

GEAC needs a make over

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It should fly sky high like other famous regulators

By a legislative accident, the Genetic Engineering Approval Committee (GEAC) in the Ministry of Environment and Forests, became the apex regulatory agency for the biotechnology sector. It happened because the Environment Protection Act, 1986, appropriated the right to regulate the release into the environment any product containing a genetically modified organism. For nearly 16 years, this anomaly was not even noticed. Now that biotechnology is on the verge of becoming a major area of economic activity, the inadequate expertise of GEAC to handle complex biotech issues has come to the fore. There is unanimity in the biotech sector that GEAC has to be given a thorough make over so that it becomes a forward looking, scientifically equipped regulatory body with an independent profile. *BioSpectrum* provides a ringside view of the cataclysmic developments within the sector, which is shaping the strong demand for a regulator the biotechnology segment could be proud of.

It was a packed auditorium at the sprawling India Habitat Center in the heart of New Delhi on November 27 to celebrate the 10th anniversary of Gene Campaign, led by the fiery activist Suman Sahai. An unassuming bureaucrat, DD Verma of the Indian Administrative Service (IAS) kept the 150-odd biotech industry stakeholders such as industry leaders, activists, journalists, members of Parliament and researchers spell bound for nearly 90 minutes. He and his colleague Ms Ranjini Warriar fielded dozens of questions flung at them from different corners with aplomb. It was a rare opportunity for the biotech community to interact intensively with two officials whose every word could make or mar the prospects of the emerging

industry.

Who are these bureaucrats? Both Verma, a joint secretary and Warriar, a director, were part of India's apex biotech regulatory agency, the Genetic Engineering Approval Committee (GEAC) attached to the Ministry of Environment and Forests (MoEF). And they had come straight from another quarterly meeting of the committee which in the morning had taken the controversial decision to ruffle an industry icon, Shantha Biotechnics, by ordering an inquiry into some clinical trial data of its Streptokinase drug.

GEAC is one of India's most feared regulatory agencies. The mere mention of the name evokes strong reactions from a cross section of biotech players. Here is a sample of the reactions: "We have been urging the total revamp of GEAC, an agency that meets only once in three months and is under pressure to look into various issues ranging from the Taj corridor to biotechnology," thundered Shantha Biotechnics chief Varaprasad Reddy to the media on November 28 in Hyderabad.

"GEAC should be wound up. It has no business to exist because we don't need genetically engineered crops in this country," emphasized agriculture policy analyst, Devinder Sharma in New Delhi. Or as Suman Sahai spat out: "GEAC represents a totally degraded regulatory system. It is a farce."

No doubt, GEAC has been under fire for nearly two years, particularly from April 2002 when it approved the first commercial use of the genetically modified (GM) product, the Bt cotton seeds.

The cotton seeds contain a gene from the soil bacterium, *Bacillus thuringiensis*, which provides protection against a major cotton pest, bollworm. GEAC has been criticized by NGO activists for being too friendly with the biotech industry. On the other hand, the industry has been highly critical of the decision making process of the regulatory agency which took over seven years to clear the first Bt cotton seeds by Monsanto-Mahyco combine. And what both the opponents and supporters of GEAC agreed was that the agency needed to be more transparent, have a more scientific structure and consult all stakeholders.

Perhaps, the public pressure had been too much on the regulatory agency. No wonder Verma tried to reach out to the people through that interaction with a cross section of the industry. Of course, Verma was batting for his boss, Meena Gupta, an additional secretary in the Ministry of Environment who is the fifth person to wear the hat of the chief of GEAC in 2003. This is, in fact, one of the major criticisms against the structure of GEAC.

Ever since the Indian economy embarked on the liberalization path in 1991, the government had set up regulatory agencies with varying powers to offer a level playing field to all the players in sensitive sectors like financial markets (SEBI), telecom (TRAI), insurance (IRDA), nuclear energy (AERB), power (CERC) to name a few. Even after over a decade of toying with independent regulatory structures, the results have been mixed. Except perhaps SEBI and IRDA, all the other regulators have faced considerable flak from the public. However, these agencies have never been criticized for the nebulous structure they work with. All of them have a defined structure, a lot of functional autonomy, are headed by a people with by and large proven expertise in their field with fixed tenures.

The most unfortunate regulator in this case has been the GEAC. That is what has riled the industry more than anything else. Headed by bureaucrats with no fixed tenure and no defined membership, the GEAC has ambled along since 1995 without any focus.

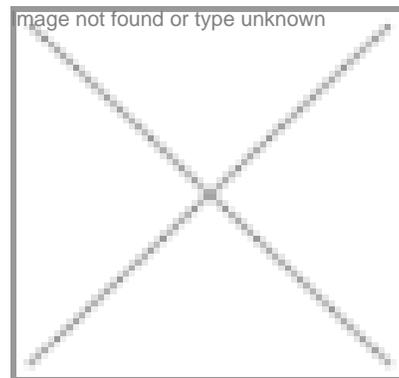
There are many reasons for this. Primarily, the policy makers have not given much attention to the biotechnology sector unlike other areas of economic activity. The other reason is that any change to a more scientific structure is being resisted by the bureaucracy (read IAS officers) who are loath to give up another parking place for their tribe in the dwindling age of government.

"They (IAS) officers have grabbed yet another strictly technical post and will resist any attempt to reform the GEAC," confided a senior technocrat who has watched this IAS versus others tussle for supremacy in the government structures for over three decades.

In fact, Verma and GEAC have added a red herring in recent months. Verma announced the induction of four scientists as permanent members of the GEAC. The GEAC will have a co-chairperson in Dr Sushil Sharma, former director of the CIMAP (Central Institute for Medicinal and Aromatic Plants), Lucknow. Three other scientists—Dr AK Bhatnagar of University of Delhi, Dr RP Sharma of Indian Agricultural Research Institute, New Delhi and Dr Subash Chand of IIT, Delhi.

This may be an attempt to stall the move at the highest levels of the government to restructure the GEAC as many representations have reached the Prime Minister AB Vajpayee from the biotech industry and senior scientists. In fact, a

proposal under consideration is the report by Prof. MS Swaminathan, the architect of India's Green Revolution in agriculture and the recipient of the First BioSpectrum Life Time Achievement Award. Prof. Swaminathan has recommended the setting up an apex regulatory agency called the Biotechnology Commission along the lines of the Space Commission or Atomic Energy Commission. Such a commission, Prof. Swaminathan said should be headed by a senior biotechnologist and have four or five full time members who are specialists in different segments that form part of biotechnology such as agriculture, health, informatics, biosafety, etc. The Biotechnology Commission could then set up permanent sub committees for each of the specialized areas to carry out full scale risk assessment and other tests on an on going basis. The proposed Biotechnology Commission should be an independent one with statutory powers to regulate the entire spectrum of the industry with appropriate punitive actions etc.



Analysts feel that the induction of four scientists, for the first time, is an attempt by the bureaucracy to stall and buy time on the move to set up the Biotechnology Commission.

There is widespread support for the setting up an independent, high power regulatory agency for biotechnology.

"We need a regulatory regime which understands the technicalities involved in the use of genetically modified products. There should be no lethargy in its functioning and the delays in the clearance process should be reduced drastically," argued Pune-based Syngenta's vice president (projects) Dr G D Pimprikar. Syngenta, one of the world's leading plant biotech company, is in the process of seeking regulatory approval for commercialization of its cotton seed based on a new variety Vip gene. Based on the ease of the regulatory process, Syngenta plans to introduce its other blockbuster biotech products in the global pipeline in India too simultaneously.

Currently, at least three major government agencies are involved in the clearance of biotechnology products in the health care and agriculture sectors. For vaccines and other health products using biotechnology, clearances have to be got from the Review Committee on Genetic Manipulation (RCGM) in the Department of Biotechnology first, then the clinical trials data have to be validated by the Drug Controller General of India (DCGI) in the Ministry of Health and the final authority for approval is the GEAC. While even in the US, there is a multiplicity of regulatory agencies such as the Federal Drug Agency (FDA), the US Department of Agriculture (USDA) and the Environmental Protection Agency (EPA). However, these agencies work in very close coordination, unlike in India, and specific timelines for approval or rejection are part of the regulatory process.



Helpless regulator

The Ministry of Environment had earlier received various complaints that spurious Bt cotton saeeds are being produced and sold in Gujarat without the approval of the Genetic Engineering Approval Committee (GEAC) constituted under Rule 1989. In response, 10 packets of cotton seeds alleged to contain the Bt gene were forwarded to Central Institute of Cotton Research (CICR) for verification report of CICR confirms that cotton seeds which are being produced and sold in Gujarat, under the following brand names, have tes positive for the presence of Cry 1 Ac gene. The report inter alia quotes "We carried out PCR and ELISA tests on eight seeds from ea the packets. We would like to confirm the following results.

The above hybrids have not been approved by the GEAC and therefore, production/sale/use of the above hybrids is a clear violation the Rule 1989 and liable for punitive action under the Environment (Protection) Act, 1986."

BioSpectrum adds: The threatened punitive action has yet to be initiated. The regulator is still "awaiting" a report from the Gujarat sta government as agriculture is a state subject.

SINo.	Brand Name	Result	Remarks
1	Brand name: Rakshak	Positive	F-1 seeds
2	Brand name: Virat	Positive	F-1 seeds
3	Brand name: Captain F-1 Hybrid Cotton Seeds.	Positive	F-1 seeds
4	Brand name: Research Hybrid Cotton F-1 (Tilak)	Positive	F-1 seeds
5	Brand name: Trishul (F1)	Positive	F-1 seeds
6	Brand name: Kavach F-1Hybrid Kapasâ€“151.	Positive	F-1 seeds
7	Brand name: Surakshaâ€“ Hybrid Cotton Seeds.	Positive	F-1 seeds
8	Brand name: Research Hybrid Cotton F-1.	Positive	F-1 seeds
9	Brand name: Krushi 357	Positive	F-2 seeds/seed mix

"A single window clearance mechanism is the best for a country like ours," emphasized Dr SD Ravetkar, senior director, Serum Institute of India Ltd, Pune. Serum is one of the country's and the world's largest makers of a variety of vaccines. "The GEAC has to evaluate the existing regulatory systems and change its structure so that it can become one of the best regulatory agencies in the world."

There is another strong reason to make GEAC a powerful, independent regulator. GEAC has so far approved only three hybrids of Bt cotton from Monsanto for cultivation in six states—Andhra Pradesh, Gujarat, Karnataka, Madhya Pradesh, Maharashtra and Tamil Nadu—after seven years of rigorous trials. In Gujarat, however, a local seed company, Navbharat Seeds, has sold large quantities of its own version of the Bt cotton. This has undercut Monsanto's Bt cotton hybrids on price and farmers have bought this because its performance was found to be better than the legally approved varieties. An industry insider explained that Navbharat could introduce the latest hybrids, as it did not have to undergo the time consuming regulatory process.

And what has the regulator GEAC done to stop the illegal use of Bt cotton seeds? Nothing much. GEAC tested 10 randomly picked up samples of Bt cotton seeds being sold in Gujarat and found that eight of them had the unapproved Bt gene (See Box item on this). GEAC does not have the power to stop the proliferation of the illegal Bt cotton varieties. GEAC officials have threatened to take punitive actions under the Environment Protection Act, 1986. However, as agriculture is a state subject, punitive action against illegal seed sellers and users could be taken only by the state governments. GEAC has asked for a report from the state government and the industry does not expect much action on this front. What is worse is that biotechnology committees at the state and district levels to monitor the use of GM products, mandated under the EPA exist only in name and are almost dysfunctional.

Certainly, GEAC has to change its methods to become an effective regulator. Part of the problem is caused by the working of the GEAC itself. **M Prabhakar Rao, president of Hyderabad based Indian Seed Industry Association, suggested that GEAC should restrict itself to the approval of a particular gene technology such as Bt gene.** "Once a gene is found to be safe, GEAC should approve its use in any of hybrids. There is no point in GEAC evaluating the performance of each and every variety of hybrids. In fact, this may be a violation of the Seeds act," Rao emphasized.

Syngenta's Pimprikar too supports this. "GEAC should restrict itself to the approval of a gene. After that leave it to the breeders to choose which hybrids to insert them. Beyond that it is a commercial decision. No breeder would use the technology in an inappropriate hybrid as it could lead to commercial failure," he added.

Another major demand of the industry is the harmonization of the different laws such as Seeds Act, EPA, Drugs and Cosmetics Act, Prevention of Food Adulteration, etc. so that companies need not run from pillar to post to comply with unwanted, intricate provisions of these legislations.

Every one is hopeful that at least in 2004, realizing the potential of biotechnology to be another engine of growth for the Indian economy, the government would act swiftly to revamp the structure of GEAC. Serious practitioners of biotech have been discussing informally the potential names of persons who should head the revamped regulatory agency.

There is almost an unwritten consensus that the best person to head the new look regulatory agency is Prof. MS Swaminathan. The living legend would be able to give the regulatory agency immense prestige, clout and also the moral authority to bring about a rapid transformation of the biotechnology sector. Industry would also be very happy if Prof. G Padmanabhan, former director of Indian Institute of Science is made the agency's co-chairperson. Between them, these two eminent scientists possess the best of the knowledge on agriculture and health care issues.

There is also a section of the industry which feels that if the government is averse to bringing in outsiders to head the agency, the GEAC should taken out of the purview of the Ministry of Environment and attached to the Council of Scientific and Industrial Research (CSIR) headed by the charismatic scientist Dr RA Mashelkar. Or at least the regulatory agency should be moved to the DBT and its secretary, Dr Manju Sharma should head it.

The biotechnology industry is waiting for a quick decision, which should bring more clarity, credibility and single-mindedness to the pursuit of biotech boom.

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