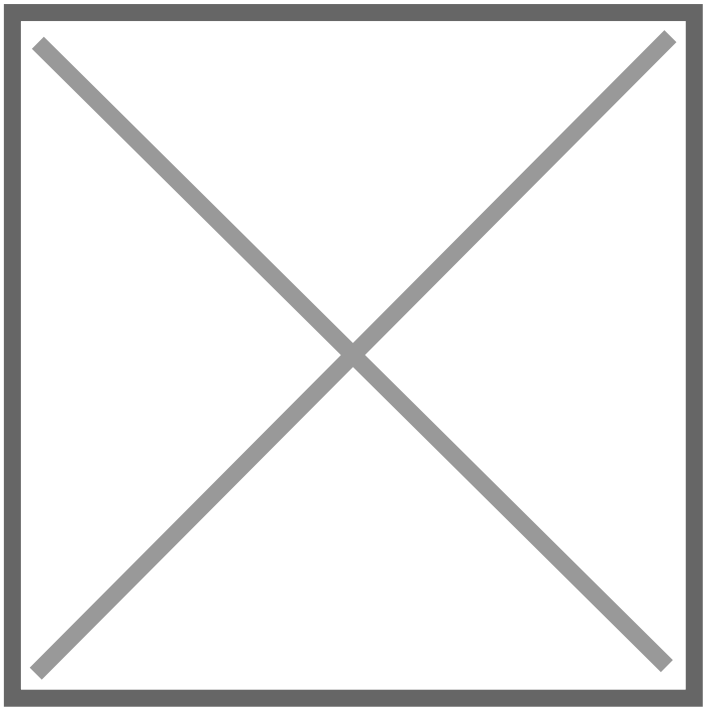
BioSpect
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

"I want to root for the triumph of the GM technology."

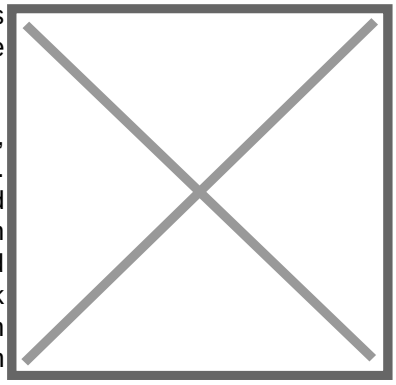
11 May 2004 | News



Dr Shanthu Shantharam

Many "biotech gurus" of Indian origin have been making waves in recent years all over the world. As the segment is new in India, these remarkable personalities have not got the attention they deserve in "India Shining". BioSpectrum will attempt to cover the information gap that exists in enabling India's nascent biotechnology industry to learn from these experts. What better way than to start this new series with the redoubtable Dr Shanthu Shantharam, who pioneered the regulatory process of Bt cotton and supervised the first field trials of this crop in the United States in the mid-1980s.

After his stint as a regulator and then as a communicator, Dr Shantharam now shuttles between Washington DC and India and other countries, spreading the good word about the beneficial effects of modern biotecnology.



Currently, he is on his own, as the President of Biologistics International LLC, Ellicott City, Maryland. He is also a senior advisor to the Sehgal Family Foundation since July 1, 2003. Dr Shantharam is a specialist in agricultural biotechnology and sustainable agriculture and an environmental policy analyst. He has over two decades of professional experience in the areas of international harmonization of biotechnology, regulatory policies and biotechnology capacity building, biotech policy development, and environmental risk assessment of Genetically Modified Organisms (GMO). Dr Shantharam was a Branch Chief with the Biotechnology Regulatory Services unit of the USDA, APHIS in Washington DC for over a decade and was head of Stakeholder Relations and Technology Communications with Syngenta International in Basel, Switzerland. He also served as their Biotechnology Regulatory Compliance Manager. While at Syngenta, he led Syngenta's communications effort for its Golden Rice and Rice Genome projects.

Dr Shantharam has been actively involved in international agricultural development scene working with the Rockefeller Foundation, USAID funded Agricultural Biotechnology for Sustainable Productivity (ABSP), Asian Rice Biotechnology Network (ARBN) at IRRI in the Philippines. Dr Shantharam was a visiting biotechnology advisor to the World Bank in 1996 and Visiting Research Fellow at the International Food Policy Research Institute (IFPRI) in Washington DC from 2000 to 2001.

Dr Shantharam received BSc (Hons) degree in Botany from Bangalore University, India MSc in Botany from the MS University of Baroda, India and a PhD in Microbiology from the Memorial University of Newfoundland in Canada. Dr Shantharam was awarded Fulbright Fellowship in 1993.

In this exclusive interview with Executive Editor N Suresh, the Big Daddy of biotech regulators shares his concerns and optimism about the recent trends in agriculture biotechnology around the world. Excerpts:

Despite strident opposition from anti-GM groups, GM products are being introduced in more and more countries like Australia, India, the Philippines and Indonesia. What do you attribute the changed scenario to?

The simple answer to your question, Ã¢â?¬Å?it is a good newsÃ¢â?¬?. It is true that global acreage of transgenic crops has increased led by the developing countries. But the technology transfer is clearly lopsided. In some instances, local governments in Australia and in some local counties like the Mendicino County in California have banned GMOs. There are many local governments like in Gottafratata in Italy that have declared their communities as anti-GMO or GMO free. There are many aberrations like these. What is distressing is that even a country like Angola that is teetering on starvation has banned GMOs.Â

I can attribute the increase in acreage of GMO in the world mainly due to the support of majority of the governments around the world and also due to the support of their own scientific community. Wherever GMOs have been grown, they have proved to be safe and environmentally friendly and economically beneficial especially to small and poor farmers. These are the main reasons why I think global acreage of GMOs has increased. But, I assure you that the problem is not yet over. Opposition to GMO in the form of spreading misinformation, turning and twisting scientific facts, and outright scare mongering is in full swing to discredit the technology. It is still a long road to large-scale adoption of GMOs around the world.

There has been a shift in the attitude to GMÂ products in the UK. The government although permitted commercial planting of maize, it imposed quite a few conditions. What is happening?

It was good news that the UK approved the commercial planting of GM maize much against the public opinion, but based on sound scientific advice. But, they also imposed stiff conditions that were very hard to comply with and Bayer had to make a business decision not to go ahead with its commercialization. This must be music to the ears of anti-biotech lobby. As they say, it is what the Ã¢â?¬Å?doctorÃ¢â?¬? ordered!Â Â

What happened was that the UK Government came under heavy criticism from within the parliament and from the outside activist groups, and it decided to pander to those pressure tactics by adding tough conditions to pacify the critics. This is as good as banning the GM technology. The UK Government did not earn any brownie points for their vacillating decision. It also sends a wrong message to the world, and similar tactics will be forced upon by the anti-biotech activists in other parts of the world to raise the regulatory burden so high that it becomes economically unviable to commercialize GMOs and the industry will be forced to beat a hasty retreat. This is clearly anti-science and anti-progress, and is going to hurt the needy and the deserving around the world in the long run. There is a huge opportunity cost.

Will the UK event cast a shadow on the European Union's (EU's) unofficial moratorium on GM products?

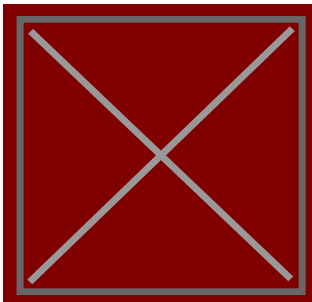
Again, it is hard to say. EU just lifted the unofficial moratorium on GMOs with its own stringent labeling and segregation rules. I think it will certainly be challenged in WTO by the US much against the wishful thinking of EU that they might have pre-empted the pending case against them at WTO. I think what the UK has done and the rules passed by EU will have a cascading effect on the developing countries that export agricultural commodities to Europe. Since most of the developing countries do not have the infrastructure and the means to label and segregate as required by EU, they would rather not allow GM plantings for fear of mixing. This once again is an indirect way of banning GMO without saying so, and this is the secret desire of many activists who are hoping against hope to get GMOs banned. The ultimate losers will be the developing countries who might need this technology more than European countries. If the developing countries strongly believe that they need modern biotechnology in agriculture to increase their food production and protect their environment, then they should band together and make a common cause to send a strong message to EU that it has to change its unscientific laws and regulations to do business with them. I believe that a strong message like that from like-minded developing countries will force EU to rethink on their unsustainable regulations.

Is the primacy of US based companies in the GM technology coming in the way of its wider acceptance? Have US-based TNCs in the agri-bio sector unwittingly become global targets for anti-US and anti-globalization groups?

You said it right. For some years now, I have maintained that EU-led opposition to GMOs and other developing countries, is definitely due to anti-US hegemony. GMOs were the latest to come in handy to anti-US, anti-WTO, anti-globalization and anti-free trade lobbies and groups most of whom are die-hard socialists and leftists. There have been very many scholastic studies to support this view. Most of these people also believe very strongly that the US private sector dictates lots of public polices in the US government and lobby with their government to take on cudgels against much of the world in various international

forums to clear paths for them to carry out their unbridled business. These forces are banded together to stop that. This is clearly an ideological battlefront and has nothing do with the safety of the technology or protecting the environment. The whole debate is completely politicized and there seems to be no end in sight. What is really sorry to note is that many of the opponents to biotechnology are very bright and highly educated, and yet have chosen to be intellectually dishonest while opposing GMO technology.
It is really hard to say now if an European MNC had promoted GMOs first, whether there would have been better acceptance. I think you will never be able to extract an answer in the affirmative from the GM-opponents on this point today. They would rather cut their nose to spite their face than to be rationale.

As one of the world's first expert regulators in this field, did you visualize the tortuous journey which GM technology has been subjected to?



Another important thing to do is to learn lessons from a wide array of assessments that have already been done elsewhere and address only those issues that are relevant to Indian agricultural background to cut down on the time and efforts required to do justice to the risk assessment.

I must admit that I did not. I was an active bench scientist before I became a biotech regulator at USDA (United States Department of Agriculture) by a quirk of an accident. Never had I imagined that I would seek a technology cop's job in my life. By and large, I think that is the mindset of active scientists even today. I still remember when drafting those environmental assessments how silly it looked for me to write those unexciting pedestrian scientific facts that are in the high school textbooks. I used to be bored with it. I was patiently counseled by our environmental attorneys about how important it was for us scientists to appreciate the laws and rules of the society and explain complex issues in a style that even a person with grade X education could comprehend. It was really testing to come down to that level of writing decision documents. It was only after almost five to six years of working at USDA that I really started to appreciate the importance of public acceptance of technology and how to make them understand basic facts.Â
Critics of science and technology really fault the scientific community for their callous attitude toward societal concerns. I think the critics of biotechnology have really given a wake up call to the scientists to tell them that it is not going to be business as usual, and that they have to take note of society's concerns and sincerely address them. I notice that scientists are trying to do their best to do so now, but they are still a long way to communicate and empathize with societal concerns.Â
At the same time, I feel that those who claim to speak for the Ã¢â?¬Å?societyÃ¢â?¬? should also make genuine efforts to understand basic aspects of science and scientific enterprise so that all of us who are really interested in progress achieve our goals in a spirit of cooperation and fairness.

In view of the enormous potential which GM technologies have, would you recommend a harmonized global regulatory process under the aegis of a UN unit such as the FAO for this sector?Â

Definitely, yes. In fact, I along with my colleagues at USDA, APHIS, had started a unique program way back in 1990 called Biotechnology Regulatory Support Activities that sponsored a series international scientific consultation on the biological impacts of major food crops that had been genetically engineered at the time. We organized a series of high-level scientific consultations to advice our agency on the prevailing scientific consensus that would be useful for our environmental assessment of GMOs. If I may say so, USDA, APHIS was the first regulatory agency in the world that promoted the idea of international harmonization of biotechnology regulations based on sound scientific consensus.Â

Already, UNEP (United Nations Environment Program) under its Convention of Biological Diversity (CBD) has instituted the International Biosafety Clearinghouse and WHO (World Health Organization) is developing food safety assessment of GM foods under Codex Alimentarius. I don't think there is any need for another UN agency like FAO to start another harmonization effort. But, FAO supports biotech harmonization by providing some the best-researched facts and figures on various issues of biotechnology in a very objective way. FAO is also involved biosafety capacity building in the developing countries.

Can you give a brief overview of the highlights of the regulatory systems being followed in handling genetically modified products in some of the world's leading nations?

Almost all countries to begin with used the case-by-case approach and slowly graduated to speedier methods of regulatory clearance process. These leading countries strictly based their regulatory reviews on best available scientific evidence, but seldom considered social and economic and efficacy issues of GMO. They stayed away from endorsing any product as well. They strictly limited themselves to addressing the safely and environmental impact issues and wanted the market place to decide on the products acceptability.Â

But, today the activists are demanding that socio-economic and ethical issues of the technology and its products also be addressed by the regulators who may or may not be qualified to carry out that kind of assessment. I think there is a place for the latter demand and is already being addressed by ever so many experts, but not under a regulatory rubric. Certainly, biotechnology regulators must not be asked to sit on the judgment of social and economic impacts of any technology. It should be left to the subject experts

Is the Indian regulatory approach that clears each hybrid incorporated with a foreign gene, the best method to handle GM products? Should the regulator stick to clearing just the technology?

It is a question to be answered by each country based on its own needs. I have heard demands from the private sector in India to clear the biosafety of the gene construct and approve it and not to bother clearing every transgenic crop variety. On the face of it, there seems to be logic to do it that way. But, as someone who has learnt a thing or two about environmental risk assessment, it is important to realize that one of the cardinal principles of environmental risk assessment is to assess the complete set of interactions of the whole organism (GMO) and its interaction with the environment into which it is being introduced demands a holistic assessment of each organism with a particular gene construct that you need to evaluate. For example, if one Bt gene construct has been evaluated in one cotton hybrid, I don't see why the same or similar construct in another cotton hybrid needs to go through any kind of elaborate testing at all. Such new lines can be cleared with just a notification for similar environmental backgrounds. That will save enormous time, efforts and costs to everyone involved. But, if the same Bt gene construct is deployed in maize or tomato that new combination needs to be completely revaluated.

Another important thing to do is to learn lessons from a wide array of assessments that have already been done elsewhere and address only those issues that are relevant to Indian agricultural background to cut down on the time and efforts required to do justice to the risk assessment. I don't see much point in reinventing the wheel and wasting time and resources by asking for all sorts of laboratory data which will be the same all over the world.

How will the world take to Syngenta's rival GM technology using Bt Vip gene?

It is really hard to say. I am not an expert on product success in the market place. It will certainly throw a challenge to crystal toxin gene technology. It has a different mode of action, broad pest-range, and is believed to be better fit into the IPM (Integrated Pest Management) program of cotton. I think new and new competition is good for the development of technology. The more, the merrier!Â

In India and other developing countries, will the plans of companies like Monsanto to introduce GM based food crops queer the pitch for this technology?

I am not aware that agri-business companies like Monsanto are trying to get into GM-based food products' business. I doubt it. GM food crops are GM food raw materials anyway. I think the regulatory authorities will definitely ask for food safety data when GM food crops come for commercialization authorization. I don't see why it should raise any new concern that has not been already addressed before elsewhere. I think there will be some hackles raised from the same quarters that have been raising biosafety and environmental questions.

Is it better for companies to stick to GM products in non-food crops and work towards gaining greater acceptance to the technology as a long-term strategy?

I think that is a wishful thinking. Diehard opponents don't distinguish between GM food and non-food GM crops. They are opposed to the GM technology per se, and they will still object. For reasons best known to the companies, they have become gun-shy and have decided not to carry out wide communication with the public to create awareness. Governments too have done precious little to educate and inform the public in the rural areas. Public acceptance of GMOs will be the key to technology transfer and how one goes about creating public awareness will decide the final outcome.Â

As you know, there is a great deal of public confusion about the performance of Bt cotton in India. What is your assessment of that situation?

Yes, I have been a keen observer of all the reports of the failures of Bt cotton from certain parts of Andhra Pradesh and Gujarat in the first year of commercialization. At the outset, I must say I have never visited any Bt cotton field anywhere in the country. All my information is from reading a variety of official and non-official reports, media reports, and anecdotal testimonies from individual farmers and scientists.Â

Most of the negative reports are not scientifically rigor de jure. They all make far-reaching conclusions that are not scientifically tenable, as they have not made any comprehensive assessment from all regions of the country where Bt cotton was cultivated. All I can say about these negative reports is that they all contain an element of truth but just an element. The reason why Bt cotton failed in certain districts of AP and Maharashtra was because of failure of rains combined with low pest infestation. There are official reports from the GEAC monitoring committee and the state government official reports on the Ministry of Environment and Forests official web site. Even though, they are all positive about the performance of Bt cotton, none of them are scientifically rigorous just like reports from the NGOs.Â

Incidentally, Monsanto just released an independently carried out survey of Bt cotton performance for 2003 cropping season by AC Nielson. It seems the report is lot more comprehensive and contains statistically significant sampling survey clearly demonstrating significant benefits in terms of yield, fiber quality, decreased pesticide use, and a premium price for Bt cotton in the market. If only the governmental authorities and NGOs had done a similar high-quality survey, their reports would have been lot more credible.Â

Let me add a caveat to all the reports. That is Monsanto' first three Bt cotton varieties were approved for only three years in the first instance. Going by public perception, there were some failures in some regions during 2002, and it seems to have done very well in 2003. We would have heard an earful if there were any failures by now. I think it is prudent to wait for the third and last year before pronouncing a final judgment on these varieties. Equally heartening to note that a dozen or so Bt lines of other seed companies have been approved for commercialization. My understanding is that these newly approved varieties are going to perform much better than the first set of Monsanto/Mahyco Bt varieties. The more the merrier! I think there is more in the offing, and I want to root for the triumph of this technology, and I am confident it will triumph as it has done elsewhere in the world.Â
As a risk assessment specialist, I want the regulatory authorities to start thinking about the deployment of the same CryA1c gene in all crop plants that would result in genetic homogeneity of a single dominant gene and has a proclivity to genetic vulnerability. This is a well-known dictum in genetics. An ecological impact analysis is called for and GEAC must commission expert ecologists, environmental scientists and population geneticists to address these issues for the long haul.

Â

Â