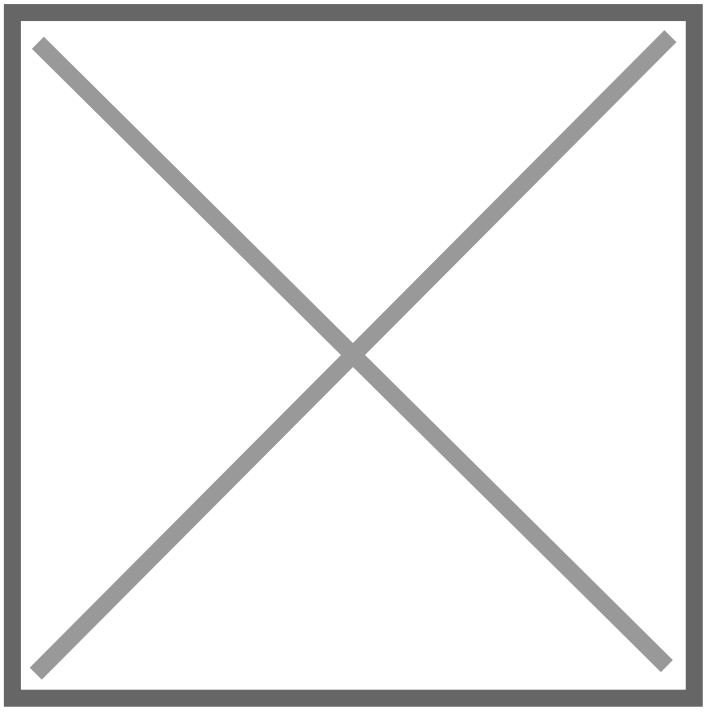
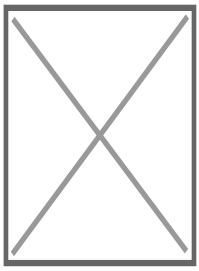


Stop talking, Just do it!

08 September 2004 | News



Indian Biotech Regulatory Reforms



Close on the heels of the global biotechnology conference in Delhi sponsored by FICCI, MSSRF and ISAAA, every Tom, Dick and Harry has spoken on the need for reforming the biotechnology regulatory system in India. Some say Indian biotech regulatory system is too lax, some say it is too tough and yet some say it is inept and ineffective. Perhaps, there is some truth in all of these. But, is there a solution to the problem? There is, but not the way they are going about it. Indian bureaucracy has invented the phrase "single window" clearance system as a cure all for every ill of the permit and license raj system. It meant different things to different people. What it meant to Kapil Sibal, the Minister of State for Science and Technology when he suggested the government would have single-window system for biotechnology is anybody's guess! At least one anti-GM activist thinks that it means lessening the regulatory burden and making it easier for the industry. The rest don't think so. It simply means providing administrative convenience of sending in your biotech application through one door without having to run from pillar to post. It does not mean that all the confusion and the turf battle within and among the ministries are over. In fact, it has just begun with ICMR throwing its hat into the ring. It certainly does not mean that the regulatory review will be speeded up, as the system itself has not been designed to put a timely process in place. It will take a long time. Then, there is a suggestion that GM crops must be covered by insurance to protect the poor Indian farmer. There is also a demand for socio-economic and ethical impact assessment of the technology and the products. Can you imagine all these issues being handled by a regulatory system that was originally cobbled together to assess biosafety and environmental impact of GM crops? There is no way all these issues can be handled by a regulatory system whose ostensible purpose is to assure the public of the safety of biotechnology and its products. This is not to say that other issues are not important, but it is just that these issues should be decided by specialized experts. Socio-economic and ethical issues are best studied by academic experts and scholars. And after a thorough public discussion and discourse a suitable public policy must be evolved to determine if those issues are best handled through a regulatory
regimen.

For now, India is struggling to put in place a scientifically rigorous biosafety and environmental impact assessment system and that is not hard to do in this day and age with so much of resource and expertise available around the world just for asking. Biotechnology regulatory oversight is not rocket science. Countries around the world have been doing it for decades now and if India is serious, it can call in experts to put together an effective and transparent regulatory review system for GM crops quickly and get on with the business of safe biotechnology development, pronto! Almost everyone who is talking on biotech regulatory system in India has not even read an environmental risk assessment document, much less carried out one.

It is no ones case that GM crops do not need regulatory oversight. The squabble is about the level of regulatory scrutiny that should be conferred on GM crops. How does one decide the level of regulatory scrutiny? By simply preparing an ex-ante risk assessment using the best possible scientific rigor and determining the specific risks and then exploring the options to manage or mitigate those risks in a cost effective way. It is equally important to assess the risks of not deploying the GM option as well. GM crops cannot and should not be considered "risky" just because some feel it is risky. All of us would be wiser to realize that regulatory oversight has a cost and it better be cost effective regulations. Otherwise, we will be denying the potential benefits of the technology by making it prohibitively expensive. To the best of my knowledge, no one in RCGM or GEAC has prepared an environmental risk assessment document for any of the of GM crops, based on which they have made their regulatory decisions so far. Surely, they have done their own "seat of the pants" review of some kind or other so far. Because it was not systematic and followed any standard methodology, it took more than six years to get the first GM Bt-cotton to the market place.

Civil society groups are crying about lack of transparency and I suspect even the applicants would appreciate a dose of the same to comply with the regulatory requirements. I suspect that the lack of transparency in the system is because they cannot explain the rational for making their decisions. Having been an author of thousands of environmental risk assessments, I can confidently tell that there is no need to hide anything about regulatory decisions on GM crops, as there is nothing to hide. Both the regulators and the applicants must do everything possible to make as much data and information public as possible. Both must realize that in this day and age when the GM crop technology is under so much of fire, everyone involved must do everything possible to assuage public concerns and do not do it just to satisfy some activists. Kiran Mazumdar-Shaw of Biocon must be congratulated for her boldness to announce the other day that Biocon has made all its clinical tests data public through its website. The agricultural biotech industry should follow the lead of Biocon in this regard and earn public trust and confidence. They can really beat the activists in their game by winning over the public directly.

The government is wasting its time by talking to people who are clueless about setting up a regulatory regimen. The only sane and balanced view I have heard in all this cacophony is an editorial entitled "Biotech Watchdog-A Single Regulator' a welcome idea" in the pages of The Financial Express datelined August 15, 2004 (http://www.financialexpress.com/fe_full_story.php?content_id=65882). Lobbying by one group or another to influence the regulatory system will continue, but the policy makers and administrators know better to put competent people in-charge and give them a free hand to do the right thing.

The need of the hour is a statutorily independent national biotechnology regulatory commission that will serve as a policy advisory body and administer a technically competent group of regulatory experts with training in environmental risk assessment. The commission's members can be drawn from different walks of life with adequate representation from all the stakeholders to ensure transparency for which everyone is crying. It will go a long way in earning pubic trust and confidence and facilitate biotechnology development for the benefit of all.

Dr. Shanthu Shantharam is the President of a biotechnology affairs consulting firm, Biologistics International in Maryland, USA.