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Transgenic Crops and Biosafety Issues Related to their Commercialization in India

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Improvement of agricultural production and productivity as well as the future versatility of agricultural production are dependent on the rational utilisation of technologies. We stand at the convergence of an incredible array of new technologies, such as recombinant DNA technology, information technology and high throughput genomics, to enhance our understanding of the structure and function of the genomes and to apply this information for plant and animal improvement. Products arising from modern biotechnology such as genetically modified (GM) or transgenic crops are providing new opportunities to achieve sustainable productivity gains in agriculture.

The transgenic crops were grown worldwide in about 68 million hectares in 2003. The engineered traits include insect pest resistance, herbicide tolerance and virus resistance. The first, and as yet the only, GM crop permitted for commercial cultivation in India is the 'Btcotton', conferring resistance to a lepidopteran insect pest, the bollworm. Transgenic crop acreage in India is currently about 100,000 hectares. Following its commercial introduction in 2002, the Bt-cotton has found overwhelming support from farmers to the extent that almost all the domestic and multinational seed companies in the country are transferring the Bt transgene (and its variants) into their agronomically superior hybrids. In addition, transgenic research and development in a number of other crop plants for various agronomic and quality traits is being pursued by several public sector institutions, in India.

The commercialisation of transgenic crops has sparked off intensive debates worldwide regarding biosafety and the impact of this powerful technology on agriculture, human health and environment. The biosafety concerns of transgenics owe their origin to the fact that tools of recombinant DNA technology have clubbed all biological systems into a 'single gene pool' providing access to even genes from completely unrelated or sexually incompatible organisms. Therefore, the transgenic technology, while providing unlimited scope for crop improvement, also imposes tremendous responsibility on the scientific community and the regulatory authorities towards ensuring biosafety.

A number of biosafety issues of transgenic crops are being debated with highly polarised views. It is imperative that rational sciencebased decisions are taken to resolve the contentious issues and evolve clear-cut national policies so that the benefits of this technology are effectively harnessed for achieving sustainable growth in agriculture without unacceptable risks either to human health and/or the environment.

The National Academy of Agricultural Sciences (NAAS), in collaboration with the XV International Genetics Congress Trust, initiated a national debate for addressing the issues related to research, biosafety testing and commercialisation of transgenic crops.[*]

[*] *Views of a large number of stakeholders were obtained electronically, and these views aided in the preparation of a 'base paper' for discussion. A brainstorming session was organised under the Convenership of Dr. R.P. Sharma, at NAAS, New Delhi, on December 1, 2004, on 'Transgenic Crops and Biosafety Issues Related to their Commercialisation in India'. The Session was attended by representatives from various public and private sector institutions, besides policy makers.*

The following issues were critically discussed during the Session:

- Relevance of transgenic crops in Indian agriculture.
- Need for prioritisation of crops/traits for transgenic research and development.
- Policy related to use of selectable markers in transgenic research.
- Policy related to biosafety testing for transgenes and transgenic events.
- Meeting the institutional requirements for biosafety testing.
- Approaches to analyse the impact of environmental concerns related to transgenic crops.
- Pre- and post-release evaluation and monitoring of transgenic crops.
- Public-private partnership in transgenic research and development.
- Managing intellectual property rights (IPR) issues related to transgenics.
- Roadmap for effectively bringing the transgenic technology from laboratory to the farmers' fields.

Recommendations

The major recommendations that emerged are given below:

- India should promote genomics and transgenic research and development keeping in view the short-term and long-term requirements of the nation, besides maintaining the global competitiveness in agriculture. The vast plant, animal and microbial biodiversity should be mined for genes of importance to sustain advances in crop and animal productivity. The transgenic approach must be judiciously integrated into the crop breeding programmes based on specific needs, particularly in cases where conventional breeding is not feasible or effective.

- For effective utilisation of the technological, financial and human resources in the public sector, it may be useful to identify priorities for transgenic research and development based on objective criteria. Besides technology development for public good, the public sector institutions must play a vital role with regard to knowledge generation so as to fill the critical gaps in relation to transgenic development. Technology generation and capitalising on the available technologies should go hand-in-hand.

- In terms of the area under transgenic crops worldwide, herbicide tolerance as a trait, ranks first. Although, herbicide tolerant transgenics offer specific advantages, in the Indian context it is not, at present, a priority trait, since, it is preferable to adopt technologies that are labour-diversifying rather than those that could be labour-displacing. Also, while setting priorities for transgenic research and development, it is important to consider the social dimensions, including employment impact, besides environmental impact.

- The coming years will witness the use of food and non-food transgenic plants as vehicles for mass production of novel vaccines, antibodies and other therapeutic proteins. During production and commercialisation of the pharma-transgenic crops it should be ensured that they do not contaminate the food chain. Appropriate guidelines should be formulated for production and handling of the pharma-transgenic crops. The developments in medical or pharmaceutical biotechnology utilising crop plants as vehicles should be monitored and the linkages with agriculture, analysed.

- Although, there is no scientific evidence of the adverse environmental effects of selectable markers (like antibiotic resistance genes) that are widely used during transgenic development, research efforts on developing and utilising 'clean gene' technologies or marker-free transgenics should be strengthened. Also, the information database regarding biosafety of the selectable markers should be upgraded to facilitate objective decisions by the regulatory authorities. Certain selectable markers like kanamycin and hygromycin resistance genes, that are proven to be safe, and other antibiotics that have outlived their clinical utility may be utilised till better alternatives are available.

- A transgene that has already undergone extensive biosafety tests should not be treated as new, even if it is a new transgenic event. Where adequate evidence is available that the recurrent parent genetic background of a notified/registered genotype is nearly restored (through field data and/or molecular data), only the agronomic performance and the level and stability of transgene expression may be analysed by two year trial data (one year of simultaneous large-scale Genetic Engineering Approval Committee (GEAC) and ICAR trial, and another year of ICAR trial). Even in case of a structurally altered transgene with no significant modifications in protein conformation, the toxicity and allerginicity tests need not be carried out, provided the predicted antigenic epitope remains the same and the level of expression of the transgene is within the defined limits.

- The toxicity and allerginicity tests for the transgenics should be prescribed on a case-by-case basis, based on the transgene, the crop and the economic product(s). Institutions with relevant expertise and facilities should be identified, upgraded, accredited and networked for enhancing the efficiency of biosafety evaluation of the transgenics. The scientific data coming from reputed national/international institutions must be duly considered for testing toxicity and allerginicty.

- The major environmental concerns arising from the possible release of transgenics should be evaluated on a case-by-case basis depending upon the gene, the crop, the trait and the target geographical location(s). The priorities and parameters of environmental impact assessment of the transgenics should be identified so that empirical data are generated on specific aspects (like gene flow and transgene invasiveness) through well-designed experiments proactively initiated by the scientific organisations. It is also important to strengthen the institutional mechanisms for analyses of the environmental/ecological effects of the transgenics.

- The Monitoring and Evaluation Committee (MEC) should be made more effective and relevant to the needs. The MEC may be a decentralised state-level committee

constituted by the Review Committee on Genetic Manipulation (RCGM), with the active involvement of SAUs. The committee must maintain rigorous standards across the country. Clear guidelines should be formulated regarding the parameters and methodology of monitoring and evaluation.

- A major bottleneck for the transgenic R&D in India, is the non-availability of suitable genes, promoters and vectors, besides efficient transformation methods (for some crops). The expertise available in the country for these important technological components must be strengthened and effectively utilised in a directed fashion. A 'National Repository' may be established to maintain relevant genes/promoters/vectors etc., and to facilitate access to the same through appropriate Material Transfer Agreement (MTAs)/MoUs for transgenic research and/or commercialisation.

- Researchers/institutions involved in transgenic R&D must consider the implications of the IPRs related to the transgenics, particularly in the context of commercialisation. It may be useful to establish a single window advisory service in India, for providing advice on IPRs pertaining to a transgenic project before its initiation.

- To effectively translate the potential transgenic events into commercially viable products, the following approaches may be considered:

    a. In the public sector institutions, transgenic development and deployment should be undertaken through a cohesive research programme in two phases. The funding agencies must ensure that the project is in a network mode with relevant expertise and intra- and inter-institutional linkages before approval. Funding for Phase I should cover all aspects related to technology development. After the review committee certifies the success of Phase I, funds for Phase II (testing and commercialisation) should be automatically released.

    b. Public sector may demonstrate a 'robust' transgenic line at the greenhouse level, and find an industry partner, wherever appropriate, for effectively taking it through commercialisation, including regulatory trials, value capture and sharing mechanisms.

    c. Public and private sector may join for developing a transgenic product concept and together seek resources for undertaking the project with a clean value-sharing arrangement.

- There is need for launching a genetic literacy movement in schools and colleges on the rapid developments taking place in the area of molecular genetics and genomics, so that there is a better understanding in the country of the opportunities and risks associated with recombinant DNA technology. This will help to promote the safe and responsible use of the tools associated with the new genetics in the country in the fields of food and agriculture, medicine, industry and the environment.