

# National Biotechnology Development Strategy

## Key Elements



**The Future Bioeconomy:**  
Translating Life Sciences knowledge into  
socially relevant, eco friendly and  
competitive products



**Department of Biotechnology**  
Ministry of Science & Technology  
Govt. of India

# National Biotechnology Development Strategy

## Key Elements

The National Biotechnology Development Strategy has been approved by the Government of India. The strategy is an outcome of a two-year-long nationwide consultation process with multiple stakeholders including concerned ministries, universities, research institutes, private sector, civil society, consumer groups, non-government and voluntary organizations and international bodies. The draft strategy, which was posted on the web, received over 300 comments from all sections of the society. The strategy has been finalized after careful scrutiny of these.

- The Government recognizes that biotechnology is a sunrise sector and hence, needs focused attention
- Approval has been accorded for the broad framework of the National Biotechnology Development Strategy and the strategic focus on sectors proposed therein
- The strategy, while enabling the full utilization of currently available opportunities in manufacturing and services, will lay a strong foundation for discovery and innovation, effectively utilizing novel technology platforms with potential to contribute to long term benefits in agriculture, animal productivity, human health, environmental security and sustainable industrial growth
- The cornerstone of the strategy is the focus on building coherence and connectivity between disciplines and to bring together variegated skills across sectors to enhance synergy
- The strategy seeks to address a number of challenges relating to the biotech sector in terms of R&D, creation of investment capital, technology transfer, absorption and diffusion, IPR, regulatory issues, building public confidence, and tailor made human capital for all these aspects
- The stated vision of the strategy is responsible use of life sciences and biotechnology to promote balanced growth of all sections of the society
- The key elements of the strategy are highlighted in the following pages.



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## Regulation

### Reinforcing the Regulatory Framework

#### National Biotechnology Regulatory Authority

A National Biotechnology Regulatory Authority would be set up as an independent, autonomous and professionally led body to provide a single window mechanism for biosafety clearance of genetically modified products and processes.

- DBT has been entrusted with the responsibility of setting up of the Authority
- Existing mechanisms, however, would continue till a full-fledged body is created with the required infrastructure and fully functional autonomy.

## Inter-ministerial Coordination

### Keeping Eye on the Big Picture

#### High Powered Inter-ministerial Coordination Committee

A High Powered Inter-ministerial Committee is to be set up:

- To effectively coordinate the development of the sector by addressing cross cutting issues and
- To debate on the desirability or otherwise of setting up of a Biotechnology Commission
- Secretary, Department of Biotechnology will chair the Committee.

## Promoting Biotech Industry

### 30% of DBT's Budget to be Spent on Public-Private Partnership Programmes

In a major departure from normal funding mechanisms, it has been decided to invest up to 30% of DBT's budget in public-private-partnership schemes by the end of the 11th Plan. This is to promote innovation, pre-proof-of-concept research, accelerated technology- and product development in biotechnologies related to agriculture, human health, animal productivity, biomanufacturing and environment.

## Joining Hands

### **Biotechnology Industry Partnership Programme for Advanced Technologies**

Biotechnology Industry Partnership Programme (BIPP) is being launched for achieving global competitiveness and generating intellectual property in frontier biotechnologies related to agriculture, health, environment, bioenergy and biomanufacturing, with focus on contributing to a long-term and sustainable bioeconomy. A novel feature of this cost-sharing scheme would be to allow the industry partner to retain intellectual property, with payment of appropriate royalty to the contributing public sector scientist(s). The scheme would be particularly directed towards finding solutions to difficult-to-fulfill and, as yet, unmet national needs through advanced technologies. Unlike the SBIRI programme (see below), large industry partners could be engaged under this scheme.

## Supporting Small and Medium Sector Innovation

### **Expanding SBIRI**

The existing Small Business Innovation Research Industry (SBIRI) scheme to promote innovation in SME's has been a success. Based on the urgent need to support innovation in small-and-medium-sector biotech enterprises, and the strong endorsement received from industry for the scheme, approval has been accorded for the expansion of the SBIRI during the 11th Plan.

## Reaching Out

### **BIRAC to Nurture Industry R&D**

A Biotechnology Industry Research Assistance Council (BIRAC) is being launched to (a) act as an interface between academic and private sector, particularly SMEs and startups, (b) nurture and catalyze R&D and innovation in biotechnology in the private sector and (c) promote public-private partnerships. The functions of BIRAC inter alia would be to:

- Trigger, transform and tend biotech startups to convert research in public and private sector into viable and competitive enterprises
- Support, strengthen and scale up small-and-medium enterprises utilizing indigenous biotechnological innovations
- Provide financial, infrastructural, institutional and mentoring support for biopreneurs so that barriers to entry are reduced

- Encourage knowledge networking among biopreneurs at national and international level to maintain technological and scientific edge
- Manage support to Biotechnology Industry Partnership Programme (see above)
- Provide other policy and institutional support for the actors involved in converting biotechnological innovations into enterprise.

## Building World Class Human Capital

In its vision to build world class human capital, the strategy has focused on the following:

- To improve and expand PhD and post-doctoral programmes in order to reach the best levels in the Asian region
- To enhance the quality of masters level and undergraduate level education
- To promote all life sciences and biotechnology at undergraduate and masters levels rather than targeted biotechnology focus as at present
- To create a translational workforce of high quality to meet short- and mid-term requirements of the country
- To strengthen education and training at university departments in 20 Universities to be identified

Some key programmes are indicated below

### Lending Luster to Learning

#### Star Colleges in Life Sciences

In an endeavour to offer young scholars an opportunity to excel in a career of choice in life sciences and biotechnology, DBT will support institutions providing undergraduate education to achieve 'Star College' status. Put simply, this means a march towards achieving a unique and world class brand in life sciences. The initiative offers support for

- Improving knowledge and skills of teachers in basic life sciences and specialized techniques
- Generating appropriate infrastructure and making it accessible to students
- Increasing availability of consumables, reagents and chemicals for students
- Ramping up curriculum that enhances creativity in asking original questions and substantial hands-on experience in designing and conducting practicals by students and



- Summer schools for exposure to platform biotechnologies and promoting creative thinking

### Clearing Cobwebs

## Reengineering of Existing University Departments

Centres of global standards combining both education and research in biotechnology will be created - through improvement in infrastructure and faculty, and encouraging new research agenda - by upgrading promising, but small departments in existing universities. Such mini-centres will focus on areas being currently addressed sub-critically or not being addressed at all. Examples of focus areas include: i) integrated chemical engineering and biology for bioenergy and biotherapeutics; ii) microbial prospecting for new bioactive molecules; (iii) novel technology platforms including application of nanoscience in agriculture, health and environment; (iv) regulatory science; (v) genomics- and proteomics-based preventive medicine; (vi) integrated food science, nutrition and nutraceuticals; (vii) new platforms for production of biomaterials; and (viii) clean environment through green manufacturing processes.

### Focus on the Young

## Human Resource Initiatives

A number of new initiatives are in the offing to encourage bright young minds to choose a career in life sciences. Examples include:

- Rapid expansion of Ph.D and post-doctoral programmes
- Novel industry-oriented programmes (e.g. degree in regulatory affairs, biomedical enterprise, biomedical quality systems and product development, bioinformatics, technology transfer and commercialization, biomedical translation research)
- Life science fellowships at college level
- Summer schools for training in biotechnology
- Regional Training Centres for teaching

### Building Academic Excellence in the Country

## New Role for DBT's Autonomous Institutes

A new role is visualized for autonomous institutions of DBT to promote excellence in R&D. Selected institutions will be financially empowered for promoting excellence in and translational R&D by supporting 'Research Resource Units' in universities and



sister institutions through extramural funding. The funds would be used through a management mechanism independent of the institute administration. The idea is to encourage DBT's autonomous institutes to develop efficient and powerful R&D networks and partnership programmes in biotechnologies.

## **Globally Oriented Training**

### **UNESCO Centre**

UNESCO Regional Centre for Science, Education and Innovation in Biotechnology is being established at Faridabad, Haryana, by DBT as part of a Health Science and Technology Cluster. The Centre will:

- Create and nurture high quality interdisciplinary human resource
- Provide globally oriented education and training
- Offer training for physicians intending to enter the biology field and short-term exposure to biologists and engineers through hospitals and medical schools
- Focus on industry-oriented training in
  - Regulatory Affairs
  - Biomedical Enterprise/ Business Development in Biotechnology
  - Biomedical Quality Systems and Product Development
  - Bioinformatics
  - Technology Transfer and Commercialization and
  - Biomedical Translational Research
  - Systems biology

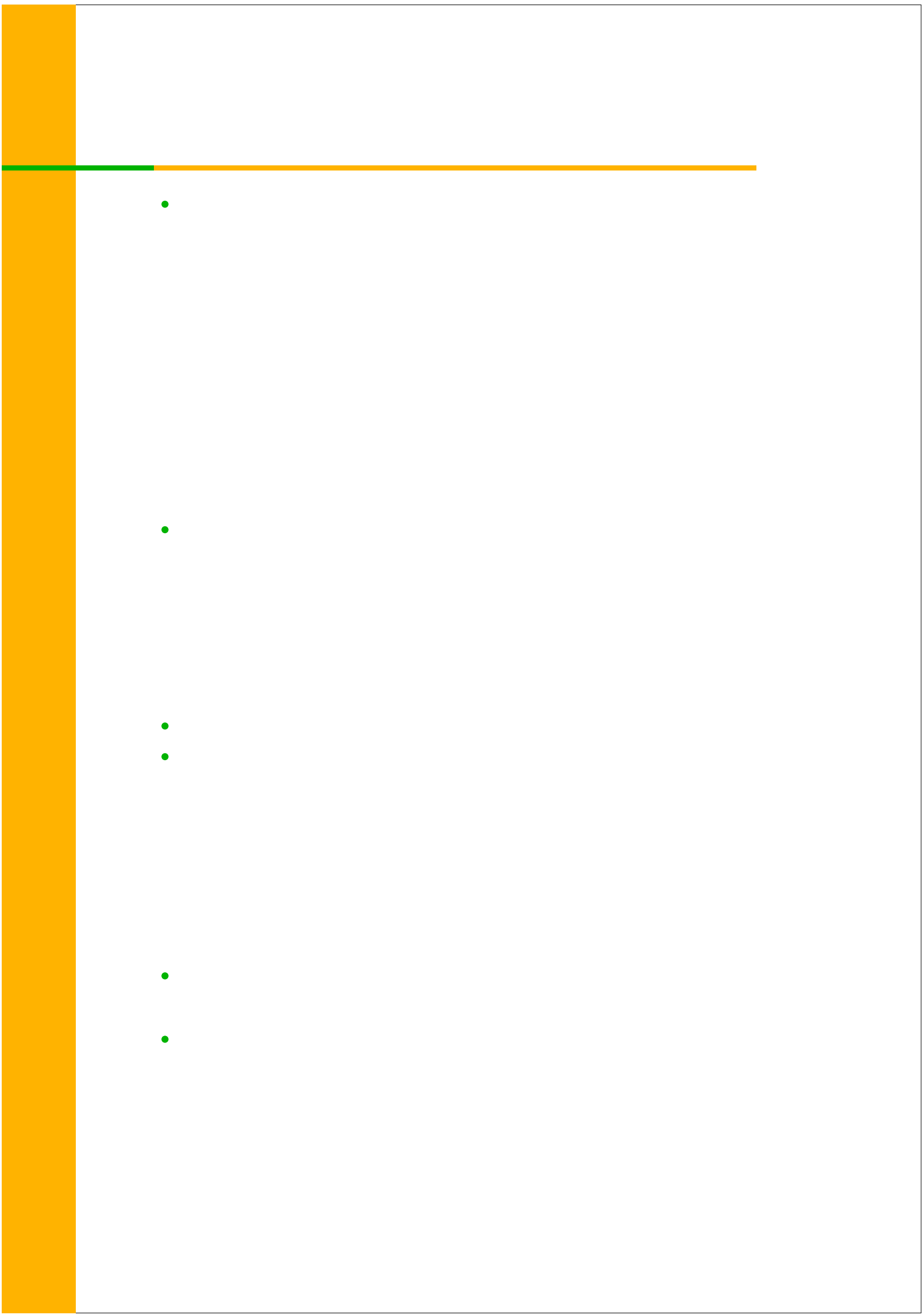
## **Reversing Brain Drain**

### **Attracting Scientists from Overseas**

Innovative re-entry packages in terms of fellowships and R&D support will be offered to young and senior scientists of Indian origin to return to Indian laboratories and pursue research on national priorities.

- A special scheme to attract mid-to-senior level scientists of Indian origin has already been launched. The fellowship is provided for at least 5 years and DBT will facilitate location in a suitable host institute in India.
- Highly attractive fellowships are being set up for young and mid level post doctoral researchers and young faculty, with R&D grants as well as ensuring mobility into and out of India over a period of 3-4 years







# Catalyzing Synergy and Innovation

## Securing Synergy

### Technology Clusters

Cluster development is a key strategy to promote innovation and accelerated technology and product development. Biotechnology being inter-disciplinary in nature, facilities for promoting scientific and engineering research, entrepreneurship and infrastructure, should be located together to nurture and promote innovation for building a successful enterprise. The clustering concept maximizes synergy and efficiency. This new approach has been given the green signal by the Government of India. Already, four technology clusters are at an advanced stage of planning:

- Agri-food Technology Cluster, to be located in Punjab at the Mohali, Knowledge City will have
  - National Agri-food Biotechnology Institute (NABI), the Food Bioprocess Unit (BPU) to provide services to startup companies, and the Agri-food Park (all three through DBT)
  - Nanotechnology Centre (through DST)
  - Indian Institute of Science Education and Research (IISER) (through HRD) and
  - Management Institute (through Govt of Punjab)
- Health Science Biotechnology Cluster, being established in Haryana at Faridabad by DBT will include
  - Translational Health Science Technology Institute,
  - Vaccine Technology Centre
  - Diagnostics Development Centre
  - Platform Technology Unit
  - Animal Facility for Studying Human Diseases and
  - UNESCO Center for Biotechnology Education and Research
- Animal Science and Biotechnology Cluster, to concentrate on issues related to animal health and productivity, and will be located around a university to be identified
- Marine Science and Technology Cluster, to focus on maximizing productivity from marine bioresources, and will be located around a university to be identified



## Ensuring Support Systems

### Beefing up Biotech Infrastructure

Availability of appropriate technological infrastructure is a prerequisite for a successful biotech enterprise. The following infrastructure facilities/support systems would be promoted during the 11th plan

- Biotech incubators, parks (at least 10)
- Repositories of biologicals for agriculturally and therapeutically important organisms, plasmids etc.
- GMP scale-up facilities for pilot production
- Large-animal houses
- Testing facilities for GMOs / LMOs
- Testing of GM crops and GM food
- DNA and stem cell banking facilities
- Gene banks
- Biosafety level III, IV labs
- Molecular and chemical libraries for screening for therapeutic leads
- Customs infrastructure and processes for biologicals
- Trade related testing-and-certification-accredited laboratories

## Scaling New Heights

### Aiming High

#### Grand Challenges Programme

Grand Challenges are fundamental problems in science or engineering, with broad applications whose solutions would be enabled by the application of high performance biotechnology resources that could become available in the near future. Grand challenges of national relevance in the area of agriculture, health, energy and environment will be identified through national and international consultations. Programmes will then be launched through multidisciplinary teams, involving public-private partnerships.

### Branching Out in New Directions

#### New Breed of Institutions to be Set Up in Critical Areas

DBT's proposal to establish new institutional structures, especially in areas very vital to India's progress but in which current strengths are suboptimal has been approved in

principle by the Government. The institutions, representing a new breed, will be designed with a strong bias for integrating science and translation, and for producing skilled personnel driven towards entrepreneurship. The areas include:

- Translational Research in Health Science and Technology
- Stem Cell Engineering and Regenerative Medicine
- UNESO Regional Centre for Science, Education and Innovation
- Agri-food Biotechnology and Bioprocessing Unit
- Animal Biotechnology
- Marine Biotechnology
- Seri- and Textile Biotechnology
- Medical Genetics and Genomics.

Besides, three Translational Molecular Medicine Centres and a Centre for Fundamental Plant Sciences will be set-up in existing institutions. Taking over of Rajiv Gandhi Centre for Biotechnology, Thiruvananthapuram from Government of Kerala has been approved.

## New Legislation

### On Guard

#### Protection of IP in Public Funded R&D

A draft bill entitled 'Public Funded R&D (Protection, Utilization and Regulation of Intellectual Property) Bill, 2007' has been prepared through inter-ministerial consultation for promotion of innovation, and would be introduced in the Parliament after obtaining cabinet approval. The proposed legislation will promote, protect and optimize the potential of public-funded R&D in a manner that is beneficial to the inventor(s) as well as to the public, and encourage innovation in SMEs, promote collaboration between government and non-government organizations, as well as catalyze commercialization of IP generated out of public-funded R&D.

### Helping Catch Criminals More Effectively

#### DNA Profiling Bill to Augment and Transform Forensic Investigation and Criminal Justice Delivery System

With the intention of enhancing protection of people in the society and



administration of justice, analysis of DNA found at the scene of crime, of the victim or offender has been used to unambiguously establish identity. A 'DNA Profiling Bill-2007' is being piloted by DBT to place the fledgling DNA profiling services - at present being offered by a limited number of institutions in the country - on a vastly expanded and sound footing state.

- The bill proposes the establishment of a statutory DNA Profiling Board with its secretariat at the prestigious autonomous institution of the DBT, Centre for DNA Fingerprinting and Diagnostics, Hyderabad as an Authority
- The Authority is to define, establish, and modify standards and to implement quality control measures including compulsory accreditation of laboratories/agencies undertaking DNA profiling services in the country satisfying stringent ethical criteria to prevent abuse or discrimination against individuals or society at large
- The Authority will also create and maintain databases of suspects, convicts, and under trials for detection of and to serve as deterrents against repeat offenders.

The proposed legislation, therefore, is set to transform forensic and criminal justice delivery system in the country. The Bill would be introduced in the Parliament, after it has been approved by the Cabinet.

### Setting Standards

#### Guidelines for Stem Cell Research

The Indian Council of Medical Research (ICMR) and DBT have jointly developed guidelines on stem cell research in the country and these will be widely circulated in the country.

## Meeting Basic Societal Needs

### Meeting Basic Needs

#### New Translational Initiatives for Mass Use Technologies

DBT will give special emphasis on translational initiatives to promote mass use technologies. The hallmark of these initiatives will be a missionary approach, fast track funding, multi-disciplinary teams with trans-sectoral skills; rapid decision making, and finding quick and viable solutions. The initiatives will be in the areas relating to

- Designer crops through genomics, informatics and plant breeding
- Novel foods and nutritive products to promote wellness and health

- Animal health and productivity
- New generation vaccines and diagnostics
- Biodrugs for common diseases
- Bio-implants and devices
- Green manufacturing processes
- Sustainable utilization of bioresources and
- Any other area relevant to societal needs

## Creative Global Collaborations

### Going Global

#### Leveraging International Partnerships

International cooperation and partnerships will be leveraged to achieve global best practices in our S&T efforts for joint IP generation, harmonization of regulatory processes, smooth trans-boundary movement of biological materials, and to access global markets for our products and processes. R&D collaborations will be forged with major international laboratories/bodies (e.g., WHO, CGIAR, MIT-Harvard University, Stanford University, Wellcome Trust) in biotechnologies related to health, agriculture and bioenergy, biomanufacturing and other relevant sectors.

## Performance Indicators

### Judging Performance

#### Measuring the Success of Implementation

The success of implementation of the biotechnology development strategy will be measured on the following parameters related to biotechnology

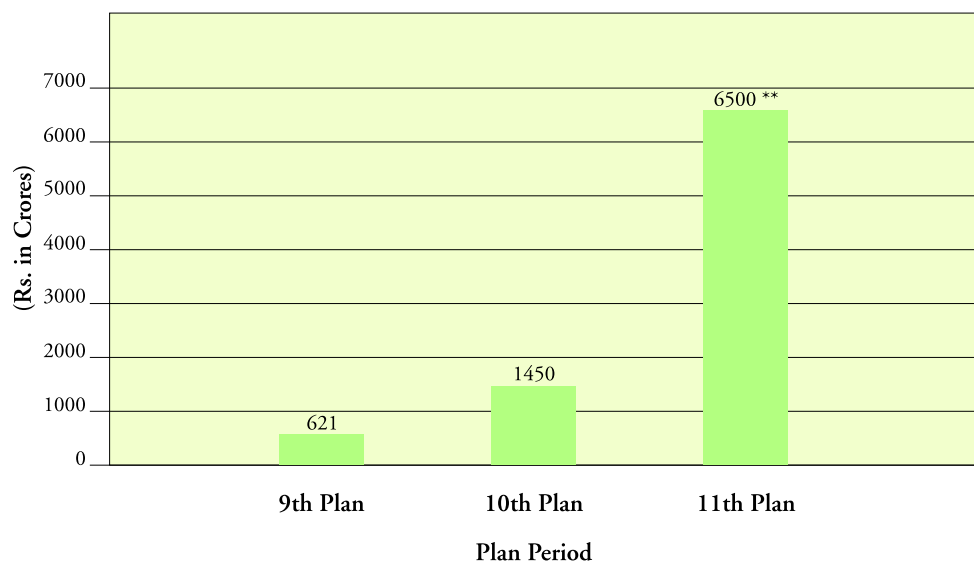
- Increase in the number of new companies and SME's engaged in R&D
- Greater enrolment of students in life sciences and biotechnology courses
- Narrowing talent gap in terms of demand and supply
- Economic/social impact of new technologies
- Increased contribution of university system to biotechnology publications in terms of quality and number
- Increased number of patents generated
- Number of international partnerships contributing to increased IPR and access



- The Indian biotech industry generating revenue of at least US \$ 7 billion annually by 2010 and
- Increased percentage of projects with private partners

## DBT's Funds

### Availability of Funds for DBT through the Plans\*



\* It is to be noted that biotechnology sector receives funding from several sources such as CSIR, DST, ICAR, ICMR, MHRD and others

\*\*Indicative figures at current costs



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## Department of Biotechnology

Ministry of Science & Technology

Govt. of India

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