deserves high priority. Value addition to primary agricultural produce through application of new technologies and enabling policies is critical for employment generation, economic development and improved health and nutrition of all sectors of society. In an emerging era of preventive health care, it is envisaged that improved food products can be developed which promote well being and prevent diseases. Designing such food

requires investment in nutrition science, nutrition-health research and innovation in process development.

The mission will have four different components

- Bio-fortification of agricultural crops with better nutritional traits for iron, zinc, vitamin A etc.
- Nutritional improvement of vegetable crops with special impetus on under utilized (neglected vegetable crop) species from different regions of the country
- Development of nutraceuticals/ health food supplements/ functional foods with proven evidence of efficacy and safety.
- Validation and utilisation of novel fortified foods such as ultra-rice.
- Low cost, durable formulations of micro-nutrients for national programme IVM, Zinc etc.
- Food biofortification strategies.

Mission mode programmes for molecular breeding of silk worm.

Although India ranks second (18%) in silk production after China (69%) it is unique in producing all the four varieties of silk - mulberry, eri, tasar and muga. However, nearly, 90% of our silk is mulberry silk. Sericulture is practiced in more than 60,000 villages providing gainful employment to over 60 lakh people mainly from the weaker sections of the society. India produces over 15,000 tonnes of silk but present production falls very much short of the domestic demand of a powerloom sector necessitating the import of around 7000 tonnes of graded silk from China and other countries. Indian silkworms can produce several crops per year (multivoltine) compared to Chinese races, which yield two crops per year (bivoltine). However, the quality of silk produced in China is much better. On the other hand Indian silkworm races have greater resistance to pests and diseases. The challenge is to develop novel high yielding silkworm breeds that produce good quality silk and showing resistance to diseases and pests. Simultaneously,

the host plants on which the silk worms feed have to be improved. The traditional processes for doing all this are very slow and hence application of biotechnology to the sector is likely to yield better dividends.

There is need to take up the following programmes:

- To develop and implement a strong programme on molecular breeding in both silkworm (disease resistance) and mulberry (for increasing leaf yield, leaf quality and drought tolerance) in mission mode manner to carry out work on mapping and identification of QTLs (gene tagging) in large scale both in silkworm and mulberry, simultaneously.
- To develop and implement a large scale mission programme on introgression of bivoltine characteristics of economic importance in to Indian multi-voltine races / varieties of silkworm through molecular marker-aided selection.

Mission mode programme on molecular breeding of crops

Induction of biotechnology is necessary to maintain our agriculture remunerative and globally competitive in the face of major challenges such as declining per capita availability of arable land; low productivity levels of crops, livestock and fisheries; heavy production losses due to biotic (insects and other pests, weeds etc.) and abiotic (salinity, drought, alkalinity etc.) stresses; heavy post-harvest crop damage during storage and transportation; and declining availability of water as an agricultural input. Investment in agriculture-related biotechnology has resulted in significantly enhanced R&D capability and institution building over the years, but progress has been rather slow in converting the research leads into usable products. Uncertainties regarding IPR management and regulatory requirements, poor risk assessment, and effective management and commercialization strategies have been the significant problems.

Among the agriculture technologies, marker assisted breeding is least controversial and has no major IPR or regulatory hurdles. Key to successfully integrating this technology into applied breeding programs will lie in identifying applications in which molecular markers offer real advantages over conventional breeding methods. MAS should be able to offer significant advantages in cases

where phenotypic screening is particularly expensive or difficult, including breeding projects involving multiple genes, recessive genes, late expression of the trait of interest, seasonal considerations, or geographical considerations. In addition to reducing the cost of breeding, MAS also has the potential to generate time savings. Depending on the benefits that a breeding program realizes from earlier release of its breeding products (which typically differ between the private and public sectors), the value of these time savings can be enormous—often justifying the additional cost involved in using MAS.

The objectives of the mission therefore are:

- To develop and implement a strong programme on molecular breeding in crops of resource poor agriculture for developing breeding products with pest and disease resistance, increased yield, quality, drought and salinity resistance in mission mode manner.
- To carry out work on mapping and identification of QTLs (gene tagging) in large scale in identified crops of benefit to resource poor farmers.
- To develop and implement a large scale programme on introgression of marker identified characteristics of economic importance into cultivars of resource poor farming systems and commercial Indian crop varieties through molecular marker-aided selection.
- To strengthen agriculture research on breeding through state-of-art of facilities, databases, gene bank of markers, human resource, and international linkages.

Mission mode project on Microbial prospecting (which would include prospecting of all categories of microbes including extremophiles/marine etc.) for industrial, agricultural, environmental, medical and therapeutic purposes.

Extremophilic microorganisms from highly evolved “eco-types’ (Guts of fauna, swamps, survivors in cold and hot ecologies) will be prospected for enzymes like xylanase, cellulase, lipase, dextranase, and proteinases which should be thermostable, (cold and heat-stable, acid/alkaline stable and organic solvent stable enzymes) for applications in various industries in bioenergy/biofuel sector,

pulp bleaching, cosmetics, detergents, sugar refining, waste clean up, and forensics, etc.

The mission includes Prospecting of the following:

- Microbes of agricultural importance
- Microbes for bioremediation
- Microbes for therapeutic purposes.
- Petroleum and natural gas by using indicator microbes.

Mission mode project on Stem Cell Biology

The potential of stem cell technology to develop therapy for many untreatable diseases through cellular replacement or tissue engineering is widely recognized. If may provide a platform for evaluation of new drugs, creation of disease models or study of developmental biology. The mission mode programme of stem cell biology aims to:

- establish institutes for "*Stem Cell Research and Regenerative Medicine"* for basic and translational research.
- explore full clinical potential of bone marrow and mesenchymal stem cells in various diseases, such as, cardiac, ocular, limb ischemia, orthopedic, etc.
- build a critical mass of human resource in the country for stem cell research.
- initiate dedicated fellowships in this area.
- establish collaboration within the country and also at international level.
- build partnership with large companies in path-breaking areas to generate large number of stem cells and make them commercially available.
- support multi-institutional network projects through public private partnership.
- promote closer interactions amongst basic scientists, clinical researchers and the industry through joint seminars, conferences, workshops, etc.

Mission mode project on Bioengineering

Bioengineering covers a wide range of areas such as tissue engineering, biomaterials for therapeutics, biomedical sensors, biomedical devices and implants, etc. Bioengineering offers opportunities for indigenous development of critical implants and devices, advanced biomaterials for therapeutic applications, tissue engineered products, etc. in coming decades. The mission mode programmes in the area of bioengineering will:

- Chart a national programme on biodesign providing an incubator for generation of new ideas to develop novel biomaterials for therapeutic applications, design of indigenous devices and implants, tissue engineered products, etc.
- Establish a stable network amongst engineers, clinicians, basic scientists and the industry.
- Create partnership with IITs, medical colleges, public research institutions having expertise in various disciplines such as chemistry, life sciences, molecular biology, medicine, engineering etc.
- Initiate programmes to facilitate indigenous production and evaluation of implants and devices which are currently available internationally but not available in the country at affordable cost.
- Promote Indian industry through product standardization and commercialization.
- Establish a regulatory mechanism for testing and validation of bioengineered products and devices.

Mission mode project on Vaccine development and delivery systems

Vaccines protect million of lives worldwide against infectious diseases. In spite of this success, close to 6.7 million children under five years of age still die each year from infections. Part of this death toll could be prevented trough better use of existing vaccines, whereas targeted research and product development are

needed for new or improved vaccines against diseases that are currently not preventable through immunization, or for which existing vaccines are of suboptimal efficacy.

Grand Challenges Projects should be supported for the following products:

Improved Vaccines to create effective single-dose vaccines; prepare vaccines that do not require refrigeration; and develop needle-free delivery systems for vaccines.

Create New Vaccines to devise reliable testing systems for new vaccines; solve how to design antigens for effective, protective immunity; and learn which immunological responses provide immunity. Priorities will be Dengu, Influnga, Tuberclosis, Malaria and emerging Indian pathogens.

Continue implementation of vaccine development projects which were initiated during 10^{th} plan under Jai Vigyan Mission programme such as rotavirus, cholera, malaria, TB, JEV, DNA based rabies (animal, human), Vi-polysaccaride typhoid, HPV, HIV/AIDS, to bring them to a logical conclusion.

3.10 International Cooperation

International cooperation and partnerships are necessary in order to be globally competitive in a knowledge-based bioeconomy. While the cost advantage has served India well in the past, in the long run our endeavour should be to reach global quality standards. For India it would be essential to forge international alliances both with public and private sector partners in developed as well as developing countries, to achieve the goal of global best practices in our S&T efforts, for joint IPR generation, harmonization of regulatory processes, smooth transboundary movement of biological materials, and to leverage better global markets for our products and processes. The absence of open markets for technology and products can lead to resistance to the adoption of new technologies, and such partnerships are crucial for the effective commercialization of biotechnology products. The scope of partnerships will not be limited to fundamental science but also include such subjects as regulation, IPR etc.

Recommendations:

DBT may continue the existing collaborative programme with USA, Finland, Denmark, UK, Germany, Switzerland, Netherlands, ASEAN, and Tunesia and promote new collaborations with these countries.

New partnerships with Australia, Canada, Norway, USA, Ukraine, South Korea, Sweden, MVI, FIND and other non profit global agaurats may be promoted.

DBT, in partnership with CII, FICCI, ABLE and Indian embassies, may make continuous and determined efforts to showcase India's achievements in biotechnology and transfer of technology at the international level. A cell would be created for this purpose in DBT

Strong partnerships may be established with international agencies such as CGIAR institutions, ICGEB and other philanthropic organizations to generate tailor-made technologies for public good; preference would be given to developing mass-based biotechnologies aimed at developing countries with enabling IPR policies.

India may offer its education and training facilities to all its neighboring countries including those in the SAARC group. In this direction, a UNESCO Centre for Biotechnology as proposed may be established in New Delhi to train quality human resource in the region.

A Biotechnology Foundation may be established for development and diffusion of technologies among the countries of the region in the areas of health, agriculture and environment that are relevant to the vulnerable sections of the society.

The working group endorsed the proposal of DBT to collaborate with global developmental and non-profit organizations such as PATH for vaccines and fortified food, FIND and WHO for medical diagnostics, biodesign, bioengineering with Stanford University & Harvard University, USA and Agriculture biotechnologies with ISAAA and PIPRA.

Alliances and partnerships for strategic innovation and technology commercialization may be explored.

3.11 Sectoral Road Maps

The department has been funding various R&D programmes/projects to individual researchers on a competitive grants basis. Considering the results of such programmes in knowledge generation, felt that many promising research leads and prototypes are left unattended without logical conclusion due to lack of networks engaged in various tasks of innovation value chain, lack of infrastructure for downstream approaches for product and process development and linkages with private sector. Therefore, the group recommended to prioritize the specific areas to be pursued each sector and developed appropriate networks while supporting individual scientists based projects for knowledge generation. Accordingly, different sectoral road map have been prepared with extensive discussions of the sub-groups, specific consultations with subject matter experts as well as international trends in cutting areas of basic and applied life sciences and biotechnology. The project proposals should be invited on open advertisement basis so that the funding may be given on competitive basis.

3.11.1 Agriculture & Allied Areas

Crop biotechnology

The efforts may continue on basic and strategic as well as application oriented research. The main emphasis, however, may be on product development and their delivery. Closer interactions between DBT, ICAR institutions, SAU, other universities and private sector would be developed to realize the objectives. The goals under application oriented basic research and product development may be as follows:

Basic research:

- Programs on engineering chloroplast for biotic/abiotic stresses and other traits.

- Engineering the biosynthetic pathways and photosynthesis for enhanced productivity, yield in important crops such as wheat, rice and oilseeds.
- Study of Quantitative characters related to water/moisture usage efficiency and tolerance to limited moisture conditions, high temperature/terminal heat surge in ambient temperature in these crops.
- Application of nanotechnology in agriculture for areas like delivery of genes in plants, bio-analytical nanosensors that could detect a single pathogenic organism long before symptoms are evident, slow and controlled release fertilizers, pesticides etc.
- The basic and strategic research related to gene discovery, allele mining, expressing profiling for selected traits/validation of their functions, reverse genetics, validation of gene function and comparative genomics.
- Development of tools like RNAi technology for post transcriptional gene silencing and targeted gene integration as well as the knockouts.

Translational research

Coordinated network / program for the improvement of pulse, oilseed, fodder, fibre and vegetable crops may be undertaken on priority. However, the traits to be improved / incorporated and techniques to be adopted may be as per recommendations of the National Task Force Headed by Prof M. S. Swaminathan and the draft National Biotechnology Development Strategy. The Department proposes to emphasize work on crops and traits such as cotton (insect, viral resistance, heterosis breeding), rice, mustard (barnase/barstar for heterosis breeding, *Alternaria* and white rust), pulses (regeneration and transformation protocol, insects/viral resistance), sorghum (shoot fly, drought resistance), sugarcane (borer, wooly aphid), maize (borer, downy mildew), etc.

Extensive QTL mapping for yield attributes, biotic and abiotic stress tolerance in rice, wheat and other crops with a view to their, isolation, modification and directional pyramiding may be promoted. Development of suitable molecular markers and their application in development of superior genotypes with active participation of plant breeders would be given high priority during the 11th plan.

Marker assisted breeding program against ug99 rust in wheat is considered important as this highly virulent race may soon appear in the country.

In the area of insect tolerance efforts may also be made to develop and use technologies other than Bt technology. At the same time efforts for understanding the mechanism of host pathogen / insect interactions and root and floral development need to be strengthened.

In biofortification and quality improvement programs, yield and yield components should not be overlooked while improving the nutritional quality.

Product development:

Mission mode approach may be used towards testing, validation, and field evaluation of the transgenic crops which have already been developed up to T1 generation and beyond, viz. Bt. Brinjal, Virus resistant Papaya, Barnase/Barstar based hybrid Mustard (if superior over conventional hybrids), Virus resistant Tomato and Tungro resistant Rice. The biosafety issues related to these crop-gene combinations may be an integral part of the mission.

Multiple rust resistant Wheat with pyramided R genes, and gall midge resistant Rice developed through MAS may be validated aiming at varietal release.

Engineering male sterility and fertility restoration for exploitation of heterosis in more number of crops.

Creation of Mutants/knockouts for Functional Genomic Studies and Gene discovery in Rice for drought tolerance.

Set up a Virtual Center of Excellence in the area of Plant Molecular Virology through networking with the relevant scientific groups/centres active in this field within the country. The Center would focus its programmes on Begomoviruses, Tospoviruses, Ilarviruses etc.

Development of DNA – Chip for detection of viral infections in crop plants, viruses, gene mining and their use in imparting broad spectrum resistance against viral infections in plants.

Application of biotechnological tools for developing aerobic rice – The programme may have participation of ICAR institutions, SAUs and other universities.

Enhanced water use efficiency in irrigated rice by breeding tolerance to limited moisture stress using molecular approaches.

Infrastructure

In order to facilitate GM crop testing and evaluation as per the regulatory requirements 3-4 integrated comprehensive facilities near the vicinity of state agriculture universities and ICAR institutions may be setup. These facilities may take up not only the work of public sector organizations but also of Indian and international private sectors like a CRO in health sector.

Towards conversion of research protocols and leads into products of relevance to Indian farming systems, 2-3 centres of translational research in agriculture biotechnology may be established.

Plant Biotechnology

Besides consolidation of ongoing programmes and converting research leads from them, the following areas may be considered as priority:

- ✓ Nutritional quality improvement in vegetable crops with special emphasis on under utilized crops.
- ✓ Improvement of tree genetic resources for enhanced productivity to meet the requirements of agro-forestry and plantation forestry.
- ✓ Promote application and translation of tissue culture technology at grass root level to fulfill the domestic market requirement.
- ✓ To promote capacity building in terms of infrastructure and human resource in plant sciences for both basic and translational research.

Basic research

The following areas where knowledge generated has to be augmented in Indian context are identified:

Apomixis: Apomixis is the phenomenon by which certain plants produce seeds without undergoing fertilization i.e. a sexual process. This phenomenon could help in development of almost limitless number of hybrid cultivars which would prove very useful for seed industry.

Androgenic haploidy: Production of haploid plants offers a rapid method for developing new crop varieties.

Plant Architecture: Plant architecture is a new paradigm in plant sciences to address scientific issues in forestry, horticulture and agronomy such as modeling plant plasticity, analyzing the determinants of interaction between growth & production, flowering and root differentiation. Programmes may be supported to understand. Project needs to be supported is understanding the function and behaviour of battery of genes involved in controlling flowering & seed setting, root differentiation, function and morphology.

Regeneration events in tissue culture: Programmes may be supported to unravel regeneration events as this study is important to understand why recalcitrant species are unable to regenerate, what are the barriers & how to over come these.

Transformation system & genetic events and intergenic gene: The ability to efficiently introduce foreign genes into plants is key to the success of the plant biotechnology. Programmes may be supported to study efficiency, reproducibility of transformation systems for increasing number of events of gene integration by Knock out and mutant approach.

Chemicals from plant cell culture: For continuous production of pure biochemcials from rare plants, cell and tissue culture in suspension systems on a large scale through genetic manipulation and bioprocessing would be an advantage. Projects on priority plants and their metabolites may be supported.

SOL Genome Initiative (Ongoing Programme): This programme was initiated during the 10^{th} plan, India became partner to the International Solanaceae Genome Initiative alongwith 10 other countries. Contributions to the International effort will allow India to access all the data produced by the International network (SGN). This includes mapping and sequence for other solanacea members. India

initiated this programme covering both structural and functional genomics aspects. This programme may continued during the 11th plan with.

Structural Genomics: This work being done at the three networking institutes and chromosome 5 may be sequenced by 2009.

Functional Genomics: The study initiated with a focus on three important characters including, nutritional quality, disease resistance and fruit ripening may continue.

Network Programmes: Tree Improvement for specific traits may be initiated for understanding Genetic Diversity Estimation for improving productivity and conservation; Improvement of complex traits by Association Genetics in Teak, Rose wood and Sandalwood; Breeding for increased metabolite content by productive engineering; Generation of tolerance to biotic and abiotic stress in Casuarina equisetifolia, Eucalyptus tereticornis; and Identification of tissue specific promoters for pathway regulation for differentiation.

Capacity building: Promote capacity building in terms of infrastructure & human resource in plant sciences for both basic and translational research through centre(s) for plant Biotechnology Research and Education.

Laboratories with rich expertise and quality infrastructure may be supported to undertake national priority programmes in collaboration with smaller laboratories / universities to build new capacities.

Create a centralized repository database of all DNA fingerprinting data generated under different projects. A common strategy may be developed for DNA fingerprinting based genetic diversity studies. All micro-satellite markers and other trait related markers developed may deposited in this database. The data generated in ongoing and new projects may also be deposited in this repository.

Biological Agents in Crop Management

The programme on biological agents such as biofertilisers and biopesticides had been implemented since the inception of the department. Several of these agents have been already marketed by the industry through technology transfer. It was recommended therefore to consolidate the existing programme and launch new

initiatives in focused manner particularly addressing requirements of organic cultivation, integrated pest management and export crops requiring chemical free certification, besides the support to the following:

Biopesticides

Promising Biocontrol agents identified from on-going projects may be commercialized; especially those for which patent applications have been filed.

- Developmental effort on novel botanical pesticides.
- Products identified in earlier programmes should be commercialized.
- Molecular characterization and genetic improvement of microbial biocontrol agents for superior traits (for e.g. transferring insect- toxin genes to phyllosphere microbes; combining multiple traits like anti-insect and anti-fungal activities in one organism).
- Continue programme on development and use of new pheromones in network mode.
- Research on mass production technologies, Shelf Life, Quality Control, Formulation, Application and Packaging, which are crucial for the commercialization of the biocontrol agents.
- Assessments of the critical factors such as demand-production mismatch, gap between demand and supply, source of availability, market Development etc.
- Post-harvest protection of grains, vegetables and fruits using eco-friendly technologies
- Biological control of crops with export potential and forest ecosystem.
- Extension product delivery activities (Technology upgradation & demonstration through farmers participatory programme and others) need to be strengthened to make biological control more popular among the farmers.
- Special research on long-term impact assessment of commercially released transgenic crops on non-target organisms.
- Human Resource Development in the area of Biological Pest Control needs to be augmented.

- Network Projects on management of diseases and pests of Ginger – a cash crop, in north-east and Himalayan region.

Infrastructure

Establish a national facility for Collection and Maintenance (*in vitro* and *in situ*) of entomopathogens (fungi, bacteria and nematodes) and their field performance

Biofertilizers

A network project may be initiated on development of biofertilizer-based organic package for yield / biomass increase of high value plantation crops, spices etc. This project will have special significance for areas / states within the two mega biodiversity hotspots of the country – the Western Ghats and North Eastern Himalayan region. Because many important medicinal plants from the natural habitat of these two regions are commercially exploited, and some of these species are threatened, their commercial cultivation is assuming importance and biofertilizer based organic agro-technology package would add value.

Promote entrepreneurship development among public and private sector institutions, NGOs and entrepreneurs for local small scale production and delivery of biofertilizer inoculants. Quality control together with farmers' advisory and adoption and linkages with State Agricultural and other Universities and scientific institutions should be ensured.

Technology packages for integrated plant health and production management of crop plants through the use of diverse combination of bioinoculants are to be developed.

Front-line demonstrations to prove techno-economic viability of biofertilizers for various annual and perennial crops should be priority.

Animal Biotechnology

The output of livestock sector is growing faster than that of other sectors of agriculture in the country due to expanding population and shift in the

consumption pattern. To meet the future demand for animal products the present level of production/productivity needs to be doubled in 15 years' time. The conventional techniques need to be complemented with newer and more efficient ones such as cloning, embryo transfer technology, genetic engineering, genomics, molecular markers, recombinant vaccines and growth promoters. A major effort in this area is suggested involving Veterinary Universities, Private Sector, and International Cooperation to scale up and augment the earlier efforts. The recommendations are based on special sub-group in these areas:

Newer/ Improved vaccines which are heat stable, broad spectrum, longer immune response, better adjuvant, less side effects and residues in milk and meat, diagnostics would be attempted on some of the following diseases: Bacteria: Brucellosis, Tuberculosis, Mastitis, Haemorrhagic Septicaemia; Virus: FMD, PPR, Buffalo Pox, Newcastle Disease, Infectious Bursal Disease, Duck Plague, Rabies; and Parasites: Liver Fluke, Trypanosomiasis, Babesiosis, Theileriosis, Anaplasmosis, Cysticercosis.

Diagnostic Methods simple to use, sensitive and specific diagnostics need to be develop for the diseases caused by Bacteria: Anthrax, Fowl Cholera, Brucellosis, Tuberculosis, Mastitis, Haemorrhagic Septicaemia; Viruses: FMD, PPR, Buffalo Pox, Newcastle Disease, Infectious Bursal Disease, Duck Plague, Rabies; Parasites: Liver Fluke, Haemonchosis, Trypanososmiasis, Babesiosis, Theileriosis, Anaplasmosis, Cysticercosis.

Molecular epidemiology of most of the infectious diseases listed above and creation of a database is a priority.

Ethno veterinary Medicines: Characterization of traditional herbal medicines at molecular level, identification of active ingredients, standardization of activity by molecular, cellular studies combined with pharmacological and toxicological approach.

Animal Production: the focus may be on development of animal feeding systems for digestability, productivity and nutrition. The areas of priority are Identification of Rumen Microbes and manipulations of genes of Rumen Microflora for better feed conversion.; Development of probiotics and other alternatives to antibiotic

feed supplements; Identification of genes responsible for lignin degrading enzymes, development of constructs using one of the yeasts as the base for combining these genes; Development of fermentation technologies using these constructs on crop residue by treatment with microbial products to improve nutritive value by release of celluloses and hemicelluloses from plant cell wall in the crop residue to produce energy rich feed; Oil meals, oil cakes and other by products of oil industry used for animal feeding as a source of protein contain mycotoxins. Technologies needs to be developed of removing of these toxins; Molecular tagging of genes for high nutritive value with micro satellite markers for development of varieties with higher nutritional value of residues; Improve protein availability from conventional and non-conventional animal feeds to increase efficiency of microbial production (EMP); Assessment of feed/ supplement induced shifts in the population structure at different taxonomic levels, with a focus on fibrolytic organisms; and Herbal feed additives as anti- oxidants and immuno-modulators to reduce methane emission and production stress.

Animal Reproduction:

Understanding the reproductive biology of livestock is essential for increasing the number and quality. Basic research should be undertaken on identification of genetically superior animals of cattle and buffaloes to increase their number, and to use them as bull mother for National Artificial Breeding Programme; and Identification of genes for higher production and diseases resistance (QTLs) and use them for selection in breeding; pregnancy diagnosis – identification of molecules for early detection of pregnancy in both small and large ruminants and Molecular diagnostic for infertility; genetics of infertility in crossbred animals; super ovulation and embryo transfer: improvement of super ovulation embryo transfer technologies; and ovum pick-up technology would be widely used in various breeds of cattle and buffalo. This will help in decreasing the cost of production of ET calves and improvement of superovulation and embryo transfer technologies.

Genetic Characterization of animal genetic resources: Molecular and genetic characterization of various traits of economic importance of indigenous breeds would be taken up. Phase II buffalo genome programme on identification of markers and their utilization for improvement of genetic traits through marker aided selection is to be taken up.

Building new capacities: The competitive research should be in development of animal models for both human and animal diseases; stem Cell Research in livestock Genomics; technologies for conservation of native breeds of livestock; whole genome sequencing of Indian breeds of livestock and poultry; conservation of endangered Wild life species; and molecular method for identification of meats from various species;

Network projects

Project on development of transgenic for animal production and development of transgenic for pharmaceutical application: Translational research should be stepped up to produce highly productive animals having capabilities of better feed conversion with disease resistance characteristics. The specific areas are development of transgenic animals both large and small ruminants for production of pharmaceuticals, health food for human etc. This would be taken up as a multicentric programme; resistance to or tolerance of other environmental stress, as a model animal to study the role of genes in the control of physiological processes; efforts would be towards the development of cloned livestock animal; and through knockout technology.

Aquaculture and Marine Biotechnology

The major challenges to be addressed are low productivity, poor management, lack of diversification, and incidence of diseases (e.g.Aeromonas infection of fish, white spot shrimp virus etc.). The potential of both fresh water and marine biota from an economic viewpoint is enormous and so far our attempts to exploit these have been feeble at best. For example, it is estimated that only 7% of the oceans

and 1% of the ocean floor have been explored. In fact, 93% of the sea is not even explored. Therein lies a tremendous opportunity. DBT programmes have been concentrating improving the technologies of production, reducing environment pollutants, demonstration, development of diagnostics and vaccines. However, basic research and application of modern molecular biological tools was not adequate. Expansion of quality of human resources and infrastructure are essential. Therefore the recommendations are:

Basic Research

The areas of priority are: structural and functional genomics of aquatic species; marine extremophiles for novel enzymes and proteins; Marine pharmaceuticals and bio-molecules for therapeutic applications; Marine biomaterials, bio-sensors, bio-adhesives, bio-flocculent, bio-surfactants, medical implants, biopolymers and bio-plastics will be encouraged in addition to bioremediation for aquaculture; stem cell development for cultivable organisms, including seaweeds and invertebrates; transgenics for faster growth, enhanced breeding, salinity tolerance in culture and ornamentals species; development of diagnostics kits and recombinant vaccines for health management in aquaculture; nutrition and aquaculture feed development through biotech approach; and genome conservation and biodiversity of aquatic organisms.

Network programmes:

Need based programmes on development of pharmaceuticals from marine resources with a possible collaboration of DOD funding

Front-line demonstrations to prove techno-economic viability of aquaculture of non-traditional species for diversification

Infrastructure & Human Resources: To fill the gap, it is recommended to:

Establish CoE in marine biotechnology in cooperation with Norway and with international standards. Similarly, M. Sc. Marine Biotechnology courses at the

existing institutes of national repute should be supported. Promote establishment of marine biotechnology incubator facility.

Explore the possibility to establish oceanaria under the private sector in collaboration with R&D institutes

Undertake training for scuba divers to study the ocean biodiversity and collection of biological samples

Seri-biotechnology

Application of tools and techniques of biotechnology for improving the productivity, enhancing the quality and improvement of host-plants in both mulberry and non-mulberry silk. This could be achieved by the following:

- To develop novel high yielding silkworm varieties producing good quality silk and resistant to diseases through marker-assisted breeding and transgenic route.
- To develop biotic / abiotic stress tolerant mulberry varieties through marker assisted breeding and transgenic route.
- To support more basic research in mulberry sericulture (both silkworm and host-plants) including research on disease surveillance and causual agents of major disease of non-mulberry silkworm.
- To develop suitable technology(s) for by-product utilization in sericulture industry and value addition to the system toward better economic gains.
- To develop various applications of silk proteins (both sericin and fibroin) for medical and cosmetic purposes besides using pupa as a source of protein and bio-fuel.
- To develop silkworm as bioreactor for producing high-value proteins.
- To promote HRD in the area of seribiotecnology by following novel and integrated approaches.

Basic research

- To support more basic research in non-mulberry sericulture (both silkworms and host-plants) including studies on genetic diversity and genetic mapping of non-mulberry silkworms and their host-plants.
- To undertake studies on bio-physical properties and improving processing technologies of non-mulberry silk. To support fundamental basic research on disease surveillance & causal agents of major diseases of non-mulberry silkworms.
- To develop a good EST data base for mulberry.
- To apply new approaches to create genetic variability in mulberry from quality point of view. To try QTL approaches for multi-genic traits.
- Studies on nutritional aspects of silkworm with reference to special feed requirements for egg production, higher feed conversion, as well as role of nutrition for disease resistance in silkworm.
- To develop suitable technologies (probably female sterile technique) to produce “male only” progenies in silkworm for higher productivity of silk.
- To develop silkworm as bioreactor for producing high-value proteins.
- To improve the quality of silk in multi-voltine based silkworm races through a mix of conventional and molecular breeding.
- To initiate work on knock-out mutants in silkworm for identification of desirable genes.

Network projects

To strengthen the existing network projects for producing NPV resistant silkworm varieties through both molecular breeding and transgenic route.

To carry out field testing of transgenic silkworms resistant to baculovirus infection (already developed through RNAi technology).

A network project to develop suitable silkworm hybrids suited to favourable and harsh seasons (Agrahani and Non-Agrahani seasons) of West Bengal.

To implement network projects on mulberry with an aim to develop varieties with various desired characteristics (moisture stress tolerant, improved leaf yield,

improved leaf quality for better silk conversion efficiency) through molecular breeding and transgenic route.

3.11.2 Bioresources Development and Utilization

National Bioresource Development Board (NBDB)

Characterization and conservation: Biodiversity characterization using remote sensing of all bioresource rich regions of the country

Quantitative assessment and mapping of bioresource of North-Eastern India, Western Himalaya and Desert region

Mission Mode programmes for conservation/utilization of under utilized plant species.

Network projects:

Sustainable utilization of bioresources for food & nutritional security and environmental security- Exploitation of underutilized crop plants:

General screening of crops for various applications like nutrition value, therapeutic value

Conservation, application of these resources, molecular mapping, identification of superior genotypes.

Inventorization of processes of existing traditional knowledge for utilization

Operationalization of 'Indian Bioresource information network' (IBIN) linking up various institutions dealing with bioresources, bringing together primary and secondary data at both spatial and non-spatial level and linking other existing databases.

Sustainable utilization of Bioresource for food & nutritional security and environmental safety:

Biotechnology for improved production and value addition of bioresources of economic importance

Biotech interventions for eco-restoration of fragile and biotech ecosystem.

Prospecting of bioresources for products of environmental, agricultural, industrial and therapeutic value

Improving socio-economic and livelihood security through Bioresource related process and product.

Setting up Rural Bioresources Complexes in other biorich States with tailor made technological intervention

Bioresource entrepreneurship Development programme for educated, unemployed, preferably rural youth, to promote Bioresource related enterprises.

Ex-situ conservation of important resources/ threatened

A major network on ex-situ conservation of all endangered/threatened species of the red data book will be initiated. In addition to conservation, mass production and reintroduction in the natural habitat will also be supported. A special thrust would be given to strengthening of existing botanical gardens for developing a focused R&D strategy not only for ex-situ conservation, but also molecular characterization.

Infrastructure

- Establishing facilities to accelerate molecular target-based screening for economically useful compounds from bioresource
- Establishing gene banks for ex situ conservation and characterization of specific bioresources (e.g sources yielding gums/resins, natural dyes etc.)
- Establishing a gene bank for maintaining ‘mined’ genes.
- A centralized Drug Discovery Technology Centre with satellite centres in different areas. A hub and spokes in other area.
- National Network for Natural Products (NNNP) or Indian Virtual Institute of Natural Products (IVIN) (A Joint Programme of DBT and CSIR.

Capacity building:

Biotech interventions for eco-restoration of fragile and biorich ecosystem, especially drought prone areas of the hot desert:

- Selection and conservation of important threatened plants of the desert eco-system
- Prospecting of biotic and abiotic stress genes from wild resources adapted to the cold and hot desert region
- Bioremediation of the desert region using microbial consortium
- Large scale multiplication and plantation of economically important species of the region for purpose of greening and afforestation
- Chemical and genetic fingerprinting of varieties adapted to the drought prone areas.
- Breeding and genetic improvement for development of drought resistant varieties.
- Molecular aspects of taxonomy would be strengthened through intensive training programmes at graduate and post-graduate levels.
- Launching of Genome clubs which may include training of school children, training of para taxonomists and training of trainers at all levels

Basic Research

Programmes on Allele mining and functional validation of identified genes.
Evaluation of genetic diversity of core germplasm of under-utilized Bioresources
Setting up of Gene banks for molecular entities
Biotechnology for improved production and value addition of bioresources of economic importance
Screening up of natural resources for economically important products, development of technologies for characterization, utilization and value addition. Priority resources identified are:-

Zingibers

Honey Bee Resources

Seabuck thorn

Non Timber Forest Products:

Value addition and Biotech interventions in Non Timber Forest Products such as resins, gums, lac and guggul etc.

Medicinal and Aromatic Plants

Basic Research

The leads obtained on the medicinal plant extracts such as the extract exhibiting promising osteogenic activity in several *in vitro* and *in vivo* test systems; a lead fraction from *Piper nigrum* having anti-tubercular activity; extract of *Terminalia arjuna* proven effective in left ventricular dysfunction; a novel peptide from *Momordica charantia* having hypoglycemic activity and anti-proliferative activity against *Entamoeba histolytica* in *Oxalis corniculata* to be pursued during XI Plan for the development of effective, safe and fully standardized herbal product or isolation and characterization of therapeutically active compounds.

Development of standard and safe herbal product or isolation and characterization of therapeutically active compounds in medicinal plants in priority disease segments such as neuro-degenerative disorders, metabolic syndrome (diabetes type-II, inflammatory disorders), tuberculosis, cancer, osteoporosis, leishmaniasis, malaria and viral disorders.

Generating genomic resources and metabolic pathway studies in selected medicinal and aromatic plants.

Studies on pathway regulation to identify rate limiting steps, cloning the relevant genes and genetic transformation for pathway over-expression in plants where bioactive molecules are known.

Basic studies to understand the use of ancient Ayurvedic concepts such as Rasa, Guna, Virya and Vipak in gauging biological activity of polyherbal formulations.

Development of biological models for validation and quality assurance of AYUSH products.

Re-confirmation of conventional markers and active constituents in context of Ayurvedic concepts such as Rasa, Guna, Virya and Vipak.

To develop suitable technologies for scale-up and conversion of useful intermediates in to value-added products.

To ensure safe and rational use of herbal drugs, studies may be undertaken on herbal drug-modern drug interaction

Network projects

A Network Project on generating data on chemical and genetic profiling of selected ten medicinal and aromatic plants species from different geographical locations should be initiated. This will help in establishing network of quality planting material hubs in India in association with various user agencies.

A Network project on “Chemical Ecology” may be initiated towards isolation, structure, synthesis and biology of organic natural products that are made by the interaction of various living species (plant to plant or plant to fungi or plant to microbes). This is extremely fertile field particularly for India where biological diversity is huge.

A Network of Chemoinformatics Centres may be established (in the pattern of Bioinformatics Centres) to help in drug-discovery research. These will be resources for accessing properties databases (including natural product databases), virtual screening, structure-based drug screening etc.

3.11.3 Basic Research and Nano-biotechnology

Basic research in Life Sciences

DBT has funded several research projects in understanding basic biological process of various living systems and their interactions. Considerable research leads have been obtained which formed basis for development of prototype production and processes. Recent dramatic advances in many areas of biological research, notably genomics, cell biology, structural biology and molecular approaches to biological function hold a great promise for future developments in biotechnology. Long term support for basic research is necessary on a broad front in order to build up several productive research groups in the country, which are capable of contributing to advanced knowledge generation and also well positioned to exploit the many breakthroughs that are anticipated.

Critically important areas of basic biology that merit sustain support such as Biology of Infectious agents & tropical pathogens; Cell Surface & Signal Transduction; Classical and Molecular genetics; Protein Engineering to generate novel useful products; Structural Biology; Chemical Biology; Systems biology; Molecular Modeling; and Molecular Epidemiology.

Network projects

System biology is the integration of biological sciences, mathematics and physics. Network projects involving multiple institutions having expertise integrated with human resource development and training university teachers and scientists in these areas should be initiated.

Nano-technology

Nanotechnology has achieved the status as one of the critical research endeavours of the early 21st century, as scientists harness the unique properties of atomic and molecular assemblages built at the nanometer scale. Over the years scientists have developed capabilities to manipulate the physical, chemical, and biological properties of these particles, which, provides researchers the capability to rationally design and use nanoparticles. Several applications of nanoparticles in biotechnology have emerged e.g. Dendrimers for targeting of cancer cells, drug delivery, imaging; Ceramic nanoparticles for passive targeting of cancer cells; Magnetic nanoparticles for specific targeting of cancer cells and tissue imaging; LH-RH-targeted silica-coated Lipid micelles for specific targeting of cancer cells; Nanoparticle-aptamer bioconjugate for targeting of prostate cancer cells; Antibody-targeted nanoparticles for thermal ablative cancer therapy and breast cancer therapy; Nanoporous zeolites for slow-release and efficient dosage of water and fertilizers for plants, and of nutrients and drugs for livestock; Nanocapsules for herbicide delivery; soil clean-up using iron nanoparticles; detection of pollutants; cleaning polluted waste streams etc. There are immense possibilities of using nanoscience for biotechnological applications.

Realizing the potential of this science, a major research initiatives may be launched in the following areas:

Strengthening of ongoing research with a focus on micro molecular chips; new sensors; nano particles for diagnostics and therapeutics; nanoparticles for soil management and photocatalysis; and crop improvement.

New areas for basic research in micromolecular chips for *in-vitro* and *in-vivo* analysis; Nano-biosensors with multiple sensing capabilities; bio-synthesis of nanoparticles; electrical characterization and application of DNA nanowire; nano technology for diagnostic/therapeutic use in enhanced photosynthesis; soil management; crop improvement and protection; nanoscale induction of foreign DNA in cells; human Health Impacts of Nanomatetrials; development of environmental absorbents; and biodegradable plastics.

Setting up of Product Development Centers : These centres would engage in basic translational research with common facilities alongwith human resource development, linkages with start-up companies and medical hospitals/agribiotech translational research centres and environmental engineers and institutions depending upon the area of specialization. Three types of centres are recommended.

Nano medicine with emphasis on Synthesis of biological nanoparticles; Biokinetics and Toxicology; Vectoring, or cell targeting; Cell identification; Drug encapsulation in nanoparticles and drug release mechanisms; and Tissue healing with nanoparticles.

Nano agriculture with focus on nanoporous zeolites for slow-release and efficient dosage of water and fertilizers for plants and of nutrients and drugs for livestock; nanocapsules for herbicide delivery; nanosensors for soil quality and for plant health monitoring; and nano particles for photocatalysis.

Nano environment with thrust on human Health Impacts of Nanomatetrials; development of Environmental Absorbents; biodegradable plastics; mineral nanoparticles; nano-engineering chemical sensors for environmental applications; Nanostructured membranes; environmental quality on the "Nano-Coast; transport of nanoparticles in the environment; potential for facilitated

transport of contaminants by nanomaterials; potential for bio-uptake and bio-accumulation of nanoparticles; implications of nanotechnology for environmental policy and society; and nanomagnets for removal of soil contaminants.

Network projects

Nanobiotechnology is a highly multi disciplinary area. Network projects involving biologists, doctors and engineers would be initiated for harnessing vast potential of Nanobiotechnology.

3.11.4 Human Health

A healthy population is essential for economic development. Important contributors to the total disease burden are infections like HIV-AIDS, tuberculosis, malaria, respiratory infections and chronic diseases affecting the heart and blood vessels, neuro-psychiatric disorders, diabetes and cancer. It is important to synchronize the technology and products with the local needs of the health system and to facilitate technology diffusion into health practice. This requires developing innovative, cheaper and user friendly technologies.

Increasing knowledge about pathogen genomes and subtypes, proteomics and metabolism, host responses to infectious challenges, molecular determinants of virulence and protective immunity and understanding knowledge of mechanisms underlying escaped immunity and ways to develop novel immunogens will guide development of vaccines and diagnostics against infectious diseases and development of innovative biotherapeutics for infectious and chronic diseases. This product related discovery science must be supported by strong capacity in translational and clinical research which is eventually very weak.

Endorsing the proposal, the working group made following suggestions:

Infectious disease biology: Consolidate the current projects /programmes and establish centres for translational Health Science Research (CTHSR).

Development of novel strategies for identification of diagnostic antigens for various infections and development of simple syndrome and DNA based diagnostic tests, PUO – DNA chip and Nano based diagnostics (Nano chips) and Micro fluids, BIOMEMS may be developed only in areas where it is cost effective, example, rapid surveillance of outbreaks, screening of travelers, where therapeutics are available for quick pathogen detection.

A Health Science Research Consortium be constituted that can potentially oversee the research done in DBT/ICMR/CSIR and other agencies, minimizing the overlaps and sealing the gaps. The consortium shall thus interface animal health research with human health research. The Centres for Translational Health Science Research and the Consortium may work closely together promoting basic research and facilitating its transition to a possibly transferable technology and, with the help of appropriate departments, to useable products through Pharma houses or relevant industries.

While certain amount of DBT funding may be earmarked for individual scientist-generated projects/programs which could be researched upon, emphasis should also be laid to generate projects through the Consortium approach for conducting further research on important IDs including the biology and host-pathogen interactions.

For the major infectious diseases, drug development has been identified, as an essential research need. India is known for research on TB, Malaria and Leishmaniasis, however, a targeted approach is now necessary to harness the skills of experts and the infrastructure for research, candidate drugs, so designed as to fit the potential targets identified through structural biology. This work may span two plan periods, but work should be so directed that there should be at least one promising candidate be ready for human trial.

A similar approach is proposed for antiviral drug development for Hepatitis ‘E’, influenza, Dengue, JE and so on. Such drugs are expected to have life-saving value. New *in-vitro* models for some of these infections may need to be developed for efficient and reliable drug screening, and possibly for vaccine preparation.

Research on biomarkers for drug resistance/susceptibility of major pathogens is to be strengthened. Studies on reliable prognosis and early diagnosis of some of these diseases need to be considered.

Emphasis has to be given to develop quality reagents for research as well as diagnostics. The Consortium/CTHSR may oversee the process of identifying the need and promoting research.

All these above a new initiatives may be supported with the additional following equipment;

- High energy photon sources for structural biology work
- M.tb aerosol facility
- P3/P4 facilities
- Robotic High-throughput screening
- Proteomic facilities
- Structural Biology Units
- GMP facilities

Basic and Translational Research

In the research mode, emphasis can be laid on the disease process including pathogen biology, host genetics, vector biology and host-pathogen interactions. This central core of activities should lead to specific, sensitive and early diagnosis, drug development including new principles of target identification, the mechanistic basis of the emergence and avoidance of drug resistance, disease spread and transmission and the mechanism of elicitation of stable anti-pathogen immune responses (Effector and Memory) including vaccine development.

Mission Mode and Network Projects

Concerted efforts towards control, management and elimination of major diseases outbreaks in the country.

DBT may be a partner for reagent development and supplies, rapid diagnostic assay systems, molecular epidemiology etc.

Although some of these research may be on epidemiology or molecular epidemiology, the emphasis must be laid onto the formulation for the usage of those data.

Implementation of new programmes on HIV/AIDS with emphasis on Immunobiology, pathogenesis, molecular typing, newer approaches for vaccine development including development of novel microbicides and their testing in collaboration with ICMR.

Full genome sequencing of *Leishmania donovani.*

Influenza “Expert Group” to address various futuristic research issues.

Dog contraceptive vaccine development.

Setting up of CoEs

Establishment of specialized Virus Research Centers at least in 4/5 strategic locations in the country to address various research issues related to viral biology, pathogenesis, biomarkers, diagnostics, vaccines, drug development and drug delivery, product formulations etc. Some of the important diseases are Influenza, Bird Flu, Hepatitis ‘C’, Cytomegalovirus etc.

Essentially, Infectious Diseases Laboratories to serve both Public Health and Clinical Services and Trainings as well as Research.

To further pursue Vi-conjugate typhoid vaccine development, its preclinical and clinical testing with the involvement of a suitable Indian biotech industry and also for other vaccines which are under R&D stage.

Centre for translational research

The new Institute to be setup should have three levels of activities- Basic, Translational and Clinical. While the Basic research is fundamental and is non-negotiably integral to the development of novel therapeutics, the research nonetheless must have a translational orientation. The Translational research activities should provide the transitional base towards clinical application of the basic findings. The clinical research should be aimed at applying the findings

recorded in experimental animals on patients. After the ex vivo recapitulation of the findings of the basic research with experimental animals, the research should progress towards the *in vivo* testing in patients in Clinical Trials e.g., in translational, clinical research centres for IDs.

Network projects programmes /projects to be initiated

Establishment of a nationwide network for the molecular ecology of infectious diseases as a joint DBT-ICMR effort would go a long way to address this lacuna.

If the provision of cutting-edge technologies for identification and molecular characterization of infectious disease agents by DBT in such centres can be coupled to the systematic, statistically valid and supervised steady collection of clinical data and material from regular population sample surveys by the ICMR institutions involved, the nucleus of a rigorous database of infectious disease in the public health domain can be built during the eleventh five-year plan as a national resource of enduring significance.

Chronic Disease Biology

Common diseases in India that pose significant problems in diagnostics, preventions for therapeutics in routine practice are oral pre malignant lesions, oral cervical, gall bladder, breast the lung cancer, retinoblastoma, rheumatic heart disease, IHD, diabetes, renal and psychiatric disorders, alcoholism, age related muscular degeneration, trauma and joint problems etc.

DBT should strengthen its on going programmes and focus on the following:

Researches on autoimmune endocrine diseases, including those involved in the thyroid-etiology pathogenesis and develop potential treatment therapies.

Promote research on development of nano medicine and innovative systems for drug delivery for cancer treatment.

Research on molecular and cellular aspects of nervous system function in health and disease to understand how nerve cells function and communicate in the brain, especially as they relate to the development of novel therapeutic approaches to neurodegenerative diseases.

Set up Clinical Research Centres for Brain Disorders in partnership with National Brain Research Centre.
Set up Centre for Liver Diseases.

Vaccine and Diagnostics

Considering that the Indian vaccine industry has highlighted India's potential by emerging as an important source of low cost vaccine for the entire developing world. Further, economic opportunities through contract research and manufacturing through global partnerships are large if supported by enabling government policies and incentives. The following recommendations are made:

Research

Research projects to be initiated in the area of vaccine stability and delivery systems.
New vaccines to be included such as influenza, hepatitis C& E, protein based pneumococcal vaccine, CMV, shigella and some of the therapeutic vaccines, combination vaccines.
Research focus on manufacturing and formulation technologies
Development of novel platform technologies for vaccine delivery systems, Nano particle based and other adjuvants.
Nano based and other novel assay methods, Novel way of measuring immune responses and defining protective immunity which is not known, Immunology in neonates and elderly and vaccines that can be effective soon after birth.
DBT may initiate a mission programme on partnership with non-profit organization in health care such as GATES foundation promoted not for profit organization Foundation for *in-vitro* Diagnostics (FIND). The DBT – FIND partnerships programme may be managed through a mission office, project director who will work with FIND officers. The modalities of sharing IPR with granted licensers for Indian companies may be explored and management support from FIND and assist Indian industry for pilot scale development. The

programme will be development, validation and diffusion. And would work together with centre for translational health science research.

Network Centres / COEs

Development of Diagnostics: A new mechanisms for product development through the following actions:

Establishment of nationwide network centres for development of simple rapid low cost diagnostic technologies for infectious and non infectious diseases (focus: TB, HCV, dengue, malaria typhoid, STD, UTI, cancer markers, chicken guniya, influenza, neonatel HIV, immunological markers for monitoring for chorological diseases etc.)

Centre for diagnostic intermediates/reagents possible in a corporative structure.

To setup Biodrug development programmes in collaboration with industry, ICMR, and other research agencies.

To set up health research consortia (DBT, ICMR, NICD) and health promotion consortia (DBT, M/o Health & FW).

Manhattan project approach for development of testable drugs based on structure biology for TB, hepatitis E, anti viral for influenza.

National epidemiological diagnostic management consortia and centre for epidemiological data storage and management for rapid response to infectious diseases. (electronic based).

Infrastructure

- To set up clinical academy centres in medical schools to initiate translational and clinical research units.
- To set up infection science department in medical schools and health science universities.
- Programmes needs to be initiated to develop technologies for public health in close collaboration with some of the national and international agencies.

- Novel strategies for genome wide production of monoclonal antibodies against infectious organisms and clinically useful biomolecules.
- Setting up of 5-6 clinical training research centres.
- Establishment of BSL 3/4 facilities (at least 2)
- Aerosol facility (2-3)
- Bio-banks (3-4) for biomarkers in diseases in partnership with FIND and ICMR.
- Transgenic animal facility (Public Private Partnership)
- Basic infrastructure to carry out biomedical research in medical schools
- Clinical proteomics facilities

Capacity Building (HRD) in Medical Biotechnology Area:

Specialty Training Programmes for paramedics and medics need to be formulated and implemented for the Infectious Disease area.

To develop a specialty courses on Infectious Diseases in Medical postgraduate institutions, Universities and colleges as per the objectives. DM (Infectious Diseases).

Post-doc fellowships to attract and retain talents with good remunerations (tax free).

Capacity building for handling dangerous viral pathogens by establishing BSL3/4 facilities in four different parts of the country to handle emerging viruses for example Nepah, Hanta, Bird Flu (chicken H5N1) etc. that have already been detected in the country.

Initiating master course in clinical and translational research.

Supporting Ph.D. and post doctoral programmes in medical schools.

MD/Ph.D. (physician scientist programme)

Setting up of clinical research training centres.

Organizing training workshops for medical and para medical graduates and post graduate students.

DM course in infectious diseases and human genetics.

Planning and grooming grant for young scientists for innovative / novel ideas.

Providing special overseas fellowships in specific areas.

Human genetics

It is recommended to initiate front line research in human genetics and genomics to improve the disease management through life style modulation, for improvement in public health, reduction of disease burden and lowering of treatment cost. Further, it was observed to establish clear understanding of genetic and environmental factors and their interactions to public health control of common/complex diseases/disorders to improve capability building and also acquisition and development of human genome technologies. The specific recommendations are:

Basic Research

Novel gene identification for monogenic and complex disorders.

Large scale mutation screening in genetic disorders with high geneotype-phenotype correlation and generation of pathogenic mutation databases for Indian populations.

Functional genomics including biochemical, cell biological and other relevant assays for gene polymorphisms.

Infectious disease genomics – high resolution genome mapping – influenza, TB, *leishmania donovani, leptospirasis,* malaria, HIV and pneumococcal.

Stem Cell Genomics – to understand molecular basis of self renewal, expansion, lineage specification, differentiation.

Genetics of Neurological disorders, Neuromuscular, Neurodegenerative, Neuropsychiatry, sensory disorders, Stroke, Cancer, Cardiovascular, Diabetes - insulin resistance, Hypertension, Asthma, Mitochondrial disease.

Gene therapy research especially for oral cancer, thalassemia etc.

To strengthen the genetic diagnosis cum counseling units.

Animal models of human genetic disorders – Mouse Molecular Genetics.

Clinical Proteomics -Establishment of Clinical Proteomics Network.

Human Genome Diversity – Catalogue genetic variations across ethnic groups, variations in relation to human health and disease.

Applied Research

Pharmacogenetics and pharmacogenomics - high throughput genetic analysis combined with pharmacokinetic and pharmacodynamic assays for identification of drug responsiveness and adverse drug reaction.

Translational research – development of cost effective diagnostic kits and tools based on population specific data.

New Born Screening – To evaluate prevalence of disorders, cost effectiveness in collaboration with ICMR.

Human resource development

Teaching & Training in medical genetics

To create academic chairs in medical colleges for human genetics.

Mid-carrier development programme to scientists/ faculty in Universities/Medical Colleges.

Establish training centres

Awareness programmes for the society

Short documentary films

Awareness clips on television and broadcasting in radio

<u>Stem cell research</u>

Stem cell research initiated in the 10th plan should be promoted and coordinated through a national strategy rather than isolated, fragmented research efforts. This will require close coordination between concerned agencies. Besides, the continuation of ongoing programmes, the following recommendations are made:

Basic research

Identification of surface markers for characterization of MSC, purification, expansion of HSC, lineage specification, differentiation potential, proliferation, migration, self renewal, control of population size, relationship to tumour formation, interaction between stem cells and microenvironment,

Translational research -To create animal models; Pre-clinical studies etc.

Human Resource Development

Attract young talented biologists from other fields into stem cell research

Support young investigators for collaborative programmes(National/International)

Fellowships for JREs, SRF and PDFs

Hands-on training for the students and PDFs

Facility/Infrastructure

Create basic biology unit in medical schools; cGMP facility for pilot or commercial production of cell based therapy products in institutional & industry setting respectively; transgenic animal facility and National Centres for stem cell research

<u>Bioenginering</u>

Bioengineering offers opportunities for indigenous development of critical implants and extra corporeal devices. Nanostructured materials and devices hold a great promise for advanced diagnostics, biosensors, targeted delivery and smart drugs. The application of nanotechnology in bioengineering together with biotechnology offers a great new range of advanced biomaterials with enhanced functionality; and intertwined with tissue engineering, it has the potential to provide true organ replacement technology of the coming decade. While recognizing this potential, it is important to assess not only the efficacy, but also safety of these new interventions with regard to human health.

Bioengieeering has not been successful areas in India despite enormous potential and market. Reasons include poor innovation and product development

oriented research, engineering, and lack of cohesive interdisciplinary teams and slow the grow industry. A key weakness has been lack of capacity in development of biodesign for scale, market, patent, cost, and productive capacity for large scale manufacturing.

The group recommended that based on the feedback from various brain storming workshops, DBT should develop substantial human resource, new products, devices, materials, molecules etc. of international quality, inter-linkages and initiatives for public private partnership. The specific recommendations endorsed are:

Research & Development

Tissue engineering-disease and organ specific such as skin, cartilage & bone repair, cornea, liver, dental & orthopaedic materials

Rapid test for diagnosis of sepsis; MEMS biosensor; disposable biosensors for rapid diagnosis of diseases; low cost neonatal medical devices, cardiovascular devices, implants and bioinstrumentation ,Indigenous production of surfactants

Networking / Partnership

International partnership (disease and activity based)

Collaboration with the industry

Linking health programmes of maternal, new born and child health to national programme

Human Resource Development

Support young investigators for collaborative programmes- National /International (Allow labs and units to be developed in medical colleges/specialized institutes)

Fellowships for JREs, SRF and PDFs,

Infrastructure

Create organ & disease specific facilities in Univ., Institutes including IITs, hospitals etc.

To establish one COE for product development and design in one of the IITs with in a network of other IITs and centres of bioengineering.

Mission projects:

To launch a mission progarmme with the following broad goals: to launch a national programme on biodesinging in collaboration with Stanford University, IITs and medical schools as well as small and medium industries. The goals are to conceptualize and design new innovative medical devices and facilitate production and validation of internationally developed technologies through industry-industry partnership at low cost.

3.11.5 Environmental Biotechnology

The committee recommended that the technologists developed in this programme may be evaluated for cost effectiveness particularly in terms of bioremediation of environmental pollutants, pesticides residues, heavy metals etc. Two areas namely biodiversity conservation and environmental remediation should be taken up in the 11^{th} plan through focused approach in collaboration with other agencies either utilizing or developing the technologies in these areas. The specific recommendations are:

Biodiversity Conservation

Department of Biotechnology is required to play a pivotal role in conservation of rare endangered and threatened (RET) species of the country in addition to other research programs which have direct or indirect relevance towards biodiversity conservation. Following are the major areas where biotechnological inputs will be of great significance.

Basic Research

Restoration of degraded habitats/landscapes /ecosystems through biotechnologies.

Molecular markers for assessing evolutionary potential of populations/species in ecosystems

Molecular ecology of invasive species and their eradication through development of host species biological control methods and also by other biotechnological interventions.

Assessment of genomic diversity and conservation of gene polls of large groups of plants such as grasses, legumes, orchids and establishment of their DNA banks

Assessments of genetic diversity of rate and endemic species but also species that are critical for ecosystem functioning.

Training in molecular tools and techniques.

Use of bio informatics in development of models useful for setting conservation priorities and in evolving effective management strategies

Establishment of data banks related to Environment Biotechnology

Long terms studies on permanent plots in the field.

Environmental Bioremediations Technologies

Environmental and health Monitoring; ecological risk assessment

Restoration of Environmental Quality (Bio & Phyto remediation)

Biodegradation of Xenobiotics-Treatment and disposal of wastes through Biotechnological routes with the production of useful chemicals/value added products

Substitution of non-renewable resource bases with renewable resources.

Resources/wastes utilization/treatment through application of rDNA technology.

Development of transgenic plants for over production of poly-beta-hydroxybutyrate-A biodegradable plastic-its characterization and modification for varied commercial applications

Development of transgenic plants for pollution control.

Chemo-enzymatic synthesis of environment friendly amphiphilic copolymers for crop protection

Strategic Actions

For the diffusion of biotechnologies to be successful the following measures should be put in place.

Ensuring effective and closer horizontal linkages between research workers and the user corporate groups

Public-private partnership in research and application of clean technologies

Capacity building and training, through workshops, of law enforcement officials, municipal workers, state government functionaries and corporate groups on role and relevance of biotechnology in waste treatment

Strict enforcement of the 'polluter pays' principle. This would require interaction with law enforcement agencies to identify areas in which R&D activities in environmental biotechnology can be initiated

Steps to encourage small and medium business companies in producing eco-friendly products, microbial consortia etc. for wider usage. It is also necessary to biostimulate and bioaugment activated biomass encountered in the common effluent treatment plants

Building greater awareness for protection of proprietary rights of microbial consortia through appropriate methods (e.g., process patent, trade mark etc.)

Greater inter-agency coordination between DBT, MoEF, ICAR, CSIR, CPCB, user agencies and industry through an inter-ministerial Task Force.

3.11.6 Food and Nutrition

To cater to the Government's Common Minimal Programme and the requirements of the National Nutrition Mission, efforts would be focused to develop micro and macro nutrient ready to eat fortified foods so as to address the incidence of malnutrition prevalent in the country especially in school going children and expected mothers.

To address the nutritional requirements of geriatric population by developing designer foods.

Nutrigenomics : Cellular, molecular and metabolic nutrition area

To develop Nutraceuticals for holistic health

To develop and validate diagnostic kits for detection of transgenic traits in GM foods taking into account, the international development of transgenic crops.

To address all issues of food safety through biotechnology research.

Post harvest processing for increased self life of perishable foods (international technology transfer/diffusion to be explored).

Exploring novel proteins from crop residues/oil cakes

Network projects

Cellular, molecular and metabolic nutrition area

Micronutrient malnutrition

Over nutrition and obesity

Pre and probiotics to meet nutritional requirements

Exploring novel proteins from crop residues

3.11.7 Industrial Biotechnology

India's potential lies in bio manufacturing, bio-services, developments of new products and processes. The potential to new products by using its traditional knowledge and diversity is a particular strength. The 11th plan may support projects aimed at developing systematic procedures for design and scale-up of bioreactors, homogenisers, chromatographic separators, precipitations and crystallization, extraction and membrane separation. The projects which were supported during the previous plan period should be taken further only if they have some promising leads for development of product/processes. The recommendations include:

Basic Research

Drug delivery system for therapeutics/biomolecules

Development of novel molecules for eradication of TB:

rDNA and molecular biology

Development of technologies

Biotransformation to make bioproducts like lysine, cystein, lovostatin, hyaluronic acid, COQ10 etc. cheap and cost effective:

Optimization of vaccine production using modern engineering techniques

Optimization of bioethanol production from cellulose and hemicellulose and from agro wastes:

Reactor Engineering and improvement in Membrane Separation Technology for recovery of insulin, erythropoetin and other recombinant DNA products where recovery is a problem:

Optimization of the production and application of xylanases, laccases, lipases and peroxidases involved in paper industry:

Development of Biotechnology tools for management of Environmental problems:

Setting up an Industry Research Assistance Cell with a view to ensure a smooth functioning of the regulatory system within the country:

Creation of Centre of Excellence in Industrial Biotechnology and Scale up Technology:

Course on Industrial Biotechnology & Industrial/Applied Microbiology will be supported at Universities/academic institutions at Masters level.

Perfection of technology for production and purification of asparginase, an anticancer drug, which was identified as a priority area

Network projects

The following thrust areas may be implemented as network programmes involving 4-5 centres/institutes to work on various activities and make corporate linkages, even marketability and deliver the products.

Biotransformation to make bioproducts like amino acids, antibiotics, drug intermediates, esters and chiral products, hyaluronic acid, COQ-10 etc. cheap and cost effective

Optimization of vaccine production using modern engineering techniques

Optimization of bioethanol production from cellulose and hemicellulose and from agro wastes

Reactor Engineering and improvement in Membrane Separation Technologies for recovery of proteins and biomolecules and other recombinant DNA products where recovery is a problem.

Optimization of the production and application of industrially important enzymes through solid state fermentation and submerged fermentation

3.12 Biotechnology for Societal Development

Life sciences and biotechnology is to promote and sustain the balanced and equitable growth of all sections of the society. If this is to be translated into reality, biotech products and processes have to target the largest number of people, be widely accessible and affordable, have large societal impact, and also address specific regional/local problems. Towards this end, it would be necessary to ensure that public investment is preferentially directed to facilitate development and diffusion of mass use technologies that are required for primary health care, food and nutrition security, employment generation and environmental wellbeing. Technologies that have the largest impact on employment generation or for added household income would be promoted. This requires ultimate sophistication in designing products for their relevance for use in less sophisticated settings and in real time, and at a cost that does not make diffusion too difficult.

The group recommended that the 10^{th} plan programmes may be consolidated and new programmes scaled up to reach larger section of people in collaboration with state governments and other development agencies may be initiated. Technology delivery systems need to be developed besides, technology development and demonstration. The specific recommendations include:

A centre for policy research related to technology creation and diffusion in health and agriculture would be setup in an existing institution. The scientific community lacks the perspective for policy framework and ability to design products/processes for mass-based technologies for health, agricultural productivity, environmental security etc in such a way as to make diffusion easy. The centre would identify needs, define product profiles, suggest methods of cost reduction and feasibility of scale up. It will also search for and nurture low-hanging technologies create networks and global partnerships among stakeholder interested in promoting the programmes

Promote entrepreneurship development, self-help groups and Anganwadi workers for undertaking village based activities and micro-financing, especially on nutraceuticals, herbal products, cosmetics, value addition and food processing etc. to empower the society at the grass root level

Create and strengthen the herbal venture fund to support the product development through linking traditional knowledge base at NIF with various biotechnology labs in private, public and NGO sector.

Support mobile research labs to create awareness among the village people and involve them in bioprocessing and extraction analysis of locally available plants, herbs and bioresources

Establish model bio-village to address the use of bioresources in a judicious integrated manner

Undertake priority on uncultivable invasive species, wild grain and untouched resources for exploitation ensuring proper benefit sharing, and protection of intellectual property rights of local communities and traditional knowledge experts

Support the projects to the school dropouts to involve them in entrepreneurship related activities for product development, bio-crafts, bioresources utilization, value addition as income and employment generation activities and train them in marketing of produce through team of young MBAs on the pattern of young professional program of CAPART

Promote bio-mela, traditional food festivals/shows to create awareness among the people and also creating country wide demand for biological based products

Develop strong bonding between private and public sector in food processing, preservation and packaging as an agri-food business

Collate technology compendium, which will be made available in the form of print media (broachers, CD etc.) for the dissemination in the rural sector through Ministry of HRD.

Training programmes for the panchayat members involving training modules and package information

Use media and mass communicators to educate people on dissemination of technology packages and its pros and cons

Make efforts on food product formulation for distribution to the school children as a mid-day meal, weaning food and nutritional study

Create think tank to generate good ideas to address new priorities in funding, project implementation and efficient monitoring mechanisms etc.

Basic Research

Proposals receiving the areas viz. biofertilizers, biopesticides, sericulture, aquaculture, mushroom cultivation, bee keeping, spirulina production, organic farming, vermicomposting, floriculture, animal husbandry, medicinal and other economically important plants, waste utilization (like agro-residue, animal residue, trash fishes, etc.), biogas production, marine resources utilization (cultivation of seaweeds, etc.), value added products from forest produce, herbal products formulation, health, environment and sanitation related activities etc. will be supported.

Network projects

Bioresource Complexes, Technology Resource Centres and Village Resource Centres would be promoted

3.13 Expansion and Remodeling of Existing Autonomous Institutions

The achievements and proposals for 11th plan of the autonomous institutions of DBT established during 8th, 9th plan and before and those established /taken over during the beginning of 10th plan were reviewed in detail by the working group. The group observed that the institutions namely NII, NCCS, CDFD, NBRC and NCPGR have made internationally competent contributions in terms of basic research as reflected in the number of patents and publications with high impact factor. Although, certain research leads have been transferred to industry for translation and product development, there is a need for pro-active promotion of translational research in specific sectors of national priority such as vaccines, diagnostics, drugs for neurological disorders, tools and methods for DNA fingerprinting, genomics and devices, stem cell therapies etc. Therefore, the institutions were directed by the group to remodel their activities balancing basic research with that of translational and innovation activities in collaboration with public and private sector agencies. In doing so, it was also recommended to expand the scope of the institutions by building centres of translation, innovations, and services alongwith focused networking. The revised proposals of the institutions therefore were endorsed by the working group as detailed below:

3.13.1 National Institute of Immunology

Basic Research

The research programmes in the eleventh plan will be the flowering of the themes developed during the tenth plan period that have focused our efforts in an integrated fashion. These programmes will extend the unique blend of expertise at the Institute for actual use by the health care sector. They involve extensive collaborations, both nationally with other sister institutions, and internationally with academic centres across the world. Specifically, the broad objectives of our research programme and ancillary activities will be:-

Elucidation of the mechanisms used by the immune system in responding to infectious pathogens so as to provide guiding principles for preventive, diagnostic and curative strategies.

Analysis of the developmental cues that control the process of reproduction and development so as to provide clues for understanding genetic as well as environmental defects, especially involving the immune system.

Examination of the organization of the genetic information and the control of its expression with particular regard to the immune system, with especial emphasis on genomics-based approaches exploiting the worldwide explosion in genetic sequence information.

Molecular characterization of the strategies used by a variety of pathogens in causing infection and disease in order to expand the possibilities of attack points for drugs in the war against infectious diseases.

Identification of new lead molecules of potential therapeutic interest through a combination of approaches integrating traditional sources of knowledge, current advances in combinatorial chemistry as well as the futuristic genomics-based predictions.

Dissection of the fundamental rules of molecular design and recognition, especially for protein molecules by cutting-edge research in the post-genomic field of proteomics so as to provide the framework for rational optimization of lead molecule activity in drug design programmes.

Provision of state-of-the-art teaching and training facilities in advanced biological sciences using an interdisciplinary approach so as to inculcate the highest level of aptitude and ability in the country's skilled manpower pool.

Dissemination of scientific information both through professional journals to the worldwide community of scholars, and through symposia, conference and public lectures to the community at large around.

Development of the infrastructure needed to expand the ability of NII to serve as a skills resource base for health care technology development.

Measurable Targets

In light of these objectives, the following achievable and measurable targets are proposed.

Analyses of the molecular mechanisms controlling commitment to immune memory and to alternate immune effector directions.

Molecular dissection of the cues for ensuring immune self tolerance and of their breakdown in autoimmune disease states.

Examination of the ability of intracellular pathogens such as Salmonella, *Mycobacteria* and *Leishmania* to enter cells, evade death and acquire nourishment.

Analyses of cell biological pathways and their combination with rationally designed delivery systems to develop novel modalities for 'magic-bullet' and 'slow-release' therapeutics.

Identification of novel tissue-specific genes exploiting the genomic revolution to address fundamental issues of tissue development and differentiation.

Elucidation of the molecular mechanisms of cell entry, replication and dissemination of viruses, particularly those crucial in public health terms such as HIV and JEV, in order to provide novel insights into possible solutions.

Development of new paradigms of protein interactions and extending them to non-protein molecules in order to contribute to the sophisticated biophysical understanding essential for rational drug design.

Culture and molecular analysis of the developmental regulation of a variety of progenitor cell lineages.

Analyses of the biochemical modes of signal transmission from the cell surface to the interior of the cell in multiple systems to look for common and unique pathways that would serve as potential points of intervention.

Examination of metabolic pathways of lipid synthesis in *Mycobacteria* and *Leishmania* with post-genomic bioinformatics-based approaches for modulation of the immune sensitivity of the pathogens.

Studies on the broad principles of molecular organization of the genome and the regulation of gene expression from the evolutionary perspective for creating novel bioinformatic paradigms.

Patenting of the novel leads of potential utility spun off from the Institutes' research base.

Exploration of the utility of these research leads with optimal pace and rigor.

Systematic pursuit of technical collaborations with the biotech industry for exploitation of these leads.

Replacement of obsolete research and infrastructural equipment in the Institute so as to maintain its cutting-edge advantage vis-à-vis world science as well as the national biotechnology sector.

Enhancement of the intellectual resource base of the Institute to maintain its innovative vigor in the decade to come by judicious and selective recruitment of world-calibre scientists of proven ability.

Vertical Translational Research Programme

Four distinct directions are planned in this area.

i. *Design of novel inhibitors for decimating pathogens*

A programme dedicated to research on novel approaches for development of potent agents against the major infectious diseases, tuberculosis and malaria may be established jointly by the National Institute of Immunology and Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR).

ii. *Development of anti-HIV microbicides*

Institute has earlier developed a facile chemo-enzymic method for one-pot synthesis of aminoglycoside antibiotics–peptide conjugates. The bio-conjugates directed against Rev-RRE and Tat-TAR interactions can be obtained in absolutely pure form, and in substantial quantity, in a single step of HPLC. It is proposed to apply the above approach to conjugate Rev and Tat peptidomimetics to antibiotics (such as paromomycin, tobramycin and neomycin and assess the bioefficacy of the aminoglycoside-peptide conjugates by profiling the HIV replication inhibition in vitro using Indian isolates of HIV.

iii. *Anti-viral vaccines*

While continuing efforts on improving and designing the JEV and HPV vaccines, efforts will be made to establish a GLP-compliant laboratory for the clinical trials of the viral vaccines. M/s Bharat Biotech, Hyderabad, has produced the rotavirus vaccine developed at the AIIMS in Vero cells under GMP conditions. This vaccine aims to reduce the incidence of diarrhea or its severity in neonatal children. This vaccine goes to clinical trials in young children in the next couple of months. These trails are supported by DBT together with PATH.

iv. *Cancer diagnostics and therapeutics*

Dissecting the specific molecular anatomy of a tumor is likely to be critical for the development of more specific, efficacious and safer cancer treatments that can be based on an individual tumor's oncogenic mechanisms. Towards this end, a cancer research programme involving a network of international as well as national collaborations is being initiated in cooperation with Centre for Cancer Research & Cell Biology at Queen's University, Belfast and India Institute of Medical Sciences (AIIMS), Safdarjung and Moolchand hospitals to develop future research in the bench to bedside direction, to determine the cellular and molecular mechanisms involved.

Establishment of Innovation foundation

The experience with technology transfer agreements has brought NII to the considered opinion that well-developed products of great potential are not reaching the marketplace as a consequence of two problems. One is a lack of a critical mass of professional biotechnological expertise in the industrial sector and de novo translational capabilities for such novel technologies. NII therefore feels that there is a need to broaden the focus of technology-oriented research by academia beyond product-specific efforts to include these more basic issues through establishment of a Innovation foundation with core facilities in the 40-acre area that NII in the progress would be give space as per activity.

As a venture takes off, the laboratory unit will be further equipped and manned jointly, resulting in optimal utilization of resources for specific purposes. Such a

modular design, with the facilities envisaged, also allows NII to propose the use of this system for establishing an innovation center for public-good projects. In order to make this design of innovation laboratories work, a substantial degree of flexibility is essential in the administrative structures of such a center.

Center for genetically defined macaque strains

Essential requirement in the course of translating world-class Indian science to the technological marketplace is the requirement for testing and related experimentation on whole animal systems, with a species that is closest to humans.

A primate facility of macaque strains of monkeys shall be established with facilities to ensure clean, genetically well-defined primate strains translates into a requirement for genetically inbred, as well as genetically manipulated strains of primates.

Training and teaching

The doctoral programme in academic affiliation with the Jawaharlal Nehru University is expected to have an increased annual intake of 25-30 students during the forthcoming plan period.

3.13.2National Centre for Cell Science

The institute has been in the forefront since its establish in cell science through it services of cell culture supply and high quality science and publications of repute and impart.

Repository

The following activities have been planned as services to the scientific community in India that will widen the horizons of the Repository services and be major value addition in the institute's commitment to increasing scientific temper:

- Complete characterization of cell lines that are being distributed from the Culture Collection.
- Distribution of new cell types like murine stem cells.

- Preparation of feeder layers for propagation of stem cells.
- Fusion of primary B cells with myeloma and preparation of hybridomas on non-mercantile basis for some important antigens, their maintenance and distribution.
- Transfection services using animal cell cultures.
- Cryopreservation of embryos for important genetically tailored animals.
- To obtain **IDA** recognition for patent deposition of microorganisms and animal cells.

Human Resource Development

The centre aims to continue development of technical manpower by way of:

- Increasing the number of research scholars, postgraduate summer trainees and project students being imparted training at the institute,
- Teaching at universities and colleges (for students and teachers),
- Tailor-made training programmes for basic training for cell & tissue culture as well as specialized technologies in generation of hybridoma and EBV transformation,
- Mass education programmes for awareness in science and technology, and

The experimental animal house facility will initiate a mandatory training program in the various areas of laboratory animal handling and experimentation for the benefit of the research scholars of the Institute on a yearly basis.

Discovery and innovation based fundamental research

Various programs have been initiated and would be continued in the areas of Cell Biology, Cancer Biology, Signal Transduction, Diabetes, Biodiversity, Infection & Immunity and Chromatin Architecture & Gene Regulation.

Focused programmes

- Diabetes Use of human fetal pancreatic islet-derived progenitor / stem-cells for diabetes cure

- Identification of anti-viral compounds with potential for development of microbicides to prevent HIV infection and transmission

Networks:

Systems Biology of Global Regulatory Networks:

- Unraveling Sequence Features in Promoters that Dictate Tissue-Specificity of Gene Expression
- DBT Inter-institutional Network program on HIV

Tuberculosis Network Program: Tuberculosis is a major problem in India and worldwide. Therefore, we are initiating a network program aiming at founding new principles of drug development and anti-tubercular immunotherapy.

New centres for translational research

- Centre for cell and tissue engineering
- Centre for immuno-thereupatics

3.13.3 Centre for DNA Fingerprinting and Diagnostics

During the 11th Plan period, the CDFD may enhance the volume and scope of its existing activities as well as undertake new activities in both Services and Research, as detailed below.

Services

The CDFD provides two kinds of fee-based services, namely, those of DNA fingerprinting and of diagnostics. During the 11th Plan, the endeavour may be to progressively reduce the quantum of support from core funds for these services without compromising on quality or societal needs, and for this purpose alternative formats may be explored such as the establishment of not-for-profit clusters within the CDFD, public-private partnerships, and so on.

DNA fingerprinting services

CDFD's mandate in this period will be to enhance its offering of services, training, extension, and quality control activities so that the potential of DNA profiling technologies for various applications is realized to its maximum at all places in the country. This mandate is to be achieved through the following approaches, working synergistically:

a. *In-house DNA profiling services*: CDFD may increase the services 4-to 5-fold in the Plan period by appointment of additional DNA examiners and by increased automation even as it positions itself to serve more as a referral centre to work on difficult or highly sensitive cases from various parts of the country.

Training of personnel and improving the technical skills of the personnel may also be undertaken, so as to enable the Centre to retain the leadership role not only in India but also in the entire South Asian region. Develop a Laboratory Information Management Systems (LIMS) which is designed to automate evidence handling and casework management, to improve the integrity and speed of evidence handling procedures, and to ensure proper chain of custody.

b. National Facility for Training in DNA Profiling (NFTDP): Recognizing that large numbers of trained DNA examiners are needed to be located at various institutes and laboratories in the country in order to increase the contributions of DNA profiling to the criminal justice delivery system, establish a new National Facility for Training in DNA Profiling (NFTDP) in the CDFD.

The NFTDP will also offer training courses in the latter areas as well. The courses to be offered by NFTDP will thus include the following:

(i) Diploma in DNA fingerprinting and diagnostics of one year duration
(ii) Post Graduate Diploma in DNA fingerprinting and diagnostics for two years duration
(iii) Refresher courses of one-month duration
(iv) Three months course on DNA fingerprinting & diagnostics
(v) Summer training for two months
(vi) Project training for six months

(vii) Training courses for forensic scientists for one month duration

(viii) Training courses for police officers and judicial officers for one month duration

(ix) Proficiency Testing Program

(x) Conferences/Workshops/Seminars etc.

c. Disaster Victim Identification Cell (DVIC): It is also proposed to set up a Disaster Victim Identification Cell (DVIC) for DNA profiling of victims of various disasters such as train accidents, fire accidents, air crashes, earthquakes, terrorist attacks, tsunami, etc. in order to assign bodies/victims to the respective families and to maintain their databases. The DVIC will not only be able to help in providing proper identification of the bodies but will also be able to assist the Authorities during settlement of financial claims or insurance compensation. The manpower and the infrastructure created at the NFTDP would be used for the activities of the DVIC.

d. Secretariat for DNA Profiling Advisory Board and Creation of National DNA Database: The CDFD has been instrumental in preparation of the draft DNA Profiling Bill 2006 which is shortly expected to be introduced in Parliament for enactment as a law. As envisaged in the draft Bill, the CDFD should house the Secretariat of the DNA Profiling Advisory Board. In addition, it is proposed to create and maintain the National DNA databank and database in the CDFD, comprising DNA profiles of different populations and of convicts and suspects. This activity in turn would be synergistic with other aspects of DNA profiling/training described above.

e. Quality control and accreditation: As provided for in the draft Bill, the CDFD should undertake the activities of quality control, quality assurance, and accreditation of the DNA profiling laboratories set up in the country in both the public sector and the private sector.

f. Other DNA profiling services: The DNA fingerprinting services to cover the areas of forensic genetics including forensic zoology and forensic botany, microbial forensics (especially in relation to potential agents of bioterrorism), wildlife conservation, identification of plant varieties and accessions, silkworm

and livestock breeding, and certification of Genetically Modified Organisms (GMOs).

Diagnostics Services

Even with its limited staff, the CDFD diagnostics group has been providing excellent referral services and counseling to children and families with inherited genetic diseases, and it is recommended to strengthen the same substantially by investments in equipment and recruitment of suitably qualified and experienced personnel.

a. Molecular genetics,
b. Cytogenetics,
c. Biochemical genetics,
d. Newborn screening center, and
e. Develop National Database for genetic disorders:

<u>R&D relating to services</u>

In relation to DNA fingerprinting services, R&D activities in the 11th Plan period will focus on the following areas:

a. Exploration of novel DNA-based methods for unique identification of individuals.
b. Development of new tools and techniques of DNA profiling from limiting quantities of and/or difficult, recalcitrant, heavily degraded, old or compromised items of forensic evidence.
c. Microbial forensics: This discipline deals with analyzing evidence from a bio-terrorism act, bio-crime or inadvertent microorganism/toxin release for attribution purposes. Establishment and development of such capacity at CDFD would require high-end instrumentation like MALDI-TOF (Matrix assisted laser disruption ionization-Time-of-Flight) and GC-MS (Gas chromatography-Mass spectroscopy) equipments.

d. Human population analysis with a view to elicit signature profiling of different caste populations of India to use them in forensic DNA fingerprinting and develop DNA databases.

e. In relation to diagnostics services, the CDFD may develop novel probes and SNPs for diagnosis of human genetic disorders in the families referred for diagnosis and counseling to the Centre.

Bacterial genetics and transcription biology

Biology of bacterial pathogens

i. Immunological studies,
ii. Pathogen evolution studies,
iii. Bioinformatics and functional genomics studies, and
iv. Genetic and structural biology studies

3.13.4 National Brain Research Centre

The mandate of National Brain Research Centre (NBRC) is to be a Centre of Excellence in Brain Research with state-of-the-art facilities, to evolve the centre through a networking approach and generate highly trained human resource. NBRC functions as a comprehensive brain research institute, which has been envisaged as a novel institute of its kind in having both intramural and extramural responsibilities. A unique role for NBRC is that it will act as a node with linkages to other centres carrying out neuroscience research in the country, acting in effect as the “hub of the wheel” rather than the wheel itself.

R&D Initiatives

Development of rationale therapies for neurodegenerative and infectious diseases of the nervous system through understanding of pathogenic mechanisms: Brain related disorders are known to contribute up to one-third of the total disease burden in both developed and developing countries. Among the

brain related disorders, which comprise of both neurological and psychiatric illnesses, a cause of serious concern are the age-related disorders such as senile dementia, Alzheimer's disease and Parkinson's disease etc.

Proteasomal dysfunction and Parkinson's disease and identification of the modulators of ubiquitin proteosome system. Traditional systems of medicine such as Ayurveda offer a knowledge base that can be utilized for development for therapeutic intervention strategies for treatment of these disorders. It is proposed to examine the neuro-pharmacological effects of plant extracts, which are used in traditional system of medicine for improving higher mental function.

Development of Cognitive Retraining modules for improving brain function in head injury patients: The increasing burden of brain disease together with improved medical treatment of the same saves lives. The lives so saved are lived with high levels of morbidity due to impairments of family, social and occupational functioning arising from cognitive deficits.

The following projects will be undertaken Brain bases of Capacity limits in Information Processing; Mental Load Deficits in Head Injury; Development of Home based Cognitive Retraining; and Programme to Improve Information Processing Capacity in Head Injury.

Development of computational tools for speech analysis: Clinically, speech is one of the earliest markers for development or acquired paediatric neurological disorders. Using digital signal processing shall be analysed speech signals from children and setting up quantifiers to assess different speech disorders and differentiate across them. These could be potentially developed into screening tools to aid speech pathologists and child psychiatrists. The specific projects include signal Processing tools to study patterns of speech production in normally developing children. A novel computational approach to study speech and language disorders. Development of a helium speech descrambler using DSP techniques.

Stochastic Activation for MR Imaging - Enhancement and Identification: The technique of stochastic activation and entropic classification is used to enhance

and identify images of brain lesions, including infection, inflammation, vascular insults, benign and malignant lesions. The procedure also grades the degree of aggressiveness of brain tumours according to the grade of malignancy

Specific projects include: Application of Stochastic Activation and Stability analysis for Brain Imaging and Therapy. Use of stochastic enhancement and grading of MR images of glioma. Non-equilibrium information theory and spatiotemporal neural processing and tensor Neuroimaging as a approach for investigating electrical conductivity and information flow in brain.

Translational Research Activities

Neural Stem Cell Research - Application of insights from basic research to animal models: This programme would comprising of both basic and translational components is focused towards understanding the basic biology of *neural stem cells* as well as to address the use of stem cells to treat disorders relating to the nervous system and for embryonic stem cell therapy for traumatic brain injury and stem cell therapy for spinal cord injury.

Clinical Research Centre for Brain Disorders (Science Medicine Complex for brain disorders at NBRC): Progress in brain research and the breathtaking advances in identifying the molecules and pathways that mediate brain functions can potentially enable us to develop cures for brain disorders. This centre shall be established to converge translational research and clinically relevant basic sciences research at one node and help conversion of advances in basic sciences into better tools for diagnosis, rational therapies and cures for treatment of brain disorders and be able to identify and successfully plan intervention for high risk groups for the developing disease. Conduct operational research to assess the cost-effectiveness and outcome of specific treatments and health services in local settings along with research, to monitor incidence and prevalence.

Brain Machine Interface: One of the greatest challenges in applied neuroscience is to build prosthetic devices that can be controlled by neural signals from the brain. It is proposed that an initiative on "Brain-machine interface" involving

experts from these areas be commenced in the 11th plan period and help develop this challenging, highly competitive, cutting edge research area. While NBRC would potentially spearhead this effort, it is proposed to also develop this initiative as a network project to be funded by NBRC through grant-in-aid provided by DBT.

Network programme

Network programme on genetics and pathogenesis of neurological and psychiatric disorders: The prevalence of large families and the close-knit social structure provide an ideal opportunity for carrying out molecular genetics on both neurological and psychiatric disorders. It is proposed to initiate multi-institutional research programme into understanding the genetic basis of complex neurological and psychiatric disorders and developmental disorders such as, autism.

*Development of neural prosthetics***:** One of of greatest challenges in applied neurosciences is to buiold prosthetic devices that can be controlled by neural signals from the brain. Such devices will provide the paralytic patients and amputees with the means to move and communicate by controlling the prosthetic device using brain activity. Therefore, to successfully develop neural prosthetics, an interdisciplinary group o fneuroscientists, mathematicians and engineers is required. It is proposed to create a network of neuron-engineering research group.

Centralized Facilities

Brain bank for Neural tissue, CSF and DNA samples: An important fact that emerged from the brainstorming session held by NBRC and its network centres was the need for a centralized repository for tissue samples from individuals suffering from various neuro-psychiatric diseases.

Primate Facility: The promise of stem cell technology has been largely restricted to applications involving cell cultures and small animals. If this technology is to be

beneficial to mankind then it is imperative that the results from these endeavors be translated into primate models before they can be used on human subjects.

Biological containment facility: A BL3 facility is required at NBRC for research work with live HIV and other organisms that infect the nervous system leading to brain damage. HIV infection is a major public health problem in this country and has significant neurological consequences

3.13.5 National Centre for Plant Genome Resource

While the programmes initiated during the Tenth Plan period would be continued and further strengthened to be taken to their logical conclusion, the Centre plans to expand and diversify its programmes during Eleventh Plan.

Basic Research

- Nutritional genomics: New genetic tools and materials for fighting macro – and micro – nutrient deficiencies.
- Plant x pathogen interaction: Manipulation of integrated defence response to infections in crops.
- Constraints in crop productivity: Downstream applications of functional genomics of stress tolerance and flowering time control and maturity time control
- Fruit ripening control: Analysis of signaling cascades in terms of multitude of inputs and outputs.
- Plant architecture: Understanding genetic interactions regulating plant habit and sexual reproduction for harnessing seed production potential.
- RNA biology revelation: Analysis of gene silencing pathways in plants through siRNAs and role in DNA replication and gene expression.
- Plant hormone world: Pathways of function in growth, development and environmental adaptation.

- Transcriptional landscaping of the plant genome: Identification of essential and inessential genome segmental features and manipulation of their organ– and temporal–specific expression for better harvest index.
- Increasing the power of molecular breeding: Fine mapping, gene tagging and comparative sequencing and expression analyses.
- Plant cell factories: Economic production of proteins, enzymes and fine chemicals.

Translation Research

Transgenics Evaluation and Technology Transfer: NCPGR plans to expand the research activities by setting up of a unit to develop transgenics and its evaluation and technology transfer which would include management of patents, material-transfer and other IPR related work. This single innovative programme would require substantial additional financial support to the extent of Rs 40 crores.

Network Programmess:

NCPGR has been able to successfully network with other institutions engaged in research in plant genomics/development of transgenic crop. It has five international collaborative programmes and has developed a close working linkage with various research institutions within the country such as IARI, PAU, HAU, UAS, CTCRI, ICRISAT, etc. The Centre would continue to work in close coordination with these and other crop improvement institutions. An effective inter-institutional programme in this respect would be of utmost importance for employing molecular markers in breeding suitable cultivars for farmers. A state of art crop bioinformatics centre shall also established.

3.13.6 Institute of Bioresource and Sustainable Development

Core activities/strategies:

Bioresources database development, including local traditional knowledge, for the priority flora, fauna and microbes of North-East Region using bioinformatics tools and techniques for Bioresources conservation, development and utilization.

Ex-situ conservation through biotechnological interventions, molecular characterization and molecular taxonomic studies for the potential priority/targeted plant, animal and microbial bioresources of the North-Eastern region of India for need based utilization and conservation.

Prospecting of identified plant, animal and microbial bioresources of North-East Region of India for target based bioactive molecules for therapeutic use, aromatic compounds, dye yielding compounds, novel genes and gene products for possible utilization.

Genetic improvement through molecular breeding approaches for chosen plant, animal and microbial bioresources of North-East Region for food, nutrition and environment security.

Development of ecologically sound rehabilitation packages for maintenance of soil fertility, prevention of soil erosion, regeneration of degraded hill and wetland ecosystems for biodiversity conservation and survival of bioresources.

Bioresources based rural technology package development for value added products and processes for employment generation and economic progress of the North-East region.

Bioresources education for capacity building on bioresources conservation and development to students, researchers, etc. and technology transfer for bioresources utilization through training of bio-entrepreneurs and biovillage development.

Multi-institutional collaborative and networking approaches to achieve the institute objectives within a time frame.

New Activities:

Innovation Centre: Genome Club, an innovative approach may be setup for regular interaction between bio-entrepreneurs, graduate students and researchers on biodiversity conservation and bioresources management. The main features of Genome Club shall be invited lectures, discussions, seminars, workshop etc. Such an approach may also act as a good idea generation system by hybridizing the traditional knowledge and scientific knowledge to develop the local demand or need which may ultimately lead to the development of problem oriented research agenda.

Network multi-institutional programme:

Network programme for integrated development on value addition for ginger and turmeric of N.E. Region for commercial exploitation

Network programme on standardization and value addition for fermented bamboo shoots of N.E. Region for commercial exploitation.

3.13.7 Institute of Life Sciences

The core research programme of ILS during the 11th plan will be strategically addressing issues on infectious disease biology in experimental as well as human models. Genetic polymorphism of genes associated with immune responses to pathogens in Indian population is an avenue that complements studies on immunity and immunoregulation in infectious disease, particularly in close-bred communities such as tribal population. The ILS plans to undertake high throughput genome analysis of the tribal population to correlate genetic polymorphism with susceptibility/resistance to infectious diseases.

Development of DNA chip based diagnostics(Collaborating institutes: Centre for Cellular and Molecular Biology, Hyderabad) : The objective is to devise a set of reactions for a single clinical specimen so that a large class of bacterial, viral and parasitic pathogens (both cultivable and non-cultivable) could be detected. These could be used not only for diagnosis of pathogens for patient care but could also

be very powerful tools for large scale epidemiological purposes in human communities.

Nanomedicine(Collaborating institutes: Sankara Nethralaya, Chennai, Hemalatha Hospitals and Research Centre and Imgenex India Ltd, Bhubaneswar): The core competence available with the existing faculty of ILS offers utilization of nanotechnology for immediate application in animal and human diseases for targeting already available drugs. Major road blocks in drug development for cancers have been in the area of refining delivery systems.

Establishment of a National Repository of C.elegans

C. elegans is a soil nematode with short generation time (3 days) and all the developmental stages can be easily cultivated *in vitro*. Several fundamental breakthroughs in biology have been made using this model system. The full genome of this parasite has been sequenced and about 4000 mutant strains with specific gene deletions are currently available for use. The ILS with its expertise available on nematodes is well placed to set up a national repository of C.elegans so that several groups in the country could use the model system as an effective tool.

Human resource development

The number of PhD scholars is expected to be around 40. This would be achieved as a corollary of induction of new faculty during the first two years of 11^{th} plan period. The institute will continue to conduct bi-annual workshops in the area of Medical and Plant Biotechnology during the next 5 years.

Infrastructure development:

Construction of the new R&D building, animal house, green house and research scholars' residence is expected to be completed by the end of 2007.

3.14 Other Recommendations

Assessment of impact of programmes

It was recommended that the impact of the programmes to be implemented in the 11th plan should have definite measurable indicators of progress from time to time. These indicators could be subject specific such as number of software developed, users of facilities in case of infrastructure programmes. In general, in all projects funded, the numbers of publications, impact factor to those publications, patents filed and granted, technologies developed, transferred and commercialized may also be thoroughly monitored for assessment of overall impact of the projects.

Novel monitoring mechanisms

The department may also to evolve innovative institutional mechanisms outside the department for coordination, management and monitoring of the programmes for effective implemention and outcome. Reengineering the existing institutions with a capacity for innovation and creating new institutions is essential for driving the strategy for world class R&D and bio-enterprise development.

Modalities implementing networks

The network programmes proposed in each of the sectoral areas should be developed by planned process of partnerships, agreements, and defined objectives for each partner on an innovative value chain from basic research to prototype /product development.

Modalities for competitive grants

The competitive grants for individual investigators should generate new knowledge rather than repetitive and duplicative. The basic research knowledge generated should have definite potential for translational activities to follow either in network mode or through public-private partnerships.

Building new capacities afresh

Adequate attention may be paid for building new capacities of research in universities and institutions which do not have adequate facilities and financial resources, although the investigators available at these places are motivated for taking up life science and biotechnology research. Linkages with established laboratories and investigators may be arranged for mentoring and ensuring quality output.

3.15 Financial Projections

Recognizing that the development of product and processes of social and economic value in biotechnology require long gestation periods involving various elements of innovation from R&D to commercialization, the working group has observed that early major initiatives are necessary for reaping the benefits in the years to come. Considering the aforesaid recommendations, the DBT has to take major new initiatives involving promotion of innovation, establishment of centre of excellence, new institutions, expansion of human resource development, upgradation of life science departments, several models of public-private partnerships, focused expansion of existing autonomous institutions and mission mode projects. Comparing investments by the leading countries and domestic /transnational companies in biotechnology in the world, the enormous potential that India can offer in this sphere, and for making India a “Biotechnology Hub” of potential investment destination, self reliant in technology with export promotion possibilities in Asia and the rest of the world, the working group strongly recommended an investment of Rs.12000 crores during the 11th plan (2007-2012). The break-up of which is at **Annexure-VII**.

Annexure-I

Constitution of Working Group on Biotechnology under the Steering Committee on Science and Technology for the Formulation of 11th Plan (2007-12)

I. Composition:

1. Dr. M.K Bhan, Secretary, DBT	Chairman
2. Prof. G. Padmanaban, Honorary Prof., IISc., Bangalore – 560012	Co-Chairman
3. Prof P.N Tandon, Former INSA President Delhi-110092	Member
4. Dr. K. Vijay Raghavan, Director, National Centre for Biological Sciences, Bangalore-560065	Member
5. Dr. E.A Siddiq, Emeritus Professor, Hyderabad-64	Member
6. Dr. S. Nagarajan, Chairperson, Protection Plant Varirety Farms Rights Authority, New Delhi-110012	Member
7. Dr. R.P Sharma, Ex-Director, NRC on Plant Biotechnology New Delhi – 110 012	Member
8. Prof. Akhilesh Tyagi, University of Delhi, South Campus, New Delhi – 110 021	Member
9. Dr. P.S Ahuja, Institute of Himalayan Bioresource Technology Palampur	Member
10. Dr. P.N Bhat, (Ex-DDG, ICAR) New Delhi	Member
11. Dr. I. Karuna Sagar, College Of Fisheries, Mangalore-571002	Member
12. Prof. K. Darmalingam, Madurai Kamaraj University, Madurai – 625 021.	Member
13. Prof. Alok Ray IIT Delhi-110016	Member

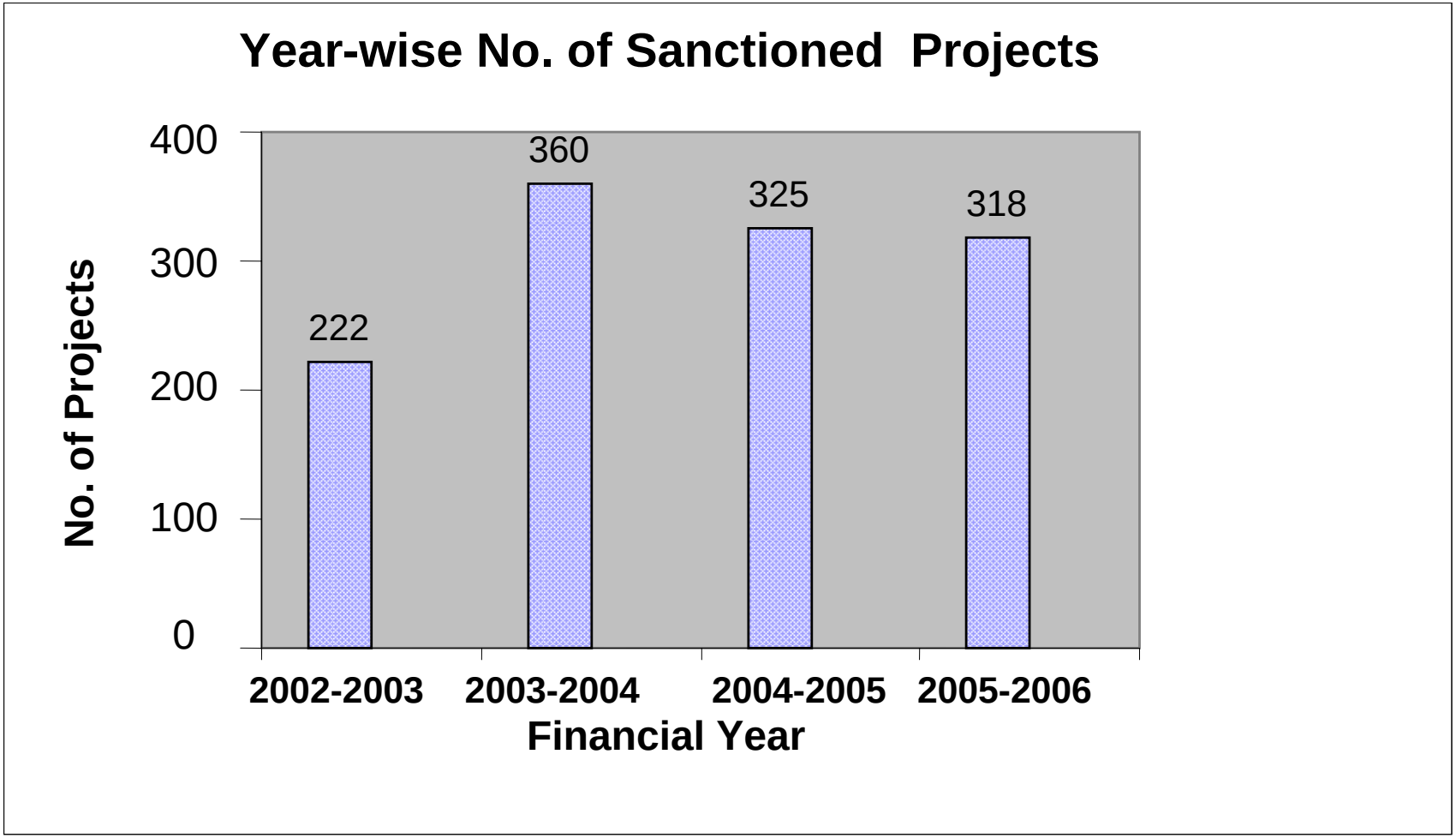
Annexure –II

14. Dr. M.M Sharma, Mumbai – 71	Member
15. Ms. Kiran Mazumdar, CMD Biocon India Ltd., Bangalore – 561229	Member
16. Ms. Deepanwita Chattopadhyay, CEO, ICICI Knowledge Park, Hyderabad-500016	Member
17. Dr. Usha Bharwhle, Mahyco Life Sciences Research Centre, JALNA-431203 (Maharashtra)	Member
18. Shri Sharad Naru, Hyderabad APIDC venture Capital Ltd, Hyderabad-500034	Member
19. Dr. Kameshwar Rao, Bangalore Executive Secretary, Foundation for Biotechnology Awareness and Education, Bangalore-560004	Member
20. Dr. Renu Swarup, Advisor, DBT	Member Secretary

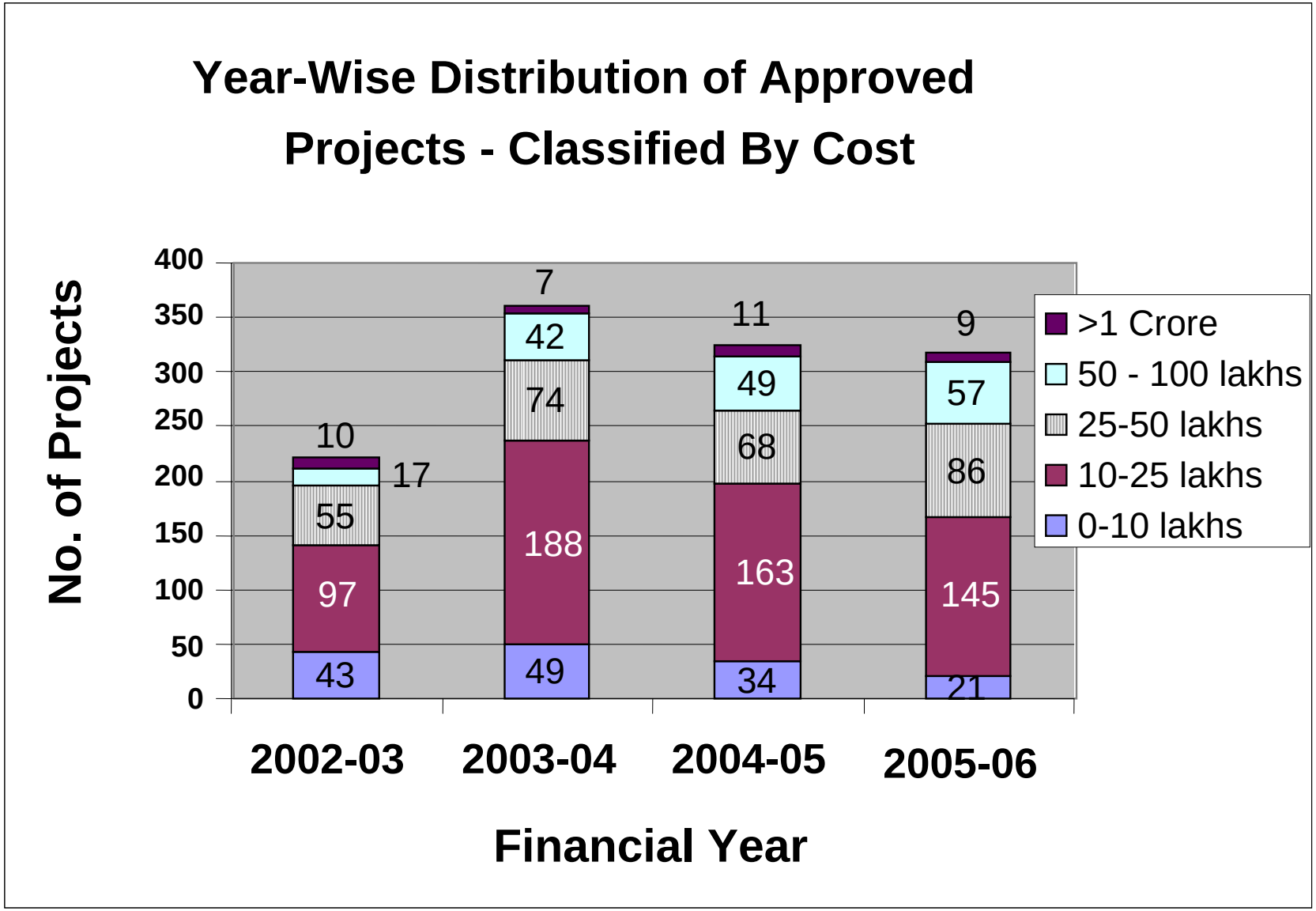
II. Terms of Reference

1. To review and assess the progress made in the areas of Biotechnology through support to various programmes and activities during the 10th Five year Plan, identifying the achievements, weaknesses/shortfalls and gap areas, including those identified in the Biotechnology strategy
2. To suggest plans and programmes to be taken up during the 11th Plan period based on the policy, approach, thrust and priorities of the Biotechnology sector, the new plans and schemes suggested should take into consideration convergence of various ongoing schemes on a priority basis, closure/merger of certain schemes based on new strategies & priorities and suggest an optimum outlay for the Biotechnology sector for the 11th Plan period.
3. The modalities of R&D funding, interagency linkages including public private partnership models may also be assessed and new strategies suggested for enhancing the growth of the sector
4. The chairman may co-opt Members for specific task
5. The expenditure on TA/DA in connection with meeting of this group would be met by the concerned department
6. The report of the group would be submitted by 31st July 2006

Annexure –II

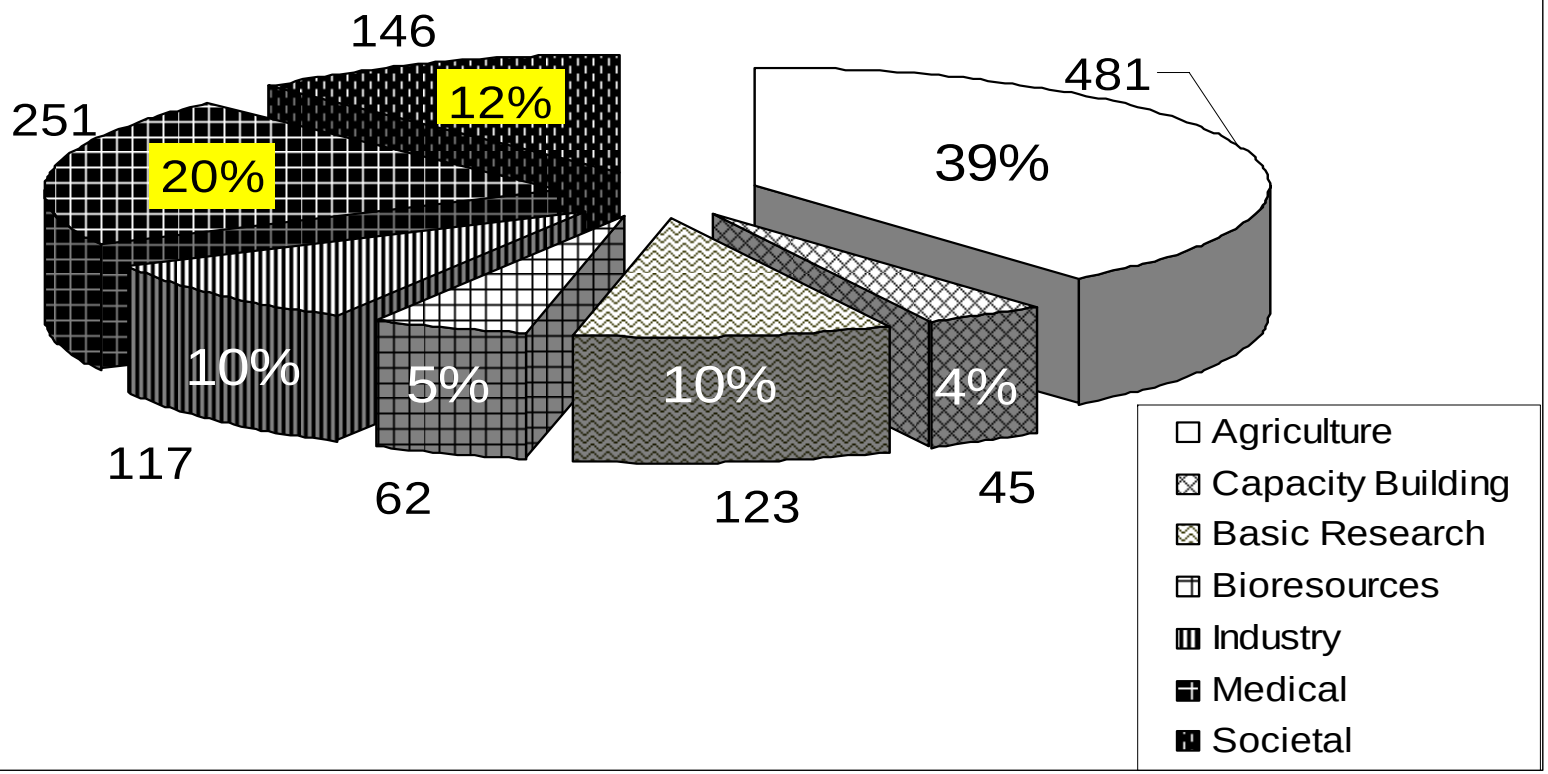

Year-wise No. of Sanctioned Projects
No. of Projects
400
300
200
100
0
222
360
325
318
2002-2003
2003-2004
2004-2005
2005-2006
Financial Year

Annexure-III



Annexure-IV

Area wise No. of Approved Projects During 01-04-2002 and 31-03-2006



Annexure-V

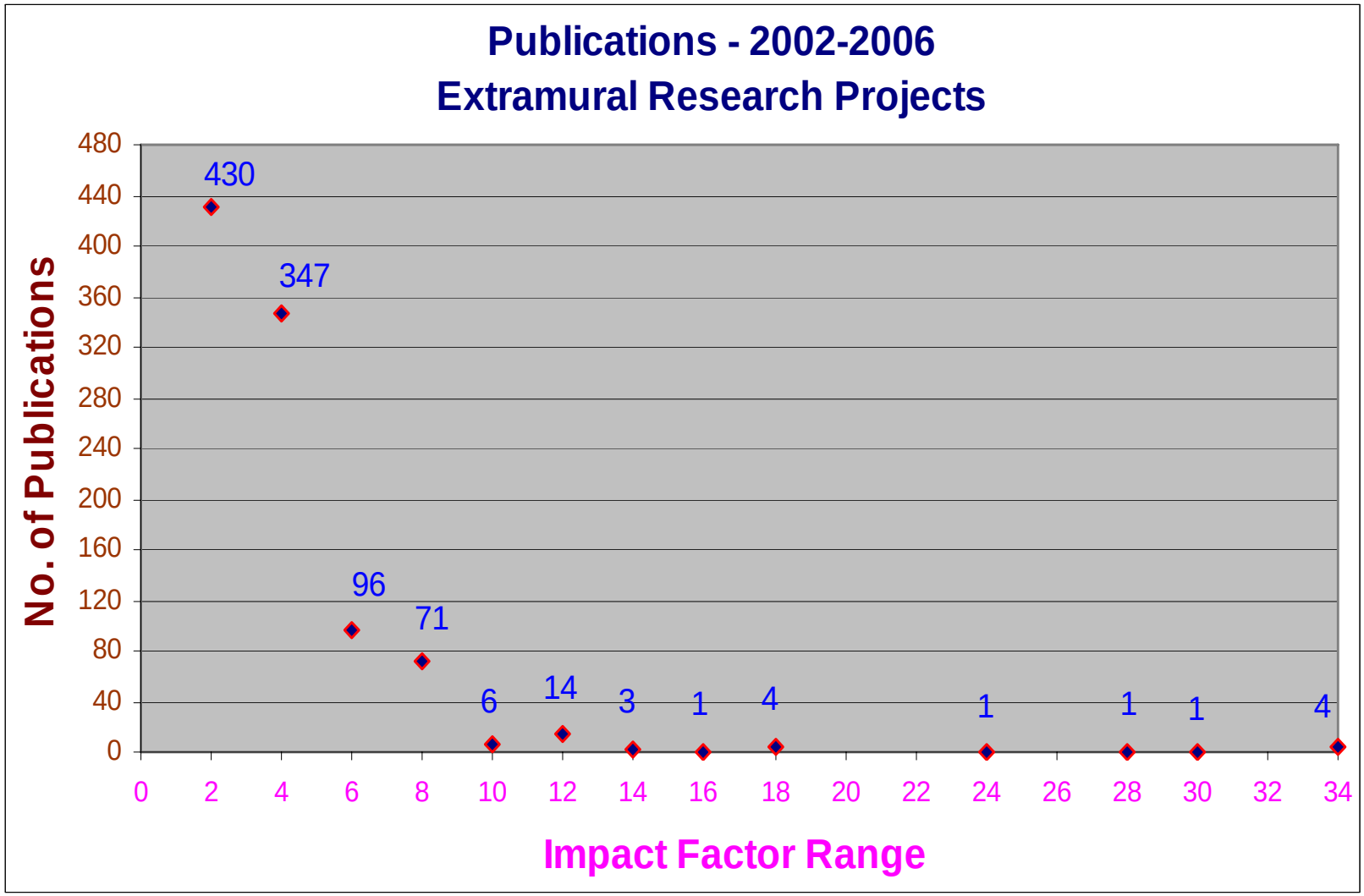
Extramural Research Outputs

Year	Publications	Technologies developed	Technologies Transferred	Products	Commer-cialized	Patents Filed	Patents Granted
2002-2003	164	30	13	7	-	34	11
2003-2004	178	41	24	8	1	36	22
2004-2005	263	45	21	4	1	42	7
2005-2006	374	118	36	5	15	46	12
Total	**979**	**234**	**94**	**24**	**17**	**158**	**52**

The above information pertains to :

Number of Projects = 519
Total Cost = Rs. 222.26 crore
Scientists involved = 254

Annexure-VI


Publications - 2002-2006
Extramural Research Projects
No. of Publications
480
440
400
360
320
280
240
200
160
120
80
40
0
430
347
96
71
6
14
3
1
4
1
1
1
4
0
2
4
6
8
10
12
14
16
18
20
22
24
26
28
30
32
34
Impact Factor Range

Annexure-VII

MINISTRY OF SCIENCE & TECHNOLOGY

DEPARTMENT OF BIOTECHNOLOGY

ELEVENTH FIVE-YEAR PLAN (2007-2012) OUTLAY

(Rs. In Crores)

Sl. No.	Name of Programme/ Scheme/ Project	Eleventh Plan Outlay
1.	Promotion of innovation	1000.00
2.	Industrial promotion and development	1500.00
3.	Human Resource Development	750.00
4.	Biotech Infrastructure	750.00
5.	Mission-mode programmes	1000.00
6.	International Cooperation	200.00
7.	Sectoral R&D	3500.00
8.	Biotechnology for Societal Development	300.00
9.	Autonomous Institutions	**3000.00**
	(i) On-going	1500.00
	(a) N.I.I.	400.00
	(b) N.C.C.S.	250.00
	(c) CDFD	200.00
	(d) NBRC	250.00
	(e) NCPGR	150.00
	(f) IBSD	100.00
	(g) ILS	150.00
	(ii) New Institutions	1500.00
TOTAL		**12000.00**