



R F D

Results Framework Document
for
Department of Bio-Tecnology

(2009-2010)

Section 1: Vision, Mission, Objectives and Functions

Vision

The vision of the department is to create biotechnology tools and technologies that address the problems of agriculture productivity, food production, nutrition security, health care and environmental sustainability affecting the large section of the society, provide new and emerging products and services at affordable prices, generate employment opportunities and make India globally competitive in the emerging bio-economy.

Mission

The Department of Biotechnology seeks to achieve its vision by facilitating emergence of a system that promotes excellence and sustains innovation through implementation of novel schemes/programmes and institutional mechanisms to:

- ensure availability of required numbers of world class scientists and professionals relevant to R&D and technology development alongwith a well trained and skilled technical work force for industry
- establish adequate infrastructure, biotechnology incubators and clusters
- catalyze early stage innovation through investments and support services
- engage public-private partnerships for development of products of social relevance for applications in agriculture, healthcare, environment and industry
- provide a fiscal, regulatory and legal framework that encourages risk taking by investors

Objectives

1. Incremental investments in academia – industry interface including public-private partnerships
2. Undertake basic and translational research for development of products and processes of social relevance
3. Establish of new breed of institutions, centres of excellence and technology platforms
4. To setup of Biotechnology Regulatory Authority of India

Functions

1. Human Resource Development along the biotech product and process value chain from discovery to market.
2. Establishment of centres of excellence and innovation for basic research, translational research, technology development, in collaboration with various institutions / universities, industry and non-profit organizations.

Section 1: Vision, Mission, Objectives and Functions

- 3 Establishment of biotech facilities and infrastructure to serve for research and services facility to public and private sectors in fulfilling the needs of technology validation, product development and formulation, regulatory tests alongwith providing research resources including genetic resources, genome libraries and databases.
- 4 To launch Grand Challenge Programmes on vaccines development, breeding crops by design, microbial prospecting bioengineering, medical devices and nutritional technologies.
- 5 To orient sectoral R&D programmes in emerging areas towards translational and product development areas in agriculture; animal sciences; vaccines and diagnostics; stem cell biology; bioengineering; nano-biotechnology; RNAi technology; biofuels and bioenergy; and bioprocessing and scale-up.
- 6 To attract young scientists from India and abroad for taking research in Indian institutions/universities.
- 7 To establish new breed of institutions in critical areas of national importance such as translational health research, stem cell biology, technology and innovation, agrifood technology, marine biotechnology, animal biotechnology, seri biotechnology, and biomedical genomics
- 8 To establish technology clusters, biotechnology industry incubators, parks and industry platform for promoting academia –industry interaction and product and process development
- 9 To launch major public-private partnership programmes for proof-of-concept research, research on futuristic technologies and provide assistance and facilitations to SMEs and other large industries for accelerating biotechnology industrial growth
- 10 10. To promote and facilitate development of products and processes that are affordable both public /private good in nature and accessible with equity

Section 2: Inter se Priorities among Key Objectives, Success indicators and Targets

Objective	Weight	Action	Success Indicator	Unit	Weight	Target / Criteria Value				
						Excellent	VeryGood	Good	Fair	Poor
						100%	90%	80%	70%	60%
1. Incremental investments in academia – industry interface including public-private partnerships	40.00	i. Launching of three projects on development of H1N1 vaccine under Biotechnology Industry Partnership Programmes(BIPP)	launching of projects	--	12.000	--	--	--	--	--
			Timely completion of activities by the end of March 31, 2010	Date	4.000	--	--	--	--	--
		ii. Approval and initiation of clinical trials for oral insulin under BIPP.	Approvals for launching BIPP scheme by Cabinet	Date	4.000	--	--	--	--	--
			Launching of projects through advertisement, screening and technical and financial appraisal as per annual target	Date	4.000	--	--	--	--	--
			Timely completion of activities by the end of March 31, 2010	Date	4.000	--	--	--	--	--
		iii. Validation Process and clinical development and scale-up of genetically engineered Follicle Stimulating Hormone for treatment of fertility disorders in women under Small Business Innovative Research Initiative (SBIRI)	Timely completion of activities by the end of March 31, 2010	Date	4.000	--	--	--	--	--
iv. Validation of silk protein blend film for burnt wound management used in dressing burns for regeneration of cells in the wounded area	Timely completion of activities by the end of March 31,2010	Date	4.000	--	--	--	--	--		
2. Undertake basic and translational research for development of products and processes of social relevance	35.00	i. Launching of a project on chickpea genome sequencing for discovery of genes related to pests/ disease resistance and nutrition	Timely completion of activities by the end of March 31, 2010	Date	14.000	31/03/2010	10/04/2010	20/04/2010	30/04/2010	01/05/2010
		ii. Initiation of phase-1 clinical trial of malaria vaccine	Timely completion of activities by the end of	Date	7.000	31/03/2010	10/04/2010	20/04/2010	30/04/2010	01/05/2010

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						Excellent	VeryGood	Good	Fair	Poor	
						100%	90%	80%	70%	60%	
			March 31, 2010								
		iii. Pilot scale production of new generation cholera vaccine for clinical trials	Timely completion of activities by the end of March 31, 2010	Date	7.000	31/03/2010	10/04/2010	20/04/2010	30/04/2010	01/05/2010	
		iv. Approval and initiation of Phase-III clinical trial of new rotaviral diarrhoea vaccine	Timely completion of activities by the end of March 31, 2010	Date	7.000	31/03/2010	10/04/2010	20/04/2010	30/04/2010	01/05/2010	
3	3. Establish of new breed of institutions, centres of excellence and technology platforms	15.00	i. Registration and operationalisation of Centre for Cellular and Molecular Platform for providing services for biomolecule characterization to industry for regulatory processes	Timely completion of activities by the end of March 31, 2010	Date	6.750	31/03/2010	10/04/2010	20/04/2010	30/04/2010	01/05/2010
		ii. Registration and operationalisation of National Development (Clinical) Service Agency (NDSA) to provide cost effective, high quality services preclinical and clinical product development support service	Timely completion of activities by the end of March 31, 2010	Date	4.500	31/03/2010	10/04/2010	20/04/2010	30/04/2010	01/05/2010	
		iii. Launching of centre of excellence on epigenetics at National Centre for Cell Science, Pune aim to understand basic and developmental biology of organisms and capacity building in this emerging areas	Timely completion of activities by the end of March 31, 2010	Date	3.750	31/03/2010	10/04/2010	20/04/2010	30/04/2010	01/05/2010	
4	4. To setup of Biotechnology Regulatory Authority of India	5.00	i. Submission of Cabinet Note for approval of establishment of Biotech Regulatory Authority of India along with necessary clearances. ii. Introduction of Biotech Regulatory Authority Bill in the Parliament	Timely completion of activities by the end of March 31, 2010	Date	5.000	31/03/2010	10/04/2010	20/04/2010	30/04/2010	01/05/2010

Section 2: Inter se Priorities among Key Objectives, Success indicators and Targets

Objective	Weight	Action	Success Indicator	Unit	Weight	Target / Criteria Value				
						Excellent	VeryGood	Good	Fair	Poor
						100%	90%	80%	70%	60%
* Efficient Functioning of the RFD System	5.00	Timely submission of Draft for Approval	On-time submission	Number	2.000	0.00	1.00	2.00	3.00	4.00
		Timely submission of Results	On- time submission	Number	2.000	0.00	1.00	2.00	3.00	4.00
		Finalize a Strategic Plan	Finalize the Strategic Plan for next 5 years	Number	1.000	0.00	1.00	2.00	3.00	4.00

* Mandatory Objective(s)

Section 3: Trend Values of the Success Indicators

Objective	Action	Success Indicator	Unit	Actual Value for FY 07/08	Actual Value for FY 08/09	Target Value for FY 09/10	Projected Value for FY 10/11	Projected Value for FY 11/12
1. Incremental investments in academia – industry interface including public-private partnerships	i. Launching of three projects on development of H1N1 vaccine under Biotechnology Industry Partnership Programmes(BIPP)	launching of projects	--	--	--	--	--	--
		Timely completion of activities by the end of March 31, 2010	Date	--	--	--	--	--
	ii. Approval and initiation of clinical trials for oral insulin under BIPP.	Approvals for launching BIPP scheme by Cabinet	Date	--	--	--	--	--
		Launching of projects through advertisement, screening and technical and financial appraisal as per annual target	Date	--	--	--	--	--
		Timely completion of activities by the end of March 31, 2010	Date	--	--	--	--	--
	iii. Validation Process and clinical development and scale-up of genetically engineered Follicle Stimulating Hormone for treatment of fertility disorders in women under Small Business Innovative Research Initiative (SBIRI)	Timely completion of activities by the end of March 31, 2010	Date	--	--	--	--	--
	iv. Validation of silk protein blend film for burnt wound management used in dressing burns for regeneration of cells in the wounded area	Timely completion of activities by the end of March 31, 2010	Date	--	--	--	--	--
2. Undertake basic and translational research for development of products and	i. Launching of a project on chickpea genome sequencing for discovery of	Timely completion of activities by the end of March 31, 2010	Date	--	--	--	--	--

Section 3: Trend Values of the Success Indicators

Objective	Action	Success Indicator	Unit	Actual Value for FY 07/08	Actual Value for FY 08/09	Target Value for FY 09/10	Projected Value for FY 10/11	Projected Value for FY 11/12
processes of social relevance	genes related to pests/ disease resistance and nutrition							
	ii. Initiation of phase-1 clinical trial of malaria vaccine	Timely completion of activities by the end of March 31, 2010	Date	--	--	--	--	--
	iii. Pilot scale production of new generation cholera vaccine for clinical trials	Timely completion of activities by the end of March 31, 2010	Date	--	--	--	--	--
	iv. Approval and initiation of Phase-III clinical trial of new rotaviral diarrhoea vaccine	Timely completion of activities by the end of March 31, 2010	Date	--	--	--	--	--
3. Establish of new breed of institutions, centres of excellence and technology platforms	i. Registration and operationalisation of Centre for Cellular and Molecular Platform for providing services for biomolecule characterization to industry for regulatory processes	Timely completion of activities by the end of March 31, 2010	Date	--	--	--	--	--
	ii. Registration and operationalisation of National Development (Clinical) Service Agency (NDSA) to provide cost effective, high quality services preclinical and clinical product development support service	Timely completion of activities by the end of March 31, 2010	Date	--	--	--	--	--
	iii. Launching of centre of excellence on epigenetics at National Centre for Cell Science, Pune aim to understand basic and developmental biology of organisms and capacity building in this emerging areas	Timely completion of activities by the end of March 31, 2010	Date	--	--	--	--	--

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4 4. To setup of Biotechnology Regulatory Authority of India	i. Submission of Cabinet Note for approval of establishment of Biotech Regulatory Authority of India along with necessary clearances. ii. Introduction of Biotech Regulatory Authority Bill in the Parliament	Timely completion of activities by the end of March 31, 2010	Date	--	--	--	--	--
* Efficient Functioning of the RFD System	Timely submission of Draft for Approval	On-time submission	Number	23	20	125	23	25
	Timely submission of Results	On- time submission	Number	23	20	23	23	23
	Finalize a Strategic Plan	Finalize the Strategic Plan for next 5 years	Number	23	40	32	23	23

* Mandatory Objective(s)

Section 4: Description and Definition of Success Indicators and Proposed Measurement Methodology

The four objectives and respective actions are based on schemes and programmes approved in the 11th Five Year Plan with annual targets and completion of processes for approval of the same. Accordingly, timely completion of specific priority projects has been chosen as the success indicators and is measured based on incremental milestones from the beginning of the year (April 2009 to March 2010) to the end of the year.

Section 5: Specific Performance Requirements from other Departments

Objective 1: Timely completion of actions involves cooperation from Department of Scientific and Industrial Research in according R&D recognition to private sector establishment and also on the timely submission of MoUs related to IPR by the companies benefitting from the projects.

Objective 2: Approval for clinical trials and field trials depend on clearances from Drug Controller of India and Genetic Engineering Approval Committee (GEAC) of Ministry of Health and Ministry of Environment and Forest, GOI respectively.

objective 3: The approval process involves inter-departmental inputs on EFC document, EFC meeting chaired by Secretary (Expenditure), Ministry of Finance and circulation of Cabinet Note for comments by relevant government department and cabinet approval. Even though, timelines for inter-ministerial consultations of EFC and Cabinet Note have already been prescribed, delays occur from certain departments of high relevance such as Ministry of Finance, Planning Commission etc.

objective 4: For introduction of Biotechnology Regulatory Authority Bill in the Parliament is an end point of the success indicator. There are various steps from Cabinet approval to introduction in the Parliament involving mainly Ministry of Law and Justice for laying of Bill and related documents as per procedure in the Parliament. The delay could happen in case of Mo Law and Justice delays the clearance of accompanying documents for laying of the Bill in the Parliament after cabinet approval (which has been initiated).