

## GM regulatory process, a multilateral experience

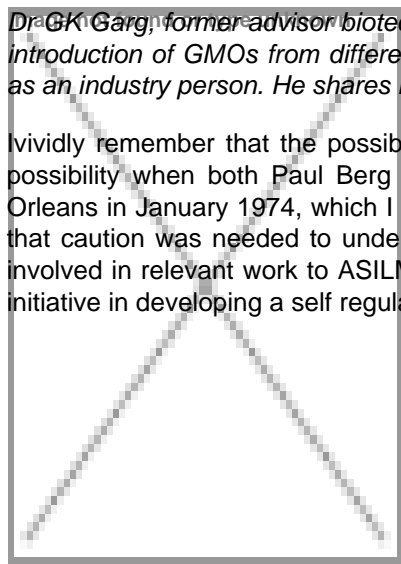
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### GM regulatory process, a multilateral experience

*Dr GK Garg, former advisor biotechnology, GB Pant University and now director (R&D) with Krishidhan Seeds Ltd, has seen introduction of GMOs from different positions-as part of regulatory system, as a biotechnologist in the university system and as an industry person. He shares his integrated perception on the past, present and future of the regulatory process.*

I vividly remember that the possibility of introducing foreign gene or through invitro manipulation of DNA became a distinct possibility when both Paul Berg and Stanley Cohen presented their work in a workshop on plasmids organized in New Orleans in January 1974, which I attended with Dr IC Gunsalus, my mentor at University of Illinois. Scientists themselves felt that caution was needed to undertake these studies. This concern found expression in invitation to all scientists who were involved in relevant work to ASILMORE conference in 1975. Indian scientists led by Late Dr NK Notani from BARC took the initiative in developing a self regulatory process for recombinant DNA technology work in India.



These scientific concerns in both the countries led to placement of well debated and discussed regulatory provisions in place. The process was accelerated with the establishment of a separate Department of Biotechnology (DBT) under the Ministry of Science in 1986. The first guidelines were made available in 1989, which led to proper legislation and establishment of formal regulatory system at all levels. Care was taken that all perceived risk, no matter, how improbable they seemed, were tackled. Procedures for various experiments for development of products as well as waste disposal were defined to ensure release of GMOs only after ensuring that there will be no threat to environment. There were always debates to counterweigh the possible benefits to health, agriculture and environment and perceived threats to the same.

As soon as transgenics became a reality in the US, intense debates preceded on acquisition of Bt cotton technology from Monsanto. Curiously, the public sector money was used to fund an interinstitutional team to develop an indigenous Bt technology in cotton, which was felt necessary due to the spurt of suicides by AP farmers attributed to the failure of their cotton crops. At the same time, the import of Monsanto technology was also permitted, under the Mahyco-Monsanto tie-up. This being the first test case, it was indeed an experience to participate in monitoring of multilocation and large-scale trial. I vividly remember the extra cautious approach of members of our monitoring and the evaluation team, exasperation of MMB people, calm, composed perseverance of young Raju Barwale and more than this the mixed expression of curiosity and hope on the faces of farmers.

The first permission for commercial release took almost seven years from the date import of gene was permitted. The introduction of Bt technology changed the whole cotton scenario. Three companies, which had dynamic leadership, immediately recognized the potential of this technology and swiftly tied up with MMB to introduce Bt genes with their own elite hybrids. Krishidhan Seeds Ltd introduced the concept of integrated R&D, production, marketing and extension, which facilitated the farmers to adopt new technologies confidently.

I am thrilled that there is a renewed interest and enthusiasm in the farmers. This reflects the success of the technology. The entry of more than one gene from India-Dr Rakesh Tuli (NBRI) and Dr Sen (IIT)-as well as those from abroad in a large number of released hybrids and those in the pipeline has ensured the necessary diversity in genes and genetic base very often emphasized by eminent scientists like Dr MS Swaminathan.

It is interesting to note that in this backdrop of success, we do hear clamor raising doubt on the real benefits of the technology and which are difficult to comprehend on sound scientific terms. I have felt amazed by emotions of some of the environmentalists to oppose a technology that uses only natural scientific process albeit with human intervention. For example, agrobacterium has been transferring genes across the species much before the scientists have even learned about its basic principles. Debates get emotionally charged without realizing that alternatives like biocontrol agents, botanical pesticides have limitations in efficacy and magnitude and Bt technology gives protection against excessive pesticide usage, which is known to have deleterious effect on human health and environment.

During monitoring visits, it was not uncommon to hear the use of up to 30 sprays on crops causing health problems to the person who sprayed. Misplaced environmental concerns have led to excessive pressure on regulatory process. While on one hand, one would like to reach this technology to each of the micro niches of agri-eco zone which will require conversion of multiple genotypes, on the other even for de-notified multi-location and SAU (State Agricultural Universities) testing is required which puts enormous pressure on this system.

The confederation of the Indian textile industry has projected requirement of 45 million bales by 2012 out of which at least 20 million bales will have to be ELS cotton. To meet these targets and so also not to compromise on food security, tremendous R&D efforts will be needed to enhance productivity and quality of all food and cash crops including vegetables and cotton.

During my visit to Mexico and the US, it was interesting to learn that countries like the US have not compromised with bio-safety issues but have kept their regulatory systems dynamic. Once convinced that a technology is safe, they have not hesitated to deregulate it. There is a tremendous amount of transparency and interaction with the industry which permits thorough examination of issues across the table. The environment becomes very friendly for sectoral growth and wealth generation, which is much needed in the agriculture sector if the benefit of economic growth has to reach rural areas.

It is heartening that India too has kept its system dynamic. Bt technology has been already partially deregulated. I feel the time has come for the government to concentrate only on bio-safety issues and not to get unduly concerned with the product suitability and quality, which the market can take care of. Our industry and farmers have become discriminating and quality conscious. Therefore, no substandard product can survive in the market. Farmers now do demand accountability and compensation from the industry if product fails to meet the claims. Setting of guidelines and random monitoring of compliance will be more effective than an elaborate process of involvement of third party in regulatory clearance. A hassle-free procedure is the best way to meet the requirement of growth and quality. I have every confidence that in face of the fact that GMOs so

far have proven harmless we are only couple of years away from liberalization and reforms in regulatory processes to accelerate the envisaged growth of agriculture sector.