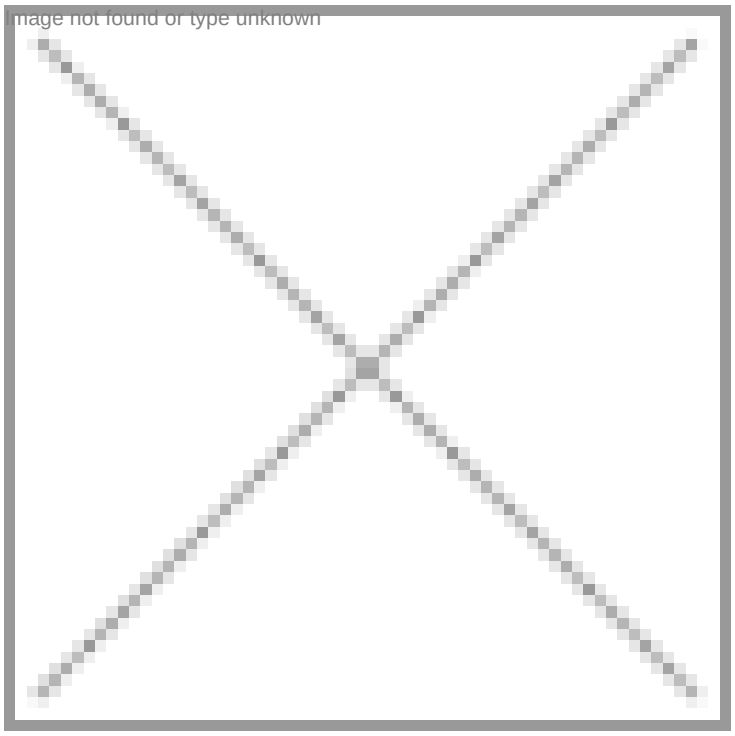
BioSpectrum
the business of Bio & Health Sciences

DBT makes headway with biotech policy

04 September 2007 | News



DBT makes headway with biotech policy

Though India does not have a National Biotech Policy in place, several concerns have been addressed and things are being streamlined.

National BT Policy: Some implementations

- DBT is supporting seven centers of excellence.
- To promote quality human resource, Star colleges are being established and teaching training program has been initiated.
- The Small Business Innovation Research Initiative (SBIRI), which is aimed to support R&D innovation, has supported 16 proposals.
- To promote large partnerships, DBT has supported a major initiative between UDSC and Mahyco.
- The stem cell strategy mission program has also been initiated.
- The National Biotech Regulatory Authority proposal has also been proposed for the cabinet approval.

The National Biotechnology Development Strategy was formulated after extensive national and global consultations. But the policy is not yet there. The strategy document, which received over 300 comments from the NGOs, industry, and various other stakeholders, is now with the cabinet and awaiting the cabinet's approval. Though the document is waiting for the cabinet clearance, the Department of Biotechnology (DBT) has implemented several of the key recommendations.

Prof. C Kameswara Rao, founder, Foundation for Biotechnology Awareness and Education (FBAE), who was on some of the committees, discussing the policy observed, "A policy should be promoting, controlling and unrestrictive. A policy cannot be closed even for a moment. You don't expect a final policy. It has to be reviewed, changed periodically and continuously updated." DBT has made a policy document almost two years ago, posted that on its website and asked for comments. "There were two task committees, one headed by Prof. MS Swaminathan for agricultural products and the other by Dr Mashelkar for pharma products. There are five different ministries involved here and they have conflicting trust. The major issue now is the biotechnology regulatory authority. There was one committee that was formed and some propositions were made. The person who was in-charge went on leave for sometime. So things are going slow. When you get around all the ministries, we will have a massive biotechnology regulatory authority, which is supposed to be a statutory and autonomous, not attached to any ministry," added Prof. Rao.

There are some parts of the national biotech policy that are already in the process of implementation. However, Prof. Rao is eagerly waiting for the national council for biotech education and training, which is supposed to function like the military council, dental council, or Bar Council. Four centers have been identified--one in Bangalore, one in TERI, New Delhi and one is in Baroda, and the fourth one will possibly be in Kolkata. These four centers are expected to be upgraded to the levels of institutes at the international level.

Dr Shama Bhat, Bhat Biotech, Bangalore highlighted that something still has to be done on the Duties. "You can import an HIV kit (diagnostic) today from China, Korea or USA without paying duty, but if you want to import raw materials, you have to pay duty. The government is discouraging Indian companies by putting duty on raw materials whereas they are encouraging the importing of diagnostic kits from places like China or Korea. The government should allow us to import raw materials without duty so that we will be able to compete with these Chinese or other countries from where kits are imported," observed Dr Bhat.

Naveen Kulkarni, CEO, Polyclone said, "The whole biotech industry, including the government, academia and the companies themselves, are in a growth phase. That means it is a learning curve. We are learning a lot of things. For example, DSIR broke the ice for the first time giving the R&D company recognition for a company like us. If you know traditionally it has been

giving R&D recognition for companies with a huge manufacturing facility and I put forth my argument that if a company has to do product development, then one is literally forcing the company to take the technology from somebody else and make profits. If innovation has to happen, this has to happen in the beginning. And that's when it matters the most."

GEAC Approvals

The 79th meeting of the Genetically Engineering Approval Committee (GEAC) was held on August 8, 2007 under the chairmanship of BS Parsheera, additional aecretary, MoEF and chairman, GEAC. The decisions taken on transgenic crops in the 79th GEAC meeting include:

The Member-Secretary GEAC informed the Committee that the RCGM in its meetings held on June 28, 2007 and July 24, 2007 has recommended one proposal for multi location field trials (MLRT) with transgenic brinjal, five proposals for pollen flow/ biosafety studies with Bt brinjal, transgenic cotton, Bt okra, Bt rice and Bt tomato and four proposals for Strip trials with transgenic rice, transgenic groundnut, Bt cotton and Bt brinjal expressing new gene event. RCGM has also recommended 52 proposals for MLRT and SAU trials, eight proposals for strip trials and 31 proposals for experimental seed production with Bt cotton expressing approved gene events.

The Committee noted that the following recommendations/decisions taken by RCGM in the meeting held on June 1, 2007 have been endorsed by the GEAC in the meeting held on June 22, 2007.

1. MLRT for new events should not be conducted in the farmers' field. MLRT should be undertaken by the Companies/Institutions either in their own premises, research farms, long-leased land or at the SAU/ICAR institutions.

2. In accordance with the Supreme Court direction an isolation distance of 200 m should be maintained.

3. Strip trials, for new events should be undertaken by the Company in their own premises/ research farms. An isolation distance of 200 m should be maintained as per Supreme Court direction.

4. Applicant should generate complete biosafety data along with MLRT.

5. The applicant should submit a validated event specific test protocol before undertaking the trials.

6. For all new events applicants to include plant parts, such as leaves/shoot/ bolls in addition to seeds in the animal feeding studies for biosafety evalua- tion in the wake of certain reports indicating adverse effects of the leaves/ shoot/bolls on animals.

7. MLRT may be conducted in minimum 1 location and maximum at 2 locations in each State.

One of the expert members opined that condition No. 4 above may not be made mandatory during the MLRT as many of the research institutions developing transgenic crops are in the process of selecting the best gene event during the MLRT. Therefore, it may not be practical to conduct the biosafety data in respect of all new gene events. The Committee while agreeing with the above suggestion also reiterated that complete biosafety data should be submitted before the proposal is considered for large scale field trials. Therefore it is up to the institution to decide for which gene event biosafety studies should be initiated and at what stage. The Committee was also of the view that in case of crops where the isolation distance prescribed under the Seed Certification Standard is higher than the 200 m prescribed by the Supreme Court, the isolation distance prescribed by the Seed Certification Standard shall be made applicable.

Permission to conduct MLRT of four transgenic Bt brinjal namely Co2-Bt, MDU1-Bt, KKM1-Bt and PLR1-Bt containing cry1Ac gene (EE1 event) at five locations i.e. Horticultural College and Research Institute, Coimbatore, Horticultural College and Research Institute, Periyakilam, Agricultural College and Research Institute, Madurai, Agricultural College and Research Institute, Killikulam and Vegetable Research Station, Palur during June-September 2007 and January-April 2008 to evaluate their Agronomic performance and efficacy in controlling fruit and shoot borer and the effect on beneficial insects. by Tamil Nadu Agricultural University (TNAU), Coimbatore.

Some of the recommendations in the biotech policy are already being implemented.

Centers of Excellence: DBT today is supporting seven Centers of Excellence (CoEs). The DBT initiated a novel scheme for creation of CoEs, which are around people who have been outstanding and can mentor the young faculty, along with the scheme of creating CoEs in the required areas. For example, the Stem Cell Centre at CMC Vellore with a funding of Rs 19 crore. DBT earmarked about Rs 60 crore for both the CoE schemes and aims to support 30-50 CoEs in the next five years.

Star colleges: To promote quality human resource, Star colleges are being established and teaching training program has been initiated.

The Small Business Innovation Research Initiative (SBIRI): DBT launched the SBIRI scheme to provide early stage funding to scientists in private industries for high risk, innovative or commercializable product proposals. DBT received 70 proposals within the first month itself and DBT has supported 16 proposals. There are plans to scale up the funding under this scheme to about Rs 100 crore or so per year.

To promote large partnerships, DBT has supported a major initiative between the University of Delhi South Campus (UDSC) and Mahyco.

Stem cell strategy: The stem cell strategy mission program has also been initiated. DBT has evolved a strategy for stem cell research for the country. Research will be promoted for therapeutic applications using adult and embryonic stem cells as well as other more readily available sources such as bone marrow, peripheral blood and umbilical cord blood cells; focus will be on basic research and study of factors that generate stem cells and how stem cells can be stopped from proliferation; study of stem cell biology will also form an important aspect; emphasis will also be on the study of expansion of haematopoietic stem cells without differentiation and gene transduction, gene regulation and plasticity of stem cells. The Guidelines categorize stem cell studies into three main groups: permissive, restrictive and prohibitive research along with suggesting a provision for a two-tier evaluation and monitoring mechanism--one at the institutional level for permissive research and the other at the national level for restrictive research.

NBRA: The National Biotech Regulatory Authority (NBRA) proposal has also been proposed for the cabinet approval. The Ministry of Agriculture, Department of Agriculture & Cooperation had submitted a Note for the cabinet for setting up of National Biotechnology Regulatory Authority (NBRA) and has resubmitted revised Note for the cabinet after the proposal was considered by the Committee of Secretaries (COS). The Government department to serve as a nodal Ministry will be decided by the Union Cabinet. If the proposal is approved by the cabinet, the Department of Agriculture and Cooperation would send the whole report to the identified Department for setting up of NBRA and taking follow up action.

Besides these, the Mashelkar Committee report on recombinant pharma products has also come into effect from April 1, 2006. According to the Task Force Report, LMOs (Living Modified Organisms) are defined as only those organisms modified by r-DNA techniques through human interventions where the end product is living modified organism. The Report has rationalized the regulatory procedure for five categories of LMOs. The report also specifies the timelines for various approvals by the regulatory committees--RCGM approval for pre-clinical animal studies: 45 days; DCGI approval for Human Clinical Trials protocol: 45 days; DCGI examination of clinical trial data and response: 90 days; and Concurrent DCGI and GEAC decisions: 45 days.

Another important highlight of the report is that it has recommended the Constitution of a Standing Technical Advisory Committee on Biotechnology Regulation under the chairmanship of an eminent scientist to redress and look into various regulatory aspects and make issue-based recommendations on case-by-case basis prior to any deviation from the regulatory mechanism.

The National Biotechnology Strategy is awaiting the final nod of the cabinet and the industry's expectation is that the policy will offer many fiscal and non-fiscal benefits.