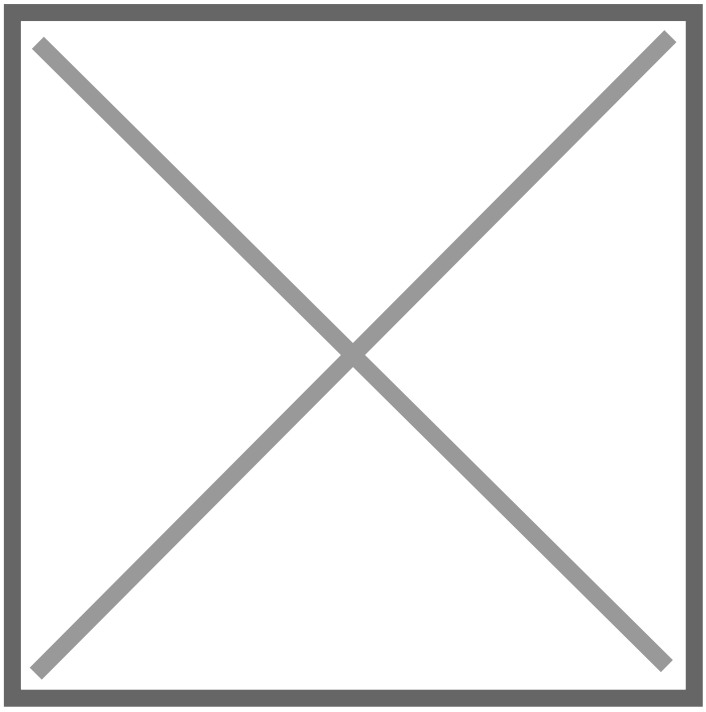
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Wanted a National Biotechnology Policy

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Wanted a National Biotechnology Policy

The cover story of BioSpectrum's inaugural issue in March 2003 pointed out that the country urgently needed a National Biotech Policy to promote the biotech sector. In this extract, we recall the voices of the industry in 2003.

In 2003, BioSpectrum pointed out that the Department of Biotechnology (DBT), set up in 1986 by the Rajiv Gandhi government, was working quietly to beef up the country's infrastructure in biotechnology. Instead of building its own parallel empire, DBT had chosen to fund a range of activities and research programs in research institutions and worked zealously to build on the strengths of the organizations in biotechnology. In spite of many such initiatives, DBT was yet another scientific department, part of the omnibus Ministry of Science and Technology. Much the same way the Department of Electronics (DoE) was till 1990s. But economic liberalization and the emergence of software industry changed the face of DoE. With a National Information Technology Policy in place and a Prime Minister's National Task Force on IT, the contours of the IT industry had changed dramatically. Aided by a relentless campaign by the National Association of Software and Services Companies (Nasscom), almost every hurdle in the path of IT was removed by 2003. IT and software became the "mantra" every minister and policy maker swore by, starting from the Prime Minister. Every state evolved its own IT policy and wooed global investors. IT had joined the "holy cows" of the government in the same way space, atomic energy, defense and national security policies had become. There was a national consensus on those sectors and they were the nation's pride.

BioSpectrum said that a similar treatment was what the biotechnology sector expected from the nation as early as in 2003. Biotechnology itself was now becoming main stream. It was no longer just some esoteric research work done by dedicated scientists in sophisticated laboratories. Across the world, biotechnology was recognized as the harbinger of a new world in areas such as health care, agriculture, industrial processes and genetics and cloning are on every one's lips.

India too had embraced biotechnology in a big way. From the labs it had entered the markets. The Hepatitis B vaccine developed in Indian laboratories and produced by Indian companies were competing against the best in the world and ensured affordability to the world's poor people. India was emerging as the new destination for the bioinformatics industry, by the world's pharma companies wanting to leverage the country's computer software strengths.

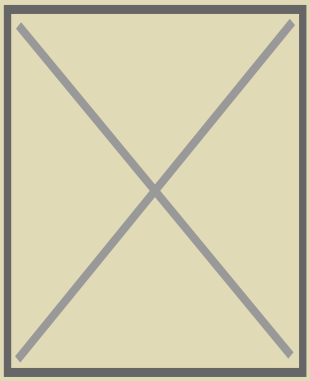
While Hepatitis B vaccine was accepted without any reservation in India, other gene-based products were facing considerable opposition to their introduction. These products had become the new symbol of hate for a section of the civil society, waiting to take on the establishment. And in the process, there was a feeling among biotechnologists that the regulations had become too stringent and counterproductive to the growth of the industry.

Hence there was the clamor for National Biotechnology Policy. Many hoped that a widely debated policy, when adapted will become the nation's property and hurdles in the path of the segment will become things of the past. Leading the demand was

widely respected geneticist and one of the architects of the Green Revolution, Prof. MS Swaminathan. Almost every one in the biotech industry, with whom BioSpectrum spoke to at that time endorsed the urgent need for a National Biotechnology Policy. And they all said that that was just the right time to formulate one. On the other hand, the DBT secretary (then) Dr Manju Sharma said the 10-year Biotechnology Vision launched by Prime Minister AB Vajpayee on 7 September 2001 was adequate to translate the national resolve on the emerging biotech sector to action points.

Thus BioSpectrum set the stage for an informed national debate on this issue in all its shades.

"There is no requirement for a separate Biotech Policy"



said the then DBT secretary Dr Manju Sharma (2003) in an exclusive interview with BioSpectrum. Excerpts:

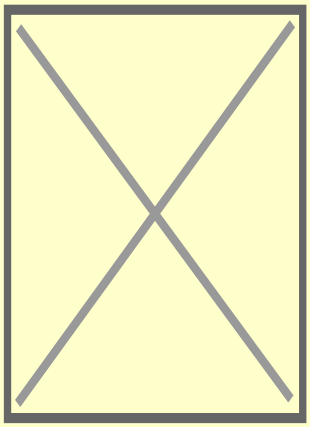
There is a big competition between various states in announcing a Biotechnology Policy. Do these efforts mesh into the national framework of biotech policy?
A 'Biotechnology Vision document' giving a Ten Year Perspective is available. This document was released by the Hon'ble Prime Minister and has thereafter been circulated by the Minister for S&T to the Chief Minister's of all states and union territories. The response has been very positive and each state has developed or is in the process of developing its own Biotechnology Action Plan. The framework of activities has already been announced by few states like Tamil Nadu, Andhra, West Bengal, Haryana, Himachal Pradesh, Kerala etc. Other states like Rajasthan, Orissa, Madhya Pradesh, Gujrat etc., are in the process of developing their own framework. The State Action Plans have been prepared in close consultation with the department and are in line with the National Biotechnology Vision formulated by DBT. The programmes have been formulated in a need based manner depending up on the priorities of the State. The emphasis is mostly on setting up of a biotechnology park or a rural biotechnology village as the case may be, mainly for taking up the biotechnology leads for benefit of the society through both industrial and ground level activities.

How is the regulatory process in India compared to that in many developed and developing countries?
The department has formulated exhaustive guidelines for biotechnology research in the areas of biosafety, clinical trials and human genetics. For the transgenic and recombinant research there is a well structured regulatory framework which is a three-tier structure. Institutional Biosafety Committee (IBSC), Review Committee for Genetic Modification (RCGM) and the Genetically Engineered Approval Committee (GEAC). For any transgenic product to be cleared, it is mandatory to go through this entire procedure which clears the product only after obtaining exhaustive data collected from multi-locational demonstration sites. Similarly in the area of drug development also, after completing the procedures the necessary clearance is required from the drug controller before the product can be released. As mentioned the regulatory procedure is in place. These guidelines have been very well appreciated by many countries.

Biotech entrepreneurs of feel that venture funds are not easy to come by. Is this correct?
The industrialization of biotechnology is strongly promoted and encouraged by the department specially for developing joint R&D programs etc. A special biotechnology venture fund has also being proposed along with certain venture capital companies. This is under consideration.

Is the DBT planning to evolve a national consensus on the introduction of genetically modified organisms and foods in the country?
Yes, the regulatory procedures required for introduction of genetically modified organisms in the country have already been outlined.

'It's time to have a National Biotech Policy'



BioSpectrum covered the Chennai Declaration made by 50 leading experts in 2003 under the guidance of Prof. MS Swaminathan. Excerpts of the same.

The country has well defined policies in the fields of atomic energy, space applications and information technology. No further time should be lost in developing a national food and agricultural biotechnology policy through political consensus. Otherwise, India will experience serious genetic divide. A similar policy is also needed in the area of medical biotechnology, which involves ethical issues with reference to both human and animal experiments.

The urgency stems from the fact that the 21st century will belong to those who help to advance the frontiers of science and technology in the areas of functional genomics, proteomics, bioinformatics and molecular breeding (i.e., genetic modification).

Equally important is to formulate a well-defined implementation plan for the national food and agriculture biotechnology policy as any policy without an appropriate and effective implementation framework will have no value. Therefore, the policy should provide the terms of reference to an autonomous and professional Biotechnology Regulatory and Advancement Commission.

The aim of regulation should be to help harness this powerful technology in a risk free and responsible manner. The Commission should not only develop and enforce a code on "don'ts", but should also propose "dos", which will help to gain benefits without risks. It should build on the Cartagena International Protocol on biosafety and introduce a system of regulation and monitoring which inspires public, political and media confidence.

Regulation for the responsible advancement of biotechnology for public good should be the motto. The National Biotechnology Regulatory and Advancement Commission, which could be attached to the Ministry of Agriculture for administrative purposes, should be headed by an eminent professional known for objectivity and credibility.

There should be a multi-stakeholder representation on the Commission and its Standing Committees, including scientists, concerned government officials, representatives of public and private sector industry, consumer and women's associations, farmers' associations and the mass media. Such a Commission will be effective only if it is created on the basis of consensus among political parties.

Some of the important responsibilities of the Commission could be:

- Create the expertise and infrastructure needed to undertake a critical and transparent scientific assessment of the food and environmental safety of Genetically Modified (GM) crops.
- Coordinate the work of the Ministries of Agriculture, Health, Environment and Science and Technology, Department of Biotechnology (DBT) in the area of biosafety assessment.
- Provide guidelines for research collaboration between public and private sectors in areas such as functional genomics, proteomics and bioinformatics as well for priorities in public investment, as for example research on drought tolerance, water use efficiency and salinity