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Biotechnology Policy should be more clear on Agribiotech

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The draft National Biotechnology Development Strategy was unveiled by Kapil Sibal, the union science and technology minister, and Dr MK Bhan, the Department of Biotechnology (DBT) secretary, on March 31. The draft policy has been made public to invite wide comments. The DBT has been receiving about 40 comments a day from the industry. Further, forums like Bangalore Bio have been used to get further inputs from the industry. The general reaction within the industry is that the draft National Biotechnology Development Strategy 2005 is "pragmatic and proactive" which is bound to enhance public-private partnerships, empower innovation, facilitate better HR and position the Indian biotechnology sector on the global platform without compromising on local issues.

BioSpectrum spoke to a cross section of industry leaders and researchers to get their viewpoints.

Noting that the pharma biotech was a much better received sector in biotechnology, Kiran Mazumdar-Shaw, CMD, Biocon Ltd, and President, ABLE, said, "The key issues in the pharma biotech sector have been addressed in the policy, one being the regulatory framework. However, the agribiotech sector has far more critical issues to be addressed." Expressing happiness over the decision to allow 100 percent FDI in the form of equity in biotech sector, she said that the Union science and technology minister, Kapil Sibal has assured that recommendations of the RA Mashelkar and Prof MS Swaminathan task force committees would be implemented.

Shaw said that the government should remove all impediments that come in the way of clinical research and the government should encourage partnering of companies. "The Union Ministry of Health is coming up with a Bill which addresses the area of bioethics and setting up a proper regulatory framework for the inclusion of humans in clinical investigations," she said.

"India has a very large disease population base which can be used for clinical development program but care should be taken to avoid cumbersome delays while conducting trials," she stated. The clinical development protocols and regulatory pathways must be streamlined, she added.

Another area which has to be addressed is biopartnering. Shaw felt, "Free exchange of biomaterials and collaborative research should be addressed in a very conscious and pragmatic way through the national biotech policy and certain areas need to addressed in terms of ease of import of many of these biomaterials."

BioAgriculture

Dr KK Narayanan, MD, Mehahelix, Bangalore and ABLE's BioAgri Coordinator, echoed and endorsed most points in the key policy recommendations in the policy but said it was unfortunate that the government had sidestepped the demand of the bioagri sector for articulation of the policy on transgenic food items. He pointed out that most parts of section in the draft biotech policy on sectoral road maps in agriculture and food biotechnology sectors were clearly outdated. "This section is very high on sentiments and very low on substance," he said emphatically. There was no adequate emphasis on the use of transgenic crops for addressing many of problems faced in the field of agriculture. "We need to promote research and use of transgenic crops," he noted.

He felt that the guiding principles are vague. "They need clarity and precision. We have been sitting on the fence for too long and we now need to take bold positions for or against certain technologies," Narayanan said. The policy should be guided by internal needs and it should be aligned with reality on the ground, he added. Pointing out the various "should nots" in the policy and commenting on a statement on edible vaccines, he said, "it is best left unsaid instead of saying something which has no scientific evidence."

Dr PK Ghosh, President, Cadila Pharma, Mumbai, informed, "The road map in the draft document is qualitatively clear. It is not clearer however, why do we have to differentiate between r-DNA and non r-DNA based applications. Restriction on the use of r-DNA technologies where benefits are enormous as in Bt cotton would be myopic. In this context it has been stated that large scale field testing of released transgenic events would be done away with. To do this, implies that we have known much about the transgenics. Such steps may be detrimental; long-term effects of transgenics can be adverse, which can be known only over long years of use. Post-released vigilance mechanism must therefore be in the hands of the government. Article 27 of the Cartagena Protocol on transboundary movement of LMOs succinctly points towards these issues."

"The most important point of the recommendations in Agri- biotechnology are embedded in the Priorities. Priority target crops, live stocks, aquaculture and marine livestock products, need to be very succinctly identified and target set for what the country wants to achieve by deploying biotechnology on these products. As the germplasms are the key inputs for agro development, specific programs need to be drawn taking into consideration our capabilities, interests, and compulsions. For the state of Gujarat, for example if we concentrate on developing disease resistant, high yielding cultivators of cotton, castor, pulses, groundnut, and a few others by biotechnological methods, we have kept our hand on the major and potential economy â€“ contributing crops. Similar exercises can be carried out for the entire country."

BT Parks and infrastructure

"We should be careful of not creating biotechnology parks as real estate ventures and we should not get into a situation where biotechnology parks remain empty," said Kiran Mazumdar-Shaw, CMD, Biocon Ltd. "We have limited resources and we must make sure that there is a high developed accountability and demonstratable kind of success in parks before we think of investing huge amounts," she said. The issue of funding BT parks and the eligibility criteria for the same should be addressed in the national biotech policy. She was also of the opinion that without the support of companies, no more BT parks should be established. "BT parks must have a common effluent treatment facility."

Deepanwita Chattopadhyay, CEO, ICICI Knowledge Park, Hyderabad, made an observation on Section 2.4: Biotech Parks, which states that "establishing biotechnology parks is essential for growth of industry ...". The purpose of biotech parks seems to be for R&D and upscaling, but what about biotech parks models based on offering lands to companies for production, she asked. She wondered if biotech parks would automatically get SEZ status and could a part of SBIRI (Small Business Innovation Research Initiative) be routed through the Technology Transfer Cells (TTCs) in biotech parks/incubators. Her suggestions include: A national policy framework for technology transfer and licensing (along with DST) with flexibility for adaptation by organizations with varying mandates and different areas of research. She further suggests setting up extension counter of BPSI/DBT at Parks and mechanism for speedy custom clearance of refrigerated and perishable goods for companies in biotech parks.

Bamasish Paul, International Biotech Park, Pune, suggested that the government should fund incubators by giving grants and soft loans to set up shared facilities and instrumentation centre. "Finance companies in the incubators and a venture fund in

association with private venture funds with an initial corpus of $100 million will be really helpful," said Paul.

According to Dr PK Ghosh, "If the parks are to be self-sustaining, they must be formed on sector specific biases. For example agro-technology based industry clusters may perhaps be a viable concept . We need to have our own agenda, which may be distinct from those practiced elsewhere. The approach would need the codification of already established and integrated existing management system approaches, applied in the context of white and green revolutions." In such a concept, the parks could be established to integrate the concepts of micro-propagation; generation of high quality fruits, flowers and vegetables; establishment of fish, poultry and animal husbandry firms; produce bio-pesticides and biofertilizers; produce biogas and electricity; produce animal vaccines; create human establishments around, which can consume substantial parts of the produce so as to assist making such concepts nearer to self reliant; develop social forestry and parks for the dwellers; and take all other actions to support human activities that are beneficial, he felt.

Another key suggestion has been establishment of such a park around larger industrial establishments where rural masses are closer. "We can build around human clusters that already exist and that have fair purchasing power. In such an integrated approach, Biotech parks in agriculture may be self-sustaining. It may work only if substantial interdependence is created and the finished products or residues of one activity can serve as the starting materials for the other. All wastes are to be recycled and final non- usable residues have to be minimum. Biotech techniques can be used to integrate the linkage stronger. It is suggested that biotech park approach be modified to imbibe the idea of developing self-sustaining biotech parks. Such a concept, worked on a 1000-hectare plot with a sum of about Rs 400 crore or more spent over a period of five years could be tried out. Public-private partnership in such endeavors is a prerequisite for success. Even one successful example will make us a pioneer. This concept needs to be boosted and where necessary can be escalated in other institutions," Dr Ghosh felt.

Biotech education and human resource development

Academician Dr G Padmanabhan said there was a need to increase the number of PhDs as a strong pool of academic leaders was necessary for innovation. "The talent pool has to be in different areas ranging from biology to engineering including areas of translational research, technology transfer, IPR and biofinancing," he stated. He also felt the need for a national task force on education and training to look at the curricula in Life Sciences and multi disciplinary learning and biotechnology training.

He was clearly not in favor of new courses or undergraduate programmes in biotechnology. He said students must be encouraged to study basic sciences and then pursue specialization in biotechnology at the postgraduate level. Stressing on a need assessment for the next five to 10 years, Prof Padmanabhan said the there was a need to identify units of excellence in universities and institutions and government fellowships to students for training with industry. He also urged the government to enhance the salaries of teachers and make research an exciting occupation. He felt that women should be encouraged to take to biotechnology. The government must give more incentives and better fellowships to students and take measures to attract NRIs to return, he added.

Dr Kuntala Jayaraman, Vellore Institute of Technology, Vellore, said B Tech and M Tech courses were highly employment generating and saw the need for the intensification of basic sciences in the syllabi for MSc courses. "MSc programmes have to be strengthened drastically as subjects such as physics, chemistry and mathematics have been neglected," she added. More credit should be given to practical courses and bureaucracy should be removed from the education system, she urged.

Prof K Kannan, founder dean, School of Biotechnology, Guru Gobind Singh Indraprastha Unversity, New Delhi, felt that it was not clear whether the draft wants to promote biotechnology or life sciences. "We have already been promoting life sciences in the country since independence and if it were enough to achieve growth in biotechnology, we should have been by now leaders in biotechnology. However, training in life science has not enabled us to move forward. The attempt by the department of biotechnology to promote the MSc program has only led to PhD program rather than growth of industry, whereas program like B Tech and M Tech program in IIT and elsewhere have directly led to employment opportunities and IITs have been hailed as drivers of national and international progress."

"The department should focus on creating at least 10 products every year and revenue generated should be apportioned for R&D. The policy should be self sustainable and people involved have to devote 90 percent of their time in making products rather than traveling abroad. It is suggested that we should initiate technology program at the school level so that many are able to make entry into the business of biotechnology at an early stage." He felt that the draft gives an impression that only route to do biotechnology is through PhD. It may be an over qualification for manufacturing, quality assurance, regulatory and marketing. R&D does not generate revenue (except contract research), but manufacturing and marketing generate revenue for R&D. Until these are strengthened, it may not be possible to envisage growth in the next 10 years," said Kannan.

He added, "Our experience shows that we need minimum of 4 to 5 years program to makes students aware of various dimensions of practice of biotechnology. The component of engineering should be at least 30 percent in any program and we

need trained teachers to teach engineering aspects of biotechnology. Further, we need a good physics, chemistry, mathematics, statistics and computer background." There needs to be a regulation on the colleges and other private institutions offering biotechnology.

Bipin Deshmane, General Manager, Shreya Biotech, Mumbai, suggested, "Biotech academic research institutes should take up research projects relevant and directly useful to biotech industry and should achieve the paradigm shift to the approach from "Publish or Perish" to "Patent and Flourish". By working in industry on deputation for a certain period of time, academicians can be oriented towards more accountability for their research projects."

Financing and Funding

This is one sector the VCs are very keenly recommending new ways of looking at funding. Sarat Naru, managing director, APIDC-Venture Capital Ltd, Hyderabad, suggests SBIRI Phase I be treated as a grant or equity as opposed to a soft loan. His argument is that big ideas that address important national needs at the 'proof of concept' level will be associated with high inherent risk. "In order to encourage truly big ideas to be proposed for 'proof-of-concept' funding, whether for the private sector or the public sector, primarily grant funding must be provided. A secondary option is to provide 'equity' funding at an appropriate valuation. Providing 'low cost debt' will not encourage the private sector to propose truly big and important ideas," Naru felt.

In SBIRI Phase II, he suggests providing equity funds with handholding, while creating leverage. "Early stage product development and commercialization also needs funding support that allows the companies to take high risks. The current lack of such activity is evidence of this. Funding through loans will not encourage companies to adopt technologies that still have significant scale up risks and commercialization risks. Consequently, equity mode of funding is proposed, where the payout is dependent only on the successful outcome of the technology. Public grants to the private sector at this stage may not be needed as proof-of-concept has been established, and the risk is somewhat lower."

Naru added, "The intent of the DBT to provide handholding or mentoring is best delivered through motivated entities already engaged in funding of such technology development and commercialization. Consequently, there must be an emphasis on co-funding/investing through such entities. In order to ensure such co-investment, formal relationships will be made with entities to co-invest together."

To achieve the best impact, all the objectives need to be accomplished in a cohesive manner. "SBIRI may invest through early stage venture capital funds, which will achieve the three objectives simultaneously: provide funding in the form of equity; provide handholding / mentoring; and, increase/leverage the capital made available by the SBIRI. This may be done through formal arrangements with such funds to match the SBIRI funding they receive, in terms of investment into Companies. In return, SBIRI will provide funds at 2 percent interest to the Fund, against the collateral of the investments made by the Fund, which will amount to a collateral of double the funding provided by the SBIRI," observed Naru.

The policy should not only address the start-ups but also help companies to be global leaders, felt Aluri Srinivasa Rao, director, investments, ICICI Venture Funds, Mumbai. He in fact suggests that the government should create a very large fund and allow companies to access this on basis of their product outcomes.

The debates and deliberations are still on and the DBT is keen on incorporating suggestions that can help this industry leapfrog.

N Suresh with Ch. Srinivas Rao, Namratha Jagtap, Rolly Dureha, and Narayan Kulkarni