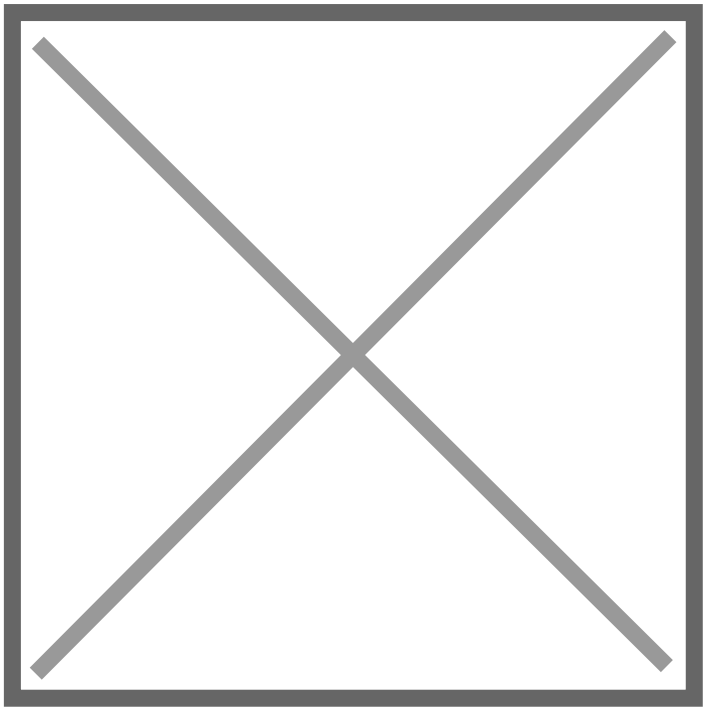
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Industry-friendly Biotech Policy Unveiled

11 April 2005 | News



The policy, called the National Biotechnology Development Strategy, was unveiled by Sibal and Bhan on March 31. The draft policy has been made public to invite wide comments. A quick reading indicates that it is clearly an industry-friendly policy with most of the major demands of the industry finding prominent mention in it.

BioSpectrum had pro-actively sought the policy maker's attention to the demands of the industry in the last two years and the BioSpectrum Awards Nite on December 10, 2004 in Bangalore was one of the forums for a lively discussion on the policy draft.

"We want the Biotech Strategy to be the road map for the next ten years in this sector. It aims to make the processes easier, quicker and friendly for the common man. The policy will provide adequate support to basic, translational and clinical research. Up to 30 percent of biotechnology research budget (of Rs 200 crore) will be spent through public-private partnerships," Sibal said.

Regarding regulatory approvals for the biotech sector, he commented, "This (regulatory approvals) is on top of the agenda to make approvals a lot more simpler and faster. The recommendations of the Swaminathan Committee for agri-biotech and the Mashelkar Committee for bio-pharma would be implemented and the effort will be to train scientists and technology transfer professionals in handling Intellectual Property Rights issues. Regional technology transfer cells will be created to provide high caliber, specialized and comprehensive technology transfer services."

Dr Bhan said, "We have two goals. One is to benefit the ordinary people and help the country's development. The other is to promote innovation." "A major aim of the Strategy is the development of human resources. We plan to set up centers of excellence in the fields of marine biotechnology, animal biotechnology, herbal medicine, molecular medicine and bio-informatics," he added.

A major policy statement is the announcement that there will be no restriction on the quantum foreign direct investment (FDI) in biotech companies. Sibal and the policy clarified that there "may not be the need for FIPB (foreign investment promotion board) approval for equity investments in biotech companies." n

N Suresh and Rolly Dureha

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Highlights from the draft

The Indian Biotechnology sector is gaining global visibility and is being tracked for emerging investment opportunities. Human capital is perceived to be the key driver for global competitiveness. Added to this is a decreasing appetite for risk capital in developed countries, which has led to a decline in the biotechnology sector in these regions where survival lifelines are being provided by the lower cost research environs of the developing world such as India.

For a country like India, biotechnology is a powerful enabling technology that can revolutionize agriculture, healthcare, industrial processing and environmental sustainability.

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. It is imperative that the principal architects of this sector along with other key stakeholders play a concerted role in formulating such a strategy to ensure that we not only build on the existing platform but expand the base to create global leadership in biotechnology by unleashing the full potential of all that India has to offer.

BioAgriculture

Transgenic plants should not be commercialized in crops/commodities where our international trade may be affected. However, their use may be allowed for generation of proof of principle, strictly for R&D, their alternate systems are not available or not suitable.

Biotechnology can deliver the next wave of technological change that can be as radical and even more pervasive than that brought about by IT. 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.

However, emphasis should not be on edible vaccines for which use in real life condition is difficult. Nutrition and balanced diet are emerging to be important health promotional strategies. Biotechnology has a critical role in developing and processing value added products of enhanced nutritive quality and providing tools for ensuring and monitoring food quality and safety.

A precautionary, yet promotional approach should be adopted in employing transgenic R&D activities based on technological feasibility, socio-economic considerations and promotion of trade.

Fiscal and trade policy initiatives

Biotechnology firms are by far the most research intensive among major industries. On an average, the biotechnology sector invests 20-30 percent of its operating costs in R&D or technology outsourcing. Government support, fiscal incentives and tax benefits are therefore critical to this sector. These measures will also help to capitalize on the inherent cost effectiveness of the Indian biotech enterprise. The suggested interventions include:

Ã¢â?¬Â¢ Exemption of import duties on key R&D, contract manufacturing/clinical trial equipment and duty credit for R&D consumer goods to enable small and medium entrepreneurs to reduce the high capital cost of conducting research.

Ã¢â?¬Â¢ Extending the 150 percent weighted average tax deduction on R&D expenditure under section 35 (2AB) until 2010 and to permit international patenting costs under this provision and enable eligibility of expenditure incurred with regard to filing patents outside India for weighted deductions u/s 35 (2 ab)

Ã¢â?¬Â¢ Enable lending by banks to biotech companies as priority sector lending. Currently banks are almost averse to lending to young biotech companies. In order to encourage banks to lend and provide banking services to the biotech sector, a significant push through appropriate policy guidelines from the Reserve Bank of India is necessary. Currently lending to agri-businesses as well as investment in Venture Funds by banks is categorized as Priority Sector Lending. Biotech as a business has similar characteristics in terms of risk as well as gestation time lines and it is therefore recommended that lending to Biotech be also categorized as Priority Sector lending.

Ã¢â?¬Â¢ Remove customs duty on raw materials imported into India, where the finished product is imported duty-free. Life Saving Drugs imported and sold in India are exempted from paying customs duty; whereas raw materials for diagnostics and other pharmaceutical biotech products manufactured in India are levied customs duty. To promote the indigenous manufacturing industry and make it competitive globally, raw materials imported by Indian manufacturers should be eligible for Duty Drawback.

Ã¢â?¬Â¢ Rationalization of import and export of biological material is considered critical for clinical research and business process outsourcing.

Ã¢â?¬Â¢ Simplification and streamlining of procedures for import, clearance and storage of biologicals, land acquisition, obtaining environmental and pollution control approvals would be simplified and streamlined within shorter time frame lines

through consultations with various central and state government departments.

Ã¢â?¬Â¢ As an effective regulatory mechanism has been put in place though recent interventions, Foreign Investment Promotion Board (FIPB) approval for equity investment may no longer be necessary.

Ã¢â?¬Â¢ Joint R&D collaboration and generation of joint IP through global partnerships would be fostered.

Ã¢â?¬Â¢ International trade opportunities would be promoted to guide R&D investment Indian biotech strengths would be aggressive by promoted globally.

Ã¢â?¬Â¢ Efforts would be made to remove hurdles for contract research especially for input output norms and tax on revenue generated through contract research/R&D.

Ã¢â?¬Â¢ Easy access to information, regarding legislation and rules and regulations for transboundary movements of biologicals would be promoted.

Ã¢â?¬Â¢ Current standards and safety of products would be enhanced.

Ã¢â?¬Â¢ Efforts would be strengthened to promote acceptance of Indian regulatory data internationally.

Ã¢â?¬Â¢ Research, trade and industrial partnership would be fostered at regional and sub-regional levels.

Ã¢â?¬Â¢ A "cluster" approach would be encouraged to operations. One significant feature of the industry is the fluidity and variety of its inter-company relationships, traditionally much greater than in other industries. It has relied to a considerable degree on contracting and outsourcing, especially "upstream" in R&D through various licensing arrangements and "downstream" through co-marketing agreements.

Ã¢â?¬Â¢ Collaborative knowledge networks would be promoted. Expanded sharing of information, including creation/use of collaborative knowledge networks (CKN), can greatly enhance a company's performance under a cluster approach. Managing the many external relationships is complex. Flexible and pervasive communications systems that allow information to flow effortlessly within and between contracting organizations will provide the key to success. Increasingly, IT advances, including web-based approaches, will provide the foundation for these systems.

Financial incentives

Availability of financial support for early phase of product development to establish proof-of-principle is the key to sustaining innovation. In this context, it is proposed to institute 'Small Business Innovation Research Initiative' (SBIRI) scheme through the Department of Biotechnology in 2005-06 for supporting small and medium size enterprises as a grant/loan. Companies with up to 1000 employees will be eligible. The scheme will support pre-proof of concept, early stage innovative research and provide mentorship and problem solving support in addition to the grant/soft loan. The SBIRI scheme will operate in two phases of innovation and product development.

Biotech Parks

Ã¢â?¬Â¢ The Department of Biotechnology will promote and support at least 10 biotech parks by 2010. Each park will necessarily meet the qualifying criteria related to the characteristics of the location, a viable business plan, management strategy and a clear definition of the partners and their roles.

Ã¢â?¬Â¢ The Department of Biotechnology will support creation of incubators in biotech parks promoted by a private industry or through public-private partnership in the form of grant upto 30 percent of the total cost or upto 49 percent in the form of equity.

Ã¢â?¬Â¢ It is proposed that a central body Biotechnology Parks Society of India (BPSI) be set up for the promotion of biotechnology parks in the country on the same lines of the Software technology Parks of India (STPI). The BPSI should be run by professionals having experience in the areas of biotechnology, knowledge in Acts and Rules relevant to biotechnology and management skills. The existing parks can become members of these new biotech parks. The BPSI would be responsible for evaluating the project proposals and advising the Department of Biotechnology on the funding pattern; facilitating industries in obtaining industrial, environmental and other relevant approvals from the central government; making recommendation regarding fiscal incentives to be granted to the biotechnology parks; providing guidance to the venture capital institutions on investment in biotech parks; providing accreditation to the parks etc.

Ã¢â?¬Â¢ Concessions to biotech companies located in biotech parks

Biotech companies located at biotech parks are eligible for benefits as per the recent changes in the Foreign Trade Policy:

Ã¢â?¬Â¢ Duty free import of equipment, instruments and consumables.

Ã¢â?¬Â¢ Tax holiday under Section 10A/ 10B of the Income Tax Act

A scheme will be put in place for operationalizing of the incentives to biotech units located in biotech parks. As a part of this scheme biotech company located in biotech parks to be allowed a five-year time frame to meet the export obligation norms under the SEZ scheme. This measure helps to address the long and unpredictable gestational time lines that are inherent to biotech product development.

Regulatory mechanisms

Ã¢â?¬Â¢ The recommendation of the Swaminathan Committee on regulation of agri-biotech products and of the Mashelkar committee on recombinant pharma products will be implemented in 2005

Ã¢â?¬Â¢ A competent single National Biotechnology Regulatory Authority be established with separate divisions for agriculture 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 with common chairman. The inter-ministerial group will evolve suitable proposals for consideration of the government.

Ã¢â?¬Â¢ A center for in-service training of all professionals, irrespective of their location, engaged in the regulatory process to be established by the Department of Biotechnology in close collaboration with other concerned departments and institutions.

Ã¢â?¬Â¢ All existing guidelines to be updated and made consistent with the recommendations of the Swaminathan and Mashelkar committees in 2005. New guidelines on transgenic research and product/process development in animal, aqua culture, food, phyto-pharma and environmental application to be put in place in 2005 by the concerned ministries/departments

As an interim measure, a special regulatory cell will be created by the DBT to build capacity in the country for scientific risk assessment, monitoring and management, to foster international linkages, support biosafety research; to obtain and review feedback from different stakeholders and provide support to industry and R&D institutions. This cell will only have a promotional and catalytic role

Ã¢â?¬Â¢ It is recommended that an event that has already undergone extensive biosafety tests should not be treated as a new event if it is in a changed background containing the tested and biosafety evaluated "event". Where adequate evidence is available that the recurrent parent genetic background of a notified/registered genotype is nearly restored (through field data/molecular data), only the agronomic performance and the level and stability of the transgene expression may be analyzed by two-year trial data by the ICAR. Even in case of a structurally altered transgene with no significant modifications in protein conformation, the toxicity and allergenicity tests need not be carried out provided the predicted antigenic epitope remains the same and the level of expression of the transgene is within the defined limits. For the released event, Department is of the view that there is no need of large-scale trials under the Genetic Engineering Approval Committee, as the biosafety aspects have been already addressed adequately before releasing the "event". Only ICAR trials may address the agronomic evaluation of the crop.

Create a cadre of resource persons

- Creation of a cadre of resource persons to provide credible information based on scientific data
- Training media personnel through Institutes of Mass Communication, colleges of journalism and others
- Capacity building among extension personnel in agricultural, fisheries, veterinary and medical sectors
- Involvement of Panchayati Raj institutions in the process of analysis and understanding the risks and benefits associated with GMOs as they will be playing an important role in the local level management of bio-diversity, access to benefit sharing etc.
- Awareness generation among undergraduate and post-graduate students in universities, colleges etc on issues related to biosafety.

- Promoting a genetic literacy movement within government and public schools through 50 genome clubs nature clubs each year.

Empowering the judiciary

- Setting up a training school for the judiciary under the aegis of Center for DNA Fingerprinting and Diagnostics, Hyderabad
- Training through the National Law Schools and other similar institutions

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Institutional mechanisms for strengthening public trust

- Establishment of a dedicated training center for biosafety, food and nutrition safety and standards as per codex alimentarius committee
- Creation of a 'National Biotechnology Awareness Fund' for providing support for the education and preparation of educational resource material for various sections of stakeholders in different regional languages of the country

Single Window Clearance

- Department of Biotechnology will act to facilitate a Single Window Clearance mechanism for establishing Biotechnology plants.
- Encourage private participation in infrastructure development like roads, water supply and effluent treatment.
- Depositories of biological materials will be created in partnership with industry on IDA model for agriculturally important organisms, medically important organisms, plasmids, cosmids and constructs of special nature generated with adequate human interventions
- State of the art large animal house facilities with GLP will be created for testing candidate vaccines and biotherapeutics. Testing facilities will be created for GMO/LMO

Innovation

- Basic and translational research in key biological processes and new materials will be supported as innovation for tomorrow. Access to the knowledge generated will be improved by supporting knowledge and social networks among stakeholders so that those with appropriate skills can convert the research output into useful products and processes.
- Research to promote innovation must be supported increasingly on a cooperative rather than a competitive basis. This requires effective communication among science agencies, research institutions, academia and industry.
- To promote India as a hub of innovation, a network of relevant stakeholders should be developed. Public investment should be used as a catalyst to promote such clustering and networking as this can lead to enhanced creativity by sharing of expertise, resources and infrastructure.
- Availability of human resource would be ensured at each phase of the product cycle.

- Strengthening technology transfer capacity

It is proposed to create several national/regional technology transfer cells (TTCs) over the next five years to provide high caliber, specialized and comprehensive technology transfer services. The services would include evaluating technology and identifying potential commercial uses, developing and executing and intellectual property protection strategies identifying potential licensees and negotiating licenses. Each TTC would service a cluster of institutions in a region or a large city.

National Task Force on education & training

A National Task Force will be created to formulate model undergraduate and postgraduate curricula in Life Sciences keeping in view, future needs. The said curricula must address the underlying need for multi-disciplinary and inter-disciplinary learning and the appropriate stage for biotechnology training.

Need assessment

There would be need assessment in 2005 for the next five years and close monitoring during the period for interim changes.