Need for management and risk assessment of genetically modified organisms

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The world agricultural production will need to increase by almost 50% by the year 2050 in view of the increasing population. The US Census Bureau has reported that the world population has doubled in 40 years (1959–99) from 3 to 6 billion, and is expected to hit 9 billion by 2045. The present world population of 7 billion poses problems for providing adequate food for all. The traditional methods of agriculture and crops will hardly be able to sustain the required levels of production[1]. Declining crop yield, rising population, erratic climate and rapid urbanization contribute to declining food availability. Biotechnology offers a plausible solution in the long run. However, it needs to be mined further for its large-scale potential, at the same time having to set priorities to build and manage risk assessment systems to ensure safety of crops and people.

Genetically modified crops or organisms (GMOs) are produced by the now well-known branch of molecular biology, the recombinant DNA technology or genetic engineering. The share of GM crops in world agriculture is increasing steadily. From 1996 to 2009, the cultivation of GM crops has seen an 80-fold increase. USA has 64 m ha of land under the cultivation of GM crops, which is the largest in the world. India's share currently is only 8.4 m ha, whereas Brazil and Argentina have 21.4 and 21.3 m ha respectively (Table 1)[2].

In India, 65% of the agricultural land is still dependent on monsoon. There is need for more investment in biotechnology-driven solutions to increase yields.

Table 1. Area under cultivation of genetically modified crops in the world

Country	Area (m ha)
USA	64.0
Brazil	21.4
Argentina	21.3
India	8.4
Canada	8.2
China	5.7
Paraguay	2.2
South Africa	2.1

Source: see ref. 2.

Therefore, it is consequential that the risks of genetic modification are better understood and safety measures, management systems and assessment tools are developed. The risk factors that need to be addressed are as follows.

(a) Short- and long-term interaction between the transgenics and the environment.

(b) Development of allergens to human/animal health, including changes in phenotypes and altered immunity.

(c) Effect on soil and water.

(d) Loss of genetic biodiversity and gene flow to wild relatives or to non-transgenic varieties.

(e) Reduction in the efficacy of pesticides, insecticides and weedicides, and production of novel toxins and development of resistance or tolerance.

(f) Production of new pathogens/bacteria/viruses.

(g) Cumulative and synergistic effects.

Specific studies on some of the above aspects such as detrimental effect of transgenics on non-target organism[3]; gene flow to wild relatives of a crop, especially on the neighbouring ecosystem and general environment[4–6]; development of resistance or tolerance[7–10]; and production of toxins[11] have been conducted. But there are hardly any reports with particular focus on India and other developing countries, although many GMOs and living modified organisms (LMOs) are being adopted for cultivation/introduction.

In addition, a contentious debate has been brewing in India among the scientists and environmentalists over the risks of the introduction of GM crops, their advantages and their impact on the environment, especially since the proposal for the introduction of GM brinjal (aubergine) was made. GM brinjal expressing the β-endotoxin (*Cry1Ac* gene) from soil bacteria, *Bacillus thuringeneisis* (*Bt*) imparting resistance against insects like brinjal shoot and fruit borer, was proposed to be introduced on a large scale. An Indian biotechnology company (MAHYCO) in collaboration with Monsanto developed the homegrown *Bt* brinjal. All was set for its introduction after Government of India Genetic Engineering Approval Committee (GEAC – the regulatory body for the testing and introduction for GMOs in India) and two other committees approved its large-scale introduction in October 2008 on the basis of trials conducted by MAHYCO. While one group of scientists was in favour of its introduction, an equally strong group led by environmentalists and many prominent scientists expressed deep apprehensions. These scientists have raised about 600 points to be addressed. More recently, some scientists have advocated a 15-year moratorium on such introductions, as they are urging more comprehensive trials before any transgenic variety is approved for commercial introduction. The Indian government postponed the introduction of *Bt* brinjal and put it under an indefinite moratorium.

Risk management actually refers to the identification, quantification and characterization of the level of exposure, and potential hazards and harm to human health and environment as a result of the introduction of GMOs/LMOs right from the cloning and expression of the required genes. This has raised several points, such as the need for the establishment of risk management systems, and a responsible and effective regulatory body that would oversee the introduction and distribution of such crops. The proposal for setting up a National Biotechnology Regulatory Authority under DBT is pending in parliament.

Although *Bt* cotton is considered a success story, there are conflicting reports of its performance under Indian conditions. In 2004, about 4.8 m ha of land was under hybrid and *Bt* cotton cultivation[12]. Even in the case of *Bt* cotton, farmers have lost a lot of money owing to untested and unauthenticated spurious seeds supplied to them at very high rates in Punjab[13], according to media reports. For sustainable development, it is critical that recognized testing laboratories be established in each crop-growing area for technically validating data for risk

assessment and management, especially in the context of a plethora of GM crops (such as brinjal, soybeans, potatoes) that are proposed to be introduced in India.

Pollution levels in certain parts of India are higher than international standards, so India could possibly be at a greater risk. In order to realize the full potential benefits of transgenic research and to solve the problems of agriculture and environment, more baseline data need to be obtained and regulatory bodies put in place. In fact, the Prime Minister's Economic Advisory Council has already advocated for clear policies for GM crops. The following aspects need to be considered:

(a) An objective review of existing guidelines (e.g. by DBT) and their stringency and developing new (if necessary) biosafety guidelines for the better protection of national heritage and population as in the Philippines and China.

(b) Development of human resource in the area. The already existing/proposed regulatory bodies (such as the proposed National Biotechnology Regulatory Authority) could include experts on biotechnology as well as in the areas of biosafety, bioethics, bioinformatics, environment, ecology and forestry.

(c) Scientific validation or otherwise of the reported hazards of transgenics with special reference to risk assessment and management.

(d) To create public awareness about the transgenics in order to protect their right for information so that people are able to cope with any hazards, if any, in time.

(e) Integration of the relevant articles of the Cartagena Biosafety Protocol (2003) adopted by CBD and the existing guidelines in the Indian context.

(f) Economic pros and cons of transgenic research, and GMOs and LMOs. At present, the economic returns are not commensurate with the huge financial inputs.

While countries like USA, UK and those in Europe, and some neighbouring countries like China and the Philippines have strong regulatory mechanisms in place, India is yet to develop a country-specific, more stringent and transparent regulatory regime. This regime should consist of facilities for state-of-the-art research on transgenics and their unbiased testing.

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