

NOT YET BORN, BIOTECH MONITOR DRAWS FIRST BLOOD

GEAC will sacrifice powers if M S Swaminathan panel gets its way

ASHOK B SHARMA
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THE regulatory mechanism for biotechnology finally shows signs of getting off the ground. For starters, the M S Swaminathan Panel on Applications of Biotechnology in Agriculture wants to cut back the powers of the existing regulatory authority, the Genetic Engineering Approval Committee.

The GEAC was a multi-disciplinary body headed by an additional secretary-level official from the Ministry of Environment and Forests. The last three years have seen six chairmen come and go, triggering a great deal of consternation in the industry.

The Swaminathan panel has suggested that pending the establishment of an autonomous Agricultural Biotechnology Regulatory Authority (ABRA), the release, notification and registration of transgenic crops for commercial cultivation be

done by the Indian Council of Agricultural Research (ICAR) and the Union agriculture ministry. The panel has limited the powers of the GEAC to "only environmental clearance".

The panel report, which has been submitted to the

Medicine Men

The Union environment ministry has constituted a 12-member taskforce headed by CSIR chief R A Mashelkar for recommending biotech applications in the pharma sector. The panel will suggest measures to streamline the regulatory mechanism and process for use of living modified organisms (LMOs) at various stages and also the mechanism for LMO imports. Industry bodies like FICCI and CII are in the panel. A similar panel is expected to be formed for processed foods.

Union agriculture ministry and will be eventually taken up for discussion in the Cabinet, criticised the existing process of clearance as "lengthy and cumbersome, as is evident from the time taken for release of Bt cotton".

With a view to hasten the process of clearance of GM crops, the panel report said "once an extant/transgene has been declared bio-safe, its derivatives need not always be evaluated for bio-safety again. Such derivative crop varieties can be evaluated on basis of largescale trials by ICAR and released after satisfactory value for cultivation and use (VCU) trials".

In the run-up to the ABRA, the Swaminathan panel suggests, approval powers for contained and open field trials for biosafety should rest with the Review Committee on Genetic Manipulation (RCGM) while the multilocal farmer's field trials are the sole responsibility of ICAR and the company con-

cerned.

The Monitoring-cum-Evaluation Committee (MEC) should report to GEAC on biosafety and environmental issues, while post-release monitoring should be the responsibility of the Union agriculture ministry and ICAR.

In practical terms, this means cutting back the GEAC's powers. At present, they are the sole authority to deny or clear a particular Bt gene on all counts, economic and environmental.

Regarding selection of crops for developing transgenics, the panel report says that national interests like external trade should be kept in view while taking up research

projects in transgenics. The importance of traditional Basmati rice and soyabean in the export market is a case in point.

The panel also suggests labelling and traceability norms for genetically modified (GM) products, establishment of Codex norms in GM foods and protection of organic farming zones and agro-biodiversity sanctuaries from the effects of cross-pollination of GM crops.

It has suggested "gathering of data on the impact of transgenics on biodiversity in crop fields, on model of recent studies in UK".

The panel report pleads for special government-sponsored insurance scheme for GM crops, venture capital assistance for the transgenic crops industry and private-public sector alliance

for production and marketing of GM seeds.

The panel report recommends farmers' participatory assessment in the evaluation of GM crops. It also suggests that till the ABRA comes into being, the GEAC should have two expert-staffed wings — one to deal with transgenic agriculture and the other for the pharma sector — headed by a biotech expert.

The report also suggests strengthening the Seeds Act and environment laws to deal with possible illegal proliferation of GM seeds. It favours mandatory registration of all released seeds and proposes a single-window information centre on all aspects of bioethics and biosafety.



SHANTHU SHANTHARAM

Public sector will lose out in GM race, warns veteran

SONU JAIN
NEW DELHI, APRIL 29

BACK in the 1980s, Shanthu Shantharam monitored the first Bt cotton trials in the US as branch chief with the US Drug Administration. Today, as president of Biologics International, he has a vantage view of India's half-hearted embrace of GM.

"If a public sector company is treated at par with private companies, it will never be able to come to the market," Shantharam warns. "There is no way the public sector can pay for the regulatory costs as it exists today."

GM technology has been attacked because it is controlled by the private sector, and GM farmers would be at the mercy of MNCs. In India, Monsanto subsidiary Mahyco pursued the Bt cotton approval for seven years before they got permission for five states. It took another two years before two Indian companies managed to get approval for the same gene.

The scene is even more dismal for other crops. Proagro, a company in the race for GM mustard, was asked to return time and again before they decided to give up.

But why doesn't the public sector — with its vast network and infrastructure — come up with a cheaper variety of Bt cotton or other GM crops? According to Shantharam, it's because they do not discover genes. "They almost seem to be suffering from an inferiority complex. The protocols of buying or importing a gene for further research takes years," he said.

Public companies, Shantharam said, should be similar to corporate bodies. "They have to have a business plan, product development plan and stage-wise development plan till, say, 2010," he said. "There have to be options from which the most economically viable ones are salvaged and the rest junked."

Shantharam, incidentally, worked with Syngenta, Switzerland, when it was developing its Golden Rice and rice genome. He has two decades of experience in the harmonisation of biotechnology regulatory policies.

"There has to be a blockbuster gene that will make GM crops a huge hit," he said. "Blockbuster genes are elements that overcome environmental challenges like drought or upgraded nutritional value like the Vitamin A rice."

The Swaminathan Foundation in Chennai, incidentally, is already working on rice that grows in saline areas. Shantharam has doubts about the yield benefit of GM in crops like wheat and rice, where effective hybrids have already pushed the limits.

But the misinformation campaign against Bt gets Shantharam's back up. "We have set up a Foundation for Biological Awareness in Bangalore that works with young scientists on countering these claims," he said.

Shantharam would also like to change the broad regulatory rules that exist in India today. "Most regulators are so nervous that they avoid decisions and instead try to find technical faults. GM companies should be asked to generate transparent data on field trials that can be shared with the world and reviewed by scientists," he said.