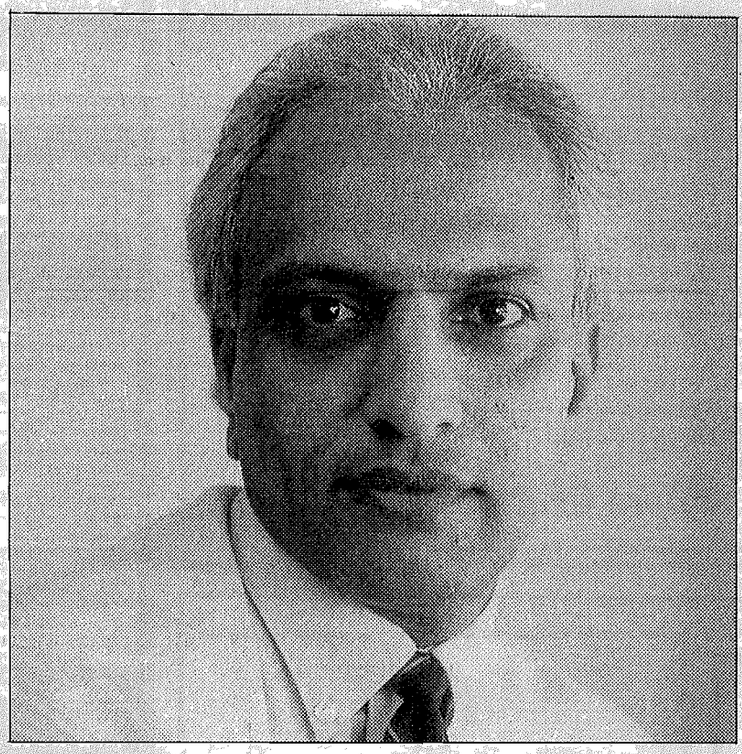
BIOTECHNOLOGY / An evaluation of the environmental impact of biotechnology products is essential before it is launched.

Need for regulation



THE rapid growth in the field of biotechnology has opened up new frontiers of knowledge for the scientists. At the same time, it has also underlined the need for an effective regulatory mechanism that can undertake a careful environmental and bio-safety evaluation of the peoducts of biotechnology research. While such a regulatory framework and the rules governing it are well developed in the advanced countries, they are yet to be developed in the third world countries — which has, perhaps, a more urgent need for it.

In the last five years India has given license to 200 odd companies working in various fields of biotechonology research and application. What would be the consequences if the research products of these companies are released into nature without a proper evaluation of its impact? Is there any regulatory body with a clearly defined set of rules to evaluate the impact of the products that are thus launched.

"The consequences could be dissastrous for a country like India" says Dr Sivaramiah Shantharam, Chief, Micro-organisms Branch, United States Department of Agriculture, Biotechnology Regulatory Programme.

According to Dr Shantharam, who is now in India on a Fullbright fellowship to help the Government of India to set up a bio-safety and environmental safety review system confirming to international standards, the regulatory mechanisms are also "conspicous by its absence".

According to Dr Shantaram, who is involved in the international harmonisation of biotechnology regulations particularly in the third world countries, such a bio-safety system becomes a necessary precondition for those countries that have initiated a biotechnology research programme primarily because the products released are being launched in an environment that is rich in bio-diversity. Therefore a careful eavaluation of its effect on such sensitive environs becomes necesary.

Secondly, an evaluation by a government body becomes all the more necessary since many crucial areas of biotechnology research is being carried out by private business houses.

"Private companies have even entered the field of genome mapping. Some companies are trying to do rice genome mapping" says Dr Shantaram "though the main project of genome mapping is state funded in US".

The possibilities, therefore, are both fascinating and at the same time frightening. Does it mean that the private business interest can control the direction of research and also the ultimate product, even in such an essential commodity like rice?

"Yes" agrees Dr Shantaram "there is such a threat". "But if you look carefully at the growth of biotechnology science the private business has always been dominant. Right now the multinationals are busy selling the technology to develop new products than the products themselves".

In most of the cases, alongwith the basic technology the buyer would have to buy many other associated products or process. In certain cases the seller of the technology will gain even from the sale of the final product by the buyer. Examples according to Dr.Shantaram are the particle bombardment gun developed by Dupont which one can achieve genetic transformation in plants, animal cells, bacteria and fungi or the polymerised chain reaction technique sold by Perkin-Elmer.

As the chief of the micro-organism branch and as a person who has been in the business of environmental evaluation of the bio-technology products in United States for several years, what is your experience in US.

"After several years of close monitoring, we are slowly relaxing the controls now in US"said Mr Shantaram. "Of course the industry is very happy about our decision".

If they are being relaxed in US why should the rules be tightened and bio-safety be regarded as such a major issue in countries like India?

This is because the possibility of gene escape through pollen is a problem of different dimension in country like India with rich bio-diversity, says Dr Shantaram. The danger will not be felt immediately but will ultimately lead to the danger of genetic uniformity.

In other words, countries like India need effective regulatory bodies tp prevent any negative fallout of bio-technology research. "All the international funding agencies are also insisting on such bio-safety control mechanism" said Dr Shantaram. Of course India has some guidelines. But guidelines are guidelines. They are not mandatory"he said.

Bio-safety and environmental safety review system are also necessary because the biotechnology research is poised for a big growth in the present decade.

"Internationally there is a marked shift towards a lot of agronomically relevant research which is multigenic. For example, in instances like the development of a drought and salinity resistent plants, nobody knows for sure how many genes are involved. But this is an area of research that is relevant to the third world also.

"Experiments are also going on to produce a variety of health products like vaccines, drugs, animal health products etc in plants. The advantages are that the extraction is easy, we can grow them in large quantities and finally plants are easier to handle." says Dr Shantaram. But the most important project according to him is the "genome mapping" project.

Human genome mapping can lead to great strides in medical biotechnology, in the detection and control of deseases etc, he said. Such ambitious research projects also points to the need for the setting up of a bio-safety and environmental safety committee.

Despite relaxation of control, in US all such research have to be assessed under the National Environmental Policy Act, he informed. "In India also the need to develop an effective evaluation procedure has been recognised and India is at present developing a bio-safety committee".

In other words, the possibility of a beetle, introduced to fight some other pest, becoming a major threat to environment and even human life, would be reduced to a great extent in the country. Or hopefully, a rose will remain as a rose, and will not end up as a uniform genetic strain.

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