Import of transgenic planting material: National scenario

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Advances in plant biotechnology have overcome several barriers to crop improvement by making available the entire global gene pool for utilization. This technology offers immense benefits in terms of increased yield, better quality and resistance to biotic and abiotic factors. Rapid advances in development and commercialization of transgenic crops in recent years have also led to considerable apprehensions and concerns about the potential impacts of transgenic crops on the environment and consequently on human and animal health. Thus, there is need for a balanced and judicious approach towards this technology based on scientific data on regular and long-term basis.

INDIA is among the few developing countries which have instituted biosafety regulations and incorporated them in national laws as far back as in 1989. The Department of Biotechnology (DBT) is the nodal agency under the Ministry of Science and Technology, Government of India which deals with all aspects of transgenics research, while the Ministry of Environment and Forests deals with the commercial release of the transgenics. Under the Indian Council of Agricultural Research (ICAR), the National Bureau of Plant Genetic Resources (NBPGR) plays a pivotal role in the import and quarantine processing of transgenic planting material in the country. Till date, 28 imports of transgenic planting material comprising nine crops with an array of transgenes have been imported from different countries and routed through NBPGR for public and private sector agencies engaged in transgenic research. Time has come for a much greater public sector investment and involvement to ensure that biotechnology fully meets the growing agriculture needs. In addition, strong collaboration between public and private sectors and involvement of farmers/public in a participatory manner also needs to be facilitated for addressing many issues related to transgenics effectively.

Transgenic crops, represent a promising technology that can make a vital contribution to global food, feed and fibre security, and also make a contribution to the alleviation of poverty, particularly in the Third World. These crops can minimize crop damage through disease and pest-resistant varieties, reduce the use of chemicals and enhance stress tolerance in crops, thereby permitting economically productive farming on unproductive lands. This technology may also improve food processing and even provide diagnostic tools for detecting plant pathogens. In addition, crops like nutritionally-enriched Golden rice promise to offer improved nutrition for millions of people in the developing countries where rice is a staple food. By enabling production of customized crop products, this technology would hold immense economic potential for agriculture in the emerging market scenario.

The global area under transgenic crops has continued to grow during the last seven years, reaching 58.7 million hectares (m ha) in 2002 which represents a 35-fold increase from 1.7 m ha in 1996. India, the largest cotton-growing country in the world, with 8.7 m ha equivalent to 25% of the world cotton hectarage, entered the club of GMO countries in the year 2002, when it accorded approval for the environmental release of three transgenic *Bt*-cotton hybrids in India. With this, the total number of countries growing transgenic crops has increased to 16 in 2002 from six in 1996 (ref. 1). These figures show that transgenic crops represent the most rapidly adopted technology according to agricultural industry standards. The potential of this technology for enhancing crop productivity has been accepted worldwide. However, because of its revolutionary nature, there are also concerns about the risks and uncertainty associated with it, which too needs to be managed effectively and simultaneously.

Regulatory mechanism for testing of transgenics in India

With the awareness of possible adverse effects of transgenics on human health and environment, India has developed an efficient regulatory mechanism to monitor experiments in plant biotechnology as well as for biosafety assessment of transgenic plants. The rules for the manufacture, use, import, export and storage of hazardous microorganisms and genetically engineered organ-

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isms or cells were framed under the Environment Protection Act (EPA) of 1986, as far back as in 1989 (ref. 2). The biosafety guidelines to monitor all experiments involving genetically improved plants, both within the laboratory/greenhouse and outside were first prescribed in 1990 (ref. 3) by DBT and were further revised in 1994 (ref. 4) and then in 1998 (ref. 5), incorporating the allergenicity and toxicity evaluation of the transgenic material. All research and field trials have to be approved by the Review Committee on Genetic Manipulation (RCGM). These experiments are strictly monitored and reviewed by the Institutional Biosafety Committee (IBSC) in the respective institutions undertaking transgenics research[6]. All imports of transgenic planting materials and seeds are through a single window, i.e. the NBPGR. The following committees are involved in the regulatory procedures pertaining to transgenics.

The Recombinant DNA Advisory Committee (RDAC)

This committee is constituted by DBT, Ministry of Science and Technology, Government of India to review the developments in biotechnology at national and international level.

Institutional Biosafety Committee

This committee is constituted by the organizations involved in research with genetically modified organisms in consultation with DBT. The committee monitors research work on recombinant DNA technology in an institution and prepares on-site emergency plans.

Review Committee on Genetic Manipulation

This committee is constituted by DBT to monitor the safety aspects of ongoing research projects and activities involving genetically engineered organisms and to bring out guidelines on the biosafety aspects of transgenic plants. The Review Committee on Genetic Manipulation (RCGM) has a sub-committee:

Monitoring cum Evaluation Committee (MEC): In consultation with RCGM, MEC designs field experiments and formats for collection and collation of scientific information on plants grown in containment as well as in the limited field trials; undertakes field visits; suggests remedial measures to adjust the trial design, and sends its recommendations to RCGM.

Genetic Engineering Approval Committee (GEAC)

The GEAC, which functions under the Ministry of Environment and Forests, is a statutory body set up for approving large-scale (research or commercial) use of genetically engineered organisms following the rules enacted in 1989 under the EPA of 1986.

State Biotechnology Coordination Committee (SBCC)

The SBCC is headed by the chief secretary of the respective state. This committee has the powers to inspect, investigate and take punitive actions in case of violations of the statutory provisions.

District Level Committee (DLC)

This committee is constituted at the district level and is headed by the district collector to monitor the safety regulations in installations engaged in the use of GMOs in research and application.

Role of NBPGR

NBPGR is the nodal agency for issuing import permit to public and private sector agencies for import of seeds for research purposes and for undertaking the quarantine processing of imported transgenic planting material. It has been authorized for the same vide Govt. of India Notification No. GSR 1067 (E) dated 5 December 1989 from the Ministry of Environment and Forests. NBPGR issues an import permit only after the import clearance is accorded by RCGM. Two documents, i.e. an import permit as well as a phytosanitary certificate from the country of origin must be present with every seed/plant consignment imported from abroad. The Director, NBPGR has been authorized to issue import permit and receive imported material from custom authorities for its quarantine processing. This is followed by allocation of exotic collection number or a national identity number to each accession of the imported transgenic material.

Status of transgenic planting material imported so far

In India, the first commercial transgenic crop (*Bt*-cotton) was grown during 2002; however transgenic planting material for research purposes was imported earlier. RCGM approved the import of 100 g seeds of transgenic cotton from Monsanto, USA to Mahyco in 1995, and the seed was imported, cleared by quarantine and planted in the greenhouse at Mahyco during January 1996 (ref. 7). Since 1997, transgenic lines are being imported on a regular basis through NBPGR. Till date, nine transgenic crops, namely *Brassica oleracea*, *B. juncea*, *B. napus*, *Oryza sativa*, *Gossypium hirsutum*, *Zea mays*, *Cicer arietinum*, *Glycine max* and *Nicotiana tabacum* have

been imported in the country for research purposes from Belgium, Philippines, USA, Australia, UK, Scotland, Switzerland, China, Canada and South Africa. Out of the 28 imports till date, 75% has been by the private sector, whereas the public sector accounts for only 25% of the import. The public sector has mainly worked on three crops, namely *O. sativa*, *Cicer arietinum* and *N. tabacum* and the material has been imported from Philippines, USA, Switzerland, Australia, Scotland and Canada. The private sector has imported seven transgenic crops, namely *B. oleracea*, *B. juncea*, *B. napus*, *Z. mays*, *G. hirsutum*, *O. sativa* and *G. max* from Belgium, USA, Australia, UK, Philippines, South Africa and China (Table 1). Overall, it appears that the private sector is mainly working on crops where there is an opportunity for value capture, while the public sector is working on major food crops like rice and chickpea.

Transgenes imported in the country

Among the transgenes introduced, transgenic *Brassica* lines have been imported with *cry9C*, *osmads*, *bar*, *barnase* and *barstar* genes which impart resistance against lepidopteran insects, photoperiod insensitivity, resistance to gluphosinate ammonium herbicide, male sterility and restoration of male fertility, respectively. Till date, maximum number of transgenes has been introduced in case of rice. The transgenes imported in rice include *Ama1* gene from *Amaranthus* for improved nutrition, *cry1Ac* and *cry19C* genes for imparting resistance against lepidopteran insects, *cry1A*(*b*) for resistance to stem borer, *Xa21* for resistance to bacterial leaf blight, *PR* genes for resistance to sheath borer, *bar* gene, herbicide Basta-resistant gene and the genes for phytoene synthase, phytoene desaturase, and lycopene cyclase involved in the synthesis of β-carotene in the endosperm of Golden rice. In addition, *cp4epsps* gene (for tolerance to glyphosate herbicide) and *aad* gene (coding for 3″-(9)-*o*-aminoglycoside adenylyl transferase and conveying resistance to streptomycin and spectinomycin) have been introduced in soybean and cotton, *cryX* and *cry1A* genes (for resistance to lepidopteran insects) and *vip3* gene (for resistance to ballworm) in cotton; *cry1Ab*, *cp4epsps* and *pat* genes (synthetic *bar* gene coding for phosphinothricin

Table 1. List of transgenic planting material imported in India through NBPGR

Year of import	Name of crop/variety	Transgene	Source country	Indenter
1997	*Brassica oleracea* var. *capitata*	*cry 9C*	Belgium	M/S Proagro PGS Ltd, Gurgaon
1997	*Brassica juncea*	*barnase*	Belgium	M/S Proagro PGS Ltd, Gurgaon
1997	*Oryza sativa*	*Ama1*	Philippines	Prof. Asis Dutta, JNU, New Delhi
1998	*Glycine max*	*cp4epsps, aad*	USA	Monsanto Ltd, New Delhi
1998	*O. sativa*	Herbicide (Basta) resistance	USA	Dr Ramesh V. Sonti, CCMB, Hyderabad
1998	*Zea mays*	*cry1Ab*	USA	Mahyco Seeds, New Delhi
1998	*Gossypium* sp.	*cp4epsps, aad*	USA	Mahyco Seeds, New Delhi
1998	*G. max*	*cp4epsps, aad*	USA	Monsanto Ltd, Mumbai
1999	*G. max*	*cp4epsps, aad*	USA	Monsanto Ltd, Indore
1999	*Brassica napus*	*osmads 1, bar*	Belgium	M/S Proagro PGS Ltd, Gurgaon
1999	*Gossypium* sp.	*cryX*	USA	M/S Mahyco Ltd, Jalana
1999	*B. juncea*	*barnase, bar*	Belgium	M/S Proagro PGS Ltd, Gurgaon
1999	*O. sativa*	*cry1Ac*	UK	M/S Mahyco Ltd, Jalana
1999	*O. sativa*	*cryAb/cry19C, bar*	Belgium	M/S Proagro PGS Ltd, Gurgaon
2000	*Gossypium* sp.	*cryX*	USA	M/S Mahyco Ltd, Jalana
2000	*O. sativa*	*cry1Ab/cry19C, bar*	Belgium	M/S Hybrid Rice International, Gurgaon
2000	*B. juncea*	*barnase, barstar, bar*	Australia	M/S Proagro PGS Ltd, Gurgaon
2001	*O. sativa*	*cry1Ab, Xa21, PR*	Philippines	Directorate of Rice Research (ICAR), Hyderabad
2001	*Cicer arietinum*	*Bean alpha A1*	Scotland	ICRISAT, Andhra Pradesh
2001	*C. arietinum*	*Bean alpha A1*	Australia	Assam Agricultural University, Jorhat
2001	*B. juncea*	*bar, bastar*	Belgium	M/S Proagro PGS Ltd, Gurgaon
2001	*Gossypium hirsutum* var. *Cot 102*	*vip-3*	USA	M/S Syngenta India Ltd, Pune
2001	*Z. mays*	*cry1Ab, pat*	USA	M/S Syngenta India Ltd, Pune
2001	*O. sativa*	Phytoene synthase, Phytoene desaturase, Lycopyene cyclase	Switzerland	Directorate of Rice Research, Hyderabad
2002	*O. sativa*	*Xa21*	Philippines	M/S Mahyco Ltd, Jalana
2002	*O. sativa*	*cry1Ab, bar*	Belgium	Hybrid Rice International Ltd, New Delhi
2002	*G. hirsutum*	GFM *cry1A*	China	Nath Seeds Ltd, Aurangabad
2002	*Nicotiana tabacum*	*Aox*	Canada	University of Hyderabad
2003	*Z. mays*	*cp4epsps*	South Africa	Monsanto India Ltd, Mumbai

acetyl transferase and isolated from *Streptomyces viridochromogenes*) in maize, *Bean alpha A1* gene for imparting resistance against *Collasobruchus chinensis*, a serious pest of stored grains in chickpea and *Aox* gene for alternate oxidase in tobacco.

Yearwise import of transgenic crops in India

There was no clear-cut trend in the import of transgenic planting material during the last six years. As discussed earlier, transgenic planting material was imported by private sector companies namely Proagro PGS Ltd and Mahyco Ltd in the years 1994 and 1995, respectively. However, the material was routed through NBPGR since 1997. It is noteworthy in Figure 1 that there was a gradual increase in the import of transgenic planting material from 1997 to 1999, after which there was a sharp decline in the import during 2000. One of the reasons for decline in the import of transgenics during 2000 may be attributed to the publication of the findings of Losey *et al.* in 1999 (ref. 8) regarding the harmful effects of *Bt*-corn on Monarch butterfly. This publication was much publicized and had raised apprehensions about the use of transgenic crops. The contradictory findings by Beringer[9] and Wraight *et al.*[10] had rebuilt the interest of researchers in transgenic crops, which might have resulted in increase in the import of transgenics thereafter. Maximum import of transgenic crops so far has been reported during 2001.

Cropwise import of transgenic crops

Relative contribution of each crop in the import of transgenic planting material is depicted in Figure 2. So far, maximum import has been done in rice transgenic lines followed by *Brassica* sp. and cotton. The dominant trait in transgenic rice and cotton lines was insect resistance followed by herbicide tolerance, whereas in *Brassica* sp. three important transgenes imported were *bar*, *barnase* and *barstar*, while in all the transgenic soybean lines herbicide tolerance was the gene of interest.

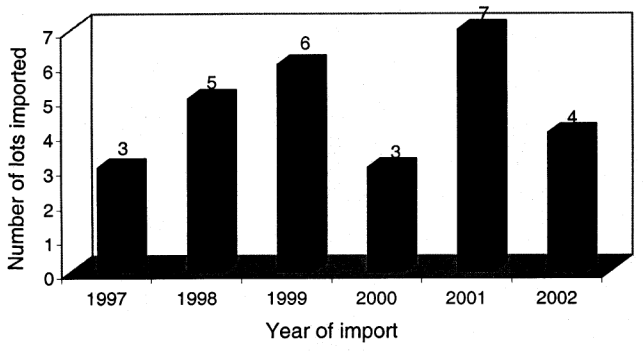

Figure 1. Yearwise import of transgenic crops since 1997.

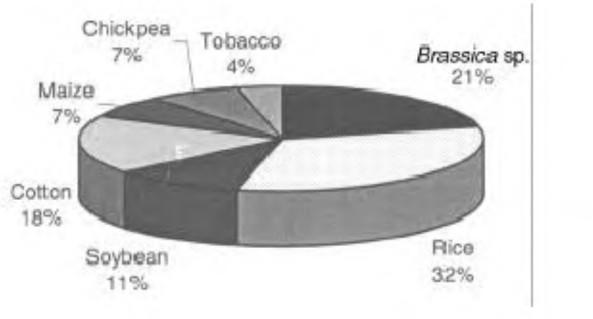

Figure 2. Cropwise import of transgenic crops in India.

With the Government of India approving commercial cultivation of *Bt*-cotton, it can now be expected that in the near future other transgenic crops will also be approved for commercialization, because it is clear that developing countries, including India need genetically modified crops to maintain sustainable agricultural production. India's foodgrain production will have to touch 490 million tonnes in another 20 years against the 200 million tonnes it produces today. Thus, India will have to replicate the green revolution which raised food production from 80 million tonnes to 200 million tonnes in 25 years, by switching to high yielding and hybrid seeds. But this time India will have to replicate the feat in a much shorter time span and with even less resources like water and land which are already under tremendous pressure from the rapidly growing population[11]. Transgenic technology has the potential to usher in a second green revolution, but with some apprehensions and concerns. On overall assessment it appears that the benefits of transgenic plants are substantial and they may outweigh risks which in many cases are presumptive and not real. Therefore, more transparency in regulatory mechanisms and biosafety and scientific expertise will be required to address the issues related to risks associated with transgenic crops in proper perspective. The regulatory approval of genetically engineered products has varied widely from country to country and from product to product. Harmonization or adoption of consistent review protocol is imperative and will lead to better overall assessment of safety and efficacy of new biotechnology-derived products. In addition, the pace of developments in research on transgenic crops has to be fastened, particularly in the public sector. Simultaneously, public awareness has to be generated regarding the perceived benefits/risks of transgenic crops. Further, there is need for greater collaboration as well as cooperation between public and private sectors to harness the benefits of transgenic crops.

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MEETINGS/SYMPOSIA/SEMINARS

Consultative Workshop on Scientific Strategies for Production of Non-edible Oil for Use as Biofuels

Date: 6–7 September 2003
Place: Bangalore

The scope of the workshop includes: Cultivation practices, Processing technologies, Technical issues, Policy options and alternatives and Creating a technical database.

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National Symposium on Astronomy in the New Millennium

Date: 10–12 October 2003
Place: Ahmedabad

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National Symposium on Molecular Modulation by oxidative stress and Cell Function

Date: 20–22 November 2003
Place: Chandigarh

Topics include: Gene expression and repression in oxidative stress, Oxidative stress and heat shock protein expression, Redox regulation pathways, ROS production and signal transduction, Oxidative stress as a mediator of apoptosis, Nutritional status, ROS production and immunity, Antioxidant enzyme systems.

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International Conference on Number Theory for Secure Communications

Date: 20–21 December 2003
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Topics include: Number theory applications, Cryptoanalysis, Signature authentication/digital watermarking, Steganography, Paper presentations.

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