Bring rational regulatory regime for rDNA biotech products

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The modern biotech industry represents the accrual of economic benefits by the application of recombinant DNA (rDNA) technology to produce genetically modified organisms (GMOs) and products thereof which have diverse applications in healthcare, agriculture, industrial products and management of environmental stresses. Indian experience in deriving these benefits has so far been limited to production of a few therapeutic proteins and one recombinant vaccine.

The turnover from such products produced locally in 2006 is estimated to be close to Rs 600 crore, along with large quantities of imports that could be minimised. In agriculture, different plant cultivators of cotton have been used to reduce the use of chemical insecticides and to improve the environment. In 2006, nearly 10 million packets of Bt cotton seeds valued at over Rs 750 crore were used and about 9.5 million acres of land were cultivated with these seeds.

In other areas the benefits from rDNA products have been through the use of diverse industrial enzymes to improve the quality of detergents and washing powders and to increase the production of cheese from milk. The basic technologies developed locally for the production of rDNA substances have, however, been instrumental to the cost effective production of several therapeutically active substances which have benefited millions of Indians, including children in combating life threatening diseases and conditions like protection from Hepatitis B by vaccination and treatment of diabetes, cancer, several viral diseases like Hepatitis B and C as also diabetic foot ulcers.

In agriculture, the basic technology of lepidopteron insect resistance was imported from multiple sources (USA &China). This has been well adopted for introducing the traits of insect resistance in Indian cotton cultivators and the technology has significantly contributed to increased production of quality cotton at lower costs. In other areas, the technologies had not been local but the genetically modified products were imported and used.

All the genetically modified products were introduced in India under the provisions of Environment (Protection) Act, 1986 and Rules thereunder. The Mashalker Committee's recommendations have been accepted to bring in more liberalisation. The moot point in these legal provisions was to ensure the safety of GMOs and products thereof. There was inadequate scientific understanding, however, about GMO products and therefore several unwanted animal toxicity data were required to be generated which did not have adequate scientific basis.

The learning process has been too long and this has hampered the fast introduction of GMO products for treating different ailments. It is high time that rules are modified to exclude all genetically modified products that are not alive and where the genetic traits have no leftover detectable traces of rDNAs or recombinant proteins. In addition, GMOs that belong to GRAS categories and are living need to be notified to be out of control from the provisions of the rules so that the cloning process progresses faster. This would enable the introduction of several recombinant products in different arena of industrial applications, including healthcare area. This would enable use of several microbes, edible yeast and certain safe mammalian cell lines from attracting the provisions of EPA and would ease molecular biology research for applications.

There are also bumps in the Indian Drugs Act and specially the revised Schedule Y. It is not often clear how the protocols for human clinical trials are to be devised. Nor are the end points adequately defined. The entrepreneurs have to make their judgement and, therefore, there are case to case variations in setting up an approved protocol and collecting data. There is an urgent need to standardised protocols and there should be notifications that elaborate the scientific basis of the elements to be taken into consideration for testing individual products.

In the provisions of Intellectual Property Rights several factors such as non-protection of clinical data for drug substances, inadequate protection of plant varieties and genetically modified seeds are other areas that are not accelerating the speed of trans-boundary movement of modern biotechnology in India. While India can live with this situation for a while, there is enormous need to strengthen and speed up directed research in public funded institutions, at least for world-class knowledge development. The speed of progress in public funded institutions can certainly be accelerated and more money may be allocated for research.

Several institutions have been created that teach biotechnology. However, the quality of training imparted to students need to be upgraded. There is a need to incorporate business skills in every curriculum of biotechnology education at the post-graduate level so that students become competent of understanding and expectedly be able to write business plans. Such courses will not only benefit India but will also enrich the human kind.

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