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Glimpses into the new biotech regulatory set-up

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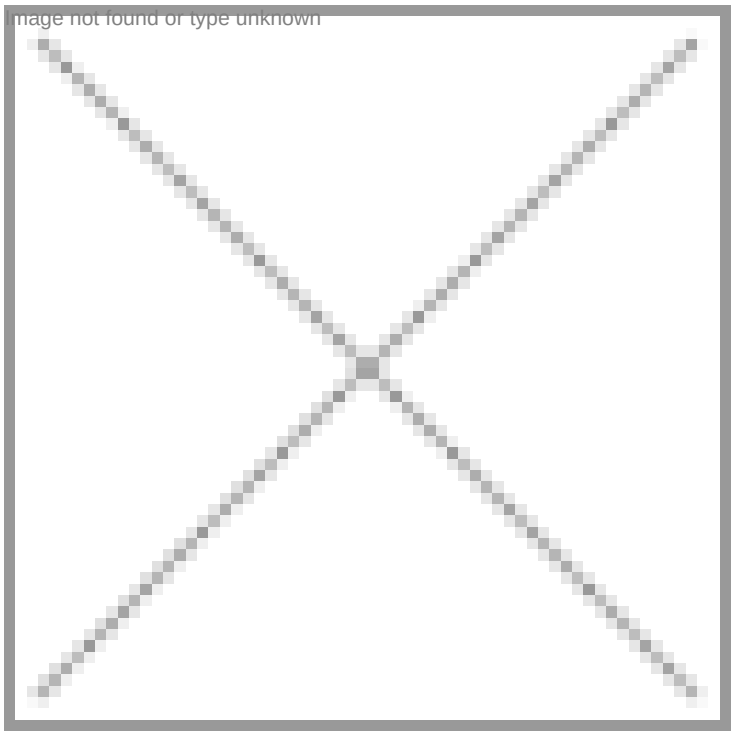


Glimpses into the new biotech regulatory set-up

After having sewn up the National Biotechnology Policy in November, 2007, the Department of Biotechnology (DBT) has shifted gears to give a concrete shape to the highly-contentious issue of setting up a National Biotechnology Regulatory Authority (NBRA) which will handle all biotech related regulatory affairs.

DBT has prepared a draft National Biotechnology Regulatory Act, which will be placed before the Parliament after September 2008. Sharing the contours of the new biotechnology regulatory authority with industry leaders during the Bangalore Bio 2008 meeting in Bangalore on April 26, Dr S R Rao, advisor, DBT, announced that the inputs and suggestions from the industry and other biotech stakeholders will be gathered in the next three to four months.

"NBRA will take into account all the concerns of the industry and try to eliminate overlapping of the areas of other similar authorities in order to act as a true catalyst for the industry. It will not hesitate to take expertise and suggestions from any person or institution of any country," Rao said.

He said the Act could cover the manufacture, production, commercial release and import of all genetically modified organisms (GMOs). The Act will confer relevant powers on NBRA to function as a safety net that ensures all biotech products are subjected regulations related to safety.

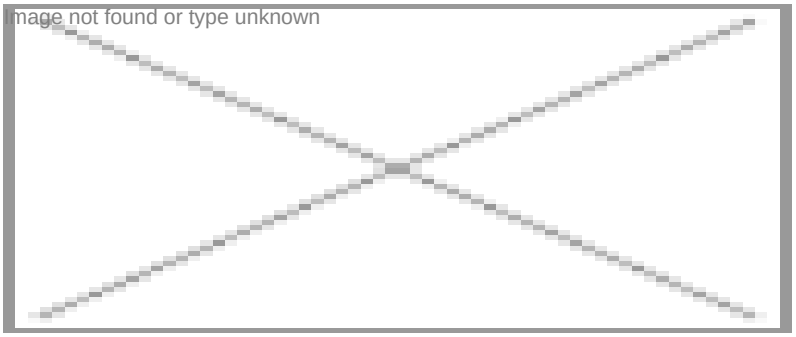
To avoid conflicts with existing legislation that overlap with some aspect of GMOs, specific categories of GM products which

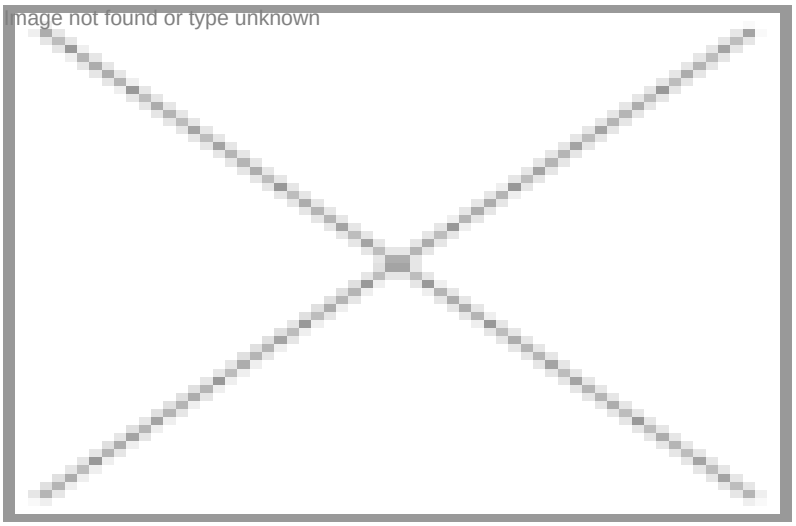
are currently regulated by other ministries/regulators will be kept out of the purview of NBRA. Essentially this means that GM foods and recombinant drugs will not be covered by NBRA but by existing regulatory guidelines of ministries of food and health. There will be however be some coordination mechanism within NBRA to deal with other regulators.

DBT team has already held extensive consultations with regulators handling biotech segment in the US and Canada in recent months. Rao said consultations with 10-12 biotech regulators from other countries are also going to be done to learn from their best practices. Similar consultations will be done with regulators of other economic activities in India too to learn from their experiences and avoid the mistakes made by them.For the purpose of this Act, "modern biotechnology" means the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

It specifically excludes: in vitro fertilization; natural processes such as conjugation, transduction, transformation; polyploidy induction; and accelerated mutagenesis.

The draft plans of the legislation will be available on the DBT website and suggestions on it could be emailed to nbra.dbt@nic.in from May 1, 2008.





Regulatory Branches

The NBRA will be headed by an eminent biotechnologist and the Authority will be supported by two advisory bodies--Inter-Ministerial Advisory Board (IMAB) and a National Biotechnology Advisory Council (NBAC).

The Act envisages the IMAB to promote and ensure inter-ministerial and departmental coordination as regards to the implementation of the regulatory system. The Board will have high level representatives from key line ministries and selected state governments.

Similarly, the NBAC will address overarching policy-related issues that may affect the regulation of the country's biotech activities. The council members will include representatives from the scientific community, private sector and the civil society.

Both these advisory bodies, however, will not be involved in product-specific reviews or decision making.

The draft legislation has suggested that the NBRA function through three major branches to deals separately with agriculture and fisheries, human and animal health, and industrial and environment applications.

- So the agriculture, forest and fisheries branch (AFFB) of NBRA will regulate GM plants, animals and micro-organisms used in agriculture, forestry or fisheries, including aquaculture.
- The human and animal health branch (HAHB) will regulate all GMs with applications in human and veterinary health, such as assessing the potential environmental risks and benefits associated with the application of GMOs in pharmaceutical development or recombinant livestock vaccine production.
- The industrial and environmental applications branch (IEAB) will regulate GMOs used in industrial manufacturing and in environmental applications, such as the use of GMOs for bioremediation of contaminated sites or oil spills.

Further, each branch will be headed by an eminent scientist who is an expert in that segment and will be designated as the Chief Regulatory Officer (CRO). NBRA will provide each branch with a Regulatory Policy Unit (RPU) and a Risk Assessment Unit (RAU). The RPUs will develop and implement branch specific policies, write the rules and provide guidance to the users. The RAU will handle the tasks of taking up science-based regulatory assessments on a regular basis.

In addition, each branch will be provided with Scientific Advisory Panels (SAPs) to gather expert inputs.

Another innovative decision is the plan to set up six cross-sectoral offices that provide inputs to the entire NRBA set up. These include:

- National and international policy coordination unit
- Communications and outreach unit
- Legal unit
- Economic analysis unit
- Monitoring, compliance and accreditation unit
- State level offices

Legislative Impact

For NRBA to function effectively, some amendments will be required in the existing regulatory Acts and Rules. These include:

- Rules for the manufacture, use, import, export and storage of hazardous microorganisms or genetically engineered organisms or cells, 1989, issued under the Environment Protection Act, 1986.
- Drugs and Cosmetic Rules (8th amendment), 1988.
- Plant Quarantine (Regulation for import into India Order 2003)

- The New Seed Bill, 2004
- The Food Safety and Standards Act, 2006

Biotech products relate to many areas and there are bound to be many conflicts between regulatory authorities. To nip such problems in the initial stage itself, the NBRA legislation would provide for regulatory exemptions for processes related to the production of GMOs and or products derived from GMOs that are regulated under other acts that address environmental protection and human health safety in a manner equivalent to the NBRA Act. For example, NBRA could recognize that the Food Safety and Standards Authority (FSSA) and DCGI (Drug Controller General of India) are the competent authorities for development and commercialization of GM foods and recombinant drugs.

Similarly, GM foods and pharmaceuticals, which have traditionally been regulated by health ministries worldwide, providing public confidence in decision making. For example, FSSA could refer the regulatory packages it receives for GM food approvals to the NBRA's Research Advisory Unit. This unit could function as the scientific panel on GM foods as defined in the FSSA. Also, the NBRA could take up the safety assessment on behalf of FSSA.

Industry Views

After Dr Rao announced the contents of the proposed regulatory set up, there was a lively discussion on the topic during the Bangalore Bio event. The president of the Banglaore-based Association of Biotechnology-Led Enterprises (ABLE), Dr KK Narayanan said: "As there are several branches under biotechnology, constituting just three branches under NBRA will not be enough and there is a need for many other branches to be included such as agriculture, fisheries etc separately instead of clubbing them all."

Other panelists and the delegates expressed concern over the opposition to GM crops by the state governments of Kerala and West Bengal. They suggested that what is good for India should be decided by the pure scientific merits only, but not by the partisan attitudes, panelists opined. Panelists suggested a need for setting up a think tank to give suggestions to NBRA on a continuous basis.

Narayanan Suresh in Bangalore