

## Regulatory regime for GM products in India

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The first green revolution saved us from the precarious situation of 'ship to mouth existence'. We attained self sufficiency in foodgrain production. The situation, however, is changing dramatically. From 170 million hectares of arable land, the availability may well be around 100 million ha by 2020 in view of the need for the increasing population as well as for greater afforestation and environmental preservation activities. The number of farmers available for agriculture will also reduce to less than 50 percent.

Thus, in the backdrop of a declining per capita availability of arable land due to ever rising population, very low productivity levels, heavy losses due to biotic (pests, pathogens and weeds) and abiotic (drought and salinity) stresses, high storage and transportation losses, and large scale nutrient deficiencies in undernourished children and expectant mothers, we have to look around for measures to increase productivity in agricultural sector through research and newer production technologies. We have to produce more from less. Therefore, we, as a nation, must adopt appropriate technologies in Indian agriculture. And, in the matter of selection of appropriate technologies, we must go in for the technologies that enable us to achieve what we want without in any way harming the environment, the health of human beings and animals.

It is in this context that agricultural biotechnology becomes very relevant. It is an important weapon for crop yield

improvement, reduction in chemicals and pesticides usage, improving food and storage quality, in providing effective resistance to pests and pathogens, and has the potential for tolerance to drought and saline conditions. In effect, it is the panacea for the various adverse agricultural conditions present in India.

There are, however, certain risks associated with this technology, as with any new technology. These risks, when handled in a cautious and scientific manner, can be either eliminated or minimized to levels that are not harmful. Hence the need for a regulatory regime.

It is a tribute to the sagacity and wisdom of the government and its scientists that, much before the first testing for the GM products could be thought of, they put in position a regulatory mechanism by promulgating a set of rules governing hazardous Microorganisms/Genetically Engineered Organisms or Cells in 1989 (Rules 1989) under the EPA. In 1990, the Department of Biotechnology (DBT) came out with a set of guidelines as required under the Rules 1989. These were revised in 1994 and 1998. The 1998 guidelines on transgenic crops, provides a set of toxicity and allergenicity parameters for evaluation of safety of the transgenic seeds, vegetables, leaves etc for the health of human beings and animals. Some toxicity protocols were also added, which include, feeding studies on lactating cows, fish and chicken. The protocols provided in the guidelines, would comprehensively indicate whether the transgenic product have any toxic potential for human and animal health. The 1998 guidelines also added genetic data on comparative economic advantage of a modified plant. It thus made the regulatory framework not only environmentally safe but economically viable also.

These guidelines are based on current scientific information and on experience gained in different countries across the world.

The stringent regulatory systems put in place are science based and transparent. The guidelines cover all eventualities and the entire spectrum of activities including deliberate and unintended/accidental release into the environment of organisms, plants, animals and products derived from rDNA techniques. There are strict protocols for risk assessment and risk management in the event of a crisis. The two main principles involved in ensuring environment safety, 'the polluter must pay' and 'precautionary principle', are embedded in these guidelines and protocols.

As a measure of abundant caution, even though a crop is commercially approved in another country, it must go through the rigorous trials and testing in India as per the established protocols before it is introduced into the environment.

The impact of GMOs on the environment, soil, plant, animal and human life, have all been studied and will be studied in future in case of other events as per the existing protocols, before approving the introduction of a particular event into the environment.

The systems developed indigenously have worked successfully till date, and have not been faulted so far by any credible scientific community. This is certainly a matter of utmost satisfaction for the Indian scientific community.

The apex regulators for transgenics, GEAC and DBT, have also evolved with the rich experience that they have gained over the years. They are now more mature and confident of the subject matter, despite its uncertainties. Before any decision is taken, a rigorous cost-benefit analysis is always done to ensure that the decisions are in the overall interests of the Indian farmers, without harming the ecology and the health of human beings and animals.

Various international agencies have also come out in favour of GM food/crop. OECD has said that the risks associated with biotechnology derived foods are not inherently different from the risks associated with conventional ones. WHO has echoed a similar sentiment by saying that it is not aware of scientifically documented cases in which the consumption of these foods has had negative human health effects. ENTRANSFOOD, a network of international experts, the Royal Society of London, and many other prestigious organizations have also made similar statements.

The implementation of the regulations involves a number of players. These include the seed companies, the farmers on whose fields the trials are conducted, the Institutional Biosafety and the Monitoring and Evaluation Committees. The seed companies are rigorously implementing the protocols prescribed by the regulators, and have also built up in-house capabilities to tackle any emergency. Till date, there has not been any let up in their responsible use of the technology.

Despite what the critics and activists have to say about the acceptance of this technology, the rigorous scientific protocols and studies conducted in India have amply demonstrated that GM products are safe for the environment, human beings and animals. The farmers have also given a thumbs-up to it, by itself enough to discredit the activists and critics.

It is thus evident that the concerns that have been raised about potential risks to both food and environment safety in the case of transgenic crops using recombinant DNA techniques have not found favor with the other stakeholders, particularly the

farmers, mainly due to the robust regulatory regime in place.