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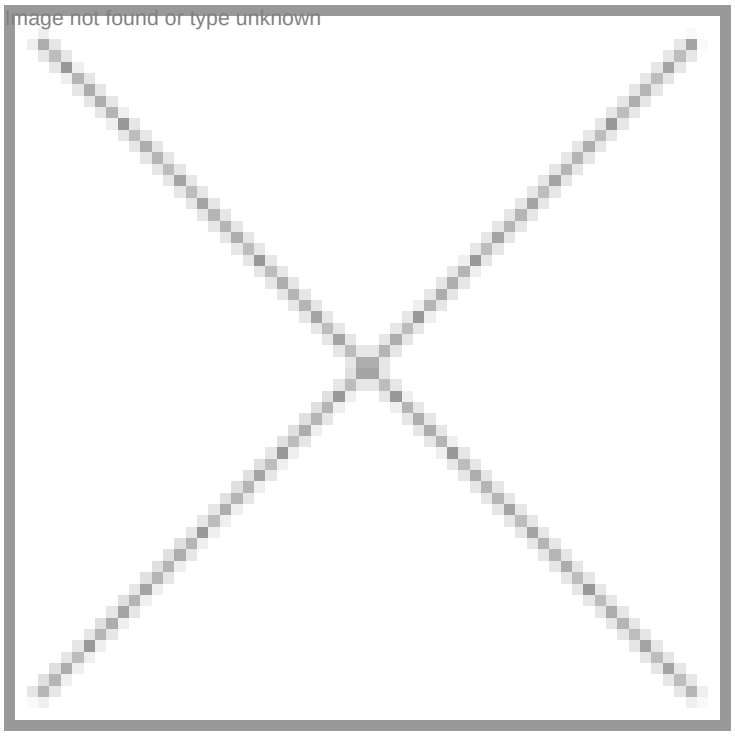
# National Biotech Policy: One Year Later

05 November 2008 | News




## National Biotech Policy: One Year Later

*A report on what all has been done towards the target areas of the policy and what is being worked upon ...*

Exactly a year ago, in November 2007, the much awaited National Biotechnology Development Strategy was approved by the Government of India after a two year-long nationwide consultation process with multiple stakeholders including ministries concerned, universities, research institutes, private sector, civil society, consumer groups, non-government and voluntary organizations and international bodies.

The strategy laid a strong emphasis on discovery and innovation effectively utilizing novel technology platforms with the potential to contribute to long-term benefits in agriculture, animal productivity, human health, environmental security and sustainable industrial growth. Dr MK Bhan, secretary, DBT in an interview with BioSpectrum emphasized on developing the innovation potential through the strategy that fosters development in areas such as translational science, clinical and field research, product development, and R&D in the industry. "The purpose of the strategy is to head towards innovation and produce novel products, while capitalizing on the current opportunities in clinical research and biosimilars," he had said. A year later, we find out what all has been achieved in this quest and what is being worked upon.

**NBRA**

Proposed:

The National Biotech Development strategy proposed the setting up of National Biotech Regulatory Authority, NBRA that would provide a single window clearance of genetically modified products and processes. It was in June 2004 that the Task Force on Application of Biotechnology in Agriculture, under the chairmanship of Dr MS Swaminathan, submitted its report recommending the setting up of a National Biotechnology Regulatory Authority (NBRA) for promotion and regulation of application of biotechnology in agriculture. After the inter-ministerial consultations on the recommendations of the MS Swaminathan Task Force report, the Department of Agriculture and Cooperation identified some areas for prioritized action and subsequently, the note for setting up the NBRA was mooted in the Cabinet by the Ministry of Agriculture.

As per the draft bill, NBRA shall be responsible to regulate the research, manufacture, importation and use of genetically engineered organisms and products derived thereof. It may specify measures to regulate the importation of genetically engineered organisms into India;
containment of genetically engineered organisms in India; clinical studies of genetically engineered organisms and derived medicines in India; environmental release of genetically engineered organisms in India; the use of genetically engineered organisms and products derived thereof as, or in, food and use in human or animal health, agriculture or other applications in India; and procedures and standards in relation to the accreditation and notification of facilities undertaking research with genetically engineered
organisms.

Current status:
The draft of the NBRA formation was placed in public domain for suggestions from stakeholders and industry and is yet to be placed before the parliament. A number of consultations with farmers, lawyers and industry have been organized. DBT has received a huge number of comments and suggestions from direct meetings. Over 300 suggestions have been received through email too.

So far, there were nine consultation meetings with various stakeholders about the biotech policy. Consultations with legal experts involving practicing lawyers from supreme court and high court, a meeting with state government officials, six with multiple stakeholders and one with print and electronic media were conducted following which the recommendations were compiled. A total of 600 people attended these consultations. After consultation with state governments, a document was created and sent to them again for their comments. Over 30 responses were received from these governments for DBT's consideration. DBT is now conducting inter-ministerial consultations regarding the presentation of the NBRA.

**BIRAC**

Proposed:
The policy proposed the launch of the Biotechnology Industry Research Assistance Council( BIRAC) to stimulate, foster and enhance the innovation capabilities of small and medium enterprises. The main aim of BIRAC was to act as an interface between academic and private sector, particularly SMEs and start-ups; nurture and catalyze R&D and innovation in the private sector; promote public-private partnership

Current status:
As an interim measure, a pilot biotechnology industry R&D assistance program, has been approved by the governmentwhich would facilitate and promote industrial research through technology transfer and IP management, technology acquisition and technology forecasting. In addition there would be a special cell that would address the needs of training and capacity building. Its main functions would include:

- Logistics, services and support for public private partnership program including support for biotech parks and incubators, research resource facilities, IP management services etc.
- Industry platform programs
- Facilitating technology assessment and transfer
- Information, research, analysis and advisory services
- Building awareness of potential opportunities and capacities in areas which require skilled human resources

**Biotechnology Industry Partnership Program (BIPP)**

Proposed:
The policy laid down the formation of BIPP to generate IPR in advanced technology areas such as agriculture, health, environment, bioenergy and biomanufacturing. This is with an aim to enter the advanced technology area, when the potential is uncertain rather than when the potential is established. A novel feature of this cost sharing scheme is to allow the industry partner to retain intellectual property, with payment of appropriate royalty to the contributing public sector scientist.

- Current status:
  The program is awaiting cabinet approval currently. It would facilitate partnership with the industry for:
- Fulfilling major unmet national technology needs in health, agriculture, energy and environment friendly or green manufacturing area.
- Increasing global competitiveness of Indian industry in new and futuristic technology.
- Evaluation and validation of already available products of high national importance.
- It will also look at shared major facilities around platform technology as core facilities.

**DBT Wellcome Trust scholarships**

Proposed:
With the aim of encouraging R&D in the country and reversing brain drain, the policy had stressed on innovative reentry packages for senior scientists in terms of fellowships to attract them to the country and motivate them to pursue research on national priorities.

Current status:
DBT announced a jointly-funded Biomedical Research Career Program with Wellcome Trust UK to fund cutting-edge biomedical research in India in September this year. The partnership was announced by Dr MK Bhan, secretary, DBT and Dr Mark Walport, Director, Wellcome Trust. The £80m scheme, jointly funded by DBT and the Wellcome Trust over five years and aims to strengthen the research base of Indian biomedical science by providing fellowship programs to support researchers from newly-qualified postdocs through to senior researchers. The program will be delivered by the Wellcome Trust/DBT India Alliance, an independent, public charitable trust based in New Delhi and established by the two partners. Each year, the Alliance is expected to award around 40 early careers fellowships, 20 intermediate fellowships and 15 senior

research fellowships.

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